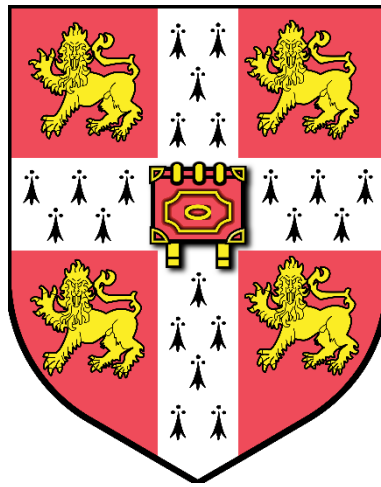


A better FIT: Risk stratification of screening intervals and FIT thresholds in bowel cancer screening



Lily Catherine Taylor

Magdalene College, University of Cambridge

September 2024

This dissertation is submitted for the degree of

Doctor of Philosophy

Declaration

This thesis is the result of my own work and includes nothing which is the outcome of work done in collaboration except as declared in the preface and specified in the text. It is not substantially the same as any work that has already been submitted, or is being concurrently submitted, for any degree, diploma or other qualification at the University of Cambridge or any other University or similar institution except as declared in the preface and specified in the text. It does not exceed the prescribed word limit for the relevant Degree Committee.

Thesis summary

A better FIT: Risk stratification of screening intervals and FIT thresholds in bowel cancer screening

Lily C Taylor

The risk of developing bowel cancer is associated with numerous lifestyle and genetic factors, meaning that individuals with a higher risk gain substantially more from screening than those at low risk. Risk stratification has therefore been suggested to improve the balance of screening harms and benefits, and to accommodate resource limitations. Within the bowel cancer screening pathway, risk stratification could be incorporated at the point of first invitation (eligibility), or at the point of the screening test via stratified screening intervals and/or referral thresholds for colonoscopy. The focus of my thesis is risk-stratified faecal immunochemical test (FIT) thresholds and screening intervals. In order for risk stratification of bowel cancer screening to be successful, the public must find it acceptable, understandable, and be willing to participate in a risk-stratified screening programme.

This thesis aims to understand public acceptability and communication needs associated with risk stratification of FIT thresholds and screening intervals within population-based bowel cancer screening, and to investigate the potential impact of risk stratification on bowel screening uptake.

My first two studies are mixed methods systematic reviews of the acceptability of risk-stratified cancer screening from the perspective of healthcare professionals (HCPs) and the general public respectively, using the Joanna Briggs Institute convergent integrated approach. I included seven papers about HCP attitudes and found that risk stratification was broadly acceptable, providing additional support and training is delivered prior to implementation. There was a paucity of research in relation to cancers other than breast and greater evidence is needed to understand acceptability of de-intensified screening for low-risk groups. I identified 22 papers considering public attitudes and found that acceptability was generally high. I then developed ten priorities for implementation across four key areas: (I) addressing public information needs; (II) understanding communication preferences for risk estimates; (III) mitigating barriers to acceptability; (IV) the role of HCPs in supporting reduced screening among low-risk groups.

To explore public acceptability of risk stratification in greater depth, specifically in relation to risk-stratified screening intervals and FIT thresholds for bowel cancer, I conducted two community juries. I found that risk stratification in this context was acceptable to informed members of the public, and the use of data within the current system in the form of age, sex, and FIT result, was considered

preferable to existing age-based screening. The use of additional lifestyle and genetic data was acceptable but required greater consideration of practical aspects before implementation. Although participants acknowledged concerns for low-risk individuals they felt this could be mitigated by carefully considered public communication.

One means of public communication is via written screening resources such as information leaflets. My fourth study, a series of think aloud interviews paired with a user testing survey, aimed to develop and test public understanding of a bowel cancer screening leaflet relating to risk-stratified screening intervals. I conducted 13 think aloud interviews in which participants identified 42 suggested changes to the screening leaflet, including clearer language, simplification of concepts related to risk stratification and additional information to evidence the safety of extending screening intervals for those at low risk. The refined leaflet was then tested using a true or false style survey ($n=20$). A minimum of 90% of participants answered each user testing statement correctly, above the pre-established threshold of understanding suggesting the final leaflet was fit for purpose and further rounds of revision and user testing were not required. Overall, I found that the public are capable of understanding information about risk-stratified bowel cancer screening presented as part of population-level screening programme information.

The information text developed in the think aloud study formed the basis for the final study in my thesis. The text was used as part of an online survey which aimed to quantify public acceptability and anticipated uptake of potential approaches to risk stratification at three points on the bowel cancer screening pathway. Participants received information about four possible screening programmes: (I) screening as usual; (II) risk-stratified eligibility; (III) risk-stratified FIT threshold; (IV) risk-stratified screening intervals. Overall acceptability of screening programmes employing risk-stratified eligibility criteria and FIT thresholds was significantly greater than for screening as usual ($p<0.001$). This high level of acceptability was maintained when participants were asked about screening practices for high-risk individuals ($p<0.0001$), indicating strong acceptability for escalation of screening. The inverse was true of de-escalating screening for low-risk groups, as low-risk practices were significantly less acceptable than an age-based approach and up to 16.8% fewer participants would take up FIT screening in this scenario compared to screening as usual ($p<0.0001$). Despite these differences, anticipated uptake for low-risk scenarios was over 75%. A similar pattern was observed when participants were asked about the impact of risk on their decision to attend colonoscopy whereby the higher the risk level, the greater the likelihood of attending. Female participants were less likely to accept one or more risk-based strategy despite reporting screening as usual to be acceptable (odds ratio [OR] 1.5, [95% confidence interval [CI] 1.1-2.0]). Finally, a combination of data derived from primary care records, lifestyle questionnaire and genetic data was

most acceptable within each strategy, indicating a preference for a more comprehensive approach to data collection.

This body of research demonstrates that risk stratification is likely to be an acceptable adjustment to the UK bowel cancer screening pathway, specifically at the point of FIT. I have identified several requirements that must be fulfilled in order to facilitate successful implementation of such an approach, including training and support for HCPs, changes to screening infrastructure and increased evidence needs. Additionally, the importance of communicating decreased screening for low-risk groups cannot be overlooked, as this represents a pivotal opportunity with potential to determine the ultimate success of risk-stratified bowel cancer screening. Future research should explore acceptability of risk stratification from an experiential perspective, seek to measure uptake of this approach in reality and ascertain the most viable strategy for grouping the population according to risk.

Contents

Declaration.....	2
Thesis summary	3
Acknowledgements.....	12
Dissemination	13
Abbreviations.....	16
List of tables and figures	19
Tables.....	19
Figures.....	21
Chapter 1 Introduction	22
1.1 Bowel cancer	22
1.1.1 Pathophysiology of bowel cancer	22
1.1.2 Incidence of bowel cancer	24
1.1.3 Outcomes for bowel cancer.....	24
1.1.4 Diagnosis of bowel cancer	25
1.2 Screening.....	26
1.2.1 The UK Bowel Cancer Screening Programme	26
1.2.2 Benefits and harms of bowel cancer screening.....	27
1.2.3 Bowel cancer screening uptake	28
1.3 Risk stratification.....	28
1.3.1 Risk factors and risk modelling for bowel cancer	28
1.3.2 Risk-stratified cancer screening	30
1.4 Acceptability.....	32
1.4.1 Defining acceptability	33
1.5 Summary	34
Chapter 2 Aim and thesis structure	36
2.1 Aim and objectives.....	36
2.2 Thesis structure.....	36

2.3 Patient and public involvement	39
Chapter 3 Acceptability of risk-stratified cancer screening from the perspective of healthcare professionals	40
3.1 Summary	40
3.2 Background	40
3.3 Aim	41
3.4 Methods	41
3.4.1 Search strategy.....	42
3.4.2 Eligibility criteria.....	43
3.4.3 Study selection.....	44
3.4.4 Data extraction.....	44
3.4.5 Quality assessment	45
3.4.6 Data synthesis	45
3.5 Results	49
3.5.1 Study selection.....	49
3.5.2 Study characteristics	51
3.5.3 Quality assessment	56
3.5.4 Strength of the evidence.....	58
3.5.5 Resulting framework.....	61
3.5.6 Qualitative synthesis findings	63
3.6 Discussion.....	77
3.6.1 Comparison with other literature	79
3.6.2 Strengths and limitations	80
3.7 Conclusions	81
Chapter 4 Acceptability of risk-stratified cancer screening from the perspective of the public	82
4.1 Summary	82
4.2 Background	82
4.3 Aim	83

4.4 Methods.....	83
4.4.1 Search strategy.....	83
4.4.2 Eligibility criteria.....	83
4.4.3 Study selection.....	84
4.4.4 Data extraction.....	84
4.4.5 Quality assessment	84
4.4.6 Data synthesis	84
4.5 Results.....	87
4.5.1 Study selection.....	87
4.5.2 Study characteristics	89
4.5.3 Quality assessment	94
4.5.4 Strength of the evidence.....	97
4.5.5 Qualitative synthesis findings	101
4.6 Discussion.....	115
4.6.1 Comparison with other literature	119
4.6.2 Strengths and limitations	119
4.7 Conclusions	120
Chapter 5 Public acceptability of risk-stratified screening intervals and FIT thresholds: A community jury study	121
5.1 Summary	121
5.2 Background	122
5.3 Aim	122
5.4 Methods.....	122
5.4.1 Study design	123
5.4.2 Participants and recruitment	125
5.4.3 Data collection	126
5.4.4 Analysis	126
5.4.5 Public participation	127

5.5 Results	127
5.5.1 Participant characteristics.....	127
5.5.2 Pre- and post-jury questionnaire results	129
5.5.3 Qualitative synthesis findings	130
5.6 Discussion.....	139
5.6.1 Comparison with other literature	139
5.6.2 Strengths and limitations	140
5.7 Conclusions	141
Chapter 6 Public understanding of information about risk-stratified bowel cancer screening: A think aloud study and user testing process	142
6.1 Summary	142
6.2 Background	142
6.3 Aim	144
6.4 Methods.....	144
6.4.1 Study design.....	144
6.4.2 Participants and recruitment	146
6.4.3 Data collection	147
6.4.4 Analysis	147
6.4.5 Public participation	148
6.5 Results	148
6.5.1 Participants characteristics	148
6.5.2 Codebook thematic analysis	149
6.5.3 User testing results	164
6.5.4 Participant reflections on risk calculation and stratification	165
6.6 Discussion.....	167
6.6.1 Comparison with other literature	168
6.6.2 Strengths and limitations	169
6.7 Conclusions	170

Chapter 7	Public acceptability and anticipated uptake of risk-stratified bowel cancer screening: An online survey study	171
7.1	Summary	171
7.2	Background	172
7.3	Aim	172
7.4	Methods.....	172
7.4.1	Study design	172
7.4.2	Participants and recruitment.....	173
7.4.3	Consent	173
7.4.4	Data collection	174
7.4.5	Analysis	174
7.4.6	Public participation	175
7.5	Results.....	175
7.5.1	General cancer beliefs	177
7.5.2	Overall acceptability of risk-stratified screening strategies.....	178
7.5.3	Acceptability of screening practices according to personalised risk score.....	182
7.5.4	Likelihood of taking up FIT screening according to personalised risk score	184
7.5.5	Impact of risk level on the decision to attend colonoscopy	186
7.5.6	Acceptability of data collection.....	188
7.6	Discussion.....	190
7.6.1	Comparison with other literature	192
7.6.2	Strengths and limitations.....	193
7.7	Conclusions	194
Chapter 8	Discussion.....	195
8.1	Thesis summary	195
8.1.1	Summary of methods.....	195
8.1.2	Acceptability of risk-stratified bowel cancer screening	195
8.1.3	Public communication requirements and considerations	197

8.1.4 Considerations specific to the provision of personal risk information	199
8.1.5 The role of healthcare professionals and health services	200
8.1.6 A systems-based analysis of risk-stratified bowel cancer screening	201
8.1.7 Outstanding evidence requirements	202
8.2 Strengths, limitations and evaluation	203
8.2.1 Reflexivity	204
8.3 Implications for policy, practice, and research	207
8.4 Conclusion	212
References	213
Appendices	234

Acknowledgements

I would like to thank my supervisors, Dr Juliet Usher-Smith and Dr Becky Dennison, who have both given up their time and expertise to support me over the past three years. To Juliet who has imparted invaluable wisdom and insight and has continually encouraged me to develop as a researcher. To Becky who has patiently and consistently supported and guided me throughout my PhD and who has also extended me her friendship.

Secondly, I am grateful to the researchers, medical students and PPI representatives that I have had the opportunity to collaborate with and who have made important contributions to this thesis. Also to my colleagues in the Prevention Group for their friendship and humour.

Thank you to my family for their love and ceaseless encouragement, especially on hard days. To Willow, always my biggest supporter, who tirelessly raises my spirits, cheers me on and inspires me to succeed academically and personally. To Robin who supplied me with endless cups of tea and coffee without complaint, celebrates even the smallest of my achievements and steps up in all the ways I am not capable of. To Buddha who is forever a ray of sunshine and source of joy. Finally, to Nan, without whose constant love and kindness I would not be the person I am today.

Dissemination

Publications resulting from this thesis:

Taylor LC, Law K, Hutchinson A, Dennison RA, Usher-Smith JA. Acceptability of risk stratification within population-based cancer screening from the perspective of healthcare professionals: A mixed methods systematic review and recommendations to support implementation. PLoS ONE. 2023; 10.1371/journal.pone.0279201.

Taylor LC, Hutchinson A, Law K, Shah V, Usher-Smith JA, Dennison RA. Acceptability of risk stratification within population-based cancer screening from the perspective of the general public: A mixed methods systematic review. Health Expectations. 2023; 10.1111/hex.13739.

Taylor LC, Dennison RA, Griffin SJ, John SD, Lansdorp-Vogelaar I, Thomas CV, Thomas R, Usher-Smith JA. Implementation of risk stratification within bowel cancer screening: A community jury study exploring public acceptability and communication needs. BMC Public Health. 2023; 10.1186/s12889-023-16704-6.

Taylor LC, Dennison RA, von Wagner C, Usher-Smith JA. Exploring public understanding of information about risk-stratified bowel cancer screening: A think aloud study with user testing. *Under review. Frontiers in Cancer Control and Society.*

Taylor LC, Dennison RA, Usher-Smith JA. Public acceptability and anticipated uptake of risk-stratified bowel cancer screening: an online survey. Preventive Medicine Reports. 2024; 10.1016/j.pmedr.2024.102927.

Conference posters and oral presentations:

Society for Academic Primary Care (SAPC) South East conference, 26 January 2023, online. Views and considerations for the implementation of risk stratification within bowel cancer screening: A community jury study.

UK Society for Behavioural Medicine (UKSBM) Annual Scientific Meeting, 28-29 March 2023, Birmingham. Structured Discussion: Refining the concept of assessment of 'acceptability' in cancer screening and early diagnosis.

Acceptability of risk stratification within population-based cancer screening from the perspective of the general public: A mixed methods review.

Cancer Research UK (CRUK) Early Diagnosis Research Virtual Series, 31 May 2023, online. A better FIT: Public acceptability of risk-stratified bowel cancer screening.

International Cancer Screening Network (ICSN) conference, 21-23 June 2023, Turin, Italy.

Acceptability of risk stratification within population-based cancer screening from the perspective of the general public.

Implementation of risk stratification within bowel cancer screening: A community jury study exploring public acceptability and communication needs.

Cambridge Public Health Showcase, 7 November 2023, Cambridge, England.

Implementation of risk stratification within bowel cancer screening: A community jury study exploring public acceptability and communication needs.

UK Society for Behavioural Medicine (UKSBM) Early Career Network Annual Webinar, 7 December 2023, online. Exploring public understanding of information about risk-stratified bowel cancer screening: A think aloud study with user testing.

Society for Academic Primary Care (SAPC) South East conference, 26 January 2024, Cambridge. Exploring public understanding of information about risk-stratified bowel cancer screening: A think aloud study with user testing.

Cambridge Public Health Showcase, 21 November 2024, Cambridge, England. Public acceptability and anticipated uptake of risk-stratified bowel cancer screening in the UK: An online survey.

Other publication contributions during this thesis:

Dannhauser FC, **Taylor LC**, Tung JSL, Usher-Smith JA. The acceptability and clinical impact of using polygenic scores for risk-estimation of common cancers in primary care: a systematic review. *Journal of Community Genetics*. 2024; 10.1007/s12687-024-00709-8.

Dennison RA, **Taylor LC**, Morris S, Boscott R, Harrison H, Moorthie S, Rossi S, Stewart G, Usher-Smith JA. Public preferences for determining eligibility for screening in risk-stratified cancer screening programmes: A discrete choice experiment. *Medical Decision Making*. 2023; 10.1177/0272989X231155790.

Moorthie S, **Taylor LC**, Dennison RA, Usher-Smith JA. Systems based analysis exploring the potential to implement risk-stratified bowel cancer screening in England. *BMC Health Services Research*. 2024. *Under review*.

Shah V, Geller G, Xu D, **Taylor LC**, Griffin SJ, Usher-Smith JA. Evaluating the impact of lifestyle-based behaviour change interventions delivered at the time of colorectal cancer screening. *Cancer Causes and Control*. 2023; 10.1007/s10552-023-01773-0.

Usher-Smith JA, Hindmarch S, French DP, Tischkowitz M, Moorthie S, Walter FM, Dennison RA, Stutzin F, Archer S, **Taylor LC**, Emery J, Morris S, Easton DF, Antoniou AC. Proactive breast cancer risk assessment in primary care: A review based on the principles of screening. *British Journal of Cancer*. 2023; 10.1038/s41416-023-0214q5-w.

Abbreviations

APC – *adenomatous polyposis coli*

AUC – area under the [receiver operator] curve

BC – bowel cancer

BrC – breast cancer

BMI – body mass index

CFIR – Consolidated Framework for Implementation Research

CI – confidence interval

COM-B – Capability, Opportunity, Motivation, Behaviour

CRC – colorectal cancer

CTC – computed tomography colonography

CVD – cardiovascular disease

DNA – deoxyribose nucleic acid

EMR – electronic medical record

EPIC – European Prospective Investigation into Cancer and Nutrition

F - female

FAP – Familial Adenomatous Polyposis

FG – focus group

FGD – focus group discussion

FHb – faecal haemoglobin

FIT – faecal immunochemical test

gFOBT – guaiac faecal occult blood test

GP – general practitioner

HCP – healthcare professional

HDI – human development index

HP – health professional

HPV – human papillomavirus

HR – human resources

HRT – hormone replacement therapy

ICO – Information Commissioner’s Office

JB I – Joanna Briggs Institute

M - male

MD – Doctor of Medicine

MMAT – Mixed Methods Appraisal Tool

MRC – Medical Research Council

MRI – magnetic resonance imaging

N/A – not applicable

NHS – National Health Service

NHSBSP – National Health Service Breast Screening Programme

OC – ovarian cancer

OR – odds ratio

ONS – Office of National Statistics

P - participant

PBCRA – personalised breast cancer risk assessment

PC – prostate cancer

PCP – primary care professional

PPI – patient and public involvement

PRA – personalised risk assessment

PRISM – Practical Robust Implementation and Sustainability Model

Q&A – question and answer

RCT – randomised controlled trial

RCT – risk communication tool

REF – reference

RIDAC – Research, Innovation and Development Advisory Committee

RPM – risk prediction model

RR – relative risk

SA – South Asian

SAU – screening as usual

SDHS – secure data hosting server

SES – socioeconomic status

SNP – single nucleotide polymorphism

SSL – Single Sockets Layer

SSP – specialist screening practitioner

TFA – Theoretical Framework of Acceptability

TI – telephone interview

TOFHL – Test of Functional Health Literacy

UK – United Kingdom

UKBCSP – United Kingdom Bowel Cancer Screening Programme

UKNSC – United Kingdom National Screening Committee

US – United States

List of tables and figures

Tables

Table 1.1 Risk factors for developing bowel cancer

Table 1.2 Summary of the potential benefits of risk stratification for the public, HCPs and healthcare services

Table 3.1 Systematic review MEDLINE search strategy

Table 3.2 Eligibility criteria for the review of acceptability of risk-stratified cancer screening from the perspective of healthcare professionals

Table 3.3 Summary of the five domains in the Consolidated Framework for Implementation Research and their meaning in the context of this systematic review

Table 3.4 Example of generation of sub-themes using thematic analysis for the review of acceptability of risk-stratified cancer screening from the perspective of healthcare professionals

Table 3.5 Summary of key study characteristics and findings for the review of acceptability of risk-stratified cancer screening from the perspective of healthcare professionals

Table 3.6 Results of the quality assessment of papers included in the review of acceptability of risk-stratified cancer screening from the perspective of healthcare professionals using the Mixed Methods Appraisal Tool

Table 3.7 Strength of the evidence and studies contributing to each construct for the review of acceptability of risk-stratified cancer screening from the perspective of healthcare professionals

Table 4.1 Eligibility criteria for the review of acceptability of risk-stratified cancer screening from the perspective of the public

Table 4.2 Summary of the seven domains of the Theoretical Framework of Acceptability and their meaning in the context of this systematic review

Table 4.3 Summary of key study characteristics and findings for the review of acceptability of risk-stratified cancer screening from the perspective of the public

Table 4.4 Results of the quality assessment of papers included in the review of acceptability of risk-stratified cancer screening from the perspective of the public

Table 4.5 Strength of the evidence and studies contributing to each theme for the review of acceptability of risk-stratified cancer screening from the perspective of the public

Table 4.6 Recommendations for communication and implementation of risk stratification

Table 5.1 Community jury timetable

Table 5.2 Inclusion and exclusion criteria for participation in the community juries

Table 5.3 Demographic characteristics for the community juries

Table 6.1 Demographic characteristics for the think aloud interviews and user testing survey

Table 6.2 Codebook thematic analysis results of the think aloud interviews

Table 6.3 Results of the user testing survey

Table 7.1 Description of the four screening strategies shown to participants in the survey

Table 7.2 Demographic characteristics of participants included in the survey study

Table 7.3 General cancer beliefs of participants included in the survey study

Table 7.4 Overall acceptability of risk-stratified screening strategies compared with screening as usual

Table 7.5 The impact of individual demographics on the likelihood that participants would find each risk-stratified strategy acceptable

Table 7.6 Acceptability of high- and low-risk screening practices according to risk-stratified screening strategy compared with screening as usual

Table 7.7 The likelihood of taking up FIT screening at different risk levels across risk-stratified screening strategies compared with screening as usual

Table 7.8 The likelihood of personal risk score impacting the decision to attend colonoscopy

Table 7.9 Acceptability of data collection methods summarised by risk-stratified screening strategy

Table 8.1 Summary of overall thesis implications

Figures

Figure 1.1 Illustration of the digestive tract highlighting the large bowel where bowel cancer occurs

Figure 1.2 Illustration of the adenoma-carcinoma sequence of tumorigenesis over a 10-15 year timeline

Figure 1.3 Illustration of the UK Bowel Cancer Screening Programme

Figure 1.4 Illustration of the potential risk stratification points on the UK bowel cancer screening pathway

Figure 2.1 Flow diagram illustrating the overall thesis structure

Figure 3.1 PRISMA flow diagram for the review of acceptability of risk-stratified cancer screening from the perspective of healthcare professionals

Figure 3.2 'Best-fit' adaptation of the Consolidated Framework for Implementation Research

Figure 4.1 Mind map of codes relating to the theme 'Impact on future screening and behaviour' colour coded according to sub-theme

Figure 4.2 PRISMA flow diagram for the review of acceptability of risk-stratified cancer screening from the perspective of the public

Figure 5.1 Change in how acceptable community jury participants found elements of risk-stratified FIT thresholds and screening intervals

Figure 6.1 Example of a leaflet section illustrating the red dots used in the marked protocol method

Figure 7.1 Overall acceptability of risk-stratified screening strategies compared with screening as usual

Figure 7.2 The impact of individual demographics on the likelihood that participants would find one or more risk-stratified strategy unacceptable, after finding screening as usual acceptable

Figure 7.3 Percentage of participants considering high- and low-risk screening practices 'somewhat or extremely' acceptable/unacceptable across screening strategies

Figure 7.4 Likelihood of taking up FIT screening at different risk levels across risk-stratified screening strategies compared with screening as usual

Figure 7.5 The likelihood that personal risk score would impact the decision to attend colonoscopy

Figure 7.6 Acceptability of data collection methods illustrated by risk-stratified screening strategy

Chapter 1 Introduction

I begin this thesis by describing bowel cancer, including its pathophysiology, prevalence, outcomes and diagnosis. This provides important context for introducing cancer screening and describing the current UK bowel cancer screening programme. I then describe how risk stratification differs from existing practices and the rationale for such an approach. As this thesis is primarily concerned with the acceptability of risk-stratified bowel cancer screening, I then focus on describing and operationalising acceptability in Section 1.4.

1.1 Bowel cancer

Bowel cancer, also known as colorectal cancer (CRC), refers to cancers that develop anywhere in the large bowel, most commonly in the colon but also in the rectosigmoid junction and rectum(1). The large bowel is the final part of the digestive system which breaks down partially digested food and where faeces moves through the body to be excreted (Figure 1.1)(2).

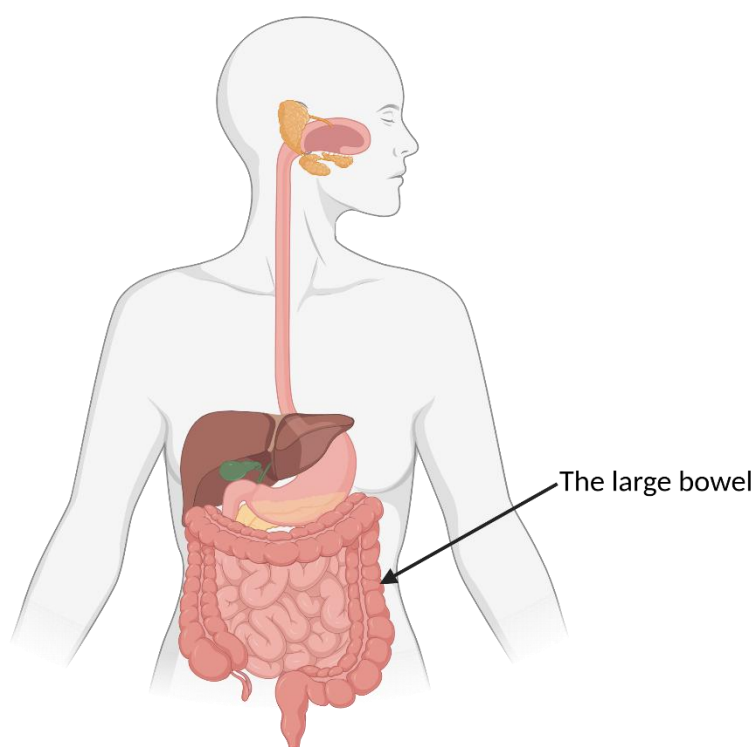


Figure 1.1 Illustration of the digestive tract highlighting the large bowel where bowel cancer occurs. Created in BioRender. Taylor, L. (2025) <https://BioRender.com/z17x924>

1.1.1 Pathophysiology of bowel cancer

The majority of bowel cancers are adenocarcinomas, which develop from precancerous lesions known as adenomas or polyps. Approximately 70% of all bowel cancers occur as a result of sporadic mutations. A further 10% of bowel cancers are attributable to inherited syndromes, half of which are

due to the two most prevalent syndromes Familial Adenomatous Polyposis (FAP) and Lynch syndrome. The remaining 20% of cancers occur in cases of familial clustering, where no inherited syndrome has been identified(3–5). As the focus of this thesis is concerned with cancer screening and those with high penetrance genetic mutations are typically managed via surveillance pathways, I will not discuss familial inherited syndromes in further detail.

A causal link between adenomas and carcinomas has been accepted since the 1970's but the actual process of tumorigenesis is the result of complex and multi-stage genetic and epigenetic changes(6). In most cases, the intestinal epithelium undergoes dysplastic changes in response to accumulating genetic mutations over the course of 10-15 years, whereby healthy epithelium progresses towards an invasive and potentially metastatic carcinoma, known as the adenoma-carcinoma sequence (Figure 1.2)(3,4,7). This pathway was hypothesised by Fearon and Vogelstein in 1990 and posits that the adenoma-carcinoma sequence typically begins as a consequence of mutations in the *adenomatous polyposis coli (APC)* gene, and tumorigenesis ensues due to further mutations in oncogenes and tumour suppressor genes. Such mutations endow the cell with carcinogenic attributes, including cellular immortality, hyperproliferation, invasive capacity and the proclivity to acquire additional mutations(7). There are alternative mechanisms by which a bowel cancer can develop, such as the serrated polyp pathway where diverse types of polyp (sessile serrated, hyperplastic, mixed type) develop into malignant tumours, however, these are less common(4).

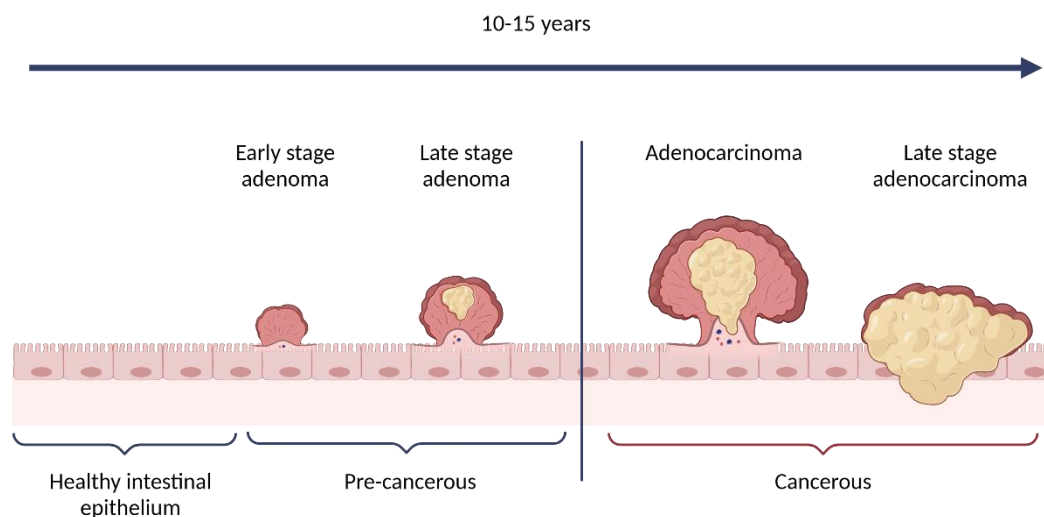


Figure 1.2 Illustration of the adenoma-carcinoma sequence of tumorigenesis over a 10-15 year timeline. Created in BioRender. Taylor, L. (2025) <https://BioRender.com/s57h632>

Bowel cancers differ in morphology depending upon the side of the large bowel they occur in. Left-sided cancers are more common, accounting for approximately 70% of all bowel cancers. They are

more likely to have tubular or villous morphology and occur more frequently in males and younger people. Left-sided cancers are also easier to detect via colonoscopy, often resulting in an earlier stage at the point of detection and improved survival outcomes(8,9). Conversely, right-sided bowel cancers are more likely to be sessile or laterally growing and occur more frequently in females and elderly individuals. Due to their flat morphology, they are harder to detect via colonoscopy and therefore, more likely to be diagnosed at a later stage resulting in poorer survivability(8–10).

1.1.2 Incidence of bowel cancer

In 2020 there were over 19 million new cases of cancer and approximately 10 million cancer deaths worldwide. Globally, bowel cancer is the third most common cancer accounting for around 10% of total cases diagnosed and is the second leading cause of mortality, responsible for 9.4% of all cancer deaths. In 2020, this amounted to over 1.9 million new bowel cancer diagnoses and more than 900,000 deaths(11). In the UK specifically, bowel cancer is the third most common cancer in both males and females, and over 42,000 new cases were diagnosed between 2016-2018(12). Furthermore, bowel cancer is the second largest contributor to cancer deaths in the UK and accounts for 10% of total cancer deaths (2017-2019)(13).

The incidence of bowel cancer varies geographically and is generally associated with greater socioeconomic development, where incidence is typically positively correlated with rising Human Development Index (HDI)(11,14). Indeed, approximately 90% of all cases were recorded in high and very high HDI countries in 2020 and incidence was four times higher in such countries than in their lower HDI counterparts. Worldwide incidence of bowel cancer is predicted to increase by over 60% during the next two decades, totalling 3.2 million global cases by 2040. This increase in total cases can be attributed to progressively rising incidence in lower HDI countries as a result of lifestyle factors, including dietary changes, lower rates of physical activity and rising body weight(14). Additionally, bowel cancer incidence is increasing among younger individuals in high-income countries, like the UK(15–17). Exarchakou et al. report that, despite overall reductions in age-standardised rates, incidence of bowel cancer among the 20-39 year age bracket has increased by almost threefold in England between 1990-2014(15). This is likely attributable to the same lifestyle factors acting in lower HDI countries detailed above. Bowel cancer is therefore of significant global concern and prevention and early detection remain the optimum strategies by which to reduce incidence and mortality rates.

1.1.3 Outcomes for bowel cancer

Outcomes for bowel cancer are associated with several factors including cancer type, the stage and grade at diagnosis, time to colonoscopy and patient health(18–20). Survival rates are slightly higher

among women, younger patients and among patients who are diagnosed with a distal cancer, which tend to have a preferable stage distribution compared to cancers diagnosed in the proximal colon or rectum(19). A population-based study conducted across nine European countries reported improved survival rates for patients with screen-detected cancers compared to those with non-screen-detected cancers. The majority of cancers detected via screening were Stage I-II (65.6%), compared to 43.6% among non-screen-detected cancers and, despite differences in the proportion of patients who had their cancer detected via screening between countries, all countries reported improved rates of survival for screen-detected cancers across the four stages. Notably, these differences are most likely attributable to the detection of less aggressive or rapidly progressing cancers through screening and the advantage of increased lead time compared with symptomatic detection, rather than an inherent benefit of the screening process(19).

As well as the length of survival, patient experiences of survival after bowel cancer diagnosis and treatment are varied. A qualitative systematic review and meta-analysis of 20 studies including focus groups, interviews and observational findings described significant short-and long-term impacts. For many this involves life with a stoma but long-term effects also include loss of or changes to bowel function and pain for those without stoma or following a stoma reversal. The review highlights challenges with physical, social, sexual and psychological function, including anxiety and depression, among bowel cancer survivors(21).

1.1.4 Diagnosis of bowel cancer

There are generally two distinct pathways to bowel cancer diagnosis: the screening pathway in which a bowel cancer is detected during population-based screening of apparently healthy individuals, and the symptomatic pathway whereby a patient experiencing symptoms of bowel cancer seeks help from a healthcare professional (HCP)(22). The concentration of haemoglobin in the stool is significantly associated with the presence and severity of bowel cancer, therefore a faecal blood test is often the first investigative test for bowel cancer in both pathways(23).

For the purposes of this thesis I will focus on the screening pathway and the typical diagnostics used within screening programmes. In 2019, NHS England implemented faecal immunochemical testing (FIT) as an alternative to the previously used guaiac faecal occult blood test (gFOBT) along with many other countries worldwide(24). However, some nations continue to use guaiac-based testing which requires a total of six faecal samples from multiple bowel movements(25,26). The FIT test is a test for the presence of haemoglobin in a single faecal sample. It is able to detect blood at a lower concentration than gFOBT and provides a quantitative result, as opposed to gFOBT which relies on visual interpretation of a colour change assay(26).

Following a positive FIT or gFOBT result, patients are typically referred for a colonoscopy which is generally considered the gold standard test for diagnosing bowel cancer(27,28). A colonoscopy involves inserting a thin tube with a camera on the end, called a colonoscope, into the large bowel. This enables the detection of pre-cancerous adenomas and malignant bowel cancers(28). Alternatives to colonoscopy include flexible sigmoidoscopy which images the lower section of the large bowel or CT colonography (CTC). Flexible sigmoidoscopy is similar to a colonoscopy but only images the rectum and sigmoid colon and is therefore unable to detect lesions further into the large bowel, but is less time consuming and requires less thorough preparation(29). CTC is also less effective at diagnosing bowel cancer but is less invasive than other options so may be more suitable for elderly or frail patients(30).

Colonoscopy requires preparation of the bowel using laxatives and presents several possible harms. These harms include false negative results whereby a cancer or adenoma is missed, perforation of the bowel, heavy bleeding, adverse responses to sedation and in very rare cases death(30,31). Nevertheless, colonoscopy also confers benefits in the form of cancer prevention and diagnosis. A recent systematic review and meta-analysis reported that the incidence of bowel cancer was approximately 52% lower among participants who received screening colonoscopy compared with those who had never been screened (relative risk [RR] = 0.48; 95% confidence interval [CI] = 0.44-0.56; $p \leq 0.001$)(24). Similarly, mortality was reduced by 62% following screening colonoscopy (RR = 0.38; 95% CI = 0.36-0.40; $P=0.010$)(32).

1.2 Screening

1.2.1 The UK Bowel Cancer Screening Programme

Many definitions of screening exist but the common themes among them can be distilled to define screening as follows(33–36): the process of proactively identifying seemingly healthy individuals within a population who have an increased risk of disease but do not yet have symptoms.

Screening is typically offered to a subgroup of the population based on age and/or sex(36). The NHS operates eleven population-based screening programmes across England, including screening for bowel cancer which has been established nationally since 2010(24,37). The UK Bowel Cancer Screening Programme (UKBCSP) is illustrated in Figure 1.3. Bowel cancer screening by FIT is currently offered biennially to those aged 60-74 and this age range is gradually being expanded to include individuals aged 50-59(38). An invitation letter and information leaflet are sent to eligible individuals registered with a GP and living in England via post, followed by the FIT kit itself and accompanying instructions(24,38). Those who have a faecal haemoglobin (FHB) concentration above the threshold of 120µg/g are offered a specialist screening practitioner (SSP) appointment to discuss having a

colonoscopy and those with FHB below the threshold are invited back to screening by FIT in two years' time(38). Participants who have a bowel cancer or precursor (polyp) identified at colonoscopy are offered further treatment and/or surveillance. Patients requiring polypectomy are referred back to a SSP and receive ongoing surveillance before being discharged into the population screening programme after 2-3 normal colonoscopies. Those who are diagnosed with a bowel cancer are referred for further investigations and ongoing treatment. For those who have a normal colonoscopy result or low-risk polyps detected, screening by FIT continues biennially(37). Additionally, bowel scope screening was introduced in 2013, offering 55-year-olds a one-off flexible sigmoidoscopy. However, this was discontinued in 2020 to assist with restoring bowel screening after it was suspended during the COVID-19 pandemic and because it was uncertain whether offering a more intrusive flexible sigmoidoscopy was more efficacious than FIT screening alone(37,39). The FIT threshold for referral to further investigation used by NHS England is 120µg/g, notably less sensitive than other national screening programmes which employ a threshold of 20-45µg/g. The NHS threshold remains high as lowering the sensitivity would significantly increase demand for colonoscopy and pathology resources, including staff, which are already constrained(40).

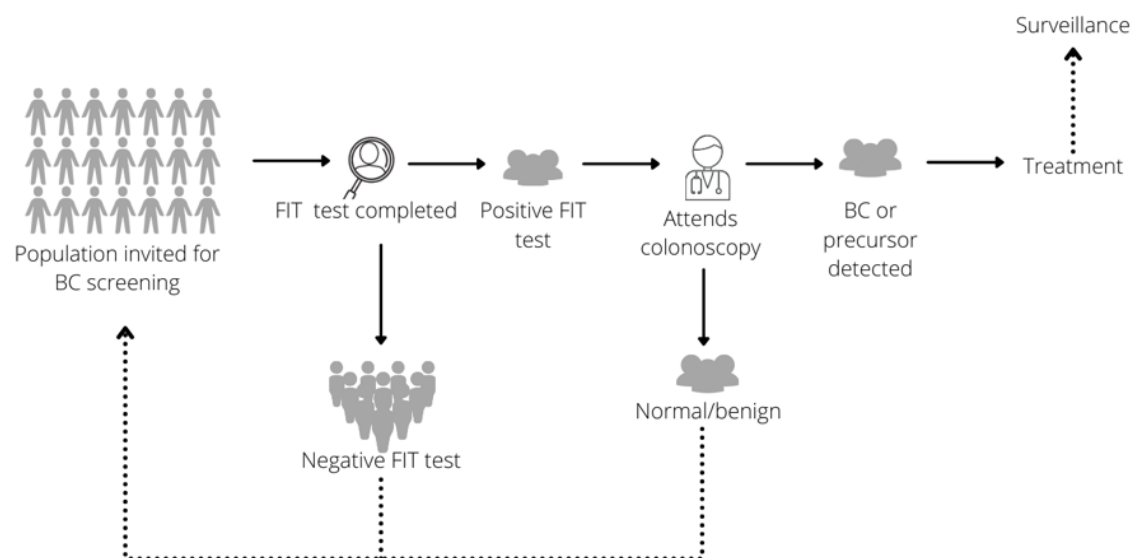


Figure 1.3 Illustration of the UK Bowel Cancer Screening Programme.

BC – bowel cancer; FIT – faecal immunochemical test

1.2.2 Benefits and harms of bowel cancer screening

According to the UK National Screening Committee (UKNSC), screening programmes should offer information to enable an informed choice as to whether or not to take part in screening. This includes information about the potential benefits and risks of participating. It is widely accepted that the prevention of cancer as a result of population-level screening contributes towards prevention

and early detection, and therefore improved health outcomes(41,42). In the case of bowel cancer, participating in screening can reduce the risk of bowel cancer-associated mortality by up to 25% and enables the removal of adenomas, reducing the risk of bowel cancer developing(43). Nevertheless, bowel screening is also associated with harms such as overdiagnosis and overtreatment (where a cancer that would never become symptomatic is diagnosed and treated), opportunity costs and adverse events associated with colonoscopy, such as bowel perforation or bleeding as detailed in section 1.1.4(42–44). There is also the potential for false positive and false negative results which may cause unnecessary anxiety and inappropriate reassurance respectively. Overall, these harms can cause adverse physical and psychological effects, as well as reducing the cost-effectiveness of screening by inefficiently distributing finite healthcare resources(42).

1.2.3 Bowel cancer screening uptake

Uptake can be defined as “The percentage of eligible people who participated in screening within the invited screening episode”(45). Sufficient uptake is required for any screening programme to be effective at reducing incidence and mortality. Bowel cancer screening specifically requires an uptake of at least 52% to achieve expected mortality reductions(45). In 2021-2022, the UKBCSP achieved an uptake rate of 68.9%, however, uptake is generally lower among certain population subgroups such as men, more deprived populations and previous non-responders(26,45,46).

1.3 Risk stratification

1.3.1 Risk factors and risk modelling for bowel cancer

In the general population there is considerable heterogeneity in individuals’ risk of developing bowel cancer according to numerous individual-level characteristics. These include lifestyle and phenotypic characteristics such as dietary habits, smoking, alcohol consumption, proportion of body fat, physical activity, family history and a multitude of genetic polymorphisms (Table 1.1)(47,48). Age, sex and FIT result are also associated with the likelihood of developing an adenoma or bowel cancer as male sex, increasing age and absolute FHB concentration are positively correlated with risk(23,49,50).

Table 1.1 Risk factors for developing bowel cancer(47,48).

Risk factor	Comparator	Relative risk
Family history of bowel cancer	Yes vs no	1.80
Sex	Male vs female	1.31
Alcohol	20 vs 0 drinks per week	1.26
Smoking	30 vs 0 pack-years	1.26
Red meat consumption	5 vs 0 weekly servings	1.13
BMI	30 vs 22 kg/m ²	1.10
Processed meat consumption	5 vs 0 weekly serving	1.09
Physical activity	Standardised physical activity score, increase of 2 points	0.88
Vegetable consumption	5 vs 0 daily servings	0.86
Fruit	3 vs 0 daily servings	0.84

BMI – body mass index

Bowel cancer risk prediction models including age, sex and FIT result have been developed with good discriminatory ability. The value of incorporating quantitative FHB concentrations into risk prediction models has been recently demonstrated by Meester et al. through development of a prognostic model for advanced neoplasia. A model incorporating age, sex and prior FHB demonstrated an area under the curve (AUC) of 0.78 for advanced neoplasia and 0.73 for bowel cancer specifically, and this discriminatory ability was sustained upon external validation(51). However, this model was developed using data from the Dutch biennial bowel cancer screening programme using a FIT threshold of 47µg/g which is considerably lower than the English threshold of 120µg/g meaning such a risk algorithm would require further validation in order to be relevant to the English screening context.

Risk modelling based on phenotypic data also demonstrates promise(49,52). A 2018 systematic review of validated risk models for the prediction of advanced colorectal neoplasia excluding FIT results or genetic risk factors reported discriminatory abilities of AUC 0.61-0.70 following meta-analysis. The most commonly included risk variables were age, sex, family history, BMI and smoking status, yet only seven out of a total of 17 original risk scores achieved a minimum AUC of 0.70 upon validation(53). Similarly, of 14 bowel cancer risk prediction scores including data that is routinely available in electronic medical records (EMR) or easily obtained via questionnaire only four models achieved discrimination above AUC 0.67 in males(54–58) and three models that excluded age had poor discrimination under AUC 0.60(54,59–61). An example of a risk model including easily accessible data is the QCancer-10 year risk algorithm which includes variables such as age, ethnicity, smoking status, alcohol consumption, family history, inflammatory bowel disease diagnoses, type 2 diabetes and personal history of other cancer types(55). QCancer10 has an externally validated AUC of 0.70 in males and 0.66 in females and is already used within primary care in the NHS(54,62).

Similar scores have been developed elsewhere, such as the LiFeCRC score based on participants from the European Prospective Investigation into Cancer and Nutrition (EPIC) study which has a validated AUC of 0.71(47).

As it stands, genetic risk prediction models display limited predictive capacity, however, this is anticipated to improve in future as more genes associated with bowel cancer are discovered and complex modelling techniques using machine learning are advanced(48). A 2020 review of risk scores including common single nucleotide polymorphisms (SNPs) for bowel cancer reported moderate discriminatory capacity for risk models including age, phenotypic risk factors and SNPs (AUC 0.64-0.67 in females and 0.67-0.71 in males)(63). Polygenic risk scores used in isolation, i.e. without other risk factors, have yielded poorer discrimination ranging from AUC 0.63 for a score based on 140 known bowel cancer SNPs to 0.65 for a score based on a Bayesian approach to genome-wide risk prediction, known as LDpred(64). One benefit of including SNPs over phenotypic data is that genetic risk performs equally well in both males and females(63).

A future consideration for cancer risk prediction is the development of risk prediction algorithms based on data mining techniques. One such algorithm has been reported to achieve an AUC of 0.88, suggesting improved prediction than aforementioned models. Nevertheless, this algorithm was analysed in a relatively small sample (194 cases and 274 controls) and greater research is needed to elucidate the risks of using data mining in healthcare(65,66).

1.3.2 Risk-stratified cancer screening

The UKNSC criteria for appraising screening programmes dictates that the benefits of screening should outweigh the physical and psychological harms(67). Whilst this may be the case on a population level, as detailed in section 1.3.1, there is significant variation in the individual risk of developing bowel cancer across the population, meaning that the harms of screening are not commensurate with the benefits for those at lower risk. Concerns over this sub-optimal balance of harms and benefits as well as resource constraints, which are particularly salient in the case of bowel cancer, has resulted in movement towards a risk-stratified approach to screening(68,69). For the purposes of this thesis, risk stratification is defined as follows:

Using two or more individual-level risk factors beyond age and sex, including lifestyle or genetic factors, in combination, to systematically determine elements of the screening programme according to individual risk.

Risk stratification would enable targeted allocation of screening resources by increasing screening for individuals found to be at the highest risk of developing bowel cancer who have more to gain

from screening and decreasing screening for individuals at lower risk; it has even been suggested that those at the lowest end of the spectrum could forgo screening(68–71). The possible benefits of a risk-adapted screening programmes are numerous and extend to the public, HCPs and healthcare services, as summarised in Table 1.2(42,68,72–74).

Table 1.2 Summary of the potential benefits of risk stratification for the public, HCPs and healthcare services.

Public	Healthcare professionals	Service provision
- Enhanced screening decision-making - Reduced harms of screening for people at low risk - Maximised early detection for people at high risk	- Enhanced screening decision-making - Improved diagnostic yield - Identification of patients suitable for lifestyle interventions and chemoprevention	- Improved screening compliance - Increased cost-effectiveness - Efficient distribution of resources

As described in section 1.3.1, multiple risk prediction models exist and could be used to tailor screening at several points on the bowel cancer screening pathway(50,70) (Figure 1.4). Firstly, the eligibility criteria could be stratified such that high-risk members of the population are invited to begin screening at a younger age and/or continue being screened into older age than those who are at lower risk (point 1)(68–70). The primary focus of this thesis, however, is the use of risk stratification in relation to FIT thresholds (point 2) for referral to further investigations and screening intervals (point 3). In these cases, high-risk individuals may be referred for colonoscopy with a lower FHb threshold at the point of FIT and vice versa for those at low risk, and/or people may be screened more or less frequently according to their personal risk(50,70).

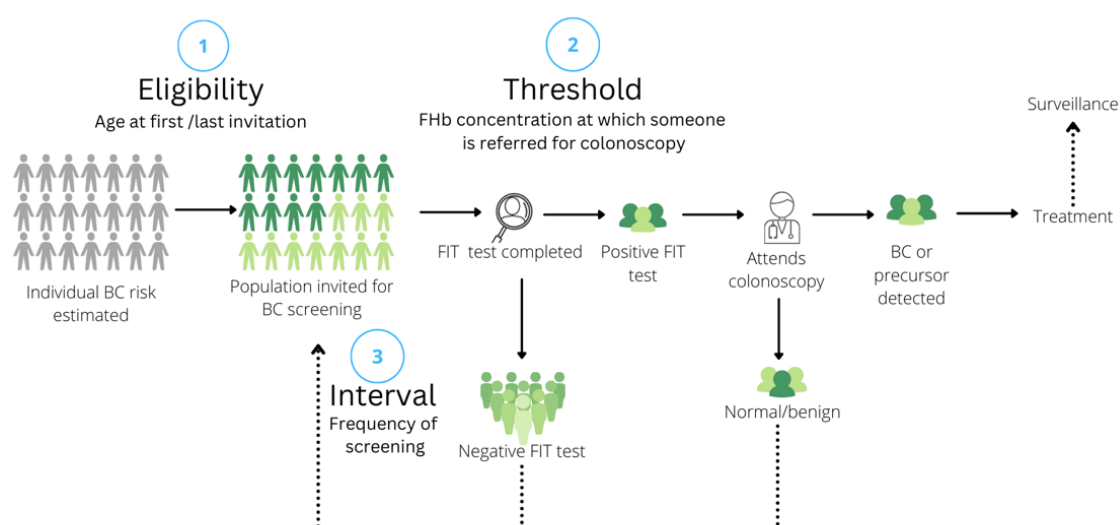


Figure 1.4 Illustration of the potential risk stratification points on the UK Bowel Cancer Screening Pathway.

BC – bowel cancer; FHB – faecal haemoglobin; FIT – faecal immunochemical test

Risk stratification appears rational in principle but in practice, transitioning from a standard screening programme with fixed characteristics to an approach in which screening opportunities are individually tailored is a complex adaptive process with many important factors to explore ahead of implementation. This shift requires not only valid and reliable means of estimating risk, but there is also a need to consider acceptability, including how equity is defined in this context and how systematic differences between population sub-groups are perceived.

1.4 Acceptability

The implementation of risk-stratified screening represents a complex intervention in healthcare. Guidance from the Medical Research Council (MRC) and the UKNSC on developing and evaluating complex interventions and population-based screening programme criteria have increasingly emphasised the importance of acceptability in this context(75–78). The UKNSC states that screening programmes must be acceptable in their entirety to stakeholders, including the public and HCPs, from a clinical, social and ethical standpoint(75). Furthermore, acceptability and patient-centredness are becoming increasingly important in healthcare quality assessment within the NHS and beyond(79,80). As such, there is clearly a need to establish acceptability before risk-stratified bowel cancer screening can be implemented. This is particularly important from the perspective of the public as their perceived acceptability of the intervention will likely impact uptake(81), determining the viability of the screening programme.

Attitudes towards recent changes to cervical screening where screening intervals have been extended from three to five years have demonstrated the impact of communication on public acceptability(82–84). Standard screening programme communication led to women reporting unmet expectations and outstanding questions following receipt of their results. Furthermore, women with lower education demonstrated poorer understanding, indicating that insufficient communication of personal risk and risk-stratified screening may widen existing inequalities(83). On the other hand, a recent randomised controlled trial (RCT) found that additional messaging including information on the safety of increased intervals and the accuracy of the screening test improved both understanding of the rationale behind risk stratification and overall acceptability of the strategy(82).

Acceptability from the perspective of HCPs is also a necessary component for success as they will be responsible for implementing and delivering the intervention with fidelity. Acceptability is fundamental to intervention effectiveness yet, despite progress in other areas such as risk

modelling, clinical impact and cost-effectiveness, there remains a paucity of research on the acceptability of risk-stratified bowel cancer screening. A 2021 review of strategies for the risk stratification of bowel cancer screening concludes that research into acceptability of risk-stratified screening for bowel cancer, using both quantitative and qualitative research methods, is the next step in moving towards implementation(48).

Acceptability is a complex and multi-faceted construct and, in the case of risk-stratified bowel cancer screening, involves numerous stakeholders. It is therefore necessary to assess acceptability using a range of approaches and with a range of different participants. In this thesis I adopt a pragmatist research paradigm, opting for practical methods, both qualitative and quantitative, to enable me to assess this multi-dimensional construct. This is also reflected in my choice of codebook thematic analysis for qualitative analyses, which bridges the gap between more positivist approaches such as coding reliability and purely inductive thematic analysis grounded in constructivism.

1.4.1 Defining acceptability

Despite its obvious importance, acceptability remains an ill-defined concept with many evaluative frameworks, including those of the MRC, neglecting to provide a clear definition(76,78,85).

Furthermore, acceptability has previously been frequently conflated or used synonymously with other terminology such as satisfaction, uptake, adherence and approval(80,81,86). In order to measure and operationalise acceptability it is necessary to establish a clear definition. Throughout this thesis I therefore define acceptability according to the Theoretical Framework of Acceptability (TFA) developed by Sekhon et al. specifically for healthcare interventions: “A multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experiential cognitive and emotional responses to the intervention”(87).

The Theoretical Framework of Acceptability

The TFA is a framework for assessing the acceptability of healthcare interventions comprised of seven constructs: affective attitude; burden; ethicality; intervention coherence; opportunity cost; perceived effectiveness; self-efficacy(87). The framework was developed following a review of systematic reviews on how acceptability had been previously utilised in healthcare research. During the development process, the authors reviewed the emerging framework against existing health psychology and behaviour change frameworks, including the Theory of Planned Behaviour, The Theoretical Domains Framework and the Common Sense Model, using these to deductively inform the TFA(87–90). In this manner, areas of overlap or convergence were consolidated. Sekhon et al. then developed operational definitions for each construct based on established definitions within

healthcare literature, including health psychology and health economics. I chose to use the final version of the TFA as a framework for assessing public acceptability as the operationalised constructs take a patient-centred approach and it can be applied to prospective interventions such as risk stratification. As the TFA was developed following a review of the existing literature and draws on multiple frameworks that have previously been developed in this area, it is a more robust and comprehensive framework than using a previously established framework in isolation(87).

The Consolidated Framework for Implementation Research

Although the TFA can be used to assess acceptability from the perspective of those delivering an intervention, I chose to use the Consolidated Framework for Implementation Research (CFIR) to assess HCP opinions on acceptability(91,92). Similar to the TFA, the CFIR is the result of a synthesis of existing implementation frameworks including the Diffusion of Innovation Theory and the PRISM model (Practical, Robust Implementation and Sustainability Model), and was later adapted to incorporate the COM-B system (Capability, Opportunity, Motivation, Behaviour)(91–95). At the highest level, the CFIR includes five inter-related domains: intervention/innovation; inner setting; outer setting; individuals; process. Although the intention behind the CFIR is not to measure acceptability exclusively, many elements of acceptability are included across the five domains. This is most notable within the ‘innovation domain’, which considers how robust, complex, and cost-effective participants perceive the intervention to be, and the ‘individuals domain’, which includes the individuals’ need for the intervention and their capacity, ability and motivation to deliver the intervention(91). Furthermore, it is better suited to measuring acceptability among HCPs and stakeholders that may be directly involved in the implementation and delivery of an intervention as it considers a wider systems context which is more reflective of their considerations than the TFA, which does not explicitly consider the wider system or the stakeholders involved.

1.5 Summary

Bowel cancer represents a significant global health concern. Population-based screening is a central strategy for reducing incidence and mortality. In the face of increasingly constrained resources and unequally distributed screening harms, risk stratification represents a strategy for improving the efficiency and safety of bowel cancer screening programmes, whilst simultaneously maximising prevention and early detection and diagnosis. However, the introduction of risk stratification is a complex intervention which necessitates understanding of its acceptability from the perspective of all stakeholders, most notably the public. Whilst progress has been made in relation to other aspects of developing and evaluating risk-stratified bowel cancer screening, there has been limited research

on acceptability and there is therefore a pressing need for quantitative and qualitative approaches to understand public acceptability to inform implementation.

Chapter 2 Aim and thesis structure

2.1 Aim and objectives

This thesis aims to understand public acceptability, preferences and communication needs associated with risk stratification of FIT thresholds and screening intervals within population-based bowel cancer screening programmes.

I planned to address four key objectives across my thesis:

1. To understand how acceptable risk stratification of population-based cancer screening is to HCPs and the general public (Chapters 3 and 4).
2. To understand acceptability of risk-stratified FIT thresholds and screening intervals specifically for bowel cancer screening and determine which strategies are most acceptable to the public (Chapters 5 and 7).
3. To understand public information needs and communication preferences for receiving information about risk-stratified FIT thresholds and screening intervals for bowel cancer screening and to develop written information to support screening decision-making (Chapters 5 and 6).
4. To investigate the potential impact of risk stratification at three points (eligibility, FIT thresholds, screening intervals) in the bowel cancer screening pathway on uptake and acceptability (Chapter 7).

2.2 Thesis structure

The overall structure of my thesis is illustrated in Figure 2.1.

I have chosen to report the methods within each chapter rather than reporting them as a separate methods chapter. This is because, with the exception of two systematic reviews, the methods I have chosen are distinct for each study. Furthermore, several of these methods, notably the community jury and think aloud studies employ relatively novel methods meaning it is helpful to have these detailed alongside the study findings as a contextual anchor.

Chapters 3 and 4 report two parallel mixed methods systematic reviews exploring acceptability of risk-stratified cancer screening from the perspective of HCPs and the public respectively. Together these studies support the value of this thesis by identifying a significant gap in the literature around acceptability for cancers other than breast and highlighting the importance of acceptability for the success of screening programmes. I also identify recommendations for successful implementation of risk-stratified screening.

Chapter 5 describes findings from a community jury study in which acceptability of risk-stratified FIT thresholds and screening intervals was explored among an informed sample of members of the public. I report on the acceptability of different strategies for risk assessment and risk stratification within bowel screening, as well as key considerations for public communication and information needs.

I then report on a think aloud interview study paired with a user testing procedure in Chapter 6. Findings from Chapter 5 were used to develop a screening leaflet reflecting a bowel cancer screening programme with risk-stratified screening intervals. This leaflet was then refined through qualitative interviews employing a think aloud method and comprehension was quantified via a user testing survey. I describe suggested changes to written bowel cancer screening communication materials generally and more specifically in relation to screening intervals in order to improve public understanding.

The final study in this thesis is a quantitative survey study described in Chapter 7. The findings detailed in Chapter 6 informed the content of the survey study and were adapted to reflect risk-stratified screening at three points on the bowel screening pathway (eligibility, FIT thresholds, screening intervals). I report on comparative acceptability of the potential strategies, modes of data collection for risk assessment and anticipated uptake of screening by FIT.

The findings from all five studies are synthesised in the discussion in Chapter 8.

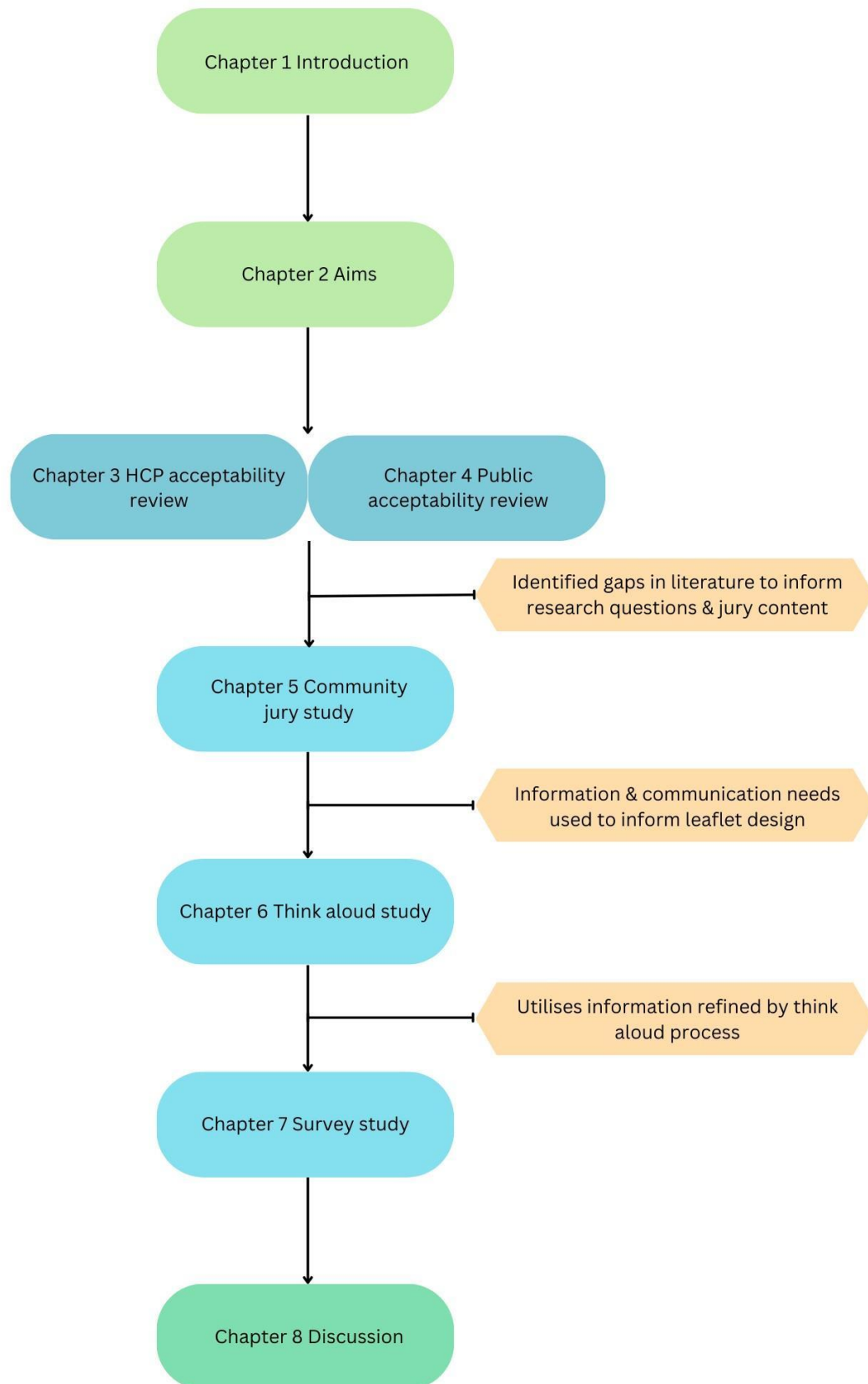


Figure 2.1 Flow diagram illustrating the overall thesis structure.

HCP - Healthcare professional

2.3 Patient and public involvement

Three patient and public involvement (PPI) representatives have been engaged across all studies in this thesis. The PPI panel were recruited as they had previous experience working on risk stratification and bowel cancer screening. They have assisted in developing and reviewing study materials and findings, and were invited to attend the community jury study detailed in Chapter 5. This involvement included video conferencing and emails, and individuals were paid for time spent on research activities in line with INVOLVE guidelines(96). A further three representatives recruited from the Cambridge University Hospitals PPI panel were involved in piloting the think aloud interview procedure detailed in Chapter 6.

Chapter 3 Acceptability of risk-stratified cancer screening from the perspective of healthcare professionals

In this chapter I describe a mixed methods systematic review of the acceptability of risk-stratified cancer screening across all cancer types from the perspective of HCPs.

This study was published in 2023(97): Taylor LC, Law K, Hutchinson A, et al. Acceptability of risk stratification within population-based cancer screening from the perspective of healthcare professionals: A mixed methods systematic review and recommendations to support implementation. PLoS One. 2023; 18(2):e0279201. DOI: 10.1371/journal.pone.0279201

3.1 Summary

Risk-based cancer screening has the potential to optimise resource allocation by targeting individuals who stand to gain the most from screening. Endorsement by HCPs is necessary for successful development and implementation of such an intervention. I therefore aimed to explore whether risk-stratified population-based cancer screening is acceptable to HCPs and sought to identify requirements for implementation.

I searched four electronic databases between 2010-2021 for relevant quantitative, qualitative and primary mixed methods citations. I used the Joanna Briggs Institute (JBI) convergent integrated approach to analyse the findings and the CFIR was used as a 'best fit' coding frame.

A total of 12,039 citations were returned and seven of these were eligible for inclusion. Six papers related to breast cancer and a single paper considered ovarian cancer. Risk stratification was considered generally acceptable; however, key areas were identified to support implementation, particularly in relation to de-escalation of screening among low-risk groups and other barriers and facilitators.

Overall, risk stratification of population-based cancer screening programmes is acceptable to HCPs. Future support and training will be required to facilitate implementation, and further research should work to strengthen the underlying evidence-base.

3.2 Background

As described in Chapter 1, risk stratification has the potential to improve the balance of screening harms and benefits whilst optimising the distribution of finite healthcare resources and has gained traction in recent years(68–70). From the perspective of HCPs, personalised screening confers benefits to service provision by allocating resources more efficiently, reducing the financial burden and opportunity cost of screening, decreasing waiting times, and potentially improving compliance

with screening recommendations(68). Additionally, population-level risk assessment may aid in the identification of individuals who are suitable candidates for risk-reducing interventions, such as medication or behavioural advice. Personalised risk scores also represent a valuable tool for clinicians to draw upon as part of shared decision-making(68). Despite these benefits, tailoring screening according to individual risk introduces additional complexity to an already complex adaptive system. This could include an increased burden engaging with and managing patients in line with their risk, supplementary workforce training, and ethical challenges when endorsing reduced screening(98). These considerations will be important not only for those responsible for executing and monitoring screening programmes, but also for HCPs who are integral to the delivery, as clinicians in primary care and those directly involved with screening are often a first point of contact for queries.

As detailed in Chapter 1, screening programmes must be acceptable to participants, wider society and HCPs from a clinical, social, and ethical perspective in order to be considered a success(75,99). Acceptability also has implications for uptake, meaning risk stratification must be delivered with fidelity if screening programmes are to achieve sufficient participation. Therefore, the views of HCPs on the acceptability of risk stratification within population-based cancer screening must be understood in order to facilitate successful development, implementation and sustainment of such a programme(69,73,98).

Previously conducted reviews with similar focus considering a single cancer type have identified a lack of acceptability research and a need for greater understanding of HCP perspectives on acceptability, including anticipated organisational barriers and facilitators(71,98,100). Furthermore, risk stratification represents a complex, large-scale change for health systems and may be influenced by organisational constraints and challenges. As such there is a need to understand acceptability within the wider organisational and structural healthcare landscape and to engage stakeholders across all areas(70,71).

3.3 Aim

To explore whether risk stratification within any population-based cancer screening programme is considered acceptable by HCPs, and to identify potential requirements for successful implementation.

3.4 Methods

The protocol was published prospectively on PROSPERO:

https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021286667

3.4.1 Search strategy

I searched MEDLINE, Embase, Web of Science, and PsychINFO electronic databases from the 1st of January 2010 to the 31st of November 2021. I developed the search string with the help of Veronica Phillips, an information specialist, using a combination of free text title and abstract search terms and MeSH terms linked with Boolean operators (AND/OR), as shown in Table 3.1. The first component of the search involved personalised risk and synonymous terms from rows one to seven which were grouped using 'OR'. Similarly, rows nine to 13 included terms associated with cancer, rows 15-17 included screening and related terms, and finally rows 18-28 incorporated acceptability and synonymous terms. These four key elements were then combined using 'AND'. I chose to restrict the date as a pragmatic decision based on the results of preliminary searches and to ensure contemporary views towards risk stratification due to more recent advances in the identification and sequencing of genetic variants and their inclusion in cancer risk prediction models(101,102). I imported the search results into Endnote reference management software to remove duplicates using the Bramer method in which field settings and custom filters are used to detect probable duplicates(103). The final results were then imported into the systematic review software Rayyan to facilitate the screening process(104).

Table 3.1. Systematic review MEDLINE search strategy.

This search was adapted for use in Embase, Web of Science, and PsycINFO.

1. "risk stratifi*".ti,ab.
2. "risk test*".ti,ab.
3. "risk predict*".ti,ab.
4. "risk assess*".ti,ab.
5. personali#ed.ti,ab.
6. "risk based".ti,ab.
7. Risk Assessment/
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. oncology.ti,ab.
10. cancer*.ti,ab.
11. neoplas*.ti,ab.
12. tumo#r.ti,ab.
13. Neoplasms/
14. 9 or 10 or 11 or 12 or 13
15. screen*.ti,ab.
16. prevent*.ti,ab.
17. Mass Screening/
18. 15 or 16 or 17
19. acceptab*.ti,ab.
20. perspective*.ti,ab.
21. opinion*.ti,ab.
22. view*.ti,ab.
23. attitude*.ti,ab.
24. perception*.ti,ab.
25. feedback.ti,ab.
26. evaluat*.ti,ab.
27. Attitude/
28. Feedback/
29. 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28
30. 8 and 14 and 18 and 29

3.4.2 Eligibility criteria

I reviewed the studies against the eligibility criteria detailed in Table 3.2. Studies conducted in relation to cancer surveillance and monitoring pathways, case finding, or the acceptability of non-risk-stratified cancer screening programmes were excluded. Studies conducted exclusively with participants harbouring high penetrance cancer genes, such as *BRCA1*, *BRCA2* or *PALB2*, were excluded as such individuals are typically managed via surveillance pathways and thus did not meet the criteria of population-based screening.

Table 3.2. Eligibility criteria for the review of acceptability of risk-stratified cancer screening from the perspective of healthcare professionals.

Inclusion criteria	Exclusion criteria
English language	Non-English language
Published and peer reviewed	Grey literature
Full text available	Full text unavailable
Quantitative, qualitative, or primary mixed methods studies	Editorials, conference abstracts, commentaries, opinion pieces, reviews, or letters
Conducted in the context of population-based screening	Cancer surveillance or monitoring programmes and case finding
Specific to risk-stratified cancer screening	Non-risk-stratified cancer screening
Includes healthcare professional, health service provider, and/or other stakeholder opinions on acceptability	Published before 2010

I conducted the database searches and removal of duplicates before undertaking an initial pilot phase to test the eligibility criteria using a subset of 200 citations. I led the pilot screening of titles and abstracts along with Rebecca Dennison (RD) and two medical students, Alison Hutchinson (AH) and Katie Law (KL). Any discrepancies were resolved in the presence of at least three reviewers and the suitability of the inclusion and exclusion criteria was discussed as a group.

3.4.3 Study selection

Following the pilot screening, I reviewed the title and abstract of all citations. A second reviewer (RD, AH, or KL) independently screened 10% of citations and again, any disagreements were resolved between at least three reviewers. All citations eligible for full text review were reviewed by myself and a second reviewer (RD, AH, or KL) and any disagreements at this stage were decided via consensus meetings with all reviewers present. I reviewed the reference lists of all eligible papers and two previously published systematic reviews about risk-based breast cancer screening(105,106) in the same manner to find any papers that were not identified through the literature search. These reviews were chosen due to their relevance to risk-stratified cancer screening among lay women and HCPs, although both were specific to breast screening.

3.4.4 Data extraction

I completed data extraction for all eligible studies using a standard form I had created for this purpose (Appendix 3.1). Data extracted at stage one included title, author (year), primary aim, setting, cancer type(s), sample size, demographics, study design, and method of analysis. I then completed a second, more detailed phase of data extraction including the key results, qualitative themes (if applicable), and the authors' primary conclusions. Phase two of data extraction was also

completed by a second independent reviewer (KL) for 50% of citations in order to reduce bias and to capture all relevant data. Data extraction was completed in two stages as stage one was a high-level phase including all eligible citations in this review and the review detailed in Chapter 4. Stage two was specific to each review and involved extracting more detailed, review-specific information.

3.4.5 Quality assessment

I used the Mixed Methods Appraisal Tool (MMAT)(107) to assess the quality of all the papers eligible for inclusion in the review (Appendix 3.2). I chose the MMAT as it is designed specifically for mixed methods research and can be used to assess five different study designs (qualitative research; quantitative descriptive studies; mixed methods research; non-randomised studies; randomised controlled trials). The MMAT involves a set of screening statements that can be answered as 'yes', 'no', or 'can't tell' and, as recommended, no studies were excluded on the basis of poor quality. I completed quality assessment for all studies alongside a second independent reviewer (RD or KL).

3.4.6 Data synthesis

I used the JBI convergent integrated approach to mixed methods systematic reviews as this method is recommended in cases where it is appropriate to answer the research question using both quantitative and qualitative data(108,109). As per this approach, I began by extracting quantitative data from the quantitative and primary mixed methods studies and transforming these data into qualitative statements. To do this, I used narrative interpretation of the data to generate a textual description, retaining any relevant numerical results and contextual anchors to preserve the integrity of the findings(109). I also extracted qualitative data from the included qualitative and primary mixed methods studies, comprised of any data included in the results sections or results data presented in supplementary materials which related to the research question. I then pooled the textual statements with the qualitative data using NVivo12 software (QSR International Pty Ltd; released 2018).

I used the CFIR as a coding frame to analyse the data, drawing on a 'best-fit' approach(110–112). I chose the CFIR as it has been developed from several other frameworks for implementation research, including the Diffusion of Innovations Theory(93), resulting in an extensive coverage of implementation domains. The five highest-level CFIR domains are summarised in Table 3.3.

Table 3.3. Summary of the five domains in the Consolidated Framework For Implementation Research and their meaning in the context of this systematic review.

CFIR domain	No. of subthemes	Meaning in this context
Intervention characteristics	8	Characteristics of risk-stratified cancer screening
Outer setting	4	External policies, guidance, and pressures
Inner setting	14	Organisational factors, such as culture and resources available within the healthcare system
Characteristics of individuals	5	Characteristics of healthcare professionals
Process	8	The spectrum of implementation activities, from planning to execution

I chose to adopt a ‘best fit’ approach to using the CFIR. This involved coding the data against the *a priori* framework (CFIR) and then using thematic analysis to accommodate data that did not fit within the initial framework domains in order to produce a final version of the coding framework that is a better fit for the data in question. The benefits of a ‘best fit’ framework approach include improved specificity to the review context and a reduction in the likelihood of data being inappropriately shoehorned into existing domains(112). I therefore chose to modify the framework in this way as not all of the data sat comfortably within the domains of the CFIR and there were also areas of convergence within the high-level domains which I felt it was valuable to aggregate into sub-themes. In line with this approach, I firstly coded all the data according to the *a priori* CFIR framework. I then reviewed the contents of the original domains and amended some construct names to better suit the meaning of the data within them. Constructs with a considerable amount of overlap were merged and I developed new definitions for constructs that were not comfortably contained within the existing framework. For example, I expanded the original construct ‘Relative advantage’, which included stakeholders’ perception of the advantage of implementing the intervention compared with an alternative solution, to also include the relative disadvantages of implementation. I renamed this construct ‘Relative advantage *or* disadvantage’ and amended the definition to ‘Stakeholders’ perception of the advantages *and* disadvantages of implementing the intervention versus *the current screening programme*’. Similarly, I redefined the construct ‘Design quality and packaging’ to ‘Design quality and *communications*’ because in this case, the intervention (risk-stratified screening) is not tangible meaning that packaging was not relevant. Nevertheless, how the intervention is presented is still important but was better reflected by considering communication. Two constructs only had one code attributed to them therefore I merged them with alternative constructs that reflected a similar sentiment. ‘Trialability’ was merged with ‘Complexity’

as participant reflections on the potential to perform a RCT centred around complexity. 'Readiness for implementation' also contained a single code and was merged with 'Knowledge and beliefs' due to concerns about feasibility being present in both constructs.

Once I had coded all the data using the 'best fit' version of the framework, I synthesised sub-themes within each framework construct via thematic analysis (Table 3.4). I summarised the content of each sub-theme and identified and interpreted areas of similarity, ambiguity, and divergence. This synthesis was an iterative process in which RD and I independently performed the initial coding and then came together to revise and refine the 'best fit' version of the framework and lower-level themes.

Table 3.4 Example of generation of sub-themes using thematic analysis for the review of acceptability of risk-stratified cancer screening from the perspective of healthcare professionals for the theme ‘Patient needs and resources’.

Data	Sub-themes (colour coded)
Outer setting	
Blouin-Bougie(113)	
Respondents mostly noted the negative psychological impacts of the implementation of BrC risk stratification (9 out of 11) on patients (e.g., anxiety, apprehension, or worries) that could lead to unnecessary complementary clinical examinations. In contrast, patients’ awareness and empowerment were seen to be potential positive effects by a number of respondents (5 out of 11).	Psychological impact
“Anxiety comes first to me. It is often the most anxious people who consulted for this kind of thing.”	Psychological impact
McWilliams(114)	
Yet the risk that women may still experience an interval cancer diagnosis was always acknowledged and one participant felt that low-risk women would still be at risk of overdiagnosis, but just a delayed diagnosis. It was felt by some that this could lead to negative psychological consequences for women and, question their confidence in breast screening overall.	Concerns about the needs of low-risk individuals
Participants explained that women should have informed choice about having their risk assessed and ability to weigh up pros and cons of less frequent screening yet, it was acknowledged by some that having choice to remain on current screening intervals if low-risk could make risk stratification untenable.	Information needs and informed decision-making
“... you need to go and check with people, enough, I would say, to say ‘Does she understand and then can she make an informed choice?’” (Screening operations/management; 2021).	Information needs and informed decision-making
Woof(115)	
They also questioned how women would perceive being at low risk and were concerned that some would assume themselves to be at no risk.	Concerns about the needs of low-risk individuals
They explained that the NHSBSP provides reassurance for many women and reducing screening automatically would take this reassurance away.	Psychological impact
Therefore, some advocated that reduced screening should be a choice but others explained that many women would be overwhelmed by the information needed to make an informed decision and would instead seek support from HCPs and the service.	Information needs and informed decision-making

BrC – breast cancer; HCP – healthcare professional; NHSBSP – National Health Service Breast Screening Programme

3.5 Results

3.5.1 Study selection

The literature search identified a total of 12,039 citations, after removal of duplicates. We excluded 11,977 of these after title and abstract review and screened the remaining 122 full texts for eligibility (Fig 3.1). Of these, six papers were considered eligible, plus an additional paper identified through searching the reference lists of the eligible citations, resulting in a total of seven included citations. The most common reasons for exclusion were non-empirical research papers (n=34) and papers that were not specifically related to the acceptability of risk-stratified cancer screening (n=27).

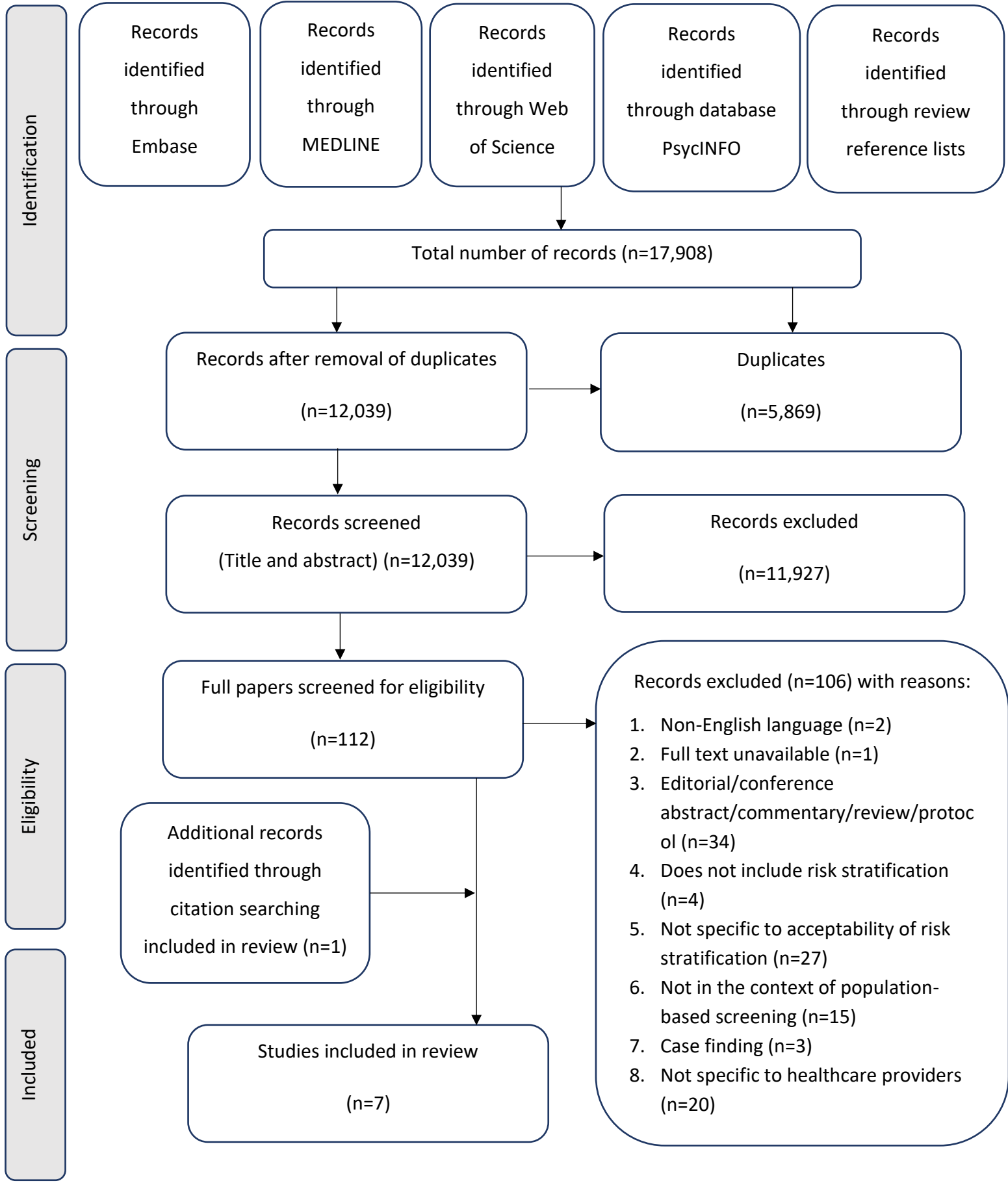


Figure 3.1 PRISMA flow diagram for the review of acceptability of risk-stratified cancer screening from the perspective of healthcare professionals.

3.5.2 Study characteristics

Study characteristics and key findings are summarised in Table 3.5. Six out of the seven studies were conducted in relation to breast cancer screening (86%)(113–118), and the single remaining study in relation to ovarian cancer screening(119). Sample sizes ranges from eleven(118) to 829(119) and studies were conducted across five high income-countries, with the majority taking place in the UK (n=4/7, 57%)(114,115,117,119). A variety of HCP roles were included across all studies, such as clinicians, public health employees, researchers and operational staff. Most of the included studies employed a qualitative methodology (n=5/7, 71%(113–116,118)), including focus groups, interviews and deliberative consultation. The remaining two studies involved a quantitative cross-sectional survey(119) and mixed methods digital concept mapping respectively(117).

Table 3.5 Summary of key study characteristics and findings for the review of acceptability of risk-stratified cancer screening from the perspective of healthcare professionals.

Author (year):	Country:	Aim(s):	Cancer type(s):	Sample size:	Type of HCP (n):	Study design:	Method:	Themes: (if applicable)	Primary conclusions:
Hann (2017)(119)	UK	To investigate UK HCPs' knowledge of OC genetics & other risk factors, & self-efficacy in discussing cancer risk & genetic testing with patients, to identify professional training needs, & explore attitudes towards population-based genetic testing and stratified risk management.	Ovarian	829	GP (32) Genetic specialist (44) Oncologist (45) Gynaecologist (15) Nurse specialist (6) Other (4)	Quantitative	Cross-sectional survey	N/A	Attitudes towards risk stratification for OC were mixed. Most HCPs were willing to discuss management options with their patients.
Fürst (2018)(116)	Germany	To assist doctors and screening participants in participatory decision-making.	Breast	15	Gynaecologist (7) GP (2) Radiologist (3) Human geneticist (1) Public health service (2)	Qualitative	Focus group	1. Assessments of individualised screening. 2. Assessments of women's need for counselling in mammography screening 2.0. 3. Assessments of the doctors' counselling competence. 4. Assessments of implementation of individualised screening.	Mammography screening 2.0 was viewed positively by most participants, but implementation was considered most critically. Concerns were expressed over time, burden, competence & guidelines.

Rainey (2018)(117)	Netherlands UK & Sweden	To ask HCPs to consider risk-based BrC screening & prevention from the perspective of eligible women to evaluate acceptability.	Breast	44	<u>Netherlands (17):</u> Researcher (7) Clinician (5) Other (5) <u>UK (15):</u> Researcher (3) Clinician (9) Other (5) <u>Sweden (12):</u> Researcher (5) Clinician (6) Other (1)	Primary mixed methods	Digital concept mapping	1. Anxiety/worry. 2. Proactive approach. 3. Reassurance. 4. Lack of knowledge. 5. Organisation of risk assessment & feedback.	Dutch, British & Swedish HCPs considered women's decision-making regarding personalised BrC screening similarly to women themselves.
Puzhko (2019)(118)	Canada	To engage HCPs in in-depth dialogue to explore feasibility of the proposed implementation strategies for a personalised BrC screening approach.	Breast	11	Genetic counsellors (3) Family physicians (8)	Qualitative	Deliberative stakeholder consultation	1. Implementation of the programme: a) Introduction of the programme & access to screening; b) Communicating results of individual risk estimation; c) Perspectives on women's decision-making regarding participation in the programme; d) Obstacles to using the model in a family physicians office; e) Referring women for follow-up; f) Correct interpretation of the programme & its advantages; g) Uncertainty about the difference between risk assessment & screening for disease.	Risk stratification required more clarity in communication with HCPs. Engagement of HCPs or a centralised system may be needed to ensure the success of a risk-stratified programme.

								2. Benefits of the programme: a) Benefits for HCPs; b) Benefits for women.	
McWilliams (2020)(114)	UK	To elicit the view of national healthcare policy decision-makers regarding implementation of less frequent screening intervals for women at low risk.	Breast	17	Radiologist, oncologist, radiographer, nurse or surgeon (6) Senior academics (6) Breast screening programme operations/ management professionals (5)	Qualitative	Semi-structured interviews	1. Producing the evidence defining low risk: a) Overcoming reservations about evidence accuracy; b) Determining a risk threshold & interval length; c) Risk stratification should be cost-effective. 2. The impact of risk stratification on women: a) Managing women as individuals; b) Balancing the harms & benefits; c) The ability to make autonomous decisions. 3. Practically implementing a low-risk pathway: a) Initial feasibility; b) Communication is essential; c) Considering service implications.	National healthcare policy decision makers found risk-stratified BrC screening generally acceptable. Before implementation there is a need to provide evidence for the accurate identification of low-risk individuals, ensure acceptability from women, demonstrate lack of harm & ensure screening programmes are capable of facilitating multiple pathways.
Blouin-Bougie (2021)(113)	Canada	To shed light on the perceptions of HCPs regarding implementation of a BrC risk stratification population-based approach.	Breast	15	GP (6) MD Specialists (5) Genetic counsellors (4)	Qualitative	Semi-structured interviews	1. Who? Target population: a) Eligible participants. 2. How? Clinical activities & What? Associated tools: a) Identification & invitation; b) Risk assessment; c) Risk communication; d) Risk management.	There were three main conditions required to facilitate acceptability of BrC risk stratification: respecting equity, knowledge management & reorganising HR to

								3. Which? Conditions or prerequisites: a) Ethical approach; b) Services organisation; c) Knowledge management; d) HR administration. 4. Why? Potential effects: a) Patients or populations; b) Services delivery.	optimise the workforce. Respondents welcomed risk stratification & agreed about some of the potential benefits.
Woof (2021)(115)	UK	To elicit views regarding implementing less frequent screening for low risk women from HCPs who implement risk-stratified screening.	Breast	28	Radiographer breast imaging manager (1) Breast screening office manager (1) Breast care nurse (1) Admin & data clerk (1) GP (3) Radiographer/ mammographer (16) Cancer screening improvement lead (2) Consultant radiologist (3)	Qualitative	Focus groups & telephone interviews	1. Reservations concerning the introduction of less frequent screening: a) Low risk screening is logical in theory; b) Questioning the reliability of risk; c) Unease towards providing screening frequency; d) Low risk is not 'no risk'. 2. Considerations for the management of public knowledge: a) Navigating media output; b) Navigating public scrutiny; c) Impact of mixed messaging & hearsay. 3. Deliberating service implications & reconfiguration management: a) Prevalent vs incident round rollout; b) Integrating a low risk screening interval.	Risk stratification was considered a logical step towards personalised screening. Less frequent screening was not unacceptable but was considered mindfully.

BrC - breast cancer; GP – general practitioner; HCP – healthcare professional; HR – human resources; mammography screening 2.0 – individualised mammography screening; MD – doctor of medicine; N/A – not applicable; OC – ovarian cancer; UK – United Kingdom.

3.5.3 Quality assessment

The results of the quality assessment using the MMAT are summarised in Table 3.6.

The single quantitative study was found to be the lowest quality of the included studies and scored 'no' or 'can't tell' in two domains reflecting uncertainty about the representativeness of the sample and evidence of response bias due to significant differences in knowledge, and self-efficacy among participants who did and did not complete the survey ($p<0.001$ and $p=0.042$ respectively)(119). All five of the included qualitative studies were of high quality across all MMAT domains(113–116,118). The primary mixed methods study was of relatively good quality and scored 'yes' in four of the five domains and 'can't tell' for the remaining domain assessing whether the quantitative and qualitative components of the study adhered to the quality criteria of each tradition of the methods involved because the risk of non-response bias (assessed as part of the quantitative component) was unclear(117).

Table 3.6 Results of the quality assessment of papers included in the review of acceptability of risk-stratified cancer screening from the perspective of healthcare professionals using the Mixed Methods Appraisal Tool.

Quantitative descriptive					
Author (year):	Relevant sampling strategy?	Representative sample?	Appropriate measurements?	Nonresponse bias?	Appropriate statistical analysis?
Hann (2017)(119)	✓	?	✓	✗	✓
Qualitative					
Author (year):	Appropriate approach?	Adequate methods?	Findings derived from data?	Substantiated interpretation?	Coherence?
Fürst (2018)(116)	✓	✓	✓	✓	✓
Puzhko (2019)(118)	✓	✓	✓	✓	✓
McWilliams (2020)(114)	✓	✓	✓	✓	✓
Blouin-Bougie (2021)(113)	✓	✓	✓	✓	✓
Woof (2021)(115)	✓	✓	✓	✓	✓
Mixed methods					
Author (year):	Adequate rationale?	Integrated components?	Adequate interpretation?	Inconsistencies addressed?	Quality of components?
Rainey (2018)(117)	✓	✓	✓	✓	?

All papers scored 'yes' for screening questions 1 and 2 (S1. Are there clear research questions? S2. Do the collected data allow to address the research questions?).

- ✓ Yes
- ✗ No
- ? Can't tell

3.5.4 Strength of the evidence

The studies that contributed to each theme are summarised in Table 3.7.

All of the included studies considered 'Knowledge and beliefs about the intervention' in detail, suggesting strong cumulative evidence for this theme. Other themes that were considered by five or more studies included 'Relative advantage or disadvantage', 'Complexity', 'Evidence strength and quality', 'Design quality and communications', 'Patient needs and resources', 'External policy and incentives' and 'Available resources', indicating robust evidence across these themes. Two inner setting themes, 'Tension for change' and 'Relative priority', were briefly contributed to by just two high quality studies(113,116) and therefore the strength of the evidence is weaker for these particular themes. Three high quality qualitative studies(113,114,118) contributed to 15 or more of the themes.

Table 3.7 Strength of the evidence and studies contributing to each construct for the review of acceptability of risk-stratified cancer screening from the perspective of healthcare professionals.

		Author (year):						
		Hann (2017)(119)	Fürst (2018)(116)	Rainey (2018)(117)	Puzhko (2019)(118)	McWilliams (2020)(114)	Blouin- Bougie (2021)(113)	Woof (2021)(115)
MMAT result:		Some concerns	High quality	Some concerns	High quality	High quality	High quality	High quality
Intervention characteristics	Intervention source				○	○	○	
	Evidence strength & quality			○	●	●	○	●
	Relative advantage or disadvantage	○	○		○	●	○	●
	Complexity		○	○	○	●	●	●
	Design quality & communications			○	●	○	●	●
	Cost		○	○		○	○	
Outer setting	Patient needs & resources			●	●	●	○	●
	External policy & incentives		○	○	○	○	●	
Inner setting	Culture		○			○	○	
	Tension for change		○					
	Compatibility					●	○	○
	Relative priority						○	
	Available resources	○	○		●		●	○
	Access to knowledge & information		○		○	○	○	
Characteristics of individuals	Knowledge & beliefs about the intervention	●	●	●	●	●	●	●
	Self-efficacy	●	○					
	Individual stage of change		○			○	○	

	Other personal attributes							
Process	Planning							
	Engaging							
	External change agents							
	Executing							
	Reflecting & evaluating							

Large circle = 'yes' for all MMAT domains

Small circle = 'no'/'can't tell' for one or more MMAT domains

Open circle = study briefly contributes to the theme

Filled circle = study strongly contributes to the theme

3.5.5 Resulting framework

The best fit CFIR framework is presented in Figure 3.2.

The majority of the CFIR framework's original themes were compatible with the data indicating that it was an appropriate framework to use in this analysis and that a wide range of implementation outcomes were identified across the included studies. Two of the original construct names and definitions were amended as described in section 3.3.6 and several constructs were not relevant to this analysis (Figure 3.2).

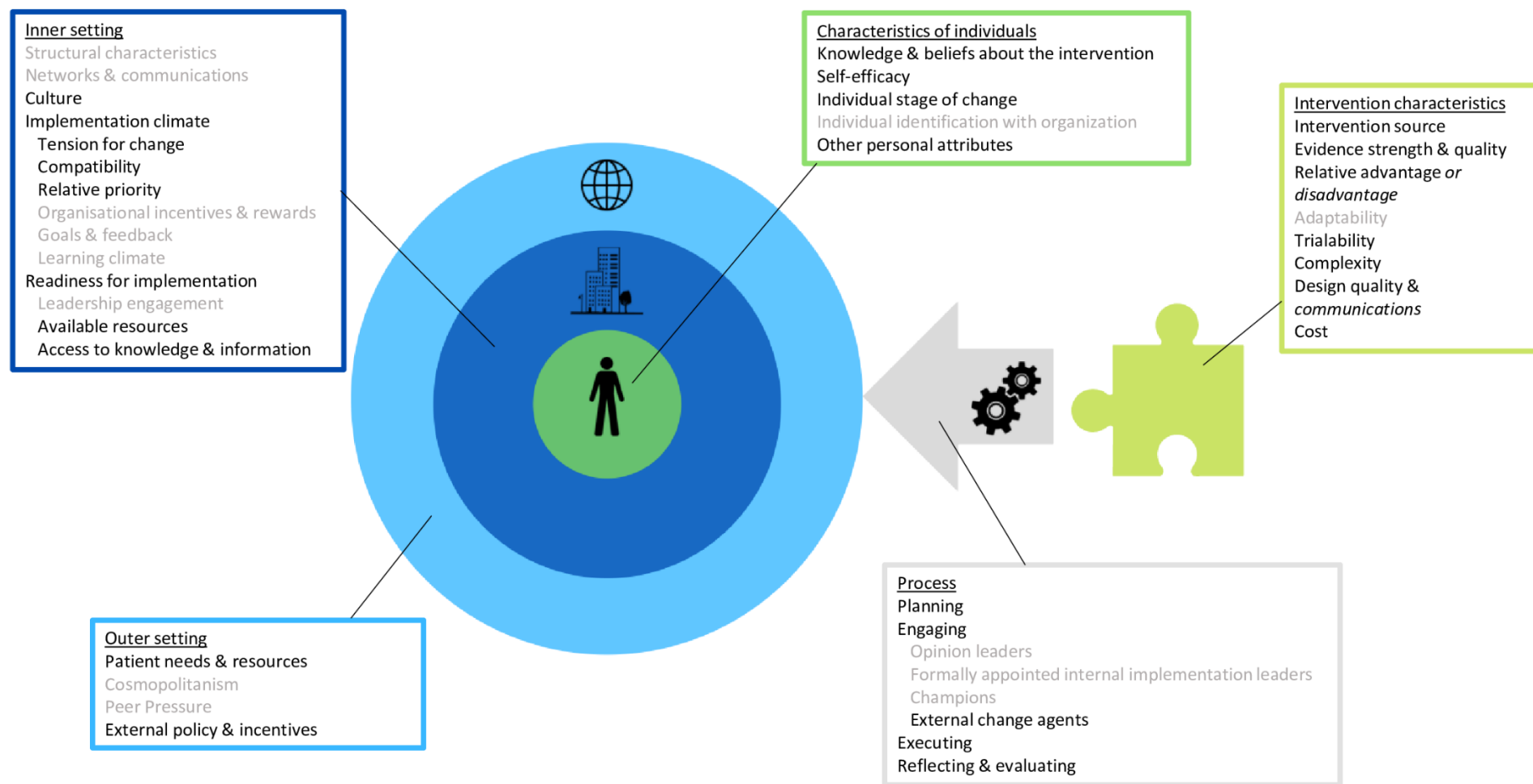


Figure 3.2 'Best-fit' adaptation of the Consolidated Framework for Implementation Research.

Framework constructs are divided across five domains. Constructs names in grey were not applicable to this analysis. Construct names in italics indicate changes made as part of the 'best fit' framework approach.

3.5.6 Qualitative synthesis findings

3.5.6.1 Intervention characteristics

Intervention source

Although the source of the intervention was only considered by HCPs in three studies, those that did consider this construct emphasized the importance of involving both HCPs and the general public in all stages of development and implementation(113,114):

“Participants identified individual beliefs about risk and knowledge of breast cancer and screening as key factors that will impact how women could respond to low-risk stratification. Participants felt this should guide the development of communication and information about a low-risk pathway to facilitate understanding.”(114)

Some concern was also raised about the role of cost in driving the development of risk-stratified screening programmes and how this might be perceived by stakeholders if it were presented as the motive behind risk stratification. One academic suggested that *“...people might be concerned that the reason this was being done was to save money, and not necessarily for a health benefit for the wider population, or particularly of benefit for the women of low-risk.”(114).*

Evidence strength and quality

Two of the included studies focused specifically on introducing low risk screening pathways, as such much of the discussion around evidence strength was in relation to de-escalation of screening for low risk cohorts(114,115). Some HCPs expressed doubt over the strength of the evidence for reducing breast cancer screening for low-risk women as part of risk stratification. Their concerns centred around the potential for interval cancers and diagnosis of aggressive, non-hormone dependent breast cancer in younger women:

“...age but not just age in terms of the effect of age on your risk. Age in terms of its effect on the likely progression rate of cancer... someone that’s 50, if they had a very low risk, I would feel a bit more worried about extending the interval beyond 3 years just because [...] the proportion of hormone dependent cancers increases with age. The younger you are, the more likely it is to be non-hormone dependent, faster moving”. (Academic; 2022)(114).

This was echoed by a general call for greater research and modelling studies to ensure that the features of a risk-stratified programme are evidence-based and not steered by implementation priorities(115,118):

“Nevertheless, HCPs explained that the interval length should ultimately be driven by

scientific evidence and safety, rather than ease of integration into the current programme.”(115)

Several HCPs suggested that demonstrating accurate risk modelling may increase stakeholders’ confidence in the resulting risk estimates and risk-based groupings(114,115). The included variables and the stability of risk estimates over time factored into consideration of the available evidence and some individuals expressed concerns that risk models may not be sufficiently accurate in the long term to allow safe de-intensification of screening among low-risk women. Despite beliefs that the strength of the evidence was the most important factor in determining the features of a risk-stratified programme, inaccuracies in self-reported data and the potentially unstable nature of certain variables used in risk modelling resulted in scepticism(115):

“How do we get around the fact that everybody’s risk increases as they get older? So if you give somebody their risk at 47 when they first come, when is that reviewed? Because we know that the majority of cancers occur in the older cohort of ladies, so your risk just increases as you get older anyway. So do you then at your six or your 12 year mammogram have another density reading and your risk is ...?” (Breast Screening Office Manager: Focus Group [FG] 1)(115).

Additionally, there was some disparity between the priorities of clinicians and other professionals. Clinicians in the UK rated concerns surrounding the accuracy of risk stratification to be the most important factor in women’s decision-making process to attend screening, however non-clinical professionals considered this the least important factor(117). Primary care professionals (PCPs) also speculated that risk stratification may contribute to cultural inequalities due to the inaccuracy of risk models in certain ethnic groups; a sentiment echoed by genetic counsellors who voiced particular reservations about the applicability of risk prediction models for different groups of patients(113):

“...genetic counsellors indicated they find RPMs [risk prediction models] generally easy to use, but not necessarily essential, because they often considered their experience and clinical judgment to be sufficient. Rather, they were concerned about the relevance of available RPMs and which of these to use for a particular patient.”(113)

Relative advantage or disadvantage

Three main sub-themes were identified when considering risk-stratified cancer screening relative to traditional cancer screening programmes: ‘Relative advantage’, ‘Relative disadvantage’, and ‘Ultimately neutral’.

Some HCPs were optimistic about the impact of risk stratification on reducing demands on staff and screening programme resources, as well as improving the consistency of service provision(113,114). Other possible advantages of a risk-stratified approach identified by HCPs included a reduction in the harms of screening, such as overdiagnosis and overtreatment, among low-risk groups. This was particularly salient in the context of breast cancer screening programmes that have previously received such criticism(115):

“I think we get criticised all the time for overtreatment and overdiagnosis and we should be seen to be trying to personalise it a bit more, but we shouldn’t overthink it and overcomplicate it in the process.” (Consultant radiologist: FG3)(115).

Providers acknowledged that in some cases, the current provision of cancer screening services are inadequate, and that introduction of a risk-stratified approach could represent an opportunity for health promotion(116,119). Genetic counsellors in particular noted that risk stratification would make risk assessment considerably more accessible, allowing individuals to avoid the lengthy wait time that currently exists for referral to such services. This is particularly advantageous for those at moderate to high risk, where access to risk information may be considered especially valuable and was discussed in some detail by Puzhko et al.:

“Women will be able to assess their risk without seeing a genetic counsellor. Those of them assigned the near-population risk will not need counselling. As a result, shorter wait lists are expected, and those with medium and high risks will have more access to genetic counselling.”(118)

Conversely, some HCPs speculated that moving away from established screening practices to a programme in which screening may be reduced for some members of the population could take away the sense of reassurance that many individuals gain from attending screening(115). In the case of well-known screening programmes that the public are already familiar with such as breast and cervical screening, changes to the screening interval might induce anxiety about cancers being missed in the interim period which may result in reduced acceptability of the programme(114):

“...already the UK (breast screening) programme gets criticised for having three yearly intervals because most European programmes have a two-year interval and they feel that three years, there’s much less of a safety net. You know, if a cancer’s missed at one screen there’s still quite a good chance that it’ll be still at an early stage at the next one two years later. But if the next one’s three years later there’s a

bit more concern. So, I would think there's not that much point going beyond four years." (Academic; 2022)(114).

Despite these seemingly opposing opinions, several HCPs recognised that implementation of risk-stratified cancer screening would likely have a neutral impact overall. For example, although reducing screening for groups of the population at lower risk may have benefits for workload and burden on staff, it is probable that the inclusion of higher risk cohorts would balance out this effect as one participant surmised(114):

"...my sense of all this is that what you're doing is trying to increase the frequency for people who are at higher risk and reduce it for people at lower risk... I think probably in terms of screening visits, consultations and so on, the overall volume of work probably wouldn't change all that much" (Academic; 2023)(114).

Complexity

HCPs acknowledged that risk-stratified cancer screening is substantially more complex than the traditional age and/or sex-based approach to screening. Participants highlighted several barriers that would need to be overcome ahead of implementation. The transition to risk-stratified screening was largely viewed with pessimism and a lack of consensus around how to address complexities was both recognised and perpetuated by HCPs(114,117):

"... do you start the new regime for just new women coming into the programme and continue the current policy for those existing in the screening programme? If you do that you create an inbuilt inequality and a two-tiered service. Or do you allow women the choice to be given a baseline test and then a new regime, or allow them to continue on their old one?" (Screening operations/management; 2027)(114).

Concerns about the time and resource investment necessary to implement such a complex intervention within an already complex healthcare system were also discussed, as well as difficulties in ensuring ethical and equitable screening opportunities(113,114):

"Participants explained that women should have informed choice about having their risk assessed and ability to weigh up pros and cons of less frequent screening yet, it was acknowledged by some that having choice to remain on current screening intervals if low-risk could make risk stratification untenable."(113)

Design quality and communications

The communication of individual risk and the underlying motivations for risk stratification were of central concern across HCPs. Participants highlighted that the communication modality should be

tailored to the individual as much as the screening programme itself, and emphasised that clarity will be essential in supporting a transition away from the current pro-screening rhetoric(113,115):

“I mean it’s quite a subtle message, isn’t it? For years and years we’ve been telling ladies you must go and have your screenings, and I think screening in the public mind is very much wrapped around screening is good always. I think it’s very hard to discuss subtleties of potential screening harms with people. (GP: telephone interview [TI]1)”(115)

Additionally, participants expressed a need for new and adaptable risk communication tools to facilitate the communication of personal risk:

“Respondents mostly noted the lack of RCTs [risk communication tools] (14 out of 15). Indeed, HPs [health professionals] indicated they provided verbal explanations to patients (13 out of 15), without necessarily using graphs or visual representations of risk, nor providing written information to patients. They wanted more RCTs, written or visual, that could be adapted to each patient, improve patients’ retention of information, and increase awareness regarding BrC prevention. A centralized computerized information resources center, in which recognized, standardized, and simplified information on BrC risk is provided, was a practical solution proposed by a respondent that could be useful for HPs and patients.”(113)

Genetic counsellors in one study suggested that the results of the personalised risk assessment *“could be posted on a website with access by health professionals. Alternatively, the results could be included in an electronic medical record (EMR) and health professionals would be able to view the results.”(118)*. The participants felt that individuals should also have access to their results at the same time as their GP and any other relevant HCPs but emphasised that a genetic counsellor should always be involved in cases where high penetrance or cancer predisposition genes are identified(118):

“If any breast cancer predisposition genes are to be tested, test results should be communicated to genetic counsellors. At the mixed session, the participants agreed that results should be available at the same time to women, their physicians, and other clinicians involved in their screening and follow-up.”(118)

Notably, perceptions of the importance of risk communication varied. In one study, Dutch clinicians believed ‘Communicating risk’ to be the most important factor in women’s decision-making process to attend risk-stratified breast cancer screening. Yet, other Dutch professionals (non-clinicians)

ranked this as the least important factor for decision-making, suggesting discord in how different providers value and prioritise such communication(117).

Cost

Several HCPs commented on the potential for increased financial costs associated with risk stratification, particularly in the context of publicly funded healthcare services where cost has a considerable influence on policy(113,114). The importance of adequately evidencing cost-effectiveness was emphasised and participants felt this was likely to be a crucial consideration for stakeholders when considering implementation(114):

“... it depends on the healthcare system, because there will be very different motivators to things like having diagnostic tests and more frequent screening when you’re having to pay for it [...] when it’s free it’s got to be cost effective and it’s got to be evidence based.” (Screening operations/management; 2027)(114)

The concept of cost was also discussed in non-monetary terms, including time and resources. Some HCPs felt that risk stratification may be a beneficial strategy in helping to alleviate current resource constraints saying that *“...it must be considered (...) whether it is actually necessary for us to screen all women”* as a result of resource limitations(116). However, other participants speculated that risk-stratified screening might actually increase costs and negatively impact waiting times in an already resource limited healthcare landscape(113). Despite the importance of cost as a consideration for HCPs themselves, when asked to consider the views of women deciding whether to engage in risk-stratified breast cancer screening, Swedish HCPs rated financial concerns as being the least important factor(117).

3.5.6.2 Outer setting

Patient needs and resources

Patient needs and resources was a diverse construct which also contains barriers and facilitators anticipated to be experienced by those who are receiving the intervention. This construct was examined in depth by HCPs across five of the included studies(113–115,117,118) and three key sub-themes were identified: ‘Psychological impact’, ‘Needs of low-risk individuals’, and ‘Information needs and informed decision making’.

HCPs tended to focus on the potential for negative consequences when considering the psychological impact of risk stratification and receipt of personalised risk estimates. Increased

anxiety, reduced reassurance, and feelings of insecurity were possible barriers suggested by participants across four studies(113–115,117):

“HCPs in The Netherlands rated anxiety/worry as most important for women’s decision-making process for participating in personalised screening (7.23/10) including statements such as: ‘Increasing the screening frequency provides insecurity’, ‘Knowing you’re high risk instils anxiety’, and ‘Having an increased risk due to non-modifiable risk factors will increase anxiety and worry’.”(117)

However, some participants also acknowledged the possibility of positive implications such as reassurance or a sense of empowerment in knowing one’s cancer risk and the ability to help other family members by informing them about a potentially elevated level of risk(113,117,118):

“HCPs in Sweden rated ‘Reassurance’ as the most important factor in women’s decision-making process for participating in personalised screening (7.45/10), which includes statements such as: ‘I experience an increased sense of safety because I know my risk’ and ‘I feel reassured because additional methods will be used when mammography is not enough’.”(117)

Two papers focused on low-risk women and considered some of the potential barriers and facilitators of risk-stratified breast cancer screening for this group specifically. HCPs questioned the ability of low-risk individuals to understand the meaning of a low risk estimate and the resulting implications for screening opportunities, as well as comprehending the potential for interval cancers and delayed diagnosis(114,115). The needs of low-risk women were largely considered in relation to barriers to accessing screening and the potential for negative effects:

“... the obvious harm is a woman’s breast cancer that could’ve been screen detected isn’t. You don’t know that’s harmful because you don’t know what type of cancer it is; [...] there’d be psychological harm to that as well as ‘I signed up to having this less frequent mammograms and I possibly could’ve had my breast cancer detected two years earlier’.” (Healthcare professional; 2029)(114)

Participants in both studies hypothesised that receiving a low risk estimate might disincentivise women to attend screening at all, seeing it as no longer being relevant to them(114,115):

“...some people might think, ‘oh, I’m low risk, I don’t need to go at all’, and then might not respond when you actually send the five year or longer letter through.” (Screening operations/management; 2023)(114)

Finally, HCPs explored public information needs and the role of informed decision-making in relation to all risk groups. Informed choice was generally viewed positively by participants, suggesting that individuals may want to be informed of the advantages and disadvantages of risk-stratified screening, but that any resulting questions should also be appropriately addressed and support offered where necessary(114,115,117,118):

“Therefore, some advocated that reduced screening should be a choice but others explained that many women would be overwhelmed by the information needed to make an informed decision and would instead seek support from HCPs and the service.”(115)

It was also acknowledged that different population subgroups may require different levels of support in understanding a risk-based approach to screening(118):

“PCPs raised the question of whether cultural differences could determine differences in the magnitude of potential benefits. For example, they suggested that certain population groups (e.g., recent immigrants) may benefit less from the program. They may be less informed on the benefits of screening in general, and it may therefore be more difficult to explain the risk-based approach to them. It was suggested that the explanations for these groups of women could be done by the trained nurse, preferably one with an understanding of cultural preferences.”(118).

External policy and incentives

HCPs identified the need for new and homogenous evidence-based guidelines to be developed if risk stratification is to be implemented, suggesting that *“revision of the screening guidelines is needed fundamentally before the procedure can be implemented in practice”*(116). Current guidelines were perceived as both inadequate and unclear, and HCPs echoed the importance of consistency:

“Some (5 out of 15) also underlined the fuzziness of the available evidence-based knowledge on BrC screening and the multiplicity of guidelines, which contribute to variations in practices among regions and settings.”(113)

3.5.6.3 Inner setting

Culture

Discourse around culture focussed on the roles and values held by different cadres of healthcare providers, particularly considering which roles or individuals should be responsible for interpreting and communicating risk estimates. It was generally accepted that risk should be interpreted by HCPs and not by lay individuals, but the perceived roles of individuals varied according to organisational

assumptions(113,116). Some participants, notably GPs, felt that all risk-related duties should be undertaken by a geneticist, believing that interpretation of risk for all risk cohorts falls within their expertise(113). Conversely, geneticists themselves were content to counsel high risk individuals but felt quite strongly that conversations about average risk patients lay outside of their domain(113):

“I do a lot of personal risk assessment for physicians who asked for and found difficult to answer patients’ inquiry [about BrC risk]. But, is this my job? No, it is not my job to estimate BrC risk for women of the general population [laughs]. My job is to take care of high-risk women.”(113)

Rainey et al., reported some discrepancies across different groups of HCPs especially in the UK, suggesting that individuals’ norms, values, and assumptions vary within the inner setting and indicating that the priorities of specialised groups like genetic counsellors may not align with the priorities of other professionals, such as GPs(117):

“Both UK clinicians (n=9) and other professionals (n=6) prioritised taking a ‘Proactive approach’ and women’s ‘Anxiety/worry’ but there were large discrepancies in their prioritisation of other themes. Clinicians prioritised concerns about accuracy of risk stratification where other professionals considered this to be the least important factor.”(117)

Compatibility

When considering compatibility of risk-stratified cancer screening, HCPs predominantly debated how well risk stratification may fit with existing screening pathways and health system organisation and in one study *“all participants acknowledged that adapting a relatively straightforward, mostly universal programme to one involving multiple pathways would not be easy...”(114)*. HCPs advocated for as much integration with existing screening infrastructure as possible, in order to minimise confusion and disruption for both HCPs and the public(113–115). However, the introduction of a risk-stratified pathway was generally discussed with pessimism and participants had doubts about feasibility when compared to more simplistic age and/or sex-based programmes(114,115).

“Seven out of thirteen respondents also emphasized the fact BrC risk stratification must be complementary to the current screening program and well-integrated into existing services. No confusion or overlaps must exist between these two approaches for HPs to be comfortable with the services’ trajectory.”(113)

One participant felt that a risk-stratified programme would be less challenging than anticipated as

individuals are already exposed to other risk-based health principles and risk itself is not an entirely novel concept(114):

“...however, one participant felt that because risk is discussed in other programmes, such as antenatal screening, it will be straightforward to communicate risk-stratified screening to women.

‘... it looks like when you start introducing risk-based screening, there’s a whole new concept. I think a lot of the preparatory groundwork in terms of general principles of it is already out there.’ (Academic; 2036).”(114)

Relative priority

Participants in one study questioned whether cancer prevention through screening programmes is the optimal use of limited healthcare resources when compared with actively treating patients who have received a cancer diagnosis(113):

‘Ideally, to be rational, it is women with cancer that should get access to an annual MRI in priority, and not her sister. Given that we have very limited resources, we have to target who can get access to services...’(113)

Available resources

HCPs across six of the included studies considered the resources available for implementation and maintenance of risk-stratified cancer screening programmes. Participants vocalised concerns about the ability for current resources to meet the demands of a risk-adapted screening programme, alongside themes of equity and managing the capacity for patient discourse(113,115,118,119). HCPs were uncertain how resources could be equitably and efficiently distributed, especially in relation to the availability and distribution of specialist geneticists and related services(113,118):

“Some interviewees explicitly highlighted that patients’ access to radiological modalities may vary according to the settings in which their prescribing physicians work; this was another source of inequity... Almost all interviewees raised the issue of the scarcity of human resources (12 out of 14), notably in genetics (8 out of 12). Many suggested more collaboration with HPs specialized in genetics and called for more resources, particularly in rural regions, for the approach to be ethically acceptable and feasible.”(113)

Managing patient conversations was a key consideration for all risk groups, most notably for those deemed to be at low risk in comparison with other cohorts(113). HCPs speculated that a new risk-based system would generate patient queries, necessitating more time for consultations and indicated that the healthcare system has an obligation to provide those answers, despite limited capacity to do so(113):

“... you’re probably going to raise those questions, so you need to make sure that there are the resources and the capacity to have those conversations with women [...] so that there is an opportunity for people, either, well, maybe it could be a telephone contact, or a face to face, to say, if you want to discuss it further, then you can either speak to somebody on the phone, or we can arrange for you to come and see somebody ...” (Academic; 2024)(113)

Despite the belief that these conversations were of value, participants were unsure which HCPs should be responsible, given the time constraints and considerable workload experienced by individuals working in the health system(115). Additionally, Hann et al., found that a lack of time and resources contributed to HCPs unwillingness to have discussions with patients about their risk status(119).

“Prior to implementation, a system should be established to manage women’s queries and concerns, although whose responsibility this should be was debated. It was suggested that radiography staff at the point of screening would not be appropriate due to time constraints within appointments...To divert questions away from frontline staff, HCPs also suggested a helpline, but it was unclear who should manage this.”(115)

Access to knowledge and information

Numerous participants encouraged an increase in accessible information about risk and risk-tailored screening and emphasised the need for improved general knowledge about genetics among HCPs(113,114,116,118). They also encouraged the provision of patient communication tools embedded within primary care to facilitate conversations with patients and knowledge exchange tools to assist with sharing information between healthcare providers and settings(113,116).

3.5.6.4 Characteristics of individuals

Knowledge and beliefs and the intervention

Knowledge and beliefs about risk-stratified screening were discussed in detail across all of the included studies and can broadly be categorised as either positive or negative beliefs about the intervention.

Overall, the concept of risk stratification was viewed as an improvement when compared with existing screening practices and the idea of tailoring exposure to screening based on individual risk was perceived as logical, resulting in an improved balance of benefits, harms, and costs(113–116,118,119). HCPs were generally aware that high-risk groups stand to gain more from increased screening, whereas low-risk individuals would experience fewer harms by being screened less. As such, they recognised that risk-stratified screening represents an improved way of distributing finite healthcare resources whilst maintaining screening opportunities for those who stand to benefit most(113–116,119):

“All participants described positive aspects of low-risk screening where women would have less inconvenience of attending, fewer occasions undergoing mammogram discomfort, reduced chance of additional tests and overdiagnosis.”(114)

Nevertheless, HCPs were cautious about deviating from existing cancer screening programmes due to concerns over public criticism, lack of confidence in advocating for reduced screening, interpreting and conveying risk, and beliefs about impacting patients’ wellbeing(114–116,119).

Puzhko et al., noted that PCPs in particular were confused about the difference between participating in risk assessment and participating in the screening programme itself. This influenced their beliefs about the benefits and harms of a risk-stratified programme with some participants emphasising *“the importance of helping women understand all the benefits and harms that this new assessment would bring to help make an informed choice”* and stating *“that the possibility of overdiagnosis needs to be explained to women”*, despite overdiagnosis being a harm associated with screening rather than risk assessment(118). This misunderstanding continued throughout the study, and it was clear that PCPs in particular would benefit from having terminology associated with risk stratification clearly defined(118):

“Moreover, in the small groups and during the mixed session, the PCP suggested providing women with online information to educate them on the risks and benefits of screening and help them make a decision regarding their participation in the

program. PCPs discussed the “absolute CVD [cardiovascular disease] risk/benefit” calculator as an example. These issues, however, are related to disease screening and not to the risk stratification. This confusion persisted throughout the small and mixed sessions.”(118)

Self-efficacy

Despite some negative beliefs about the intervention, HCPs largely reported feeling confident in their ability to implement stratified cancer screening. Over 80% of participants were willing to discuss risk-stratified interventions for ovarian cancer with individuals at all risk levels (88.3% for low risk, 85.0% for intermediate risk, 82.2% for high risk) and would feel confident in explaining what low, intermediate and high-risk scores mean to their patients after being informed of the risk boundaries (88.3% for low risk, 83.6% for intermediate risk, 87.7% for high risk)(119). Notably, slightly fewer participants reported confidence in explaining an intermediate risk score and willingness to discuss risk-stratified interventions with high-risk women was reduced in comparison with intermediate and low-risk groups(119).

Individual stage of change

Although many HCPs were in favour of risk-stratified screening in principle, some participants expressed a reluctance to deviate from traditional screening practices, most notably for long established screening programmes such as for breast cancer(113,114,116):

“Even though some participants acknowledged other screening programmes (such as cervical) have varied screening frequencies, current breast screening intervals are long established underpinning reluctance of a substantial departure.”(114)

Other personal attributes

Some providers expressed general confusion around screening guidelines and practices, particularly in relation to genetics, and genetic counsellors expected that improved knowledge of genetics among other HCPs would increase the efficiency of their own role by ensuring that referrals to specialist genetic services are appropriate(113).

3.5.6.5 Process

Planning

The concept of planning implementation of risk-stratified screening in advance was explored by participants in five of the included studies(113–116,118). A key concern within this was planning which risk factors should be included in order to supply a risk model that is acceptable to both the public and HCPs and how this data should be collected(113–115):

“The approach needed to invite potential eligible women remained unclear to respondents (14 out of 15); however, they proposed solutions based on available recognized BrC risk factors that can be easily collected to pre-select women to be invited. The most recurrent of these were family history, breast density, and age. Other suggestions to complete this activity were to use a self-administered questionnaire, to use networks and family members as information relays, or to invite women via letter like to the current screening program.”(113)

Additionally, HCPs advocated for pilot testing and feasibility assessment before risk-stratified screening is rolled out on a larger scale(114,118):

“Feasibility work and pilot testing were viewed as fundamental to minimise issues ‘... you can’t change a direction of a cruise ship overnight, you sometimes need a bit of time to filter information, let people be aware of it, know that there’s work being done. But, it’s a bit like a drip feed process. But you don’t want that to be too long either, so finding the balance will be really challenging.’ (Healthcare professional; 2030).”(114)

Engaging

Engaging members of the public and increasing awareness of risk-stratified cancer screening was discussed by participants in two of the included studies(113,118). Participants identified the value of exposing both HCPs and the general public to the concepts of risk assessment and risk stratification to promote acceptability(113,118):

“At the mixed session, it was agreed that an alternative way to advertise and introduce the risk-based approach (i.e., rather than through PCP offices), such as through a public advertising campaign, should be considered.”(118)

External change agents

Participants were wary of mainstream media having the ability to portray risk-stratified cancer screening negatively and the potential this has to confuse the public or adversely affect uptake(114,115). To prevent this, HCPs suggested early engagement with the media to influence public perceptions in a positive way, whilst also mitigating miscommunication by ensuring that the evidence shared by media sources is evidence-based(114,115).

“... we maybe don’t use the media enough because patients and women, the public get so much mixed, they get a lot of their information from the media and a lot of it is inaccurate or confused, or even the mainstream news channels, they distort things or abbreviate it.”

(Healthcare professional; 2037)(114)

Executing

When reflecting on how to successfully execute risk-stratified screening, HCPs focused on the necessary infrastructure; this was especially important as current infrastructure was seen as outmoded and incapable of handling the operations necessary for risk stratification(113,114,118). Participants identified a need for improvements to EMR systems and advised that these should be integrated with risk assessment and communication tools to streamline the process for PCPs(113,118):

“We must have good computerized medical records and the same for everybody, as well as governmental tools we can access in them. It should be integrated in our electronic system in which there is a tab for risk assessment. Once you have filled it up, it adds to the patient’s medical records. It would be ideal...”(113)

Reflecting and evaluating

In addition to pilot studies, HCPs recommended feedback and evaluation processes take place at all stages of implementation, including ongoing monitoring after the initial introduction of risk-stratified screening to facilitate long-term fidelity of the intervention across geographic regions and risk groups(114,118):

“Should a risk-stratified approach be implemented, all participants discussed the need for monitoring procedures to ensure women are invited at the right time and allocated to correct pathways.”(114)

3.6 Discussion

My findings suggest that HCPs find many aspects of risk-stratified cancer screening to be acceptable but robust evidence is essential in facilitating maximum acceptability and endorsement. In general, risk stratification was perceived as a logical strategy to improve the balance of benefits and harms associated with screening whilst remaining mindful of cost and resource limitations. Based on the barriers and facilitators explored in the synthesis, I identified a series of recommendations that apply generally to support successful implementation of risk-stratified interventions.

Although risk stratification was broadly accepted, increased evidence for the efficacy of risk-stratified screening and more specifically for the safety of reducing screening for low-risk groups is required for HCPs to endorse the intervention with confidence. PCPs will require additional training to appropriately recommend risk-stratified interventions to high-risk individuals and to adequately communicate risk, a task which has previously been managed by genetic specialists. Additionally,

clear guidance for those at moderate risk could help to increase HCP confidence in advising such individuals.

Increased evidence for and validation of a risk model using risk factors that are practical to obtain is necessary to address concerns about data accuracy, self-reported variables and utility across different patient populations. Additionally, cost-effectiveness evidence will be necessary for policy makers, especially within publicly funded healthcare systems, but cost should not be communicated to the general public as a primary motivator behind risk stratification. Portraying risk stratification as a money-saving exercise has the potential to undermine communication of the health-related benefits of risk-based screening.

The complexity of risk stratification represents a key barrier to implementation. A screening programme that requires more resources is likely to be deemed unacceptable to HCPs. Concerns about time and resource constraints should be addressed by providing evidence that risk-stratified screening programmes will not increase the burden on already resource-limited healthcare services. Ahead of implementation, health systems should have the capacity to meet increased public communication and support needs that may be generated by the introduction of a new screening pathway. PCPs in this review felt strongly that these needs should not fall to frontline staff or exacerbate existing workforce constraints, thus an alternative system such as an external helpline could improve acceptability.

Individual roles within a risk-stratified screening programme should be defined and developed with input from HCPs to maximise acceptability. Time and additional training will likely be required to support HCPs in moving away from habitual screening practices towards adopting skilled and sustained practice of risk-based screening. Some HCPs, particularly in primary care, may have lower rates of self-efficacy and genetic knowledge, resulting in confusion between risk assessment, screening and diagnostic investigations. As a result, it is essential to clearly define these distinct concepts in training materials as HCPs believed that interpretation of risk scores is part of the clinician's role and should not be left to lay individuals(116,118). To assist with communication, risk communication tools that are compatible with existing technological infrastructure should be developed, enabling shared decision-making in a standardised format that is accessible to all members of the population.

All related healthcare infrastructure should be compatible with and capable of executing risk-stratified screening and these processes should be integrated to enable routine use within clinical practice. Revised screening guidance should be issued alongside this, providing uniform guidance that is congruent with policy advice and grounded in evidence.

My findings identified the media as potential external change agents, having the ability to influence public perceptions in both positive and negative ways. Engaging the media early on is necessary to facilitate dissemination of accurate information and to build credibility of the intervention. This may be instrumental in reassuring low-risk individuals facing a reduction in screening compared with traditional screening practices.

Many HCPs highlighted the importance of engaging patients in shared decision-making and consulting the general public throughout all stages of development and implementation. Informed choice and patient support should be prioritised to minimise negative psychological impacts of risk stratification and ensure the approach is understood and accepted by the public. Ultimately, my findings suggest that for HCPs to find risk-stratified cancer screening acceptable, it is essential to understand whether it is acceptable from the perspective of the general public.

3.6.1 Comparison with other literature

The positive attitudes of HCPs reported in this review are largely consistent with attitudes of the general public, with many studies reporting optimistic views of the public about risk-based cancer screening (Chapter 4)(69,73,120–133). In particular, I found that HCPs reported concerns about the evidence behind de-intensification of screening for low-risk groups and the potential for psychological and physical ramifications of screening reduction or cessation. The public have expressed similar concerns, emphasising that reducing screening is overall less acceptable than increasing screening for those at higher risk(69,122,123,125,127–129,131,134–136). Both HCPs and the public also support clear and accessible communication to facilitate informed choice and shared decision-making, and to prevent widening inequalities(126,137). I explore the views of the general public towards risk-stratified cancer screening in greater detail in my systematic review in Chapter 4.

Recent changes to cervical cancer screening programmes using human papillomavirus (HPV) testing to alter screening intervals have also encountered similar barriers to acceptability among HCPs. Some such studies report positive attitudes towards increased screening intervals for women with a normal HPV co-test whereas others cite concerns about potential harms such as pre-cancers and interval cancers due to longer intervals(138,139). I found that for long-established screening programmes, such as mammography screening, HCPs were reluctant to accept substantial change from what has long been considered the norm. This has been similarly reported as a barrier to moving away from traditional cervical screening guidelines and procedures(140). In the case of changes to the cervical screening pathway, educational interventions have successfully improved HCP acceptability(141), indicating that adequately addressing training and education needs in

relation to risk stratification, as I have recommended in this review, could likewise improve the overall acceptability of risk-based screening.

As I have discussed in the findings of this review, considering polygenic risk is integral to conversations about risk stratification as potential risk algorithms may incorporate genetic data. HCP attitudes toward polygenic testing in clinical practice outside of risk stratification have previously been explored and barriers to acceptability, including the potential for incorrect risk estimates and insufficient evidence underpinning risk algorithms, reflect the concerns discussed in my review(142). Additionally, Smit et al. found that genetic knowledge and self-efficacy in requesting polygenic risk testing and integrating risk scores into clinical practice was lacking. In parallel with my findings, this applied most notably to non-genetic specialists, such as PCPs(142).

3.6.2 Strengths and limitations

Use of an established implementation framework, the CFIR, is a key strength of my review(110). I made minimal changes to the existing framework as part of the 'best fit' approach, suggesting that the CFIR was a suitable choice of framework to interpret this data(112). Use of the framework also enabled me to identify several gaps in the literature relating to issues of implementation and systems-level change, rather than just the fundamentals of acceptability. These areas require additional research specifically exploring the changes required across healthcare systems to enable implementation which could be achieved through stakeholder interviews or consensus building workshops. Similarly, the use of a mixed methods approach was a strength as it enabled me to include quantitative, qualitative and primary mixed methods studies to increase the breadth of the review. The quality of the included studies was high, particularly for the qualitative papers which increases confidence in my overall findings. A final strength was the adoption of clear and robust definitions for 'risk stratification' and 'acceptability' which ensures the findings of my review are both specific and highly relevant.

The majority of included studies related to breast cancer screening, which may reduce the applicability of my findings across different cancer types or in relation to new cancer screening programmes. The paucity of research considering risk stratification of screening programmes for cancers other than breast should be addressed in future research. Furthermore, all included studies were conducted in high-income countries which meant I was unable to comment on the views of HCPs in low-income countries where cancer screening programmes may be more recently established and age and/or sex-based screening processes less ingrained in clinical practice.

I chose to exclude studies that related to familial cancer syndromes or high penetrance genetic variants meaning that my findings do not extend to these population groups. However, these groups

are typically recognised as being at elevated risk and are not included in population-based screening hence the rationale for exclusion. My search only identified seven eligible papers out of a large number of citations (over 12,000), highlighting the challenge of conducting systematic reviews in implementation research where reporting terminology is frequently heterogenous. Additionally, I did not include any grey literature or unpublished literature meaning my findings are potentially subject to publication bias. I did conduct a pilot search of the grey literature using Google Advanced Search and did not identify any relevant citations, allowing me to conclude that the risk of missing data is low.

3.7 Conclusions

In this review, I have explored the acceptability of risk-stratified cancer screening from the perspective of HCPs and identified key recommendations for implementation. My findings add support to the existing evidence from work with the public that risk stratification is generally acceptable, highlighting barriers and facilitators to implementation including increasing the evidence for de-escalation of screening, navigating resource constraints, and the importance of public involvement and communication. A key finding is that risk stratification must be considered acceptable to the public if it is to be acceptable to HCPs. I therefore synthesise the existing literature relating to the public acceptability of risk-stratified screening in Chapter 4 before researching public attitudes toward risk-stratified bowel cancer screening specifically in Chapters 5, 6 and 7.

Chapter 4 Acceptability of risk-stratified cancer screening from the perspective of the public

In this chapter I describe a mixed methods systematic review of the acceptability of risk-stratified cancer screening across all cancer types from the perspective of the public.

This study was published in 2023(143): Taylor LC, Hutchinson A, Law K, et al., Acceptability of risk stratification within population-based cancer screening from the perspective of the general public: A mixed-methods systematic review. *Health Expectations*. 2023; 26(3):989-1008. DOI: 10.1111/hex.13739.

4.1 Summary

Risk-stratified cancer screening has the potential to improve the balance of harms, benefits and resources. Public acceptability has implications for engagement, uptake and the success of such programmes. In this study, I, therefore, aimed to understand whether risk stratification of population-based cancer screening programmes is acceptable to the general public.

I searched four electronic databases from January 2010 to November 2021 and included qualitative, quantitative and primary mixed-methods citations. I used the JBI convergent integrated approach(109) to synthesise my findings and the TFA as a coding frame(144).

The search returned 12,039 citations, 22 of which were eligible for inclusion. Risk stratification was generally acceptable to the public who, in some cases, preferred it to existing screening practices. I identified priorities for implementation spanning four key areas: public communication, public information needs, barriers to accessibility and the role of HCPs, particularly in supporting de-escalation of screening.

Overall, I found that the public are largely accepting of risk-stratified population-based cancer screening and highlight areas to support successful implementation.

4.2 Background

As discussed in Chapter 1, implementation of risk stratification generates ethical challenges associated with introducing systematic differences in how we treat subgroups of the population. This includes considerations for equity and accessibility, such as whether modifiable lifestyle risk factors are included in risk algorithms, and how to fairly screen individuals for whom we lack risk data.

Public acceptability is essential to implementing and sustaining a risk-stratified screening programme as it has direct implications for uptake and adherence(75).

4.3 Aim

To explore whether risk stratification within population-based cancer screening programmes is considered acceptable by the general public and in what context.

4.4 Methods

The protocol was published prospectively on PROSPERO:

https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021286667

4.4.1 Search strategy

I followed the same method as stated in section 3.4.1 and the search for both systematic reviews was conducted in tandem using the same search string. Briefly, I developed the search string with assistance from an information specialist in order to search four electronic databases from the 1st of January 2010 to the 31st of November 2021. The search string was comprised of four components containing synonyms for key search terms and linked using Boolean operators (AND/OR). The full search string is shown in Table 3.1. Duplicates were removed in Endnote reference management software using the Bramer method and imported into Rayyan systematic review software to facilitate citation screening(103,104).

4.4.2 Eligibility criteria

Studies were reviewed against the eligibility criteria detailed in Table 4.1.

As in Chapter 3, studies relating to surveillance and monitoring, case finding, or acceptability of non-risk-stratified cancer screening programmes were excluded. Similarly, study populations with exclusively high penetrance cancer genes were not eligible for inclusion.

Table 4.1. Eligibility criteria for the review of acceptability of risk-stratified cancer screening from the perspective of the public

Inclusion criteria	Exclusion criteria
English language	Non-English language
Published and peer reviewed	Grey literature
Full text available	Full text unavailable
Quantitative, qualitative, or primary mixed methods studies	Editorials, conference abstracts, commentaries, opinion pieces, reviews, or letters
Conducted in the context of population-based screening	Cancer surveillance or monitoring programmes and case finding
Specific to risk-stratified cancer screening	Non-risk-stratified cancer screening
Includes public opinions on acceptability	Published before 2010

4.4.3 Study selection

As described in section 3.4.3, I screened all titles and abstracts and a second reviewer (RD, AH, or KL) independently screened 10%. All citations eligible for full text review were reviewed by two reviewers (LT and RD, AH, or KL) and disagreements were resolved through consensus meetings. Citations were reviewed for eligibility in either systematic review simultaneously. Finally, this process was repeated for the reference lists of eligible papers and two closely related systematic reviews exploring attitudes and perceptions towards risk-based breast cancer screening(105,106).

4.4.4 Data extraction

Data extraction was completed using the same approach as in section 3.4.4, where a second independent reviewer (AH) completed data extraction for 50% of eligible citations.

4.4.5 Quality assessment

As in section 3.4.5, I completed quality assessment for all eligible papers using the MMAT(107) alongside a second independent reviewer (RD or AH). I chose the MMAT for its relevance to mixed methods research and because it is applicable to all study designs eligible for this review, enabling comparison.

4.4.6 Data synthesis

As described in section 3.4.6, I chose the JBI convergent integrated approach to analysis, transforming the quantitative data into textual descriptions via narrative interpretation and combining this with the qualitative data in NVivo12 software. This method is appropriate for research questions that can be answered by both quantitative and qualitative approaches.

I chose to use the TFA as a coding frame to analyse the data(144). I chose the TFA as it is a framework developed specifically for use in assessing healthcare interventions that can be used to

explore anticipated or prospective acceptability of an intervention, such as risk-stratified screening, that has not yet been implemented. Unlike the CFIR, which I used in Chapter 3, and other process-driven frameworks, the TFA adopts a more auto-centric approach considering individual cognitive and emotional responses. The seven TFA domains are described in Table 4.2.

Table 4.2. Summary of the seven domains of the Theoretical Framework of Acceptability and their meaning in the context of this systematic review.

TFA domain	Meaning in this context
Affective attitude	How the public feel about risk-stratified cancer screening
Burden	The perceived amount of effort required to participate in a risk-stratified screening programme
Ethicality	How well risk stratification aligns with an individual's values
Intervention coherence	How well the public understand risk-based screening and how it works
Opportunity cost	The benefits, resources, or principles that must be given up in order to participate in risk-stratified screening
Perceived effectiveness	How likely the public feel that risk-stratified screening will achieve its goal(s)
Self-efficacy	How confident the public are about participating in risk-based screening

RD and I performed the initial coding using the TFA independently before coming together in a series of meetings to iteratively revise and confirm the content of each domain. We reviewed the contents of the seven TFA domains and generated themes and sub-themes by interpreting areas of similarity across the dataset. The sub-themes were created where ideas converged or diverged in a meaningful way as explained in detail in section 3.4.6 and illustrated in Figure 4.1.

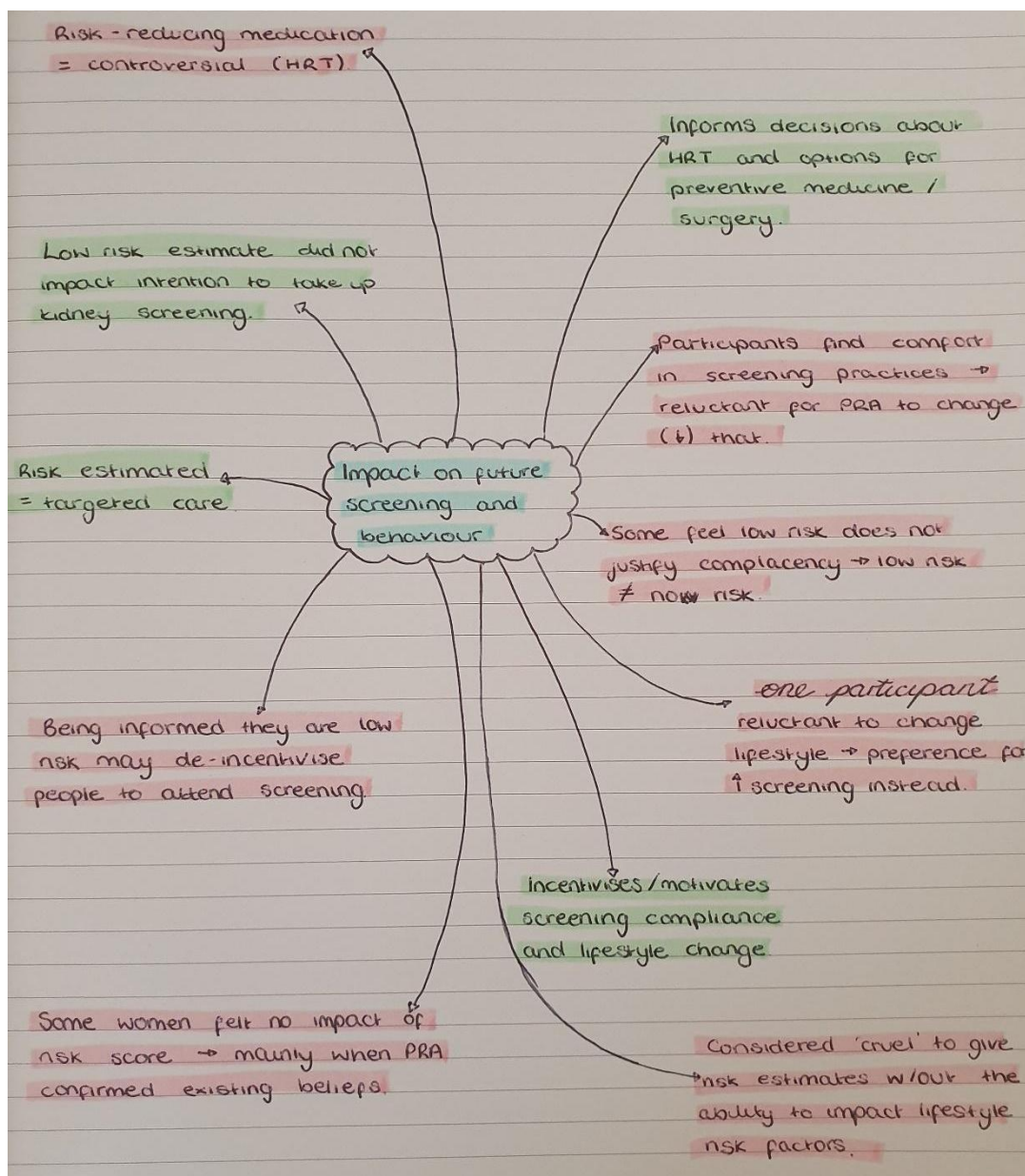


Figure 4.1 Mind map of codes relating to the theme 'Impact on future screening and behaviour' colour coded according to sub-theme.

Green – positive impact. Pink – negative impact

HRT – hormone replacement therapy; PRA – personalised risk assessment.

4.5 Results

4.5.1 Study selection

Following the removal of duplicate citations, the literature search generated a total of 12,039 results. 11,977 of these were excluded after title and abstract review. Following full text review, a further 92 citations were excluded. The most common reasons for exclusion were non-empirical articles (n=34) or articles that were not specific to the acceptability of risk-stratified screening (n=27) (Fig 4.2). Six papers were excluded as they were not related to public attitudes and were instead included in Chapter 3. Two additional citations were identified through reference list searching, resulting in a total of 22 papers meeting the eligibility criteria for inclusion in this review.

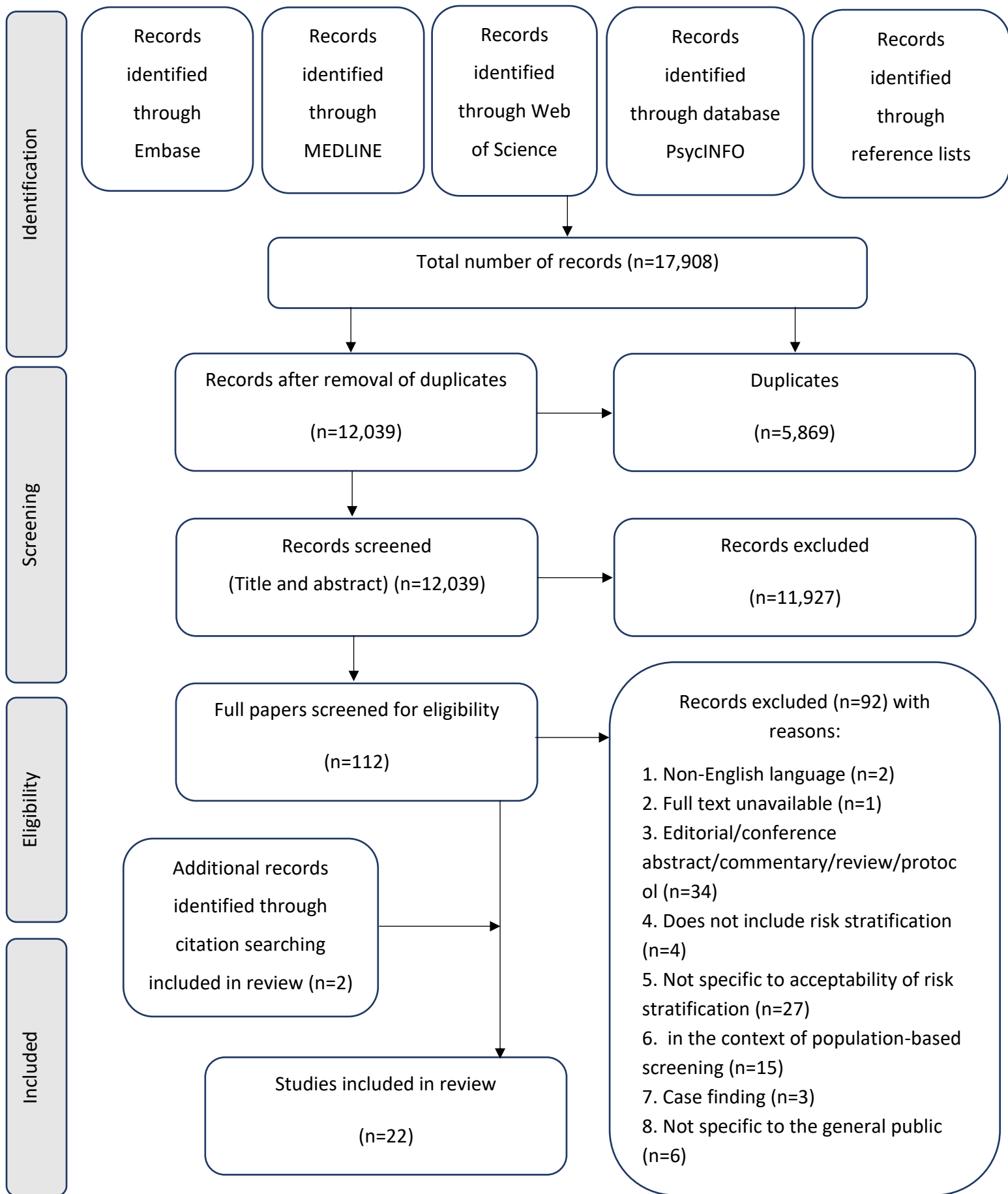


Figure 4.2 PRISMA flow diagram for the review of acceptability of risk-stratified cancer screening from the perspective of the public.

4.5.2 Study characteristics

Study characteristics and key findings are summarised in Table 4.3.

The majority of studies were conducted in relation to breast cancer screening (n=15/22, 68%)(69,121–123,125–127,129,131,133–135,137,145,146). Four studies focused on ovarian cancer (n=4/22, 18%)(73,124,130,132) and the remaining four studies focused on all cancer types, kidney, prostate and colorectal cancer respectively(120,123,128,136). Sample sizes ranged from eight(124) to 10,000(123) participants across nine quantitative (n=9/22, 41%)(69,73,120–123,134,136,145) and 13 qualitative studies (13/22, 59%)(124–133,135,137,146). No primary mixed methods studies were eligible for inclusion. The majority of included studies took place in the UK (n=13/22, 59%)(69,73,120,124–126,130,132–135,145,146), four in the Netherlands (n=4/22, 18%)(122,131,135,146), three each from Sweden(123,135,146) and Australia (n=3/22, 14%)(127–129), two from the US (n=2/22, 9%)(136,137) and a single study was conducted in Canada (n=1/22, 5%)(121). Participant characteristics varied in terms of age and sex, and two studies specifically explored views of ethnic minority populations(126,130).

Table 4.3 Summary of key study characteristics and findings for the review of acceptability of risk-stratified cancer screening from the perspective of the public.

Author & year:	Setting (country):	Cancer type(s):	Sample size:	Age:	Sex:	Study design:	Method of data collection:	Author's primary conclusion(s):
Meisel (2015)(145)	UK	Breast	942	18-74	F	Quantitative	Home-based interview survey within ONS survey	Women were positive about adjusting mammography screening in line with personal genetic risk. Effective communication materials should be developed to minimise resistance to reducing screening frequency for those at lower genetic risk.
Koitsalu (2016)(123)	Sweden	Breast & prostate	10,000	20-74	M & F	Quantitative	Online cross-sectional survey	Risk-stratified screening has the possibility to be accepted by the general public. Knowledge about, interest & acceptability of the prospect of risk-stratified screening for BrC & PC will help when implementing new screening strategies.
Meisel (2016)(73)	UK	Ovarian	829	18-74	F	Quantitative	Home-based interview survey within ONS survey	Women in the UK are ready to accept the introduction of population-based genetic testing for personalisation of future OC screening programmes.
Piper (2018)(136)	US	Colorectal	1,054	>50	M & F	Quantitative	Mail-based survey	Many veterans are resistant to stopping low-value CRC screening & are sceptical about CRC risk & life expectancy predictions, even using risk calculators. Risk stratification may be met with resistance. Future research is needed to understand how to effectively communicate with patients.
Ghanouni (2020a)(69)	UK	Breast	933	40-70	F	Quantitative	Face-to-face survey within unrelated survey	Women were generally in favour of risk assessment & more frequent stratified screening. Common barriers included worry & preferring not to know risk status. Letters/emails were preferred for receiving very low risk status & face-to-face for very high risk. GPs were the preferred sources of information. Participants were relatively unwilling to accept less frequent or no screening for very low risk.

Ghanouni (2020b)(134)	UK	Breast	698	40-70	F	Quantitative	Online survey with vignettes	No information on order effect of preferences was observed. Information order did affect risk perceptions. Women who perceive themselves as high risk may be particularly resistant to less frequent screening.
Rainey (2020a)(122)	Netherlands	Breast	942	50-75	F	Quantitative	Structured survey presented in two parts	Dutch women were generally in favour of receiving BrC risk & personalised screening recommendations. Acceptance depends on assigned risk category – most challenging for low-risk. Education on the benefits & harms of risk-based screening is key to acceptability & informed decision-making.
Mbuya-Bienge (2021)(121)	Canada	Breast	4,293	30-69	F	Quantitative	Structured online survey	Risk-stratified BrC screening is likely to be supported by Canadian women. Further research should seek to understand why some women are reluctant to provide personal & genetic information for risk assessment & how interactions between different factors shape women's' views.
Usher-Smith (2021)(120)	UK	Kidney	668	45-79	M & F	Quantitative	Online population-based survey	Risk stratification of starting age based on phenotypic or genetic risk modelling is acceptable to the majority of individuals & has the potential to increase uptake.
Henneman (2011)(131)	Netherlands	Breast	26	42-73	F	Qualitative	Semi-structured focus groups	Women currently offered BrC screening based on age have a positive attitude towards screening for BrC. More research is needed if women in the low-risk group are to be no longer offered mammography screening.
Meisel (2013)(132)	UK	Ovarian	56	Mean 45	M & F	Qualitative	Guided focus groups	The public may be broadly positive about population-based genetic testing for OC & would support risk-stratified screening, providing preventive advice was offered alongside the programme.
Rahman (2015)(124)	UK	Ovarian	8	25-58	F	Qualitative	Semi-structured interviews	Despite variation in age, family history & OC experiences, there was strong consensus that a population-based risk prediction, stratification & screening program for OC should be introduced. The main anticipated benefit was relief & reassurance for the majority of the population who would be classified at low risk of developing OC.

Hann (2018)(130)	UK	Ovarian	62	18+	M & F	Qualitative	Community-based focus groups	Population-based risk assessment & stratified management may be acceptable to many SA men & women in the UK. Attitudes towards cancer screening were positive. Views on risk-reducing surgery were mixed. There is a need for tailored OC awareness campaigns within SA communities.
He (2018)(137)	US	Breast	29	40-74	F	Qualitative	Semi-structured focus groups and surveys	Some women thought risk-based screening made sense. Willingness to abandon traditional screening in favour of risk stratification was mixed. Broad acceptability of risk-based screening will require clearer communication about its rationale & feasibility & consistent messages from HCPs.
Lipsey (2019)(129)	Australia	Breast	52	48-72	F	Qualitative	Focus groups	Although risk stratification is a feasible concept to women who are currently engaged in BrC screening, participants were particularly concerned about a lower risk cohort being lost to the system, the importance of communication & the motivations behind the change.
Rainey (2019)(135)	Netherlands, UK, Sweden	Breast	143	40-75	F	Qualitative	Focus-groups with semi-structured interview guide	Acceptability of risk-based screening & prevention is mixed. More intensive screening for women above average risk was generally welcomed. Screening pathways for the other risk categories & general prevention strategies were met with some scepticism. Women's perceptions were informed by a lack of knowledge, cultural norms, & common emotional concerns, highlighting the importance of tailored educational materials & risk counselling to aid informed decision making.
Rainey (2020b)(146)	Netherlands, UK, Sweden	Breast	143	40-74	F	Qualitative	Semi-structured focus groups	Existing healthcare policy & care pathways will impact implementation of risk-based BrC screening. Country-specific assessment, communication protocols & uniform screening recommendations need to be developed. Additional training needed for HCPs.
Woof (2020)(126)	UK	Breast	19	47-73	F	Qualitative	Semi-structured interviews	Risk stratification was viewed favourably. To avoid exacerbating inequities, information should be provided in multiple languages & modalities & offer the opportunity to speak to a HCP about risk. Completion of personal risk

								information should be via paper questionnaires, as well as online.
Dunlop (2021)(128)	Australia	All types	40	18-69	M & F	Qualitative	Semi-structured interviews	Acceptability of risk-stratified screening for different cancers may be impacted by type of screening test, level of attachment to the screening programme & the type of cancer itself. Acceptance of risk-stratified screening is high, but most people are unlikely to forgo screening altogether even if at low-risk.
Kelley-Jones (2021)(133)	UK	Breast	25	40-70	F	Qualitative	Interviews	There is high, but not universal, acceptability of risk-stratified BrC screening. Support & guidance, tailored to screening values & preferences may be required at all levels of risk.
McWilliams (2021)(125)	UK	Breast	23	46-74	F	Qualitative	Semi-structured interviews	It is acceptable to receive a low risk estimate as part of BC screening, from the perspective of a well-educated, mainly white British sample. Challenges were highlighted in ensuring informed choice around the introduction of less frequent screening for women at low risk of breast cancer. Any approach where screening is reduced for low-risk women should be clearly explained & evidence-based.
Sierra (2021)(127)	Australia	Breast	31	21-70	F	Qualitative	Individual interviews and focus groups	Implementation of a PBCRA is acceptable. Women are particularly concerned with actionability of results & reduced screening, especially for those who view themselves as high risk. It will be important to educate the wider population, both women & HCPs, on BrC genetics, risk factors, & determine optimal risk-category-specific screening methods. Systems must be in place to deliver genomic information with adequate emotional & psychological support.

BrC – breast cancer; CRC – colorectal cancer; F – female; GP – general practitioner; HCP – healthcare professional; M – male; MMAT – Mixed Methods Appraisal Tool; OC – ovarian cancer; ONS – Office of National Statistics; PBCRA – personalised breast cancer risk assessment; PC – prostate cancer; PRA – personalised risk assessment; RSBS – risk-stratified breast screening; SA – South Asian.

4.5.3 Quality assessment

The results of the quality assessment using the MMAT are summarised in Table 4.4.

Ten studies were considered high quality across all assessed domains (n=10/22, 45%)(73,123–126,128–130,133,145). The remaining twelve studies were of lower quality and scored ‘no’ or ‘can’t tell’ in at least one domain. Among the quantitative studies, the most common domains in which to score a ‘no’ or ‘can’t tell’ related to representativeness of the sample and risk of non-response bias. Among qualitative studies, the most common domain in which to score a ‘no’ or ‘can’t tell’ related to coherence between the qualitative data sources, collection, analysis and interpretation.

Table 4.4 Results of the quality assessment of papers included in the review of acceptability of risk-stratified cancer screening from the perspective of the public using the Mixed Methods Appraisal Tool.

Quantitative descriptive					
Author (year):	Relevant sampling strategy?	Representative sample?	Appropriate measurements?	Nonresponse bias?	Appropriate statistical analysis?
Meisel (2015)(145)	✓	✓	✓	✓	✓
Koitsalu (2016)(123)	✓	✓	✓	✓	✓
Meisel (2016)(73)	✓	✓	✓	✓	✓
Piper (2018)(136)	✓	✗	✓	✗	✓
Ghanouni (2020a)(69)	✓	✗	✓	✓	✓
Ghanouni (2020b)(134)	?	✓	✓	✓	✓
Rainey (2020a)(122)	✓	?	✓	✗	✓
Mbuya-Bienge (2021)(121)	✓	✓	✓	?	✓
Usher-Smith (2021)(120)	✓	✗	✓	✓	✓
Qualitative					
Author (year):	Appropriate approach?	Adequate methods?	Findings derived from data?	Substantiated interpretation?	Coherence?
Henneman (2011)(131)	✓	✓	✓	✓	?
Meisel (2013)(132)	✓	✓	✓	✓	?
Rahman (2015)(124)	✓	✓	✓	✓	✓
Hann (2018)(130)	✓	✓	✓	✓	✓
He (2018)(137)	✓	✓	✓	✓	?
Lippey (2019)(129)	✓	✓	✓	✓	✓
Rainey (2019)(135)	✓	✓	✓	✓	?

Rainey (2020b)(146)	✓	✓	?	✓	?
Woof (2020)(126)	✓	✓	✓	✓	✓
Dunlop (2021)(128)	✓	✓	✓	✓	✓
Kelley-Jones (2021)(133)	✓	✓	✓	✓	✓
McWilliams (2021)(125)	✓	✓	✓	✓	✓
Sierra (2021)(127)	✓	?	✓	✓	✓

All papers scored 'yes' for screening questions 1 and 2 (S1. Are there clear research questions? S2. Do the collected data allow to address the research questions?).

✓ Yes

✗ No

? Can't tell

4.5.4 Strength of the evidence

The distribution of evidence across themes is illustrated in Table 4.5.

Overall there were 18 subthemes identified across the seven domains of the TFA. The majority of themes were contributed to by multiple studies; however some were considered only briefly. For example, 'The importance of prevention and early detection' was only discussed in three of the included studies(123,124,128). Conversely, the strength of the evidence was greatest for 'The impact of knowing your risk' which was covered by a total of 16 studies, six of these in detail(122,124,125,130,132,135). Notably, the qualitative studies included numerous themes in detail, with four qualitative papers contributing across 10 themes(125,127,128,133).

Table 4.5 Strength of the evidence and studies contributing to each theme for the review of acceptability of risk-stratified cancer screening from the perspective of the public

		Author (year):																					
		Meisel (2015)(145)	Koitsalu (2016)(123)	Meisel (2016)(73)	Piper (2018)(136)(50)	Ghanouni (2020a)(69)	Ghanouni (2020b)(134)	Rainey (2020a)(122)	Mbuya-Bienge (2021)(121)	Usher-Smith (2021)(120)	Henneman (2011)(131)	Meisel (2013)(132)	Rahman (2015)(124)	Hann (2018)(130)	He (2018)(137)	Lippey (2019)(129)	Rainey (2019)(135)	Rainey (2020b)(146)	Woof (2020)(126)	Dunlop (2021)(128)	Kelley-Jones (2021)(133)	McWilliams (2021)(125)	Sierra (2021)(127)
MMAT result:		✓	✓	✓	✗	✗	?	✗	?	✗	?	?	✓	✓	?	✓	?	✗	✓	✓	✓	✓	?
Affective attitude	General thoughts about risk stratification	●		○	○	○	○		○	●			○										
	How to communicate risk estimates		○			○		○				○	●		○	○		●	○	○	●	○	○
	The impact of knowing your risk	○	○	○		○		●		○	○	●	●	●			●		○	○	○	●	○
Burden	Barriers to accessibility												●	○			○	●				○	○
	Emotional or psychological burden		○			○					○	○	○	○			○			○	○	○	○
Ethicality	The importance of prevention & early detection		○										○						○				

	Is risk stratification fair?										○						○		○	○	○	
	The motivation behind transitioning to a risk-stratified screening programme													○	○	○				○		
Intervention coherence	Risk stratification is logical in principle										○			○	○				○	○	○	○
	Understanding the evidence for risk stratification				○						●	○	○	○	○	○	○			●	●	○
Opportunity cost	Cost of screening & of lifestyle changes										○			○				○				
	Data security, privacy, & the potential for discrimination										○	○			○				○			○
Perceived effectiveness	Considerations for people at low risk		○		○				○		○	○			○	○			○	●	○	○
	The impact of HCP involvement on implementation & delivery		○										○		○		○	○	○	○		○
	The impact of risk assessment on wider outcomes														○				○	○		○
Self-efficacy	Feelings of personal responsibility											○	○				○		○	○	○	○
	A need for help & guidance from HCPs												○						○	○	○	

	Willingness to participate in risk assessment		○	○		○		○	○									○			○		

Large circle = 'yes' for all MMAT domains
Small circle = 'no'/'can't tell' for one or more MMAT domains
Open circle = study briefly contributes to the theme
Filled circle = study strongly contributes to the theme

4.5.5 Qualitative synthesis findings

4.5.5.1 Affective attitude

General attitudes towards risk stratification

The concept of risk stratification was considered generally acceptable across many of the included studies(69,73,120,121,136,145,145), with one study reporting that over 70% of women would take up risk-stratified breast screening if offered(69):

“The majority of women reported that it is a good or very good idea to use personal information (72.8%) and results from genetic tests (72.8%) to identify women who are at high, average, or low risk of developing breast cancer and to change how often women are invited for breast screening based on this information (63.5%).”(69)

A comprehensive risk score, comprised of age, sex, BMI, smoking status, family history and lifestyle, or a genetic risk score was perceived as being more acceptable than less comprehensive models(120) and the inclusion of genetic variables in risk modelling was viewed positively(59). However, one study reported that the prospect of a risk-stratified cancer screening programme was met with more caution than risk assessment alone(133).

In general, the desire to receive personalised risk information was high across the included studies; however, it was considered essential that participation in risk assessment should not be mandated(135):

“Women in all three countries emphasised, however; that participation should be optional, offering screening according to current country guidelines to women who do not want to adopt this approach.”(135)

Additionally, increasing the intensity of screening for high-risk cohorts was perceived as less acceptable among participants with ethnic minority status(145). Nevertheless, South Asian participants in a UK-based study remained positive about having a genetic risk assessment despite being informed that this information may be less accurate for ethnic minority groups(130).

How to communicate risk estimates

Increasing cancer risk was generally associated with an increase in the perceived need for consultation with a HCP(69,122–124,126,146). Participants speculated that receiving a high-risk estimate would generate anxiety and additional questions that would necessitate a consultation, either face-to-face or via telephone or video call(69,122–124,126,146).

“She said someone with a high risk, it would be quite scary and they might have so many questions that are buzzing through their head then at that point. So it would be better really for someone in that position who’s in a higher risk to be able to be told face-to-face. (Fatima, 60, via interpreter)”(126)

A trusted HCP, such as a GP or specialist nurse, was suggested to deliver such results(69,122,123,126,146). Participants generally felt that receiving average or below-average risk estimates via letter was appropriate(69,123,126,146).

Opinions varied on how best to present risk-based information and some participants proposed multiple formats to maximise understanding, including visual aids/diagrams, relative risk and absolute risk, percentage risk, and age-related risk(124,127,146). Women in one study also encouraged the provision of written risk information that they could take away and reflect upon(146). In two studies, participants indicated a preference for comparative risk information, where individual risk is provided in the wider context of a ‘ladder of risk’(124,133). Delivering results in this way helped to put risk into perspective, enabling participants to weigh-up and contextualise their individual risk(73,133).

“...women indicated that it would be useful to receive their personal risk feedback and screening recommendations as ‘a ladder of risk’ as this may reflect how they evaluate their level of risk:

‘...the human psyche does weigh things up and you look at who’s above you and below you... placing yourself on a sort of scale.’ (17: Occasional screening attendee, 51 years)”(133)

Many participants expressed a desire to receive educational and preventative advice as part of a risk assessment or risk-stratified screening programme(124,128,129,132,135). Public education was of high importance, with participants wanting to know about changes to the screening programme, risk factors, options for risk reduction, and cancer itself(124,129,132,135).

“So does that mean maybe an education process? Not just a testing process, and filling in a form and having a little chat, but an education process, so you understand all of those factors better... because you’ve had it all explained to you. (Participant 4, Focus group 3).”(129)

The impact of knowing your risk

Discussion around the impact of knowing your risk tended to focus on the potential advantages. Many participants found knowledge of personalised cancer risk to be empowering, stating that it

would help to raise awareness and enable people to be proactive about reducing their risk(126,130,132,135). Participants speculated that a low risk result would provide reassurance and relief(124,125,128,132) and that high-risk individuals would also stand to benefit from the 'safety net' of increased surveillance or early intervention(124,130,133). One participant suggested that being more aware of your high-risk status and taking action to increase perceived control of your risk level could result in high-risk individuals feeling less stressed overall(135).

"So you are aware of it, and you know how to prevent it, getting information, what are the risks, and how to do your daily activity, your daily lifestyle, maybe that can change... (FG2, woman, London)"(130)

Participants speculated that knowledge of personal risk could also help them to make informed decisions about HRT, risk-reducing medication or prophylactic surgery, lifestyle characteristics, and future screening attendance(120,122,125,131,133).

The potential disadvantages of receiving a risk estimate were also considered, albeit in less detail than the advantages. One such area of concern was the introduction of an intermediate risk category. Some participants felt that falling outside of the low-risk category, yet not receiving the same benefits as a high-risk group may serve to increase intermediate-risk individuals' anxiety without any obvious advantage(124).

"The concept of an intermediate risk group was met with some hesitancy by the participants. A number of women were unsure of what benefit having this information would provide. The perception was that individuals in this risk category may be concerned at being at increased risk compared to the low-risk group, but without being offered the surveillance or prevention options available to those in the high-risk group."(124)

In one study, individuals who already considered themselves to be at high risk of developing breast cancer due to a strong family history did not find the personalised risk assessment to be impactful. They continued to feel that they were at increased risk regardless of the risk assessment and still expressed a preference for increased screening opportunities(127). Similarly, some women hypothesised that if perceived breast cancer risk does not correlate with the results of a personalised risk assessment then the resulting screening recommendations will be less acceptable(135). Some individuals felt that a low-risk result does not justify "complacency" and one woman described is as "cruel" to deliver risk-feedback without also providing advice about lowering said risk via lifestyle changes(132).

4.5.5.2 Burden

Barriers to accessibility

Barriers to accessibility were considered by participants in six of the included studies(125–127,130,137,146). Participants in one study found it difficult to provide the risk information required(125) and others felt that completing a risk assessment or providing risk results online would represent a barrier to accessibility for many, particularly older generations(126,130). Some participants noted that they would rely on help from younger family members to access an online risk questionnaire, otherwise they would be unable to take part(130). Ease of access was considered a predictor of participation in both risk assessment and in a risk-based screening programme. Financial burden, location, perceived effort, and the type of screening test offered contributed to the idea of convenience(127). As such, women were likely to experience more difficulty accessing mammography services where scheduling was inconvenient and insurance coverage inadequate(137).

“Easy to access, easy to send off, cheaper, you know all of those things are going to get more people involved. (49 years, general population)”(127)

Culture-specific concerns about accessibility

Two studies explicitly examined the potential for cultural barriers when trying to access risk-based cancer screening(126,130). One study of British Pakistani women reported that participants were likely to experience challenges due to language barriers on top of computer literacy issues. The ideal solution was to receive all information, including risk estimates, as a letter in their first language so that women would be able to be autonomous without relying on an interpreter. However, it was recognised that this may not be immediately feasible and instead women suggested the option to request translated versions if desired. Nevertheless, the authors explained that not all women in British Pakistani communities are literate in the languages they speak which may exacerbate accessibility issues when communicating risk-related information in written formats(126).

“Women acknowledged that if materials could not be automatically provided in their spoken language, the option to request translated versions would be beneficial. However, providing translations would not make materials accessible for all, with many of the women identifying that not all women in their communities are literate in the languages they speak.”(126)

A focus group study of UK South Asians also raised multiple barriers to access. Language was again reported as a barrier, as well as the preference for males and females to see HCPs of their own sex.

Participants went on to explain that knowledge of ovarian cancer more generally, including prevention and risk, is lacking and that community-based education would be beneficial, especially in instances where English is not a first language. Some participants suggested that a high-risk estimate may impact marriage prospects for younger women and the ability to have children is also of cultural importance which may influence the perceived acceptability of risk-reducing surgery(130).

Emotional or psychological burden

The psychological impact of risk assessment and risk-informed screening was reflected upon widely in 11 of the included studies with the primary concern being the potential for increased stress and anxiety, particularly for individuals in receipt of a high-risk result(69,123–125,127,128,130–133,135). Although participants recognised that anxiety levels are partially dependent upon an individual's disposition or personality, it was largely agreed that receiving a personalised risk estimate may have a negative emotional impact.

“All women agreed that the PBCR [personalised breast cancer risk assessment] has the potential to cause anxiety or stress, especially when identifying women at above-average risk. The additional knowledge may affect an individual's peace of mind or create feelings of panic, helplessness, and the perception that cancer is inevitable. Some women feel it may be better not to know their cancer risk, however; this is dependent on their personality as some individuals are more prone to anxiety.”(127)

One participant described themselves as a ‘natural born worrier’ and felt that they would worry regardless of their risk estimate; being high-risk would cause worry about the harms of increased screening but equally, they would worry about false negatives or a late diagnosis if they reduced their screening(125). However, the majority of participants felt that the psychological impact would be greatest among high-risk cohorts who would suffer both the emotional burden and logistical inconvenience of increased screening, with one person stating that “A high-risk result almost feels like a diagnosis”(128,130,133,135). Equally, potential for worry was cited as the most common reason not to participate in a breast cancer risk assessment (14%)(69). Multiple participants raised concerns over the intrusive nature of increased screening. One woman described it as a “shadow” and another felt that a high-risk label is something they would carry for the rest of their life(128,131,133).

In light of these issues, participants suggested there should be the option for HCPs to be aware of risk estimates without the general public needing to find out themselves(46). Others indicated that

there is evidently a need for psychological support for people at high-risk, both before and after risk assessment. Participants felt that such support should be provided by an appropriate medical professional, such as a genetic counsellor or psychologist, and that this should be delivered face-to-face(132).

4.5.5.3 Ethicality

The importance of prevention and early detection

Early detection and prevention were valued attributes of cancer screening programmes and participants derived a sense of proactivity from engaging in screening(128). Participants in one study stated that their views on risk stratification would not vary according to different cancer types as they felt strongly that all cancers should be treated equally.

“Overwhelmingly, participants felt that early detection of cancer in the broad sense was important and expressed faith in cancer screening to prevent and detect cancer early. Many described screening as a proactive measure in the ‘battle’ against cancer, often providing a definitive answer.”(128)

Nonetheless, breast cancer was explicitly remarked upon by most participants due to feelings of respect and in reference to well-established screening practices(128). A second study reported that 97% of women would definitely or maybe attend mammography screening regardless of screening frequency, emphasising its perceived importance(123).

Is risk stratification fair?

Several aspects of risk-stratified cancer screening were discussed as having the propensity to be unfair or discriminatory. One area of contention was whether it was fair to prioritise older people as they are more at risk of developing cancer compared with prioritising younger people who may have more to lose(125). Others felt that access to screening was already too limited and that those either side of the screening age are unfairly excluded, particularly older people who have made substantial contributions to health insurance policies or national health insurance. Increases in life expectancy were used to further justify this argument(131). Some participants speculated about how ‘strict’ screening recommendations may be and many felt that people should have the ability to choose to attend screening if they were concerned about suspected cancer symptoms(133,146). One woman highlighted that she found it unfair not to be able to choose her own cervical cancer screening intervals, whereas others felt ill-equipped to make independent decisions about screening frequency(125).

“In one account, a woman viewed it as unfair to not be allowed to make her own decision despite acknowledging that the cervical screening interval changes depending on age. However, others wanted to be told how frequently they should attend mammograms as would feel unable to decide on their own.”(125)

In one study participants felt strongly that the same risk assessment should be offered to all individuals in the interest of fairness and accuracy(146). Additionally, some participants inconclusively queried how to fairly categorise people who declined to provide personal risk information. For others this was not a consideration as they had assumed participation in risk assessment would be mandatory(133).

Cost as the motivation behind transitioning to risk-stratified screening

The predominant concern expressed over the motivation behind transitioning to risk stratification was the role of cost. Participants in several studies were suspicious that cost-cutting was driving the shift towards personalised screening and that this was being done at a detriment to health and wellbeing and in the absence of a suitable evidence-base(125,129,135,137).

“We’re so used to...hearing the politicians going on about the money and we’re going to do this because it’s better for you...It’s got nothing to do with the money. Which we all know is not true. (Participant 6, FG 2)”(129)

Conversely, participants did consider that tailored screening could optimise the use of national funding by allowing high-risk groups to receive more screening for the same level of financial investment, representing a more efficient use of resources(125). Participants emphasised the need to communicate the rationale behind the transition in a clear and considered way to avoid appearing at odds with initiatives aimed at promoting screening uptake(125).

4.5.5.4 Intervention coherence

Risk stratification is logical in principle

Participants were generally optimistic about the concept of risk stratification, and many considered it to be logical in principle. Compared to current screening practices, participants generally believed risk-stratified screening to be more efficient and cost-effective, and that improved efficiency would translate into reduced screening burden for low-risk groups making for a better screening programme overall(127,131,133). Additionally, one participant felt that risk stratification was logical because it could increase early detection, and that this would reduce the need for treatment later down the line(125).

“It really makes sense with all that added information and you can only get better treatment... the old system seems a bit dated. (11: Pre-eligible, 46 years)”(133)

Several participants felt that using genetics and novel technologies should be embraced as a “natural progression” to modernise longstanding screening practices(128,129,133). Despite this, participants in one study who initially considered risk stratification to be a logical concept found the idea of de-intensifying screening for low-risk cohorts to be illogical and hard to believe(128).

Understanding the evidence for risk stratification

Many participants expressed a lack of understanding about current cancer screening practices, including screening intervals and eligibility criteria, and did not understand what evidence changes to the screening guidelines are based on, despite being regular attendees. This made it difficult for them to suggest the features that a risk-stratified screening programme should have(125,133,137).

“Nearly half of the women were confused about current mammography guidelines, including when to start or how often to go. Few understood why screening guidelines changed:

‘You know it’s always changing and we really don’t know what they base it on or what their group is that they’re making those decisions.’”(137)

Equally, understanding of the potential harms and benefits of screening was low, particularly in relation to false positives and overdiagnosis, making it more challenging for participants to weigh up whether to accept diverse screening intervals(125,133). In some cases, even after being informed about a genetic risk assessment, participants struggled to understand that personalised risk assessment is not a diagnostic test for cancer and that being at higher risk did not imply that the development of cancer is inevitable(130).

Despite poor understanding of current guidelines, participants appeared to understand the concept of using a composite risk score to tailor cancer screening once it had been explained to them(129,133).

“Women seemed to understand the idea of combining individual risk measures to compute an overall level of personal risk and appreciated the rationale for this in terms of their perceived limitations of a ‘one size fits all’ screening model.”(133)

Nevertheless, there were areas where participants wanted more evidence to support their understanding and decision making. Some questioned how different risk factors were weighted and how accurate risk estimates would be(125,135,137). In one study, Swedish women had faith that

personalised screening would be dictated by scientific evidence whereas British and Dutch women had greater concerns whether risk prediction was appropriately linked to cancer development(135). A key concern for participants in several studies was the unstable nature of certain included variables, notably lifestyle factors like body mass index, physical activity, and hormonal medications(129,131). As such, some individuals expressed a preference for a periodic re-assessment to account for the impact of any changes on risk(129,133,135).

Specific considerations regarding genetics

Understanding and impact of genetic risk in particular was explored in four of the included studies(127,129,131,132). Participants debated the appropriate age to offer a genetic risk assessment and considered factors such as the ability to give consent, maturity/responsibility, and the value of receiving genetic information at a given time(127,131):

“Why not just have an umbrella genetic screening to show prevalence and maybe initially to start with one particular age group that has propensity to acquire cancer of some description at a certain stage later in life?”(132)

Most participants felt genetic testing should be offered to young adults in order to identify high-risk individuals sufficiently early, but some also suggested introducing it for teenagers or even newborns(127,131).

Concerns were raised about a perceived over-emphasis on genetics as part of risk modelling in two studies(129,131). Participants felt that a high genetic risk does not mean you are certain to develop cancer and that other risk factors, predominantly lifestyle characteristics, could be overlooked or neglected(129,131).

“Too much emphasis on genetics. Really it’s only called for if there’s an obvious family lineage in my opinion. And even then, you’d probably just confirm what you already know. (Participant 9, FG 2)”(129)

One woman expressed doubts in the accuracy of genetic risk and felt that the link between DNA and cancer was too vague(131). However, others were enthusiastic about the inclusion of genetic information and suggested it before being prompted. They anticipated the utility of genetic risk assessment across a spectrum of cancer types and even for use in relation to other diseases(131,132).

4.5.5.5 Opportunity cost

Healthcare system and individual costs

Several participants in one study voiced reservations about the financial impact of population-based genetic testing, believing that there are other areas of healthcare where these funds may be better spent(131).

“Of course, I think I’m supportive, but let’s be real. You can only spend your money once. Is it wise to spend our money on this? There may be other healthcare projects that need financial support more than this one. (48 years)”(131)

Others mentioned the potential cost to the individual of making changes to diet and lifestyle factors and the effect this could have on fairness(146). For some participants considerations about the costs of risk-stratified screening were seldom discussed(130).

Data security, privacy and the potential for discrimination

In accordance with the Intervention Coherence domain, many participants had opinions about the potential cost of implementing a programme that used genetic risk specifically. Thoughts around data security, privacy, and the potential for discrimination from insurers or employers were central to these discussions. Although some participants were satisfied with the use of genetic information to inform risk modelling, they had reservations about how this information would be kept confidential and private to avoid unlawful or inappropriate usage(128,129).

“...the individual getting that information I’m okay with, it’s when it starts going into a big bucket-o-data that I get concerned because once again, it’s about the controls around that. (Male, 42 years, average risk)”(128)

Another central concern was how genetic information might impact the cost of insurance or the level of cover, and whether employers may discriminate based on what one participant described as a “genetic passport”(127,129,131). Others felt unconcerned by the use of genetic information in insurance matters, either not mentioning it or actively supporting its use(129,132).

4.5.5.6 Perceived effectiveness

Considerations for people at low risk

Considerations relating to low-risk cohorts were varied and were debated more widely than the notion of increased screening for high-risk across eleven of the included papers(121,123,125,127–129,131–133,136,137). Koitsalu et al. reported that 87% of participants would be willing to increase screening following a high-risk result, whereas only 20% of women and 34% of men would accept reduced screening following a low-risk result(123). Some participants reported positive or neutral reactions to the idea of reduced screening, others had few considerations to impart, and in one

study the majority of women found a 5-year mammography interval to be unacceptable(125,129,132). These differences generated discussions weighing up the potential benefits and risks of de-escalated screening among low-risk groups. Participants generally recognised the benefits of risk stratification for low-risk individuals, citing a better use of funds and healthcare resources and a reduction in harms, namely false positives(128,133,137). Conversely, fears were expressed about safety, including possible interval cancers and late-stage diagnoses as a result of a longer screening interval and the value of screening was felt to outweigh the risk of harm(125,129,133,137). For breast cancer specifically, menopause was of particular concern due to associated hormonal changes and some women in this age bracket found it especially challenging to accept reduced mammography screening(133).

Several participants noted that familiarity with the screening programme and the experience of being a regular attender might affect perceptions of reduced screening(127,129,133). Many participants derived a sense of reassurance and security from their current screening practices which made it harder for them to accept a reduction in screening(127,129). However, participants speculated that there may be an endowment effect, with younger generations who are not existing screening attenders finding it more acceptable to screen low-risk groups less intensively(127,129,133):

“Overall acceptors’ had mixed responses to the prospect of foregoing screening if at very low risk. Although some considered it reasonable and rational, acceptability was conditional on clearly sign-posted self-referral pathways for screening. There were also indications of an endowment effect with some ‘overall acceptors’ who were regular attenders suggesting that although they would find it personally unacceptable, they could see future generations of women thinking otherwise.”(133)

Similarly, participants considered the impact of the screening test itself on the acceptability of screening reduction or cessation. Some individuals felt more willing to reduce or stop screening if at low risk in instances where the screening tests and/or prior preparation were perceived as unpleasant or invasive, namely colonoscopy and cervical smear(128). On the contrary, one study found that over 40% of people experienced at least some degree of discomfort accepting bowel screening cessation, even when recommended by a HCP. However, higher trust in the HCP recommending cessation was positively associated with willingness to stop screening (OR 1.19; 95% CI, 1.07-1.32)(136).

Participants acknowledged that a low risk of developing cancer does not equate to no risk at all and therefore expressed a preference for reduced frequency of screening rather than complete

cessation, which was largely viewed as unacceptable(131). Those who found even reduced screening unacceptable conveyed a need for more reassurance, either through a physical examination conducted by a HCP or through supplementary self-funded screening(129,133). For some, the acceptability of de-escalated screening relied on clear evidence-based communication from the healthcare service. The knowledge that changes to the screening programme were supported by research and that the health service felt confident in the recommendation was, therefore, a facilitator of acceptability(125,133).

The impact of HCP involvement in implementation and delivery

A central theme within this construct was trust, in relation to both individual HCPs and healthcare institutions. Participants felt that trusted organisations or individuals should endorse and deliver risk assessment and that confidence in HCPs would impact the believability of risk-stratified screening advice and risk-reducing interventions(127,128,135). Young participants appeared to have greater trust in HCPs than older participants when considering divulging personal information to assess cancer risk (66% vs 60%, $p>0.001$)(123). Although professional endorsement was seen as an essential part of an effective risk-stratified programme, several participants were sceptical about the ability of their HCP to deliver this. Interactions with GPs were described as “distressing”, “a battle”, or paternalistic and others felt that their GP lacked the appropriate knowledge to discuss risk-reducing interventions with moderate to high-risk patients(124,146).

“Another concern for women at moderate to high risk was the knowledge of their GPs. The majority of British FGD [focus group discussion] participants indicated that their GP was insufficiently informed about tamoxifen/raloxifene and their usage as preventative medication. Consequently, a majority of GPs refused to prescribe the risk-reducing medication...”(146)

Another caveat to effective implementation was the possibility of contradicting advice from different HCPs, for example between primary and secondary care, and the news media(127,135). As such, participants identified a need for standardisation and suggested implementation of specific pathways and protocols to improve fidelity between primary and secondary care(146).

The impact of risk assessment on wider outcomes

Participants were largely positive about the prospect of personalised risk assessments but most agreed that the results of a risk assessment should be actionable. They maintained that appropriate risk-management infrastructure and screening options should be available after risk assessment if stratification is to be successful(127).

“However, women felt that successful implementation of the PBCRA relies on the availability of appropriate risk management strategies and adequate connection to health and support systems. Furthermore, women found the prospect of the test more appealing when more management and screening options were made available to them.”(127)

4.5.5.7 Self-efficacy

Feelings of personal responsibility

The concept of personal responsibility was discussed in seven of the included papers and was most salient in the context of reducing screening opportunities for low-risk cohorts(124,125,127,128,132,133,135). Several participants identified that this scenario may place additional personal responsibility on people to mitigate their risk and to remain aware of any changes in their health(125,127,133,135). Participants perceived an increased sense of autonomy to act upon risk information and expressed a need to know what symptoms to look out for and when to seek medical attention, with some labelling this increased responsibility as a “burden”(124,127,133). Although some individuals believed screening-decision making to be a personal responsibility, others considered a shared-decision making process with HCPs, family members, and even friends(135). Some recognised that not everyone has the same capacity to act upon their risk result and felt that this could increase feelings of guilt and stigma(135).

“It puts a lot of responsibility for health on women and not everyone is equally capable of maintaining a healthy lifestyle; financially or intellectually. It can’t become a woman’s own faults if she develops breast cancer. (Dutch participant)”(135)

Additionally, women, more so than men, felt a responsibility to be cognisant of their genetic risk for the sake of their future offspring(132). Some individuals felt that personal responsibility may exacerbate feelings of complacency among people who already take little responsibility for their own health(128). Melanoma was explored in some detail by one study as being conceptually distinct from other cancer types due to more obvious visibility. Some participants felt that this would make it easier for people to take personal responsibility for and that screening cessation for low-risk groups may be more acceptable in this instance. Other participants who were existing attenders at melanoma screening felt more resistance towards foregoing screening and less confidence in their ability to self-screen(128).

A need for help and guidance from HCPs

Participants in four studies communicated a need for support or guidance from HCPs in relation to aspects of a risk-stratified screening programme(124,125,128,133). Some participants felt unfamiliar with screening principles and recognised the limits of informed choice in this context. As such, they expected support and guidance to be provided by an appropriate professional(125).

“When asked how they would decide whether to opt for longer screening intervals, women identified the limits of ensuring informed choice within screening as they felt unaccustomed to deliberate about how much they interact with such programmes. This led women to expect that guidance from healthcare professionals in the field would be provided.”(125)

In two studies, participants considered their hypothetical willingness to stop screening after a low-risk result and the provision of advice and reassurance from experts was thought to be fundamental to acceptability(128,133). Others conveyed a lack of self-efficacy in checking themselves for symptoms and indicated a preference for being able to request a physical examination from their PCP if concerned(133). Similarly, there was a desire for training or advice in self-examination for low-risk groups to enable them to remain vigilant(133). This was echoed by a study examining ovarian cancer in which women insisted that a successful programme should provide participants with information about ovarian cancer itself and associated symptoms if women are expected to make informed decisions about whether to participate in risk prediction(124).

Willingness to participate in risk assessment

Most women were willing to complete a questionnaire, including information about reproductive and family history, provide a blood or saliva sample, and have a mammogram as part of a breast cancer risk assessment(121,122,133,146).

“Most women were prepared to have a mammogram (96.2%), complete a questionnaire (95.9%), and provide a blood sample (97.6%) for breast cancer risk assessment.”(122)

One study found that participants who had high levels of cancer worry were more willing to undergo cancer risk assessment than individuals who reported that they never worried about cancer (OR 1.89, $p=0.031$)(69). Willingness to provide genetic information as part of a risk assessment was varied but Koitsalu et al. reported that 70% of participants felt comfortable providing such information, compared to only 63% who were willing to provide phenotypic data(123).

4.6 Discussion

My findings suggest that risk stratification of population-based cancer screening is likely to be accepted by the public, who considered it to be a logical strategy and superior to existing screening practices. Comprehensive risk scores and the inclusion of genetic information was generally perceived favourably and participants considered personal risk information as a potential source of empowerment. Numerous benefits were identified for both high and low risk groups; low-risk individuals may feel reassured and relieved whereas those at high-risk benefit from the safety and reassurance of increased screening. Some participants also noted that risk information has wider advantages, such as informing lifestyle decisions. Nevertheless, my synthesis also highlighted outstanding areas of concern and key areas of consideration for successful implementation and communication. Based on these findings, I developed recommendations for implementation of risk-stratified screening grouped by four key areas (Table 4.6).

The first key area relates to communicating risk information in an actionable way and comprises three recommendations. The second area also includes three recommendations and focuses on the information that the public need. Thirdly, I have made two recommendations regarding mitigation of barriers to accessibility, such as computer literacy and language barriers. Although these factors do not apply exclusively to risk-stratified screening, participants felt that a new programme should be mindful of exacerbating existing inequalities. Finally, I have made two recommendations that encourage HCPs to support low-risk cohorts because trust in those endorsing and delivering risk-stratified screening is crucial to gain public acceptability.

Table 4.6 Recommendations for communication and implementation of risk stratification.

Area of consideration	Recommendation	Details
Communication preferences	Personalised risk estimates should be delivered in an actionable way & be presented in varied formats to maximise comprehension.	● Risk estimates should be presented in the context of future actions, including implications for screening, lifestyle change &, in some cases, risk-reducing medication or surgery. ● Risk-based screening strategies should be presented alongside evidence that supports them to alleviate difficulty in understanding of harms and benefits. ● Risk estimates should be provided in a variety of formats, including numerical, gist-based, diagrammatic & comparative expressions of risk & should be provided in writing to aid shared decision-making & personal reflection.
	High risk estimates should be communicated face-to-face.	● Above average risk estimates should be communicated in person by an appropriately trained HCP, e.g. a GP or specialist nurse. ● Average and below average risk estimates should be communicated via letter, with the option to contact a HCP if desired.
	National communication should avoid contradicting existing screening campaigns & be cautious of the motivation behind the transition.	● National communication should not contradict existing public health campaigns aiming to increase screening uptake. ● National communication should promote the benefits of risk stratification to individual health & be mindful of presenting cost &/or resource limitations as the primary motivation behind implementation.
Information needs	Information regarding the rationale behind risk stratification, included risk factors & ways to reduce personal cancer risk should be provided.	● Public desire for information is high. Information about the rationale behind risk stratification, the risk factors included in risk models, options for risk management & advice on reducing personal cancer risk should be readily available. ● Desire for education about cancer & cancer prevention is also high, particularly among minority groups where such information may currently be lacking.
	Information about self-checking for cancer symptoms & reassurance to seek help when needed should be publicly available.	● Individuals may experience feelings of increased responsibility for their own health following receipt of a risk estimate &/or a reduction in screening.

		Information on self-checking for cancer symptoms should be publicly available & low-risk cohorts in particular should be reassured about seeking professional help when necessary.
	The public need reassurance about the use of genetic data.	- Inclusion of genetic data in risk models should be communicated mindfully, acknowledging public concerns regarding data security & potential discrimination. - The association between genetic risk factors & the development of cancer(s) should be clearly evidenced.
Barriers to accessibility	Screening-related resources should be made available online & on paper, & in multiple languages.	- Internet usage represents a barrier, particularly for older individuals, therefore, risk assessment & delivery of risk estimates should also be made possible using written materials. - All information relating to the screening programme should be available in other languages in the first instance or upon request. - HCPs should be sensitive to possible cultural implications of receiving a high-risk estimate on factors such as marriage & childbearing.
	Provision of risk information should not be mandated.	Completion of the risk assessment should not be mandatory but there is a need to define how people with missing risk information should be treated.
The role of HCPs	Evidence for the safety of reduced screening should be clearly communicated by trusted HCPs & healthcare organisations.	- Cessation of screening for low-risk groups is unlikely to be acceptable to the public. - The safety of reduced screening should be evidenced to address fears about interval cancers & late-stage diagnoses. - Information related to reducing screening should be communicated clearly by trusted HCPs & healthcare organisations to facilitate acceptability. - Existing screening attenders & women in a menopausal age bracket may need increased support from HCPs to overcome resistance to de-intensified screening.
	HCPs should have appropriate knowledge & training to facilitate informed decision-making with patients.	- Patients may have insufficient understanding of screening principles to make informed decisions. HCPs should be able to provide reliable advice & support as part of a shared decision-making process. - PCPs in particular should be equipped with sufficient knowledge & resources to support patients & overcome negative perceptions of primary care.

		● Information provided by HCPs should be uniform across healthcare services & national policy. ● Specialist psychological support should be available to patients at very high risk.

GP – general practitioner; HCP – healthcare professional; PCP – primary care professional

4.6.1 Comparison with other literature

The attitudes of the public are generally consistent with the views of HCPs and wider stakeholders reported in Chapter 3. Both groups appear largely optimistic about risk stratification but expressed concerns about reducing screening among low-risk cohorts. Communication needs and the role of HCPs were also identified as key areas of consideration among both groups. Although the public had more defined opinions about specific communication modalities and the importance of trust. Conversely, HCPs, specifically within primary care, highlighted their need for training in order to manage and communicate with their patients at different risk levels. Additionally, resource limitations were more salient among HCPs, whereas the public were more likely to consider potential barriers to accessibility and feelings of personal responsibility for seeking help.

Another systematic review that was conducted by Rainey et al. considered public perceptions of risk-stratified breast screening and strategies for primary prevention(105). Although not all of the studies included by Rainey et al. were eligible for inclusion in my review, I included an additional 16 papers, eight of which considered cancers other than breast. Both reviews identified that receiving risk information was considered empowering and participants advocated for both online and written screening materials. However, I also identified the need for in-person delivery of high-risk results, potential barriers for minority groups, such as language and cultural norms, and the role of self-efficacy for those at low risk.

As previously discussed, communication as a facilitator of public acceptability has been further exemplified by reactions to recent changes to cervical screening intervals in the UK where the public felt inadequately informed of the evidence behind interval changes(82,83). In line with concerns raised in my review, women with a greater understanding of the rationale behind extending the screening interval were more accepting of policy changes(82). The impact of insufficient communication and education on widening inequalities was of concern in my review and the reality of this has been demonstrated by cervical screening changes, as less educated women demonstrated poorer understanding, indicating that inferior communication can exacerbate existing inequalities(83,147). Together, this highlights the need for future communication of changes to cancer screening programmes to provide transparent evidence and reassurance in public communications.

4.6.2 Strengths and limitations

The TFA strengthened this study by providing structure and ensured key components of acceptability were not overlooked(144). However, some findings covered several of the constructs, such as those considering Affective Attitude and Ethicality, making it challenging to separate some themes. The

relevance and specificity of included papers was improved by the adoption of transparent and pre-established definitions for acceptability and risk stratification. Use of a recognised approach to conducting mixed-methods systematic reviews and the inclusion of quantitative and qualitative studies contributed to comprehensive findings. Finally, my review includes views on acceptability of risk-stratified screening across many different cancer types, including existing and prospective screening programmes, thus increasing the utility and applicability of my findings. However, the majority of studies were conducted in the context of breast cancer, indicating a need for more evidence pertaining to other types of cancer in future.

All included studies were conducted in high income settings with well-established cancer screening programmes, meaning there is an absence of evidence on acceptability among the public in lower income countries who may be less familiar with routine population-based screening. Additionally, the strength of the evidence could have been influenced by the diverse aims of the included studies. A further limitation is the potential for publication bias due to exclusion of unpublished literature, although a pilot search did not identify any relevant unpublished studies or grey literature suggesting the risk of missing such data is low.

4.7 Conclusions

In this review I have explored the acceptability of risk-stratified cancer screening from the perspective of the general public and discussed recommendations for implementation across four key areas. My findings suggest that risk stratification of population-based cancer screening programmes is perceived favourably by the general public. Key considerations for implementation include actionability of risk results; delivery of public information about risk-stratified screening; mitigating barriers to accessibility; and defining roles of clinicians in supporting patients, particularly low-risk groups. These findings are congruent with my findings from Chapter 3, suggesting that overall acceptability from HCPs and the public, two key stakeholder groups, is high. There is, however, a notable dearth of evidence relating to cancers other than breast and only a single paper considered risk stratification of bowel cancer screening. My results therefore highlighted a need for further research into the public acceptability of risk stratification for bowel cancer screening specifically. I report my research on this in Chapters 5, 6 and 7.

Chapter 5 Public acceptability of risk-stratified screening intervals and FIT thresholds: A community jury study

In this chapter I describe a community jury study exploring the acceptability of risk-stratified screening intervals and FIT thresholds from the perspective of the public.

This study was published in 2023(148): Taylor LC, Dennison RA, Griffin SJ, et al., Implementation of risk stratification within bowel cancer screening: a community jury study exploring public acceptability and communication needs. BMC Public Health. 2023; 23(1):1798. DOI: 10.1186/s12889-023-16704-6.

This publication reports the results of four community juries, two of which are the subject of this chapter. The other two juries are not reported here as they focused on risk-stratified eligibility for bowel cancer screening led by RD and, therefore, were not a part of my thesis.

5.1 Summary

As population-based screening programmes move towards a risk-stratified approach, it is necessary to demonstrate public acceptability and communicate such changes effectively. In this study, I aimed to explore the social and ethical considerations of implementing risk stratification of FIT thresholds and screening intervals within the English bowel cancer screening pathway.

I conducted two community juries addressing risk stratification of thresholds for referral to colonoscopy and screening intervals. The juries first considered the use of age, sex and FIT result and later considered risk scores including lifestyle and genetic factors. After being informed about the topic through expert presentations about screening, ethical principles and strategies for risk stratification, participants deliberated over the research questions and reported their final verdicts. I analysed the transcripts using codebook thematic analysis.

Overall, risk stratification of bowel cancer screening at these points on the screening pathway was acceptable to the informed public. The use of age, sex and FIT result, data that are readily available within the screening system, was viewed as an obvious next step and could be implemented immediately, ahead of more complex strategies. The addition of lifestyle and genetic data was also preferred over age-based screening. The need for clear and effective communication about changes to the screening programme and individual risk estimates, as well as consideration about the practicalities of data collection were highlighted.

5.2 Background

In Chapters 3 and 4 I have shown that risk-stratified cancer screening is generally acceptable to the public and to HCPs. However, there remains a need to specifically explore acceptability in the context of screening for bowel cancer. There is potential to tailor both the FIT threshold for referral to colonoscopy and the screening interval according to personal risk (Figure 1.4). Using age, sex and FIT result represents an opportunity for risk stratification using data readily available within existing screening programmes that would incur little to no extra cost(49). Lifestyle and genetic factors could also be included in risk models but would require additional investments from participants and the healthcare system, such as completing genetic testing and questionnaires to record lifestyle characteristics.

Risk stratification raises issues of equity when considering systematic differences between subgroups of the population and challenges social perceptions of the value of screening, particularly in regard to de-intensified screening for low-risk groups. The UKNSC specifically states that any screening programme must be acceptable from a societal perspective and public views could have significant implications for screening uptake(75). As described above, there are several potential strategies to implement risk stratification into the bowel screening pathway and different variables that may be included in risk modelling. Therefore, there is a need to understand public attitudes towards these different strategies as well as public communication needs in order to facilitate acceptability.

5.3 Aim

To explore the social and ethical considerations relating to using absolute levels of FHB concentration with or without other individual level characteristics to determine the threshold for further investigations (colonoscopy) and the screening interval following screening by FIT.

Secondarily, I sought to understand how best to communicate risk-stratified screening strategies to the wider public.

5.4 Methods

Community juries are a deliberative democratic method in which members of the public are brought together to address a particular research question(149). Participants are firstly informed about the subject through a series of expert presentations and are given time to reflect and deliberate as a group before providing a final verdict or consensus (if possible). I chose this method over a focus group as risk stratification is a complex topic that requires the consideration of values, evidence, and ethical concepts and therefore participants benefit from the opportunity to be informed before

being asked to answer the research question(s)(150,151). The community jury method is also novel in that it encourages participants to consider the perspective of wider society, rather than their own individual viewpoint as might happen in an interview setting(149). I have used the CJCheck Framework to comply with systematic and transparent reporting standards for community juries(152) (Appendix 5.1).

5.4.1 Study design

Ethics approval was granted by the Cambridge Psychology Research Ethics Committee, reference: PRE.2022.011.

I led two community juries to explore the use of risk stratification at two points within the bowel cancer screening pathway:

1. FIT threshold: the absolute Fhb concentration at which someone is referred to colonoscopy
2. Screening interval: the frequency of screening by FIT

Each community jury took place across two consecutive days in sessions of approximately four hours duration in May 2022. I held the juries online using Zoom videoconferencing software (Zoom Video Communications) to capture a geographically diverse sample. Technical checks were performed by the recruitment company, iPoint Research Ltd (www.i-point.co.uk), beforehand to ensure participants were familiar with using the videoconferencing software and to minimise the impact of any technical difficulties on the day. I also collated an information pack that was distributed to participants before the juries including a summary of previous community jury findings(153), a glossary of key terminology, and a copy of the expert presenter slides and biographies (Appendix 5.2).

The community jury timetable was based on outlines of previously conducted juries and the CJCheck framework (Table 5.1)(152,153). I specifically asked each jury to consider risk stratification from the perspective of society as a whole and to assume that all of these strategies would be supported by suitable risk models. The juries began with expert presentations and an opportunity for questions with each of the presenters. I chose to introduce the types of data used to calculate risk in two stages to facilitate understanding without overwhelming the jurors, as a large amount of information was conveyed in a relatively short time. Firstly, risk stratification using age, sex and FIT result (data that are readily available within the screening programme) was introduced. On the second morning of the juries, we presented information about using additional data to determine risk as a potential strategy for the future. This included data such as family history, diet, physical activity, smoking and other phenotypic factors, and genetic information. The presentations included

an explanation of each approach to risk stratification, including what the risk score would include and the data collection required, as well as examples of screening programme outcomes including number of cancers detected/missed and potential interval cancers. The pre-recorded expert videos were approximately 15 minutes long and each expert then joined the video call immediately after for the question and answer (Q&A) session. I invited the expert presenters on the basis of their expertise in public health and/or risk-stratified cancer screening.

Following an opportunity for questions, the jurors were invited to discuss what they had learned and to consider a series of scenarios illustrating risk stratification during a facilitated discussion session which I led with the support of Rebecca Dennison. At least one PPI member was also present to observe. I was careful to remain impartial throughout the jury discussions to avoid biasing the jurors and referred any questions back to the expert presenters to maintain my role as an independent facilitator. Finally, I asked the participants to deliberate on their own (I turned my microphone and camera off but remained available via the chat) to reach a verdict on the following research questions:

Acceptability of risk stratification

1. Is it acceptable to use information we currently have available (age, sex, previous screening results) to decide the *cut-off for a positive FIT test* and why?
2. Is it acceptable to use information we currently have available (age, sex, previous screening results) to decide *screening intervals* and why?
3. Is it acceptable to use other types of information you have heard about (lifestyle and genetics) to decide the *cut-off for a positive FIT test* and why?
4. Is it acceptable to use the other types of information you have heard about (lifestyle and genetics) to decide *screening intervals* and why?
5. Are there any requirements that would need to be met in order for the above to be considered acceptable?

Communication preferences

1. What information does the public need to know about these screening strategies?
2. What information would you include on the bowel cancer screening website/leaflet?

The participants nominated a spokesperson to deliver their verdicts and feedback to the senior researcher, Juliet Usher-Smith.

Table 5.1. Community jury timetable.

Approximate duration	Time	Content
Day one		
45 mins	9:00	Welcome, introductions, and plan for the jury
15 mins	9:45	Expert presentation 1: Why we screen for bowel cancer and what are the potential benefits and harms <i>Professor Simon Griffin</i>
20 mins	10:00	Q&A session 1
15 mins	10:20	Comfort break
15 mins	10:35	Expert presentation 2: Ethical considerations around bowel cancer screening programmes <i>Dr Stephen John</i>
20 mins	10:50	Q&A session 2
15 mins	11:10	Comfort break
15 mins	11:25	Expert presentation 3: The current approach to bowel cancer screening and how risk stratification could be incorporated <i>Dr Iris Lansdorp-Vogelaar</i>
20 mins	11:40	Q&A session 3
50 mins	12:00	Facilitate deliberation session 1
10 mins	12:50	Summary
End of day one		
Day two		
20 mins	9:00	Welcome, reflections and recap of day one
15 mins	9:20	Expert presentation 4: How risk stratification could be incorporated into bowel cancer screening in the future <i>Dr Iris Lansdorp-Vogelaar</i>
20 mins	9:35	Q&A session 4
20 mins	9:55	Comfort break
1 hour	10:15	Facilitated deliberation session 2
15 mins	11.15	Comfort break
75 mins	11:30	Unfacilitated deliberation session 1
20 mins	12:40	Present recommendation
Summary and end of jury		

5.4.2 Participants and recruitment

Typically, community juries involve approximately 12 to 25 participants, although juries have been conducted with fewer than 12 members and successful juries have previously been held online with nine participants(64,69). As this study was conducted online, I aimed to recruit between eight to ten participants per jury to improve ease of facilitation and avoid potential communication barriers relating to the online context. In practice, I recruited seven participants for the first jury and nine participants for the second jury using a market recruitment company, iPoint Research. I purposefully sampled by age, sex, social grade and geographic location. I also requested at least one member of each jury to have previously been invited to attend screening and chosen to decline in order to

capture the views of previous non-attenders. The inclusion and exclusion criteria are described in Table 5.2. I chose to exclude participants with a personal history of bowel cancer or with expertise in medicine to avoid bias in their opinions and to ensure results were reflective of the general population as opposed to patients or HCPs. The recruitment company obtained informed consent, allocated participants to each jury and reimbursed them at their recommended rate.

Table 5.2. Inclusion and exclusion criteria for participation in the community juries.

Inclusion	Exclusion
Aged between 50-74 (the current target age for bowel cancer screening across England, Scotland and Wales)	Personal history of bowel cancer
Current resident in England	Expertise in medicine
	Participated in previous community juries led by this research group

5.4.3 Data collection

I recorded field notes over the course of the community juries including the verdicts and key justification. I used the Zoom video record function to record all the Q&A sessions, facilitated deliberations, unfacilitated deliberations, and delivery of the final verdicts. These recordings were transcribed verbatim and I then pseudonymised them to ensure participants were unidentifiable. The transcription company are members of the Information Commissioner's Office (ICO) and the upload process uses 256bit Secure Sockets Layer (SSL) encryption.

I also designed pre- and post-jury questionnaires based on a previously developed survey(120). I used these questionnaires to collect demographic information and to compare individual attitudes to bowel cancer screening before and after participating in the community juries (Appendices 5.3 and 5.4). The questionnaire was hosted on Qualtrics, and I created personal links for each participant to facilitate comparison of pre- and post-jury responses.

5.4.4 Analysis

I analysed the pseudonymised transcripts using thematic analysis(154) in NVivo 12 alongside (RD) to ensure transparency of the coding process, limit bias from individual perspectives and to encourage reflexivity. I chose to use codebook thematic analysis over other thematic typologies, like inter-rater reliability or reflexive thematic analysis, as this approach aligns well with a pragmatic research paradigm and confers benefits of both deductive and inductive coding(154,155). Thematic analysis enables elucidation and coding of both explicit (observable surface-level descriptions) and implicit (conceptual or latent) meanings within the data(154). The deductive element of the codebook approach involves development of a preliminary coding frame or 'codebook' based on the research

question(s), topic or interview guides, prior literature searching and preliminary data analysis. This is followed by an inductive component to identify further patterns and findings that may fall outside the scope of the initially predicted coding frame(155). Whilst generation of an *a priori* coding frame may be time consuming, codebook thematic analysis results in a more focused and structured analysis overall(154,155).

RD and I began by familiarising ourselves with the data by independently reading and reviewing the transcripts, recordings and my field notes to develop the high-level coding frame which was agreed upon during consensus meetings (Appendix 5.5). I coded all the transcripts according to this initial coding frame and the process of inductive thematic analysis was used to explore in detail the key reasons underlying the jurors support or rejection of particular strategies to develop lower-level sub-themes. I aggregated data into unifying themes during an iterative process of coding and consensus deliberation.

I used Stata 15(156) to analyse the quantitative data collected from the pre- and post-jury questionnaires. I used descriptive statistics to summarise participant characteristics and Wilcoxon Signed Rank tests to identify changes in individuals' attitudes towards risk-stratified screening.

5.4.5 Public participation

The role of PPI in this study was broadly agreed upon in advance to establish an understanding of their responsibilities and expected time commitment. Three PPI members contributed to the design of this study by providing feedback on the community jury materials via email conversations and video conferencing. PPI members who attended the community juries were reimbursed for their time spent attending the juries, associated meetings and reviewing documentation, in line with INVOLVE guidelines(96). It was agreed upon with the PPI panel that they would prefer to assume an observational role during the juries.

5.5 Results

5.5.1 Participant characteristics

A total of 16 participants took part across the two juries (Table 5.3). The majority of participants were White (n=13, 81.3%), had not completed a degree (n=11, 68.8%) and were middle or lower middle class (n=13, 81.3%). One participant in each jury had been previously invited to cancer screening and had declined to attend (n=2, 12.5%).

Table 5.3 Demographic characteristics for the community juries.

	Jury 1	Jury 2	All (%)
Total N	7	9	16 (100.0)
Age range			
50-59	3	2	5 (31.3)
60-69	3	5	8 (50.0)
70-74	1	2	3 (18.8)
Sex			
Male	3	5	8 (50.0)
Female	4	4	8 (50.0)
Ethnicity			
White	6	7	13 (81.3)
Asian/Asian British	1	0	1 (6.3)
Black, African, Caribbean/Black British	0	1	1 (6.3)
Mixed/multiple ethnic group	0	1	1 (6.3)
Education			
Not completed A levels or equivalent	2	2	4 (25.0)
Completed A levels or equivalent	2	2	4 (25.0)
Completed further education but not a degree	1	2	3 (18.8)
Completed a Bachelor's degree or higher	2	3	5 (31.3)
Geographic region			
England (London and South East)	3	5	8 (50.0)
England (North or North West)	2	4	6 (37.5)
England (Midlands)	1	0	1 (6.3)
England (Yorkshire and the Humber)	1	0	1 (6.3)
Social grade			
B (middle middle class)	3	2	5 (31.3)
C1 (lower middle class)	2	6	8 (50.0)
C2 (skilled working class)	2	1	3 (18.8)
Self-reported health			
Excellent	0	1	1 (6.3)
Very good	2	2	4 (25.0)
Good	2	4	6 (37.5)
Fair	3	1	4 (25.0)
Poor	0	1	1 (6.3)
Smoking status			
Never smoke cigarettes or cigars	3	3	6 (37.5)
Used to smoke cigarettes or cigars	2	4	6 (37.5)
Smoke up to 20 cigarettes or cigars per day	2	2	4 (25.0)
Self-reported weight			
About the right weight	1	5	6 (37.5)
Slightly overweight	4	4	8 (50.0)
Very overweight	2	0	2 (12.5)
Personal history of cancer			
Yes	1	2	3 (18.8)
No	6	7	13 (81.3)
Family history of cancer			
Yes	5	3	8 (50.0)
No	1	5	6 (37.5)

Don't know/prefer not to say	1	1	2 (12.5)
Screening history			
Previously invited	6	8	14 (87.5)
Previously attended	5	7	12 (75.0)

5.5.2 Pre- and post-jury questionnaire results

Most participants found the different elements of risk-stratified screening intervals and FIT thresholds to be very acceptable both before and after the juries (Figure 5.1). Small, statistically significant increases in this measure were observed for the acceptability of using individual risk, sex, age and screening result to determine FIT cut-offs and/or screening intervals. Confidence intervals were wider in the pre-jury questionnaire, suggesting that there was less variation in participant responses after the juries had taken place. One participant was recruited to the jury late as a replacement for someone who was unable to attend and therefore did not complete the pre-jury questionnaire.

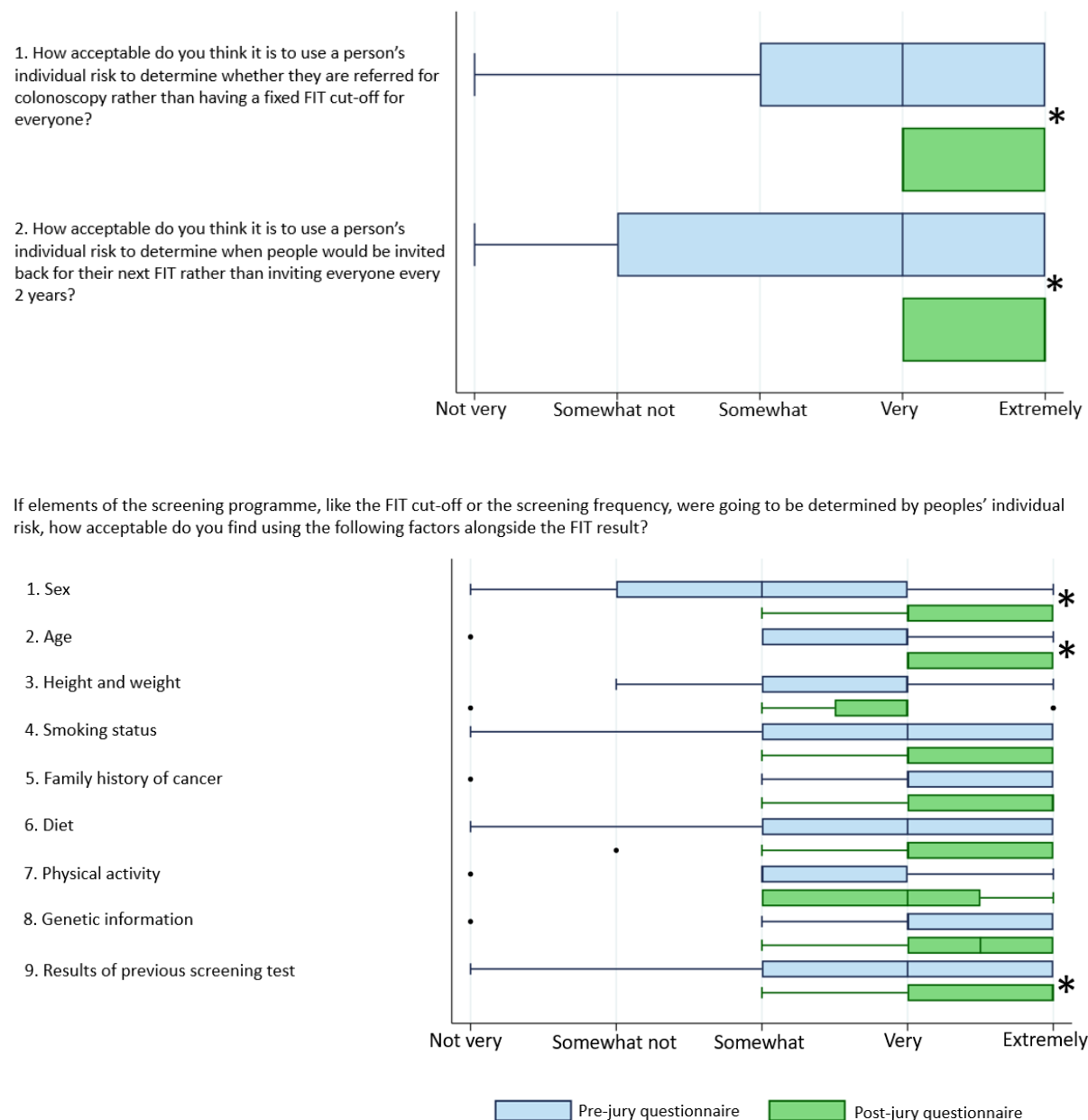


Figure 5.1 Change in how acceptable community jury participants found elements of risk-stratified FIT thresholds and screening intervals.

** $p < 0.05$ Wilcoxon Signed Rank test.*

Questionnaire 1 $n=15$; questionnaire 2 $n=16$.

5.5.3 Qualitative synthesis findings

5.5.3.1 General advantages of risk stratification

Jurors were able to identify a diverse range of anticipated benefits of a risk-stratified bowel cancer screening programme. These included benefits to individuals, wider health system benefits, reducing screening-associated harms and promoting behaviour change through increased awareness.

Individual screening outcomes

Risk stratification was considered a way for individuals to benefit because *“it gives the chances of the people that are high risk to be able to help them if they’ve got it”* – Participant [P]1.4. Participants were positive about prioritising those at high risk and supporting them throughout the screening process and beyond, in terms of diagnosis and treatment:

“...I would rather, if I am high risk, be at the total top of the priority list and then the resources aren’t being wasted on those that are at low risk and have got no or very little chance of getting it, and then all that resource should go towards those people... and really making sure that they are taken through a journey that the funds are available...” – P1.2

Some participants reflected specifically upon risk-based screening intervals and felt that for individuals at high risk *“...one year could be life or death if you’re that vulnerable to get it”* – P1.4.

Wider benefits

Participants also considered benefits beyond the individual level, considering wider advantages such as improved cost-effectiveness and resource allocation, including time, money and staff:

“Just basically in my mind effective risk stratification, surely it’ll give improved efficiency and utilisation of further services which in the end surely will lead to a reduction in wasted resources.” – P1.3

The economic advantages of risk stratification were considered in the context of a financially constrained healthcare system and in relation to potential opportunity costs. Participants considered how money saved from risk stratification could be used more efficiently to benefit other areas within the NHS, such as treatment of cancers or services for other conditions:

“I wouldn’t want to be tested; if I’m at low risk just leave me alone and let others get on with it... take my £6 [cost of FIT] and spend it somewhere else.” – P1.2

Participants in jury 2 considered that screening unhealthy people who are at high risk as a result of poor lifestyle is ultimately worthwhile in order to benefit the health service by saving money and resources in the longer term:

“...You’re not necessarily doing it for their benefit, you’re doing it for the benefit of the amount of money you’re spending in the NHS. If you don’t sort people like that

out, right, and they get missed it's going to cost the NHS a lot more money further on down the line. So it's not just about 'Oh, well those people don't look after themselves so we're not looking after them', it's a case of 'Well, okay, those people don't look after themselves, but we need to make sure that we take the appropriate action to stop them costing us a hell of a lot more money.' – P2.7

Reducing harms

In general, jury discussions tended to focus on the benefits of risk stratification for high-risk people who stand to receive increased screening, rather than the potential for low-risk individuals to avoid harm. Nevertheless, multiple participants acknowledged the potential to avoid the negative emotional and psychological impacts of unnecessary screening and overtreatment for people who are at low risk:

"...Trying to get everybody screened there's lots of potential unnecessary treatments and anxiety and stress that people will go through..." – P1.2

Potential for behaviour change

A final benefit suggested by the jurors was the potential for behaviour change in response to increased awareness of bowel cancer and associated risk factors. Some participants hypothesised that knowledge of personal risk of bowel cancer might motivate some people to adopt long term changes to their lifestyle, partly in order to avoid more intense screening:

"Yeah, I think most people know anyway about some of the health behaviours that aren't the healthiest things... smokers know smoking isn't good for them and high fat foods are not good for them but we do it anyway, but to say somebody's at higher risk ... it might prompt people to make lifestyle changes over the long term, you know, because it keeps it fresh in their mind that 'Mm, yeah, maybe I don't want to be going for the screening quite so often', so long term they might make more positive changes." – P2.5

5.5.3.2 General caveats of risk stratification

Participants in both juries considered the possible caveats of risk-stratified bowel cancer screening.

Impact on people with a low cancer risk

Whilst attitudes towards risk stratification were generally positive, participants voiced concerns about how de-intensification of screening could impact upon low-risk cohorts. One participant felt

that risk-stratified screening intervals were too rigid and may lead to low-risk people being disadvantaged:

“The challenge I got from yesterday was that it seemed to me it could be quite fixed and rigid, whatever you change, and therefore that could... It’s not that it’s not fair, it’s just that because it’s fixed it could cause a problem for certain people... I like the idea but I think there needs to be a flexible approach ... It’s very simple to put them [low-risk people] in a compartment on their own and say ‘Okay, they’re okay for the next three years’, I just don’t feel very comfortable with that.” – P2.8

Some participants were particularly concerned about the potential for screening cessation for those at low risk and largely found this to be an unacceptable strategy:

“Yeah, they’re saying that if it’s such a low risk they don’t need to screen them. Even if there is a slight risk I think they need to be screened.” – P1.4

Distasteful impression

Participants in both juries were concerned that risk stratification of the FIT threshold constitutes rationing of screening resources and felt uncomfortable with the idea of making rationing decisions. When presented with scenarios illustrating the implications of risk-adapted screening on an individual basis many participants found it challenging to make such decisions, even though the overall concept seemed acceptable:

*“It’s a very difficult one but my first instinct is that if they both have the same blood count [faecal haemoglobin level] then they do deserve the same place in the queue.”
– P2.6*

Some jurors reflected that their views differed when considering the concept of risk stratification from the perspective of the whole population rather than specific and personal scenarios in which two people are directly compared:

“I think it’s a really difficult one. Because I understand everything you’re saying there, once you put the algorithm in place, the algorithm then... dictates it, but I’m sure P1.6 would agree that if P1.6 or myself or any of us were in that situation it’s completely different for the individual when they’re in that situation and what they’d like as care. So whilst I see the point that, you know, if somebody’s got too... lots of blood then they get fast-tracked into a colonoscopy, the moment I’ve got blood in my

poo I'd want at least everything done possible to get the colonoscopy if I needed that, rather than have to wait a year and that could be too late by then.” – P1.2

As discussed in greater detail in section 5.5.3.5, confusion that people with a concerning level of blood in their faeces may be excluded from receiving a colonoscopy clearly contributed to these concerns.

Complexity

Finally, participants considered whether implementing risk stratification may in reality increase the burden on the healthcare system by exacerbating costs and workforce constraints rather alleviating such issues.

“I was thinking of more resources and training and people to actually do the work of the additional people that might be put through.” – P2.8

Several jurors also expressed that having multiple possible strategies for risk stratification and risk calculation increased the level of complexity, making it more challenging to implement as well as potentially discouraging the public from participating in the screening programme:

“I think the more complicated it gets made, the harder it is for people. You know, we’re going along with the sample and, you know, the degrees of blood and everything but the more complicated it is people will maybe back off and be like ‘Oh I’ve got to fill in forms and...’ ...I know you’ve got to progress but the more complicated you make things, sometimes it puts people off.” – P1.5

5.5.3.3 Verdict

Both juries generally viewed the concepts of risk-stratified FIT thresholds and screening intervals in the same way and did not find them to be fundamentally different in terms of overall acceptability. I have therefore chosen to report their views on both strategies together.

Using data within the system

Participants were unanimous in their decisions that using age, sex and FIT result is an acceptable strategy for tailoring FIT thresholds and screening intervals according to risk. They considered these risk factors as a logical starting point as the data are readily available and described it as “low-hanging fruit” (P1.6), a “no brainer” (P2.3 and P2.7) and “an easy win” (P2.2). One participant equated risk stratification to other situations in life that may already be determined by age and/or

sex, suggesting that people are already familiar with such a concept and are therefore likely to find it acceptable:

“And I think that people mostly accept that there are differences between men and women in life, you know, things happen at different ages for all sorts of people, things affect men that don’t affect women and vice versa, so I don’t really see it being a big issue... so long as they were furnished with the facts about why this was being done.” – P1.1

In jury two specifically, participants felt that FIT result should be weighted most heavily when calculating individual risk as they felt blood in the stool *“is a red flag irrespective of your age and your sex”* (P2.6). However, they also acknowledged that any screening programme is unlikely to be a perfect fit for everyone:

“It might not be best for everyone but would hopefully be the best for most people.”
– P2.6

Collecting additional data

Participants were largely optimistic when asked about the acceptability of collecting additional data to inform risk modelling for FIT thresholds and screening intervals. They expressed few reservations about the inclusion of lifestyle risk factors and generally believed that the more data included in the risk models the better:

“I think they should all be included; I think it’s necessary. All the facts in front of you... can’t not help actually.” – P1.4

Despite their optimism, participants felt that the addition of lifestyle and/or genetic risk factors was a consideration for the future; a concern that related to the practicalities of data collection and the potential for ethical challenges, such as data security, privacy and discrimination:

“...Genetics, yes, which we all say is a factor that needs to be included... but it’s not sort of immediate. The first one [age, sex and FIT result] was sort of like this can happen now, it’s the low-hanging fruit, and then moving on to the long-term thing which was genetics and lifestyle and so on.” – P1.2

Participants in both juries suggested a weighting system for each of the risk factors included in the risk model and emphasised that providing additional data should not be mandated and instead be a personal choice:

“I think there was a view expressed that lifestyle should not be mandated or sort of... it should not be an issue for discrimination for not having treatment and that any sort of questionnaire it would be up to the patient to decide what personal information the person would reveal about their lifestyle, they could not be forced to do it.”- P2.6

5.5.3.4 Communication preferences

Information about the programme

The desired level of information relating to a risk-stratified programme varied across both juries but was generally high. Some participants advocated for a transparent approach, suggesting that the public should be more informed as *“they’ll pay more attention”* (P2.7) and believing that *“it’s important to educate people about the risk factors”* (P2.2). Participants also acknowledged the need to balance the importance of publicising relevant information with causing anxiety and potentially reducing uptake by sharing too much information:

“And I think that the public aren’t mostly that stupid and will understand if you just explain to them that it is about risk and, you know, if you get screened more it’s because you’re at more higher risk... Women are less likely, men are more likely higher risk, age is a factor. So it doesn’t take much information to be given out to show exactly what the risk is and why that strategy has been undertaken... if you’re going to ‘scare’ people by saying, you know, “You’re not above the threshold but you’re close to it” then... you need to back that up with things that are going to... cancel out the ‘fear factor’.” – P1.6

Similarly, jurors were cautious of framing risk stratification in the context of limited colonoscopies and felt that inclusion of numerical statistics (e.g. odds ratios) was unnecessarily complicated.

“In my past experience, if something is of limited availability everybody wants to jump on the bandwagon and get it because by its very nature it’s limited...” - P1.5

Several participants suggested providing more detailed information about the risk calculator on the NHS website so that people who are interested can seek it out of their own volition.

A final consideration that arose frequently in both juries was the perceived importance of public education to increase societal awareness of bowel cancer, screening and prevention, not just in relation to risk-based elements of the programme:

“I think the public need to know that there is a screening strategy in the first place, they need to know how to go about accessing it and when they should...” – P2.6

Participants felt that education was important in helping people decide whether to participate in screening and they reflected that *“you don’t really see a lot of information about bowel cancer” (P2.4).*

“I think it’s the requirement so that if you’re being invited to have screening you know why you’re being invited to screening.” – P2.5

Information about personal risk

As with information about the programme, the desire for information about personal risk of bowel cancer varied considerably among the jurors. Some participants felt that it would be more acceptable to inform individuals about changes to screening intervals providing they also receive education about the rationale behind any risk-based changes:

“...it’s going to be key...to put the patient information to keep them informed why, also if you’re low risk why you’re lower risk and why it’s [screening interval] going to be moved to three years as opposed to two years and if you’re high risk move to one year. I think the patient needs all the information they can get in order to understand the rationale behind it, basically.” – P2.3

Some participants felt strongly that individual risk levels should be disclosed and that to avoid doing so would constitute *“hiding the truth”* (P2.9). Additionally, in some cases, knowledge of personal risk was thought to act as an incentive to participate in screening or to take mitigating action:

“I would want to know if I was high risk. I would want to know because it would ensure that I would make sure I send the test back... So if you get a little bit of a fright saying ‘You need to be tested in a year’ it would ensure that people do take the test and send it back, in my opinion.” – P1.7

Conversely, other participants did not wish to know their personal risk of bowel cancer, primarily due to anxiety and one participant highlighted that while a high risk score may generate anxiety, a low risk score may incite complacency:

“I wouldn’t like to receive a letter that says I’m low risk, medium risk or high risk. Low risk would make me a bit blasé and just not bothered. High risk would make me panic.” – P2.5

Similarly, there was little desire to be informed of a borderline result due to the potential for increased worry without the reassurance of a colonoscopy:

“I think if I had a test and I was just below the threshold but in the high [risk] category and I was going to be put into the one-year... I was going to be tested again in a year, me personally, I would just like a letter to say ‘Oh you’ve had a test, we’ll be testing you again in a year’s time, we’ll contact you.’... I don’t really need to know what’s happening in the interim period.” – P1.2

A proposed solution to managing these dichotomous opinions was to include minimal information about personal risk in a letter but to hold more information about individual risk within primary care records to enable people to request it if desired:

“I would let everybody know that, yes, the information is there to find out what their risk level is if they want to.” – P2.7

Language and communication channels

Throughout the jury discussions, participants emphasised the importance of positive, simple and lay friendly language when communicating with the public. The use of diagrams like the ones used in the expert presentations were encouraged to make the information digestible. A multitude of communication channels were identified, including television, radio, social media, text messaging, billboards and through GP practices. Accessibility of these channels was a key concern, necessitating a tailored approach for different groups of the population, e.g. using offline methods to target older individuals who may not access the internet or social media.

“There’s no one-size-fits-all but... they have to get the information out there somehow, somewhere, so if that’s on bus-stops, on the tube, on signposts, leaflets, wherever, it’s got to be short, sweet and simple to direct people towards a website where they can get more information.” – P2.6

5.5.3.5 Areas of confusion

Participants were exposed to a large volume of new information during the juries, which the expert presenters and I endeavoured to present as clearly as possible and they helped one another to consolidate their understanding. Nevertheless they appeared to find certain aspects of risk stratification confusing. Some participants worried that people with a concerning level of blood detected by the FIT test would be excluded from receiving a colonoscopy on the basis of being low risk according to other factors, despite discussing this with the experts:

“...there’s obviously something in the 62 year old man that needs investigating and which ages or anything shouldn’t come into it if there’s a possibility and it’s really, really important catching it in the early stages.” – P1.4

In general, the concept of stratified screening intervals was easier to grasp than changes to the FIT threshold. This was demonstrated in participant discourse as they tended to use screening intervals as the example when sharing their thoughts and opinions.

5.6 Discussion

Risk stratification of both screening intervals and FIT thresholds for referral to colonoscopy were acceptable to informed members of the public. Participants were convinced that the potential benefits gained at individual and societal levels justified moving away from age-based screening. The perceived benefits outweighed concerns that risk stratification could negatively impact low-risk individuals, be unethical or unfair, or be too complex. Clear and effective communication was considered crucial, regarding the bowel cancer screening programme in general and risk-stratified elements in particular.

Stratifying FIT thresholds and intervals based on age, sex and FIT results was considered an obvious change to the current screening programme. Participants believed this could be implemented as soon as validated risk models and screening infrastructure were established, and that this strategy would be acceptable to the wider public. The predictive ability of lifestyle and genetic information was acknowledged and their inclusion was considered acceptable, providing simple and accurate data collection would be possible. However, this strategy was considered a step for the future due to the practicalities of data collection.

Public desire for information to enable understanding of the rationale behind risk stratification appears high, particularly information about risk factors and mitigating personal risk. Participants generally considered personal risk feedback to be important, but opinions varied on the level of detail that should be provided. Receipt of risk feedback was, therefore, proposed to be optional rather than automatic.

5.6.1 Comparison with other literature

The general acceptability of risk stratification reported here aligns with previous research considering risk stratification across different cancer types among less informed participants, including the systematic review described in Chapter 4(153,157). These findings are also consistent with previously published community jury studies considering risk-stratified eligibility criteria for cancer screening in general and for bowel cancer specifically, which included similarly informed

participants(148,153). The high acceptability of providing personal information for cancer risk assessment reported here is congruent with previous studies in which many members of the public considered completing a questionnaire or providing a genetic sample for risk calculation to be acceptable(121,122,128,133,153). Community jury participants generally believed the more information included in risk estimation the better; this is supported by a survey about the acceptability of different approaches to determining eligibility in which a comprehensive risk score was preferable to more simplistic models(120). Conversely, previous community juries considering risk-stratified cancer screening have reported greater reservations around the inclusion of lifestyle factors in risk estimation to determine eligibility, fearing that people may falsify their responses or that the information may become outdated(148,153). Juries concerned with risk-based eligibility also appeared less concerned with the complex nature of the intervention, whereas jurors considering risk-stratification at the point of the screening test, whether in relation to threshold or interval, were apprehensive about the complexity of collecting additional data and integrating stratification into existing infrastructure(153).

The desire for clear and transparent public communication in relation to risk factors and screening programme changes has been exemplified across different cancer types, as well as in this study(124,128,129,132,135). Similarly, preference for diagrams and lay-friendly language is well-evidenced(127,129,146). In the context of recent changes to NHS England cervical cancer screening intervals, insufficient public communication has been demonstrated as a barrier to acceptability(82–84). Jury participants suggested capitalising on multiple channels and outlets to communicate risk stratification, the value of which is emphasised by the low acceptability of extended cervical screening intervals after such changes were made without public announcement(84).

5.6.2 Strengths and limitations

The community jury method enabled me to gain an in-depth, society-centric understanding of the public's views on risk-stratified bowel cancer screening and priorities for communication. Importantly, participants were informed about the topic, had opportunities to question experts and had time to contemplate their personal views and preferences for wider society. Although they found the topic complex, significant misunderstandings were addressed and the participants confirmed whether their views changed as result. Therefore, I believe these areas of confusion are unlikely to have biased the overall conclusions, but this does highlight areas in which the public may require greater clarity. As the jury was hypothetical in nature I was unable to assess participants' real-life responses to being offered less frequent screening following a low risk estimate. Nevertheless, all participants acknowledged the serious nature of the topic and together they considered a wide range of implications.

An inevitable limitation is recruitment bias, specifically the inclusion of participants with more interest in cancer and screening than the general populous. Although each jury included a participant who had declined a previous invite to screening, general attitudes towards screening were favourable. Use of a recruitment company may have helped to reduce this in comparison with alternative approaches such as recruitment via posters in GP practices. A further advantage to this recruitment strategy and the online setup enabled inclusion of participants from across England with varied demographic characteristics.

Future research should explore how best to feasibly facilitate public understanding of risk stratification and associated concepts, given that the degree of education provided in a research context such as within community juries, is not possible at population level. Additionally, the feasibility of providing some information individually via the screening letter with the option to access more detailed information online via EMR requires evaluation. As healthcare systems increasingly offer access to online interfaces and resources this is likely to become increasingly viable(157). Additional development and validation of risk prediction models is also required, as well as further research engaging the public to identify how to group the population and describe such risk groups.

5.7 Conclusions

In this community jury study I have explored the acceptability of risk-stratified bowel cancer screening, specifically in relation to screening intervals and FIT thresholds. I have also considered public information needs and communication preferences. I have shown that risk-stratified bowel cancer screening was considered preferable to current age-based screening practices. The use of readily available data (age, sex, FIT result) was viewed positively and could be implemented immediately from an acceptability standpoint. The inclusion of additional risk factors was also acceptable but seen as aspirational due to the feasibility of data collection. These findings further those reported in Chapter 4, indicating overall acceptability of risk stratification is high and this is likely to extend to bowel cancer specifically, although larger scale quantitative research is needed to confirm this. I report my research on this in Chapter 7. These results also exemplify potential areas of confusion and elucidated personal differences in desire for information. As such, greater understanding of public information requirements and interpretation of screening information is needed if risk stratification is to be communicated on a population level. I report my research on this in Chapter 6.

Chapter 6 Public understanding of information about risk-stratified bowel cancer screening: A think aloud study and user testing process

In this chapter I describe a set of think aloud interviews used to refine a public-facing information leaflet for risk-stratified bowel cancer screening intervals followed by a user testing process.

6.1 Summary

The communication of personal cancer risk and risk-related concepts to the public remains challenging and mathematical concepts are often poorly understood by lay individuals. There is a need to explore public information requirements and understanding of communication about risk-stratified screening as this may impact decisions about screening uptake. I aimed to develop and test public understanding of a bowel cancer screening leaflet relating to risk stratification of FIT screening intervals.

A risk-stratified bowel cancer screening leaflet was adapted from the existing NHS England screening leaflet and piloted with input from a patient and public involvement panel. The resulting leaflet was used in 13 think aloud interviews using a marked protocol design to identify areas that required improvement to facilitate public understanding. The think aloud interviews were analysed using codebook analysis and the final leaflet was tested by 20 participants via a user testing survey.

Interview participants identified 42 suggestions for improved clarity and comprehension, 35 of which were incorporated into the refined leaflet. They advocated for clearer language and layout, including the use of bullet points, and identified several common areas of misunderstanding. Additional information was suggested to mitigate cancer worry. A minimum of 90% of user testing survey participants answered each true or false statement correctly after reading the final information leaflet.

The think aloud interviews suggested that specific elements of the risk-stratified bowel screening leaflet were challenging to understand and required improvement. A refined version of the leaflet performed well in user testing indicating that most comprehension issues had been resolved and that the public would be capable of understanding information about risk stratification presented as part of a population-level screening programme.

6.2 Background

As demonstrated in Chapters 4 and 5, adequate communication of risk stratification is essential to facilitate understanding of and confidence in risk estimation and to maximise public acceptability. Risk perception is a complex multidimensional construct, comprised of deliberative, affective and

experiential components(158). Consequently, communicating personalised risk estimated and risk-adapted screening schedules to the general population in a meaningful way remains challenging, particularly considering that lay individuals typically have a poor understanding of the harms and benefits associated with screening(159–161).

Despite receiving personalised risk information, many members of the public still tend to overestimate their chances of developing cancer and are unwilling to accept a risk estimate that contradicts their internalised beliefs(161,162). A systematic review and meta-analysis by Bayne et al. found that 87% of participants recall their personal risk immediately after delivery. However, fewer than 50% of those individuals considered their risk score to be accurate and 71% believed the risk score given to them was lower than their actual risk(161). Additionally, percentages, frequencies and other mathematical concepts are challenging for the public to comprehend and previous literature has identified a preference for gist-based risk presentation alongside supporting diagrams or graphics and/or comparative risk statements which allow for contextualisation of personal risk(133,158,160–164). Previous research has also indicated that cancer risk assessment does not trigger significant emotional harm and that low-risk individuals are unlikely to experience substantial negative impacts on screening or lifestyle behaviours(159,165). Further, communicating personal cancer risk in a mindful manner may temper feelings of anxiety among higher risk cohorts(165).

A further challenge identified in Chapter 4 is avoiding contradiction of existing public health messaging, which has traditionally been aimed at promoting uptake, when communicating the rationale behind the implementation of risk-stratified screening. This is of particular concern when communicating reduced screening for low-risk individuals, especially in the context of poor public knowledge of screening harms. Indeed, even in cases where public understanding of the harms and benefits of screening is good, this does not necessarily translate into intentions to participate in screening(160,165). Previously, participants receiving supplementary information about screening harms have continued to make decisions about whether to attend screening according to their prior beliefs(160). Additionally, participants in the current bowel cancer screening programme receive their results as either positive or negative, meaning that the population are mostly unaware that a negative result may still include some blood. This established messaging may be challenging to move away from when explaining the characteristics behind risk-stratified groupings.

Ahead of implementation of risk-stratified bowel cancer screening, there is therefore a requirement to understand public information needs and how these relate to communication of risk, screening outcomes and changes to the overall programme.

6.3 Aim

To develop and test public understanding of text for risk-stratified bowel cancer screening information relating to FIT screening intervals.

6.4 Methods

The existing NHS England bowel cancer screening leaflet delivered prior to the point of invitation (Appendix 6.1) was adapted to incorporate details about a hypothetical bowel cancer screening programme in which the screening interval is stratified according to individual risk. The original leaflet contains public sector information licensed under the Open Government Licence V3.0 (<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>). Adaptations to the leaflet were informed by the findings of the community jury study detailed in Chapter 5 and input from two PPI members. The leaflet was firstly piloted with three members of the Addenbrookes PPI panel before being used in a set of think aloud interviews. Findings from the think aloud interviews informed improvements to the leaflet which was then used in a user testing procedure to test public understanding.

During a think aloud study participants are asked to complete a given task whilst simultaneously ‘thinking aloud’ about their internal cognitive processes. Information that is processed during a task is only available within the short-term memory for a brief period of time, necessitating concurrent reporting of a participant's thoughts. Consequently, participants who are asked to self-report their thinking processes often provide responses which poorly reflect the thoughts actually involved in mediation of the task(166). As such, the process of spontaneously verbalising the cognitive process that occurs during a task provides novel insights into participant’s thoughts, which in turn provides insight into the research question. I chose the think aloud method as it has been successfully used in multiple scientific disciplines, including healthcare and health psychology research, and is a distinct qualitative method to introspection which is typically explored in traditional interview techniques(163,166–171).

6.4.1 Study design

Ethical approval was granted by the Cambridge Psychology Research Ethics Committee, reference: PRE.2023.023.

Think aloud interviews

I conducted 13 think aloud interviews in April and May of 2023. Each interview lasted up to one hour and took place online using Zoom videoconferencing software. A technical check was performed by

the recruitment company, iPoint Research Ltd, before each interview to familiarise the participants with videoconferencing and reduce the risk of technical issues arising.

During the interview, participants were asked to read the screening information leaflet (Appendix 6.2) and to 'think aloud' by verbalising their internal thought processes. I opted to use a 'marked protocol' design in which a series of small red dots were distributed at specific points throughout the text in order to prompt participants to vocalise their thinking (Figure 6.1). I placed these dots at the end of individual sentences, short paragraphs (i.e. two to three short sentences), bullet points and at points that were highly relevant to the research question. I chose the marked protocol as this method has previously produced more authentic responses than an unmarked protocol when utilised in a similar research setting(163).

Bowel cancer screening outcomes

As shown in the flow chart below, there are 4 possible outcomes.

If your FIT kit detects **some blood** above the screening range you will be offered a colonoscopy regardless of your risk score. ●

If the result of your FIT kit shows **no blood or a tiny amount of blood** and you have a **low risk** based on the risk factors listed above you will be invited back for screening in 3 years' time. ●

If the result of your FIT kit shows **no blood or a tiny amount of blood** and you have an **average risk** based on the risk factors listed above you will be invited back for screening in 2 years' time. ●

If the result of your FIT kit shows **no blood or a tiny amount of blood** and you have a **moderate or high risk** based on the risk factors listed above you will be invited back for screening in 1 years' time. ●

Figure 6.1 Example of a leaflet section illustrating the red dots used in the marked protocol method.

In line with previous research, participants were first asked to complete a warm-up task to ensure they understood what was expected of them and to help them feel at ease thinking aloud in front of a researcher(166). A short pilot text unrelated to bowel cancer screening (Appendix 6.3) was used to ask participants to respond to each prompt using the marked protocol design. Participants who initially failed to vocalise a response at each red dot in the first half of the pilot text had the think

aloud procedure explained again and were given more time to practice using the second half of the text before attempting the think aloud interview. No participants failed to complete both halves of the pilot exercise.

User testing survey

The user testing procedure involved asking participants to read a refined version of the information leaflet before answering a series of true or false statements to test their understanding in the context of an independent survey. A threshold of 80% was required for each true or false statement to be considered appropriately comprehensible, in line with the Test of Functional Health Literacy in Adults (TOFHL) scores and a previously conducted think aloud study in this research area(162,163). Typically, after each round of testing the survey information is improved in areas where the true or false statements were answered correctly by fewer than 80% of participants.

6.4.2 Participants and recruitment

Think aloud interviews

I initially recruited 15 members of the public via iPoint Research. The sample was purposefully recruited by age, sex, social grade, geographic region in England and previous attendance at bowel cancer screening. Demographic information was collected via a short survey hosted on Qualtrics and each participant received a personalised link to complete the survey (Appendix 6.4) from the recruitment agency. The list of personal identifiers was stored on the Cambridge School of Clinical Medicine Secure Data Hosting Service (SDHS).

iPoint Research approached participants using their standardised template and the participant information sheet (Appendix 6.5) to enable them to decide whether to take part in the interviews. The recruitment company also facilitated reimbursement of participants at their recommended rate.

Inclusion and exclusion criteria were the same as those for the community jury study detailed in Table 5.2. Briefly, participants were aged 50-74 without personal history of bowel cancer or expertise in medicine and had not participated in previous community jury studies conducted by this research group in which the concept of risk stratification was explained in detail.

Written informed consent was obtained from all participants by iPoint Research prior to taking part in the think aloud interviews, using the consent form in Appendix 6.6. The consent form included the principal investigator's contact details to allow participants to ask any questions before giving consent. Verbal consent was also confirmed at the start of each think aloud interview and participants were free to withdraw their consent at any time. Recordings and raw transcripts were confidential and all results pseudonymised.

User testing survey

I aimed to recruit up to 100 participants to complete the user testing survey in rounds of 20 individuals at a time. I recruited participants using the Prolific platform (www.prolific.com) where participants volunteer to take part in studies and are compensated at an agreed hourly rate. I planned to repeat the user testing survey rounds until each user testing statement was answered correctly by 80% of participants or the maximum limit of five rounds was reached. Participants were purposefully recruited by age and sex to achieve a balanced sample. Participants were eligible if they were aged 50-74 years, resident in the UK, spoke English, had no medical expertise or a personal history of bowel cancer.

Individuals who were interested in taking part were shown a brief summary of the study (Appendix 6.7), in line with standard recruitment practices on the Prolific platform. If they then decided to take part they were able to download the participant information sheet and complete written online consent at the start of the survey (Appendices 6.8 and 6.9). All participants were free to withdraw consent at any point by returning their submissions on the Prolific website (a specific feature of Prolific).

6.4.3 Data collection

Think aloud interviews

I collected the data via online interviews held on Zoom videoconferencing software and recorded them using Zoom's record function. The interviews were then transcribed verbatim by an external transcription company, as detailed in Chapter 5, and I then reviewed and pseudonymised them. Demographic data was collected using the aforementioned online survey (Appendix 6.4).

Zoom recordings were saved onto a password protected computer and I immediately uploaded them to the SDHS before deleting the local copies.

User testing survey

The user testing survey was hosted via Qualtrics and any anonymous demographic data was stored on the university shared drive (Appendix 6.10).

6.4.4 Analysis

Think aloud interviews

I analysed the think aloud interview transcripts using thematic codebook analysis to understand the thought processes and reasoning participants applied to specific parts of the leaflet text and to identify potential barriers to understanding. As in Chapter 5, I chose codebook thematic analysis for its combined deductive and inductive approach to coding and because the structure of the leaflet

lent itself to development of an initial codebook(154,155). I used the leaflet section headings to inform an initial high-level coding frame, deductively coding the data according to topic. This was then further differentiated according to the leaflet sub-headings. I reviewed the data coded within each sub-heading and generated suggested leaflet amendments based on the views and preferences expressed in the data, as well as areas of misunderstanding. These suggestions were tabulated and colour-coded using a traffic light system to indicate the feasibility of including such changes in the refined leaflet. I also used the same method to analyse participant reflections on risk stratification.

User testing survey

The user testing survey was analysed using descriptive statistics whereby the percentage of participants who answered each user testing statement correctly was calculated.

6.4.5 Public participation

Two members of the public contributed to the initial development of the information leaflet and participant-facing study documents. A further three members of the Addenbrookes PPI panel participated in pilot think aloud interviews and provided feedback on both the think aloud method and the information leaflet.

6.5 Results

6.5.1 Participants characteristics

A total of thirteen participants aged 50-74 took part in the think aloud interviews (Table 6.1). Two of the fifteen initially recruited failed to attend their interviews. I chose not to re-recruit the missing participants as previous research has demonstrated that over 80% of usability concerns are likely to be identified by as little as five participants(172). Additionally, I noted that during the later interviews the same comments and ideas were arising, suggesting I had collected sufficient data with which to draw conclusions about the research question. There was a fairly even split between male (53.8%) and female (46.2%) participants and the sample included a range of ethnicities. The sample was more educated than average and all participants had at least completed A levels or equivalent further education. The majority of participants had a family history of cancer (61.5%) and 84.6% had previously attended cancer screening. A further 20 individuals participated in the user testing procedure. The sample was evenly balanced between males and females and aged between 50-69 years. All twenty participants were white and 60.0% had a bachelor's or postgraduate degree. Three survey participants (15.0%) had a personal history of cancer and the majority had a family history of cancer (55.0%). Previous screening attendance was high (80.0%) and in both the interviews and the user testing, only one participant had previously declined an invitation to screening respectively.

Table 6.1 Demographic characteristics for the think aloud interviews and user testing survey.

Characteristics	Think aloud interviews (n/%)	User testing survey (n/%)
Total N	13 (100.0)	20 (100.0)
Age (years)		
50-54	2 (15.4)	7 (35.0)
55-59	5 (38.5)	5 (25.0)
60-64	1 (7.7)	6 (30.0)
65-69	4 (30.8)	2 (10.0)
70-74	1 (7.7)	0
Sex		
Male	7 (53.8)	10 (50.0)
Female	6 (46.2)	10 (50.0)
Ethnicity		
Asian/Asian British	1 (7.7)	0
Black, African, Caribbean/Black British	2 (15.4)	0
Mixed/multiple ethnic group	1 (7.7)	0
White	8 (61.5)	20 (100.0)
Other	1 (7.7)	0
Education		
Not completed A levels, further education or equivalent	0	2 (10.0)
Complete A levels, further education or equivalent	4 (30.8)	6 (30.0)
Completed a bachelor's degree	1 (7.7)	10 (50.0)
Completed a postgraduate degree	1 (7.7)	2 (10.0)
Social grade		
A (upper middle class)	0	2 (10.0)
B (middle class)	5 (38.5)	5 (25.0)
C1 (lower middle class)	3 (23.1)	4 (20.0)
C2 (skilled working class)	2 (15.4)	7 (35.0)
D (working class)	1 (7.7)	0
E (lowest level of subsistence)	2 (15.4)	2 (10.0)
Personal history of cancer		
Yes	0	3 (15.0)
No	13 (100.0)	17 (85.0)
Family history of cancer		
Yes	8 (61.5)	11 (55.0)
No	5 (38.5)	9 (45.0)
Screening history		
Previously invited	12 (92.3)	17 (85.0)
Previously attended	11 (84.6)	16 (80.0)

6.5.2 Codebook thematic analysis

The think aloud interview results are detailed in Table 6.2. Interview participants suggested a total of 42 potential changes to the screening leaflet and the final refined version of the leaflet is included in Appendix 6.11. Thirty-two of these changes were able to be incorporated in full (illustrated in green),

three were partially incorporated (orange) and the remaining seven changes were rejected (red). The most common reason for rejecting a change to the leaflet was where only one participant suggested the change, whereas several others had expressed positive views about that section. The most commonly suggested changes that I was able to incorporate related to clarity and improving readability, for example by using bullet points, simplified language or removing areas of unnecessary detail that may cause confusion. In some cases (e.g. 3. Why we offer bowel screening) participants suggested breaking large sections of text into shorter paragraphs to improve readability; whereas, in other areas, they suggested merging paragraphs to cut down on repetition (e.g. 2.1 Language and terminology). The section of the leaflet that generated the most suggested changes was 'Possible benefits and risks of bowel cancer screening', a section that had been included in the original NHS leaflet. Participants suggested seven changes to this section of the leaflet, all of which were able to be incorporated into the refined version. Many of the suggested changes to this section related to reducing possible areas of confusion. For example, adding sentences to clarify that the term 'screening' refers to FIT as opposed to colonoscopy and removing the terms 'false positive' and 'false negative' as, although the overall concept seemed to make sense, participants found the terms themselves to be confusing. Similarly, several suggested changes to this section involved adding statements of reassurance relating to alternative sources of blood in the stool and the ability to seek help from a GP if symptoms of bowel cancer develop in between invites to screening. Overall, twenty-five suggested changes related to sections of the screening leaflet that were included in the NHS England leaflet, with the remaining seventeen concerning risk-stratified elements specifically.

Table 6.2 Codebook thematic analysis results of the think aloud interviews.

Leaflet section	Suggested change	Outcome	Supporting quote
1. How the bowel works			
1.1 Picture of the bowel	More detail/labelling of other organs ✗	Only one individual suggested this change, whereas others were positive about the picture. When trialled it made the picture more confusing and detracted from the bowel.	<i>"...It doesn't explain the middle section of the small intestine. It doesn't explain what the liver is. It doesn't explain what the stomach is." (P5)</i> <i>"Was that picture helpful, do you think?"</i> <i>"Yeah, very helpful..." (P11)</i> <i>"...I really love the picture..." (P6)</i>
	Use colour to highlight which part is the bowel ✗	Only one individual suggested this. Other participants were positive about the original image.	<i>"You might want to change the colour, for example, so make the colon bright orange the rest of it shaded... to emphasise the part you're interested in..." (P5)</i>
2. Bowel cancer	Break up the text ✓	More paragraphs were added to break up the text and improve readability.	<i>"...might be useful to, kind of, maybe incorporate some bullet points or something, maybe break it up a little bit..." (P6)</i>
	Include statistics on incidence/survival ✓	Participants were generally keen for more information. Sentences about bowel cancer incidence and development time were added.	<i>"So yes I think people should know what the developments are, how serious it had become, how long have you got to live if you get it, what's the options, what the treatments are. Is there a big survival rate now..." (P7)</i>
2.1 Language and terminology	Image or diagram of a polyp and/or its progression to cancer to support the text ✗	This is challenging to add without using a medical or scientific diagram that could be confusing. Instead, the repetition about polyps in the first two sections was consolidated to improve clarity.	<i>"A little bit [challenging to understand] because I'd say if you knew what a polyp was then you'd understand it more. But if there's an image of a polyp maybe in the tract that would make you understand. More pictures as it were than words." (P10)</i>
	Merge two paragraphs to avoid repeating information ✓	These paragraphs were rearranged to improve clarity.	<i>"...Instead of just repeating the whole paragraph you could just say generally that this is why we screen, and to remove polyps etc... So, you're talking about</i>

			something else rather than repeating some information then adding a little bit.” “So, those two paragraphs could probably be merged?” “Yeah, yeah, yeah. Possibly yeah.” (P10)
	Differentiate between polyps and piles ●	Although the distinction between polyps and haemorrhoids was not specifically added, piles are mentioned earlier in the leaflet as a possible alternative cause of blood in the faeces.	“The polyps, that polyp thing is that the same as a haemorrhoid?... Well I thought they were the same thing. I would be pleased to see this is different from a...” (P12)
3. Why we offer bowel screening	Change heading to ‘Why bowel screening is important’ ●	The heading was amended to ‘Bowel cancer screening’ to better reflect the breadth of information. The participant’s suggestion of ‘Why bowel screening is important’ was rejected on the basis of being overly prescriptive/paternalistic.	“But it could be bowel cancer and then also a sub-heading of cancer screening. I think we don’t need to know why you offer it because, you know why you offer it.” (P10) “Again, I would, kind of say in there why is it important, you know, rather than why we offer it because when you say why we offer it it’s like well you can have it or you can not have it, it’s more like, you know, it’s your health, so you want to know why it’s important.” (P6)
	Break up the text ✓	More paragraphs were added to break up the text and improve readability.	“...I mean this is just me, and I think the way people absorb information just now again, like, you know, you can prevent this by early detection bullet point da da da, you know, just, kind of, keep it... maybe make it stand out a little bit more. I mean there is not an awful lot of text there so I think I would read it, but I just think maybe the way it’s, kind of, laid out could be a little bit more engaging.” (P6)
4. Who we invite			
4.1 Interacting with the GP	Mention the option for assistance from a HCP ✓	A sentence was added to refer individuals who require assistance to complete the FIT kit to the screening programme helpline.	“Because obviously it keeps mentioning kits, I assume these are home kits. Which generally, possibly they’re living alone, and they can’t do it themselves for whatever reason, it doesn’t mention whether you can

			<i>get help from a GP. From a nurse or something... and I think some people obviously being elderly might not be able to do the test properly themselves" (P10)</i>
5. How bowel cancer screening works	Change heading to better reflect the paragraph content (e.g. 'The screening kit) ✓	The heading was amended as suggested.	<i>"Yeah, yeah. I mean as I say it's not actually explaining it. The title says how bowel cancer screening works but obviously that would be quite scientific in terms of trying to understand. So it's more about what the kit looks like sort of thing." (P10)</i>
	Who would do the colonoscopy? ✓	A sentence explaining that colonoscopy is typically performed in hospital by a trained HCP was added.	<i>"My first thought on paragraph one would be, well who would be doing it. Who would be doing the examination? Would you be called in or would your GP do it?" "Who would do the further investigations?" "Yeah." (P12)</i>
	Clarify that people don't need further tests <i>because nothing concerning is found</i> ✓	A sentence was added as suggested.	<i>"Are we saying that most people do not need any further tests because they don't detect anything abnormal in the sample? ... So why not say that? Why not say most people do not need further tests because nothing untoward is found? Or nothing outwardly untoward. Because what you're saying there is, what you could read into, that is most people do not need any further tests but it's not explaining why." (P5)</i>
	Clarify that FIT is done at home ✓	The leaflet specifies that FIT is a home testing kit.	<i>"You could ask if you could take somebody with you or can somebody be there when you're testing. Just in case at certain ages people like my mum were probably a bit frightened. She'd say, would you come with me? Or, you know, would you be there when I'm doing the kit?" (P8)</i>
6. Bowel cancer symptoms	Add that looser poo means runny ✓	The word 'runny' has been added in brackets as suggested.	<i>"I mean that one already says loose poo and I thought that meant it's more runny... But then maybe it should say runny then...But looser, I mean when you think about loose you think about tight and loose you see so it's kind of a funny word to use." (P10)</i>

	Highlight the importance of speaking to a GP if you have symptoms ✓	A suggestion to visit a GP if symptoms persist for 3 weeks or more was added.	<i>"I would highlight that. I wouldn't just grey it. But I would also further highlight or underline perhaps please speak with your GP... If somebody has got these sorts of symptoms for more than three weeks and they can't get hold of their GP, for whatever reasons, the temptation is just to leave it." (P5)</i>
7. Possible benefits and risks of bowel cancer screening			
7.1 Benefits	Clarify that screening is FIT, not colonoscopy ✓	An explanation that home screening is completed using the FIT kit was added.	<i>"Yes sorry I'm a bit unclear what the screening compared to the... the difference between the screening and the colonoscopy, yes." (P6)</i>
	Numbers instead of bullet points ✓	The points are now numbered.	<i>"Maybe you need to put it like one, two, three, do you know what I mean?" (P6)</i>
7.1.1 Reduces your risk of dying from bowel cancer by 25%	Remove – sufficient to say it reduces the risk of dying ✓	This statistic was removed.	<i>"Not great is it. I mean if it said 50%... the percentage wouldn't make much difference. 'It would greatly reduce your risk' rather than putting a percentage. I probably wouldn't bother with that. Because to me that sounds quite low." (P12)</i> <i>"To tell you the truth I never really understand this because 25% to me is just a number. I can't really comprehend that with anything." (P10)</i> <i>"I'm going to be brutally honest in my perspective if I was looking at it, you know, I'd be like, 25% wow that's quite low... I'd probably not include it." (P13)</i> <i>"I think yes once you see 25% that makes it evaluative and then all of a sudden you're thinking oh so 75%, you know, have kind of had it by then anyway, is there much point doing it?... And I don't like that 25% personally, but that's just me." (P6)</i>

7.2 Risks	Describe complications or just remove as colonoscopy is only relevant to 2% of people ✓	This sentence was amended to explain the possible complications of colonoscopy.	<i>"Yeah. But I mean obviously the first one is 'might cause complications' for example, during or after colonoscopy. But only those who have been through that will understand what the complications might be because you heard from the practitioner."</i> <i>"Do you think that those complications should be included here as an example of what that means?"</i> <i>"No because it's a screening kit that you're going to give us. That doesn't really affect you, does it? So, it's not really part and parcel of the kit that you're going to be sending out. So you could remove that completely. That could be in, like, a further package where you say you have to go and get a colonoscopy and then there's risks there." (P10)</i> <i>"Okay, that is really interesting because it is telling us there that it may cause complications, for example during or after. It would be nice if we knew what those complications might be." (P11)</i> <i>"I think I'd like to know exactly what they mean by complications and how much of a risk it is. It's not really saying that it might affect one in ten or one in 20 or whatever. A bit more information on that would be a lot better." (P3)</i>
	False positive/negative terminology not understood ✓	The explanations of false positive and false negative were retained but the terms themselves have been removed to avoid adding confusion.	<i>"And do you think it's clear what is meant by the false positive?"</i> <i>"No. No, I'm not sure what that means." (P13)</i> <i>"Detect blood in the stools, it might be a false positive. I don't know if that's particularly necessary. Why do you want to detect the false positive?" (P4)</i>

			<i>"But saying a false negative result, some people will understand, some won't. Whether it takes away from the overall narrative, I don't know. I would say it probably doesn't add." (P5)</i>
	Reassure help seeking from a GP ✓	An additional reminder about help seeking was added.	<i>"If you've had the tests, got a lot of negative out of the way and then you're still having the symptoms I think it's good to get back in touch with your GP and maybe go through it all again. Don't ignore, that's what I say." (P8)</i>
	Include examples of what could cause false positive, e.g. haemorrhoids ✓	Haemorrhoids, anal fissure and diverticulitis have been added as alternative causes of blood.	<i>"Like if you didn't say haemorrhoid I wouldn't know, you know where the bleeding was coming from, So, it needs more explaining and more reassurance." (P13)</i>
8. Risk of developing bowel cancer			
8.1 Risk factors	1.8 times statistic may discourage women ✗	The statistic was retained as only one participant expressed concerns that it may discourage women. Other participants felt it would be valuable in encouraging men to participate.	<i>"I don't think it's necessary. I think it should say more men than females develop bowel cancer. But it's trying to highlight the fact that they both get it because this seems to err on the side that females might not need to get checked." (P10)</i> <i>"Yeah definitely, because if a man is reading this as well, that will prompt him to like, you are more prone to getting bowel cancer than the other half." (P11)</i> <i>"Or that males are more likely to get it than females. Because females are more likely to test than males, because females aren't so finicky, if you know what I mean. I would imagine that most women wouldn't think twice about testing. Where a man might be more delicate." (P2)</i>
	Separate red meat versus fibre, fruit ✓	This sentence was split into two points as suggested.	<i>"I don't get this point where it says 'eating a diet high in red meat, red and processed meat, low in fibre,</i>

	and veg into two sentences		<i>vegetables and fruits.’ Does that mean eating too many vegetables and fruits or not eating enough vegetables and fruits?” (P10)</i>
	Add a sentence about changing your lifestyle to lower your risk ✓	A sentence about a healthy lifestyle was added after the list of risk factors.	<i>“Because stopping smoking reduces the risk of you getting it sort of thing. I’d like to see that said a little bit more, in these bullet points. Scattered about here and there. If you do this it will reduce your risk.” (P12)</i>
	Order the factors in terms of contribution to risk ✗	As the bowel cancer risk algorithm is hypothetical at this stage it is not feasible to reflect the weighting of different risk factors. However, they are grouped into broad categories: behavioural characteristics, inflammatory bowel diseases and family history.	<i>“I think that having a history of bowel cancer should probably be the first one in the list. Because that’s probably more of a hereditary thing isn’t it? If somebody in the family has already had it, you’re more likely at risk to get it.” “So, do you think maybe this list should be in order of how much these things affect your risk?” “I think so, yeah. Yeah, definitely.” (P10)</i>
	Quantify ‘too much alcohol’ and family history ✗	This is challenging to quantify and the relevance also varies between individuals.	<i>“I wonder how much is too much alcohol?” (P11) “Yeah, but they come up with these things of, you can only drink X amount of units... If they said to me, right you can only have two pints a night, I’d understand. Or you could have only two whiskies a night. But all this other nonsense of units, I don’t know what that means.” (P3) “For example, I know my mother had a bowel cancer... So yeah, it would be nice to know when they say family history of bowel cancer, can you quantify that in some way.” (P5)</i>
8.2 Risk calculator	Remove sliding scale sentence - confusing ✓	This sentence was removed as suggested.	<i>“A sliding scale. It’s a little bit wordy that bit. A sliding scale is used so that the factors that contribute most to your risk level are weighted more highly than factors which only impact your... I don’t like that sentence at all. I don’t understand what it means.” (P12)</i>

			<i>"Yeah, yeah. Because it's like it is saying high risk, low risk, isn't it? Like where you are on the scale I suppose."</i> (P13) <i>"Yes, I think sliding scale is not necessarily going to be beneficial to anyone. I mean if I know these are the risks or these things then surely they are things to be taken into consideration."</i> (P6) <i>"I'm just thinking about these risk factors and things. I'm not sure if it's worthwhile explaining to people how you calculate the risk, like using the sliding scales. I'm not sure people will understand it."</i> (P9)
	Remove automatically calculated sentence – obvious/unnecessary ✓	This sentence was removed as suggested.	<i>"Again that last line where it says 'A risk level will automatically be calculated for everyone in a screening programme' you'd expect that anyway. So, if everyone gets a screening you would expect it to be part of that... Again, yeah that whole section there could just be removed."</i> (P10)
	Reduce repetition of the words 'risk/risk factors' ✓	This section was condensed and repetition has been reduced.	<i>"I think this risk, risk, risk it has to be clarified out because you're speaking about risks through it, but it's actually meaning slightly different things in different sections. Or it's just too much risk..."</i> (P6)
9. Bowel cancer screening outcomes			
9.1 Referred for colonoscopy			
9.2 Screening intervals	Again reassure help seeking from a GP if needed ✓	A final reminder not to wait until your next screen to seek help if you have concerning symptoms was added.	<i>"Yeah that would be nice. So, we can come back anytime if we develop symptoms. That would be nice, yeah."</i> (P11)

			<i>"I mean presumably if you were worried yourself you could then request your GP... if you had any of the other symptoms before this time limit you could request that in the meantime... Yeah, because it doesn't say there does it. But if you were worried in the meantime between now and year three... but if you were worried about any of the symptoms, you could still... they're not telling you to wait that long are they, that's just what they'll do as a minimum. But if you were worried in the meantime you could still go and see somebody. I'd like to see something like that, yeah." (P12)</i> <i>"So if there was a caveat or something that said statistically the chance of there being a problem is X, or there's a very, very small chance there could be a problem and it's not considered to be sufficient to be concerned, however, if you are unduly concerned, then speak to your GP and discuss what you need to do next sort of thing." (P5)</i>
	Add a statistic to support the safety of intervals (e.g. bowel cancer takes ~10 years to develop) ✓	The time it takes for bowel cancer to develop is covered in the introductory sections.	<i>"If people knew that is how long it would take to develop, then that is comforting to know that. That this is the screening, you have been invited yearly, two years, three years time. That is more reassuring, and I know that if something goes wrong within those three years, I will still be in that window of getting help." (P11)</i> <i>"Yes, because my immediate thought is that it's too long. But there must be a reason why they think that it's okay to do it in three years."</i> <i>"So you'd like a bit more information about that?"</i> <i>"Yeah." (P3)</i>

			<i>"Yeah I just always wonder. They do that for all the screening don't they, it's three years usually. Is it just resources, I don't know?... I think it would be a nice little addition to explain why three years, yeah." (P4)</i> <i>"So if I was considered to be, personally, if I was considered to be low risk based on the risk factors, but there was some blood I would want to do something about that and if there was some sort of caveat and a reference was made to that caveat, I'd feel more comfortable about that. What you don't want to do in my view is to leave people in limbo where they're not sure." (P5)</i> <i>"Well for me it would justify why there's a three-year wait if I knew what evidence was there." (P9)</i>
	Include examples of risk profiles ✕	Example risk profiles were not added at this stage as these are more likely to be included in alternative communication about collecting risk information or delivering risk results.	<i>"Yeah. Like this little box you've got here, low risk, you know what I mean? People who don't smoke, people who don't drink, people who are between I don't know 18 to 35, it doesn't run in the family, eats a good, balanced diet, exercises. Then you've got moderate. The man, 35 to 50, I mean slightly overweight, eats processed food, might run in the family, doesn't exercise as much. Just a breakdown of, you know, what box am I?" (P13)</i>
	Explain what is meant by 'a tiny amount of blood' ◐	A sentence was added to 'The screening kit' section to explain that a tiny amount of blood is not visible to the naked eye and is not a cause for concern. The absolute faecal haemoglobin concentration was not added as it is not easily understood.	<i>"It's good that you asked because it did confuse me. Not confuse me. It did, what's a tiny amount of blood? What's a lot of blood? So I don't know till I see it... I mean no blood is no blood. A tiny blood is blood, so on a definite negative no blood, positive some blood, it might confuse people. Well if it was only a little bit... blood is blood." (P1)</i>

			<i>"What's the difference between a tiny amount and a lot of blood?... If I was to see that... a tiny amount, I would be horrified. And again, what's above average blood. As I say, I wouldn't know the difference. If any blood... tiny amounts or a lot of blood, you would be straight to the doctor." (P7)</i>
9.3 Flow chart	Remove horizontal arrows - considered confusing ✓	These arrows were removed as suggested.	<i>"...So it makes no sense, I don't understand this."</i> <i>"What if you read it from top to bottom?"</i> <i>"What, from column to column?... Oh right, sorry."</i> <i>"Instead of down and columns it wants me to read it across." (P13)</i> <i>"Yeah, I'm trying to understand it. I mean I know it's what I've said but I'm just trying to think is it from top to bottom?" (P8)</i>
	Simplify it, possibly use images or reduce the text ✓	The text in the flow chart was reduced.	<i>"Basically, I mean flow charts that goes back to school days. I don't know, I don't think anybody would be comfortable understanding how flow charts work in this scenario."</i> <i>"Do you think it's better to have just text and not a flow chart?"</i> <i>"Yeah or even just simple images to okay, screening, blood, colonoscopy. Rather than all these words because flow charts aren't the easiest thing to follow sometimes." (P10)</i> <i>"I'm not sure. I'm looking at it thinking there's an awful lot of information there and what does it actually mean? Does that make sense?" (P5)</i>
	Add a column for 'worries or symptoms in between' ✓	This column was added to the flow chart as suggested.	<i>"I don't suppose you could have anything else in this flow thing, saying worries in between screenings? Contact your GP, or something, I don't know." (P12)</i>

	Specify this refers to screening with FIT, not colonoscopy ✓	The use of the FIT kit is specified.	<i>"That's what I'm confused about. So, invited again in one years' time if I fall between the ages of 60 to 74. So if I'm moderate or higher risk then I have a colonoscopy in a years' time, every year?" (P13)</i>
10. Invited for FIT test in 1-3 years	Bold 'being aware of symptoms' ✓	This section is highlighted in bold as suggested.	<i>"Okay, so again I like the way you bolded some of it, the result does not have bowel cancer, or it will never develop in the future, but what's important to me is not that bit, that makes me nervous and my blood pressure goes right up. What's important to me is being aware of the symptoms of bowel cancer is very important." (P6)</i>
11. Invited for colonoscopy	Use percentages not raw numbers ✓	A percentage value was added as suggested.	<i>"Or you could put down 98% I suppose... Yeah. Yeah, probably. Because we sort of understand percentages better than we do numbers sometimes. If you say 99 pence and you say £1, you understand that 99 percent is cheaper than £1." (P10)</i>
11.1 Picture of the percentage of people referred to colonoscopy			
11.2 Other causes of blood in your stool	Mention other causes earlier in the leaflet ✓	Haemorrhoids and diverticulitis are cited earlier in the leaflet.	<i>"Where it says down here other things that may cause blood in your poo – haemorrhoids, that wasn't mentioned in the first, the original part. It mentions polyps and things so that's new information here and obviously you could put the whole line here I suppose... Yeah, I think anything that could concern should be at the beginning of the whole list. You're not getting new information at the end of the information guide. Because somebody might have haemorrhoids and just disregard it because... and go actually, there's a new list at the end as well." (P10)</i> <i>"I'm glad you've mentioned piles there because I think a lot of people get it confused. Polyps and piles. It would</i>

			<i>be nice if that was at the front as well, because I think a lot of people confuse the two.” (P12)</i> <i>“There’s no mention of diverticulitis. That causes blood in your poo if it becomes infected. Yet there’s no mention of it anywhere. I know this is all about bowel cancer, but it says like bowel polyps, haemorrhoids, but there’s no mention of diverticulitis which could give symptoms of bowel cancer, because you could have blood in your poo through that. I think that’s a mishap there, that should be added to the list that it could be cause then, it could have cause blood.” P3</i>

FIT – faecal immunochemical test; GP – general practitioner; HCP – healthcare professional

Green ✓ – change was incorporated in full

Orange ◐ – change was partially incorporated

Red ✗ – change was not incorporated

6.5.3 User testing results

A total of twenty participants completed the user testing survey (Table 6.1). A minimum of 90% (18/20) of participants answered each of the true or false statements correctly. As this was greater than the 80% threshold of comprehension I considered the leaflet to be fit for purpose and no subsequent rounds of user testing were required.

The results of round one of user testing are summarised in Table 6.3. The vast majority of participants answered the statements about risk-stratified elements of the screening programme correctly. Overall, seven true or false statements were answered correctly by 100% of participants. For example, 100% knew that the statement suggesting that people with a low risk of bowel cancer will never be offered a colonoscopy regardless of their FIT result was false. The statements 'Most people who do the FIT will need further tests' and 'Information about your lifestyle will be used to determine your personal risk of bowel cancer' were answered correctly by the fewest number of participants (90%).

Table 6.3 Results of the user testing survey.

Question	Percentage correct
Participating in screening lowers the risk of dying from cancer	95
The FIT test is done at home	100
Most people who do the FIT will need further tests	90
Only women are sent a FIT test	100
Bowel cancer is more common in people over the age of 60	100
People only need to do the FIT test once in their lifetime	100
The FIT test can miss a bowel cancer	95
People who need to have further tests always have bowel cancer	100
Smoking and drinking too much alcohol increases your risk of developing bowel cancer	95
Information about your lifestyle will be used to determine your personal risk of bowel cancer	90
People who have a high risk are guaranteed to get bowel cancer	100
The FIT test can detect blood in your stool that is not caused by bowel cancer	95
The result of your FIT test and your personal risk of bowel cancer will be used to determine when you will next be invited for screening	100*
If you have a low risk of bowel cancer based on your lifestyle, you won't ever be offered a colonoscopy regardless of the result of the FIT test	100

FIT – faecal immunochemical test

* *n=19*

6.5.4 Participant reflections on risk calculation and stratification

Throughout the think aloud interviews participants expressed their individual views about risk and risk-stratified screening.

6.5.4.1 Risk factors and risk calculation

Most participants were positive about the inclusion of risk factors in the leaflet. They felt that it was a useful *“alert for a lot of people”* (P8) who may be unaware of their elevated risk, serving as a stimulus for behaviour change or as an incentive to participate in screening:

“Actually yeah. If somebody’s doubting about having the screening, doing the screening, or participating, on seeing the things that could actually help develop an issue, might make them feel more inclined ‘Well, I’ll go and get screened. I’m not going to change my diet or my alcohol intake but I’ll do a screening’.” – P9

However, for many, reading about bowel cancer risk factors caused them to immediately reflect on their own risk level. This appeared to cause some degree of anxiety for participants who felt they had potentially risky lifestyle traits:

“So that’s me, not being active enough. I’m overweight and I can’t stand veg, I will not eat veg. So that’s it, I might as well quit now, goodbye (laughs).” – P13

Nevertheless, the concept of using these factors as part of a risk calculator was viewed extremely positively. Participants liked the idea that *“as long as you’re being honest about it, it will tell you your risk and then you can cut those risks”* (P3), seeing the risk estimate as an opportunity for behaviour change.

The leaflet explains that *“estimating the risk of bowel cancer is not 100% perfect. People who have a high risk are not guaranteed to develop bowel cancer. Similarly, it is not guaranteed that people with a low risk will not develop bowel cancer.”* Participant opinions on this sentiment were varied: some felt it was reassuring to those at high-risk whilst simultaneously encouraging those at low risk to remain vigilant, others felt it was simply a fact of life and others still, found themselves questioning the point of risk prediction if they may get cancer regardless of their risk score:

“It doesn’t guarantee that you’ll necessarily get bowel cancer, or that the low-risk people might get it. It’s just that’s the way the cookie crumbles probably.” – P2

6.5.4.2 Risk stratification and screening outcomes

Participants were broadly accepting of a risk-stratified approach to bowel cancer screening and considered it a sensible strategy:

“I mean it’s what you’d hope... a low-risk patient doesn’t need to waste both of their times coming back often, but a medium and high risk has got to come more often, dependent on their risks...” – P1

Several participants also liked that the risk estimate would be actionable by having a tangible impact on screening practices:

“...I think that’s really good. ‘You’ll be invited to the next screening.’ I think it’s nice that people don’t feel that they’re left in the lurch. They’ve filled in a questionnaire and then they never hear anything else. That’s nice to think that they’ve put their time in, so the professionals will then put their time in to analyse what’s been said. So I think that’s good.” – P12

All participants were enthusiastic about the prospect of increasing screening for people at higher risk of developing bowel cancer with many finding it “reassuring” (P10) that they’re “taking it serious” (P9) and going to “keep an eye on you” (P1). However, most were reluctant to accept an increased screening interval of three years and many wanted a one-year screening interval to be offered to everyone, despite acknowledging that this was unlikely to be feasible. For several participants, the immediate reaction to the extended interval was that “anything could happen in three years” (P3). One individual went so far as to say they would be so concerned by the increased interval that they would request a re-test in a shorter period of time and several required more information about the safety of the three-year interval in order to accept it:

“Yes, I mean personally I would like to know, I mean what is that based on? What are you basing these decisions on for one year or two years?” – P6

Despite some concern over risk-stratified intervals, most participants were reassured to learn that people would still be referred for a colonoscopy if they had a concerning FHB concentration, regardless of their risk level:

“The first bit’s very good. If they detect blood you’ll be offered a colonoscopy, so that’s excellent. I’d be very happy with that.” – P2

A comment that came up repeatedly throughout the leaflet but most notably at this stage, was the desire for reassurance around seeking help from a GP at any time if concerned or

symptomatic. Some participants required this addition to the leaflet in order to accept the risk-adapted intervals. Others were concerned that, without this caveat, people would simply wait for their next screening despite feeling anxious or developing bowel cancer symptoms leading to an increase in interval cancers and late-stage diagnoses:

“Exactly, because I think you always have to make that clear. That don’t just wait for the three years to be up..., you might not be here to tell the tale. That... if anything changes then obviously seek help professionally. I think that’s always important for people to know. ‘Oh, I’m alright for three years’ – no you’re not. Just like a lump in our breasts, we don’t wait for the next screening.” – P8

6.6 Discussion

This is the first think aloud study to explore public understanding of information about risk-stratified screening intervals for bowel cancer screening. The interviews identified over forty areas of the information leaflet that required improvement, and more than half of these related to the original information provided about bowel cancer screening rather than the new content on risk stratification. This suggested that the original NHS leaflet may not have met the needs of some members of the screening population. Although parts of the leaflet were retained from the NHS version, many participants still reported areas of confusion or a lack of clarity in these sections. Notably, improved clarity was needed in relation to the harms and benefits of screening, with suggested removal of terminology such as ‘false positive/negative’ due to poor understanding. Additionally, participants were vocal throughout the interviews advocating for greater reassurance about contacting their GP at any time if they had concerns or symptoms, rather than waiting for their next invite to screening. It is not clear how the original leaflet was developed meaning a lack of patient and public input could conceivably have contributed to such issues.

Within the sections of the leaflet that were specific to risk stratification, participants found the ‘Risk calculator’ section to be the most challenging part of the leaflet. They suggested that the process of weighting risk factors and the automation of a risk algorithm were unnecessary details and encouraged simplification of the terminology. No participants expressed concerns about the intensification of screening for high-risk individuals, yet many expressed concerns about reducing screening via a three-year screening interval for people at low risk. Some felt that three years was too long to wait in between tests and reading this caused feelings of anxiety or concern. They, therefore, preferred more information to be added, specifically about the time taken for bowel cancer to develop, which helped to reassure participants that the extended interval was both safe and evidence derived.

The high proportion of participants answering the user testing survey statement correctly in the first round indicates that, following incorporation of suggestions from the think aloud interviews, the refined leaflet successfully addressed the majority of issues with understanding. It also demonstrates that members of the public are capable of understanding written information about risk-stratified screening for bowel cancer when it is delivered as part of the screening leaflet.

6.6.1 Comparison with other literature

The finding that the original NHS leaflet used in my study may not be meeting the needs of all members of the target population is consistent with similar think aloud studies using NHS cancer screening leaflets(171,173) and other NHS information leaflets as a starting point for the development and testing of public-facing materials(174). The finding that think aloud participants struggled to understand the risks associated with cancer screening and the concepts of false positive and false negative results was somewhat unsurprising as public understanding of the harms of screening is generally poor. Furthermore, previous studies exploring public views towards cervical and lung cancer screening leaflets have reported similar areas of misinterpretation(173,175). Nevertheless, insufficient understanding and communication of these concepts potentially impedes informed decision-making for screening participants, part of the UKNSC criteria for the implementation of screening programmes(75). A further specific area of confusion in this study was the statistic that screening reduces the risk of dying from bowel cancer by 25%. Participant responses to this statistic varied but were typically negative, with some participants finding it an underwhelming incentive to participate and others misinterpreting the risk of dying from bowel cancer therefore being 75%. A 2019 study exploring interpretations of the NHS cervical screening information leaflet similarly found that participants misunderstood statistics about how far screening reduces cervical cancer incidence, often leading to overestimations in the number of women who will be diagnosed with cervical cancer(173). This suggests that public understanding of numerical statistics about cancer incidence and mortality may not be strong enough to warrant inclusion of such statistics in screening-related information.

Poor public understanding of complex or medically related terminology has also been well documented in relation to cancer and other healthcare topics. Previous studies of public-facing information materials have identified difficulties in reading and understanding the names of investigative tests, such as colposcopy and colonoscopy, and participants have struggled with technical terms and “*jargon*”(171,173,174,176). In my interviews, participants mainly found the idea of adenomas confusing as the term ‘polyp’ was often conflated with ‘piles’. A previous think aloud study relating to age-based bowel cancer screening identified errors in interpreting and pronouncing

the terms 'colonoscopy', 'colorectal' and 'adenoma' but did not encounter similar conflation between adenoma and haemorrhoids as reported here(171).

A 2017 systematic review found that visual aids help to promote risk understanding and literacy compared with narrative risk information(177). Over 70% of the included studies reported a positive effect of visual aids and participants have also expressed positive opinions about graphical presentations of risk and screening outcomes(173,176,177). However, opinions of the supporting graphics were mixed in my think aloud study, specifically relating to the flow chart which communicated both risk and screening outcomes. Participants advocated for simplification of graphics and visual aids such as the flow chart, in order to promote understanding among people who may struggle to understand the narrative explanation provided.

Finally, the propensity for cancer screening leaflets to elicit emotional responses has also been previously observed(171,175,176). A 2022 think aloud study relating to NHS targeted lung health checks found that presentation of lung cancer symptoms generated personal appraisal, in a similar way to participants in my study who vocalised thoughts on self-reflection after reading about risk factors for bowel cancer(175).

6.6.2 Strengths and limitations

A notable strength of this study was the use of the think aloud method, which I chose in order to explore aspects of cognition and processing that may otherwise have been unobservable using an alternative method that requires retrospective recall of a participant's thoughts and reactions(178). Likewise, the think aloud method has demonstrated prior success in similar settings(160,168,171). Input from a PPI panel and pilot interviews with PPI representatives improved comprehension and readability ahead of the initial think aloud interviews. Additionally, I used a marked protocol to ensure that the data I collected covered the risk-stratified portion of the leaflet in sufficient detail. This helped to identify the majority of comprehension issues during the think aloud stage, meaning that the refined leaflet performed well in the user testing procedure. Finally, the use of the user testing procedure itself was a strength as it enabled me to verify public understanding of the final version of the leaflet in a context more similar to that in which it would be used than the think aloud interview setting.

A potential limitation is that the final leaflet may not be appropriate for use in adults with low literacy or for individuals where English is not a first language, particularly given the high degree of education in the study population. Further research is needed to develop and test communication materials for easily overlooked populations. Only one of the think aloud participants had previously declined an invite to screening, indicating that the vast majority of the sample viewed screening

positively. This may have contributed towards concerns about reducing screening opportunities and the views of screening averse individuals may differ. There is also the possibility that study participants, in both the interviews and the survey, read the information leaflet more carefully than they would do in reality as a consequence of the research context.

6.7 Conclusions

In this think aloud interview study paired with a user testing procedure I have explored public information needs and understanding of a hypothetical bowel cancer screening programme incorporating risk-stratified screening intervals. Participants suggested forty-two changes to the original NHS leaflet, suggesting it may not currently meet the needs of the general public. Participants expressed confusion over specific elements of risk prediction and risk stratification, suggesting a preference for less information in favour of simplicity in this context. Overall, I have demonstrated that the public are generally capable of understanding written information about risk-based screening intervals when presented as part of a population-level screening programme. The refined information text I have generated here provides the basis for the survey study detailed in Chapter 7.

Chapter 7 Public acceptability and anticipated uptake of risk-stratified bowel cancer screening: An online survey study

7.1 Summary

Despite generally positive public views towards cancer risk stratification, there is a need to quantitatively explore public acceptability relating specifically to bowel cancer across the screening pathway. I aimed to quantify public acceptability and anticipatory uptake of risk stratification at three different points on the bowel cancer screening pathway, compared to current screening practices.

I conducted an online population-based survey of 1,203 adults. The main outcome measures were overall acceptability of risk-stratified screening strategies (at the point of eligibility, threshold and interval) compared to screening as usual, and the acceptability of high- and low-risk screening practices within each strategy. I also measured anticipated uptake of FIT screening for each strategy and the acceptability of four different strategies for data collection (GP records, phenotypic data, genetics or all three combined). I used multivariable logistic regression to explore the characteristics associated with reporting one or more risk-adapted strategies as unacceptable.

Acceptability of risk-stratified eligibility and thresholds was significantly higher than for screening as usual ($p < 0.001$). Across all risk-stratified strategies, high-risk screening practices were significantly more acceptable and low-risk practices significantly less acceptable than current screening practices ($p < 0.0001$). The likelihood of taking up FIT if at high-risk was significantly higher for all risk-based strategies, but significantly lower for all strategies if at low-risk ($p < 0.0001$). Participants who found screening as usual acceptable but found one or more risk-based strategies unacceptable were more likely to be female [OR 1.5, CI 1.1-2.0]. Finally, I observed statistically significant differences in the acceptability of data collection methods ($p < 0.0001$), with participants favouring the most comprehensive approach, regardless of the risk-based strategy.

Overall, participants expressed high levels of acceptability for risk-stratified bowel cancer screening and this was maintained for high-risk screening practices, whereas low-risk screening practices were less likely to be acceptable. Similarly, anticipated FIT uptake was higher than for screening as usual when participants considered being at high risk, but they anticipated being significantly less likely to take up FIT if at low risk. A more comprehensive approach to collecting risk information is likely to be preferred and women in particular may benefit from targeted communication to facilitate acceptability.

7.2 Background

The previous chapters in this thesis have demonstrated that public acceptability of risk-stratified cancer screening, specifically bowel cancer screening, is high. Participants in Chapter 5 perceived risk stratification favourably, particularly when using readily available data in the form of age, sex and FIT results. Similarly, the inclusion of lifestyle and/or genetic risk information was viewed positively, but the logistics of data collection represented a potential challenge to implementation. Despite these optimistic results, there remains a need to quantitatively explore public acceptability of risk-stratified bowel cancer screening at different points on the screening pathway. Furthermore, the success of any screening programme is reliant on sufficient uptake which may be impacted by significant changes to the programme, such as a move towards risk stratification(45). Several options for the collection of risk information exist and should be explored to understand their impact on acceptability. Before trials of risk-stratified approaches to bowel cancer screening programmes can be conducted, there is, therefore, a need to quantify the potential impact on screening uptake and the attitudes of the public towards different strategies and data collection methods.

7.3 Aim

To quantify public acceptability and anticipated uptake of risk stratification strategies at three different points in the bowel cancer screening pathway in comparison with current bowel cancer screening practices.

7.4 Methods

7.4.1 Study design

Ethics approval was granted by the University of Cambridge Humanities and Social Sciences Research Ethics Committee, reference: 23.349.

The survey used in this study is included in Appendix 7.1 and was hosted online via Qualtrics (www.qualtrics.com). The survey incorporated collection of demographic information, including data on age, sex, ethnicity, education, self-reported socioeconomic status (SES), and data on lifestyle, family and personal history of cancer and cancer beliefs.

The survey was designed to enable me to quantify how acceptable participants found the proposed strategies and how likely they are to complete a FIT kit as part of each strategy according to risk level (low, average or high). Text from the information leaflet developed and refined in Chapter 6 was used to firstly provide background information about four potential screening strategies (Table 7.1).

Table 7.1 Description of the four screening strategies shown to participants in the survey.

Strategy:	Brief description:
Strategy A: screening as usual	Age-based eligibility, fixed FIT threshold, and uniform screening interval.
Strategy B: risk-stratified eligibility	Screening starting age is dependent on individual risk.
Strategy C: risk-stratified FIT threshold	Threshold for referral to further investigations (typically colonoscopy) is dependent on individual risk.
Strategy D: risk-stratified interval	Interval between FIT screening rounds is dependent on individual risk.

Participants received information about all four strategies prior to answering any questions to eliminate potential order effects. They were then asked to consider the current screening programme (Strategy A: screening as usual) and whether they would attend FIT screening if offered as part of this programme. They were reminded briefly of each risk-stratified strategy before being asked about the acceptability of each programme, the acceptability of providing risk information, FIT uptake for low, average and high personal risk and whether their risk score would impact their decision to attend a colonoscopy. Finally, they were asked about overall acceptability for each strategy comparatively. All outcomes were measured using five-point Likert scales.

7.4.2 Participants and recruitment

A sample of approximately 1,200 adult individuals residing in the UK and representative of the UK population in terms of age, sex, and ethnicity was recruited through the Prolific platform (www.prolific.com). Prolific is an online recruitment platform for researchers where individuals volunteer to take part in studies and are compensated for their time with an agreed hourly rate. Participants received £7.50 per hour via Prolific for their participation in the study. This sample size was estimated to be sufficient using a confidence interval of 95% with a 5% margin of error and the UK population as the overall population size. However, as a pragmatic decision relating to the funding available for the survey and to accommodate sub-group regression analysis, I chose to oversample as much as possible.

7.4.3 Consent

In line with standard recruitment through the Prolific platform, participants interested in taking part saw a brief summary of the study (Appendix 7.2). If they still wished to take part they opened the survey and were able to download PDF copies of the full participant information sheet (Appendix 7.3) and consent form (Appendix 7.4). Written online consent was then obtained from each participant before they began the survey.

All participants were free to withdraw their consent at any time and for any reason by returning their submission via the Prolific website (a specific feature of the Prolific platform). Data from returned submissions was therefore not saved or used within the study. Data from partial submissions where any of the non-sociodemographic questions were completed and the submission was not returned to Prolific were retained for the analysis.

7.4.4 Data collection

Prolific provided participants with the survey link which was hosted online using the Qualtrics platform (www.qualtrics.com). The survey took a median time of 15 minutes and 54 seconds to complete.

7.4.5 Analysis

I used descriptive statistics to characterise the participants, their attitudes toward the different screening strategies and their intention to take up bowel cancer screening. For each scenario I report levels of acceptability for each mode of data collection ('extremely acceptable – extremely unacceptable') and the level of likelihood that they would take up FIT testing within the risk-stratified programmes for each possible risk level ('extremely likely – extremely unlikely'). I also used the Friedman test to test for differences between the screening scenarios and report the relevant p-values within the tables. I chose the Friedman test as my data was not normally distributed and I aimed to compare four categorical groups with the same participants in each. Where the Friedman test was significant, I also conducted Wilcoxon Signed Rank pairwise tests to further explore differences between individual strategies as this test is applicable to paired ordinal variables.

Finally, multivariate logistic regression was used to investigate the influence of different participant characteristics on the acceptability of the four strategies and to explore demographic characteristics of participants who found one or more risk-stratified scenario 'somewhat or extremely unacceptable'. I adjusted the regression analysis for variables that I had an *a priori* rationale to include: age (younger versus older than 50 years), sex (male versus female), smoking status (ever smoker vs non-smoker), ethnicity (white versus non-white), education (degree vs no degree), SES (deciles 1-3 versus deciles 4-10) and personal history of cancer (history of cancer versus no history of cancer), where all variables were treated as binary. The results of these analyses are presented as odds ratios with 95% confidence intervals.

All analyses were conducted in Stata Version 17(179) with statistical significance set at $p < 0.01$.

7.4.6 Public participation

Three PPI members contributed to this survey study through email and by reviewing and commenting on the survey itself. They provided comments on the structure and flow of the survey and comprehensibility of the questions.

7.5 Results

At the time the survey was conducted there were 37,588 participants registered with Prolific who met the eligibility criteria. A total of 1,203 participants completed the survey with an average completion time of 15 minutes and 54 seconds, 123 individuals returned their submission to Prolific and 16 timed-out. One participant was excluded as they had failed to provide any survey data but had neglected to return their submission. The demographic characteristics of the 1,203 participants included in the survey are detailed in Table 7.2. Reflecting the demographic distribution of the UK population, there was a fairly even distribution of male and female participants (48.1% and 51.9% respectively). The majority of participants were White (86.9%) and most individuals self-reported as being in the central four socioeconomic deciles (79.7%). 479 (39.9%) were educated to degree level and a further 221 (18.4%) had completed a postgraduate degree. Personal history of cancer was reported by 64 (5.3%) participants and 7 (0.6%) had a history of bowel cancer. Opinions of bowel cancer screening were positive, with the majority of participants (89.7%) agreeing with the statement that bowel cancer screening is 'always a good idea'.

Table 7.2 Demographic characteristics of participants included in the survey study.

Characteristics	Total (%)
Total N	1203 (100)
Age (years)	
18-29	241 (20.0)
30-39	220 (18.3)
40-49	202 (16.8)
50-59	243 (20.2)
60-69	234 (19.5)
70+	63 (5.2)
Sex	
Male	578 (48.1)
Female	625 (51.9)
Ethnicity	
Asian/Asian British	89 (7.4)
Black, African, Caribbean/Black British	40 (3.3)
Mixed/multiple ethnic group	19 (1.6)
White	1,045 (86.9)
Other	10 (0.8)
Self-reported socioeconomic status	
1-3 (lowest deciles)	145 (12.1)
4-5	400 (33.3)
6-7	558 (46.4)
8-10 (highest deciles)	100 (8.3)
Education level	
Not completed A levels, further education or equivalent	181 (15.0)
Complete A levels, further education or equivalent	320 (26.6)
Completed a bachelor's degree	479 (39.9)
Completed a postgraduate degree	221 (18.4)
Other	2 (0.2)
Employment status	
Employed full-time	558 (46.4)
Employed part-time	173 (14.4)
Self-employed	105 (8.7)
Studying	36 (3.0)
Not currently working (unemployed, homemaker, retired, disabled, ill)	320 (26.6)
Other	11 (0.9)
Self-reported health status	
Excellent	112 (9.3)
Very good	451 (37.5)
Good	428 (35.6)
Fair	172 (14.3)
Poor	40 (3.3)
Tobacco smoking status	
Never smoked	737 (61.2)
Used to smoke	376 (31.3)
Currently smoke	90 (7.5)
Self-reported weight	
Underweight	32 (2.7)

About right	531 (44.1)
Overweight	640 (53.2)
Personal history of cancer	
Yes	64 (5.3)
No	1,139 (94.7)
Personal history of bowel cancer	
Yes	7 (0.6)
No	1,196 (99.4)
Screening history	
Abdominal aortic aneurysm (ultrasound, men > age 65)	
Invited	55 (4.6)
Attended	57 (103.6)
Bowel (stool sample, all aged 50 or 60-74)	
Invited	366 (30.4)
Attended	340 (92.9)
Breast (mammogram, women aged 50-71)	
Invited	274 (22.8)
Attended	253 (92.3)
Cervical (smear test, women ages 25-64)	
Invited	546 (45.4)
Attended	503 (92.1)
Opinion of bowel cancer screening	
Always a good idea	1,079 (89.7)
Sometimes a good idea/it depends	121 (10.1)
Never a good idea	3 (0.3)

7.5.1 General cancer beliefs

The participants' general cancer-related beliefs are summarised in Table 7.3. Few participants (3.7%) expressed cancer fatalism by stating that they would not want to know if they had cancer and the vast majority were aware of the benefits of early detection (96.3%).

Table 7.3 General cancer beliefs of participants included in the survey study.

	Strongly agree/agree (n/%)	Neither agree nor disagree (n/%)	Disagree or strongly disagree (n/%)
“These days, many people with cancer can expect to continue with normal activities and responsibilities.”	828 (68.8)	253 (21.1)	121 (10.1)
“Most cancer treatment is worse than the cancer itself.”	303 (25.2)	495 (41.2)	404 (33.6)
“I would NOT want to know if I have cancer.”	44 (3.7)	112 (9.3)	1,046 (87.0)
“Cancer can often be cured.”	811 (67.5)	304 (25.3)	87 (7.2)
“Going to the doctor as quickly as possible after noticing a symptom of cancer could increase the chances of surviving.”	1,157 (96.3)	35 (2.9)	10 (0.8)
“Some people think a diagnosis of cancer is a death sentence.”	1,044 (86.9)	109 (9.1)	49 (4.1)

7.5.2 Overall acceptability of risk-stratified screening strategies

The overall acceptability of each screening strategy is summarised in Table 7.4 and illustrated in Figure 7.1. Acceptability of all three risk-stratified screening strategies was high, with ≥1000 (83.1%) participants ranking all strategies as ‘somewhat or extremely acceptable’. The acceptability of risk-stratified eligibility criteria and risk-stratified FIT thresholds was significantly more acceptable than the current age/sex-based approach to screening ($p<0.001$). Although the difference between the acceptability distributions of screening as usual and risk-stratified screening intervals were not significant ($p=0.0454$), a greater number of participants reported that risk-stratified intervals were extremely acceptable than for screening as usual (604 vs 547).

Table 7.4 Overall acceptability of risk-stratified screening strategies compared with screening as usual.

Acceptability	Screening as usual (n/%)	Risk-stratified eligibility (n/%)	Risk-stratified threshold (n/%)	Risk-stratified interval (n/%)
Friedman test <i>p</i> -value	<0.0001			
Wilcoxon Signed Rank <i>p</i> -value	Ref	0.0003	0.0001	0.0454
Extremely acceptable	547 (45.5)	632 (52.5)	635 (52.8)	604 (50.2)
Somewhat acceptable	444 (36.9)	389 (32.3)	384 (31.9)	395 (32.8)
Neither	104 (8.7)	92 (7.7)	98 (8.2)	108 (9.0)
Somewhat unacceptable	100 (8.3)	75 (6.2)	76 (6.3)	80 (6.7)
Extremely unacceptable	8 (0.7)	15 (1.3)	10 (0.8)	16 (1.3)

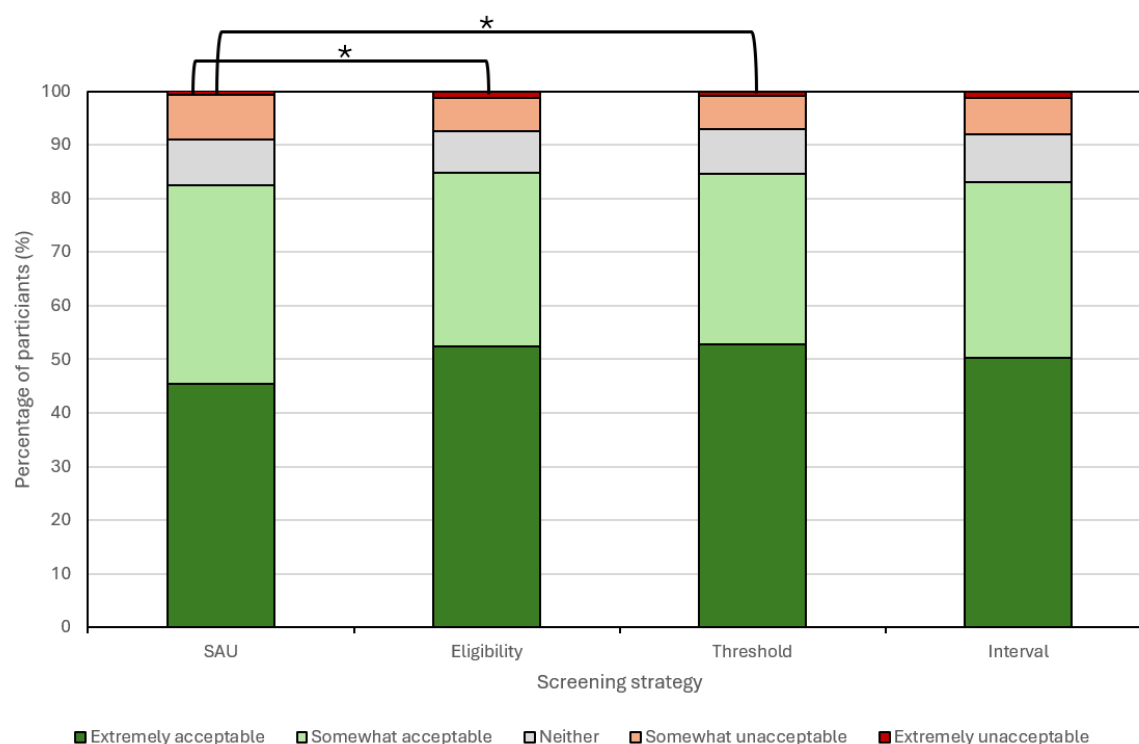


Figure 7.1 Overall acceptability of risk-stratified screening strategies compared with screening as usual.

* Wilcoxon Signed Rank test *p*-value<0.0001. All other *p* values non-significant (*p*>0.001).

SAU Screening as usual

Table 7.5 shows the impact of individual demographic characteristics on the likelihood of finding each risk-stratified strategy acceptable. Female participants were significantly less likely to find risk-stratified screening intervals acceptable than male participants (OR 0.6 [0.5-0.9], $p=0.004$). However, this result was not statistically significant for risk-stratified eligibility and screening thresholds ($p=0.028$ and 0.078 respectively). This suggests that females may be less likely to find risk stratification acceptable than males.

Table 7.5 The impact of individual demographics on the likelihood that participants would find each risk-stratified strategy acceptable.

Demographic characteristics	OR [95% CI]	<i>p</i> -value
Eligibility		
Age (under 50)	1.0 [0.7-1.4]	0.982
Sex (female)	0.7 [0.5-1.0]	0.028
Ethnicity (white)	1.1 [0.7-1.8]	0.598
Education (degree)	1.2 [0.8-1.7]	0.334
SES (lower)	0.8 [0.5-1.3]	0.454
Smoking (non-smoker)	0.9 [0.7-1.3]	0.707
Personal cancer history (yes)	2.2 [0.9-5.6]	0.099
Threshold		
Age (under 50)	1.0 [0.7-1.3]	0.814
Sex (female)	0.8 [0.5-1.0]	0.078
Ethnicity (white)	1.3 [0.8-2.0]	0.313
Education (degree)	1.2 [0.9-1.7]	0.304
SES (lower)	0.7 [0.5-1.2]	0.180
Smoking (non-smoker)	1.1 [0.8-1.5]	0.751
Personal cancer history (yes)	2.8 [1.0-7.8]	0.054
Interval		
Age (under 50)	1.0 [0.7-1.3]	0.897
Sex (female)	0.6 [0.5-0.9]	0.004
Ethnicity (white)	1.0 [0.6-1.6]	0.939
Education (degree)	1.3 [0.9-1.8]	0.109
SES (lower)	0.9 [0.6-1.4]	0.545
Smoking (non-smoker)	0.9 [0.7-1.3]	0.696
Personal cancer history (yes)	2.6 [1.0-6.6]	0.047

OR – odds ratio; CI – confidence interval; SES – socioeconomic status

These findings were consistent when investigating the impact of demographic characteristics on the likelihood of finding one or more risk-stratified strategy unacceptable despite finding current screening practices acceptable (Figure 7.2). Females were significantly more likely to find risk stratification unacceptable but age/sex-based screening acceptable (OR 1.5 [95% CI 1.1-2.0], $p=0.008$). No other demographic factors had a significant impact.

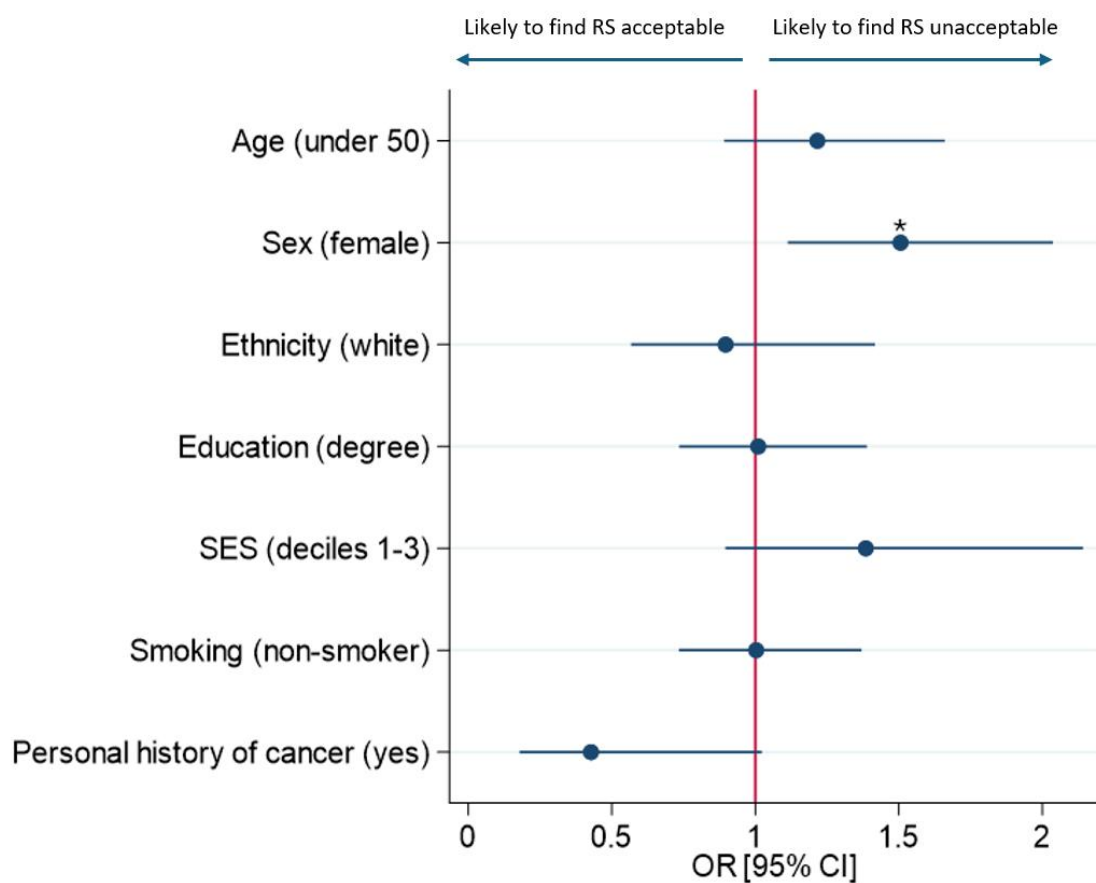


Figure 7.2 The impact of individual demographics on the likelihood that participants would find one or more risk-stratified strategy unacceptable, after finding screening as usual acceptable.

* $p=0.008$

N=280

SES – socioeconomic status

7.5.3 Acceptability of screening practices according to personalised risk score

The acceptability of differing intensity screening practices according to risk for each risk-stratified screening programme compared with the current age/sex-based screening practices is summarised in Table 7.6 and Figure 7.3. For all three risk-stratified strategies, acceptability of high-risk screening practices was significantly higher than for screening as usual (screening as usual: 82.4% 'somewhat or extremely acceptable'; eligibility: 97.1%; threshold: 95.6%; interval: 97.5%; $p<0.0001$). Conversely, the acceptability of reduced screening for low-risk cohorts was significantly less acceptable than screening as usual for all three risk-stratified screening strategies (screening as usual: 82.4%; eligibility: 66.8%; threshold: 73.2%; interval: 70.1%; $p<0.0001$). However, the overall acceptability of these low-risk strategies was still fairly high, with $\leq 3\%$ of participants finding the strategy to be 'extremely unacceptable'. The difference between the acceptability of high- and low-risk screening practices was noticeable, with up to 30.3% greater acceptability for intensified screening compared with reduced screening. Up to 19.6% of participants reported that reducing screening for low-risk individuals was 'somewhat or extremely unacceptable', compared to 9% for screening as usual and $\leq 1.2\%$ for high-risk practices.

Table 7.6 Acceptability of high- and low-risk screening practices according to risk-stratified screening strategy compared with screening as usual.

Acceptability	Screening as usual (n/%)	Eligibility (n/%)	Threshold (n/%)	Interval (n/%)
High-risk screening practices				
Friedman test <i>p</i> -value	<0.0001			
Wilcoxon Signed Rank <i>p</i> -value	REF	<0.0001	<0.0001	<0.0001
Extremely acceptable	547 (45.5)	1,040 (86.5)	884 (73.5)	986 (82.0)
Somewhat acceptable	444 (36.9)	127 (10.6)	266 (22.1)	187 (15.5)
Neither	104 (8.7)	21 (1.8)	40 (3.3)	23 (1.9)
Somewhat unacceptable	100 (8.3)	5 (0.4)	11 (0.9)	5 (0.4)
Extremely unacceptable	8 (0.7)	10 (0.8)	2 (0.2)	2 (0.2)
Low-risk screening practices				
Friedman test <i>p</i> -value	<0.0001			
Wilcoxon Signed Rank <i>p</i> -value	REF	<0.0001	<0.0001	<0.0001
Extremely acceptable	547 (45.5)	267 (22.2)	409 (34.0)	325 (27.0)
Somewhat acceptable	444 (36.9)	536 (44.6)	472 (39.2)	518 (43.1)
Neither	104 (8.7)	163 (13.6)	142 (11.8)	151 (12.6)
Somewhat unacceptable	100 (8.3)	200 (16.6)	149 (12.4)	176 (14.6)
Extremely unacceptable	8 (0.7)	37 (3.1)	31 (2.6)	33 (2.7)

SAU - Screening as usual

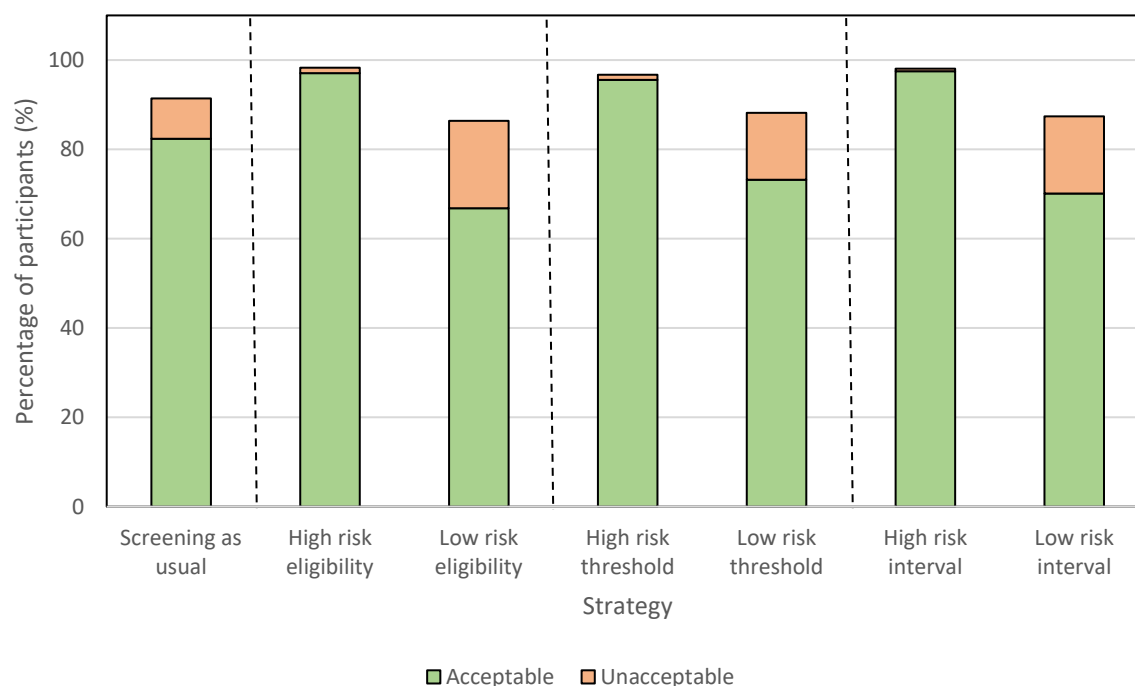


Figure 7.3 Percentage of participants considering high- and low-risk screening practices ‘somewhat or extremely’ acceptable/unacceptable across screening strategies.

SAU Screening as usual

7.5.4 Likelihood of taking up FIT screening according to personalised risk score

The likelihood of taking up FIT screening according to personalised risk score is summarised in Table 7.7 and Figure 7.4. The likelihood of taking up FIT screening was significantly different across the four screening strategies for all three risk levels ($p < 0.0001$). Pairwise comparisons between each strategy and screening as usual were also significant, aside from average risk eligibility and screening as usual ($p = 0.1544$). The anticipated likelihood of taking up FIT when participants considered being at high risk was significantly higher for all three risk-based strategies (screening as usual: 93.8% ‘somewhat or extremely likely’; eligibility: 97.1%; threshold: 97.1%; interval: 97.4%; $p < 0.0001$). However, acceptability was significantly lower for all three risk-based strategies when participants were asked to consider themselves as low-risk (screening as usual: 93.8%; eligibility: 82.0%; threshold: 78.2%; interval: 77%; $p < 0.0001$). For the average risk scenario, the difference between screening as usual and eligibility was non-significant, but a small decrease in the likelihood of prospectively taking up FIT was observed for risk-stratified threshold and intervals ($p < 0.0001$).

Table 7.7 The likelihood of taking up FIT screening at different risk levels across risk-stratified screening strategies compared with screening as usual.

Likelihood of taking up FIT	Screening as usual (n/%)	Eligibility (n/%)	Threshold (n/%)	Interval (n/%)
High risk				
Friedman test <i>p</i> -value	<0.0001			
Wilcoxon Signed Rank <i>p</i> -value	REF	<0.0001	<0.0001	<0.0001
Extremely likely	927 (77.1)	1,093 (90.9)	1,093 (90.9)	1,093 (90.9)
Somewhat likely	201 (16.7)	74 (6.2)	75 (6.2)	78 (6.5)
Neither	29 (2.4)	18 (1.5)	20 (1.7)	15 (1.3)
Somewhat unlikely	27 (2.2)	9 (0.8)	8 (0.7)	11 (0.9)
Extremely unlikely	19 (1.6)	9 (0.8)	7 (0.6)	6 (0.5)
Average risk				
Friedman test <i>p</i> -value	<0.0001			
Wilcoxon Signed Rank <i>p</i> -value	REF	0.1544	<0.0001	<0.0001
Extremely likely	927 (77.1)	890 (74.0)	813 (67.6)	813 (67.6)
Somewhat likely	201 (16.7)	238 (19.8)	309 (25.7)	306 (25.4)
Neither	29 (2.4)	43 (3.6)	53 (4.4)	55 (4.6)
Somewhat unlikely	27 (2.2)	18 (1.5)	17 (1.4)	20 (1.7)
Extremely unlikely	19 (1.6)	14 (1.2)	11 (0.9)	9 (0.8)
Low risk				
Friedman test <i>p</i> -value	<0.0001			
Wilcoxon Signed Rank <i>p</i> -value	REF	<0.0001	<0.0001	<0.0001
Extremely likely	927 (77.1)	646 (53.7)	542 (45.1)	517 (43.0)
Somewhat likely	201 (16.7)	340 (28.3)	398 (33.1)	409 (34.0)
Neither	29 (2.4)	89 (7.4)	131 (10.9)	150 (12.5)
Somewhat unlikely	27 (2.2)	96 (8.0)	103 (8.6)	98 (8.2)
Extremely unlikely	19 (1.6)	32 (2.7)	29 (2.4)	29 (2.4)

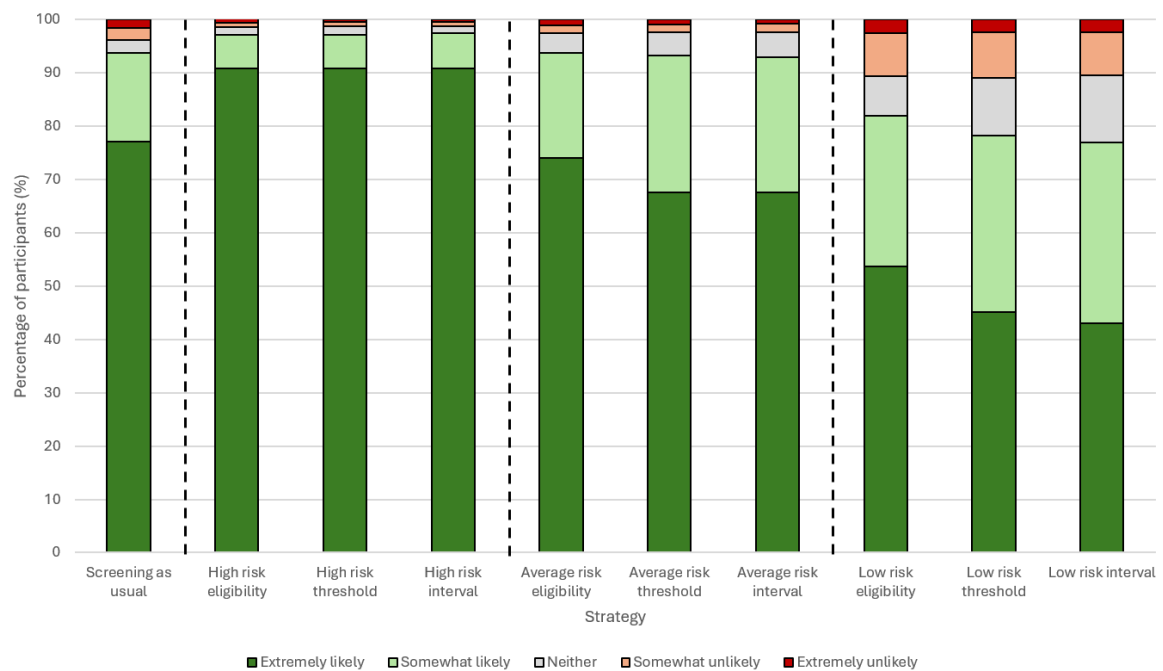


Figure 7.4 The likelihood of taking up FIT screening at different risk levels across risk-stratified screening strategies compared with screening as usual.

7.5.5 Impact of risk level on the decision to attend colonoscopy

The impact of risk level on the decision to attend colonoscopy is summarised in Table 7.8 and Figure 7.5. The likelihood of personal risk score impacting the decision to attend colonoscopy was significantly different across the risk-stratified strategies for all three risk levels ($p < 0.0001$).

Table 7.8 The likelihood of personal risk score impacting the decision to attend colonoscopy.

	Much more likely	A bit more likely	No change	A bit less likely	Much less likely
High risk					
<i>p</i> -value (Friedman)	<0.0001				
Eligibility	956 (79.5)	121 (10.1)	118 (9.8)	4 (0.3)	4 (0.3)
Threshold	969 (80.6)	103 (8.6)	125 (10.4)	2 (0.2)	4 (0.3)
Interval	978 (81.3)	92 (7.7)	125 (10.4)	3 (0.3)	5 (0.4)
Average risk					
<i>p</i> -value	<0.0001				
Eligibility	480 (39.9)	429 (35.7)	266 (22.1)	23 (1.9)	5 (0.4)
Threshold	543 (45.1)	398 (33.1)	243 (20.2)	14 (1.2)	5 (0.4)
Interval	575 (47.8)	360 (29.9)	246 (20.5)	15 (1.3)	7 (0.6)
Low risk					
<i>p</i> -value	<0.0001				
Eligibility	185 (15.4)	338 (28.1)	424 (35.3)	204 (17.0)	52 (4.3)
Threshold	192 (16.0)	373 (31.0)	422 (35.1)	181 (15.1)	35 (2.9)
Interval	197 (16.4)	394 (32.8)	413 (34.3)	156 (13.0)	43 (3.6)

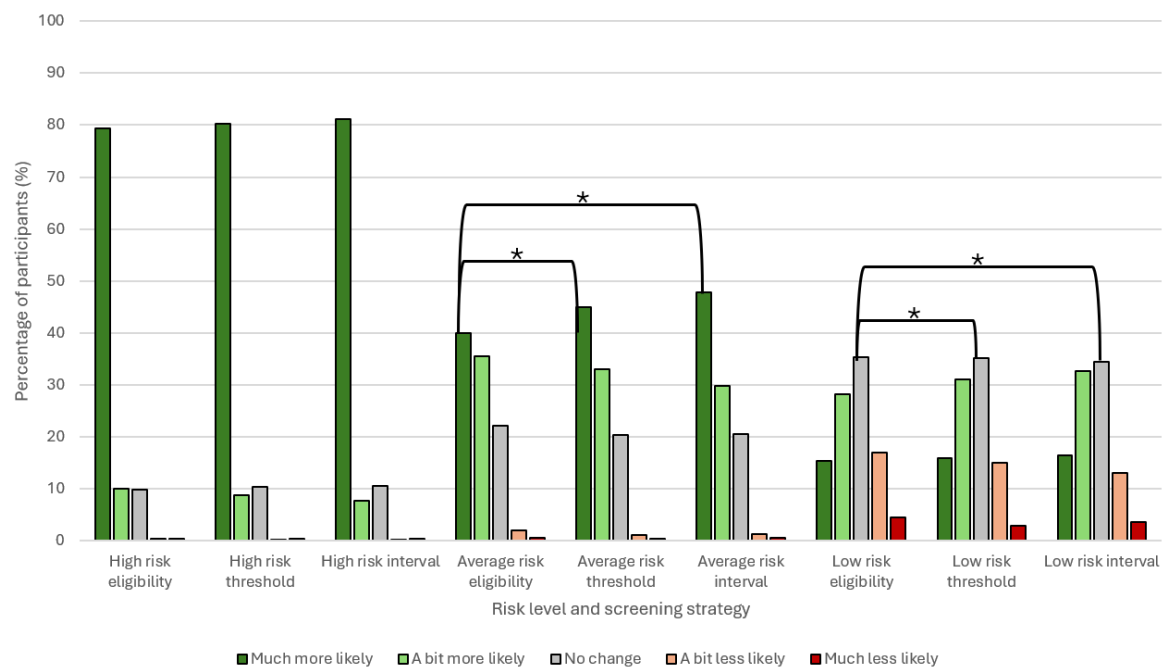


Figure 7.5 The likelihood that personal risk score would impact the decision to attend colonoscopy.

* Wilcoxon Signed Rank test *p*-value<0.0001. All other *p* values non-significant (*p*>0.001).

7.5.6 Acceptability of data collection

The acceptability of four modes of collecting personal risk information across the three risk-stratified strategies are summarised in Table 7.9 and Figure 7.6. Overall acceptability of all four modes of data collection was high with the combination of GP records, phenotypic and genetic data collection ranked as 'extremely acceptable' by the highest number of participants for all three risk-stratified programmes. A minority of participants ranked the data collection methods as 'somewhat or extremely unacceptable'. The distribution of responses was similar for risk-stratified eligibility, FIT threshold and screening interval although, the differences in acceptability between the modes of data collection were statistically significant ($p < 0.001$) for all three risk-stratified screening scenarios.

Table 7.9 Acceptability of data collection methods summarised by risk-stratified screening strategy.

	Extremely acceptable (n/%)	Somewhat acceptable (n/%)	Neither acceptable nor unacceptable (n/%)	Somewhat unacceptable (n/%)	Extremely unacceptable (n/%)
Risk-stratified eligibility					
Friedman test <i>p</i> -value	<0.0001				
GP records	779 (64.8)	314 (26.1)	54 (4.5)	44 (3.7)	12 (1.0)
Phenotypic data	752 (62.6)	346 (28.8)	63 (5.2)	31 (2.6)	11 (0.9)
Genetic data	796 (66.2)	311 (25.9)	57 (4.7)	28 (2.3)	11 (0.9)
GP records, phenotypic and genetic data	811 (67.4)	313 (26.0)	45 (3.7)	25 (2.1)	9 (0.8)
Risk-stratified threshold					
Friedman test <i>p</i> -value	0.0001				
GP records	810 (67.3)	308 (25.6)	41 (3.4)	35 (2.9)	9 (0.8)
Phenotypic data	763 (63.4)	351 (29.2)	53 (4.4)	27 (2.2)	9 (0.8)
Genetic data	812 (67.5)	307 (25.5)	53 (4.4)	23 (1.9)	8 (0.7)
GP records, phenotypic and genetic data	826 (68.7)	297 (24.7)	55 (4.6)	19 (1.6)	6 (0.5)
Risk-stratified interval					
Friedman test <i>p</i> -value	0.0007				
GP records	803 (66.8)	317 (26.4)	41 (3.4)	34 (2.8)	8 (0.7)
Phenotypic data	773 (64.3)	335 (27.9)	62 (5.2)	27 (2.2)	6 (0.5)
Genetic data	815 (67.8)	295 (24.5)	62 (5.2)	23 (1.9)	7 (0.6)
GP records, phenotypic and genetic data	826 (68.7)	302 (25.1)	49 (4.1)	22 (1.8)	4 (0.3)

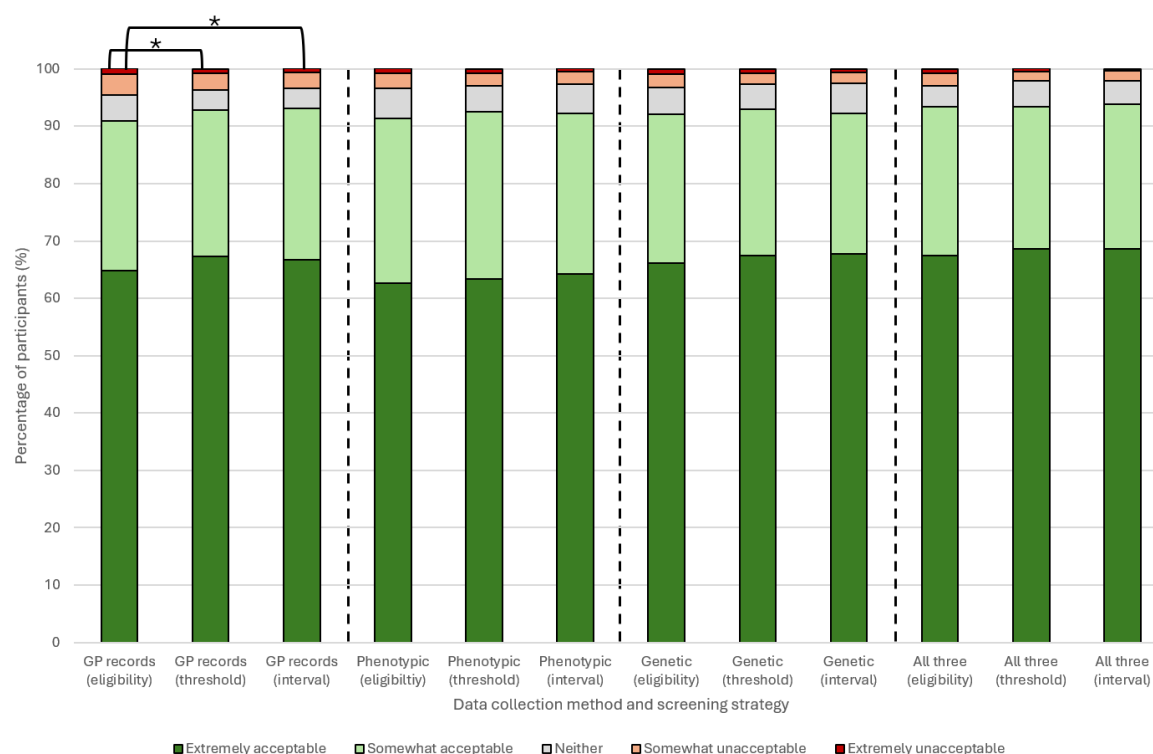


Figure 7.6 Acceptability of data collection methods illustrated by risk-stratified screening strategy.

*Wilcoxon Signed Rank test $p < 0.001$. All p values comparing each data collection method *within* the same strategy were significant ($p < 0.001$). All other p values comparing each data collection method *between* strategies were non-significant ($p > 0.001$).

7.6 Discussion

This online survey study involved questions about the acceptability of risk stratification, anticipated FIT uptake and data collection options at three distinct points on the bowel cancer screening pathway. This is the first study to quantify these differences in relation to risk-stratified eligibility criteria, FIT thresholds and screening intervals specifically. I discuss both absolute and comparative outcomes.

Overall, the acceptability of the risk-stratified strategies was high. In the case of stratified eligibility criteria and FIT thresholds, risk-based screening was perceived as more acceptable than the current age-based approach. Although, this result was not significant for a screening programme employing risk-stratified intervals. Increasing screening opportunities among high-risk groups was reported to be extremely acceptable, more so than screening as usual. Yet the inverse was true of de-intensifying screening for low-risk cohorts, which participants reportedly found less acceptable by up to 15.6% than a programme based on age. Similarly, de-intensified screening for low-risk groups was

up to 30.3% less acceptable than increasing screening for those at high risk. Logistic regression results suggest that females may be less likely to find stratified screening acceptable despite finding screening as usual acceptable, compared with males, after adjusting for other characteristics. This warrants mindful communication with females specifically ahead of and throughout implementation to maximise acceptability in this group.

Participants were more likely to take up screening by FIT if they had a hypothetically high risk of developing bowel cancer compared to a hypothetically average or low risk. This suggests that receiving a high-risk estimate encourages participation in FIT screening and that those with the most to gain from screening are highly likely to attend. When participants were asked to consider being categorised as having a low risk of developing bowel cancer, they reported that they would be significantly less likely to take up FIT, negatively impacting on uptake by as much as 16.8% compared with prospective uptake of the current screening programme. These findings indicate that reducing bowel cancer screening for low-risk cohorts is less acceptable to the public and FIT uptake may be significantly reduced as a consequence. Sufficient uptake is essential in order for screening programmes to have adequate impact on incidence and mortality rates. However, a potential reduction in uptake of almost 17% could have a significant impact on these outcomes(45). Furthermore, anticipated uptake following a high-risk label was only 3.6% higher than for screening as usual, suggesting that low-risk estimates have a greater likelihood of impacting upon uptake than categorising individuals as high risk. A similar pattern was observed when participants were asked about the impact of personal risk on the decision to attend colonoscopy. These results indicate that receiving a high-risk estimate may encourage attendance at colonoscopy screening, whereas receipt of a low-risk score may inadvertently reduce or discourage colonoscopy attendance. Willingness to repeat FIT screening if close to the threshold for referral was high, which is reassuring as this is a potential strategy for a programme with risk-based thresholds. Although the results of this survey are anticipatory, as opposed to experiential, they are of significance in identifying possible obstacles to successful implementation of risk-adapted screening for bowel cancer.

Finally, the acceptability of all three data collection methods considered in the survey was strong. At least 62% of participants rated all options for data collection as 'extremely acceptable', however the most acceptable option within each risk-based strategy was to collect data using a combination of GP records, surveys to obtain phenotypic data and genetic data via a cheek swab, indicating that a more comprehensive approach to data collection is preferable to the public.

7.6.1 Comparison with other literature

The finding that risk-stratified bowel cancer screening is largely acceptable and potentially even more acceptable to the general public than age-based screening is congruent with the findings reported in Chapters 4-6 of this thesis. Similarly, the finding that increasing screening for high-risk groups is more acceptable than reducing screening has been discussed in some detail throughout these studies. For example, many participants in the think aloud interviews detailed in Chapter 6 expressed concerns over extended screening intervals but supported a reduced interval for those at high risk. Additionally, community jury participants were averse to screening cessation for those at low risk and had greater reservations about reducing screening compared with increasing screening for high-risk groups, as reported in Chapter 5. As mentioned in Chapters 1, 4 and 5, previous communication of extending intervals for cervical cancer screening has caused push-back from members of the public due to reduced acceptability(82–84). The early identification of this potentially negative impact on uptake as a result of low-risk labelling could assist in avoiding negative public discourse associated with implementation of risk-based bowel screening. Furthermore, my findings from Chapter 4 highlight the possibility that communicating de-intensification of screening to the public may appear at odds with promotional screening materials, representing a further potential pitfall of low-risk categorisation. In order to prevent a significant negative impact, the framing of low-risk results and categories should be carefully considered. As opposed to assigning low-risk labels, it may be that lower risk individuals are incorporated within the average risk group who then receive either a higher FIT threshold or increased screening interval by default. Those at higher risk would then still benefit from increased screening opportunities without increasing resources and costs, which would add pressure to the healthcare system, or inadvertently reducing FIT uptake.

The finding that females may be less accepting of risk-based screening than males may be attributable to differences in prior screening exposure and experiences of being a regular attendee at cancer screening. Females are typically invited to attend both breast and cervical screening from a younger age than bowel cancer screening and this may result in an endowment effect(133). As detailed in Chapter 4, Section 4.5.5.6, this may be particularly impactful in relation to mammography screening for breast cancer, as women in the studies included in my systematic review reflected upon breast screening as being an especially respected and well-established programme.

Several studies have considered the impact of personalised risk information on screening uptake in numerous cancer types. A 2018 systematic review of the effect of personalised cancer risk information on intentions and behaviour largely reported that, contrary to my findings, risk information is unlikely to impact intentional or actual attendance at screening(180). However, over

80% of the included studies were conducted in the US where cancer screening operates quite differently to English population-based screening programmes which may explain some degree of difference. Studies conducted on both hypothetical and experiential uptake of screening for kidney, bowel and breast cancer within the UK context have reported similar patterns on uptake when participants are presented with high and low risk estimates. In these instances, participants were more likely to attend screening at increased risk level compared with those at low risk(160,181).

7.6.2 Strengths and limitations

A key strength of this study is the use of information text developed with public input via the think aloud study and tested through a user-testing procedure as described in Chapter 6. Similarly, the input of a PPI panel in both of these studies contributes to the readability of the resulting text. Additionally, all information about the different screening strategies was delivered to participants in advance of the survey questions which enabled me to limit any potential order effects. Finally, the survey method accommodated the collection of information on a wide range of variables whereas an alternative study design, such as a discrete choice experiment, may have limited this to information about preferences only.

A limitation of my study is that anticipated FIT uptake rates reported by participants in my survey are higher than the uptake rates we see in reality (approximately 69%), even for the screening as usual strategy(45). Thus it is challenging to say how representative my findings are likely to be in practice. Furthermore, these results enable me to comment on how the decision to attend a colonoscopy may be impacted by receipt of personalised risk estimates but, without a baseline measure of colonoscopy uptake, it is impossible to say what prospective colonoscopy uptake rates would actually be. Future research on the impact of risk stratification on FIT uptake and colonoscopy attendance in practice will be necessary, but these findings remain useful in identifying barriers to implementation in advance. The use of arbitrary low, average and high-risk groupings rather than providing absolute or relative risk information is also a possible limitation. Knowledge of the percentage risk conveyed by the risk groupings may have influenced participants perceptions of acceptability and/or uptake. Additionally, I am unable to comment on the impact of perceived personal risk of bowel cancer on survey responses. Finally, as well as the potential for self-selection bias, the participants in my study were highly educated, many to undergraduate or postgraduate degree level. As prior research has demonstrated that educated individuals are more likely to uptake and adhere to screening for bowel and other cancers, it is possible that the anticipated uptake rates I have reported are higher than they would be for the English population(182,183).

7.7 Conclusions

In this survey study I have investigated the acceptability and anticipated uptake of risk-stratified bowel cancer screening compared with current screening practices, with a focus on risk-based eligibility criteria, FIT thresholds and screening intervals. I have also explored acceptability of different approaches to collecting risk information and willingness to engage in repeat FIT testing for those close to the referral threshold. I have demonstrated that risk-stratified bowel cancer screening at these points on the screening pathway is acceptable to the general public. However, I also report that uptake may be significantly reduced among low-risk populations, necessitating careful consideration of risk categories and associated public communication. Overall, these findings support those reported in my previous thesis chapters, contributing to a significant body of evidence underscoring the acceptability of risk stratification in the context of bowel cancer screening, with the caveat that it is appropriately communicated to the public. My results also suggest opportunities for facilitating greater acceptability and uptake through communication with specific groups, such as those at lower risk and females who may have imbibed traditional screening rhetoric to a greater degree. I will explore these findings in greater depth in Chapter 8.

Chapter 8 Discussion

In this thesis, I aimed to understand public acceptability and communication preferences for risk-stratified FIT thresholds and screening intervals as part of bowel cancer screening programmes. Additionally, I sought to identify public communication needs associated with such an approach. Following detailed descriptions of the methods and results in Chapters 3 to 7, I will now discuss the overall findings and implications of my thesis as a whole.

8.1 Thesis summary

8.1.1 Summary of methods

As illustrated in Figure 2.1, I began by conducting a pair of parallel systematic reviews to establish the state of the evidence on stakeholder acceptability of risk stratification in the context of screening programmes for any cancer type (Chapters 3 and 4). I then narrowed my focus to bowel cancer specifically and explored the acceptability of different strategies for risk-based bowel screening with informed members of the public using the community jury method (Chapter 5). I used the data generated by the juries relating to information and communication needs to learn from the perspective of members of the public, who had greater opportunity to understand the topic. These findings were used to inform my subsequent study developing an information leaflet communicating risk-stratified screening intervals using think aloud interviews and a user testing process (Chapter 6). Finally, an online population-based survey enabled me to further investigate the acceptability of different approaches to risk-based screening for bowel cancer, including the mode of data collection to inform a risk algorithm and anticipated uptake of FIT screening according to risk level (Chapter 7). I have discussed the findings of each individual study and comparison with existing literature in significant detail within each chapter, I will therefore not repeat them here and instead present a synthesis of findings from my thesis by theme.

8.1.2 Acceptability of risk-stratified bowel cancer screening

The acceptability of risk-stratified screening for bowel cancer was a uniting theme across the studies included in this thesis, with every study contributing evidence relating to the concept of acceptability. A key finding is that the public are generally accepting of risk stratification for cancer screening programmes, including risk-based eligibility, FIT thresholds and screening intervals for bowel cancer. This is perhaps the most important finding from this body of work as acceptability is a fundamental tenet of success for screening programmes and without evidencing acceptability there would be little purpose in further pursuing risk stratification for bowel cancer screening.

In the case of bowel screening specifically, the concept of risk stratification was viewed as a logical adjustment to existing screening practices and the public perceive the benefits to outweigh any costs. Identified benefits included decreased demands on screening services and resources, improved consistency in service provision, reduced harms for low-risk individuals, an opportunity for health promotion and increased accessibility of risk assessment. Evidence from across this body of work suggests that the public have the potential to find risk-stratified screening to be more acceptable than an age-based programme. In the case of HCPs, acceptability is intrinsically linked with public perceptions of screening, such that a risk-adapted screening programme would only be acceptable to professionals providing it is also accepted by the public. Additionally, a risk-stratified screening programme that increased the time and/or resource burden on the healthcare service would be fundamentally unacceptable to HCPs and also less likely to be accepted by the public. This emphasises the need to balance increased screening for high-risk groups with reducing screening among those at lower risk in order to operate within the confines of the available healthcare resources.

Despite strong overall acceptability for the intervention, a key finding from this thesis is that the intensification of screening for individuals at high risk of developing bowel cancer was perceived as more acceptable than reducing screening among those at low risk in all five studies. Although this has been reported previously, in this thesis I was able to explore the views of intensifying and de-intensifying screening both qualitatively and quantitatively and in the context of screening for bowel cancer specifically. Risk stratification was generally perceived as a way for high-risk groups to benefit from prioritisation and targeted support. Conversely, despite acknowledging the possible benefits of reducing screening if at low risk, including reduced emotional, psychological and even physical harms, many participants still had fears that reducing screening would be unsafe, leading to interval cancers and later stage diagnoses. Furthermore, findings from Chapters 4 and 5 indicate that complete cessation of screening for those at lowest risk is unacceptable to the public, with up to 40% of participants reporting discomfort associated with stopping bowel cancer screening(136). Previous literature has identified evidence to suggest that the public may be more willing to accept reduced screening in cases where the screening test is perceived as unpleasant, such as FIT, compared with other screening programmes where the screening test itself is perceived more favourably(128). This may mean that bowel cancer screening is a good candidate for being one of the first screening programmes to introduce a risk-based strategy.

A previous community jury considering risk-stratified eligibility for cancer screening reported that participants were wary of favouring people who had made unhealthy lifestyle choices by prioritising them for screening(153). This belief was not shared by participants in my community jury study who

felt that investing screening resources in people with an unhealthy lifestyle and therefore a higher risk of bowel cancer was justified by the potential for long-term financial gain through prevention and early detection.

Across the potential risk-based strategies, anticipated uptake was higher when individuals were told they were at higher risk, suggesting that people who receive a high-risk estimate may be more likely to take up FIT screening than members of the screening population who receive an average or low risk estimate. Indeed, up to 20.4% more participants were likely to take up screening by FIT when they were hypothetically labelled as high risk, compared with being told they had a hypothetical low risk. I also observed that people anticipated being more likely to attend a colonoscopy following a high-risk result than a low-risk result. This suggests that high risk estimates encourage attendance for both FIT and colonoscopy, whereas a lower risk label may inadvertently discourage people from taking up screening or further investigation. As a result, risk categorisation and communication of low-risk results in particular must be carefully considered and researched in practice. It may be advisable to avoid labelling members of the public as low risk to prevent significant issues with uptake and greater research is needed to ascertain the optimum strategy for categorising risk levels. Finally, the survey study results also demonstrate that females may be less accepting of a risk-stratified screening programme, which may require specifically targeted communication to address women's concerns.

8.1.3 Public communication requirements and considerations

As demonstrated particularly in Chapters 4 and 5, public desire for information is high. Participants specifically wanted information about the rationale behind risk stratification, the included risk factors, ways of managing or reducing their personal risk of bowel cancer and information about cancer in general. A multitude of communication outlets were suggested including television and radio broadcasts, social media, text messaging and via primary care. Throughout the studies in this thesis, participants advocated for clear, consistent and lay friendly communication about bowel cancer screening and risk stratification more specifically. They felt that screening information and resources should be available via various outlets, on paper and online as well as in multiple languages. However, there is a need to balance this appetite for information with potential feelings of anxiety or overwhelm which may negatively impact screening attendance.

It is not only important to communicate with the public about both screening and bowel cancer, but also to convey risk-related elements, including details of risk assessment and the impact of risk on screening practices. Although the findings of Chapter 6 demonstrated that the existing NHS bowel cancer screening leaflet does not meet the needs of all members of the screening population in its

current form, participants were able to understand written information about a risk-stratified version of the programme communicated in this manner. Alongside receipt of risk information, participants wanted reassurance about seeking help from primary care services if necessary and on self-monitoring for symptoms of cancer, especially for people in low-risk groups for whom screening opportunities would be decreased. Participants in the community juries reported in Chapter 5 who were more informed suggested that risk factors should be weighted according to their contribution to individual risk. However, less informed members of the public found information about the specifics of a risk calculator/algorithm and the process of weighting risk factors within that to be confusing as part of the information leaflet used in the think aloud interviews. As such, they did not consider this to be important or necessary information to convey. Nevertheless, this should be made available elsewhere, such as online, for individuals who do wish to learn more about risk estimation. Despite not wanting information about the accuracy of a risk algorithm in both the juries and the think aloud interviews, the public generally seem to understand and accept that risk estimation is not 100% accurate, with most think aloud participants considering this in a positive light or as an unavoidable fact of life.

Confusion over terminology associated with screening harms in Chapter 6 demonstrated a need for enhanced clarity when communicating the benefits and risks of taking part in bowel cancer screening. Additionally, the public struggled to understand the meaning of false positives and false negatives, often understanding the general concept but finding the terminology itself to be confusing. These areas of misunderstanding are consistent with the systematic review findings described in Chapter 4, as well as wider literature, and underscore the importance of mindful communication in informed decision-making(160,165). Misunderstanding in the community jury study led to some participants falsely believing that low risk people may be denied a colonoscopy despite having a concerning level of FHB. This is specifically relevant for a programme involving stratified FIT thresholds and would require carefully considered communication to prevent such confusion from occurring at a population level.

A number of contextual factors were considered by participants across the studies. A key consideration centred around cost as the driving factor behind the shift to risk stratification. Although demonstrating cost-effectiveness was important to HCPs and, to a certain extent, the public, when portrayed as a motivating factor it undermined the public's confidence in the approach and suggested that money may be saved at the expense of patient benefit. Similarly, the public does not need to be told about the limited nature of colonoscopy services as jury participants suggested that this may serve to increase demand. To date, national communications about cancer screening programmes have perpetuated a pro-screening rhetoric and participants identified that this may

appear contradictory to information about risk stratification, where some members of the population will experience reduced screening. The media were identified as external change agents, having the potential to facilitate or impede public acceptability via their portrayal of screening programme changes. HCPs suggested that the media should be engaged early and throughout the process of implementation to maximise public acceptability and control the narrative around risk stratification, minimising the spread of misinformation.

8.1.4 Considerations specific to the provision of personal risk information

The provision of risk information and the types of data to include in a risk algorithm were considered in Chapters 4, 5 and 7. Desire for personal risk information was varied, with some individuals simply keen to learn more about their risk status and some, particularly female participants, feeling a duty to obtain information for the benefit of their wider families and themselves. This could result in a sense of empowerment, increased awareness and the ability to be proactive about lifestyle change. Participants further speculated that a high-risk result would allow people to benefit from the security of increased surveillance whereas low risk individuals would feel a sense of reassurance and relief. Conversely, some individuals did not wish to know about their risk estimate and only wanted to know when they would be invited for screening or further investigations, seeing this as burdensome or a potential source of anxiety. This suggests a layered approach to delivering risk feedback would be optimal, with participants firstly receiving a basic level of information with the opportunity to request more detailed information elsewhere, such as online or through primary care(184). Notably, the utility of being placed in an intermediate or average risk category was questioned as having no obvious advantages and HCPs were less confident explaining what this risk result means compared with a high or low risk status(119). Additionally, previous literature has determined that people may be unwilling to accept a risk score that differs from their internalised beliefs about their own risk. Where this is the case, the individual may be less accepting of changes to the screening regimen(127).

In general, participants wanted actionable risk estimates that could have a tangible impact on screening and lifestyle choices. They felt these should be shared in a variety of formats including visual and diagrammatic representations of risk such as icon arrays, relative and absolute risk, percentage risk, age-related risk and a ladder of risk to enable comparative interpretations. The public also felt that high risk estimates in particular needed to be delivered face-to-face by a suitably trained HCP and that people receiving such results should have the ability to access psychological support. Average and low risk results can be communicated via letter. This point of contact with the public can also be viewed as a 'teachable moment' for the opportunistic delivery of lifestyle interventions to promote behaviour change. However, community jury participants and participants

included in the systematic review of public acceptability felt strongly that provision of personal risk information should not be mandated.

As well as how risk information is communicated to individuals following risk assessment, it is necessary to define which risk variables and methods of data collection are acceptable to the public and this was specifically explored in Chapters 4, 5 and 7. Survey participants reported that GP records, lifestyle questionnaires or cheek swabs to collect genetic data are all acceptable methods of collecting risk information, but they preferred the more comprehensive strategy of combining all three approaches. A similar sentiment was expressed by community jury participants; however, they acknowledged that inclusion of lifestyle and genetic data is a more complex pursuit, both ethically and practically, than using data readily available within the healthcare system, i.e. age, sex and Fhb from FIT. Therefore, from an acceptability standpoint, it is reasonable to conclude that a strategy using such readily available data could be implemented immediately ahead of more complex strategies including additional risk variables. Participants in the juries were effectively suggesting incremental change to the screening programme so that the benefits of risk stratification can begin to be realised immediately with future amendments to refine the approach over time.

One possible caveat that was identified in the systematic review of public acceptability reported in Chapter 4 was public reservations about genetic data specifically. I identified concerns about possible data security issues, invasion of privacy and the potential for discrimination, notably from insurance providers and employers. Although these concerns about genetic data were not echoed by the subsequent studies in my thesis, it remains a valuable consideration when developing risk models and designing public communication materials as it may be a barrier to acceptability for certain members of the population. Similarly, questions remain regarding the use of modifiable risk information, such as smoking status, diet and alcohol consumption. Such risk factors may be misreported and are subject to change over time, potentially necessitating periodic re-assessment and introducing further complexity. Additionally, some individuals may be unable or unwilling to provide risk data meaning clear and consistent guidance will be required for managing such cases within a risk-adapted programme. A final caveat is the complexity of providing risk information. A highly complex means of data collection was considered burdensome and therefore a barrier to participation. Furthermore, online means of data collection were perceived as barriers to certain members of society, like the elderly who may have low computer literacy.

8.1.5 The role of healthcare professionals and health services

The role of healthcare professionals must be clearly defined ahead of implementation to enable the workforce to deliver and endorse the intervention with confidence and fidelity. HCPs and PCPs in

particular will require supplementary knowledge and training to fulfil their role in shared decision-making with patients. Chapter 3 identified confusion and poor understanding of terminology associated with risk stratification among PCPs and others, including conflation between risk assessment and the screening test itself, despite beliefs that risk information should be delivered by HCPs. Such concepts must be clearly communicated to the public and therefore HCP knowledge must be strengthened before taking on this responsibility. Furthermore, conversations about personal risk estimates that have traditionally been managed by genetic specialists may fall within the remit of general practitioners if bowel cancer screening becomes risk based. Therefore, increased training in primary care will be vital to ensure PCPs feel confident navigating such conversations as well as requiring the development of risk communication tools that are compatible with existing healthcare infrastructure. Facilitating trust in the HCPs and health services responsible for endorsing risk-adapted screening will be crucial in alleviating public scepticism and empowering individuals to accept less screening(136).

HCPs identified that all aspects of risk stratification must be compatible with existing infrastructure in primary care and screening services to avoid overburdening healthcare services. As many functions as possible should be automated to lessen staff burden and enable routine usage in clinical practice.

8.1.6 A systems-based analysis of risk-stratified bowel cancer screening

Outside the scope of my PhD I have also been part of a set of stakeholder interviews seeking to explore the implementation of risk stratification for bowel cancer screening in England using a systems-based approach developed by the Royal Academy of Engineering(185). We explored the views of eleven key stakeholders and used their insight to elucidate barriers to implementation. Interview participants included members of the UKNSC and the Research, Innovation and Development Advisory Committee (RIDAC) for bowel cancer, individuals involved directly in programme delivery, such as IT personnel, those employed within the screening programme including screening hub directors and endoscopists, and wider stakeholders who may be impacted by changes to the UKBCSP, like GPs. Many of the findings complement my overall thesis results as well as highlighting additional areas of importance relating to four key areas: (I) people perspective; (II) systems perspective; (III) design perspective; (IV) risk perspective.

In the people perspective an essential finding was that the optimum strategy for risk stratification remains uncertain and that a lack of consensus on this decision represents a decision making 'bottleneck' for implementation. In line with the views of HCPs described in my thesis, those in bowel cancer screening also recognised that staff would require supplementary training, the content

of which would need to be determined by the chosen risk-adapted strategy, and that the intervention must be applied with fidelity to prevent exacerbation of inequalities. Some interview participants expressed concern that risk stratification has the potential to overload limited colonoscopy services. Other participants were able to assuage this issue by explaining that the system has an element of flexibility built in to act as an internal 'shock absorber' and prevent overwhelming the screening service.

When considering the systems perspective, participants confirmed findings from my thesis indicating a need for additional evidence through trials and feasibility studies as well as validation and assessment of potential risk algorithms. However, participants in the stakeholder interviews also identified that a sufficient evidence threshold and appraisal criteria must be established in order to fulfil these needs. Similarly, they felt that outcome criteria for the programme and design of a mechanism for monitoring said outcomes needs to be established prior to the implementation stage.

Within the design perspective, views again echoed those reported across my thesis. Participants highlighted risk stratification as a learning opportunity for behaviour change through patient communication. Similarly, they also desired a highly automated process to prevent strain on staff and, as stakeholders, emphasised the importance of health economic modelling and cost-effectiveness evidence. However, it was also appreciated that this may require 'frontloading' of resources in order to realise gains in the long-term. Finally, stakeholders reflected that although primary care data seems well suited for use in a risk algorithm, in many cases this data is of poor quality and challenging to access.

Finally, a key consideration in the risk perspective was the impact of risk stratification on other areas of the health service. Participants identified a need to evaluate the impact on wider areas of the system such as radiology services if CTC scans are used as a diagnostic tool and pathology resources if more cancers are being detected.

8.1.7 Outstanding evidence requirements

Two key areas of outstanding evidence requirements came out of these studies. Firstly, the public and HCPs both require greater evidence and reassurance before screening can be reduced for lower risk population groups. Concerns towards the de-escalation of screening were identified throughout this thesis, with reduced screening being perceived as less acceptable and requiring more caution than increasing screening for people above average risk. This indicates that the public view the harms of screening as secondary to the potential of being diagnosed with a cancer. This sentiment is consistent with a discrete choice experiment asking participants to weigh up attributes of a risk-

stratified screening programme where they favoured lives saved over any reduction in harms, such as unnecessary diagnostic procedures following a false positive screening test(186). The primary concern identified by HCPs in Chapter 3 was safety and this will need to be evidenced if they are to endorse risk-stratified screening and effectively communicate with patients at all risk levels.

Secondly, an evidence requirement specifically identified by HCPs was the need for improved risk models that have been extensively validated in the populations in which they are intended for use, including ethnic minority groups. An acceptable risk model is one that uses easily obtainable data to allay concerns about accuracy, particularly for self-reported variables which may be prone to misrepresentation. Overall, the features of a risk-stratified screening programme should be based on evidence rather than being driven by implementation priorities. As such, pilot trials and feasibility studies will be necessary ahead of implementation to ensure whole system readiness for the intervention.

8.2 Strengths, limitations and evaluation

The individual strengths and limitations associated with each study have previously been reported in detail within the individual chapters. I will now discuss the overall strengths and limitations of my thesis as a whole.

A major strength of this thesis is the mixed methods approach, reflective of a pragmatist standpoint, that enabled me to explore multiple facets of acceptability. This also allowed me to interpret my quantitative findings in greater depth using insight from my qualitative findings. I have also investigated not only acceptability, which is of utmost importance ahead of implementation, but additionally I have explored a key facilitator of acceptability in the form of public communication. The approach I have taken to understanding these concepts has been an evidence-driven process as each study in my thesis has been informed by the subsequent study, starting with two rigorous systematic reviews. Additionally, the inclusion of participants who had previously declined to attend screening is a strength, forming a more representative idea of public opinions than solely recruiting regular attenders at screening who may be more likely to perceive screening favourably.

This thesis has been a collaborative working opportunity for myself, medical students and other researchers from within and beyond my own institution. This increased the diversity of perspectives when designing and analysing these studies and improved methodological rigour by involving more senior researchers with valuable experience to learn from. The findings of this thesis contributed to a workshop that aimed to summarise the main findings of my work and closely related research led by my group. The workshop included ten researchers and three PPI members. This benefits this

thesis as the findings have therefore undergone a validation exercise to strengthen their interpretation.

Overall, these studies were subject to demographic bias towards a white and well-educated perspective, particularly notable in the user testing survey aspect of the think aloud study. This resulted in an under-representation of social groups who are typically less likely to take up screening, hence more research is required to establish the views of screening averse members of the population. This is likely linked to a response bias whereby individuals with greater interest in screening and/or bowel cancer and more positive attitudes to screening are more likely to take part in related research. However, I did attempt to mitigate this impact by including participants who had previously declined screening as detailed above. Additionally, I only recruited proficient English speakers which further limits the generalisability of these findings. Finally, although the online nature of the studies enabled greater geographic reach, it may have prevented some individuals with insufficient digital resources or literacy from taking part.

Given greater time and financial resources, this thesis may have been strengthened through greater PPI involvement through co-production, as the PPI contribution was largely confined to reviewing already developed materials and findings. I feel this would have been particularly valuable in generating the initial leaflet used in the think aloud interviews and may have identified many of the issues with comprehension ahead of time, allowing the interview discussion to focus on the addition of risk-related information. Furthermore, I would have repeated the think aloud process to develop leaflets about risk-stratified eligibility and FIT thresholds to ensure this information was understandable to participants in the user testing procedure. I also feel the user testing process itself would have added greater value if I had repeated it among different population subgroups, for example, non-native English speakers or adults with low literacy, to quantify how far the leaflet serves the needs of the general populous. Finally, in relation to the survey study, I would have phrased the question about whether risk information would impact the decision to attend colonoscopy differently. I would instead have asked how likely the participants would be to attend colonoscopy according to risk level, as the existing question was challenging to interpret without a baseline measure of how likely the participants were to attend.

8.2.1 Reflexivity

It is important to consider how my personal identity and my identity as a researcher may have impacted interactions with participants and my analytical interpretations of the data generated in this thesis. Although this had the potential to shape the survey study design and analysis of all my

findings, I will mainly discuss reflexivity in relation to the qualitative studies detailed in Chapters 5 and 6 where I interacted directly with participants.

I am young, white and female with no personal or close family history of bowel cancer and I am not yet eligible for bowel cancer screening. On the face of it, I appear to be an 'outsider' in relation to my research topic. However, I do have experience of attending cervical cancer screening and therefore have some familiarity with receiving the screening invitation, taking up a screening test which is often perceived as unpleasant (as with FIT testing) and with the emotions associated with awaiting results. During the think aloud interviews, I found that this perspective helped me to develop rapport specifically with female participants as we were able to draw parallels from our shared experience of cervical cancer screening to aid participant understanding of the bowel cancer screening leaflet. In both the community jury study and the think aloud interviews, I considered that my young age relative to the participants may have shifted the traditional power balance between researcher and participant. My identity as a younger person and as a PhD candidate confers my student status and situates me as a less established researcher, which I suspect reduced the perceived asymmetry of power between myself and the participants in a positive way. This potentially situated me as being more accessible and approachable than a senior researcher.

I must also acknowledge my academic standpoint with regards to supporting the implementation of risk stratification. Although I took care not to express my personal views during data collection, I did feel surprised that in many cases participants demonstrated strong pro-screening attitudes and a clear reluctance to reduce screening opportunities, despite receiving information about the harms of screening and the rationale behind implementing a risk-based programme. In approaching the research question through an academic lens I failed to fully appreciate the level of respect and importance that many of the members of the public feel towards cancer screening.

I feel I have inhabited two very different roles as a researcher in the community jury study and the think aloud interviews. My role in the juries was very intentionally to act as an impartial facilitator. The participants received all information about the research topic from a panel of expert presenters and I referred any questions they raised back to those experts, even when I knew the answer myself, in order to maintain the distinction between facilitators and experts. Conversely, the one-on-one think aloud interviews required me to assume a slightly different role as both facilitator and researcher. In this case, when participants had questions I answered them to the best of my knowledge as there was nobody else to refer back to. For example, some participants had difficulty pronouncing terminology associated with bowel cancer, asking how to pronounce adenoma, what it means and whether it differs from haemorrhoids. I believe both of these approaches were suitable

for the setting in which they were used. The intention behind acting as an impartial facilitator in the juries was to encourage participants to speak freely with one another during the facilitated discussions for which I was present, which they may have felt more guarded doing had I presented myself as an expert. Although the more blended role I assumed in the interviews was borne out of necessity (being the only researcher present) I felt it enhanced my ability to build rapport with the participants, which is arguably more important in this setting than in the juries where I was more interested in their interactions with each other than with me. Furthermore, I found that the think aloud participants were more likely to share personal experiences of cancer and beyond. For example, one participant shared how their reading and processing ability had changed following a stroke. Others shared stories of loved ones who had been diagnosed with or died from cancer, or talked about personal health issues like their experience of living with type 2 diabetes. Assuming a more engaged role than simply facilitating may have allowed participants the ability to share more personally and in turn enabled me to express genuine responses.

I held these studies in an online setting. This decision was partly driven by the Covid-19 pandemic as I started planning the community jury study in late 2021 when some pandemic restrictions were still in place. The online format was also an opportunity to maximise demographic diversity by sampling participants from across the country. In many ways, using videoconferencing appeared to make participants feel more at ease and comfortable as they were in a familiar environment which may have empowered them to speak more freely than they would have in perhaps an office or academic setting. For me personally, I found the experience of leading qualitative research online made me feel less nervous than when I present or speak in person, which seemed to positively impact the discourse as I felt more engaged and able to communicate effectively. It is, however, possible that videoconferencing represented a barrier in cultivating strong researcher-participant relationships, but I did not intuitively feel this to be the case. The online setting did prove challenging in the community jury study during the unfacilitated discussion as I found there was no real way to 'leave the room'. I turned my microphone and camera off but had told participants I could be reached via the chat if necessary, which meant that they were aware that I would be able to see and hear them. I did move away from my computer during this time and only checked the chat periodically, but there is still the potential that participants felt inhibited by the knowledge that I may be observing them.

During the think aloud interviews I used a pilot text to familiarise participants with the process of vocalising their thoughts. The topic of the text was starting a vegetable garden and I used photos from my own garden to illustrate this. In some cases I found this to be a useful tool for finding common ground early on as participants shared their own experiences and in many case their own

enjoyment of gardening. I found this highly valuable in building rapport and enabling participants to feel at ease in sharing their thoughts throughout the interviews.

8.3 Implications for policy, practice, and research

The wider implications of the work reported in this thesis are summarised in Table 8.1. I report the overall implications according to four high level themes focussed on designing an acceptable risk-based screening programme, communicating such a programme to the public, generating outstanding evidence and, finally, accommodating HCP requirements.

The fundamental takeaway from this research is that risk-stratified bowel cancer screening very much has the potential to be acceptable and even preferable to the public. Although a lack of consensus about the design of such a programme has hindered progress to date, the public seem to conceptualise risk stratification in broadly the same manner regardless of the point on the pathway at which it is implemented. Additionally, accounting for current public and stakeholder preferences, the optimum risk algorithm includes accurate, non-modifiable variables that are readily available. Furthermore, the public find the use of primary care data in risk prediction to be highly acceptable. It is therefore reasonable to conclude that researchers and policy makers should pursue incremental changes to the bowel cancer screening programme starting with utilisation of age, sex and FHB, data derived from EMR in primary care to calculate personal risk and, providing communication is optimal, such a programme is highly likely to be accepted by the general public.

The findings from my thesis have contributed to the evidence base of a five-year programme of research funded by Cancer Research UK. This grant will investigate bowel cancer risk stratification using quantitative FHB results with the aim of providing the necessary evidence to support implementation. The project aims to determine feasibility and potential outcomes of using risk-stratified FIT intervals and to investigate the value of including additional risk factors, alongside absolute FHB concentration, to calculate bowel cancer risk. Additional elements include exploring the acceptability of this approach in practice, to both the public and HCPs, with a focus on health inequalities and engaging diverse communities, as well as a process evaluation and health economic modelling. The research on acceptability builds directly on the studies I have conducted by investigating the concept of acceptability in practice within a large-scale cohort study and increasing depth of understanding in relation to population sub-groups. My community jury study, think aloud interviews and quantitative survey describe public acceptability of risk-stratified FIT intervals specifically, as well as reporting on the acceptability of data included in risk estimation; both of these contribute to the state of the evidence underlying the cohort study. Furthermore, the results of my survey suggest that uptake may be negatively impacted following receipt of a low-risk label and

indicate that impact on uptake should be quantified in practice, ahead of implementation, and that alternative options for framing risk categories should be explored. This cohort study situated within the NHS BCSP represents an ideal opportunity to build on my findings.

Table 8.1 Summary of overall thesis implications.

Theme	Implications
Designing an acceptable risk-stratified screening programme for bowel cancer	• The informed public are accepting of risk stratification for bowel cancer screening in England at the point of FIT thresholds or screening intervals. • A risk-based screening programme has the potential to be preferable over age-based screening. • An acceptable risk-stratified programme does not increase the burden on primary care services. • Cessation of screening is unacceptable to the public. • Reduction of screening for low-risk cohorts is less acceptable to the public and uptake rates for FIT screening may suffer as a result of labelling individuals as being at low risk of developing bowel cancer. • Delivery of personal risk scores to the public is acceptable providing these are actionable and have a clear and tangible impact on screening. • Provision of risk information as part of a risk-based screening programme must not be mandated. • The public prefer a comprehensive risk model but acknowledge increased practical and ethical complexity and therefore suggest incremental changes starting with readily available data. • HCPs view an acceptable risk model as one that includes easily obtainable, non-modifiable risk variables.
Considerations for communicating a risk-stratified bowel cancer screening programme to the public	• Reducing screening for low-risk individuals is less acceptable to the public despite communication of the harms of screening. Clear and curated communication is needed to facilitate acceptability. • Receipt of a low-risk result may unintentionally decrease uptake due to feelings that screening is no longer relevant/necessary. Further research is required to identify the optimum strategy for risk categorisation and to determine whether avoiding labelling individuals as low risk can prevent negative impacts on uptake.

	• Females may be more reluctant to deviate from age-based screening than males due to increased familiarity with female cancer screening regimens. Targeted communication is necessary to address concerns about deviating from existing practices among females specifically. • Information about the programme should be distributed via multiple outlets, in varied formats and framed positively to maximise awareness and mitigate feelings of anxiety. • Co-development of patient-facing materials is necessary to maximise breadth of understanding, reduce confusion around key concepts, such as harms, and facilitate acceptability. • Public communication materials should include reassurance about help-seeking and self-monitoring. • Preferences for the communication of personal risk information and information about risk stratification, including risk modelling, is varied. Public communication should take a layered approach, providing basic information via the screening programme with the ability to easily access more detailed information elsewhere, such as online. • Reducing costs and managing limited colonoscopy resources should not be presented as the motivation behind transitioning to a risk-based programme. Health-related benefit should be conveyed as the motive behind risk stratification. • Public communication should be framed in relation to the benefits of risk stratification, such as more cancers detected or lives saved, as this is more salient than reducing harms. • The ability of the media to act as ‘change agents’ should be harnessed early on and maintained throughout implementation to manage public discourse around screening programme changes. • Public indications of receptiveness to behaviour change interventions at the point of receiving risk information should be capitalised on as a learning opportunity.

Generating evidence required to implement risk-stratified bowel cancer screening	• More evidence is required in relation to the inclusion of genetic data in bowel cancer risk models from the perspective of both public acceptability and associated legislation. • Clear guidance must be developed for screening members of the population for whom the system lacks risk information. • The complex nature of the intervention requires whole system readiness in order to facilitate easeful implementation. This requires data on workforce implications, cost effectiveness evidence, feasibility evaluation and pilot trials embedded within the NHS BCSP. • Risk communication tools should be developed for routine use in primary care that are compatible with existing EMR and wider healthcare infrastructure, and are fully automated.
Meeting the needs of HCPs within a risk-stratified screening programme for bowel cancer	• HCPs and PCPs in particular require training to understand the intervention and appropriately communicate changes to the screening programme and personal risk information and its implications for screening and behaviour. • The roles of all HCPs and stakeholders involved in delivery of the screening programme must be clearly defined through consensus ahead of implementation. • Trust in HCPs and the NHS is an essential facet of acceptability, particularly if the public are to accept reduced screening. Trust needs to be increased and maintained in order to realise successful change at a national level. However, current sociopolitical factors inevitably have an impact, rendering trust a challenging objective.

BCSP – bowel cancer screening programme; EMR – electronic medical records; FIT - faecal immunochemical test; HCP – healthcare professional; NHS – National Health Service

8.4 Conclusion

In this thesis I have demonstrated strong acceptability of risk-stratified bowel cancer screening, predominantly for FIT thresholds and screening intervals. I suggest that the optimum strategy for risk-based bowel cancer screening, from the perspective of acceptability, involves incremental programme changes beginning with readily available risk data. I have identified vital caveats and considerations to facilitate public acceptance and have put some of these into practice through the development of a risk-based screening leaflet. Additionally, I have demonstrated that prospective uptake of a programme employing risk stratification is high for high- and average-risk categories but decreases when individuals are categorised as low risk. This lays the groundwork for future studies to measure the impact on uptake in practice and explore alternative approaches to risk framing. Future research is required to evidence the safety of reducing screening for those at lower risk and to establish suitable risk models for the whole population. Furthermore, I propose that HCPs will require additional training and support, including risk communication tools embedded in primary care infrastructure, if they are to successfully and reliably communicate risk and facilitate shared decision-making with patients. These findings will be crucial in developing trials of risk-based screening for bowel cancer and communicating these changes to participants and eventually the wider public.

References

1. IARC Working Group on the Evaluation of Cancer-Preventive Interventions. Colorectal cancer screening. Lyon (FR): International Agency for Research on Cancer; 2019. 1. Colorectal Cancer [cited 2024 Mar 11]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK553197>
2. National Cancer Institute (NCI). NCI Dictionary of Cancer Terms: Large intestine [Internet]. NCI; 2011 [cited 2024 Mar 11]. Available from: <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/large-intestine>
3. Menon G, Recio-Boiles A, Lotfollahzadeh S, Cagir B. Colon Cancer. [Updated 2024 Apr 20]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 [cited 2024 Mar 11]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK470380>
4. Kasi A, Handa S, Bhatti S, Umar S, Bansal A, Sun W. Molecular Pathogenesis and Classification of Colorectal Carcinoma. Curr Colorectal Cancer Rep [Internet]. 2020 Sep [cited 2024 Mar 11];16(5):97-106. doi: 10.1007/s11888-020-00458-z
5. Kastrinos F, Syngal S. Inherited colorectal cancer syndromes. Cancer J [Internet]. 2011 Nov-Dec [cited 2024 Mar 12];17(6):405-15. doi: 10.1097/PPO.0b013e318237e408
6. Hill MJ, Morson BC, Bussey HJ. Aetiology of adenoma--carcinoma sequence in large bowel. Lancet [Internet]. 1978 Feb 4 [cited 2024 Mar 12];1(8058):245-7. doi: 10.1016/s0140-6736(78)90487-7
7. Fearon ER, Vogelstein B. A genetic model for colorectal tumorigenesis. Cell [Internet]. 1990 Jun 1 [cited 2024 Mar 12];61(5):759-67. doi: 10.1016/0092-8674(90)90186-i
8. Yashiro M, Carethers JM, Laghi L, Saito K, Slezak P, Jaramillo E, et al. Genetic pathways in the evolution of morphologically distinct colorectal neoplasms. Cancer Res [Internet]. 2001 Mar 15 [cited 2024 Mar 12];61(6):2676-83
9. Jess P, Hansen IO, Gamborg M, Jess T; Danish Colorectal Cancer Group. A nationwide Danish cohort study challenging the categorisation into right-sided and left-sided colon cancer. BMJ Open [Internet]. 2013 May 28 [cited 2024 Mar 12];3(5):e002608. doi: 10.1136/bmjopen-2013-002608
10. Mangone L, Pinto C, Mancuso P, Ottone M, Bisceglia I, Chiaranda G, et al. Colon cancer survival differs from right side to left side and lymph node harvest number matter. BMC Public Health [Internet]. 2021 May 12 [cited 2024 Mar 12];21(1):906. doi: 10.1186/s12889-021-10746-4

11. Bray F, Laversanne M, Sung H, Ferlay J, Siegel RL, Soerjomataram I, et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin* [Internet]. 2024 May-Jun [cited 2021 Aug 6];74(3):229-263. doi: 10.3322/caac.21834
12. Cancer Research UK. Bowel cancer incidence statistics [Internet]. Cancer Research UK; 2015 [cited 2024 Mar 14]. Available from: <https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/bowel-cancer/incidence>
13. Cancer Research UK. Bowel cancer mortality statistics [Internet]. Cancer Research UK; 2015 [cited 2024 Mar 15]. Available from: <https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/bowel-cancer/mortality>
14. Morgan E, Arnold M, Gini A, Lorenzoni V, Cabasag CJ, Laversanne M, et al. Global burden of colorectal cancer in 2020 and 2040: incidence and mortality estimates from GLOBOCAN. *Gut* [Internet]. 2023 Feb [cited 2024 Mar 14];72(2):338-344. doi: 10.1136/gutjnl-2022-327736
15. Exarchakou A, Donaldson LJ, Girardi F, Coleman MP. Colorectal cancer incidence among young adults in England: Trends by anatomical sub-site and deprivation. *PLoS One* [Internet]. 2019 Dec 5 [cited 2024 Jul 5];14(12):e0225547. doi: 10.1371/journal.pone.0225547
16. Chambers AC, Dixon SW, White P, Williams AC, Thomas MG, Messenger DE. Demographic trends in the incidence of young-onset colorectal cancer: a population-based study. *Br J Surg* [Internet]. 2020 Apr [cited 2024 Jul 5];107(5):595-605. doi: 10.1002/bjs.11486
17. Araghi M, Soerjomataram I, Bardot A, Ferlay J, Cabasag CJ, Morrison DS, et al. Changes in colorectal cancer incidence in seven high-income countries: a population-based study. *Lancet Gastroenterol Hepatol* [Internet]. 2019 Jul [cited 2024 Jul 5];4(7):511-518. doi: 10.1016/S2468-1253(19)30147-5
18. Cancer Research UK. Survival for bowel cancer [Internet]. Cancer Research UK; 2021 [cited 2024 Apr 16]. Available from: <https://www.cancerresearchuk.org/about-cancer/bowel-cancer/survival>
19. Cardoso R, Guo F, Heisser T, De Schutter H, Van Damme N, Nilbert MC, et al. Overall and stage-specific survival of patients with screen-detected colorectal cancer in European countries: A population-based study in 9 countries. *Lancet Reg Health Eur* [Internet]. 2022 Jul 6 [cited 2024 Apr 16];21:100458. doi: 10.1016/j.lanepe.2022.100458
20. Forbes N, Hilsden RJ, Martel M, Ruan Y, Dube C, Rostom A, et al. Association Between Time to Colonoscopy After Positive Fecal Testing and Colorectal Cancer Outcomes: A Systematic Review. *Clin*

- Gastroenterol Hepatol [Internet]. 2021 Jul [cited 2024 Apr 16];19(7):1344-1354.e8. doi: 10.1016/j.cgh.2020.09.048
21. Rutherford C, Müller F, Faiz N, King MT, White K. Patient-reported outcomes and experiences from the perspective of colorectal cancer survivors: meta-synthesis of qualitative studies. J Patient Rep Outcomes [Internet]. 2020 Apr 25 [cited 2024 Apr 16];4(1):27. doi: 10.1186/s41687-020-00195-9
 22. Vega P, Valentín F, Cubiella J. Colorectal cancer diagnosis: Pitfalls and opportunities. World J Gastrointest Oncol [Internet]. 2015 Dec 15 [cited 2024 Mar 20];7(12):422-33. doi: 10.4251/wjgo.v7.i12.422
 23. Buron A, Román M, Augé JM, Macià F, Grau J, Sala M, et al. Changes in FIT values below the threshold of positivity and short-term risk of advanced colorectal neoplasia: Results from a population-based cancer screening program. Eur J Cancer [Internet]. 2019 Jan [cited 2024 Jul 14];107:53-59. doi: 10.1016/j.ejca.2018.11.004
 24. NHS England. Bowel cancer screening programme overview [Internet]. GOV.UK; 2015 [cited 2024 Apr 26]. Available from: <https://www.gov.uk/guidance/bowel-cancer-screening-programme-overview>
 25. Senore C, Basu P, Anttila A, Ponti A, Tomatis M, Vale DB, et al. Performance of colorectal cancer screening in the European Union Member States: data from the second European screening report. Gut [Internet]. 2019 Jul [cited 2024 Mar 20];68(7):1232-1244. doi: 10.1136/gutjnl-2018-317293
 26. Moss S, Mathews C, Day TJ, Smith S, Seaman HE, Snowball J, et al. Increased uptake and improved outcomes of bowel cancer screening with a faecal immunochemical test: results from a pilot study within the national screening programme in England. Gut [Internet]. 2017 Sep [cited 2024 Mar 20];66(9):1631-1644. doi: 10.1136/gutjnl-2015-310691
 27. Nierengarten MB. Colonoscopy remains the gold standard for screening despite recent tarnish: Although a recent study seemed to indicate that colonoscopies are not as effective as once thought at detecting colorectal cancer, a closer look at the study clears the confusion. Cancer [Internet]. 2023 Feb 1 [cited 2024 Mar 22];129(3):330-331. doi: 10.1002/cncr.34622
 28. Millien VO, Mansour NM. Bowel Preparation for Colonoscopy in 2020: A Look at the Past, Present, and Future. Curr Gastroenterol Rep [Internet]. 2020 May 6 [cited 2024 Mar 22];22(6):28. doi: 10.1007/s11894-020-00764-4

29. Juul FE, Cross AJ, Schoen RE, Senore C, Pinsky PF, Miller EA, et al. Effectiveness of Colonoscopy Screening vs Sigmoidoscopy Screening in Colorectal Cancer. JAMA Netw Open [Internet]. 2024 Feb 5 [cited 2024 Mar 22];7(2):e240007. doi: 10.1001/jamanetworkopen.2024.0007
30. NHS England. Bowel cancer screening: having a colonoscopy [Internet]. GOV.UK; 2022 [cited 2024 Mar 22]. Available from: <https://www.gov.uk/government/publications/bowel-cancer-screening-colonoscopy/bowel-cancer-screening-having-a-colonoscopy-fit>
31. Gimeno-García AZ, Quintero E. Role of colonoscopy in colorectal cancer screening: Available evidence. Best Pract Res Clin Gastroenterol [Internet]. 2023 Oct [cited 2024 Mar 22];66:101838. doi: 10.1016/j.bpg.2023.101838
32. Zhang J, Chen G, Li Z, Zhang P, Li X, Gan D, et al. Colonoscopic screening is associated with reduced Colorectal Cancer incidence and mortality: a systematic review and meta-analysis. J Cancer [Internet]. 2020 Aug 15 [cited 2024 Mar 25];11(20):5953-5970. doi: 10.7150/jca.46661
33. World Health Organization (WHO). Cancer - Screening and early detection [Internet]. WHO; 2010 May 16 [cited 2024 Apr 25]. Available from: <https://www.who.int/europe/news-room/fact-sheets/item/cancer-screening-and-early-detection-of-cancer>
34. NHS. NHS screening [Internet]. NHS; 2024 [cited 2024 Apr 25]. Available from: <https://www.nhs.uk/conditions/nhs-screening/>
35. UK National Screening Committee. Population screening explained [Internet]. GOV.UK; 2023 Jan 20 [cited 2024 Apr 25]. Available from: <https://www.gov.uk/guidance/population-screening-explained>
36. UK National Screening Committee. UK National Screening Committee: About us [Internet]. GOV.UK [cited 2024 Apr 25]. Available from: <https://www.gov.uk/government/organisations/uk-national-screening-committee/about>
37. Koo S, Neilson LJ, Von Wagner C, Rees CJ. The NHS Bowel Cancer Screening Program: current perspectives on strategies for improvement. Risk Manag Healthc Policy [Internet]. 2017 Dec 4 [cited 2021 Jun 29];10:177-187. doi: 10.2147/RMHP.S109116
38. NHS. Bowel cancer screening [Internet]. NHS; 2021 Nov 8 [cited 2022 Jul 14]. Available from: <https://www.nhs.uk/conditions/bowel-cancer-screening/>
39. UK National Screening Committee. Adult screening programme: Bowel cancer [Internet]. GOV.UK; 2018 [cited 2024 Apr 25]. Available from: <https://view-health-screening-recommendations.service.gov.uk/bowel-cancer/>

40. Bowel Cancer UK. Rolling FIT out in England [Internet]. Bowel Cancer UK; 2018 Jun 28 [cited 2024 Apr 26]. Available from: <https://www.bowelcanceruk.org.uk/news-and-blogs/research-blog/rolling-fit-out-in-england/>
41. World Health Organization (WHO). Health topics: Cancer [Internet]. WHO [cited 2024 Jan 29]. Available from: <https://www.who.int/health-topics/cancer>
42. Lew JB, Feletto E, Wade S, Caruana M, Kang YJ, Nickson C, et al. Benefits, harms and cost-effectiveness of cancer screening in Australia: an overview of modelling estimates. *Public Health Res Pract* [Internet]. 2019 Jul 31 [cited 2022 Jul 14];29(2):29121913. doi: 10.17061/phrp2921913
43. NHS England. NHS bowel cancer screening: helping you decide [Internet]. GOV.UK; 2024 [cited 2024 Apr 25]. Available from: <https://www.gov.uk/government/publications/bowel-cancer-screening-benefits-and-risks/nhs-bowel-cancer-screening-helping-you-decide>
44. Marcus PM, Prorok PC, Miller AB, DeVoto EJ, Kramer BS. Conceptualizing overdiagnosis in cancer screening. *J Natl Cancer Inst* [Internet]. 2015 Feb 6 [cited 2021 Oct 14];107(4):djv014. doi: 10.1093/jnci/djv014
45. NHS England. Bowel Cancer Screening Annual Report 2021 to 2022 [Internet]. GOV.UK; 2024 [cited 2024 Apr 25]. Available from: <https://www.gov.uk/government/publications/bowel-cancer-screening-annual-report-2021-to-2022/bowel-cancer-screening-annual-report-2021-to-2022>
46. Hirst Y, Stoffel S, Baio G, McGregor L, von Wagner C. Uptake of the English Bowel (Colorectal) Cancer Screening Programme: an update 5 years after the full roll-out. *Eur J Cancer* [Internet]. 2018 Nov [cited 2024 Apr 25];103:267-273. doi: 10.1016/j.ejca.2018.07.135
47. Aleksandrova K, Reichmann R, Kaaks R, Jenab M, Bueno-de-Mesquita HB, Dahm CC, et al. Development and validation of a lifestyle-based model for colorectal cancer risk prediction: the LiFeCRC score. *BMC Med* [Internet]. 2021 Jan 4 [cited 2022 Jul 14];19(1):1. doi: 10.1186/s12916-020-01826-0
48. Lansdorp-Vogelaar I, Meester R, de Jonge L, Buron A, Haug U, Senore C. Risk-stratified strategies in population screening for colorectal cancer. *Int J Cancer* [Internet]. 2022 Feb 1 [cited 2022 Jul 14];150(3):397-405. doi: 10.1002/ijc.33784
49. Kortlever TL, van der Vlugt M, Dekker E, Bossuyt PMM. Individualized faecal immunochemical test cut-off based on age and sex in colorectal cancer screening. *Prev Med Rep* [Internet]. 2021 Jun 9 [cited 2022 Jul 14];23:101447. doi: 10.1016/j.pmedr.2021.101447

50. Auge JM, Pellise M, Escudero JM, Hernandez C, Andreu M, Grau J, et al.; PROCOLON Group. Risk stratification for advanced colorectal neoplasia according to fecal hemoglobin concentration in a colorectal cancer screening program. *Gastroenterology* [Internet]. 2014 Sep [cited 2022 Jul 14];147(3):628-636.e1. doi: 10.1053/j.gastro.2014.06.008
51. Meester RGS, van de Schootbrugge-Vandermeer HJ, Breekveldt ECH, de Jonge L, Toes-Zoutendijk E, Kooyker A, et al; Dutch colorectal cancer screening working group. Faecal occult blood loss accurately predicts future detection of colorectal cancer. A prognostic model. *Gut* [Internet]. 2023 Jan [cited 2022 Aug 22];72(1):101-108. doi: 10.1136/gutjnl-2022-327188
52. Stegeman I, de Wijkerslooth TR, Stoop EM, van Leerdam ME, Dekker E, van Ballegooijen M, et al. Combining risk factors with faecal immunochemical test outcome for selecting CRC screenees for colonoscopy. *Gut* [Internet]. 2014 Mar [cited 2022 Sept 28];63(3):466-71. doi: 10.1136/gutjnl-2013-305013
53. Peng L, Weigl K, Boakye D, Brenner H. Risk Scores for Predicting Advanced Colorectal Neoplasia in the Average-risk Population: A Systematic Review and Meta-analysis. *Am J Gastroenterol* [Internet]. 2018 Dec [cited 2024 Apr 15];113(12):1788-1800. doi: 10.1038/s41395-018-0209-2
54. Usher-Smith JA, Harshfield A, Saunders CL, Sharp SJ, Emery J, Walter FM, et al. External validation of risk prediction models for incident colorectal cancer using UK Biobank. *Br J Cancer* [Internet]. 2018 Mar 6 [cited 2024 Apr 15];118(5):750-759. doi: 10.1038/bjc.2017.463
55. Hippisley-Cox J, Coupland C. Development and validation of risk prediction algorithms to estimate future risk of common cancers in men and women: prospective cohort study. *BMJ Open* [Internet]. 2015 Mar 17 [cited 2024 Apr 15];5(3):e007825. doi: 10.1136/bmjopen-2015-007825
56. Tao S, Hoffmeister M, Brenner H. Development and validation of a scoring system to identify individuals at high risk for advanced colorectal neoplasms who should undergo colonoscopy screening. *Clin Gastroenterol Hepatol* [Internet]. 2014 Mar [2024 Apr 15];12(3):478-85. doi: 10.1016/j.cgh.2013.08.042
57. Ma E, Sasazuki S, Iwasaki M, Sawada N, Inoue M; Tsugane S; Japan Public Health Center-based Prospective Study Group. 10-Year risk of colorectal cancer: development and validation of a prediction model in middle-aged Japanese men. *Cancer Epidemiol* [Internet]. 2010 Oct [cited 2024 Apr 15];34(5):534-41. doi: 10.1016/j.canep.2010.04.021

58. Driver JA, Gaziano JM, Gelber RP, Lee IM, Buring JE, Kurth T. Development of a risk score for colorectal cancer in men. *Am J Med* [Internet]. 2007 Mar [cited 2024 Apr 17];120(3):257-63. doi: 10.1016/j.amjmed.2006.05.055
59. Colditz GA, Atwood KA, Emmons K, Monson RR, Willett WC, Trichopoulos D, Hunter DJ. Harvard report on cancer prevention volume 4: Harvard Cancer Risk Index. Risk Index Working Group, Harvard Center for Cancer Prevention. *Cancer Causes Control* [Internet]. 2000 Jul [cited 2024 Apr 15];11(6):477-88. doi: 10.1023/a:1008984432272
60. Johnson CM, Wei C, Ensor JE, Smolenski DJ, Amos CI, Levin B, et al. Meta-analyses of colorectal cancer risk factors. *Cancer Causes Control* [Internet]. 2013 Jun [cited 2022 Jul 14];24(6):1207-22. doi: 10.1007/s10552-013-0201-5
61. Wei YS, Lu JC, Wang L, Lan P, Zhao HJ, Pan ZZ, et al. Risk factors for sporadic colorectal cancer in southern Chinese. *World J Gastroenterol* [Internet]. 2009 May 28 [cited 2024 Apr 15];15(20):2526-30. doi: 10.3748/wjg.15.2526
62. NHS England. Supporting GPs with electronic cancer decision support (CDS) tools [Internet]. NHS England [cited 2024 Apr 15]. Available from: <https://transform.england.nhs.uk/key-tools-and-info/digital-playbooks/cancer-digital-playbook/supporting-gps-with-electronic-cancer-decision-support-tools/>
63. Saunders CL, Kilian B, Thompson DJ, McGeoch LJ, Griffin SJ, Antoniou AC, et al. External Validation of Risk Prediction Models Incorporating Common Genetic Variants for Incident Colorectal Cancer Using UK Biobank. *Cancer Prev Res (Phila)* [Internet]. 2020 Jun [cited 2024 Apr 15];13(6):509-520. doi: 10.1158/1940-6207.CAPR-19-0521
64. Thomas M, Sakoda LC, Hoffmeister M, Rosenthal EA, Lee JK, van Duijnhoven FJB, et al. Genome-wide Modeling of Polygenic Risk Score in Colorectal Cancer Risk. *Am J Hum Genet* [Internet]. 2020 Sep 3 [cited 2024 Apr 15];107(3):432-444. doi: 10.1016/j.ajhg.2020.07.006
65. Househ M, Aldosari B. The Hazards of Data Mining in Healthcare. *Stud Health Technol Inform* [Internet]. 2017 [cited 2024 Apr 15];238:80-83. PMID: 28679892
66. Shanbehzadeh M, Nopour R, Kazemi-Arpanahi. Comparison of Four Data Mining Algorithms for Predicting Colorectal Cancer Risk. *J Adv Med Biomed Res* [Internet]. 2021 Feb [cited 2024 Apr 15];29(133):100-108. doi:10.30699/jambs.29.133.100
67. C Kitchener H, Canfell K, Gilham C, Sargent A, Roberts C, Desai M, et al. The clinical effectiveness and cost-effectiveness of primary human papillomavirus cervical screening in England: extended

- follow-up of the ARTISTIC randomised trial cohort through three screening rounds. *Health Technol Assess* [Internet]. 2014 Apr [cited 2024 Apr 29];18(23):1-196. doi: 10.3310/hta18230
68. Hull MA, Rees CJ, Sharp L, Koo S. A risk-stratified approach to colorectal cancer prevention and diagnosis. *Nat Rev Gastroenterol Hepatol* [Internet]. 2020 Dec [cited 2021 Sep 30];17(12):773-780. doi: 10.1038/s41575-020-00368-3
69. Ghanouni A, Sanderson SC, Pashayan N, Renzi C, von Wagner C, Waller J. Attitudes towards risk-stratified breast cancer screening among women in England: A cross-sectional survey. *J Med Screen* [Internet]. 2020 Sep [cited 2021 Oct 11];27(3):138-145. doi: 10.1177/0969141319883662
70. Hall AE, Chowdhury S, Hallowell N, Pashayan N, Dent T, Pharoah P, et al. Implementing risk-stratified screening for common cancers: a review of potential ethical, legal and social issues. *J Public Health (Oxf)* [Internet]. 2014 Jun [cited 2021 Oct 14];36(2):285-91. doi: 10.1093/pubmed/fdt078
71. Cairns JM, Greenley S, Bamidele O, Weller D. A scoping review of risk-stratified bowel screening: current evidence, future directions. *Cancer Causes Control* [Internet]. 2022 May [cited 2022 Jul 14];33(5):653-685. doi: 10.1007/s10552-022-01568-9
72. Chowdhury S, Dent T, Pashayan N, Hall A, Lyratzopoulos G, Hallowell N, et al. Incorporating genomics into breast and prostate cancer screening: assessing the implications. *Genet Med* [Internet]. 2013 Jun [cited 2022 Jul 14];15(6):423-32. doi: 10.1038/gim.2012.167
73. Meisel SF, Rahman B, Side L, Fraser L, Gessler S, Lanceley A, et al.; PROMISE-2016 study team. Genetic testing and personalized ovarian cancer screening: a survey of public attitudes. *BMC Womens Health* [Internet]. 2016 Jul 26 [cited 2021 Oct 11];16:46. doi: 10.1186/s12905-016-0325-3
74. Thomas C, Mandrik O, Saunders CL, Thompson D, Whyte S, Griffin S, et al. The Costs and Benefits of Risk Stratification for Colorectal Cancer Screening Based On Phenotypic and Genetic Risk: A Health Economic Analysis. *Cancer Prev Res (Phila)* [Internet]. 2021 Aug [cited 2024 Apr 29];14(8):811-822. doi: 10.1158/1940-6207.CAPR-20-0620
75. UK National Screening Committee. Criteria for a population screening programme [Internet]. GOV.UK; 2022 Sep 29 [cited 2024 May 9]. Available from: <https://www.gov.uk/government/publications/evidence-review-criteria-national-screening-programmes/criteria-for-appraising-the-viability-effectiveness-and-appropriateness-of-a-screening-programme>

76. Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. Framework for design and evaluation of complex interventions to improve health. *BMJ* [Internet]. 2000 Sep 16 [cited 2024 May 1];321(7262):694-6. doi: 10.1136/bmj.321.7262.694
77. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ* [Internet]. 2015 Mar 19 [cited 2024 May 1];350:h1258. doi: 10.1136/bmj.h1258
78. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ* [Internet]. 2021 Sep 30 [cited 2024 May 1];374:n2061. doi: 10.1136/bmj.n2061
79. Leatherman S, Sutherland K. The Quest for Quality: Refining the NHS Reforms: A Policy Analysis and Chartbook [Internet]. London: Nuffield Trust; 2008 [cited 2024 May 1]. Available from: <https://www.nuffieldtrust.org.uk/sites/default/files/2017-01/quest-for-quality-report-web-final.pdf>
80. Dyer TA, Owens J, Robinson PG. The acceptability of healthcare: from satisfaction to trust. *Community Dent Health* [Internet]. 2016 Dec [cited 2024 May 9];33(4):242-251. doi: 10.1922/CDH_3902Dyer10
81. Sidani S, Miranda J, Epstein DR, Bootzin RR, Cousins J, Moritz P. Relationships between personal beliefs and treatment acceptability, and preferences for behavioral treatments. *Behav Res Ther* [Internet]. 2009 Oct [cited 2024 May 1];47(10):823-9. doi: 10.1016/j.brat.2009.06.009
82. Marlow LAV, Nemec M, Barnes J, Waller J. Testing key messages about extending cervical screening intervals. *Patient Educ Couns* [Internet]. 2022 Aug [cited 2022 Oct 13];105(8):2757-2762. doi: 10.1016/j.pec.2022.04.006
83. Mulcahy Symmons S, Waller J, McBride E. Testing positive for Human Papillomavirus (HPV) at primary HPV cervical screening: A qualitative exploration of women's information needs and preferences for communication of results. *Prev Med Rep* [Internet]. 2021 Aug 19 [cited 2022 Oct 13];24:101529. doi: 10.1016/j.pmedr.2021.101529
84. Nemec M, Waller J, Barnes J, Marlow LAV. Acceptability of extending HPV-based cervical screening intervals from 3 to 5 years: an interview study with women in England. *BMJ Open* [Internet]. 2022 May 4 [cited 2022 Oct 14];12(5):e058635. doi: 10.1136/bmjopen-2021-058635
85. O'Cathain A, Croot L, Duncan E, Rousseau N, Sworn K, Turner KM, et al. Guidance on how to develop complex interventions to improve health and healthcare. *BMJ Open* [Internet]. 2019 Aug 15 [cited 2024 May 8];9(8):e029954. doi: 10.1136/bmjopen-2019-029954

86. Park SY, Nicksic Sigmon C, Boeldt D. A Framework for the Implementation of Digital Mental Health Interventions: The Importance of Feasibility and Acceptability Research. *Cureus* [Internet]. 2022 Sep [cited 2024 May 1];14(9). doi:10.7759/cureus.29329
87. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Serv Res* [Internet]. 2017 Jan 26 [cited 2022 Jul 14];17(1):88. doi: 10.1186/s12913-017-2031-8
88. Ajzen I. The theory of planned behaviour. *Organ Behav Hum Decis Process* [Internet]. 1991 Dec [cited 2024 May 9];50(2):179-211. doi: 10.1016/0749-5978(91)90020-T
89. Michie S, Johnston M, Abraham C, Lawton R, Parker D, Walker A. Making psychological theory useful for implementing evidence based practice: a consensus approach. *BMJ Qual Saf* [Internet]. 2005 [cited 2024 May 9];14:26-33. doi: 10.1136/qshc.2004.011155
90. Diefenbach M, Leventhal H. The Common-Sense Model of Illness Representation: Theoretical and Practical Considerations. *J Soc Distress Homeless* [Internet]. 1996 Jan [cited 2024 May 9];5(1):11-38. doi: 10.1007/BF02090456
91. Damschroder LJ, Reardon CM, Widerquist MAO, Lowery J. The updated Consolidated Framework for Implementation Research based on user feedback. *Implement Sci* [Internet]. 2022 Oct 29 [cited 2024 May 9];17(1):75. doi: 10.1186/s13012-022-01245-0
92. Damschroder, L.J., Aron, D.C., Keith, R.E. et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Sci* [Internet]. 2009 Aug 7 [cited 2024 May 9];4(50). doi: 10.1186/1748-5908-4-50
93. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q* [Internet]. 2004 [cited 2022 Jul 14];82(4):581-629. doi: 10.1111/j.0887-378X.2004.00325.x
94. Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. *Jt Comm J Qual Patient Saf* [Internet]. 2008 Apr [cited 2024 May 9];34(4):228-43. doi: 10.1016/s1553-7250(08)34030-6
95. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci* [Internet]. 2011 Apr 23 [cited 2024 May 9];6:42. doi: 10.1186/1748-5908-6-42

96. National Institute for Health and Care Research (NIHR). UK Standards for Public Involvement [Internet]. NIHR [cited 2021 Jun 24]. Available from: <https://sites.google.com/nihr.ac.uk/pi-standards/home>
97. Taylor LC, Law K, Hutchinson A, Dennison RA, Usher-Smith JA. Acceptability of risk stratification within population-based cancer screening from the perspective of healthcare professionals: A mixed methods systematic review and recommendations to support implementation. PLoS One [Internet]. 2023 Feb 24 [cited 2024 Nov 1];18(2):e0279201. doi: 10.1371/journal.pone.0279201
98. Pashayan N, Antoniou AC, Ivanus U, Esserman LJ, Easton DF, French D, et al. Personalized early detection and prevention of breast cancer: ENVISION consensus statement. Nat Rev Clin Oncol [Internet]. 2020 Nov [2022 Jul 14];17(11):687-705. doi: 10.1038/s41571-020-0388-9
99. Dobrow MJ, Hagens V, Chafe R, Sullivan T, Rabeneck L. Consolidated principles for screening based on a systematic review and consensus process. CMAJ [Internet]. 2018 Apr 9 [cited 2022 Jul 14];190(14):E422-E429. doi: 10.1503/cmaj.171154
100. Rainey L, van der Waal D, Jervaeus A, Wengström Y, Evans DG, Donnelly LS, et al. Are we ready for the challenge of implementing risk-based breast cancer screening and primary prevention? Breast [Internet]. 2018 Jun [cited 2022 Jul 14];39:24-32. doi: 10.1016/j.breast.2018.02.029
101. Harrison H, Thompson RE, Lin Z, Rossi SH, Stewart GD, Griffin SJ, et al. Risk Prediction Models for Kidney Cancer: A Systematic Review. Eur Urol Focus [Internet]. 2021 Nov [cited 2021 Sep 30];7(6):1380-1390. doi: 10.1016/j.euf.2020.06.024
102. Lee A, Mavaddat N, Wilcox AN, Cunningham AP, Carver T, Hartley S, et al. BOADICEA: a comprehensive breast cancer risk prediction model incorporating genetic and nongenetic risk factors. Genet Med [Internet]. 2019 Aug [cited 2022 Jul 14];21(8):1708-1718. doi: 10.1038/s41436-018-0406-9
103. Bramer WM, Rethlefsen ML, Kleijnen J, Franco OH. Optimal database combinations for literature searches in systematic reviews: a prospective exploratory study. Syst Rev [Internet]. 2017 Dec 6 [cited 2022 Jul 14];6(1):245. doi: 10.1186/s13643-017-0644-y
104. Ouzzani M, Hammady H, Fedorowicz Z, Elmagarmid A. Rayyan-a web and mobile app for systematic reviews. Syst Rev [Internet]. 2016 Dec 5 [cited 2022 Jul 14];5(1):210. doi: 10.1186/s13643-016-0384-4
105. Rainey L, van der Waal D, Wengström Y, Jervaeus A, Broeders MJM. Women's perceptions of the adoption of personalised risk-based breast cancer screening and primary prevention: a

systematic review. *Acta Oncol* [Internet]. 2018 Oct [cited 2022 Jul 14];57(10):1275-1283. doi: 10.1080/0284186X.2018.1481291

106. Bellhouse S, Hawkes RE, Howell SJ, Gorman L, French DP. Breast Cancer Risk Assessment and Primary Prevention Advice in Primary Care: A Systematic Review of Provider Attitudes and Routine Behaviours. *Cancers (Basel)* [Internet]. 2021 Aug 18 [cited 2022 Jul 14];13(16):4150. doi: 10.3390/cancers13164150

107. Hong QN, Pluye P, Fàbregues S, Bartlett G, Boardman F, Cargo M, et al. Mixed Methods Appraisal Tool (MMAT), version 2018. Registration of Copyright (#1148552), Canadian Intellectual Property Office, Industry Canada [cited 2022 Jul 14].

108. Stern C, Lizarondo L, Carrier J, Godfrey C, Rieger K, Salmond S, et al. Methodological guidance for the conduct of mixed methods systematic reviews. *JBISynth* [Internet]. 2020 Oct [cited 2022 Jul 14];18(10):2108-2118. doi: 10.11124/JBISIR-D-19-00169

109. Aromataris E, Lockwood C, Porritt K, Pilla B, Jordan Z, editors. *JBIS Manual for Evidence Synthesis*. JBI [Internet]; 2024 [cited 2024 Aug 21]. Available from: <https://synthesismanual.jbi.global>

110. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* [Internet]. 2009 Aug 7 [cited 2024 Aug 21];4:50. doi: 10.1186/1748-5908-4-50

111. Carroll C, Booth A, Cooper K. A worked example of “best fit” framework synthesis: A systematic review of views concerning the taking of some potential chemopreventative agents. *BMC Med Res Methodol* [Internet]. 2011 Mar 3 [cited 2022 Jul 14];11,29. doi: 10.1186/1471-2288-11-29

112. Carroll C, Booth A, Leaviss J, Rick J. “Best fit” framework synthesis: refining the method. *BMC Med Res Methodol* [Internet]. 2013 Mar 13 [cited 2022 Jul 14];13,37:1-16. doi: 10.1186/1471-2288-13-37

113. Blouin-Bougie J, Amara N, Simard J. Toward a Population-Based Breast Cancer Risk Stratification Approach? The Needs and Concerns of Healthcare Providers. *J Pers Med* [Internet]. 2021 Jun 10 [cited 2021 Oct 11];11(6):540. doi: 10.3390/jpm11060540

114. McWilliams L, Woof VG, Donnelly LS, Howell A, Evans DG, French DP. Risk stratified breast cancer screening: UK healthcare policy decision-making stakeholders’ views on a low-risk breast screening pathway. *BMC Cancer* [Internet]. 2020 Jul 22 [cited 2021 Oct 11];20,680. doi: 10.1186/s12885-020-07158-9

115. Woof VG, McWilliams L, Donnelly LS, Howell A, Evans DG, Maxwell AJ, et al. Introducing a low-risk breast screening pathway into the NHS Breast Screening Programme: Views from healthcare professionals who are delivering risk-stratified screening. *Womens Health (Lond)* [Internet]. 2021 Jan-Dec [cited 2021 Oct 11];17:17455065211009746. doi: 10.1177/17455065211009746
116. Fürst N, Kiechle M, Strahwald B, Quante AS. Mammography Screening 2.0 - How Can Risk-Adapted Screening be Implemented in Clinical Practice?: Results of a Focus Group Discussion with Experts in the RISIKOLOTSE.DE Project. *Geburtshilfe Frauenheilkd* [Internet]. 2018 May [2022 Jul 14];78(5):506-511. doi: 10.1055/a-0603-4314
117. Rainey L, van der Waal D, Donnelly LS, Evans DG, Wengström Y, Broeders M. Women's decision-making regarding risk-stratified breast cancer screening and prevention from the perspective of international healthcare professionals. *PLoS One* [Internet]. 2018 Jun 1 [cited 2021 Oct 11];13(6):e0197772. doi: 10.1371/journal.pone.0197772
118. Puzhko S, Gagnon J, Simard J, Knopper BM, Siedlikowski S, Bartlett G. Health professionals' perspectives on breast cancer risk stratification: understanding evaluation of risk versus screening for disease. *Public Health Rev* [Internet]. 2019 [cited 2022 Jul 14];40,2. doi: 10.1186/s40985-019-0111-5
119. Hann KEJ, Fraser L, Side L, Gessler S, Waller J, Sanderson SC, et al; PROMISE study team. Health care professionals' attitudes towards population-based genetic testing and risk-stratification for ovarian cancer: a cross-sectional survey. *BMC Womens Health* [Internet]. 2017 Dec 16 [cited 2022 Jul 14];17(1):132. doi: 10.1186/s12905-017-0488-6
120. Usher-Smith JA, Harvey-Kelly LLW, Rossi SH, Harrison H, Griffin SJ, Stewart GD. Acceptability and potential impact on uptake of using different risk stratification approaches to determine eligibility for screening: A population-based survey. *Health Expect* [Internet]. 2021 Apr [cited 2021 Oct 11];24(2):341-351. doi: 10.1111/hex.13175
121. Mbuya Bienne C, Pashayan N, Brooks JD, Dorval M, Chiquette J, Eloy L, et al. Women's Views on Multifactorial Breast Cancer Risk Assessment and Risk-Stratified Screening: A Population-Based Survey from Four Provinces in Canada. *J Pers Med* [Internet]. 2021 Feb 2 [cited 2021 Oct 11];11(2):95. doi: 10.3390/jpm11020095
122. Rainey L, van der Waal D, Broeders MJM. Dutch women's intended participation in a risk-based breast cancer screening and prevention programme: a survey study identifying preferences, facilitators and barriers. *BMC Cancer* [Internet]. 2020 Oct 6 [cited 2022 Jul 14];20(1):965. doi: 10.1186/s12885-020-07464-2

123. Koitsalu M, Sprangers MA, Eklund M, Czene K, Hall P, Grönberg H, et al. Public interest in and acceptability of the prospect of risk-stratified screening for breast and prostate cancer. *Acta Oncol* [Internet]. 2016 [cited 2022 Jul 14];55(1):45-51. doi: 10.3109/0284186X.2015.1043024
124. Rahman B, Meisel SF, Fraser L, Side L, Gessler S, Wardle J, et al. Population-based genetic risk prediction and stratification for ovarian cancer: views from women at high risk. *Fam Cancer* [Internet]. 2015 Mar [cited 2021 Oct 11];14(1):135-44. doi: 10.1007/s10689-014-9769-5
125. McWilliams L, Woof VG, Donnelly LS, Howell A, Evans DG, French DP. Extending screening intervals for women at low risk of breast cancer: do they find it acceptable? *BMC Cancer* [Internet]. 2021 May 29 [cited 2021 Oct 11];21(1):637. doi: 10.1186/s12885-021-08347-w
126. Woof VG, Ruane H, French DP, Ulph F, Qureshi N, Khan N, et al. The introduction of risk stratified screening into the NHS breast screening Programme: views from British-Pakistani women. *BMC Cancer* [Internet]. 2020 May 20 [cited 2022 Jul 14];20(1):452. doi: 10.1186/s12885-020-06959-2
127. Sierra MA, Wheeler JCW, Devereux L, Trainer AH, Keogh L. Exploring Implementation of Personal Breast Cancer Risk Assessments. *J Pers Med* [Internet]. 2021 Sep 30 [cited 2022 Jul 14];11(10):992. doi: 10.3390/jpm11100992
128. Dunlop K, Rankin NM, Smit AK, Salgado Z, Newson AJ, Keogh L, et al. Acceptability of risk-stratified population screening across cancer types: Qualitative interviews with the Australian public. *Health Expect* [Internet]. 2021 Aug [cited 2021 Oct 11];24(4):1326-1336. doi: 10.1111/hex.13267
129. Lippey J, Keogh LA, Mann GB, Campbell IG, Forrest LE. "A Natural Progression": Australian Women's Attitudes About an Individualized Breast Screening Model. *Cancer Prev Res (Phila)* [Internet]. 2019 Jun [cited 2022 Jul 14];12(6):383-390. doi: 10.1158/1940-6207.CAPR-18-0443
130. Hann KEJ, Ali N, Gessler S, Fraser LSM, Side L, Waller J et al. Attitudes towards a programme of risk assessment and stratified management for ovarian cancer: a focus group study of UK South Asian's perspectives. *BMJ Open* [Internet]. 2018 Jul 18 [cited 2021 Oct 11];8:e021782. doi: 10.1136/bmjopen-2018-021782
131. Henneman L, Timmermans DR, Bouwman CM, Cornel MC, Meijers-Heijboer H. 'A low risk is still a risk': exploring women's attitudes towards genetic testing for breast cancer susceptibility in order to target disease prevention. *Public Health Genomics* [Internet]. 2011 [cited 2022 Jul 14];14(4-5):238-47. doi: 10.1159/000276543

132. Meisel SF, Side L, Fraser L, Gessler S, Wardle J, Lanceley A. Population-based, risk-stratified genetic testing for ovarian cancer risk: a focus group study. *Public Health Genomics* [Internet]. 2013 [cited 2022 Jul 14];16(4):184-91. doi: 10.1159/000352028
133. Kelley-Jones C, Scott S, Waller J. UK Women's Views of the Concepts of Personalised Breast Cancer Risk Assessment and Risk-Stratified Breast Screening: A Qualitative Interview Study. *Cancers (Basel)* [Internet]. 2021 Nov 19 [cited 2022 Jul 14];13(22):5813. doi: 10.3390/cancers13225813
134. Ghanouni A, Waller J, Stoffel ST, Vlaev I, von Wagner C. Acceptability of risk-stratified breast screening: Effect of the order of presenting risk and benefit information. *J Med Screen* [Internet]. 2020 Mar [cited 2022 Jul 14];27(1):52-56. doi: 10.1177/0969141319877669
135. Rainey L, Jervaeus A, Donnelly LS, Evans DG, Hammarström M, Hall P, et al. Women's perceptions of personalized risk-based breast cancer screening and prevention: An international focus group study. *Psychooncology* [Internet]. 2019 May [cited 2021 Oct 11];28(5):1056-1062. doi: 10.1002/pon.5051. Epub 2019 Mar 25. PMID: 30848018; PMCID: PMC6593462.
136. Piper MS, Maratt JK, Zikmund-Fisher BJ, Lewis C, Forman J, Vijan S, et al. Patient Attitudes Toward Individualized Recommendations to Stop Low-Value Colorectal Cancer Screening. *JAMA Netw Open* [Internet]. 2018 Dec 7 [cited 2022 Jul 14];1(8):e185461. doi: 10.1001/jamanetworkopen.2018.5461
137. He X, Schifferdecker KE, Ozanne EM, Tosteson ANA, Woloshin S, Schwartz LM. How Do Women View Risk-Based Mammography Screening? A Qualitative Study. *J Gen Intern Med* [Internet]. 2018 Nov [cited 2022 Jul 14];33(11):1905-1912. doi: 10.1007/s11606-018-4601-9
138. Roland KB, Greek A, Hawkins NA, Lin L, Benard VB. Provider beliefs associated with cervical cancer screening interval recommendations: A pilot study in Federally Qualified Health Centers. *Prev Med Rep* [Internet]. 2015 [cited 2022 Jul 14];2:444-447. doi: 10.1016/j.pmedr.2015.05.008
139. Roland KB, Benard VB, Greek A, Hawkins NA, Manninen D, Saraiya M. Primary care provider practices and beliefs related to cervical cancer screening with the HPV test in Federally Qualified Health Centers. *Prev Med* [Internet]. 2013 Nov [cited 2022 Jul 14];57(5):419-25. doi: 10.1016/j.ypmed.2013.04.012
140. Tatar O, Wade K, McBride E, Thompson E, Head KJ, Perez S, et al. Are Health Care Professionals Prepared to Implement Human Papillomavirus Testing? A Review of Psychosocial Determinants of Human Papillomavirus Test Acceptability in Primary Cervical Cancer Screening. *J Womens Health (Larchmt)* [Internet]. 2020 Mar [cited 2022 Jul 14];29(3):390-405. doi: 10.1089/jwh.2019.7678

141. Benard VB, Greek A, Roland KB, Hawkins NA, Lin L, Saraiya M. Change in Provider Beliefs Regarding Cervical Cancer Screening Intervals After an Educational Intervention. *J Womens Health (Larchmt)* [Internet]. 2016 May [cited 2022 Jul 14];25(5):422-7. doi: 10.1089/jwh.2015.5706
142. Smit AK, Sharman AR, Espinoza D, Wallingford C, Young MA, Dunlop K, et al. Knowledge, views and expectations for cancer polygenic risk testing in clinical practice: A cross-sectional survey of health professionals. *Clin Genet* [Internet]. 2021 Oct [cited 2022 Jul 14];100(4):430-439. doi: 10.1111/cge.14025
143. Taylor LC, Hutchinson A, Law K, Shah V, Usher-Smith JA, Dennison RA. Acceptability of risk stratification within population-based cancer screening from the perspective of the general public: A mixed-methods systematic review. *Health Expect* [Internet]. 2023 Jun [cited 2024 Feb 22];26(3):989-1008. doi: 10.1111/hex.13739
144. Sekhon M, Cartwright M, Francis JJ. Acceptability of health care interventions: A theoretical framework and proposed research agenda. *Br J Health Psychol* [Internet]. 2018 Sep [cited 2022 Jul 14];23(3):519-531. doi: 10.1111/bjhp.12295
145. Meisel SF, Pashayan N, Rahman B, Side L, Fraser L, Gessler S, et al. Adjusting the frequency of mammography screening on the basis of genetic risk: Attitudes among women in the UK. *Breast* [Internet]. 2015 Jun [cited 2022 Jul 14];24(3):237-41. doi: 10.1016/j.breast.2015.02.001
146. Rainey L, van der Waal D, Jervaeus A, Donnelly LS, Evans DG, Hammarström M, et al. European women's perceptions of the implementation and organisation of risk-based breast cancer screening and prevention: a qualitative study. *BMC Cancer* [Internet]. 2020 Mar 24 [cited 2021 Oct 11];20(1):247. doi: 10.1186/s12885-020-06745-0
147. Dodd RH, Obermair HM, McCaffery KJ. A Thematic Analysis of Attitudes Toward Changes to Cervical Screening in Australia. *JMIR Cancer* [Internet]. 2019 Apr 11 [cited 2022 Oct 25];5(1):e12307. doi: 10.2196/12307
148. Taylor LC, Dennison RA, Griffin SJ, John SD, Lansdorp-Vogelaar I, Thomas CV, et al. Implementation of risk stratification within bowel cancer screening: a community jury study exploring public acceptability and communication needs. *BMC Public Health* [Internet]. 2023 Sep 15 [cited 2024 Mar 26];23(1):1798. doi: 10.1186/s12889-023-16704-6
149. Smith G, Wales C. The theory and practice of citizens' juries. *Policy and Politics* [Internet]. 1999 [cited 2022 Sep 22];27(3):295-309. doi: 10.1332/030557399782453118

150. Degeling C, Rychetnik L, Street J, Thomas R, Carter SM. Influencing health policy through public deliberation: Lessons learned from two decades of Citizens'/community juries. *Soc Sci Med* [Internet]. 2017 Apr [cited 2022 Jul 14];179:166-171. doi: 10.1016/j.socscimed.2017.03.003
151. Rychetnik L, Carter SM, Abelson J, Thornton H, Barratt A, Entwistle VA, et al. Enhancing citizen engagement in cancer screening through deliberative democracy. *J Natl Cancer Inst* [Internet]. 2013 Mar 20 [cited 2022 Jul 14];105(6):380-6. doi: 10.1093/jnci/djs649
152. Thomas R, Sims R, Degeling C, Street JM, Carter SM, Rychetnik L, et al. CJCheck Stage 1: development and testing of a checklist for reporting community juries - Delphi process and analysis of studies published in 1996-2015. *Health Expect* [Internet]. 2017 Aug [cited 2022 Aug 24];20(4):626-637. doi: 10.1111/hex.12493
153. Dennison RA, Boscott RA, Thomas R, Griffin SJ, Harrison H, John SD, et al. A community jury study exploring the public acceptability of using risk stratification to determine eligibility for cancer screening. *Health Expect* [Internet]. 2022 Aug [cited 2022 Aug 2];25(4):1789-1806. doi: 10.1111/hex.13522
154. Braun V, Clarke V. Conceptual and design thinking for thematic analysis. *Qual Psychol* [Internet]. 2022 [cited 2023 Aug 31];9(1):3-26. doi: 10.1037/qap0000196
155. Roberts K, Dowell A, Nie JB. Attempting rigour and replicability in thematic analysis of qualitative research data; a case study of codebook development. *BMC Med Res Methodol* [Internet]. 2019 Mar 28 [cited 2024 Jun 11];19(1):66. doi: 10.1186/s12874-019-0707-y
156. StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC
157. Hägglund M, McMillan B, Whittaker R, Blease C. Patient empowerment through online access to health records. *BMJ* [Internet]. 2022 Sep 29 [cited 2022 Nov 15];378:e071531. doi: 10.1136/bmj-2022-071531
158. Riedinger C, Campbell J, Klein WMP, Ferrer RA, Usher-Smith JA. Analysis of the components of cancer risk perception and links with intention and behaviour: A UK-based study. *PLoS One* [Internet]. 2022 Jan 13 [cited 2022 Oct 7];17(1):e0262197. doi: 10.1371/journal.pone.0262197
159. Usher-Smith J, von Wagner C, Ghanouni A. Behavioural Challenges Associated With Risk-Adapted Cancer Screening. *Cancer Control* [Internet]. 2022 Jan-Dec [cited 2022 Oct 7];29:10732748211060289. doi: 10.1177/10732748211060289
160. Usher-Smith JA, Mills KM, Riedinger C, Saunders CL, Helsing LM, Lytvyn L, et al. The impact of information about different absolute benefits and harms on intention to participate in colorectal

- cancer screening: A think-aloud study and online randomised experiment. PLoS One [Internet]. 2021 Feb 16 [cited 2021 Oct 6];16(2):e0246991. doi: 10.1371/journal.pone.0246991
161. Bayne M, Fairey M, Silarova B, Griffin SJ, Sharp SJ, Klein WMP, et al. Effect of interventions including provision of personalised cancer risk information on accuracy of risk perception and psychological responses: A systematic review and meta-analysis. Patient Educ Couns [Internet]. 2020 Jan[cited 2022 Oct 7] ;103(1):83-95. doi: 10.1016/j.pec.2019.08.010
162. Weinstein ND, Atwood K, Puleo E, Fletcher R, Colditz G, Emmons K. Colon cancer: risk perceptions and risk communication. J Health Commun [Internet]. 2004 Jan-Feb [cited 2022 Oct 13];9(1):53-65. doi: 10.1080/10810730490271647
163. Smith SG, Wolf MS, Obichere A, Raine R, Wardle J, von Wagner C. The development and testing of a brief ('gist-based') supplementary colorectal cancer screening information leaflet. Patient Educ Couns [Internet]. 2013 Dec [cited 2022 Jul 14];93(3):619-25. doi: 10.1016/j.pec.2013.08.013
164. Usher-Smith JA, Silarova B, Lophatananon A, Duschinsky R, Campbell J, Warcaba J, et al. Responses to provision of personalised cancer risk information: a qualitative interview study with members of the public. BMC Public Health [Internet]. 2017 Dec 22 [cited 2022 Oct 7];17(1):977. doi: 10.1186/s12889-017-4985-1
165. French DP, Southworth J, Howell A, Harvie M, Stavrinou P, Watterson D, et al. Psychological impact of providing women with personalised 10-year breast cancer risk estimates. Br J Cancer [Internet]. 2018 Jun [cited 2022 Oct 13];118(12):1648-1657. doi: 10.1038/s41416-018-0069-y
166. Eccles DW, Arsal G. The think aloud method: what is it and how do I use it? Qualitative Research in Sport, Exercise and Health [Internet]. 2017 [cited 2023 Sep 28];9(4), 514-531. doi: 10.1080/2159676x.2017.1331501
167. Gardner B, Tang V. Reflecting on non-reflective action: an exploratory think-aloud study of self-report habit measures. Br J Health Psychol [Internet]. 2014 May [cited 2023 Sep 28];19(2):258-73. doi: 10.1111/bjhp.12060
168. Darker CD, French DP. What sense do people make of a theory of planned behaviour questionnaire?: a think-aloud study. J Health Psychol [Internet]. 2009 Oct [cited 2023 Sep 28];14(7):861-71. doi: 10.1177/1359105309340983
169. Ericsson KA, Fox MC. Thinking aloud is not a form of introspection but a qualitatively different methodology: reply to Schooler (2011). Psychol Bull [Internet]. 2011 Mar [cited 2022 Jul 14];137(2):351-4. doi: 10.1037/a0022388

170. Fox MC, Ericsson KA, Best R. Do procedures for verbal reporting of thinking have to be reactive? A meta-analysis and recommendations for best reporting methods. *Psychol Bull* [Internet]. 2011 Mar [cited 2022 Jul 14];137(2):316-44. doi: 10.1037/a0021663
171. Smith SG, Vart G, Wolf MS, Obichere A, Baker HJ, Raine R, et al. How do people interpret information about colorectal cancer screening: observations from a think-aloud study. *Health Expect* [Internet]. 2015 Oct [cited 2022 Jul 14];18(5):703-14. doi: 10.1111/hex.12117
172. Nielsen J. Estimating the number of subjects needed for a thinking aloud test. *Int J Hum Comput Stud* [Internet]. 1994 Sep 1[cited 2022 Oct 13]; 41(3):385-397. doi: 10.1006/ijhc.1994.1065
173. Okan Y, Petrova D, Smith SG, Lesic V, Bruine de Bruin W. How Do Women Interpret the NHS Information Leaflet about Cervical Cancer Screening? *Med Decis Making* [Internet]. 2019 Oct [cited 2024 Jun 7];39(7):738-754. doi: 10.1177/0272989X19873647
174. Angelova N, Taylor L, McKee L, Fearn N, Mitchell T. User testing a patient information resource about potential complications of vaginally inserted synthetic mesh. *BMC Womens Health* [Internet]. 2021 Jan 25 [cited 2024 Jun 11];21(1):35. doi: 10.1186/s12905-020-01166-4
175. Jallow M, Black G, van Os S, Baldwin DR, Brain KE, Donnelly M, et al. Acceptability of a standalone written leaflet for the National Health Service for England Targeted Lung Health Check Programme: A concurrent, think-aloud study. *Health Expect* [Internet]. 2022 Aug [cited 2024 Jun 7];25(4):1776-1788. doi: 10.1111/hex.13520
176. Gorman LS, Ruane H, Woof VG, Southworth J, Ulph F, Evans DG, et al. The co-development of personalised 10-year breast cancer risk communications: a 'think-aloud' study. *BMC Cancer* [Internet]. 2022 Dec 5 [cited 2024 Jun 7];22(1):1264. doi: 10.1186/s12885-022-10347-3
177. Garcia-Retamero R, Cokely ET. Designing Visual Aids That Promote Risk Literacy: A Systematic Review of Health Research and Evidence-Based Design Heuristics. *Hum Factors* [Internet]. 2017 Jun [cited 2024 Jun 7];59(4):582-627. doi: 10.1177/0018720817690634
178. Zhang LJ, Zhang D. *The Routledge Handbook of Research Methods in Applied Linguistics*. London: Routledge; 2020 [cited 2024 Jul 23]. Think-aloud protocols; 302-312.
179. StataCorp. 2021. *Stata Statistical Software: Release 17*. College Station, TX: StataCorp LLC
180. Usher-Smith JA, Silarova B, Sharp SJ, Mills K, Griffin SJ. Effect of interventions incorporating personalised cancer risk information on intentions and behaviour: a systematic review and meta-analysis of randomised controlled trials. *BMJ Open* [Internet]. 2018 Jan 23 [cited 2024 May 29];8(1):e017717. doi: 10.1136/bmjopen-2017-017717

181. Evans DG, Donnelly LS, Harkness EF, Astley SM, Stavrinou P, Dawe S, et al. Breast cancer risk feedback to women in the UK NHS breast screening population. *Br J Cancer* [Internet]. 2016 Apr 26 [cited 2021 Oct 11];114(9):1045-52. doi: 10.1038/bjc.2016.56
182. Power E, Miles A, von Wagner C, Robb K, Wardle J. Uptake of colorectal cancer screening: system, provider and individual factors and strategies to improve participation. *Future Oncol* [Internet]. 2009 Nov [cited 2024 May 31];5(9):1371-88. doi: 10.2217/fon.09.134
183. Damiani G, Basso D, Acampora A, Bianchi CB, Silvestrini G, Frisicale EM, et al. The impact of level of education on adherence to breast and cervical cancer screening: Evidence from a systematic review and meta-analysis. *Prev Med* [Internet]. 2015 Dec [cited 2024 May 31];81:281-9. doi: 10.1016/j.ypmed.2015.09.011
184. Toes-Zoutendijk E, de Jonge L, Breekveldt ECH, Korfage IJ, Usher-Smith JA, Lansdorp-Vogelaar I, et al. Personalised colorectal cancer screening strategies: Information needs of the target population. *Prev Med Rep* [Internet]. 2023 Jul 16 [cited 2024 Jun 27];35:102325. doi: 10.1016/j.pmedr.2023.102325
185. Clarkson J, Bogle D, Dean J, Tooley M, Trewby J, Vaughan L, et al. Engineering better care: a systems approach to health and care design and continuous improvement [Internet]. London: Royal Academy of Engineering; 2017 Aug [cited 2024 Jun 27]. Available from: <https://www.eng.cam.ac.uk/uploads/news/files/engineering-better-care-report-web-3mb-20170922.pdf>
186. Dennison RA, Taylor LC, Morris S, Boscott RA, Harrison H, Moorthie SA, et al. Public Preferences for Determining Eligibility for Screening in Risk-Stratified Cancer Screening Programs: A Discrete Choice Experiment. *Med Decis Making* [Internet]. 2023 Apr [cited 2024 Jun 14];43(3):374-386. doi: 10.1177/0272989X231155790
187. PAMCo. Interview and Questionnaire [Internet]. London: PAMCo; [cited 2024 Jul 4]. Available from: <https://pamco.co.uk/methodology/interview-and-questionnaire/>
188. Cancer Research UK, University College London, Kings College London and University of Oxford. Cancer Awareness Measure toolkit version 2.1 Cancer Research UK Cancer Awareness Measure (CAM) Toolkit (version 2.1). 2007 [cited 2021]. https://www.cancerresearchuk.org/sites/default/files/health_professional_cancer_awareness_measure_toolkit_version_2.1_09.02.11.pdf

189. Smits SE, McCutchan GM, Hanson JA, Brain KE. Attitudes towards lung cancer screening in a population sample. *Health Expect* [Internet]. 2018 Dec [cited 2024 Aug 22];21(6):1150-1158. doi: 10.1111/hex.12819
190. BRFSS. Behavioral Risk Factor Surveillance System [Internet]. 2006 Jan 23 [cited 2024 Jul 4]. Available from: <https://www.cdc.gov/brfss/questionnaires/pdf-ques/2006brfss.pdf>
191. Simon AE, Forbes LJ, Boniface D, Warburton F, Brain KE, Dessaix A, et al; ICBP Module 2 Working Group, ICBP Programme Board and Academic Reference Group. An international measure of awareness and beliefs about cancer: development and testing of the ABC. *BMJ Open* [Internet]. 2012 Dec 18 [cited 2024 Aug 22];2(6):e001758. doi: 10.1136/bmjopen-2012-001758

Appendices

Chapters 3 & 4

Appendix 3.1 Mixed methods systematic review data extraction form.....236

Appendix 3.2 Mixed Methods Appraisal Tool.....237

Chapter 5

Appendix 5.1 Community jury study CJ Check reporting checklist.....239

Appendix 5.2 Community jury participants information pack.....240

Appendix 5.3 Community jury pre-study questionnaire.....256

Appendix 5.4 Community jury post-study questionnaire.....266

Appendix 5.5 Community jury study codebook thematic analysis coding frame.....271

Chapter 6

Appendix 6.1 The original NHS screening leaflet used in the think aloud interview study.....273

Appendix 6.2 Think aloud study initial risk-stratified screening leaflet.....284

Appendix 6.3 Think aloud study pilot text.....293

Appendix 6.4 Think aloud study demographic questionnaire.....295

Appendix 6.5 Think aloud study participant information sheet.....301

Appendix 6.6 Think aloud study consent form.....305

Appendix 6.7 Think aloud study user testing Prolific summary.....307

Appendix 6.8 Think aloud study user testing participant information sheet.....308

Appendix 6.9 Think aloud study user testing consent form.....312

Appendix 6.10 Think aloud study user testing survey.....313

Appendix 6.11 Think aloud study refined risk-stratified screening leaflet used for user testing.....315

Chapter 7

Appendix 7.1 Survey study survey.....323

Appendix 7.2 Survey study Prolific summary.....	343
Appendix 7.3 Survey study participant information sheet.....	344
Appendix 7.4 Survey study consent form.....	348

Appendix 3.1 Mixed methods systematic review data extraction form

Phase one															
Citation details							Demographic details					Study design			
Record number	First author	Year	Title	Primary aim	Setting	Cancer type(s)	Sample size	Age	Sex	Ethnicity	Other	Study type (quant/qual/mixed)	Brief description of method	Professional or public acceptability	Measure of acceptability
Phase two															
Citation details				Study details											
Record number	First author	Year	Title	Study type (quant/qual/mixed)	Themes & subthemes (if applicable)	Outcomes or findings of significance to the review objectives	Author's conclusions	Reviewer initials and comments							

Appendix 3.2 Mixed Methods Appraisal Tool(107)

Category of study designs	Methodological quality criteria	Responses			
		Yes	No	Can't tell	Comments
Screening questions (for all types)	S1. Are there clear research questions?				
	S2. Do the collected data allow to address the research questions?				
	<i>Further appraisal may not be feasible or appropriate when the answer is 'No' or 'Can't tell' to one or both screening questions.</i>				
1. Qualitative	1.1. Is the qualitative approach appropriate to answer the research question?				
	1.2. Are the qualitative data collection methods adequate to address the research question?				
	1.3. Are the findings adequately derived from the data?				
	1.4. Is the interpretation of results sufficiently substantiated by data?				
	1.5. Is there coherence between qualitative data sources, collection, analysis and interpretation?				
2. Quantitative randomised controlled trials	2.1. Is randomization appropriately performed?				
	2.2. Are the groups comparable at baseline?				
	2.3. Are there complete outcome data?				
	2.4. Are outcome assessors blinded to the intervention provided?				
	2.5. Did the participants adhere to the assigned intervention?				
3. Quantitative non- randomised	3.1. Are the participants representative of the target population?				
	3.2. Are measurements appropriate regarding both the outcome and intervention (or exposure)?				
	3.3. Are there complete outcome data?				
	3.4. Are the confounders accounted for in the design and analysis?				
	3.5. During the study period, is the intervention administered (or exposure occurred) as intended?				
4. Quantitative descriptive	4.1. Is the sampling strategy relevant to address the research question?				
	4.2. Is the sample representative of the target population?				
	4.3. Are the measurements appropriate?				
	4.4. Is the risk of nonresponse bias low?				

	4.5. Is the statistical analysis appropriate to answer the research question?				
5. Mixed methods	5.1. Is there an adequate rationale for using a mixed methods design to address the research question?				
	5.2. Are the different components of the study effectively integrated to answer the research question?				
	5.3. Are the outputs of the integration of qualitative and quantitative components adequately interpreted?				
	5.4. Are divergences and inconsistencies between quantitative and qualitative results adequately addressed?				
	5.5. Do the different components of the study adhere to the quality criteria of each tradition of the methods involved?				

Appendix 5.1 Community jury study CJ Check reporting checklist(152)

1. Planning
 - a) Was the stakeholder/committee's role clearly described? ✓
 - b) Was the selection of experts (who was chosen and why) adequately described? ✓
 - c) Were the experts roles clearly defined? ✓
 - d) Was the jury 'charge' or instruction clearly described? ✓
2. Jurors/participants
 - a) Was the recruitment strategy clearly described? ✓
 - b) Were inclusion/exclusion criteria reported? ✓
 - c) Was the type of participant/juror described? (unaffected public/affected public/advocate) ✓
 - d) Were the demographics of the jurors reported? ✓
(age/gender/education/attainment)
3. Procedure
 - a) Was the role and experience of the facilitator described (e.g. impartial/informed/member of research team/independent) ✓
 - b) Were materials provided to the jurors adequately described and accessible? ✓
 - c) Was the expert cross-examination opportunities described? ✓
 - d) Was the jury outcome reported? ✓
4. Scheduling
 - a) Was the schedule (how often and interval) and length (days/hours) of juror meetings reported? ✓
 - b) Was the daily schedule of events described? ✓
 - c) Was the number of presenters and their topics described? ✓
 - d) Are the expert presentations available? *Presentations are available upon request through the repository.*
 - e) Were the lengths of the presentations reported? ✓
5. Other
 - a) Were the jurors paid? ✓
 - b) How many jurors were there? ✓
 - c) What was the influence of the jury outcome on policy? ✓
 - d) What was the framing/nature of jury deliberations? ✓
 - e) What was the influence of the commissioning body on the jurors? ✓

Appendix 5.2 Community jury participants information pack

Information pack cover letter:



Dear participant

Thank you for agreeing to take part in the STRAT-BCS II Community Jury study.

Included with this pack are some documents that will support your participation.

Before the community jury, please take a look at:

1. The timetable for the two days,
2. The guide for how to use Zoom,
3. The biographies of the presenters,
4. The summary of the findings of our previous study (what we already know),
5. Glossary of key terms.

You have also been provided with a unique link to an online questionnaire by iPoint. Before the community jury, please could you complete the questionnaire by following the unique link. We expect completing the questionnaire to take approximately 10 minutes. We will ask you to complete a second questionnaire at the end of the jury.

Shortly before the community jury, we will send you a copy of the PowerPoint slides from the expert presentations. You might want to refer to these slides during the expert sessions and deliberations. The experts will talk through them so there is no need to look at them before the jury.

You might find it helpful to have a pen and paper ready in case you want to write down any notes or questions that you have during the jury.

If you have any problems on the day of the jury, please contact [phone number and email address redacted].

Yours sincerely

Lily, Becky, and Juliet

STRAT-BCS II study researchers

Expert biographies

Prof Simon Griffin

Simon is Professor of General Practice at the University of Cambridge and a GP in Cambridge. He also holds positions at Aarhus University Denmark, NHS England and the Academy of Medical Sciences, among others.

He leads a research programme that contributes to efforts aimed at preventing the growing burden of diabetes, obesity and related disorders by translating knowledge into preventive action, plus evaluating the effectiveness of a range of strategies from behaviour change to screening. He has completed over 35 trials and authored over 450 publications, but what he really likes to do is surf.



Dr Stephen John

Stephen is a Senior Lecturer in the Philosophy of Public Health at the University of Cambridge, with interests in a variety of topics including the philosophy of science, applied ethics and political philosophy. He is affiliated with the Leverhulme Centre for the Future of Intelligence, with Cambridge University's Public Health Strategic Research Network, and the Cambridge Cancer Centre.

Stephen is particularly interested in how concepts such as certainty, communication, chance and categorisation are used in policy-making, and has explored case studies ranging from the Intergovernmental Panel on Climate Change to contemporary alcohol policy. His current research involves debates over the early detection and prevention of cancer.



Dr Iris Lansdorp-Vogelaar

Iris is an Associate Professor at the Department of Public Health of Erasmus University Medical Center in the Netherlands and leads research on the evaluation of screening for gastrointestinal disorders. She is also a member of the Dutch Colorectal Cancer Screening Program Advisory Committee, European Cancer Network, and the Cancer Intervention and Surveillance Modelling Network, among others.

Iris' research focuses on the monitoring and evaluating of screening interventions using computer simulation models, with an emphasis on bowel and oesophageal cancer screening. Her work has been used to inform bowel cancer screening recommendations



and guidelines in The Netherlands and the US. She is interested in how bowel cancer risk prediction can be used to inform personalised screening.

Community jury timetable:

Timetable



Day 1

9:00	Welcome, introductions and plan for the juries
9.45	Expert presentation and Q&A 1: Why we screen for bowel cancer and what are the potential benefits and harms
10:20	Break
10.35	Expert presentation and Q&A 2: Ethical considerations around bowel cancer screening programmes
11:10	Break
11:25	Expert presentation and Q&A 3: The current approach to bowel cancer screening and how risk stratification could be incorporated
12:00	Facilitated deliberation 1
12:55	Summary
13:00	End

Day 2

9:00	Welcome and reflections
9:20	Expert presentation and Q&A 4: How risk stratification could be incorporated into bowel cancer screening in the future
10:00	Break
10:15	Facilitated deliberation 2
11:15	Break
11:30	Unfacilitated deliberation Present recommendations
12:55	Summary
13:00	End

What we already know:



What we already know

Our plans for the STRAT-BCS II study have been informed by earlier research. This includes two previous community jury studies. We have summarised key findings from these studies below and will talk through it at the start of your jury.



Objectives

We carried out these studies with the aim of exploring public views on different approaches to inviting people for cancer screening, including how acceptable they considered risk stratification to be. One study explored this across all cancer screening programmes and a second study focused on inviting people to bowel cancer screening.

Risk stratification involves estimating each person's risk of developing a cancer (based on factors like their age, sex, smoking, diet, and genes) and deciding when to offer them screening according to that risk. People with a higher risk of cancer might be invited to attend cancer screening at a younger age than people with a lower risk of cancer.

Design

We carried out five online community juries with between seven and ten members of the public in each. Three juries on screening for all cancers took place in 2021 and two juries on bowel cancer took place in 2022. Three or four experts provided the participants with information on the following topics, which were adapted for each study:

- What is screening and what are the potential benefits and harms,
- Ethical considerations around screening and determining eligibility,
- How is eligibility for screening currently determined and what is risk stratification,
- The potential effects of introducing risk stratification.

Findings

We found that the idea of risk stratification was, in general, an acceptable approach for deciding who to invite for cancer screening. Four juries agreed on this verdict, while six out of the ten participants in the other jury supported risk stratification in some form.

The main reasons for supporting risk stratification were:

- It is the best way to find the people who will benefit most for screening;
- It would be more efficient, considering that there are not enough healthcare resources to screen more people;
- It would be an opportunity to increase public awareness of cancer risks;
- It would reduce the number of people having unnecessary anxiety or treatment after screening.

However, there were concerns about how fair risk stratification would be:

- Some participants worried that some people might miss out on screening because they did not have a risk assessment (e.g. if they were not registered with a GP or their medical records were out of date);
- Some participants thought that it was important to predict cancer risk using risk factors that were permanent (suggesting genetics rather than factors to do with lifestyle that people may or may not make choices about, like smoking or diet). Other participants thought that the most accurate approach to estimating risk should be used;
- All juries discussed how fair it was for people at low risk of cancer not to be routinely offered screening. Many participants agreed with someone who said, “I’d say that is the thing that sits most uncomfortably with me, but I do recognise it is those added lifestyle factors that mean that that person is more likely to develop cancer, so we have to screen those people”;
- One jury thought risk stratification might lead to more people needing follow-up and treatment, and they wanted assurance that enough healthcare resources would be available for this.

Finally, we found that the participants would accept risk stratification if their concerns about fairness were addressed and there was appropriate public education. This would need to include an explanation of why the risk stratification approach was used, why each factor was included in the risk assessment and cancer prevention advice using simple-to-understand language.

Where the STRAT-BCS II study fits in

The first study was a general discussion about including risk stratification when inviting people for cancer screening and we encouraged the participants not to think about a specific type of cancer or screening test. The second study was focused on including risk stratification when inviting people to attend bowel cancer screening specifically.

The STRAT-BCS II study that you are participating in aims to explore public views on other ways that risk stratification could be incorporated into bowel cancer screening – changing the length between screening invites and the point at which someone needs to be referred for further investigations based on peoples’ risk of developing cancer.

Zoom guide:



Zoom user guide

Introduction

This brief guide explains the features of Zoom videoconferencing software that we will use during the STRAT-BCS II Community Jury study. Please make sure you are familiar with the features mentioned in this guide before the first day of the jury to enable it to run smoothly.

If you need more support, please contact iPoint [phone number redacted] or Lily Taylor [email address redacted]. More guidance on setting up and using Zoom is also available at the Zoom Help Centre (<https://support.zoom.us/hc/>).

In advance of the community jury day

Please download the Zoom application from <https://zoom.us/download>.

We strongly recommend you use the Zoom app rather than accessing it through the internet (web browser) because many of the functions cannot be used in the browser version.

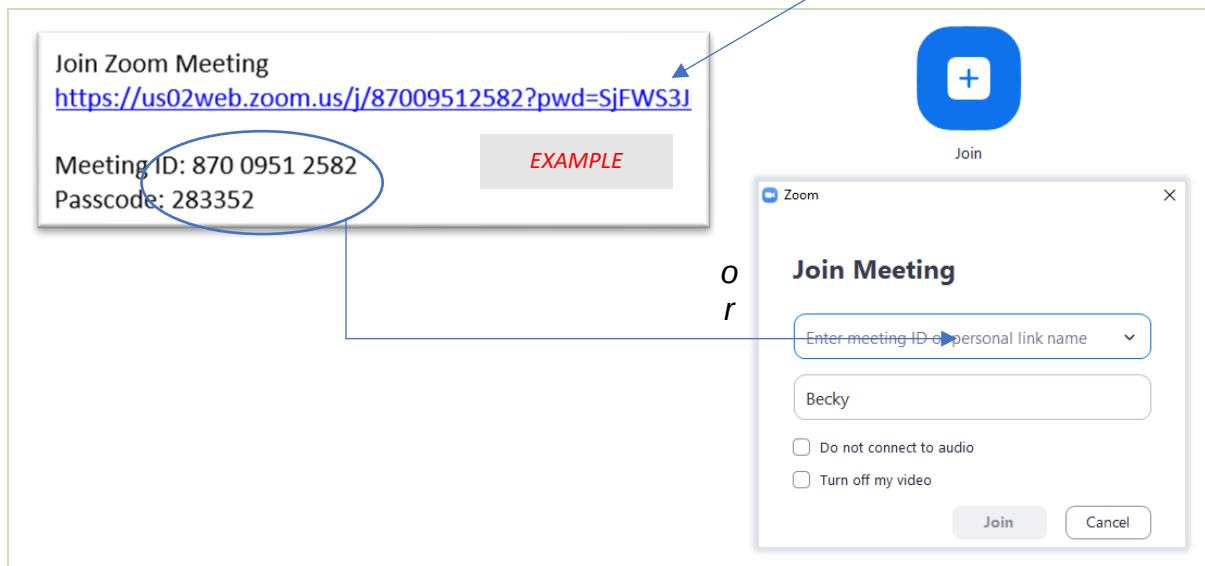
Please use a computer, laptop or tablet (e.g. iPad). Please do not join from a mobile.

Make sure you have the necessary equipment – a webcam, microphone and speakers (built-in or plugged in). A headset or earphones can help to avoid audio feedback. Make sure your device is connected to a power supply.

Plan a quiet and comfortable place to take part in the jury. Please make sure this is a private place where other adults will not overhear.

Joining the Zoom meeting

You don't need a Zoom account – just click on the Zoom link in your invite or open the Zoom app and enter the meeting ID and password.



Please join the meeting using a screen name that you are happy to use for the duration of the jury (the other participants will see it). This could be your real first name or another name you would prefer to use. Please do not include your surname. If you would like to change your name that appears under your video during the meeting, right-click on the video of yourself and the option to change your name will appear (if you are using an iPad, touch 'participants' on the menu bar, then touch your name, then the option to rename yourself will appear).

The host may re-name you at the start of the jury if necessary.

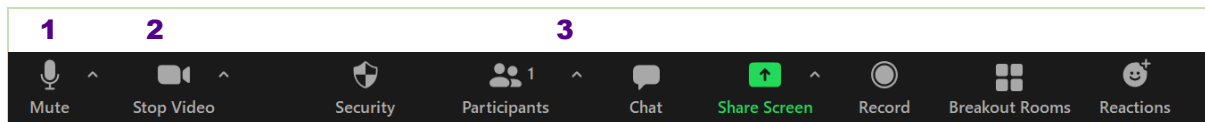
When you join the meeting you will initially be in a waiting room. Please wait for the host to let you in.

If you leave the meeting for any reason during the study, please re-join in the same way as soon as you can.

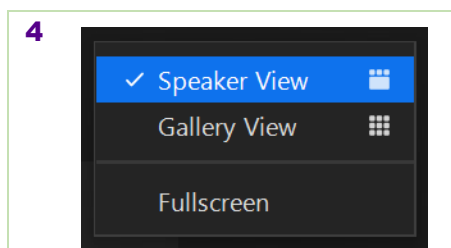
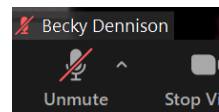
Basic navigation and helpful hints for attendees

The Zoom menu bar will appear at the bottom of the Zoom window once the meeting begins. If you can't see it, move the mouse slightly and the bar will appear.

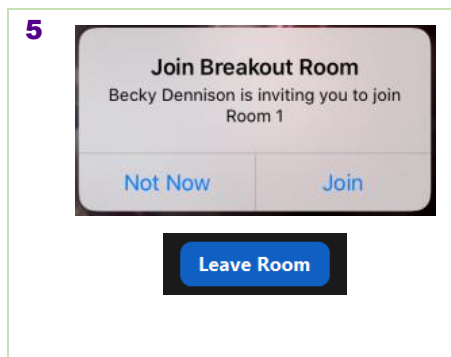
Note that the placement of the menu bar might be different if you are not using a computer. The menu bar is along the top on an iPad and you may have to click 'more' to access some of the functions.



1. Mute/Unmute: click on the mic icon to mute/unmute your microphone. The mic will be marked in red when it is muted (see right). Please mute your microphone when you're not speaking.
2. Video on/off: click on the video icon to turn your video on/off. Please try to keep your video on, particularly during the deliberation sessions.
3. Chat: you can use the chat function to write messages. These can be sent privately to the host or to everyone on the call.



4. View: change the display view by moving the mouse and selecting 'view' in the top right hand corner. If you would like to see the speaker, use 'speaker view'. We recommend this during the *expert presentations*. If you'd like to see everyone on the call, use the 'gallery view'. We recommend this during the *jury deliberations*.



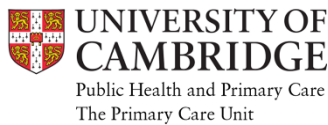
5. Breakout rooms: we may use breakout rooms during the study. When you are invited to join a breakout room, please click 'join'. If you need to return to the main room before the end of the meeting, please select 'leave room' in the menu bar. Make sure not to leave the meeting!



Key terms

Key term:	Definition:
Polyp	Polyps are growths in the bowel. They are not cancer but may turn into cancer over time.
FIT test	The screening test used in England is called the faecal immunochemical test or FIT test. You can do it yourself at home. You collect a small sample of poo on a small plastic stick, put it into the sample bottle and post it to a lab for testing. The FIT test is used to find out if there are small amounts of blood in your poo.
FIT test threshold/ cut-off	The amount of blood, if any, found in your poo is used to class your FIT result as “positive” or “negative”. If the amount of blood is found to be above a certain level (the threshold or cut-off), it is classed as positive and if the amount is found to be below this level, it is classed as negative. Having a negative FIT result means the amount of blood detected in your poo is below the cut-off for a positive FIT test result. It might not mean there was no blood detected in your poo sample, only that there was less blood in your poo than the positive cut-off amount.
Colonoscopy	If you are found to have a positive FIT test this means there was blood found in your poo sample and you will be invited for a further test called a colonoscopy. A colonoscopy is where a thin tube with a camera inside is passed into your bottom to look for signs of polyps or bowel cancer.
Screening interval	The time between FIT screenings. In the current programme people are invited to do a FIT test every 2 years.
Interval cancer	An interval cancer is a bowel cancer found during the time after a negative FIT result and before the next FIT screening.
Risk stratification	Risk stratification involves estimating each person’s risk of developing a cancer (based on factors that increase their risk of that cancer like their age, sex, smoking status, diet, and genes) and deciding how they should be offered screening based on that risk. People with a higher risk may be screened more frequently than those who have a lower risk.

Community jury study consent form:



STRAT-BCS II: STRATification in Bowel Cancer

Screening II – Community jury study

Consent form

You must initial **all** of the boxes to be eligible to take part in the study.

	Please initial
1. I confirm that I have read and understood the information sheet dated [insert date] for this study. I have had the opportunity think about the information, ask questions, and have these answered satisfactorily.	xx
2. I understand that my participation is voluntary and I am free to withdraw at any time before or during the community jury, without giving reason.	xx
3. I understand that, given the nature of the group discussion, the research team may not be able to identify and withdraw the comments I have made in this discussion if I want to do so.	xx
4. I understand and agree to the discussion being recorded and transcribed for analysis purposes.	xx
5. I understand that anonymous direct quotations from my discussion and my answers in the questionnaire may be published in journals or presented at conferences, but without my name or other identifying details used.	xx
6. I understand that anonymous information collected as part of my involvement in this study may be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel.	xx
7. I understand that anonymous information collected as part of my involvement in this study will be used to support other research in the	xx

future and may be shared anonymously with other academic researchers external to the project within the UK and beyond.

8. I agree to take part in this study.

XX

Name of participant

Date

Signature

Principal investigator: Dr Juliet Usher-Smith	[address redacted]
Email:	[email address redacted]

STRAT-BCS II: STRATification in Bowel Cancer

Screening II – Community jury study

Participant Information Sheet

Thank you for considering taking part in our community jury study to explore the public's views on different approaches to screening for bowel cancer.

Please take time to read this information carefully to understand why the research is being done and what it will involve for you.

Who is organising the research?

The study is being led by doctors and researchers at the University of Cambridge. It is funded by the National Institute for Health Research and has been reviewed by the University of Cambridge Psychology Research Ethics Committee.

What is the purpose of the study?

The aim of screening is to diagnose cancer early. It has been suggested that it might be a good idea to tailor some aspects of the bowel cancer screening pathway according to peoples' individual risk, for example, by inviting some people to be screened more frequently than others. The aim of this study is to find out what people think about this.

We are asking people to take part in an online community jury. This is where a group of members of the public are given information about a certain topic, in this case whether the

screening interval and test threshold for bowel cancer screening should be based on individual risk, and then discuss the topic between themselves to reach a group decision. Through this, we are hoping to understand public thoughts and perceptions on screening according to individual cancer risk and what the best ways to introduce this would be.

Who is taking part?

We are recruiting 8–10 members of the public for each jury using iPoint Research Ltd. People aged between 50 and 74 years who have not had bowel cancer will be able to take part. You *don't* need to have any background knowledge about cancer in general (or about bowel cancer) to take part because we are interested in what non-expert members of the general public think about these issues.

iPoint Research is the authorised research recruitment partner for this study and is an authorised market research agency in the UK. iPoint Research will be responsible for initial communications with you and arranging the sessions.

Do I have to take part?

Your involvement in this study is entirely voluntary and you can leave at any time without giving a reason and there will be no consequences for doing so. If you choose to withdraw after the start of the jury, it may not be possible to delete all of the information you have provided due to difficulty in identifying individual participants' comments in the group discussion.

What happens next?

Before the jury, you will be asked to complete an online consent form and then complete a survey with some basic questions about yourself. This will include background questions such as your age, sex, and occupation, and some questions about you and your family's general health. It will also include questions about your thoughts on cancer screening.

During the jury itself, you will be given information about bowel cancer and the bowel cancer screening programme by a panel of experts (doctors and researchers). You will have an opportunity to ask the experts any questions you might have. You will then be asked to consider different ways in which bowel cancer screening programmes could be organised.

You will have time to discuss those as a group and will then be asked to provide a decision as a group, similar to how a jury in a court of law is asked to provide a verdict.

The jury will be conducted online using Zoom video conferencing. We will encourage you to have your video turned on but will not insist on it. All the discussions as well as the group decision and reasons will be video recorded using Zoom. The recordings will then be transcribed by an external company who will have signed a confidentiality agreement.

After the jury has ended you will also be asked to complete another brief survey.

How much time will it take?

Each jury will involve two sessions of about four hours duration; these will be held over two consecutive days using Zoom video conferencing. Breaks will be provided during the sessions.

What are the possible benefits of taking part?

By taking part in this study, you will have an opportunity to help influence cancer screening programmes by sharing your views and opinions. You will gain information about bowel cancer screening and the potential for future approaches using risk stratification.

Are there any disadvantages or risks of taking part?

Discussing the risks surrounding cancer screening can be a sensitive topic. If you become upset by anything during the juries, you may exit it at any stage and there are no consequences associated with doing so. If you have worries about cancer screening you can also contact your GP or find further information on cancer and support organisations on the Cancer Research UK or Macmillan Cancer Support websites (www.cancerresearchuk.org; www.macmillan.org.uk).

Will I be paid for taking part?

Yes, you will receive a gratuity as a thank you for your time and input. This will be processed by iPoint Research and you will receive this within 5–7 working days after the end of the study. Please see the information provided in the invitation.

Will my taking part in this study be kept confidential?

All information that is collected from you during the course of the study is anonymised and stored securely.

The University of Cambridge is the sponsor for this study based in the UK. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Cambridge will keep identifiable information about you 12 months after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at <https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data>.

What will happen to the results of the study?

This research is important for informing decision makers during the development of health policies. All findings will be published in peer-reviewed scientific journals and presented at national and international conferences. Anonymous direct quotations from the study may be used but you will not be identifiable in any of these. We can provide a summary of the results for you as well as share the completed publications with you. Anonymous information from the study may also be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel. It may also be shared anonymously with other academic researchers external to the project in the future to support other research.

What if there is a problem or something goes wrong?

If you have any concerns or complaints about any aspects of the study, you can telephone the study lead, Dr Juliet Usher-Smith, on [phone number and email address redacted].

Alternatively, if you would like to write to her, please send your letter to:

Dr Juliet Usher-Smith

STRAT-BSC study

[Address redacted]

If you post a letter, there may be a delay in our response because we are not able to monitor post as frequently since the COVID-19 pandemic. We will reply to your email or letter in writing, unless you enclose your telephone number and wish to discuss your concerns by telephone.

**Thank you very much for reading this information sheet
and choosing to take part in this study**

STRAT-BCS II: STRATification in Bowel Cancer Screening II – Community jury

Online questionnaire (1) – to be completed before the community juries

Question	Answer	Validation of question/reference
<i>[Note that this content will be delivered online so the formatting looked slightly different to in this document. The participants also will not see the headings in grey boxes.]</i>		
Consent		
I confirm that I have read and understood the participant information sheet and have given consent to take part in this study.	[tick box]	
I understand that my taking part is voluntary and that I am free to leave at any time, without giving any reason.	[tick box]	
I understand that anonymous information collected as part of my involvement in this study may be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel.	[tick box]	
I understand that information collected as part of my involvement in this study will be used to support other research in the future and may be shared anonymously with other academic researchers external to the project within the UK and beyond.	[tick box]	
By clicking 'I agree' you are indicating that you have read and understood this consent form and agree to participate in this research study. ['I agree'/submit form]		

Thank you for agreeing to complete this questionnaire. Please answer every question. If you are uncertain about how to answer a question, then please select the closest option.

Demographics

Demographic information

In this first section we would like to ask you a few questions about yourself. These questions allow us to make sure we are including people from a range of different backgrounds and see if different groups of people have different views. We will not be able to identify you from your answers.

How old are you?	• 50-54 years • 55-59 years • 60-64 years • 65-69 years • 70-74 years	
What is your sex? (A question about gender identity follows) Some of the scenarios we will be discussing will consider whether the sex of individuals should influence screening frequency and the threshold of the screening test. This would be the sex that individuals are assigned at birth. To help us see if responses differ between people of different sexes, please let us know your sex assigned at birth.	• Female • Male	Cambridge's The Healthcare Improvement Studies (THIS) Institute guidance released March 2021
Is the gender you identify with the same as your sex registered at birth?	• Yes • No (please enter your gender identity)	Cambridge's The Healthcare Improvement Studies (THIS) Institute guidance released March 2021

What is your ethnic group? Choose one option that best describes your ethnic group or background.	• Asian/Asian British • Black/African/Caribbean/Black British • Mixed/Multiple ethnic group • White • Other (please describe)	Ethnic groups are the top-level groups used in the UK Census and PAMCo(187)
What is your highest education level?	• Finished school at or before the age of fifteen • Completed GCSEs, O Levels or equivalent • Completed A Levels or equivalent • Completed further education but not a degree • Completed a Bachelor's degree • Completed a Master's degree or PhD • Other (please describe)	Validated from Cancer Awareness Measure (CAM) toolkit, (pre-2014, as 2014 onwards has not been validated)(188)
Which of the following best describes the <i>main income earner's</i> main/most recent job? This could be you: the main income earner is the person in your household with the largest income. If the main income earner is retired and has a pension, please answer for their most recent occupation. If the main income earner is not in paid employment but has been out of work for less than 6 months, please answer for their most recent occupation.	• Business owner – responsible for 1-4 employees • Business owner – responsible for 5-24 employees • Business owner – responsible for 25+ employees • Top/senior manager in large organisation; qualified senior professional <i>e.g. main board director, senior civil servant, headteacher, partner in professional practice, surgeon</i> • Middle manager or executive in large organisation; senior manager of small organisation; qualified	The ABC1–C2DE framework is a validated method of determining social grade.(189) PAMCo uses an updated version of this question(187)

	professional (no senior management responsibility) e.g. <i>department manager, teacher, engineer, accountant, doctor, manager of small building firm</i> • Non-management office role; middle manager in small organisation; qualified nurse; performing artist e.g. <i>secretary, personal assistant, clerical worker, office worker, call centre agent, salesperson, nurse or nursery nurse, police constable/sergeant, actor, musician, sportsperson</i> • Manual worker - manager – responsible for 25+ employees • Manual worker - manager – responsible for 1-24 employees • Skilled manual worker (no responsibility for other employees) e.g. <i>HGV driver, train/bus/ambulance driver, chef, hairdresser, mechanic, plumber, bricklayer, carpenter, painter, electrician, caterer, specialised machinery operator, fire-fighter, pub/bar worker</i> • Unskilled or semi-skilled manual worker (no responsibility for other employees) e.g. <i>farm worker, cleaner, postal worker, van driver, care worker, waiter, taxi driver, shop assistant, apprentice/trainee in skilled trade</i>	

	• Casual worker or no regular income • Full time student	
Lifestyle and screening history		
<i>Lifestyle and screening history</i> <i>The following questions are about your lifestyle and your past screening decisions. Please answer as honestly as you can as this will help us with our analysis.</i>		
In general, would you say your health is	• Excellent • Very good • Good • Fair • Poor	Validated question from CDC for self-rate health(190)
What is your tobacco smoking status?	• Never smoked cigarettes or cigars • Used to smoke cigarettes or cigars • Smoke up to 20 cigarettes or cigars per day • Smoke 20 or more cigarettes or cigars per day	From lung cancer study, Smits et al., 2018(189)
How would you describe your weight?	• Underweight • About the right weight • Slightly overweight • Very overweight	
Have you ever had cancer?	• Yes • No	
Have your parents or any brothers or sisters ever had cancer?	• Yes • No • Don't know/prefer not to answer	

Has anyone close to you (e.g. a partner or close friend) ever had cancer?	• Yes • No • Don't know	
Have you been invited to take part in any of the following screening programmes (please note that they are not offered to everyone)? Information is in the format of (what it involves, who it is offered to)	• Yes/No/Not Eligible ○ Abdominal Aortic Aneurysm screening (ultrasound, men aged over 65) ○ Bowel Cancer screening (poo sample or colonoscopy, men and women aged 60-74) ○ Breast Cancer screening (mammogram, women aged 50-70) ○ Cervical Cancer screening (smear test, women aged 25-64)	
Which of the following screening programmes did you take up the invitation to take part in?	• Yes/No/Not Eligible ○ Abdominal Aortic Aneurysm screening (ultrasound, men aged over 65) ○ Bowel Cancer screening (poo sample or colonoscopy, men and women aged 60-74) ○ Breast Cancer screening (mammogram, women aged 50-70) ○ Cervical Cancer screening (smear test, women aged 25-64)	

Thoughts and beliefs about cancer		
<i>The next section asks about your thoughts and beliefs about cancer. Please answer as honestly as you can as this will help us with our analysis. The questions are about YOUR opinion and so there is not a correct answer.</i>		
Below are some statements that are sometimes made about cancer. For each of these statements how much do you agree or disagree with them? • These days, many people with cancer can expect to continue with normal activities and responsibilities. • Most cancer treatment is worse than the cancer itself. • I would NOT want to know if I have cancer. • Cancer can often be cured. • Going to the doctor as quickly as possible after noticing a symptom of cancer could increase the chances of surviving. • Some people think a diagnosis of cancer is a death sentence.	• Strongly agree • Agree • Neither disagree nor agree • Disagree • Strongly disagree	Cancer beliefs, taken from Smits et al., 2018(189) (and made specific to bowel cancer, rather than lung cancer), which were based on validated questions from the ABC measure.(191)
Introduction to bowel cancer screening and risk stratification		
<i>In the current bowel cancer screening programme in England, participants are asked to complete a test called the faecal immunochemical test (FIT) to see if they need further investigations for bowel cancer. FIT tests check for tiny amounts of blood in poo. A FIT test does not diagnose cancer, but it is a simple way to find out if someone might benefit from further tests. More blood in poo in general means someone is more likely to have a bowel cancer while someone with no blood in their poo is less likely to have a bowel cancer. Like all tests, FIT tests are not perfect. People with a small amount of blood in their poo can still have a cancer and people with lots of blood in their poo do not all have a cancer.</i> <i>In the current programme, FIT results above a certain value are classed as 'positive' and those below a certain value are classed as 'negative'. People who have a 'positive' test are referred for a colonoscopy. This is when a thin flexible tube with a camera on the end is used to look inside the bowel. The colonoscopy test does carry some risks. It is usually done in a hospital and requires people to take medicine beforehand to clean out their bowels and they usually need to take a day off work. People are offered a sedative and most people only experience mild pain or no pain during the colonoscopy. Having a colonoscopy is usually safe but in rare cases it can cause harm to the bowel that requires admission to hospital, this happens to about 1 in every 2000 people who have a colonoscopy. Those who test 'negative' on FIT are not referred for a colonoscopy but instead invited back to have another FIT test in 2 years.</i> <i>As well as the amount of blood in the poo found on FIT, a person's risk of developing bowel cancer depends on many other factors. Things that can increase your risk include:</i>		

- Getting older (8 out of 10 people diagnosed with bowel cancer are over 60)
- Being male (males are 1.8 times more likely to develop bowel cancer than females)
 - Not being active enough
 - Being overweight
- Eating a diet high in red and processed meat
- Eating a diet low in fibre, vegetables and fruits
 - Smoking
- Drinking too much alcohol
- Having type 2 diabetes
- Having inflammatory bowel disease (ulcerative colitis or Crohn's disease)
- Having a family history of bowel cancer

As the risk of bowel cancer varies based on these factors, we could use this information collected by a questionnaire and the results of the FIT test to determine people's risk of developing bowel cancer. This risk could then be used to determine features of the screening programme. This could mean that instead of inviting everyone to begin bowel cancer screening at the same time, the age at which people are invited to start screening could be based on risk of developing bowel cancer. This could also mean that instead of having a fixed cut-off of blood on the FIT test for everyone, the cut-off for referral to colonoscopy could be based on person's individual risk. For example, someone who has a higher risk of developing bowel cancer based on their age and sex might be referred for a colonoscopy with a lower FIT result than someone who was at lower risk of developing bowel cancer based on their age and sex. The risk of developing bowel cancer could also be used together with the FIT result to decide how often individual should be invited back for screening. For example, someone who has a higher risk of developing bowel cancer might be invited back for another FIT test more often than someone who was at lower risk of developing bowel cancer.

Please answer the following questions honestly. We would like to know YOUR opinion. This exercise may raise questions for you which we hope to address further in the community jury.

Acceptability of risk stratification:		
1. How acceptable do you think it is to use a person's individual risk to determine whether they are referred for colonoscopy rather than having a fixed FIT cut-off for everyone? 2. How acceptable do you think it is to use a person's individual risk to determine when people would be invited back for their next FIT rather than inviting everyone every 2 years?	• Not at all acceptable – extremely acceptable (1-6) ○ Not at all acceptable ○ Not very acceptable ○ Somewhat unacceptable ○ Somewhat acceptable ○ Very acceptable ○ Extremely acceptable	Adapted from 'Acceptability and potential impact on uptake of using different risk stratification approaches to determine eligibility for screening: a population

		based survey' survey(120)
Mode of risk stratification: All the factors below are known to affect someone's risk of developing bowel cancer. If elements of the screening programme, like the FIT cut-off or the screening frequency, were going to be determined by peoples' individual risk, how acceptable do you find using the following factors alongside the FIT result? 1. Sex 2. Age 3. Height and weight 4. Smoking status 5. Family history of cancer 6. Diet 7. Physical activity 8. Genetic information 9. Results of previous screening tests Now, please rank the options that you considered to be acceptable in order of acceptability, with 1 being most acceptable and 9 being least acceptable.	• Not at all acceptable – extremely acceptable (1-6) ○ Not at all acceptable ○ Not very acceptable ○ Somewhat unacceptable ○ Somewhat acceptable ○ Very acceptable ○ Extremely acceptable • Rank in order of acceptability, with 1 being most acceptable and 9 being least acceptable	
How to decide the cut-off: If any of the risk factors are used, there are different ways that could be used to decide what the cut-off for referral to have a colonoscopy should be. How important do you think the following factors are in deciding what the cut-off for a colonoscopy should be? • The number of cancers missed in people who are not referred for a colonoscopy. • The number of people who have a colonoscopy who do not have a cancer.	• Not at all important – extremely important (1-6) ○ Not at all important ○ Not very important ○ Somewhat unimportant ○ Somewhat important ○ Very important ○ Extremely important	

Thank you for completing the survey. Your time and contribution are very much appreciated.

STRAT-BCS II: STRATification in Bowel Cancer Screening II – Community jury

Online questionnaire (2) – to be completed at the end of the community jury

Question	Answer	Validation of question/reference
<i>[Note that this content will be delivered online so the formatting looked slightly different to in this document. The participants also will not see the headings in grey boxes.]</i>		
Thank you for taking part in the community juries. For the final part of this study, we invite you to complete the follow-up questionnaire below.		
Next		
Thank you for agreeing to complete this questionnaire. Please answer every question. If you are uncertain about how to answer a question, then please select the closest option.		
Risk stratification questions		
Targeting screening programmes by looking at risk factors for bowel cancer <i>In the current bowel cancer screening programme in England, participants are asked to complete a test called the faecal immunochemical test (FIT) to see if they need further investigations for bowel cancer. FIT tests check for tiny amounts of blood in poo. A FIT test does not diagnose cancer, but it is a simple way to find out if someone might benefit from further tests. More blood in poo in general means someone is more likely to have a bowel cancer while someone with no blood in their poo is less likely to have a bowel cancer. Like all tests, FIT tests are not perfect. People with a small amount of blood in their poo can still have a cancer and people with lots of blood in their poo do not all have a cancer.</i> <i>In the current programme, FIT results above a certain value are classed as 'positive' and those below a certain value are classed as 'negative'. People who have a 'positive' test are referred for a colonoscopy. This is when a thin flexible tube with a camera on the end is used to look inside the</i>		

bowel. The colonoscopy test does carry some risks. It is usually done in a hospital and requires people to take medicine beforehand to clean out their bowels and they usually need to take a day off work. People are offered a sedative and most people only experience mild pain or no pain during the colonoscopy. Having a colonoscopy is usually safe but in rare cases it can cause harm to the bowel that requires admission to hospital, this happens to about 1 in every 2000 people who have a colonoscopy. Those who test 'negative' on FIT are not referred for a colonoscopy but instead invited back to have another FIT test in 2 years.

As well as the amount of blood in the poo found on FIT, a person's risk of developing bowel cancer depends on many other factors. These include age, sex, smoking, BMI/being overweight, diet, how much physical activity someone does, family history and genetics. Some or all of these factors can be used alongside the FIT result to estimate a person's risk of having a bowel cancer. That individual risk could then be used to determine whether they are referred for a colonoscopy or not. This would mean that instead of having a fixed cut-off of blood on the FIT test for everyone, the cut-off for referral to colonoscopy would depend on these other risk factors and the person's individual risk. For example, someone who has a higher risk of developing bowel cancer based on their age and sex might be referred for a colonoscopy with a lower FIT result than someone who was at lower risk of developing bowel cancer based on their age and sex.

Some or all of the risk factors could also be used together with the FIT result to decide when an individual should be invited back for screening. For example, someone who has a higher risk of developing bowel cancer based on their age and sex and FIT result might be invited back for another FIT test sooner than someone who was at lower risk of developing bowel cancer.

Please answer the following questions honestly. We would like to know YOUR opinion.

Acceptability of risk stratification: 1. How acceptable do you think it is to use a person's individual risk to determine whether they are referred for colonoscopy rather than a fixed FIT cut-off for everyone? 2. How acceptable do you think it is to use a person's individual risk to determine when people would be invited back for their next FIT rather than inviting everyone every 2 years?	• Not at all acceptable – extremely acceptable (1-6) ○ Not at all acceptable ○ Not very acceptable ○ Somewhat unacceptable ○ Somewhat acceptable ○ Very acceptable ○ Extremely acceptable	Adapted from 'Acceptability and potential impact on uptake of using different risk stratification approaches to determine eligibility for screening: a population based survey' survey(120)

Mode of risk stratification: All the factors below are known to affect someone's risk of developing bowel cancer. If elements of the screening programme, like the FIT cut-off or the screening frequency, were going to be determined by peoples' individual risk, how acceptable do you find using the following factors alongside the FIT result? 1. Sex 2. Age 3. Height and weight 4. Smoking status 5. Family history of cancer 6. Diet 7. Physical activity 8. Genetic information 9. Results of previous screening tests Now, please rank the options that you considered to be acceptable in order of acceptability, with 1 being most acceptable and 9 being least acceptable.	• Not at all acceptable – extremely acceptable (1-6) ○ Not at all acceptable ○ Not very acceptable ○ Somewhat unacceptable ○ Somewhat acceptable ○ Very acceptable ○ Extremely acceptable • Rank in order of acceptability, with 1 being most acceptable and 9 being least acceptable	
How to decide the cut-off: If any of the risk factors are used, there are different ways that could be used to decide what the cut-off for referral to have a colonoscopy should be. How important do you think the following factors are in deciding what the cut-off for a colonoscopy should be? • The number of cancers missed in people who are not referred for a colonoscopy. • The number of people who have a colonoscopy who do not have a cancer.	• Not at all important – extremely important (1-6) ○ Not at all important ○ Not very important ○ Somewhat unimportant ○ Somewhat important ○ Very important ○ Extremely important	
Your experience of the community jury		

1. Overall, the presentations by the experts... a. Helped me understand the issues b. Were referred to during our deliberation c. Helped discussion between community jury members	• Strongly disagree • Disagree • Undecided • Agree • Strongly agree • <i>Additional comments</i>	
2. Overall, the facilitator... a. Helped to stimulate the group's reflections b. Respected the opinions of participants	• Strongly disagree • Disagree • Undecided • Agree • Strongly agree • <i>Additional comments</i>	
3. Overall, during the discussions between jurors... a. I felt comfortable sharing my ideas b. I could express disagreements c. I remained engaged throughout the experience d. Everyone was offered the opportunity to state their views e. I considered there might be a difference between what I would want for myself, and what I would recommend for the community as a whole f. I discussed my preferences and values in relation to the jury question g. I considered the views of others during the deliberation.	• Strongly disagree • Disagree • Undecided • Agree • Strongly agree • <i>Additional comments</i>	
4. The outcomes of our jury... a. Our community jury reached a clear recommendation/s b. Our community jury's recommendation/s directly addressed the question we were given at the start c. We discussed why we made our recommendations. d. We made our recommendations for the community as a whole not just for ourselves.	• Strongly disagree • Disagree • Undecided • Agree • Strongly agree	

	Additional comments	
5. Other comments (OPTIONAL): Do you have anything to add about your experience on this community jury?	Additional comments	
<i>Thank you for completing the survey. Your time and contribution are very much appreciated.</i>		

Appendix 5.5 Community jury study codebook thematic analysis coding frame

1. Proposed strategy to determine eligibility/thresholds/intervals (verdict)
a. Using data within system
b. Collecting additional data
c. Additional comments
2. Pros of risk stratification over alternative strategies
a. Individual benefit
Learn about yourself
Logical (given the restraints)
Opportunity for more screening if high-risk
Opportunity for early detection
b. NHS and resources use
Balance benefits to NHS and public
Cost-effective
More efficient distribution of resources
c. Potential to avoid harms
Harms are 'collateral damage'
Harms weren't important in decision making
d. Potential for behaviour change
e. Other
3. Cons of risk stratification over alternative strategies
a. Distasteful or unethical perception
b. Too complex or expensive for NHS
Expensive
Better to invest elsewhere e.g. colonoscopies
Labour-intensive to collect data
Overload the system
When to stop
c. Access to screening in low risk
d. High risk doesn't mean will get cancer
e. Other
Are FIT results accurate enough to base stratification on?
Will high-risk take up screening?
Will low-risk have healthier lifestyles?
4. Confusion over risk stratification
Concept of FIT thresholds
Family history equals genetics
High-risk characteristics would be automatically included
Involvement of GP
Low-risk characteristics would be completely excluded
More people might require screening
Not referred despite concerning amount of blood in faeces
Risk assessment and screening
Risky behaviours would exclude people from screening
5. Other
a. Access to GP and support
b. Cancer risk worry

c. Fairness and ethics
Fair means all included in risk assessment
Fair means choice and respecting individual decisions
Including choices as risk factors
'Rewarding' unhealthy behaviour
d. How much benefit is needed
e. Individuals who cannot provide information
f. Individuals who don't want to take part
g. Lifestyle risk factors
Balance concerns and risk prediction
BMI more objective than behaviours (smoking, diet, alcohol, exercise) directly
Cost of changing lifestyle/potential for change
Honesty (but that's for own good)
Lifestyle does change
People probably know what they should do
Right to choose unhealthy behaviours
Weighting of lifestyle factors in risk model
h. Other
Risk stratification might be applied to other cancers
Young people with lives ahead of them versus older people with higher risk of disease
Collecting and securing personal data
6. Communication
a. Channels and outlets
b. Language
c. Level of information about individual risk
d. Level of information about the programme
e. Level of information provided versus available elsewhere
f. Prevention advice and education
g. Programme publicity
h. Other
7. Other general points
a. Personal stories
b. Evaluation and feedback

Why we offer bowel cancer screening

We offer screening to detect bowel cancer when it is at an early stage in people with no symptoms. This is when treatment is more likely to be effective. Screening can also find polyps. These are abnormal clumps of cells in the bowel. Polyps are not cancers, but may develop into cancers over time. Polyps can be easily removed, which reduces the risk of bowel cancer developing.

Regular bowel cancer screening reduces the risk of dying from bowel cancer.

Who we invite

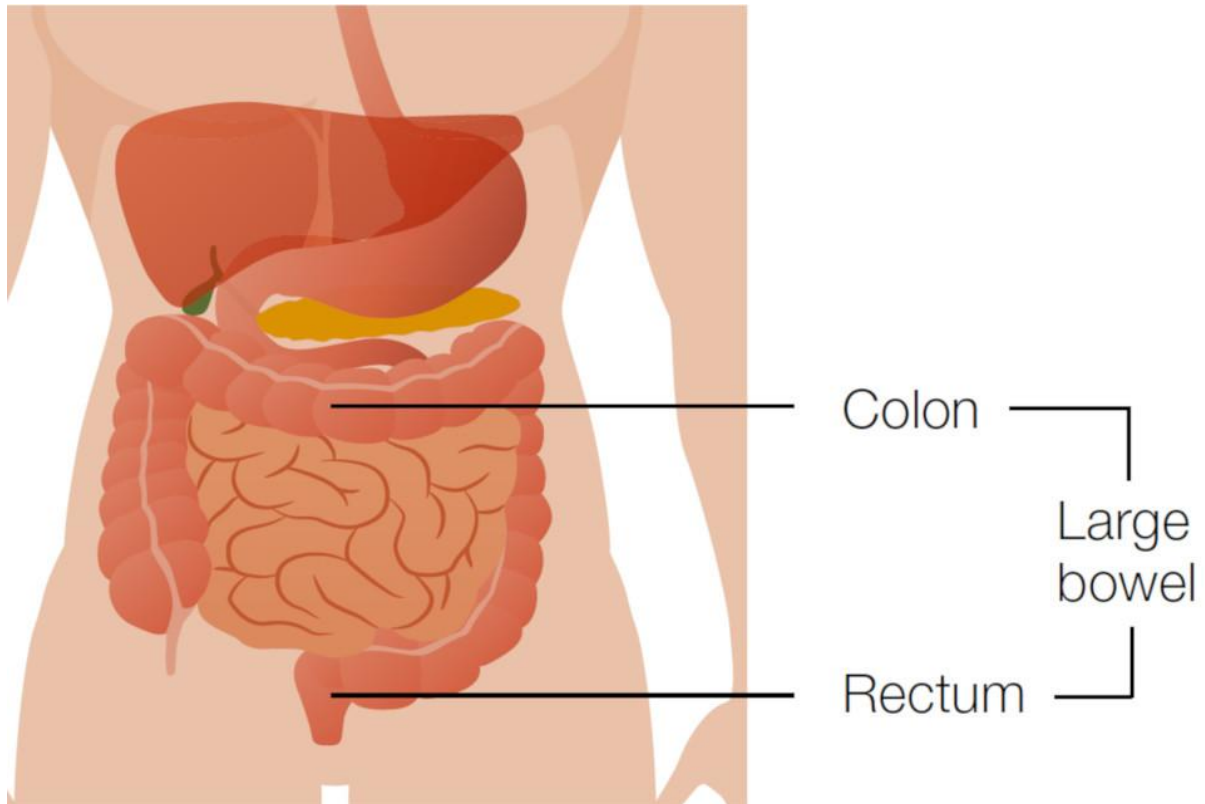
We offer bowel cancer screening using a home testing kit to everyone in England from the age of 60. Your GP practice gives us your contact details so please make sure they always have your correct name, date of birth and address. Many GPs also like to have your mobile number and email address.

We offer screening every 2 years between the ages of 60 and 74. We are gradually extending this age range, and people aged 56 are now being invited as part of this process. If you are over 74, you can ask for a kit every 2 years by calling our free helpline on 0800 707 60 60.

You may be asked to take part in a research project (a 'clinical trial'). Research helps the NHS improve bowel cancer prevention and treatment for people in the future. You can choose whether to take part or not. Your choice will not affect your bowel cancer screening.

How the bowel works

The bowel is part of your digestive system. It takes nutrients and water from food and turns what is left into poo (also known as faeces, stools or bowel motions). As illustrated below, the colon and rectum make up the large bowel.



The colon and rectum make up the large bowel.

Bowel cancer

Bowel cancer is also known as colon, rectal or colorectal cancer. Sometimes the cells that make up the bowel grow too quickly and form a clump of cells known as a bowel polyp (some types of polyp are called an 'adenoma'). Polyps are not bowel cancers but they can sometimes change into a cancer over a number of years.

Risks of developing bowel cancer

Everyone, whatever your sex, is at risk of developing bowel cancer. Things that can increase your risk include:

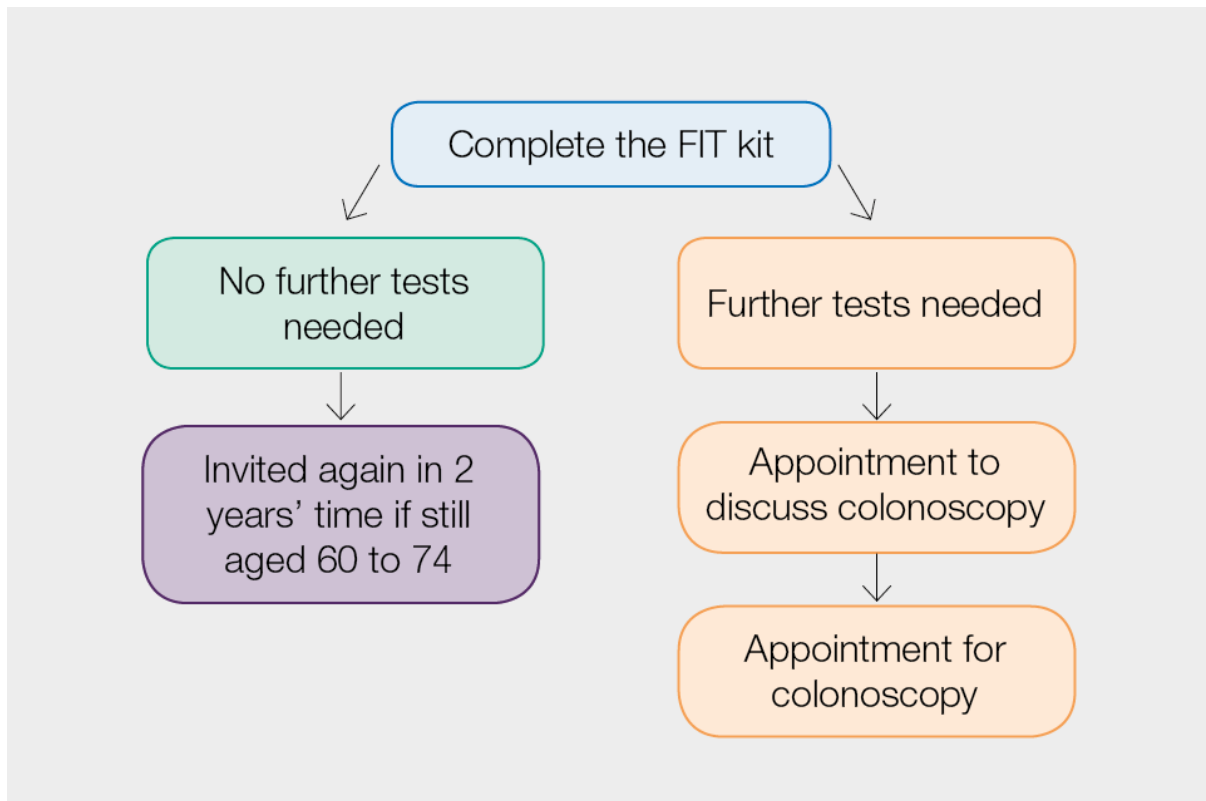
- getting older (8 out of 10 people diagnosed with bowel cancer are over 60)
- not being active enough
- being overweight
- a diet high in red and processed meat and low in fibre, vegetables and fruits
- smoking
- drinking too much alcohol
- having type 2 diabetes
- having inflammatory bowel disease (ulcerative colitis or Crohn's disease)
- a family history of bowel cancer

How bowel cancer screening works

We send you an invitation letter with information about bowel cancer screening. The information is to help you decide whether to take part. Then we send you a faecal immunochemical test, or 'FIT kit' for short. It detects blood in your poo (blood you would not notice by eye). We look for blood because polyps and bowel cancers sometimes bleed. Finding blood does not diagnose bowel cancer but it means you need further tests (usually a bowel examination).

Most people's screening result shows they do not need any further tests.

Some people will need further tests. If this is the case for you, we will offer you an appointment to talk about having a colonoscopy. Colonoscopy looks at the inside of your bowel. We use colonoscopy to find the source of the blood.



For most people, no further tests are needed. People who do need further tests will be offered an appointment to discuss colonoscopy.

Reduce your risk of bowel cancer

Having bowel cancer screening reduces your risk of dying from bowel cancer by at least 25%.

You can also reduce your risk of bowel cancer by:

- keeping physically active
- keeping a healthy weight
- eating plenty of fibre – for example, choose wholegrain and wholemeal foods
- eating plenty of vegetables and fruit
- eating less red meat and especially less processed meat
- drinking less alcohol
- not smoking

Using the FIT kit

We have a [short animation that shows you how to use the FIT kit](#).

The animation is available with subtitles and in British Sign Language. Subtitled versions are provided in English, Arabic, Bengali, Chinese (simplified and traditional), Farsi, Gujarati, Polish, Portuguese, Punjabi and Urdu.

You use the FIT kit in the privacy of your home. It's a simple way to collect a tiny sample of poo. The kit (pictured below) is a small plastic bottle with a stick attached inside the lid. You use the stick to collect the sample, which you seal into the bottle. There are instructions with each kit.

Once used, you post the kit in its prepaid packaging to a laboratory for processing. Using the kit takes just a few minutes and it's an easy and effective way to screen for early bowel cancer.

If you're not sure whether you should use the kit, please call our free helpline on 0800 707 60 60 for advice. For example, if you have had surgery and have an artificial opening that allows poo from the bowel to pass (a stoma) then you might want to call us.



Instructions for using the FIT kit are inside the lid of the packaging. You can use a clean disposable container to collect your sample.

Bowel cancer screening results

You should receive a results letter within 2 weeks of sending in your sample. As shown in the flowchart above, there are 2 possible results.

No further tests needed at this time

Most people (about 98 out of 100) have this result. It means that we did not find any blood in your sample, or only a tiny amount which is within the screening range.

This result does not guarantee that you do not have bowel cancer, or that it will never develop in the future. Being aware of the symptoms of bowel cancer is very important (see section on symptoms below). We will offer you bowel cancer screening again in 2 years' time if you are under the age of 75.

Further tests needed

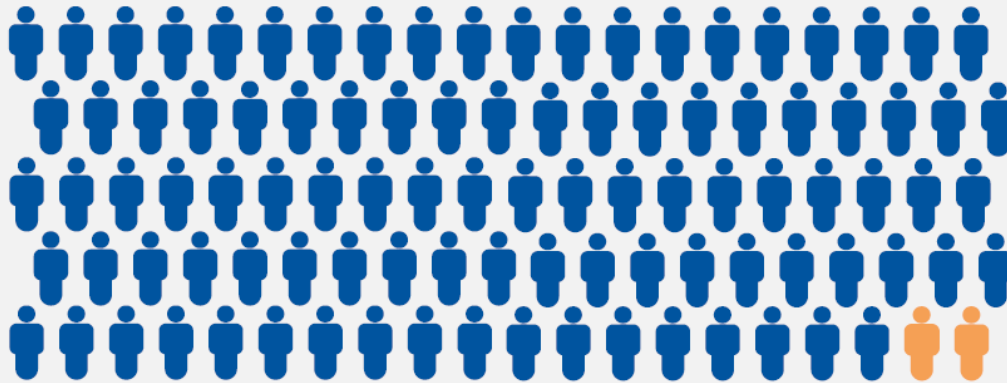
About 2 in every 100 people have this result. It means that we found an amount of blood in your sample above the screening range.

This does not mean that you have cancer, but it does mean we will offer you an appointment to discuss having a colonoscopy. Several things can cause blood in poo, such as:

- haemorrhoids (piles)
- bowel polyps
- bowel cancer

Having further tests (usually a colonoscopy) means we can look for the cause of the blood.

98 do not need
further tests



2 will need
further tests

For every 100 people getting their FIT kit results, 98 do not need further tests, and 2 will need further tests.

What happens to samples after testing

Once we have analysed the FIT sample, we record the result onto a database and then destroy the test kit and contents.

We keep the database information so we can check you are treated correctly. We also use it to monitor the performance of the bowel cancer screening programme.

If you need further tests

We will offer you an appointment at a local screening centre (usually in a hospital). This is to discuss having a more detailed examination of your bowel (colonoscopy). The colonoscopy is to see if there is a problem that needs treatment.

A specialist screening practitioner (SSP) will talk with you about your screening result and answer any questions you have. He or she will discuss colonoscopy with you, and check if you are fit enough for the procedure.

If you are fit for colonoscopy and want to go ahead with the examination, we will arrange an appointment for you. If we do not think you are fit enough for colonoscopy, we may offer you a different investigation such as a computerised tomography (CT) scan (sometimes called a 'virtual colonoscopy').

Colonoscopy

Only around 2 in 100 people who complete the FIT kit need a colonoscopy.

Colonoscopy looks at the lining of your large bowel. A colonoscopy specialist (usually a doctor or nurse) passes a thin flexible tube with a tiny camera attached (a colonoscope) into your back passage (rectum). They guide the colonoscope around your large bowel. If they find any polyps, they can usually remove them painlessly using a wire loop passed down the colonoscopy tube. They will check any removed polyps for cancer cells.

Colonoscopy is the best way to diagnose bowel cancer. For most people, colonoscopy is straightforward. But as with most medical procedures, complications can happen. These include:

- a hole (perforation) in the bowel caused by the colonoscope (around 1 person in 1,700); around half of people with a perforation will need surgery to repair it
- heavy bleeding needing a transfusion (around 1 person in 2,400)

In rare cases, people have died following colonoscopy complications. However, the most recent published national colonoscopy audit recorded no deaths. The audit looked at 20,085 colonoscopies carried out for both screening and symptom investigations^{[\[footnote 2\]](#)}.

For more information, you can read our [leaflet about colonoscopy](#).

Remember, most people who complete the FIT kit will **not** need a colonoscopy

Possible benefits and risks of bowel cancer screening

Being aware of the possible benefits and risks will help you decide whether or not to take part in bowel cancer screening.

Benefits

Bowel cancer screening:

- reduces your risk of dying from bowel cancer by at least 25%
- allows us to remove any polyps found during colonoscopy, which reduces your risk of developing bowel cancer
- can be completed at home in private

Risks

Bowel cancer screening might:

- cause complications, for example, during or after colonoscopy
- miss a cancer if it was not bleeding when you used the FIT kit

It is important to be aware of the symptoms of bowel cancer even if you have screening. No screening test is 100% effective. If you do not need further tests after using the FIT kit this does not guarantee that you do not have bowel cancer, or that it will never develop in the future.

No screening test is completely effective. In bowel cancer screening this is because:

- a polyp or cancer can sometimes be missed if it was not bleeding when the screening test was taken (a 'false negative' result)
- bowel cancer may develop in between screening tests

Bowel cancer symptoms

Symptoms of bowel cancer include:

- blood in your poo (faeces)
- looser poo, pooing more often and/or constipation
- a pain or lump in your abdomen (tummy)
- feeling more tired than usual for some time
- losing weight for no obvious reason

Please remember that these symptoms do not necessarily mean that you have bowel cancer. But if you have any of these symptoms for 3 weeks or more, please speak with your GP. It is important to do this even if you have recently had bowel cancer screening or a colonoscopy.

Bowel cancer screening is not a test for symptoms.

Treatment for bowel cancer

A diagnosis of bowel cancer is unlikely. But if it does happen, we will refer you to a team of specialists who will look after you.

If the cancer is in a polyp removed during a colonoscopy, regular check-ups may be all you need.

The main treatment for bowel cancer is surgery. In some cases, the specialists may offer you chemotherapy or radiotherapy.

Not all bowel cancers found at screening are curable. But for people who have bowel cancer found at its earliest stage, over 90% are still alive 5 years later. [\[footnote 3\]](#)

Confidentiality

The NHS screening programmes use personal information from your NHS records to invite you for screening at the right time. NHS England also uses your information to ensure you receive high quality care and to improve the screening programmes. Find out more about [how your information is used and protected, and your options](#).

More information

For more information about bowel cancer screening call our free helpline on 0800 707 60 60.

If you have hearing or speech difficulties you can use the Relay UK service to contact us. Dial 18001 then 0800 707 60 60 from your textphone or the [Relay UK app](#).

You can also:

- talk to your GP
- read the [NHS.UK information on bowel cancer screening](#)
- visit [GOV.UK](#) and search for 'bowel cancer screening'
- read our [leaflet about colonoscopy](#)
- read [information for transgender and non-binary people about NHS population screening programmes](#)

If you are 75 or over and would like a FIT kit, please call our free helpline on 0800 707 60 60. You can ask for a kit every 2 years.

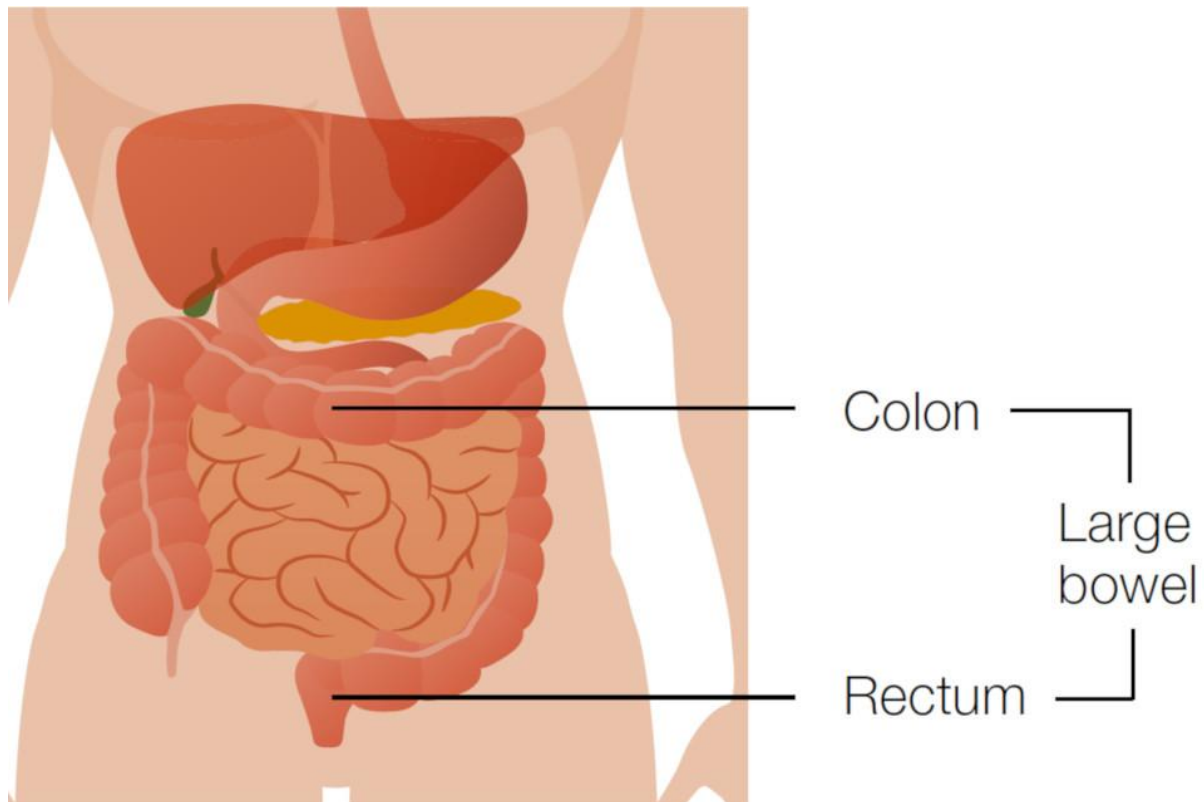
Find out [how to opt out of screening](#).

Except where indicated, all statistics are from PHE.

1. Hewitson P and others. 'Cochrane systematic review of colorectal cancer screening using the fecal occult blood test (hemoccult): an update'. American Journal of Gastroenterology 2018: 103(6), pages 1541 to 1549.↵
2. Gavin, DR and others. 'The National colonoscopy audit: a nationwide assessment of the quality and safety of colonoscopy in the UK'. Gut 2013: 62(2), pages 242 to 249.↵
3. Office for National Statistics dataset [Cancer survival in England - adults diagnosed](#), released August 2019.↵

How the bowel works

The bowel is part of your digestive system. It takes nutrients and water from food and turns what is left into poo (also known as faeces, stools or bowel motions). As illustrated below, the colon and rectum make up the large bowel.



Bowel cancer

Bowel cancer is also known as colon, rectal or colorectal cancer. Sometimes the cells that make up the bowel grow too quickly and form a clump of cells known as a bowel polyp (some types of polyp are called an 'adenoma'). Polyps are not bowel cancers but they can sometimes change into a cancer over a number of years.

Why we offer bowel cancer screening

We offer screening to detect bowel cancer when it is at an early stage in people with no symptoms. This is when treatment is more likely to be effective. Screening can also find polyps. These are abnormal clumps of cells in the bowel. Polyps are not cancers but may develop into cancers over time. Polyps can be easily removed, which reduces the risk of bowel cancer developing.

Regular bowel cancer screening reduces the risk of dying from bowel cancer.

Who we invite

We offer bowel cancer screening using a home testing kit to everyone in England from the age of 60. Your GP practice gives us your contact details so please make sure they always have your correct name, date of birth and address. Many GPs also like to have your mobile number and email address.

We offer screening between the ages of 60 and 74. We are gradually extending this age range, and people aged 56 are now being invited as part of this process. If you are over 74, you can ask for a kit by calling our free helpline.

How bowel cancer screening works

We send you an invitation letter with information about bowel cancer screening. The information is to help you decide whether to take part. Then we send you a faecal immunochemical test, or 'FIT kit' for short. It detects blood in your poo (blood you would not notice by eye). We look for blood because polyps and bowel cancers sometimes bleed. Finding blood does not diagnose bowel cancer but it means you need further tests (usually a bowel examination). We will also ask you to complete a questionnaire about your lifestyle. ●

Most people do not need any further tests.

Some people will need further tests. If this is the case for you, we will offer you an appointment to talk about having a colonoscopy.

Colonoscopy looks at the inside of your bowel. We use colonoscopy to find the source of the blood.

For most people, no further tests are needed. People who do need further tests will be offered an appointment to discuss colonoscopy.

Bowel cancer symptoms

Symptoms of bowel cancer include:

- blood in your poo (faeces)
- looser poo, pooing more often and/or constipation
- a pain or lump in your abdomen (tummy)
- feeling more tired than usual for some time
- losing weight for no obvious reason

Please remember that these symptoms do not necessarily mean that you have bowel cancer. But if you have any of these symptoms for 3 weeks or more, please speak with your GP. It is important to do this even if you have recently had bowel cancer screening or a colonoscopy.

Possible benefits and risks of bowel cancer screening

Being aware of the possible benefits and risks will help you decide whether or not to take part in bowel cancer screening.

Benefits

Bowel cancer screening:

- reduces your risk of dying from bowel cancer by at least 25%
- allows us to remove any polyps found during colonoscopy, which reduces your risk of developing bowel cancer
- the FIT kit can be completed at home in private ●

Risks

Bowel cancer screening might:

- cause complications, for example, during or after colonoscopy
- miss a cancer if it was not bleeding when you used the FIT kit
- detect blood in your stool that is not caused by a polyp or bowel cancer (a 'false positive') ●

It is important to be aware of the symptoms of bowel cancer even if you have screening. No screening test is 100% effective. If you do not need further tests after using the FIT kit this does not guarantee that you do not have bowel cancer, or that it will never develop in the future. ●

No screening test is completely effective. In bowel cancer screening this is because:

- a polyp or cancer can sometimes be missed if it was not bleeding when the screening test was taken (a 'false negative' result)
- bowel cancer may develop in between screening tests ●

Risk of developing bowel cancer

Everyone is at risk of developing bowel cancer. Things that can increase your risk include:

- getting older (8 out of 10 people diagnosed with bowel cancer are over 60)
- being male (males are 1.8 times more likely to develop bowel cancer than females) ●
- not being active enough
- being overweight
- eating a diet high in red and processed meat and low in fibre, vegetables and fruits ●
- smoking
- drinking too much alcohol ●
- having type 2 diabetes
- having inflammatory bowel disease (ulcerative colitis or Crohn's disease)
- having a family history of bowel cancer ●

As the risk of bowel cancer varies based on these factors, we will use this information from your questionnaire and the results of your screening test to determine your risk of bowel cancer. ●

We will then use this risk to determine whether you will be offered further tests and when you will next be invited for screening. ●

Your risk of bowel cancer will be determined using a risk calculator based on the risk factors listed above. A sliding scale is used so that the factors that contribute most to your risk level are weighted more highly than factors which only impact your risk level slightly. ●

A risk level will automatically be calculated for everyone in the screening programme. ●

As with screening tests, the way of estimating the risk of bowel cancer is not 100% perfect. People who have a high risk are not guaranteed

to develop bowel cancer. Similarly, it is not guaranteed that people with a low risk will not develop bowel cancer. ●

Bowel cancer screening outcomes

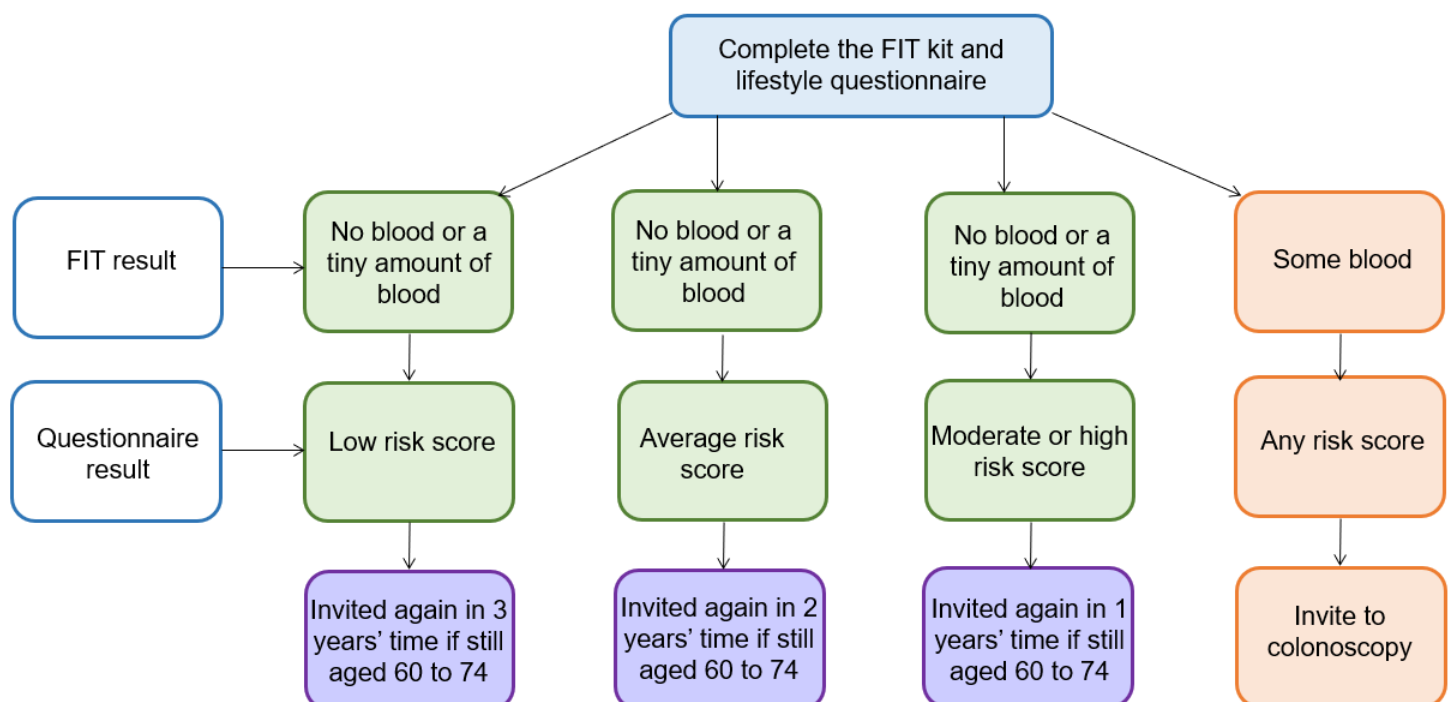
As shown in the flow chart below, there are 4 possible outcomes.

If your FIT kit detects **some blood** above the screening range you will be offered a colonoscopy regardless of your risk score. ●

If the result of your FIT kit shows **no blood or a tiny amount of blood** and you have a **low risk** based on the risk factors listed above you will be invited back for screening in 3 years' time. ●

If the result of your FIT kit shows **no blood or a tiny amount of blood** and you have an **average risk** based on the risk factors listed above you will be invited back for screening in 2 years' time. ●

If the result of your FIT kit shows **no blood or a tiny amount of blood** and you have a **moderate or high risk** based on the risk



factors listed above you will be invited back for screening in 1 years' time. ●

Invited for FIT test in 1-3 years

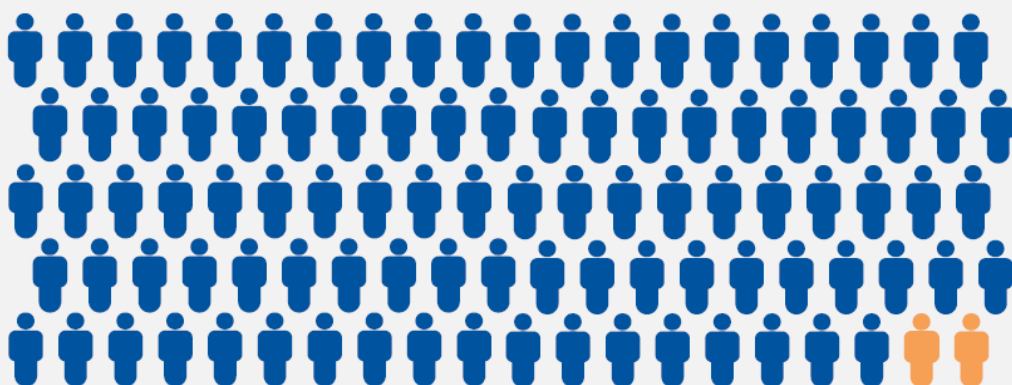
Most people (about 98 out of 100) have this result. It means that we did not find any blood in your sample, or only a tiny amount which does not need to be investigated.

This result does not guarantee that you do not have bowel cancer, or that it will never develop in the future. Being aware of the symptoms of bowel cancer is very important.

Invited for colonoscopy

About 2 in every 100 people have this result. It means that we found an amount of blood in your sample above the screening range.

98 do not need
further tests



2 will need
further tests

This does not mean that you have cancer, but it does mean we will offer you an appointment to discuss having a colonoscopy. Several things can cause blood in poo, such as:

- haemorrhoids (piles)
- bowel polyps
- bowel cancer

Having further tests (usually a colonoscopy) means we can look for the cause of the blood.

For every 100 people getting their FIT kit results, 98 do not need further tests, and 2 will need further tests.

This information has been adapted for research purposes from NHS England promotional material (<https://www.gov.uk/government/publications/bowel-cancer-screening-benefits-and-risks/nhs-bowel-cancer-screening-helping-you-decide#more-information>).

This leaflet contains public sector information and all content is available under the Open Government Licence v3.0 (<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>).

Think aloud study – practice text:

Starting a vegetable garden

Starting a vegetable garden is a great way to grow fresh, healthy foods and can be done outdoors, on a balcony or even a windowsill. ● The best time to start growing vegetables is spring time and you should choose an area that gets plenty of light. It is also a good idea to make sure there is a water source nearby. ●

Planting your vegetables in containers can be helpful as you can move plants around to suit your space. Containers can also be used on balconies and windowsills where you can't plant directly into the soil. ●



Some vegetables are easier to grow than others and these make good beginner crops. Potatoes, salad leaves, peas and beans are some easy vegetables to start

with. ● For balcony or indoor gardening chillies are a good option as they like a warm and sunny environment. ●

If you do decide to plant your vegetable garden directly outside, it is helpful to know what sort of soil you have. Most vegetables prefer a neutral soil so it can be useful to do a soil pH test before you plant your crops, which will tell you how acidic or alkaline your soil is. ●

Online questionnaire

Online questionnaire – to be completed before the think aloud interview and user testing survey

Question	Answer	Validation of question/reference
<i>[Note that this content will be delivered online so the formatting looked slightly different to in this document. The participants also will not see the headings in grey boxes.]</i>		
Consent		
I confirm that I have read and understood the participant information sheet and have given consent to take part in this study.	• [tick box]	
I understand that my taking part is voluntary and that I am free to leave at any time, without giving any reason.	• [tick box]	
I understand that anonymous information collected as part of my involvement in this study may be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel.	• [tick box]	
I understand that information collected as part of my involvement in this study will be used to support other research in the future and may be shared anonymously with other academic researchers external to the project within the UK and beyond.	• [tick box]	

By clicking 'I agree' you are indicating that you have read and understood this consent form and agree to participate in this research study. ['I agree'/submit form]		
Thank you for agreeing to complete this questionnaire. Please answer every question. If you are uncertain about how to answer a question, then please select the closest option.		
Demographics		
<i>Demographic information</i> <i>In this first section we would like to ask you a few questions about yourself. These questions allow us to make sure we are including people from a range of different backgrounds and see if different groups of people have different views. We will not be able to identify you from your answers.</i>		
How old are you?	• 50-54 years • 55-59 years • 60-64 years • 65-69 years • 70-74 years	
What is your sex? (A question about gender identity follows) Some of the scenarios we will be discussing will consider whether the sex of individuals should influence screening frequency and the threshold of the screening test. This would be the sex that individuals are assigned at birth. To help us see if responses differ between people of different sexes, please let us know your sex assigned at birth.	• Female • Male	Cambridge's The Healthcare Improvement Studies (THIS) Institute guidance released March 2021
Is the gender you identify with the same as your sex registered at birth?	• Yes • No (please enter your gender identity)	Cambridge's The Healthcare Improvement Studies (THIS) Institute guidance released March 2021

What is your ethnic group? Choose one option that best describes your ethnic group or background.	• Asian/Asian British • Black/African/Caribbean/Black British • Mixed/Multiple ethnic group • White • Other (please describe)	Ethnic groups are the top-level groups used in the UK Census and PAMCo(187)
What is your highest education level?	• Finished school at or before the age of fifteen • Completed GCSEs, O Levels or equivalent • Completed A Levels or equivalent • Completed further education but not a degree • Completed a Bachelor's degree • Completed a Master's degree or PhD • Other (please describe)	Validated from Cancer Awareness Measure (CAM) toolkit, (pre-2014, as 2014 onwards has not been validated)(188)
Which of the following best describes the <i>main income earner's</i> main/most recent job? This could be you: the main income earner is the person in your household with the largest income. If the main income earner is retired and has a pension, please answer for their most recent occupation. If the main income earner is not in paid employment but has been out of work for less than 6 months, please answer for their most recent occupation.	• Business owner – responsible for 1-4 employees • Business owner – responsible for 5-24 employees • Business owner – responsible for 25+ employees • Top/senior manager in large organisation; qualified senior professional <i>e.g. main board director, senior civil servant, headteacher, partner in professional practice, surgeon</i> • Middle manager or executive in large organisation; senior manager of small organisation; qualified	The ABC1–C2DE framework is a validated method of determining social grade.(189) PAMCo uses an updated version of this question(187)

	professional (no senior management responsibility) e.g. <i>department manager, teacher, engineer, accountant, doctor, manager of small building firm</i> • Non-management office role; middle manager in small organisation; qualified nurse; performing artist e.g. <i>secretary, personal assistant, clerical worker, office worker, call centre agent, salesperson, nurse or nursery nurse, police constable/sergeant, actor, musician, sportsperson</i> • Manual worker - manager – responsible for 25+ employees • Manual worker - manager – responsible for 1-24 employees • Skilled manual worker (no responsibility for other employees) e.g. <i>HGV driver, train/bus/ambulance driver, chef, hairdresser, mechanic, plumber, bricklayer, carpenter, painter, electrician, caterer, specialised machinery operator, fire-fighter, pub/bar worker</i> • Unskilled or semi-skilled manual worker (no responsibility for other employees) e.g. <i>farm worker, cleaner, postal worker, van driver, care worker, waiter, taxi driver, shop assistant, apprentice/trainee in skilled trade</i>	

	• Casual worker or no regular income • Full time student	
Screening history		
Screening history <i>The following questions are about your lifestyle and your past screening decisions. Please answer as honestly as you can as this will help us with our analysis.</i>		
Have you ever had cancer?	• Yes • No	
Have your parents or any brothers or sisters ever had cancer?	• Yes • No • Don't know/prefer not to answer	
Has anyone close to you (e.g. a partner or close friend) ever had cancer?	• Yes • No • Don't know	
Have you been invited to take part in any of the following screening programmes (please note that they are not offered to everyone)? Information is in the format of (what it involves, who it is offered to)	• Yes/No/Not Eligible ○ Abdominal Aortic Aneurysm screening (ultrasound, men aged over 65) ○ Bowel Cancer screening (poo sample or colonoscopy, men and women aged 60-74) ○ Breast Cancer screening (mammogram, women aged 50-70)	

	○ Cervical Cancer screening (smear test, women aged 25-64)	
Which of the following screening programmes did you take up the invitation to take part in?	• Yes/No/Not Eligible ○ Abdominal Aortic Aneurysm screening (ultrasound, men aged over 65) ○ Bowel Cancer screening (poo sample or colonoscopy, men and women aged 60-74) ○ Breast Cancer screening (mammogram, women aged 50-70) ○ Cervical Cancer screening (smear test, women aged 25-64)	
<i>Thank you for completing the survey. Your time and contribution are very much appreciated.</i>		

Think aloud study – participant information sheet

Exploring people's understanding of bowel cancer screening information.

Thank you for considering taking part in our study to explore the public's understanding of information relating to bowel cancer screening.

Please take time to read this information carefully to understand why the research is being done and what it will involve for you.

Who is organising the research?

The study is being led by doctors and researchers at the University of Cambridge. It is funded by the National Institute for Health Research and has been reviewed by the University of Cambridge Psychology Research Ethics Committee.

What is the purpose of the study?

The aim of screening is to diagnose cancer early. It has been suggested that it might be a good idea to tailor some aspects of the bowel cancer screening pathway according to peoples' individual risk, for example, by inviting some people to be screened more frequently than others. The aim of this study is to find out what information people would need about this and how they would like it to be communicated to make sure it is understandable.

Who is taking part?

We are recruiting about 15 members of the public using iPoint Research Ltd. People aged between 50 and 74 years who have not had bowel cancer and do not have medical expertise will be able to take part. You *don't* need to have any background knowledge about cancer in general (or about bowel cancer) to take part because we are interested in how non-expert members of the general public think about these issues.

iPoint Research is the authorised research recruitment partner for this study and is an authorised market research agency in the UK. iPoint Research will be responsible for initial communications with you and arranging the sessions.

Do I have to take part?

Your involvement in this study is entirely voluntary and you can leave at any time without giving a reason and there will be no consequences for doing so.

What happens next?

Before the study, you will be asked to complete an online consent form and then complete a survey with some basic questions about yourself. This will include background questions such as your age, sex, and occupation, and some questions about your screening history.

The main part of the study is a think aloud interview. This is a type of interview where the researcher will ask you explain your thoughts as you read a passage of informative text. We will ask you to pause each time you reach a red dot in the text and say aloud what is going through your mind.

The interview will be conducted online using Zoom video conferencing. We will encourage you to have your video turned on but will not insist on it. The interview will be video recorded using Zoom. The recordings will then be transcribed by an external company who will have signed a confidentiality agreement.

At the end of the study you will be asked to complete a short questionnaire containing true or false questions about the information you discussed in the interview.

How much time will it take?

The interview will take approximately 45 minutes to an hour to complete and will be held on Zoom.

What are the possible benefits of taking part?

By taking part in this study, you will have an opportunity to help influence cancer screening programmes by sharing your views and opinions. You will gain information about bowel cancer screening and the potential for future approaches using risk stratification.

Are there any disadvantages or risks of taking part?

Discussing the risks surrounding cancer screening can be a sensitive topic. If you become upset by anything during the interview, you may exit it at any stage and there are no consequences associated with doing so. If you have worries about cancer screening you can also contact your GP or find further information on cancer and support organisations on the Cancer Research UK or Macmillan Cancer Support websites (www.cancerresearchuk.org; www.macmillan.org.uk).

Will I be paid for taking part?

Yes, you will receive a gratuity as a thank you for your time and input. This will be processed by iPoint Research and you will receive this within 5–7 working days after the end of the study. Please see the information provided in the invitation.

Will my taking part in this study be kept confidential?

All information that is collected from you during the course of the study is anonymised and stored securely.

The University of Cambridge is the sponsor for this study based in the UK. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Cambridge will keep identifiable information about you 12 months after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at <https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data>.

What will happen to the results of the study?

This research is important for informing decision makers during the development of health policies. All findings will be published in peer-reviewed scientific journals and presented at national and international conferences. Anonymous direct quotations from the study may be used but you will not be identifiable in any of these. We can provide a summary of the results for you as well as share the completed publications with you. Anonymous information from the study may also be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel. It may also be shared anonymously with other academic researchers external to the project in the future to support other research.

What if there is a problem or something goes wrong?

If you have any concerns or complaints about any aspects of the study, you can telephone the study lead, Dr Juliet Usher-Smith, on [phone number and email address redacted].

Alternatively, if you would like to write to her, please send your letter to:

Dr Juliet Usher-Smith

STRAT-BSC study

[address redacted]

If you post a letter, there may be a delay in our response because we are not able to monitor post as frequently since the COVID-19 pandemic. We will reply to your email or letter in writing, unless you enclose your telephone number and wish to discuss your concerns by telephone.

**Thank you very much for reading this information sheet
and choosing to take part in this study**

Think aloud study consent form

Exploring people's understanding of bowel cancer screening information.

You must initial **all** of the boxes to be eligible to take part in the study.

	Please initial
1. I confirm that I have read and understood the information leaflet dated [insert date] for this study. I have had the opportunity think about the information, ask questions, and have these answered satisfactorily.	
2. I confirm that I do not have formal medical expertise or a history of bowel cancer.	
3. I understand that my participation is voluntary and I am free to withdraw at any time without giving reason.	
4. I understand and agree to the interview being recorded and transcribed for analysis purposes.	
5. I understand that anonymous direct quotations from my interview and my answers in the questionnaire may be published in journals or presented at conferences, but without my name or other identifying details used.	
6. I understand that anonymous information collected as part of my involvement in this study may be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel.	
7. I understand that anonymous information collected as part of my involvement in this study will be used to support other research in the future, and may be shared anonymously with other academic researchers external to the project within the UK and beyond.	
8. I agree to take part in this study.	

Name of participant

Date

Signature

Principal investigator:	Dr Juliet Usher-Smith	[address redacted]
Email:	[email address redacted]	

Survey introduction and instructions

Summary text and instructions seen by participants on Prolific

Study title for participants: Exploring people's understanding of bowel cancer screening information.

In this study, we are hoping to learn about how people interpret and understand information about bowel cancer screening.

You will first see a detailed information sheet and be asked to complete an online consent form. Next, you will be asked a few questions about yourself, including your screening history.

In the main part of the study, we will present you with information on bowel cancer screening that has been developed for the purposes of this study. We will ask you to read through the information provided and then answer a short set of true or false questions about what you have read.

Only people without expertise in medicine (e.g. no doctors, nurses, medical researchers) and people who do not have a history of bowel cancer are eligible for this study.

The website works best in Chrome and you will find it easier to see the questions and the graphics if you click the "open study in new window" button.

User testing study – participant information sheet

Exploring people's understanding of bowel cancer screening information.

Thank you for considering taking part in our study to explore the public's understanding of information relating to bowel cancer screening.

Please take time to read this information carefully to understand why the research is being done and what it will involve for you.

Who is organising the research?

The study is being led by doctors and researchers at the University of Cambridge. It is funded by the National Institute for Health Research and has been reviewed by the University of Cambridge Psychology Research Ethics Committee.

What is the purpose of the study?

The aim of screening is to diagnose cancer early. It has been suggested that it might be a good idea to tailor some aspects of the bowel cancer screening pathway according to peoples' individual risk, for example, by inviting some people to be screened more frequently than others. The aim of this study is to find out what information people need and how they would like it to be communicated to make sure it is understandable.

Who is taking part?

We are recruiting about 100 members of the public using the Prolific platform. People aged between 50 and 74 years who have not had bowel cancer and do not have medical expertise will be able to take part. You *don't* need to have any background knowledge about cancer in general (or about bowel cancer) to take part because we are interested in how non-expert members of the general public think about these issues.

Do I have to take part?

Your involvement in this study is entirely voluntary and you can leave at any time without giving a reason and there will be no consequences for doing so.

What happens next?

You will first be asked to complete an online consent form and then complete a survey with some basic questions about yourself. This will include questions about your age, sex, lifestyle, employment and education. It will also include questions about your screening history.

In the main part of the study you will be presented with information about a bowel cancer screening programme that has been specifically developed for this study. Once you have read the information you will be asked to complete a short set of true or false questions about what you have read.

If you want to withdraw from the study, you can return your submission on the Prolific website. This will not affect your Prolific rating and your data will not be saved or used in the study. If you only complete part of the survey but choose not to return your submission in Prolific, your data may still be used in the study.

How much time will it take?

The task will take approximately 20 minutes to complete.

What are the possible benefits of taking part?

By taking part in this study, you will have an opportunity to help influence cancer screening programmes by sharing your views and opinions. You will gain information about bowel cancer screening and the potential for future approaches.

Are there any disadvantages or risks of taking part?

Discussing the risks surrounding cancer screening can be a sensitive topic. If you become upset by anything during the interview, you may exit it at any stage and there are no consequences associated with doing so. If you have worries about cancer screening you can also contact your GP or find further information on cancer and support organisations on the Cancer Research UK or Macmillan Cancer Support websites (www.cancerresearchuk.org; www.macmillan.org.uk).

Will I be paid for taking part?

Yes, there is a £2.50 (£7.50 per hour) reward for the time you spend doing this task. This will be paid to you through Prolific once your answers to the task have been accepted by the researchers.

Will my taking part in this study be kept confidential?

All information that is collected from you during the course of the study is anonymised and stored securely.

Furthermore, Prolific will not share any personal or identifiable information about you with the researchers. Please visit the Prolific website for more details of their data privacy policy:

https://www.prolific.co/assets/docs/Prolific_privacy-policy.pdf

What will happen to the results of the study?

This research is important for informing decision makers during the development of health policies. All findings will be published in peer-reviewed scientific journals and presented at national and international conferences. You will not be identifiable in any of these publications. After the study we will send you a summary of the results via Prolific.

At the end of the study the anonymous data will be stored in an online database so that it is publicly available. This is called “open data”. This practice is integral to the research process as it will allow others to verify results and avoid duplicating research. Anonymised data are made available on a website, free of charge, to anyone interested in the research, or who wished to conduct their own analysis of the data. We would therefore have no control over how these data are used.

What if there is a problem or something goes wrong?

If you have any concerns or complaints about any aspects of the study, you can telephone the study lead, Dr Juliet Usher-Smith, on [phone number and email address redacted].

Alternatively, if you would like to write to her, please send your letter to:

Dr Juliet Usher-Smith

User testing study

[address redacted]

If you post a letter, there may be a delay in our response because we are not able to monitor post as frequently since the COVID-19 pandemic. We will reply to your email or letter in writing, unless you enclose your telephone number and wish to discuss your concerns by telephone.

Thank you very much for reading this information sheet

and choosing to take part in this study

User testing survey consent form

Exploring people's understanding of bowel cancer screening information.

- Please tick each box
1. I confirm that I have read and understood the information sheet for this study on the previous pages. I have had the opportunity to think about the information, ask questions, and have these answered satisfactorily. ☐
 2. I confirm that I do not have formal medical expertise or a history of bowel cancer. ☐
 3. I understand that my participation is voluntary, and I am free to withdraw at any time without giving reason and this will not affect my Prolific approval rating. ☐
 4. I understand that if I withdraw from the study by returning my submission in Prolific, my data will not be used. If I do not return my submission, my data may be used even if I do not complete the study. ☐
 5. I understand that data provided by Prolific as part of my involvement in this study and my responses to the survey will be stored in an online database so that it is publicly available at the end of the study ("open data"). ☐

By clicking 'I agree' below you are indicating that you have read and understood this consent form, and agree to take part in this research study.

I agree

Please click [here](#) to download a copy of the participant information sheet and consent form, including the researchers' contact details.

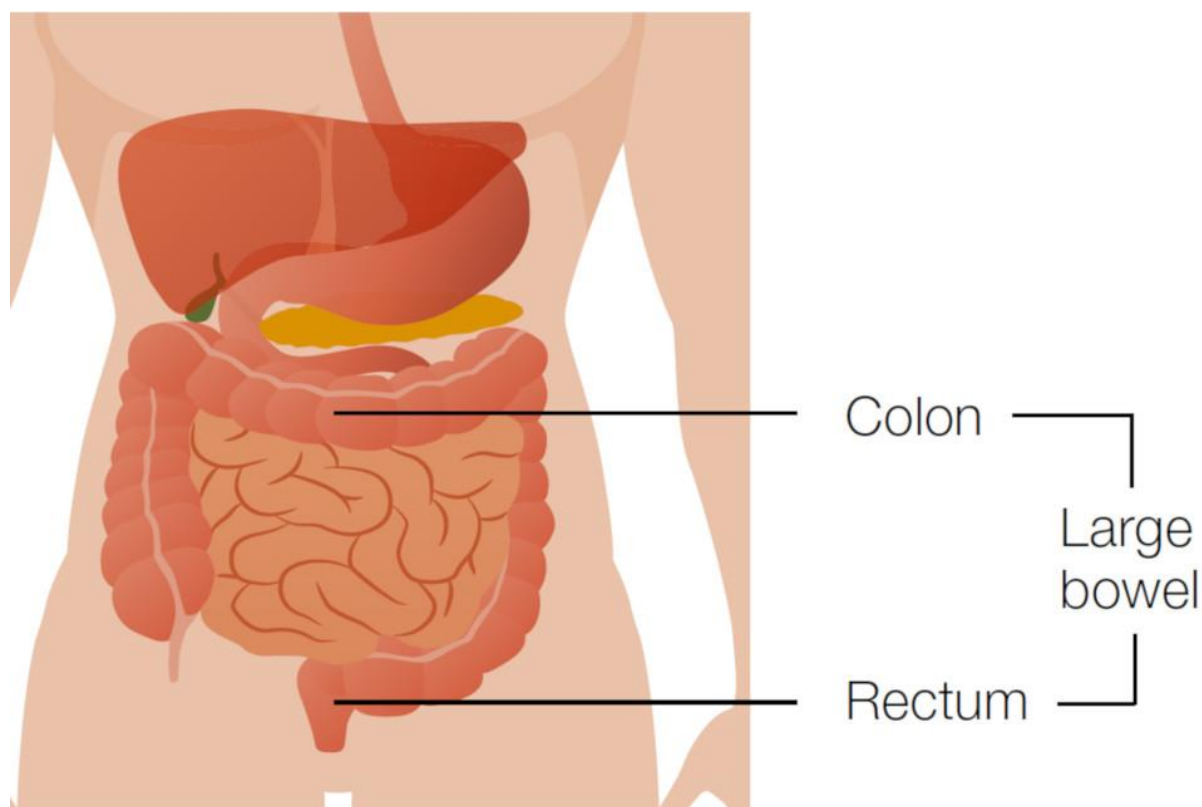
Think aloud study – user testing statements

Question	Responses	Correct answer
<i>[Note that this content will be delivered online so the formatting looked slightly different to in this document. The participants also will not see the headings in grey boxes.]</i>		
Introduction for user testing only participants		
<i>Thank you for participating in this short user testing survey. Please download the information leaflet here [insert link to Open Science Framework resources] and read it through carefully. This should take you 5-10 minutes. Once you have read the information thoroughly you will be asked to complete a short set of true or false statements relating to what you have read.</i>		
Original leaflet questions		
Participating in screening lowers the risk of dying from bowel cancer.	• True • False	True
The FIT test is done at home.	• True • False	True
Most people who do the FIT test will need further tests.	• True • False	False
Only women are sent a FIT test.	• True • False	False
Bowel cancer is more common in people over the age of 60.	• True • False	True
People only need to do the FIT test once in their lifetime.	• True • False	False

The FIT test can miss bowel cancer.	• True • False	True
People who need to have further tests always have bowel cancer.	• True • False	False
Additional questions		
Smoking and drinking too much alcohol increases your risk of developing bowel cancer.	• True • False	True
Information about your lifestyle will be used to determine your personal risk of bowel cancer.	• True • False	True
People who have a high risk are guaranteed to get bowel cancer.	• True • False	False
The FIT test can detect blood in your stool that is not caused by bowel cancer.	• True • False	True
The result of your FIT test and your personal risk of bowel cancer will be used to determine when you will next be invited for screening.	• True • False	True
If you have a low risk of bowel cancer based on your lifestyle, you won't ever be offered a colonoscopy regardless of the result of the FIT test.	• True • False	False

How the bowel works

The bowel is part of your digestive system. It takes nutrients and water from food and turns what is left into poo (also known as faeces, stools or bowel motions). As illustrated below, the colon and rectum make up the large bowel.



Bowel cancer

Bowel cancer is also known as colon, rectal or colorectal cancer. Bowel cancer is the fourth most common cancer in the UK. If found early, bowel cancer can often be successfully treated.

Sometimes the cells that make up the bowel grow too quickly and form an abnormal clump of cells known as a **bowel polyp** (some types of polyp are called an 'adenoma'). Polyps are not bowel cancers but they can sometimes change into a cancer over a number of years. This means bowel cancer usually takes about 10 to 15 years to develop.

Bowel cancer screening

We offer screening to detect bowel cancer when it is at an early stage in people with no symptoms.

Screening can also find polyps. Polyps can be easily removed, which reduces the risk of bowel cancer developing.

Regular bowel cancer screening reduces the risk of dying from bowel cancer.

Who we invite

We offer bowel cancer screening using a home testing kit to everyone in England from the age of 60. Your GP practice gives us your contact details so please make sure they always have your correct name, date of birth and address. Many GPs also like to have your mobile number and email address.

We currently offer screening between the ages of 60 and 74. We are gradually extending this age range, and people aged 56 are now being invited as part of this process. If you require assistance to complete your home testing kit or you are over 74 and would like to ask for a kit, you can call our free helpline.

The screening kit

We send you an invitation letter with information about bowel cancer screening. The information is to help you decide whether to take part. Then we send you a home testing kit called a faecal immunochemical test, or 'FIT kit' for short. It detects blood in your poo (blood you would not notice by eye). We look for blood because polyps and bowel cancers sometimes bleed. Finding blood does not diagnose bowel cancer but it means you need further tests (usually a bowel examination). We will also ask you to complete a questionnaire about your lifestyle.

Most people do not need any further tests because they do not have a concerning level of blood in their poo. A tiny amount of blood may be detected which is not visible to the naked eye and is not a cause for concern.

Some people will need further tests. If this is the case for you, we will offer you an appointment to talk about having a colonoscopy.

Colonoscopy looks at the inside of your bowel and is done in hospital by a trained healthcare professional. We use colonoscopy to find the source of the blood.

Bowel cancer symptoms

Symptoms of bowel cancer include:

- blood in your poo (faeces)
- looser (runny) poo, pooing more often and/or constipation
- a pain or lump in your abdomen (tummy)
- feeling more tired than usual for some time
- losing weight for no obvious reason

Please remember that these symptoms do not necessarily mean that you have bowel cancer. But if you have any of these symptoms for three weeks or more, please speak with your GP. It is important to do this even if you have recently had bowel cancer screening or a colonoscopy.

Possible benefits and risks of bowel cancer screening

Being aware of the possible benefits and risks of completing your FIT kit will help you decide whether or not to take part in bowel cancer screening.

Benefits

Bowel cancer screening:

- reduces your risk of dying from bowel cancer
- allows us to remove any polyps found during colonoscopy, which reduces your risk of developing bowel cancer.

Risks

Bowel cancer screening might:

- cause complications during or after a colonoscopy. In rare cases, people may have a reaction to the sedation, have heavy bleeding afterwards or get a small tear in their bowels
- miss a cancer if it was not bleeding when you used the FIT kit
- detect blood in your stool that is not caused by a polyp or bowel cancer. This could be caused by something else, such as piles (haemorrhoids) or diverticular disease and might mean that you have unnecessary further investigations.

It is important to be aware of the symptoms of bowel cancer even if you have screening. No screening test is 100% effective. In bowel cancer screening this is because:

- a polyp or cancer can sometimes be missed if it was not bleeding when the screening test was taken
- bowel cancer may develop between screening tests.

If you do not need further tests after using the FIT kit this does not guarantee that you do not have bowel cancer, or that it will never

develop in the future. If you have symptoms for three weeks or more, please visit your GP even if you have participated in screening.

Risk of developing bowel cancer

Everyone is at risk of developing bowel cancer. Things that can increase your risk include:

- getting older (8 out of 10 people diagnosed with bowel cancer are over 60)
- being male (males are 1.8 times more likely to develop bowel cancer than females)
- not being active enough
- being overweight
- eating a diet high in red and processed meat
- eating a diet low in fibre, vegetables and fruits
- smoking
- drinking too much alcohol
- having type 2 diabetes
- having inflammatory bowel disease (ulcerative colitis or Crohn's disease)
- having a family history of bowel cancer

A healthy lifestyle can help to lower your risk of bowel cancer.

As the risk of bowel cancer varies based on these factors, we will use this information from your questionnaire and the results of your screening test to determine your risk of bowel cancer.

We will then use this to determine whether you will be offered further tests and when you will next be invited for screening.

As with screening tests, the way of estimating the risk of bowel cancer is not 100% perfect. People who have a high risk are not guaranteed to develop bowel cancer. Similarly, it is not guaranteed that people with a low risk will not develop bowel cancer.

Bowel cancer screening outcomes

As shown in the flow chart on the next page, there are 4 possible outcomes.

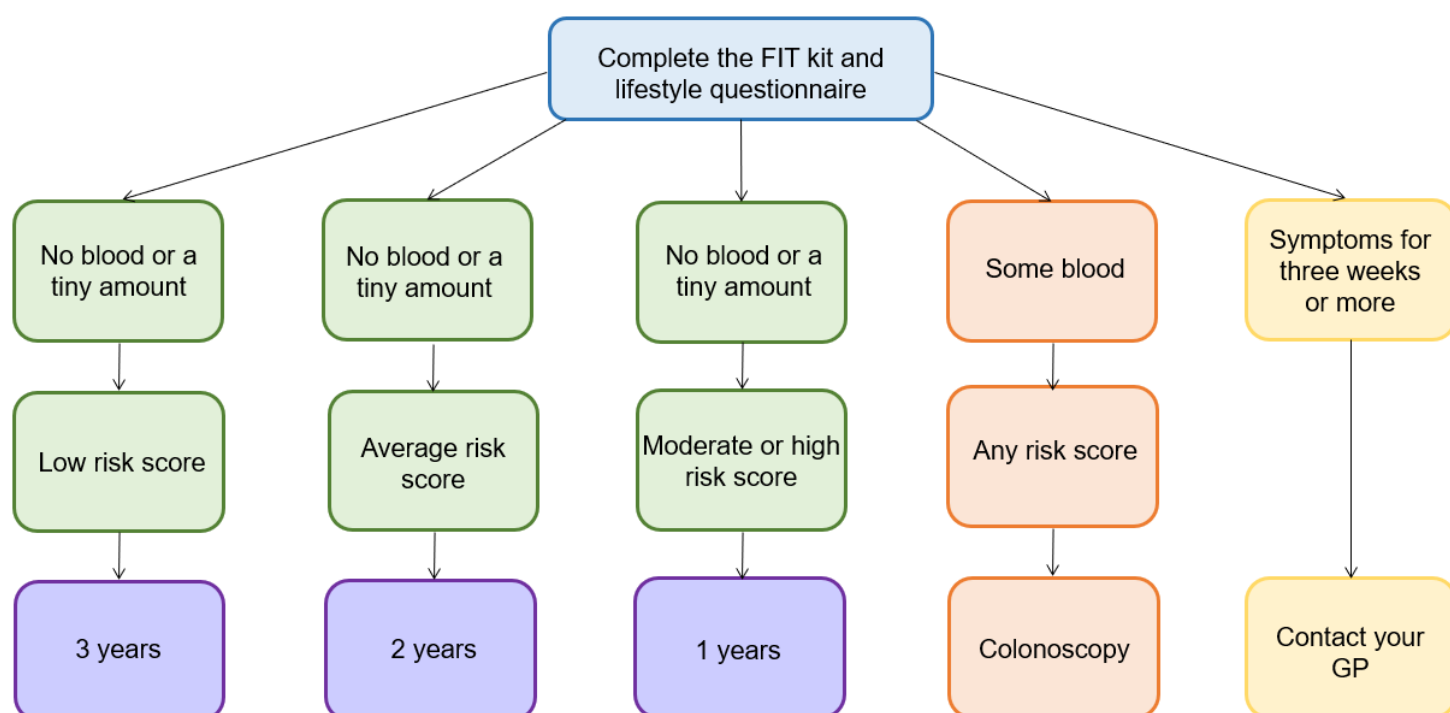
If your FIT kit detects **some blood** above the screening range you will be offered a colonoscopy regardless of your risk score.

If the result of your FIT kit shows **no blood or a tiny amount of blood** and you have a **low risk** based on the risk factors listed above you will be invited to complete another FIT kit in 3 years' time.

If the result of your FIT kit shows **no blood or a tiny amount of blood** and you have an **average risk** based on the risk factors listed above you will be invited to complete another FIT kit in 2 years' time.

If the result of your FIT kit shows **no blood or a tiny amount of blood** and you have a **moderate or high risk** based on the risk factors listed above you will be invited to complete another FIT kit in 1 years' time.

If you develop symptoms of bowel cancer between screening tests that last for three weeks or more, please contact your GP. Don't wait for your next invite to screening.



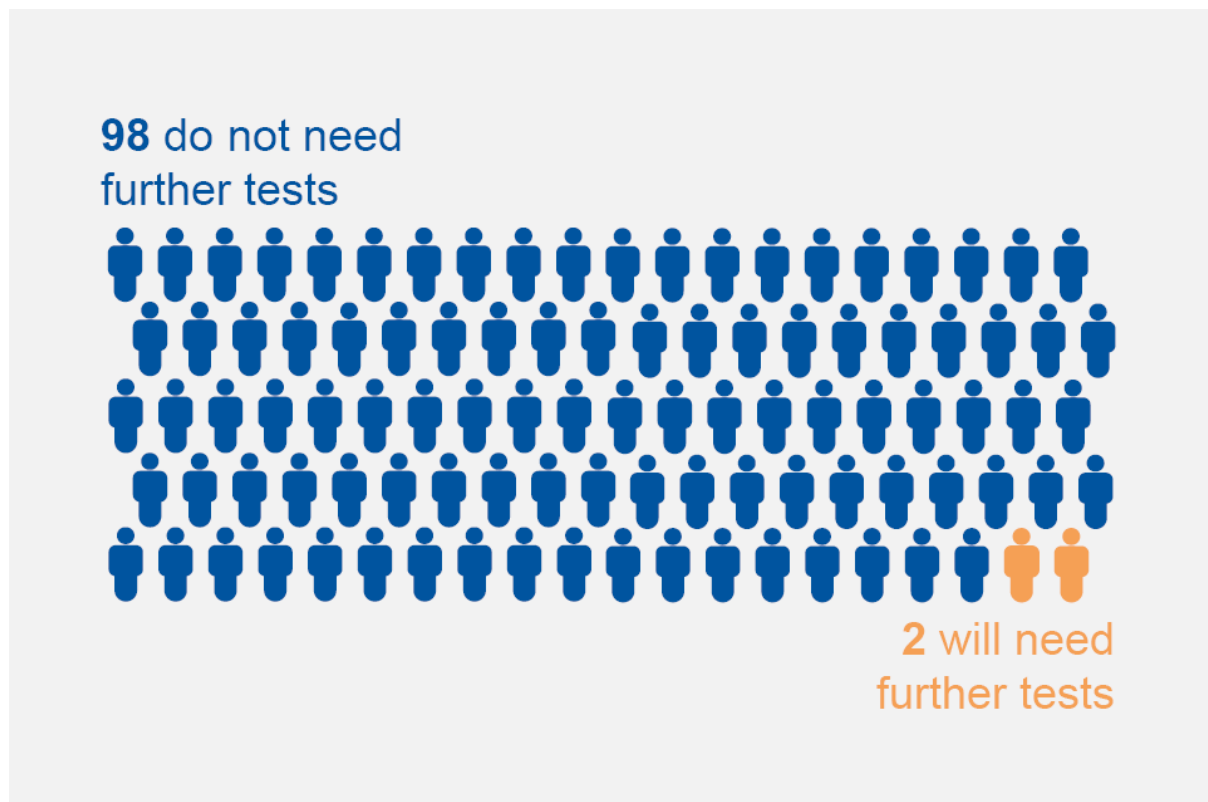
Invited for FIT test in 1-3 years

Most people (about 98%) have this result. It means that we did not find any blood in your sample, or only a tiny amount which does not need to be investigated.

This result does not guarantee that you do not have bowel cancer, or that it will never develop in the future. **Being aware of the symptoms of bowel cancer is very important.**

Invited for colonoscopy

About 2 in every 100 people (2%) have this result. It means that we found an amount of blood in your sample above the screening range.



This does not mean that you have cancer, but it does mean we will offer you an appointment to discuss having a colonoscopy. Several things can cause blood in poo, such as:

- piles (haemorrhoids)
- anal tear (fissure)
- diverticular disease
- bowel polyps

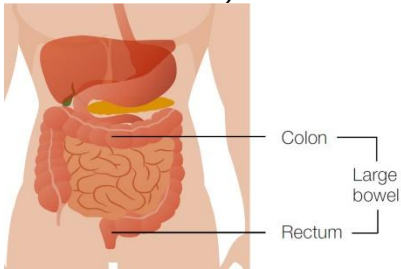
- bowel cancer

Having further tests (usually a colonoscopy) means we can look for the cause of the blood and remove any polyps or detect a cancer.

This information has been adapted for research purposes from NHS England promotional material (<https://www.gov.uk/government/publications/bowel-cancer-screening-benefits-and-risks/nhs-bowel-cancer-screening-helping-you-decide#more-information>).

This leaflet contains public sector information and all content is available under the Open Government Licence v3.0 (<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>).

STRAT-BCS II: STRATification in Bowel Cancer Screening II – Survey study

Question	Answer	Validation of question/reference
[Note that this content will be delivered online so the formatting looks slightly different to in this document. The participants will not see the headings in grey boxes]		
Thank you for agreeing to complete this questionnaire. Please answer every question. If you are uncertain about how to answer a question, then please select the closest option.		
Bowel cancer screening		
Please read the following information about bowel cancer and bowel cancer screening that may be provided as part of a potential bowel cancer screening programme. Please note that this information has been developed for the purposes of this research only and is not reflective of current screening practices. There is a lot of information to take in so please read carefully.		
<u>How the bowel works</u> The bowel is part of your digestive system. It takes nutrients and water from food and turns what is left into poo (also known as faeces, stools or bowel motions). As illustrated, the colon and rectum make up the large bowel.		
		
<u>Bowel cancer</u> Bowel cancer is also known as colon, rectal or colorectal cancer. Bowel cancer is the fourth most common cancer in the UK. If found early, bowel cancer can often be successfully treated.		
Sometimes the cells that make up the bowel grow too quickly and form an abnormal clump of cells known as a bowel polyp (some types of polyp are called an 'adenoma'). Polyps are not bowel cancers but they can sometimes change into a cancer over a number of years. This means bowel cancer usually take about 10-15 years to develop.		
<u>Bowel cancer screening</u> Everyone in England is offered screening to detect bowel cancer when it is at an early stage in people with no symptoms.		

Screening can also find polyps. Polyps can be easily removed, which reduces the risk of bowel cancer developing.

Regular bowel cancer screening reduces the risk of dying from bowel cancer.

Who we invite

Bowel cancer screening using a home testing kit is offered to everyone in England from the age of 60. This is similar in Wales, Scotland and Northern Ireland.

Screening is currently offered between the ages of 60 and 74. This age range is being gradually extended downwards, and people aged 56 are now being invited as part of this process.

The screening kit

You will receive an invitation letter with information about bowel cancer screening. The information is to help you decide whether to take part. Then we send you a home testing kit called a faecal immunochemical test, or 'FIT kit' for short. It detects blood in your poo (blood you would not notice by eye). We look for blood because polyps and bowel cancers sometimes bleed. Finding blood does not diagnose bowel cancer but it means you will need further tests (usually a bowel examination).

Most people do not need any further tests because they do not have a concerning level of blood in their poo. A tiny amount of blood may be detected which is not visible to the naked eye and is not a cause for concern.

Some people will need further tests. If this is the case for you we will offer you an appointment to talk about having a colonoscopy. Colonoscopy looks at the inside of your bowel and is done in hospital by a trained healthcare professional. We use colonoscopy to find the source of the blood.

Bowel cancer symptoms

Symptoms of bowel cancer include:

- Blood in your poo (faeces)
- Looser (runny) poo, pooing more often and/or constipation
- A pain or lump in your abdomen (tummy)
- Feeling more tired than usual for some time
- Losing weight for no obvious reason

Possible benefits and risks of bowel cancer screening

Being aware of the possible benefits and risks of completing your FIT kit will help you decide whether or not to take part in bowel cancer screening.

Benefits

Bowel cancer screening:

1. Reduces your risk of dying from bowel cancer
2. Allows us to remove any polyps found during colonoscopy, which reduces your risk of developing bowel cancer.

Risks

Bowel cancer screening might:

1. Cause complications during or after a colonoscopy. In rare cases, people may have a reaction to the sedation, have heavy bleeding afterwards or get a small tear in their bowels
2. Miss a cancer if it was not bleeding when you used the FIT kit
3. Detect blood in your stool that is not caused by a polyp or bowel cancer. This could be caused by something else, such as piles (haemorrhoids) or diverticular disease, and might mean that you have unnecessary further investigations.

It is important to be aware of the symptoms of bowel cancer even if you have screening. No screening test is 100% effective. In bowel cancer screening this is because:

- A polyp or cancer can sometimes be missed if it was not bleeding when the screening test was taken
- Bowel cancer may develop between screening tests.

If you do not need further tests after using the FIT kit this does not guarantee that you do not have bowel cancer, or that it will never develop in the future. If you have symptoms for three weeks or more, please visit your GP even if you have participated in screening.

Risk of developing bowel cancer

Everyone is at risk of developing bowel cancer. Things that can increase your risk include:

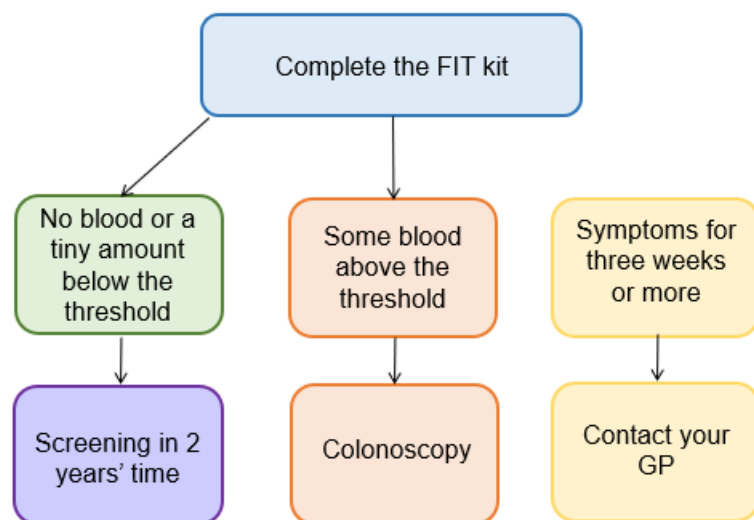
- Getting older (8 out of 10 people diagnosed with bowel cancer are over 60)
- Being male (males are 1.8 more likely to develop cancer than females)
- Not being active enough
- Being overweight
- Eating a diet high in red and processed meat
- Eating a diet low in fibre, vegetables and fruit
- Smoking
- Drinking too much alcohol
- Having type 2 diabetes
- Having inflammatory bowel diseases (ulcerative colitis or Crohn's disease)
- Having a family history of bowel cancer
- Having certain genetic factors.

A healthy lifestyle can help to lower your risk of bowel cancer.

In your opinion, bowel cancer screening is:

- Always a good idea

	• Sometimes a good idea/it depends • Never a good idea	
Screening strategy A: Screening as usual background information		
<u>The current screening programme</u> In the current bowel cancer screening programme, screening is offered every two years to everyone between the ages of 60-74 regardless of their personal risk of developing bowel cancer. The threshold for referral, meaning the amount of blood detected by the FIT kit, is the same for everyone. This means that anyone over a predefined threshold will be referred for a colonoscopy. Anyone under the threshold will not be referred for a colonoscopy, regardless of their personal risk of developing bowel cancer. <u>Bowel cancer screening outcomes</u> As shown in the flow chart below, there are two possible outcomes for this screening programme. If your FIT kit detects some blood above the threshold for referral you will be offered a colonoscopy. If the result of your FIT kit shows no blood or a tiny amount of blood below the threshold for referral you will be invited to complete another FIT kit in 2 years' time.		



Risk stratification strategies

As you have read, your risk of developing bowel cancer may be higher or lower than average depending on your age, sex, lifestyle factors, family history and also genetic factors.

You will now be asked to read about three potential bowel cancer screening programmes that use personal risk information to adapt or tailor screening. The first uses risk to decide when to start bowel cancer screening, the second uses risk to decide when to refer people for further tests, and the third uses risk to decide how often to invite people.

As with screening tests, the way of estimating the risk of bowel cancer is not 100% perfect. People who have a high risk are not guaranteed to develop bowel cancer. Similarly, it is not guaranteed that people with a low risk will not develop bowel cancer.

Please read this information carefully as you will then be asked to answer a series of questions about the potential programmes.

Screening strategy B: Risk-stratified eligibility criteria background information

Using risk to decide **when to start** bowel cancer screening

As the risk of bowel cancer varies based on your risk factors, in this programme your risk of bowel cancer would be estimated from information already in your GP records or you would be asked to complete a questionnaire and/or a saliva sample (to collect genetic information). This information would then be used to determine your risk of bowel cancer.

Your estimated risk of bowel cancer will then be used to determine when your first invite to bowel cancer screening will be. People with a low risk will be invited later than those at average risk and people with high risk will be invited sooner.

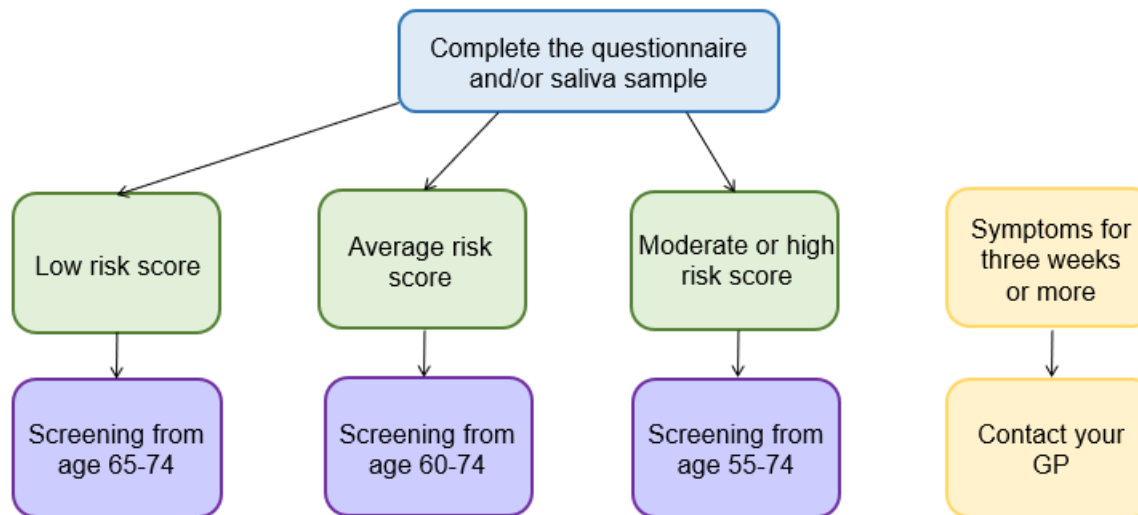
Bowel cancer screening outcomes

As shown in the flow chart below there are 3 possible outcomes for this screening programme.

If you have a **low risk** based on the risk factors listed previously you will be invited to have bowel cancer screening between the ages of 65 to 74 years.

If you have an **average risk score** based on the risk factors listed previously you will be invited to have bowel cancer screening between the ages of 60 and 74 years.

If you have a **moderate or high risk** based on the risk factors listed above you will be invited to have bowel cancer screening between the ages of 55 and 74.



Screening strategy C: Risk-stratified FIT threshold background information

Using risk to decide **when to refer** people for further tests

As the risk of bowel cancer varies based on your risk factors, in this programme your risk of bowel cancer would be estimated from information already in your GP records or you would be asked to complete a questionnaire and/or a saliva sample (to collect genetic information). This information would then be used to determine your risk of bowel cancer.

This estimated risk of bowel cancer will then be used together with the result from the FIT test to determine whether you will be offered further tests (either a repeat FIT test or a colonoscopy). Those with blood above the threshold will always be offered colonoscopy. Similarly, those with no or only a tiny amount of blood will always be invited for screening again in two years. The risk will affect those people with blood close to, but below the threshold. For those people, if they are high risk they would be referred for colonoscopy and if they are low or average risk they would be sent another FIT test in 6 weeks.

Bowel cancer screening outcomes

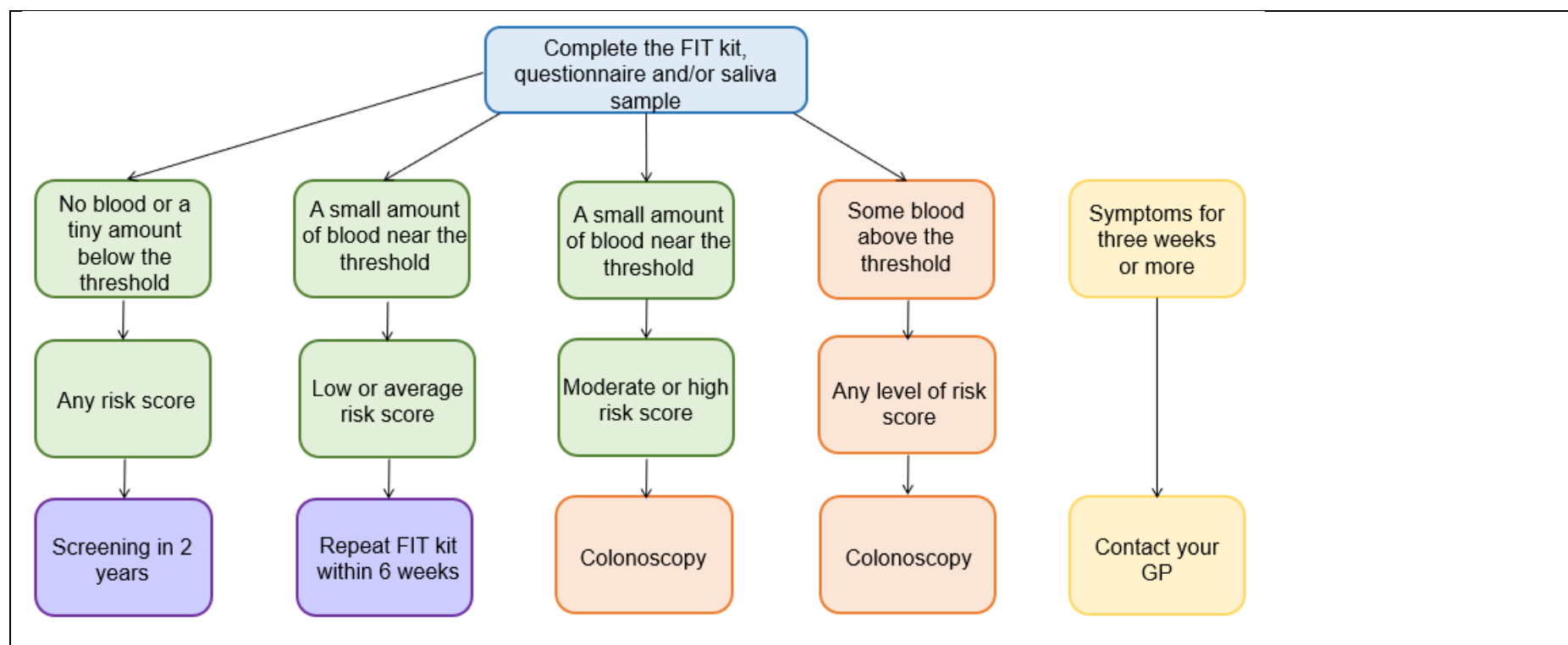
As shown in the flow chart below, there are four possible outcomes for this screening programme.

If your FIT kits detects **some blood** above the screening threshold you will be offered a colonoscopy regardless of your risk score.

If the result of your FIT kit shows **no blood or a tiny amount of blood** below the screening threshold you will be invited to FIT screening in 2 years time.

If the result of your FIT kit shows a **small amount of blood** near the threshold and you have a **low or average risk** based on the risk factors listed previously you will be invited to complete another FIT test within 6 weeks to see if you need a colonoscopy.

If the result of your FIT kit shows a **small amount of blood** near the threshold and you have a **high risk** based on the risk factors listed previously you will be offered a colonoscopy.



Strategy D: Risk-stratified screening interval background information

Using risk to decide **how often to invite** people for bowel cancer screening

As the risk of bowel cancer varies based on your risk factors, in this programme your risk of bowel cancer would be estimated from information already in your GP records or you would be asked to complete a questionnaire and/or a saliva sample (to collect genetic information). This information would then be used to determine your risk of bowel cancer.

This estimated risk of bowel cancer will then be used to determine when you will next be invited for screening if you have no blood or only a tiny amount below the threshold. People with a high risk would be invited back sooner than those at average risk and those at low risk would be invited back later.

Bowel cancer screening outcomes

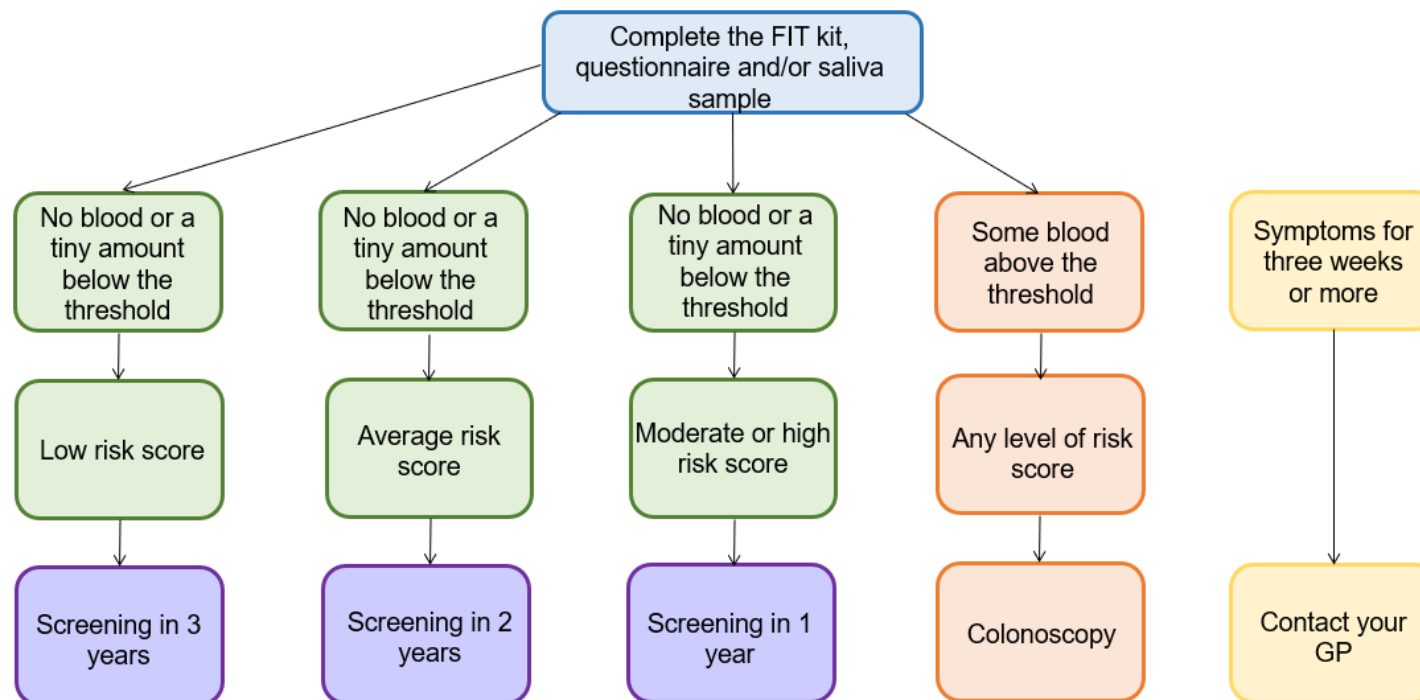
As shown in the flow chart below, there are four possible outcomes.

If your FIT kit detects **some blood** above the screening threshold you will be offered a colonoscopy regardless of your risk score.

If the result of your FIT kit shows **no blood or a tiny amount of blood** and you have a **low risk** based on the risk factors listed previously you will be invited to complete another FIT kit in 3 years' time.

If the result of your FIT kit shows **no blood or a tiny amount of blood** and you have a **moderate or high risk** based on the risk factors listed previously you will be invited to complete another FIT kit in 2 years' time.

If the result of your FIT kit shows **no blood or a tiny amount of blood** and you have a **moderate or high risk** based on the risk factors listed above you will be invited to complete another FIT kit in 1 years' time.



Screening strategy A: Screening as usual questions		
<i>You will now be asked to answer questions about each of the potential screening programmes you have read about.</i> <u>The current screening programme</u> As a reminder, in the current bowel cancer screening programme, screening is offered every two years to everyone between the ages of 60-74 regardless of their personal risk of developing bowel cancer. The threshold for referral, meaning the amount of blood detected by the FIT kit, is the same for everyone. This means that anyone over a predefined threshold will be referred for a colonoscopy. Anyone under the threshold will not be referred for a colonoscopy, regardless of their personal risk of developing bowel cancer. All those with blood under the threshold are invited back every 2 years.		
If you were sent a FIT kit as part of this screening programme, how likely would you be to complete it?	- Extremely likely – extremely unlikely(1-5) - Extremely likely - Somewhat likely - Neither likely nor unlikely - Somewhat unlikely - Extremely unlikely	
If you were recommended to have a colonoscopy as part of this screening programme, how likely would you be to attend?	- Extremely likely – extremely unlikely(1-5) - Extremely likely - Somewhat likely - Neither likely nor unlikely - Somewhat unlikely - Extremely unlikely	
Screening strategy B: Risk-stratified eligibility criteria questions		
<u>Using risk to decide when to start bowel cancer screening</u> As a reminder, in this programme your risk of bowel cancer would be estimated from information already in your GP records or you would be asked to complete a questionnaire and/or a saliva sample (to collect genetic information). This information would then be used to determine your risk of bowel cancer. This estimated risk of bowel cancer would then be used to determine when your first invite to bowel cancer screening will be.		
How acceptable are each of these components of this screening programme:	- Extremely acceptable – extremely unacceptable (1-5) - Extremely acceptable	Adapted from 'Acceptability and potential impact on uptake of using different risk

a) Individual risk estimates are used to decide when people are invited to start bowel cancer screening b) People at high risk of developing bowel cancer are invited to start screening sooner than average c) People at low risk of developing bowel cancer are invited to start screening later than average	○ Somewhat acceptable ○ Neither acceptable nor unacceptable ○ Somewhat unacceptable ○ Extremely unacceptable	stratification approaches to determine eligibility for screening: a population based survey' survey ¹
How acceptable would this screening programme be to you if it included the following information when calculating your risk score: a) Information that is already available in GP records b) Additional information about lifestyle and family history collected from people using a survey/questionnaire c) Genetic information collected using a saliva sample d) Information from GP records, additional information collected using a survey/questionnaire, and genetic information collected using a saliva sample	• Extremely acceptable – extremely unacceptable (1-5) ○ Extremely acceptable ○ Somewhat acceptable ○ Neither acceptable nor unacceptable ○ Somewhat unacceptable ○ Extremely unacceptable	
How likely would you be to complete a FIT kit as part of this screening programme if: a) You were told you were at high risk of developing bowel cancer b) You were told you were at average risk of developing bowel cancer c) You were told you were at low risk of developing bowel cancer	• Extremely likely – extremely unlikely(1-5) ○ Extremely likely ○ Somewhat likely ○ Neither likely nor unlikely ○ Somewhat unlikely ○ Extremely unlikely	
Imagine you had completed a FIT test as part of this screening programme and were recommended to have a colonoscopy: a) How would being told you are at high risk of bowel cancer influence your decision to have a colonoscopy? b) How would being told you are at average risk of bowel cancer influence your decision to have a colonoscopy? c) How would being told you are at low risk of bowel cancer influence your decision to have a colonoscopy?	• Much more likely to have a colonoscopy – much less likely to have a colonoscopy(1-5) ○ Much more likely to have a colonoscopy ○ A bit more likely to have a colonoscopy	

	○ Would not change anything ○ A bit less likely to have a colonoscopy ○ Much less likely to have a colonoscopy	
Screening strategy C: Risk-stratified FIT threshold questions		
<u>Using risk to decide when to refer people for further tests</u> As the risk of bowel cancer varies based on your risk factors, in this programme your risk of bowel cancer would be estimated from information already in your GP records or you would be asked to complete a questionnaire and/or a saliva sample (to collect genetic information). This information would then be used to determine your risk of bowel cancer. This estimated risk of bowel cancer together with the result from the FIT test will then be used to determine whether you will be offered further tests (either a repeat FIT test or a colonoscopy).		
How acceptable are each of these components of this screening programme: a) Individual risk estimates are used to decide when people are referred to have further tests (either a repeat FIT test or a colonoscopy) b) People at high risk of developing bowel cancer are referred to have a colonoscopy at a lower threshold of blood in their FIT test c) People at low risk of developing bowel cancer are referred to have a colonoscopy at a higher threshold of blood in their FIT test	• Extremely acceptable – extremely unacceptable (1-5) ○ Extremely acceptable ○ Somewhat acceptable ○ Neither acceptable nor unacceptable ○ Somewhat unacceptable ○ Extremely unacceptable	Adapted from 'Acceptability and potential impact on uptake of using different risk stratification approaches to determine eligibility for screening: a population based survey' survey ¹
How acceptable would this screening programme be to you if it included the following information when calculating your risk score: a) Information that is already available in GP records b) Additional information about lifestyle and family history collected from people using a survey/questionnaire c) Genetic information collected using a saliva sample d) Information from GP records, additional information collected using a survey/questionnaire, and genetic information collected using a saliva sample	• Extremely acceptable – extremely unacceptable (1-5) ○ Extremely acceptable ○ Somewhat acceptable ○ Neither acceptable nor unacceptable ○ Somewhat unacceptable	

	○ Extremely unacceptable	
How likely would you be to complete a FIT kit as part of this screening programme if: a) You were told you were at high risk of developing bowel cancer b) You were told you were at average risk of developing bowel cancer c) You were told you were at low risk of developing bowel cancer	• Extremely likely – extremely unlikely(1-5) ○ Extremely likely ○ Somewhat likely ○ Neither likely nor unlikely ○ Somewhat unlikely ○ Extremely unlikely	
In this screening programme, imagine the result of your FIT test was near the threshold for referral to colonoscopy. How willing would you be to repeat the FIT test to see whether or not you needed to have a colonoscopy?	• Extremely willing – extremely unwilling(1-5) ○ Extremely willing ○ Somewhat willing ○ Neither willing nor unwilling ○ Somewhat willing ○ Extremely willing	
Imagine you had completed a FIT test as part of this screening programme and were recommended to have a colonoscopy: a) How would being told you are at high risk of bowel cancer influence your decision to have a colonoscopy? b) How would being told you are at average risk of bowel cancer influence your decision to have a colonoscopy? c) How would being told you are at low risk of bowel cancer influence your decision to have a colonoscopy?	• Much more likely to have a colonoscopy – much less likely to have a colonoscopy(1-5) ○ Much more likely to have a colonoscopy ○ A bit more likely to have a colonoscopy ○ Would not change anything ○ A bit less likely to have a colonoscopy	

	○ Much less likely to have a colonoscopy	
Screening strategy D: Risk-stratified screening interval questions		
<u>Using risk to decide how often to invite people for bowel cancer screening</u> As a reminder, in this programme your risk of bowel cancer would be estimated from information already in your GP records or you would be asked to complete a questionnaire and/or a saliva sample (to collect genetic information). This information would then be used to determine your risk of bowel cancer. This estimated risk of bowel cancer will then be used to determine when you will next be invited for screening.		
How acceptable are each of these components of this screening programme: a) Individual risk estimates are used to decide how often people are invited to screening b) People at high risk of developing bowel cancer are invited to screening more often than average c) People at low risk of developing bowel cancer are invited to screening less often than average	• Extremely acceptable – extremely unacceptable (1-5) ○ Extremely acceptable ○ Somewhat acceptable ○ Neither acceptable nor unacceptable ○ Somewhat unacceptable ○ Extremely unacceptable	Adapted from 'Acceptability and potential impact on uptake of using different risk stratification approaches to determine eligibility for screening: a population based survey' survey(120)
How acceptable would this screening programme be to you if it included the following information when calculating your risk score: a) Information that is already available in GP records b) Additional information about lifestyle and family history collected from people using a survey/questionnaire c) Genetic information collected using a saliva sample d) Information from GP records, additional information collected using a survey/questionnaire, and genetic information collected using a saliva sample	• Extremely acceptable – extremely unacceptable (1-5) ○ Extremely acceptable ○ Somewhat acceptable ○ Neither acceptable nor unacceptable ○ Somewhat unacceptable ○ Extremely unacceptable	
How likely would you be to complete a FIT kit as part of this screening programme if: a) You were told you were at high risk of developing bowel cancer	• Extremely likely – extremely unlikely(1-5) ○ Extremely likely ○ Somewhat likely	

b) You were told you were at average risk of developing bowel cancer c) You were told you were at low risk of developing bowel cancer	○ Neither likely nor unlikely ○ Somewhat unlikely ○ Extremely unlikely	
Imagine you had completed a FIT test as part of this screening programme and were recommended to have a colonoscopy: a) How would being told you are at high risk of bowel cancer influence your decision to have a colonoscopy? b) How would being told you are at average risk of bowel cancer influence your decision to have a colonoscopy? c) How would being told you are at low risk of bowel cancer influence your decision to have a colonoscopy?	• Much more likely to have a colonoscopy – much less likely to have a colonoscopy(1-5) ○ Much more likely to have a colonoscopy ○ A bit more likely to have a colonoscopy ○ Would not change anything ○ A bit less likely to have a colonoscopy ○ Much less likely to have a colonoscopy	
Comparing strategies		
<i>Thank you for reading the information about the different bowel cancer screening programmes carefully. We will now ask you to compare the four possible programmes you have read about.</i>		
In your opinion, how acceptable are these strategies: a) Screening as usual – everyone is invited to screening at the same stage and referred to have a colonoscopy with the same amount of blood detected by the FIT kit b) Using personal risk to decide when to start or stop bowel cancer screening c) Using personal risk to decide when to refer people for further colonoscopy d) Using personal risk to decide how often to invite people for bowel cancer screening	• Extremely acceptable – extremely unacceptable (1-5) ○ Extremely acceptable ○ Somewhat acceptable ○ Neither acceptable nor unacceptable ○ Somewhat unacceptable ○ Extremely unacceptable	
In a few words, why?	• Free text comment box	

Demographics		
<u>Demographic information</u> <i>In this section we would like to ask you a few questions about yourself. These questions allow us to make sure we are including people from a range of different backgrounds and see if different groups of people have different views. We will not be able to identify you from your answers.</i>		
How old are you?	• 18-29 • 30-39 • 40-49 • 50-59 • 60-69 • 70-79 • 80+	
What is your sex? (A question about gender identity follows) Some of the scenarios considered whether the sex of individuals should influence screening. This would be the sex that individuals are assigned at birth. To help us see if responses differ between people of different sexes, please let us know your sex assigned at birth.	• Male • Female	Cambridge's The Healthcare Improvement Studies (THIS) Institute guidance released March 2021
Is the gender you identify with the same as your sex registered at birth?	• Yes • No (please enter your gender identity)	Cambridge's The Healthcare Improvement Studies (THIS) Institute guidance released March 2021
What is your ethnic group? Choose one option that best describes your ethnic group or background.	• Asian/Asian British • Black/African/Caribbean/Black British • Mixed/Multiple ethnic group • White • Other (please describe)	Ethnic groups are the top-level groups used in the UK Census and PAMCo(187)
What is your highest education level?	• Finished school at or before the age of fifteen • Completed GCSEs, O levels or equivalent • Completed A levels or equivalent	Validated from Cancer Awareness Measure (CAM) toolkit, (pre-2014, as 2014 onwards has not been validated)(188)

	- Completed further education but not a degree - Completed a Bachelor's degree - Completed a Master's degree or PhD - Other (please describe)	
Are you currently:	- Employed full-time - Employed part-time - Unemployed - Self-employed - Full-time homemaker - Retired - Still studying - Disabled or too ill to work - Other (please describe)	
Where would you put yourself on the socioeconomic ladder? Think of this ladder as representing where people stand in our society. At the top of the ladder (10) people are better off, with most education, most money, and best jobs. At the bottom of the ladder (1) are people worst off, with least education, least money, and worst jobs. Please choose where you would put yourself on the ladder.	10 9 8 7 6 5 4 3 2 1	
Lifestyle and screening history		
<u>Lifestyle and screening history</u> <i>The following questions are about your lifestyle and your past screening decisions. Please answer as honestly as you can as this will help us with our analysis.</i>		
In general, would you say your health is:	- Excellent - Very good - Good	Validated question from CDC for self-rate health(190)

	• Fair • Poor	
What is your tobacco smoking status?	• Never smoked cigarettes or cigars • Used to smoke cigarettes or cigars • Smoke up to 20 cigarettes or cigars per day • Smoke 20 or more cigarettes or cigars per day	From lung cancer study, Smits et al., 2018(189)
How would you describe your weight?	• Underweight • About the right weight • Slightly overweight • Very overweight	
Have you ever had cancer?	• Yes • No	
Have you ever had bowel cancer?	• Yes • No	
Have your parents or any brother or sisters ever had cancer?	• Yes • No • Don't know/prefer not to answer	
Has anyone close to you (e.g. a partner or close friend) ever had cancer?	• Yes • No • Don't know/prefer not to answer	
Have you been invited to take part in any of the following screening programmes (please note that they are not offered to everyone)? Information is in the format of (what it involved, who it is offered to)	• Yes/No/Not Eligible ○ Abdominal Aortic Aneurysm screening (ultrasound, males aged over 65) ○ Bowel Cancer screening (poo sample or colonoscopy, males	

	- and females ages 60-74) ○ Breast Cancer screening (mammogram, females aged 50-70) ○ Cervical Cancer screening (smear test, females aged 25-64)	
Which of the following screening programmes did you take up the invitation to take part in?	• Yes/No/Not Eligible ○ Abdominal Aortic Aneurysm screening (ultrasound, males aged over 65) ○ Bowel Cancer screening (poo sample or colonoscopy, males and females ages 60-74) ○ Breast Cancer screening (mammogram, females aged 50-70) ○ Cervical Cancer screening (smear test, females aged 25-64)	
Thoughts and beliefs about cancer		
<u>Thoughts and beliefs about cancer</u> The next section asks about your thoughts and beliefs about cancer. Please answer as honestly as you can as this will help us with our analysis. The questions are about YOUR opinion, so there is not a correct answer.		
Below are some statements that are sometimes made about cancer. For each of these statements how much do you agree or disagree with them? • These days, many people with cancer can expect to continue with normal activities and responsibilities.	• Strongly agree • Agree • Neither disagree nor agree • Disagree • Strongly disagree	Cancer beliefs, taken from Smits et al., 2018(189) (and made specific to bowel cancer, rather than lung cancer), which were based

• Most cancer treatment is worse than the cancer itself. • I would NOT want to know if I have cancer. • Cancer can often be cured. • Going to the doctor as quickly as possible after noticing a symptom of cancer could increase the chances of surviving. • Some people think a diagnosis of cancer is a death sentence.		on validated questions from the ABC measure(191)
End of survey		
<u>End of survey</u> <i>Thank you for completing the survey. Your time and contribution are very much appreciated.</i>		

STRAT-BCS II: STRATification in Bowel Cancer

Screening II – Survey Study

Survey introduction and instructions

Summary text and instructions seen by participants on Prolific

Study title for participants: Exploring people's views on different approaches to bowel cancer screening and whether they would take part (STRAT-BCS II Survey).

In this study, we are hoping to learn about what people think are the best strategies for determining different features of the screening programme.

You will first see a detailed information sheet and be asked to complete an online consent form. At the end you will be asked a few questions about yourself, including your thoughts and beliefs about cancer.

In the main part of the study, we will present you with a series of questions relating to different strategies for bowel cancer screening programmes. We will include information about what each screening programme involves. For each question, you will be asked how acceptable the strategy is to you and whether or not you would participate in such a screening programme.

STRAT-BCS II: STRATification in Bowel Cancer

Screening II – Survey

Participant Information Sheet

Thank you for considering taking part in our study to explore the public's views on different approaches to screening people for bowel cancer.

Please take time to read this information carefully to understand why the research is being done and what it will involve for you.

Who is organising the research?

The study is being led by doctors and researchers at the University of Cambridge. It is funded by the National Institute for Health Research and has been reviewed by the University of Cambridge School of Humanities and Social Sciences Ethics Committee.

What is the purpose of the study?

The aim of screening is to diagnose cancer early. It has been suggested that it might be a good idea to tailor some aspects of bowel cancer screening according to peoples' individual risk, for example, by inviting some people to be screened more often than others. The aim of this study is to find out what people think about this and whether they would participate.

Who is taking part?

We are recruiting about 1200 members of the public resident in the UK and representative of the UK population in terms of sex and ethnicity using the Prolific platform. People aged 18 and over will be able to take part. You *don't* need to have any background knowledge about cancer in general (or about bowel cancer) to take part because we are interested in what non-expert members of the general public think about these issues.

Do I have to take part?

Your involvement in this study is entirely voluntary and you can leave at any time without giving a reason and there will be no consequences for doing so.

What happens next?

Before you begin the survey you will be asked to complete an online consent form. We will then present you with some background information about different strategies for bowel cancer screening and then ask a series of questions about how you feel about each of the strategies. The end of the survey will include some basic information about yourself, including questions about your age, sex, lifestyle, employment and education. You will also be asked about your thoughts and beliefs about cancer and cancer screening.

The survey will be hosted online by Qualtrics. Your responses will be recorded by Qualtrics and stored confidentially. No personally identifiable information will be collected.

How much time will it take?

The survey will take approximately 20 minutes to complete, however you can take as much time as you need.

What are the possible benefits of taking part?

By taking part in this study, you will have an opportunity to help influence cancer screening programmes by sharing your views and opinions. You will gain information about bowel cancer screening and the potential for future approaches using risk stratification.

Are there any disadvantages or risks of taking part?

Discussing the risks surrounding cancer screening can be a sensitive topic. If you become upset by anything during the survey, you may exit it at any stage and there are no

consequences associated with doing so. If you have worries about cancer screening you can also contact your GP or find further information on cancer and support organisations on the Cancer Research UK or Macmillan Cancer Support websites (www.cancerresearchuk.org; www.macmillan.org.uk).

Will I be paid for taking part?

Yes, there is a £2.50 (£7.50 per hour) reward for the time you spend doing this task. This will be paid to you by Prolific once your answers to the task have been accepted by the researchers.

Will my taking part in this study be kept confidential?

All information that is collected from you during the course of the study is anonymised and stored securely.

The University of Cambridge is the sponsor for this study based in the UK. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Cambridge will keep any identifiable information about you 12 months after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at <https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data>.

What will happen to the results of the study?

This research is important for informing decision makers during the development of health policies. All findings will be published in peer-reviewed scientific journals and presented at national and international conferences. You will not be identifiable in any of these publications. After the study we will send you a summary of the results via Prolific.

At the end of the study the anonymous data will be stored in an online database so that it is publicly available. This is called “open data”. This practice is integral to the research process as it will allow others to verify results and avoid duplicating research. Anonymised data are made available on a website, free of charge, to anyone interested in the research, or who wishes to conduct their own analysis of the data. We would therefore have no control over how these data are used.

What if there is a problem or something goes wrong?

If you have any concerns or complaints about any aspects of the study, you can telephone the study lead, Dr Juliet Usher-Smith, on [phone number and email address redacted].

Alternatively, if you would like to write to her, please send your letter to:

Dr Juliet Usher-Smith

STRAT-BSC study

[address redacted]

**Thank you very much for reading this information sheet
and choosing to take part in this study**

STRAT-BCS II: STRATification in Bowel Cancer

Screening II – Survey Study

Consent form

- Please tick each box
1. I confirm that I have read and understood the information sheet for this study on the previous pages. I have had the opportunity to think about the information, ask questions, and have these answered satisfactorily. ☐
 2. I understand that my participation is voluntary, and I am free to withdraw at any time without giving reason and this will not affect my Prolific approval rating. ☐
 3. I understand that if I withdraw from the study by returning my submission in Prolific, my data will not be used. If I do not return my submission, my data may be used even if I do not complete the study. ☐
 4. I understand that data provided by Prolific as part of my involvement in this study and my responses to the survey will be stored in an online database so that it is publicly available at the end of the study ("open data"). ☐

By clicking 'yes' you are indicating that you have read and understood this consent form, and agree to take part in this research study.