

Avoiding conflicts of interest and reputational risks associated with population research on food and nutrition: the Food Research risk (FoRK) guidance and toolkit for researchers

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Standfirst:

Researchers wishing to interact with the food industry can be subject to conflicts of interest and reputational risks, but new guidance from Cullerton et al should help researchers navigate this tricky territory, make informed decisions, and minimise adverse outcomes.

Introduction

Poor diet is a growing global public health challenge contributing to increases in non-communicable diseases (NCDs) in all countries.¹ The commercial food sector is widely recognised to shape consumer food environments, which in turn, directly influence population diets.² The commercial food sector's impacts on diets and NCDs represent a huge externality – that is a cost generated by industry but borne by other sectors.³ Achieving healthier diets in populations to reduce NCDs requires action by the commercial food sector, but evidence suggests this is unlikely to happen without external pressure.⁴ Despite this, research funding bodies and institutions are increasingly encouraging researchers to work with the commercial food sector to identify solutions to prevailing failures of the food system.^{5,6}

However, the primary goals of the commercial food sector and population health researchers may not be well aligned.³ This misalignment of purpose can create challenges if the two groups engage in research together, leading to conflicts of interest. Conflicts of interest are defined as “situations where an individual has an obligation to serve a party or perform a role and the individual has either: 1) *incentives* or 2) *conflicting loyalties*, which encourage the individual to act in ways that breach his or her obligations.”⁷ Furthermore, some elements within the commercial food sector engage in well-documented tactics to influence research outcomes and public policy, such as specifying the design and conduct of research and may include practices regarded as unethical such as preventing publication of unfavourable results.⁸⁻¹¹ Any interaction between researchers and the commercial food sector therefore needs careful consideration, as it can undermine the credibility of research and researchers, resulting in an erosion of trust among the public and policymakers, and scepticism of published research.^{12,13} Furthermore, it can result in biased research distorting the evidence base and may result in the commercial sector to better placed to influence public health policymakers.^{14,15}

The commercial food sector is diverse, ranging from farmers to transnational food corporations, and therefore the range of potential for goal misalignment with population health and associated research is broad. Interactions between researchers and the commercial food sector can thus result in a diverse set of outcomes, including those carrying none to high levels of research bias and reputational risk.^{16,17} With scarce government funding for research in many countries and the potential to positively influence practices within the food industry, researchers are asking for guidance on ways to interact to minimise risk of reputational or other consequences.^{18,19}

While guidance on interacting with the commercial food sector exists for governments and non-government organisations,^{20,21} and for dietary guideline development committees,²² there is no

internationally agreed guidance for population health researchers. These researchers often have different research needs from clinical research when interacting with the food industry, for example, evaluating whether changes to a supermarket will result in an increase in healthier purchasing,²³ or whether a restaurant adding a levy to sugary drinks will sell fewer of them.²⁴ Both examples rely on in-kind support from the food industry. The absence of guidance has given rise to disagreements about acceptable levels and types of interaction. To resolve these tensions, we set about a programme of research and international consensus-building to develop clear guidance to help researchers navigate this terrain, to assess opportunities to interact with the commercial food sector, and to prevent and manage conflicts of interest.

Aims and Scope

The Food Research Risk (FoRK) toolkit and guidance aims to support researchers in making decisions about whether and how to interact with commercial food sector organisations at all stages of the research process. The FoRK tools aim to reduce risks to scientific integrity by exploring the potential for conflicts of interest in interactions with commercial organisations, revealing the implications of different kinds of interaction. The toolkit and guidance thus support thinking and dialogue on this issue, while also guiding decision making.

We designed the FoRK toolkit for researchers working in population-level nutritional epidemiology, public health nutrition, dietary public health and food policy evaluation (termed population health researchers throughout). This relatively narrow focus was chosen as researchers whose focus is whole populations have research interests that are somewhat different from those of clinical or laboratory-based scientists. In population health, the main point of concern is promoting and protecting the health of the entire population.²⁵ Public policy, including regulation, is often a key focus. Such policies are often poorly aligned with the goals of the commercial food sector.³ Consequently, scientific evidence generated by population health researchers regularly underpins government actions that are contrary to the preferences of the commercial sector. Undertaking research to prevent disease and promote health may therefore result in conflicts with commercial food sector organisations whose products have been associated with raised risk of diet-related health conditions.

The FoRK guidance and toolkit should both increase the capacity of population health researchers to assess risk when considering opportunities to interact with the commercial food sector, and guide researchers in managing those relationships if interaction proceeds. It is important to note that the definition of conflict of interest above,²⁶ has the concept of *risk* at the heart of it. When we refer to risk we are referring to risk from conflicts of interest, which can result in biased research, but also reputational risk to individual researchers and research institutions, all of which may lead to public mistrust of science.²⁷

The FoRK guidance and toolkit are not designed to be used to assess and guide policymaking activities, as the primary interests and challenges of governments and policy officers are somewhat different from the primary interests of researchers and other guidance is available assist in this area.²¹

Development of the FoRK guidance and toolkit

This FoRK guidance and toolkit were developed using a systematic, iterative process.

We began with an event in 2015 for a diverse group of academic experts, debating the principles of how to engage the commercial food sector in population health research to serve the public interest.²⁸ This was followed by a systematic scoping review to identify the principles that have been used or proposed to govern interactions between the commercial food sector and population health researchers.²⁹ The principles identified in the review then formed the basis of a two-stage Delphi study of population health researchers to identify and build consensus on these key principles; and a survey of relevant, non-academic stakeholders, to identify their views on the principles.¹⁹

While these studies identified key areas of consensus amongst researchers (namely research governance, transparency and publication), there remained areas of disagreement. The principles that had the highest level of disagreement related to which commercial sector food organisations population health researchers consider it appropriate to interact with, and whether interactions should involve accepting direct funding, attending industry sponsored events or accepting in-kind funding.

We convened an international workshop to resolve the issues in April 2018. Forty-one population health researchers from high, middle and low-income countries came together for two days in an independently facilitated event. We aimed to achieve clarity regarding minimising risks arising from interactions with the commercial food sector. Participants included leading figures in the field as well as early and mid-career researchers. The researchers represented the full breadth of interests at which the guidance is aimed. Participants also had a range of experiences of interacting with the commercial food sector, ranging from no contact at all (n = 30, 73%) to actively collaborating (n = 2, 5%) or receiving commercial food sector research grants (n =9, 22%).

A range of issues was considered, with most of the workshop involving in-depth discussion of five themes identified from our prior research^{19 29} relevant to preventing or managing conflicts of interest: publication, transparency, research governance, funding and risk assessment. There was strong support for the development of overarching guidance and associated tools to aid decision-making throughout the research process, particularly for risk assessment of potential commercial food sector organisations and governance of research processes, including protocol development, implementation of fieldwork and analysis, and publication.

Drawing on the published literature identified in our systematic review²⁹ and the feedback from the workshop, draft guidance with a series of 'thinking tools' was developed. We completed three rounds of pilot testing incorporating feedback at each stage. This began with eight different researchers and/or research groups piloting the initial tool.. We then asked all 41 workshop participants to pilot the tool further using a real-life example. Twenty-one participants provided feedback. Finally, twelve researchers from a range of countries, who had not been involved in the workshop, piloted the guidance.

In developing this guidance, we involved people from across the spectrum of interacting with the commercial food sector, including those who strongly believe risks outweigh benefits and vice versa. As a result, in the consensus building process some participants stated that the guidance was too lenient and others that it was too restrictive. Our primary objective is to ensure the integrity of

science and we believe we have achieved a fair and balanced approach in the guidance. However, there are few absolutes in this area. Opinions on these issues are likely to vary according to personal and institutional preferences, as well as ethical and political stances on a wide range of related issues (e.g. the morality of wealth and profit). We anticipate that the guidance and toolkit will be refined and developed in accord with scientific and ethical principles over time. However, ultimately, the toolkit and guidance are not prescriptive, but thinking tools that allow researchers to make informed decisions about how to act with integrity, so they should be of value to a wide range of researchers.

Sections within the FoRK guidance and toolkit

In Box 1 we list the sections of the FoRK toolkit. The specific tools and guidance can be found in the supplementary materials.

Box 1: Toolkit components:

1. A **flow chart** that summarises which tools should be used at which stages of the research process (Figure 1).
 2. A **guidance document**, which sets out in detail how to use Tools A and B and the evidence that underpins them
 3. A tool to assess the risk profile of commercial food companies and associated organisations (**Tool A, Part 1**)
 4. A tool to assess the risks of different *types of interactions* with commercial food companies and associated organisations (**Tool A, Part 2**)
 5. A tool to enable an overall *risk-benefit analysis* for specific interactions (**Tool B**)
 6. A tool to guide *negotiations* with commercial food companies or associated organisations concerning specific interactions (**Tool C**)
 7. A tool to guide *research governance* requirements for interactions involving commercial food companies or associated organisations (**Tool D**)
 8. A tool to guide the *communication of findings* from research involving interactions with commercial food companies or associated organisations (**Tool E**)
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How to use the FoRK guidance and toolkit

Here, we briefly summarise how the FoRK guidance and toolkit should be used. Figure 1 illustrates the stages of the research process at which each tool should be used. We encourage researchers to utilise the Toolkit when they are first considering interacting with a commercial food sector organisation (e.g. a food company, a trade association, or industry funded think tank).

Familiarisation with the challenges of safely interacting with such organisations, as well as the kinds of information needed to make decisions will help in using the tools effectively. The toolkit is divided into two parts. Tools A and B are intended to help researchers decide about interacting with a commercial food sector organisation, whereas Tools C-E are intended to support decision-making among researchers committed to working with a commercial food sector organisation. Tools C-E thus aim to minimise the negative impacts of an interaction on scientific integrity.

We recommend that researchers start by using Tool A-Part 1 when they are thinking about interacting with a commercial food sector organisation. This takes researchers through a number of questions that will help achieve clarity on whether to interact with an organisation (including circumstances under which interaction might/should be avoided), and if proceeding with industry interaction, how to minimise the risk of undue industry influence.. It focuses in particular on the levels of risk associated with different types of organisations. Tool A-Part 2 takes this a step further by exploring the types of interactions that are envisaged and helps researchers to assess the risks and benefits of each. The two parts of Tool A enable researchers to see that there are greater risks to research integrity associated with some types of organisation and interaction. Through a systematic process, completing these tools will help researchers to decide the level of risk they are prepared to accept for anticipated benefits. Tool B brings together the risk and benefit assessments completed in Tool A to provide an overall assessment. While such an overall score is ultimately somewhat arbitrary, it provides a helpful guide to overall level of risk allowing researchers to consider this before proceeding.

Risk assessments are inherently difficult as people tend to be overconfident about their ability to independently assess risk and the range of outcomes that may occur.^{30 31} Ideally, the risk assessment (Tool A and Tool B) should be undertaken by one or more (independent) professional colleagues with whom the researcher does not work with directly.

If researchers have committed to an interaction with a commercial food sector organisation, then Tools C, D and E will support their decision making with respect to negotiating interactions, research governance, and the communication of findings respectively. We recommend that these tools are completed at the earliest suitable stage of the interaction and then reviewed at regular intervals to maximise their impact on the whole process.

We encourage researchers who do engage with the commercial food sector to complete all tools and publish their risk assessments alongside their research, similar to the way in which other reporting guidelines are used (e.g. the STROBE and other check lists). We recommend that journals and research funders also adopt the toolkit and recommend its use to their authors and funding applicants respectively.

To illustrate how the tools can aid decision making among researchers, four examples of different kinds of interactions with commercial food sector organisations are described in Table 1. We encourage those using the toolkit to provide their own examples in this format, if possible with citations, via a form on the FoRK Toolkit web page: <https://www.mrc-epid.cam.ac.uk/research/studies/diet-research-food-industry/>. We also invite feedback on the Toolkit. This will enable researchers to learn from each other's' experience and facilitate the refinement of the FoRK toolkit and guidance over time.

Strengths and limitations

The principles embodied in the tools were derived from a systematic review of existing research and other scholarly contributions, on which we derived partial consensus through a formal Delphi process.^{19 29} Further rigour was attained by convening an independently facilitated, two-day workshop of international experts, at which additional consensus was achieved about the principles and agreement reached on the format of the guidance and toolkit. Finally, piloting of prototype

versions of the guidance and toolkit by experts provided detailed feedback enabling modifications to improve comprehension and utility. Nevertheless, the guidance and toolkit would benefit from further field testing and feedback to determine their strengths and limitations, and to facilitate continuous improvement. Concepts within the guidance and toolkit could also apply to other research fields within healthcare or population health. We encourage users to test the materials and provide feedback to the authors so that we can refine them and improve their usefulness.

There is limited empirical work in this field and therefore many subjective judgements had to be made in developing the materials, particularly the risk assessment tool. Through multiple rounds of piloting, we attempted to strengthen the scoring methodology. However, we acknowledge its subjective nature, and emphasise that there are no right or wrong answers, and the decisions that researchers take as a result will necessarily involve a degree of personal judgement, informed by the principles set out in the guidance. We acknowledge that there is no single solution to the challenges posed by conflicts of interest in population health research involving the commercial food sector, but we anticipate that using the FoRK guidance and toolkit will be an important step in achieving clarity of thought and transparency of actions and reporting.

While these tools assist and guide individual research teams to make decisions about industry interactions, they do not address broader sector-level concerns. An example of this is the systemic research focus on industry-friendly topics, such as studies about nutrients and production styles.¹¹ Further concerns include funding of guideline committee members, advocacy groups, and journals by the commercial food sector.³² Strategies such as these puts researchers at risk of influence from the commercial food sector often without even realising it.

Lastly, we acknowledge that we are likely to have implicit biases. We have attempted to make ourselves aware of these and approached the research with reflexivity by frequently acknowledging our own biases throughout the research, using an independent, external facilitator at the international consensus meeting and gaining perspectives from many researchers throughout the research process. Nevertheless, we think it likely that the FoRK toolkit can be improved over time and welcome feedback via the toolkit web page.

Conclusions

Through a systematic process of evidence synthesis, consensus building, and evidence-informed design and piloting, we developed the FoRK guidance and toolkit to help population health researchers decide whether and how to interact with commercial food sector organisations. We encourage researchers to use and critically reflect on the materials, and to contribute to continual improvement of the toolkit. The materials may provide a template that can be adapted to guide interactions between other researchers and other commercial sectors.

Summary box:

- Interacting with commercial food companies can result in conflicts of interest for population health researchers, which may bias research findings and contribute to reputational risks.
- By developing consensus on established principles for clarifying and negotiating these challenges, we have developed guidance and a toolkit that support principled decision making in population health research.

- The FoRK guidance and toolkit is a practical tool for researchers, research funders and academic journals. We encourage widespread use in everyday practice and evaluation over time to refine and improve the guidance and toolkit.

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Contributors

Fieldwork was undertaken by KC, supported by MW. All authors contributed to the development of the proposals for the research, securing funding, the activities of the research, the interpretation of data and development of the toolkit and guidance. KC and MW led the writing of this article. All authors made substantive intellectual contributions to all aspects of the research and writing of this article, and approved the final version. MW is guarantor for the work. KC is a public health nutritionist and policy researcher; JA is a public health researcher and policy evaluator; NGF is a public health doctor, nutritional epidemiologist and NIHR Senior Investigator and acknowledges support from MRC Epidemiology Unit (Grant No. MC/UU/00006/3); OF is a communications and knowledge exchange expert; MW is a public health doctor, food systems expert and policy evaluator. Further sources of information that have contributed to the guidance and toolkit are set out in the main text above.

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Competing interests

All authors have completed the ICMJE uniform disclosure form at <http://www.icmje.org/disclosure-of-interest/> and declare: all authors had financial support from the UK Medical Research Council for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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Patient and Public Involvement: We received no funding for public involvement and did not involve patients or the public as the study was focused on developing specific guidance for researchers concerning conflicts of interest with industry. As a result, no patients or members of the public were involved in the design, conduct, reporting, or dissemination plans of our research.

Data sharing: No additional data available.

Transparency: The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: All participants in the workshop and involved in the pilot testing of the toolkit will be sent a copy of the published manuscript. We will present this work at scientific conferences and to professional groups. We have also developed a plain language summary of findings which is available on the project website, together with a form to provide feedback on the guidance and toolkit.

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Figures and tables to be inserted in the main text:

Figure 1: A flow chart that summarises which tools should be used at which stages of the research process

Table 1: Illustrative examples of the use of the FoRK Toolkit to assess risks of proceeding with an interaction with a commercial entity (currently placed at end of manuscript)

Supplementary materials

1. FoRK Toolkit

Tool A, Part 1: A tool to assess the *risk profile* of commercial food sector organisations

Tool A, Part 2: A tool to assess the risks of different *types of interactions* with commercial food sector organisations

Tool B: A tool to enable an overall *risk-benefit analysis* for specific interactions

Tool C: A tool to guide *negotiations* with commercial food sector organisations concerning specific interactions

Tool D: A tool to guide *research governance* requirements for interactions involving commercial food sector organisations

Tool E: A tool to guide the *communication of findings* from research involving interactions with commercial food sector organisations

2. FoRK Guidance document, which sets out in detail how to use Tools A and B and the evidence that underpins them.

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Table 1: Illustrative examples of the use of the FoRK Toolkit to assess risks of proceeding with an interaction with a commercial entity.

	Tool A, Part 1	Tool A, Part 2	Tool B	Tool C	Tool D	Tool E
Example 1: a transnational processed food corporation wishes to fund an academic post at a university	Score 17 ('High Risk'): The company represents a high risk because its products, their production and marketing are harmful to health	Rating: 'High Risk'. Interaction represents a high risk because the company will provide direct funding albeit with no direct influence from the company on the appointment or role.	Not completed as all risks rated 'high' and no further interaction considered appropriate.	Not completed as no further interaction considered.	Not completed as no further interaction considered.	Not completed as no further interaction considered.
Example 2: invitation to independently evaluate an intervention designed to increase purchases of healthy food in a national grocery chain	Score 10: The company represents a 'high risk' – Although its overall aims and food offer are broad, it does sell a moderately high proportion of unhealthy processed foods, plus tobacco and alcohol.	Rating 'Low Risk': The proposed interaction (independent evaluation of an intervention to promote sales of healthier and more sustainable foods) represents a low risk, providing key safeguards in place.	Rating likely low risk to benefit ratio: The company will deliver the intervention, which focuses on the promotion of healthier food sales. The researchers will have control of the independent evaluation and will receive unlimited access to commercial data. The research could provide a 'health halo' for the company, but negative results might also be damaging for the company and there are no restrictions on publication of findings without involvement of the company.	Interaction resulted in agreed processes that maintain safeguards for the academic partners' reputational integrity, including rights of access to data, rights to publish and scientific independence.	Independent oversight of the research and ongoing relationship has been established. A register of interests has been established by the research team and is update biannually. Interests, including those represented by this study, will be reported by all members of the research team in all outputs of the research.	A publication policy has been established by the research team and made available to the company for information. The researchers will only publish findings in journals and at conferences of organisations that are independent of commercial funding.

	Tool A, Part 1	Tool A, Part 2	Tool B	Tool C	Tool D	Tool E
Example 3: invitation to a senior academic to join a national advisory group alongside the CEO of a regional fruit and vegetable wholesaler with international trading links in a high-income country	Score 6: The company represents a low risk. The company only sells fruits and vegetables. It sources produce from within the country as well as imports from around the world. It has direct relationships with farms in low-income countries and invests in those farms and associated community development and education for their workers and their families.	Rating: the interaction represents a low risk as it involves participation in a government-led policy expert group with industry involved and no funding received.	The interaction may lead to beneficial public policy on promoting healthy and sustainable diets. There may be reputational risks from the interaction between the academic and the company representative, but this is unlikely. There is also a risk that historically government-led policy expert groups which include commercial stakeholders have resulted in limited sustainable policy action.	The government department organising the advisory group has clear terms of reference as well as safeguards, including a publicly available register of members' interests.	There will be a publicly available records of all meetings.	The government department has agreed a publication and communications policy for the advisory group. Reports on substantive topics will be made available to the public.
Example 4: a national industry association for the dairy sector has invited a researcher to join a panel with other academics, politicians and industry spokespersons at an industry organised event to promote industry approaches to promoting healthier diets through consuming dairy products	Score 8: The organisation represents a high risk, as while it makes and promotes foods considered reasonably 'healthy' the association has a direct commercial interest in the research topic or intervention.	Rating 'High Risk' as it is an invitation to speak at an event sponsored and/or organised by a food organisation/s. While content the academic can speak on is unrestricted, travel cost and honorarium are paid by the company.	The benefits for the researcher would include participating in a high-profile event with politicians, and the opportunity to share their research findings, and a monetary honorarium offered by the organisation. However, both the financial payment and involvement in this potentially 'health-washing' event, represent a significant reputational risk for the academic. On balance the academic considered the risks to outweigh the benefits.	Not completed as no further interaction considered	Not completed as no further interaction considered	Not completed as no further interaction considered

