

Informed consent: an empty promise? A comparative analysis between Italy and England, Wales, and Scotland

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Abstract

Informed consent (IC), as the process of sharing information between patients and clinicians before undertaking a medical treatment, signals a number of ‘good intentions’. IC, in its theoretical formulation, can be seen as valuing the expertise and contributions of both clinicians and patients, giving expression to the aspirations of both promoting patient autonomy and facilitating doctors to work in partnership with their patients. The Supreme Court judgment in *Montgomery v Lanarkshire Health Board*¹ and the Italian legislation on IC² are, in this respect, worthy of analysis as both provide valid examples of these ‘good intentions’. However, the reality of how IC has been translated in courtrooms does not always match these the expectations. This article, through a comparative reflection, will claim that a gap between the ‘law in theory’ and the ‘law in practice’ is common to both legal systems. The article ultimately claims that changes in both legal and policy approach are needed in order to better safeguard IC.

Keywords

Autonomy, decision-making-process, informed consent, negligence, partnership

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Introduction

This article examines the issue of informed consent (IC), particularly how the liability of clinicians for violations of IC has been translated in courtrooms, through a comparative

1. [2015] UKSC 11
2. Law n.219/2017

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approach to the legal frameworks as they currently stand in the two³ legal systems of Italy and England, Wales, and Scotland. The analysis begins with an overview of the Supreme Court judgment⁴ in *Montgomery v Lanarkshire Health Board*,⁴ as the reference point for an examination of IC in England, Wales, and Scotland. It then moves to consider the Italian legislation and case law surrounding IC, particularly legislation n. 219/ 2017, together with the Supreme Court judgment in '*San Martino bis*'. The broad aim of these first sections of the article is to demonstrate to the reader the shared 'good intentions' of both legal systems 'behind the laws' on IC while also highlighting the existence of ongoing practical limitations. The final part of the article conducts a closer comparative exercise between both legal systems. Though this might appear simplistic, it is self-evident that there is a structural difference between the legal framework in England, Wales, and Scotland, being a common law system, and the Italian framework, a civil law system. This preliminary consideration helps us to understand some of the reasons why, as will be unpacked throughout the article, IC is regulated differently. In the domestic context, we do not find any legislation addressing the issue of IC in its broad formulation; this is left to case law, particularly the Supreme Court judgment⁵ in *Montgomery*. It is legislation n. 219/ 2017 that fundamentally regulates IC in Italy, although this is also accompanied by relevant Supreme Court judgment. However, despite inevitable structural differences, they have parallel aspirations and parallel challenges. Both legal systems have shared 'good intentions', although both also dramatically fail to offer a real possibility of successfully safeguarding IC. Ultimately, the aim of this comparative analysis is to highlight that IC is often safeguarded in 'theory' but left unprotected in 'practice', as well as arguing for a change in approach. It claims that more research is needed to understand how law and policy can more clearly and concretely safeguard this key patient right.

England, Wales, and Scotland: the 'good intentions' behind *Montgomery*?

The 2015 Supreme Court judgment in *Montgomery* is the key point of reference for a discourse concerning IC in England, Wales, and Scotland.⁵ This is because the judgment enshrined the right of every patient to be informed, as well as to receive information concerning the risks, benefits, and reasonable alternatives to the proposed treatment.⁶ The judgment followed in the footsteps of previous professional guidelines, particularly the General Medical Council (GMC) guidelines on consent 2008⁷, and, as will be shown

3. Using a pure-IC perspective, this article is considering two different jurisdictions, namely, (1) Italy and (2) England, Wales, and Scotland.

4. [2015] UKSC 11

5. This judgment was delivered along with the two leading judgments of Lord Kerr and Reed and the supporting judgment of Lady Hale.

6. *Montgomery* at [87].

7. GMC, Consent: patients and doctors making decisions together, 2008, available at: https://www.gmc-uk.org/static/documents/content/Consent_-_English_0617.pdf (accessed 19 March 2021).

below, consolidated an evolutionary path of domestic case law. Ultimately, it will be highlighted that *Montgomery*, and hence IC, is an expression of two key ‘good intentions’, namely, facilitating doctors working in partnership with their patients and the promotion of patients’ autonomy.

Delivered with the agreement of seven judges, *Montgomery* concerned negligence liability for a failure to disclose the risks of a vaginal birth to a pregnant diabetic woman of short stature (Mrs Montgomery). The newborn suffered brain damage as a result of shoulder dystocia, which is the inability of the baby’s shoulders to pass through the pelvis during vaginal delivery. Mrs Montgomery successfully argued that the non-disclosure of this risk, in her circumstances, was indeed negligent. Mrs Montgomery should have been offered the alternative of an elective caesarean section, given the heightened risk of shoulder dystocia for women with her clinical background.

The Supreme Court judgment in *Montgomery* cemented a move away from a doctor-centred (and thus paternalistic) stance, as enshrined in the previous standard of information disclosure in *Bolam v Friern Hospital Management Committee*.⁸ In *Bolam*, justice McNair explained to the jury that a clinician ‘is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art’⁹ (words which became known as ‘the *Bolam* test’). The paternalistic stance of *Bolam*¹⁰ is clearly shown by the standard of information disclosure laid down in this case, whereby both risk assessment and treatment options were determined by medical expertise and assessment alone. From the later case of *Sidaway v Board of Governors of the Bethlem Royal Hospital*¹¹ to modern cases like *Pearce v United Bristol Healthcare NHS Trust*¹² and *Chester v Afshar*,¹³ case law has gradually moved away from expressing the determination to value patients’ voices through IC, and thus enhance their autonomy. *Montgomery* can, in this respect, be considered a key point on a journey that started much earlier. Ultimately, however, it is this 2015 Supreme Court judgment that clearly expresses that patients are no longer to be regarded as mere passive recipients of clinicians’ advice, but as ‘person[s] holding right[s]’,¹⁴ via the safeguard of IC.

In this sense, the novelty of the *Montgomery* approach lies in complementing the precedent of the past while also advancing on the journey outlined above. Prior to *Montgomery*, information-sharing was still considered to be part of the medical expertise and merely an exercise of professional skill and judgement. *Montgomery* distinguishes between the assessment of risks and benefits, which still forms part of the medical expertise according to the *Bolam*-standard, and the information-sharing which can also be shaped by the patient’s point of view.¹⁵

8. [1957] 1 WLR 583

9. *Bolam* at [587].

10. *Bolam* at [121]

11. [1985] AC 871

12. [1998] EWCA Civ 865

13. [2004] UKHL 41

14. *Montgomery* [at 75].

15. A M Farrell, M Brazier, ‘Not so New Directions in the Law of Consent? Examining *Montgomery v Lanarkshire*’, *Journal of Medical Ethics* 42 (2015), p. 86.

According to Lord Kerr and Lord Reed, the gradual legal evolution leading towards *Montgomery* has also signified a change in how patients are perceived. The latter are treated

so far as possible as adults who are capable of understanding that medical treatment is uncertain of success and may involve risks, accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices.¹⁶

Through a new test of negligence liability, the ‘materiality test’ of disclosure¹⁷, medical professionals are called upon to place patients at the heart of the disclosure process, balancing more clinical considerations with patients’ needs. The materiality test is structured around two limbs, which represent two alternative¹⁸ routes for assessing what information should be disclosed.¹⁹ The first limb focuses on the disclosure of what a reasonable person in the patient’s position would wish to know. A reasonable person in the patient’s position should thus be made aware, for instance, of reasonable treatment options²⁰ and the associated medical risks / benefits / alternatives whose primary, though not exclusive, assessment belongs to clinicians.²¹ The second limb focuses on the particular patient’s needs and, in circumstances where it is reasonable for the doctor to be aware of them, requires the disclosure of more patient-oriented information. In this sense, although it is sufficient to rely on only one limb for the test of materiality to be satisfied, what emerges on a more general level is that information disclosure is no longer purely a question of doctors’ expertise, but of balancing this with patients’ needs. The materiality test implies that clinical and patient-oriented aspects should be taken into account when assessing the materiality of information.²² In addition, information disclosure is no longer focused on the

16. *Montgomery* at [81]

17. *Montgomery* at [85].

18. See on this point: S Pattinson, *Medical Law and Ethics*, 5th ed. (London: Sweet & Maxwell, 2021), p. 116.

19. See for an interpretation of the materiality test: M Dunn, K W M Fulford, J Herring, A Handa, ‘Between the Reasonable and the Particular: Deflating Autonomy in the Legal Regulation of Informed Consent to Medical Intervention’, *Health Care Analysis* 27 (2019), p. 110. My paper relies on the interpretation of the first limb of the materiality test as provided by Dunn et.al. at p. 119, where they claim that ‘reasonable’ can mean the limb of what is ‘normatively justifiable’ for the patient to be made aware of in the circumstances.

20. Unless the patient openly refuses to receive information – see *Montgomery* at [85].

21. E Cave, C Milo, ‘Informing the Patients: The Bolam Legacy’, *Medical Law International* 20(2) (2020), pp. 112–117.

22. The importance of balancing medically oriented and patient-oriented elements in the IC process in light of *Montgomery* has also been stressed in J Herring, K M W Fullford, et al., ‘Elbow Room for Best Practice? Montgomery, Patient’s Values, and Balanced Decision-making in Person-centred Clinical Care’, *Medical Law Review* 25(4) (2017), p. 582. It should be specified that the two components do not carry the same weight. The second limb is relevant only when it is reasonable for clinicians to be aware of more subjective circumstances. For a look at recent case law spelling out the standard of disclosure, see: *Plant v El-Amir* [2020] EWHC 2902 (QB) and *McNab’s Executor v Greater Glasgow Health Board* [2020] CSOH 53.

magnitude of risks²³ arising or on the patient proactively asking questions.²⁴ There is a desire to limit the risk of a priori exclusion of material information from the medical side. The duty to obtain IC is strictly and clearly tied to a partnership approach to the doctor–patient relationship, since it is only when a collaboration between clinicians and patients is sought that both medical expertise and patients’ needs and values can be balanced.²⁵ Patient autonomy and medical partnership both matter.

Some commentators²⁶ challenge the novelty of the *Montgomery* approach, considering it a mere reiteration of what was already stated at the soft-law level in the GMC guidance on consent and the National Institute for Health and Care Excellence (NICE) guidelines.²⁷ A move towards a new model for consent which highlights patients’ contributions was already emphasised in professional guidelines and pre-*Montgomery* case law. Ultimately, this line of reasoning considers the *Montgomery* approach as a mere ‘echo’ of the soft-law regulation and case law. In this vein, it appears to be correct to state that the *Montgomery* case should not be considered in isolation, something that Lords Kerr and Reed recognized within the judgment itself.²⁸ The decision should indeed be placed within the context of a gradual evolution of the healthcare practice, as expressed in pre-*Montgomery* case law and soft-law regulation. This gradual evolution was also prepared by other legal and social aspects. On a purely legal level, the *Montgomery* case is the predictable outcome of a change in the healthcare law context²⁹ at both the national and international levels. However, it is also indicative of wider social changes. Negligence case law, coupled with the enactment of the Human Rights Act 1998, has gradually prepared the ground for a new understanding of the doctor–patient relationship. The context in which the *Montgomery* case was delivered was also one in which patients could easily access medical information, for instance, via the use of online platforms (e.g. Google).³⁰

23. *Montgomery* at [89].

24. *Montgomery* at [73].

25. *Montgomery* at [77–78; 81; 90].

26. A Farrell, A Brazier, ‘Not so New Directions in the Law of Consent? Examining *Montgomery* v Lanarkshire health Board’, *Journal of Medical Ethics* 42 (2016), p. 85; C Foster, ‘The Last Word on Consent? *Montgomery* is the Belated Obituary, not the Death Knell, of Medical Paternalism’, *New Law Journal* 165 (2015), p. 8. See also: M Campbell, ‘*Montgomery* v Lanarkshire Health Board’, *Common Law World Review* 44(3) (2015), p. 222; S W Chan, E Tulloch, E S Cooper, A Smith, W Wojcik, J E Norman, ‘*Montgomery* and Informed Consent: Where are We Now?’ *BMJ* 357 (2017), p. j2224; M Lamb, ‘*Montgomery*: A Symbolic or Substantive Change to the Law?’, *North East Law Review* 5 (2017), p. 25; C P McGrath, ‘Trust me, I’m a patient. . .’: Disclosure Standards and the Patient’s Right to Decide’, *Cambridge Law Journal* 74(2) (2015), p. 211.

27. GMC, ‘Consent’, see especially para 5; NICE, ‘Caesarean Section’, 2012, available at: <https://www.nice.org.uk/guidance/cg132/Chapter/1-guidance#womancentred-care-2> (accessed 19 March 2021).

28. *Montgomery* at [81].

29. See also: Campbell, ‘*Montgomery*’.

30. See on this point: H L Dreyfus, S E Dreyfus, *Mind over Machine: The Power of Human Intuition and Expertise in the Era of the Computer* (Oxford: Blackwell, 1986), pp. 16–52, 101–120; E Reid, ‘*Montgomery* v Lanarkshire Health Board and the Rights of the Reasonable Patient’, *Edinburgh Law Review* 19(3) (2015), p. 360. See also *Montgomery* at [76].

Patients should no longer be framed as ‘passive recipients’³¹ of medical advice, but as persons whose voices need to be heard. For these reasons, it might be too reductionist to consider *Montgomery* as a purely symbolic judgment.

It is thus the case that *Montgomery* has marked a crucial step in the move towards a focus on patients’ autonomy and medical partnership.³² Pre-*Montgomery* case law and GMC guidelines³³ were expressions of a desire to give more space to patients’ views (i.e. autonomy) in the medical context. *Montgomery* is a response to that need, clearly expressed via (1) the provision of a new test of disclosure, which balances clinical contributions and patient voices (autonomy),³⁴ and (2) the acknowledged relevance attributed to dialogue and advice between the parties and the importance of reaching a shared decision (medical partnership).³⁵

Montgomery, in this sense, was a clear expression of a desire to cement a partnership-oriented and patient-centred practice through IC. Both medical partnership and patients’ autonomy should thus be considered key ‘good intentions’ behind IC developments.

The reality behind the ‘good intentions’: the limitations of Montgomery

Although *Montgomery* represents a significant step towards the protection of medical partnership and patient-centred practices (autonomy) through IC, these aspirations are also bounded by several limitations. Two key limitations will be outlined below: (1) the broad limitations arising from the law of negligence per se, and (2) the pervasive influence of the previous standard of disclosure as laid down in *Bolam*. Both limitations provide further explanations for why a gap between the ‘good intentions’ and the ‘law in practice’ can be observed. This article will ultimately show that there is still a long way to go in the journey of unpacking the ‘good intentions’ of *Montgomery* in courtrooms.

The broad limitations arising from the law of negligence. Liability in negligence is structured in such a way as to limit the possibility for patients to make a successful claim for a *pure* violation of IC (namely, one which is not associated with any physical or psychological harm to the claimant). Negligence is indeed not actionable per se and requires that an actual harm arises as a result of the breach of duty. In this sense, liability does not arise for a failure to protect the decision-making process (i.e. IC), but only when this is reflected in a recognised harm.

31. *Montgomery* at [75].

32. T Elliot, ‘Case Comment: A Break with the Past? Or More of the Same?’, *P.N.* 31(3) (2015), p.190; Reid, ‘Montgomery’, p. 360; Image P, ‘After Bolam: What’s the Future for Patient Consent?’, *The Lancet* (2016), available at: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)32114-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)32114-6/fulltext) (accessed 19 March 2021).

33. New GMC 2020 guidelines on consent both confirm and further expand the ‘good intentions’ of *Montgomery*. See: GMC, Decision making and consent, 2020, available at: https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors—decision-making-and-consent-english_pdf-84191055.pdf?la=en&hash=BE327A1C584627D12BC51F66E790443F0E0651DA (accessed 29 April 2021).

34. *Montgomery* at [87]

35. *Montgomery* at [90]

It should be added that to date, courts have been very reluctant to grant damages³⁶ for a failure to satisfy the right to IC when this is the *solo* violation. IC has been mostly valued in courts only when coupled with the existence of an actual harm, as is the case, for instance, with ‘wrongful birth’.³⁷ Take, for example, the wrongful birth case of *Mordel v Royal Berkshire NHS Foundation Trust*³⁸ where the failure to comply with an IC process led the court to award damages to the claimant.³⁹ In this case, which applied the *Montgomery* ruling, the claimant was granted damages for a breach of the IC process by the clinician. She claimed that had she known about the possibility of her child having Down’s syndrome, she would have had an abortion. In this case, the court held that there was a failure within the informative process which, in line with *Montgomery*, had to imply that a space for a more extensive dialogue had to be found, one that goes beyond a mere ‘yes or no’ approach.

It is the case that the lack of a successful claim for a *solo* violation of IC might be due to (1) the general reluctance of courts to grant damages for a violation of IC processes itself, where this does not result in harm beyond the informative violation per se, and also (2) to the potential difficulty in proving that the harm arising is causally⁴⁰ related to clinicians’ lack of disclosure.

However, it is claimed here that a pure violation of IC is worthy of legal protection in and of itself, since it challenges the safeguard of patients’ autonomy⁴¹ and medical

36. See on this point *Shaw v Kovac and University Hospitals of Leicester NHS Trust* [2017] EWCA Civ 1028, at 4, 64–65.

37. This term describes the prenatal negligence leading to the birth of a disabled child. Key precedents in the context of actions that parents can bring are: *Parkinson v St James and Seacroft University Hospital NHS Trust* [2001] EWCA Civ 530 and *Groom v Selby* [2001] EWCA Civ 1522 where the Court of Appeal held that the extra expenses associated with the raising of a child with a significant disability may be claimed. For recent evolutions in case law, see: *Evie Toombes v. Dr. Philip Mitchell* [2020] EWHC 3506 For an overview of this topic, concerning the actions that the child can bring and ethical issues arising, see: S Pattinson, *Medical Law and Ethics*, 6th ed. (London: Sweet & Maxwell, 2020), pp. 329–345.

38. [2019] EWHC 2591 (QB)

39. As part of a previous research study concerning informed consent and abortion, I have personally investigated this issue via two freedom of information requests to National Health Service (NHS) Resolution. My enquiry was related specifically to the extent of negligence claims involving informed consent in the specific context of abortion, beyond the remit of wrongful birth cases. However, NHS resolution has not been able to provide data on this issue, which appears to be due to problems with its search engine system.

40. See on this point: G Turton, ‘Informed Consent to Medical Treatment Post-Montgomery: Causation and Coincidence’, *The Modern Law Review* 27(1) (2018), pp. 108, 115–134.

41. In a pre-*Montgomery* piece, Purshouse highlighted the importance of patients’ autonomy while recognising the unsuitability of the tort of negligence for this aim to be achieved without disrupting established tort law principles and their coherence. See C Purshouse, ‘Liability for Lost Autonomy in Negligence: Undermining the Coherence of Tort Law?’, *Torts Law Journal* 22(3) (2015), pp. 226–249. Post-*Montgomery* see: T Keren-Paz, ‘Compensating Injury to Autonomy in English Negligence Law: Inconsistent Recognition’, *Medical Law Review* 26(4) (2018), 585–609.

partnership. In other words, the failure to protect the decision-making process (IC) is a violation which should be worthy of a legal protection per se, if the ‘good intentions’ behind IC are to be protected.

Viewed more closely, the limitations of the law of negligence cannot be overcome by reliance on wider tort law claims, particularly the law of battery. In battery, liability arises every time there is a direct and intentional application of force from one person to another without the latter’s consent.⁴² It positively requires that, within the medical context, before any medical intervention is put into place, the requirements for a valid consent are satisfied. These can be broadly identified⁴³ as: the patient’s capacity, the disclosure of broad information, the voluntariness of the decision, and compliance with public policy. The first, the patient’s capacity, concerns the mental status of the patient, the Mental Capacity Act 2005 (MCA) requiring the application of a two-stage test for incapacity that evidences (1) the lack of an ‘impairment or disturbance of the mind or brain’⁴⁴ and (2) the ability of the patient to understand, retain, use, or weigh the medical information relevant to the decision and to communicate their decision.⁴⁵ The law of battery also safeguards the voluntariness of the decision, requiring it to be free from undue influence, that is to say, from certain third parties’ pressure and/or coercion.⁴⁶ When it comes to information disclosure, however, to meet the requirement for a valid consent, the law of battery requires only the provision of general and broad information,⁴⁷ merely providing an overview of the medical intervention in question. It does not require any extra or more detailed information-sharing processes.

It is thus the case that battery can be a useful legal tool to protect against treatments without a valid consent⁴⁸, but it is of limited application to protect the patient, more widely, from an uninformed medical decision (i.e. without IC). This is because, as argued by Cave, ‘informed consent is not necessarily valid (if it is not voluntary or capacitous) and consent that is valid is not necessarily adequately informed. This flows from the different informational thresholds that apply in battery and negligence’.⁴⁹

42. See for an overview of the challenges arising from the law of tort and consent: E Jackson, ‘Informed Consent and the Impotence of Tort’, in: S A M McLean, ed., *First Do No Harm: Law, Ethics and Healthcare. Applied legal philosophy* (Aldershot: Ashgate Publishing, 2006), pp. 273–286; A Maclean, *Autonomy, Informed Consent and Medical Law* (Oxford: Oxford University Press, 2009), pp. 191–213.

43. MCA 2005 ss. 2-3.

44. MCA 2005 s 2(1).

45. See MCA 2005 section 3(1).

46. *Re T (Adult: Refusal of Treatment)* [1993] Fam 95

47. *Chatterson v Gerson* (1981) 1 All ER 257, whereby for a patient to give valid consent they only need to be told ‘in broad terms’ the nature of the procedure, that is to say, only the central aspects of the medical procedure.

48. This can be contrasted with recent attempts of the Court of protection to ‘force abortion’ on women with learning disabilities (*An NHS Foundation Trust v AB & Ors* [2019] EW COP 26). This was then reversed by the Court of Appeal in *Re AB (Termination of pregnancy)* [2019] EWCA Civ 1215.

49. E Cave, ‘Valid Consent’, *Journal of Medical Ethics* 47 (2021), pp.1, 4.

A preliminary challenge to the *Montgomery* ideal of IC stems from the inherent broad limitations of the law of negligence, and hence the lack of a concrete safeguarding in law of IC per se, something that the law of battery is of no assistance in overcoming.

The 'Bolam legacy'. The second limitation of the 'good intentions' of *Montgomery* is found in the pervasive influence of the previous standard of disclosure as laid down in *Bolam*. There is indeed a tension between what Cave and Milo have phrased as the '*Montgomery* supremacy' and 'the *Bolam* legacy'.⁵⁰ In that paper, it was argued that *Bolam* remains relevant to aspects of medical advice, and that the patient-centredness (autonomy) enshrined in *Montgomery* is not uniformly applicable across all aspects of medicine. It is claimed here that, crucially, such a challenge supports the idea that the 'good intentions' behind IC can be undermined by the influence of the previous standard of disclosure as laid down in *Bolam*.

Cave and Milo outlined four interpretative challenges as evidence of a *Bolam* legacy. I am here only briefly recalling two of them since they are the most relevant for this analysis. First, the *Bolam* test has relevance in relation to constructive knowledge of risks associated with proposed treatment.⁵¹ The disclosure of material information implies that clinicians should know about these risks. However, if information on risk is material, but the clinician was not aware of it, this opens the question as to the reasonableness of the clinician's position and how this ought to be judged. In *Duce v Worcester Acute Hospitals NHS Trust*,⁵² the *Montgomery* test was spelled out in a two-part test:⁵³ the first reflects on the clinician's awareness of the risks and falls under the remit of *Bolam*, while the second refers to the reasonableness of risk disclosure which is determined by the court and falls under the remit of *Montgomery*. In light of *Duce*, it therefore appears that *Bolam* and *Montgomery* will apply concurrently to different aspects of the disclosure issue.

In addition, there is still a lack of clarity concerning the separation between the selection of treatment options and the disclosure of options, and hence the relevant test to be applied in these circumstances. Cave and Milo⁵⁴ have argued that the two tests, *Bolam* and *Montgomery*, are likely to sit alongside each other in the assessment of constructive knowledge of risk and reasonable alternative options and their communication to patients. While *Bolam* remains relevant to aspects of medical advice, the precise line of division between the *Bolam* and *Montgomery* materiality tests is not yet clear. This issue creates an overlap between the two standards of disclosure.⁵⁵

50. Cave and Milo, 'Informing the Patients', p. 103.

51. Op. cit., p. 112.

52. [2018] EWCA Civ. 1307

53. *Duce* at [83-85]

54. Cave and Milo, 'Informing the Patients', p. 113.

55. More recently, however, in *McNab's Executor v Greater Glasgow Health Board* [2020] CSOH 53 four aspects were considered in a medical negligence claim. These were all analysed through a *Bolam*-legacy and with no weight to a patient-centred approach. See at [104], where it was stated that 'In approaching the informed consent part of the pursuers' case, I have addressed the following questions: (a) Was there an increased risk of sepsis because of the previous episode? (b) What matters did Ms Seaward have a duty to discuss with the deceased? (c) What did Ms Seaward discuss with the deceased? (d) Did the deceased understand any advice tendered?'

The existence of an ongoing tension between a ‘*Bolam* legacy’ and a ‘*Montgomery* supremacy’ crucially represents an additional limitation of the ‘good intentions’ of *Montgomery*. Medical partnerships and patient autonomy both matter. However, the safeguard of IC as a patient-oriented approach is challenged by a tension between the two standards of disclosure. Specifically, the risk is that of a return to a doctor-centred approach, and with it the possibility of undermining patient autonomy.

Conclusion

Montgomery, as the referral point for an analysis of IC, in the domestic context is filled with what I call ‘good intentions’. The protection of both medical partnerships and patient autonomy as the principles behind IC represents clear positive aspects and a step forward from the previous doctor-centred approach in *Bolam*. However, these ‘good intentions’ risk being stated in theory, but denied in practice. Two limitations have been provided above as evidence of this challenge: the inherent unsuitability of the law of negligence in safeguarding IC per se, and the ongoing tension between *Montgomery* and *Bolam* and hence the standard of disclosure to be followed. The next section will analyse the regulation and case law surrounding IC in Italy to show that, despite the inevitable differences, the gap between the ‘law in theory’ and the ‘law in practice’ is clearly also present in that legal context. This comparative analysis will ultimately call for much needed reflection on how IC can be better protected.

The Italian scenario on IC: the ‘good intentions’ behind IC in the Italian context

Having explored potentials and limitations of the judgment in *Montgomery*, this article now moves to a parallel analysis of the Italian legal framework concerning IC. The Italian framework comprises both legislation and case law on IC. For the purpose of our analysis, I will be focusing on the law n. 219/2017 and the most relevant Supreme Court judgment on the topic. It will be apparent through the below analysis that the Supreme Court (Corte di Cassazione) judgment in *San Martino bis*⁵⁶ goes some way towards highlighting the relevance and remit of IC, particularly the consequences of the violation of

56. For an overview of the San Martino judgments, see: G Vettori, ‘Danno non patrimoniale e diritti inviolabili’, *Obbl e contr* 26972 (2009), p. 103 ; E Navarretta, ‘Danni non patrimoniali: il compimento della Drittwirkung e il declino delle antinomie’, *Nuova giur civ comm* II (2009), p. 81; F D Busnelli, ‘Le Sezioni unite e il danno non patrimoniale’, *Riv dir civ* (2009), p. 97 ; C Castronovo, ‘Danno esistenziale: il lungo addio’, *Danno e resp*, 5 (2009); D Poletti, ‘La dualità del sistema risarcitorio e l’unicità della categoria deidanni non patrimoniali’, *Resp civ prev*, 76 (2009); P Cendon, ‘L’urlo e la furia’, *Nuova giur civ comm*, II (2009), p. 79; C Scognamiglio, ‘Il sistema del danno non patrimoniale dopo le decisioni delle Sezioni unite’, *Resp civ prev* (2009), p. 261; A Procida Mirabelli di Lauro, ‘Il danno non patrimoniale secondo le Sezioni Unite. Un “de profundis” per il danno esistenziale’, *Danno e resp* (2009), p. 32.; R Pardolesi, R Simone, Danno esistenziale (e sistema fragile): ‘die hard’, *Foro it* (2009), I, c. 128.

such right on the side of clinicians. However, crucial limitations still exist that problematise an actual safeguarding of IC, and hence of medical partnerships and patient autonomy. This reflection will then lead to a closer comparative analysis of differences and shared challenges of the two chosen legal systems. A crucial gap between ‘good intentions’ and law in practice exists in both legal systems.

The law on IC in Italy: law n. 219/2017

Since 2017, the Italian legal framework has entrusted the regulation of IC to a hard-law tool, law n. 219/2017. This is the first ever legislation enacted in Italy on this topic. Prior to this, IC was largely left to case law.⁵⁷ The relevant act, in this sense, reflects the gradual evolution of case law on this topic from a doctor-centred approach⁵⁸ to a more patient-centred perspective⁵⁹ and attempts to provide a clearer point of reference. This act is, however, not devoted exclusively to IC, but is part of a broader regulatory framework concerning end-of-life decisions, particularly advance directives. It is at art. 1,⁶⁰ s.1/11, that an understanding of principles and the standard of disclosure surrounding IC is outlined.

As far as principles are concerned, art. 1 s.1 and 2⁶¹ are of key relevance. S.1 states that the legislation will, at a more general level, protect the right to life, right to health, dignity, and autonomy of every patient. S.2 then goes on to outline that ‘a relationship of care and trust between a doctor and a patient is to be promoted, this is based upon informed consent where the autonomy of the patient and the competences and professional autonomy of the clinician meet’. It is hence clear from these enunciations that the Italian legislation attaches primary importance to, among others, medical partnerships and patient autonomy as the two foundational principles⁶² behind IC.

57. For an overview of key judgments that marked the gradual evolution of case law towards the safeguard of informed consent in Italy, see: Cass., 16 October, 2007, n. 21748, where it is claimed that no treatment can be provided by a clinician without the provision of IC from the patients’ side; Cass., 09 February, 2010 n. 2847 where the burden of proving that IC was safeguarded rests on the clinician; Cass. 16 May 2013, n. 11950, where the Court claimed that the violation of IC violates both patient’s right to health and patient’s autonomy.

58. See on this point: Cass., 23 maggio 2001, n. 7027, in *Riv. It.Med.Leg.*, 2009, 337, where the process of disclosure was marked by a doctor-centred perspective. Here, it was claimed that patients needed to have ‘the full knowledge of the medical intervention, of its risks, and foreseeable outcomes and of its possible negative consequences’. No express mention of patients’ needs, beyond a clinical perspective, is included in this context.

59. On this point: Cass. 16 May 2013, n. 11950, where the Court claimed that the violation of IC violates both a patient’s right to health and patient autonomy.

60. For an overview of the Italian doctrine on this point, see: Razzano G, *La legge 219/2017 su consenso informato e DAT, fra libertà di cura e rischi di innesti eutanasi* (Giappicelli, 2019).

61. See on this point: P Zatti, ‘Brevi note sull’interpretazione della legge n.219 del 2017’, (2019) *NLCC*, p.1.

62. This also echoes the Italian Constitution at art. 12, 13, 32 and the ECHR art. 1, 2, 3 concerning the right to life, right to health, and respect of dignity of every person. See on this point: S Canestrari, ‘Consenso informato e disposizioni anticipate di trattamento: ‘una buona legge buona’’, *Il corriere giuridico* 3 (2018), p. 301.

A further clear endorsement of such principles is found at s.8, where it is stated that ‘the time invested in a communicative exchange between a clinician and a patient, is a time of care’. S.8 clearly enunciates two things: first, that IC is an ongoing communicative process, which is not merely fulfilled with a ‘signature on a paper’, but involves dialogue and communication between the parties; second, that IC is not to be framed as an obstacle to the timely administration of a medical treatment; quite the opposite, in fact. The time spent in disclosing information is treated as an integral part of medical care and can crucially serve patients’ interests, here expressed in the desire to support their autonomy via information awareness.

It is thus the case that from the outset, Italian law also recognizes as two foundational principles the same ‘good intentions’ identified at the heart of *Montgomery*, namely, patient autonomy and medical partnerships. This, as we will further unpack later, is a first point of contact between the two legal systems.

The articulation of the standard of disclosure is then found in s.3⁶³, which states that

every person has a right to be made aware of his/her health conditions, and to be informed in a complete, up-to-date and understandable way concerning diagnosis-prognosis, benefits and risks connected to diagnosis and suggested treatments, as well as alternatives and possible consequences of the refusal of a medical treatment or further diagnostic checks.

In this passage, the law details the characteristics of the disclosure process, calling for a process that is accurate, up to date, and framed in a way that patients can understand. However, s.3 crucially lacks an explicit mention of whether the standard is to be judged in light of a doctor-centred approach or a patient-centred one. This *lacuna* can possibly be bridged via a broad interpretation of what seems to be the ‘spirit’ of art. 1. In this sense, particularly in light of art. 1 (s.1 and 2), it can be said that the standard of disclosure can be interpreted as being led by a patient-centred dimension, rather than a purely doctor-centred one. According to s.3, read together with the principles enunciated in s.1 and 2, it is thus the case that doctors owe a duty to disclose information in a way that patients can understand and that provides a comprehensive picture of risks/benefits/alternatives. Nevertheless, the lack of clear guidance on how the standard of disclosure should be assessed still leaves open the possibility of misinterpretations, and with it the likelihood of a return to a purely doctor-centred approach.

A further risk of a return to a doctor-centred stance is also evident with s.3’s requirement of a ‘complete’ disclosure. S.3 does not specify how this is to be interpreted. This is particularly concerning, as if ‘complete’ is interpreted as ‘full’ disclosure, and then this risks potentially ‘bombarding’ patients with information which would not always be relevant to them.

In addition, and partially counterbalancing the lack of clarity expressed concerning the standard of disclosure, a clearer patient-centred approach is endorsed where a right to refuse IC is also granted (s.3). Patients not only have a right to be made aware of

63. See on this point: I Sardella, ‘La nuova responsabilita’ sanitaria: quali novita’ in tema di consenso informato’, *Danno e responsabilita’* 2 (2019), p. 161; R Calvo, ‘La nuova legge sul consenso informato e il c.d. biotestamento’, *Studium Iuris*, 6 (2018), p. 689.

information, they also have a corresponding right to refuse to receive it altogether.⁶⁴ It is also interesting to note that patients can also decide to allocate a third party or a family member who will be in charge of this information and provide consent on his or her behalf. The latter scenario is particularly tied with end-of-life decisions, which the remaining parts of the legislation are devoted to.

It is hence the case that, despite some preliminary challenges from the literal formulation of the Italian legislation, both the relevance of a medical partnership and the relevance of an autonomy-oriented approach are valued. In this respect, the Italian legislation endorses the same ‘good intentions’ noted in *Montgomery*, upon which IC is based.

The reality behind the ‘good intentions’ in the Italian system: the ‘San Martino bis judgment’ and the lack of a clear mechanism of redress

Beyond the existence of ‘good intentions’, however, the reality is not free from legal challenges. An exploration of the most relevant Italian case law in this field reveals a gap between the ‘law in theory’ and the ‘law in practice’. This section will particularly explore the hardships in safeguarding of IC per se, especially when this is not connected with the existence of a harm on the side of the claimant.

The key point of reference to understand where this limitation lies is judgment n. 28985/2019 of the Italian Supreme Court (Corte di Cassazione), known as the ‘*San Martino bis* judgment’.⁶⁵ In this case, a cancer patient sought damages for the non-disclosure of the risk of myelopathy arising from excessive radiotherapy. The patient’s claim was unsuccessful because this risk was still unknown by the scientific community at the time (1986).

Despite this being an unsuccessful claim, it is still relevant to unpack how the court addressed the issue of IC in this context. The court begins its analysis acknowledging that an ‘omission’, that is to say, the lack of information disclosure from the doctor’s side, is conduct which has the potential to lead to a series of ‘offences’ (so-called pluri-offensive conduct). This is because such behaviour has the potential to harm the patient’s right to health, as well as their right to autonomy. This also means that to prove that factual causation exists, the claimant needs to show that the clinician’s conduct infringed both rights.

64. Art 1, s.3.

65. It should be clarified that the *San Martino bis* judgment(s), delivered in 2019, is formed by a block of 10 judgments (declarations) of the third section of the Supreme Court (i.e. Corte di Cassazione), from n. 28985 to n. 28994. We are here focusing only on n. 28985 as this is the most significant for an analysis of the status quo in Italy. It is also noteworthy that these 10 judgments were preceded, in 2008, by another block of four pronouncements of the ‘Sezioni Unite’ of the Italian Supreme Court (so called ‘*San Martino*’). Those from 2008 were an expression of the *Sezioni Unite*, which means that they were the result of a shared vision of the Supreme Court together, whereas those from 2019 were an expression of only one of them, which aspires to create a key precedent for future judgments. Another factor to be noted is that both in 2008 and in 2019 the analysis was conducted in the context of an evaluation of ‘non-economic damages’ arising from pre-existent non-contractual relationships, as it is per the doctor-patient.

In light of this starting point concerning the nature of the offence and the rights that are challenged by such conduct, the Supreme Court attempted to outline five possible scenarios where IC may have been violated and offer guidance on when damages may be recovered for that violation.⁶⁶

The first scenario arises where there is a lack of or insufficient information disclosure concerning a treatment that the patient would have undergone anyway, even if he or she had been correctly informed. If such treatment were performed negligently, leading to physical and mental harm to the patient, the only damage that could be recovered is for the violation of the right to health. The latter, according to the court, should be granted in a way that redresses (1) an external violation⁶⁷, meaning the dynamic-relational implications (or better social and relational) of the negligent conduct, and (2) an internal violation, referred to the internal suffering of the patient (e.g. grief, fear, lack of self-esteem, desperation). In this case, however, it is to be noted that the focus is on the negligent administration of the treatment, rather than the violation of IC per se.

The second scenario concerns the failure to disclose or the provision of insufficient information related to a treatment that the patient would possibly not have undergone had she or he been correctly informed, combined with negligent performance of the treatment resulting in physical and mental harm to the patient. In this instance, the Supreme Court outlines that both violations of the right to health and right to autonomy, as broadly related to the violation of IC, can be recovered. The violation of the right to health is in this instance causally related to both the negligent conduct of the clinician in performing the treatment and the information deficit.

The third scenario is the failure to provide information (or sufficient information) regarding a treatment that the patient would have potentially not undergone had they been correctly informed. In this case, the medical treatment has been administered correctly by the clinician; however, some minor complications arise, for example, an aggravation of a patient's pre-existing clinical condition. In this circumstance, both the right to autonomy and the right to health can be compensated, the latter taking into account the difference between the pre-existent clinical conditions and their subsequent deteriorations. In this case, it should be highlighted that the violation of both rights is here causally related to the violation of the information deficit.

The fourth scenario is the omission or insufficient information related to a medical treatment that the patient would have undergone anyway had they been correctly informed. In this case, the treatment was correctly performed and there was no negative impact on the patients' health. In these circumstances, the Supreme Court has highlighted that no damages will be recovered. The violation of IC per se does not lead to any compensation.

66. It must also be noted that the Court has recently included clear guidelines on how to calculate the provision of damages for violation of IC. See: Tribunale Ordinario di Milano n. 3949, 10-3-2021.

67. For a critical analysis, see: S Brandani and G Navone, 'La liquidazione monetaria del danno non patrimoniale', *NLCC* 374 (2020), p. 404 ; on the dynamic-relational aspect of damages, see: P Perlingieri, *Il diritto civile nella legalità costituzionale secondo il sistema italo-europeo delle fonti – vol. IV – Attività e responsabilità* (Edizioni scientifiche Italiane, 2020), p. 379.

The fifth and final scenario is the one and only hypothesis where the Supreme Court outlines the possibility of granting damages for violation of the right to autonomy, and thus IC per se. However, the court appears to be extremely vague in delineating this scenario. The court highlights that an omission or a lack of diagnosis from which a violation of the right to health does not arise can still lead to damages if non-economic consequences arise on the side of the claimant. The latter are explained as subjective sufferings and limitations of one's liberty, in both a physical and a psychological sense. It is thus not clear whether the court is referring to the hypothetical claim in wrongful birth⁶⁸, for the existence of a diagnostic omission, or to something else, for example, by recognising more broadly the loss of autonomy to make an informed choice, as is the case where there is a serious failing in the information-sharing process.

Although the Italian Supreme Court judgment in '*San Martino bis*' advances things in a positive direction, by attempting to provide a clear outline of five hypothetical scenarios where the violation of IC can be safeguarded, only one of these hypotheses, admittedly the most opaque⁶⁹ (i.e. the fifth scenario), entails a possibility of safeguarding IC per se. However, the complexity related to the possibility of an actual redress is further influenced by the burden of proof on the claimant. The latter needs to prove that had they been rightly informed, they would have not undergone the treatment. In addition, a further aspect that the claimant needs to prove in order to recover damages is the existence of a harm (whether financial or otherwise) which is causally related to the violation.⁷⁰

It is hence the case that compensation for the violation of IC per se is very rare, being confined to the most extreme scenarios. In the vast majority of cases, even in the Italian legal context, the redress is theoretical,⁷¹ rather than actual.

Differences, common challenges, and possible ways forward

Having briefly explored the legal frameworks concerning IC both in England, Wales, and Scotland and in Italy, this section will embark on a closer comparative exercise. This reflection will be focused on two key aspects of IC, concerning (1) the standard of care and (2) the degree of information disclosure. This comparative analysis will outline the existence of some commonalities between the two legal systems with regard to (1) and differences with regard to the latter (2). This analysis will then be followed by a reflection on a key 'shared challenge', namely, the lack of a clear safeguarding of IC.

Standard of disclosure

The first issue which might be considered worthy of a comparative analysis is, crucially, the standard of care. From an analysis of Italian law, it is apparent that the Act⁷² lacks clarity in

68. See on this point the judgment of the Italian Supreme Court 2015 n. 25767.

69. See on this point: G Navone, 'La responsabilit  del medico per inosservanza dell'obbligo informativo', *NLCC* 6 (2020), p. 1394.

70. For a broader look at the liability in negligence for medical professionals, see law n. 24/17, so-called 'legge Gelli-Bianco', at art. 7.

71. Navone, 'La responsabilit ', p. 1396.

72. Art 1, s. 3.

this respect. Particularly, as noted above, it is not clear whether the assessment of what information should be disclosed is to be conducted from the doctor's point of view or not.

Further case law has *prima facie* gone some way towards attempting to tackle this issue. Take as an example the Supreme Court judgment 2019 n. 23328.⁷³ Here, the court specifies the importance of tailoring the disclosure process in light of patients' educational backgrounds and subjective needs, and beyond the framing of IC as a signed document, so as to protect patients' knowledge and understanding of information. This judgment may go some way towards tackling the lack of clarity concerning the standard of disclosure and orienting it in a more patient-centred way. However, on closer analysis, this judgment risks only specifying the characteristics of the disclosure process, in its call for a process that is framed in a way that patients can understand. But patient understanding is clearly differentiated from an assessment of the standard of disclosure. The former gives *the direction or the orientation of disclosure* (i.e. understanding of information), whereas the latter asks *what to disclose* (i.e. standard of disclosure). This still leaves the issue of the standard of disclosure unclear, since it lacks a clear enunciation of whether this is to be judged in light of a doctor-centred approach or a patient-centred one.

Above I have suggested that one way to overcome this challenge, and thus to fill this evident lacuna, is to look at the broad interpretation of the spirit of the law which emphasizes patient-centredness. However, even this suggestion does not rule out possible misinterpretations, and with it a return to what was stated above concerning an unclear and possibly doctor-centred approach.

Montgomery, conversely, is clearer at least in the wording of the standard of disclosure. The judgment proposes this new test of materiality,⁷⁴ where key importance is to be given to both medical partnerships and patient autonomy, as has been noted in previous sections. However, this does not mean that *Montgomery* is free from broader practical challenges in the context of standard of disclosure. It has been noted above that the relationship with the previous standard of care, as laid down in *Bolam*, is still challenging, leaving the balance between doctor-centred and patient-centred approaches in a problematic state.

When it comes to the enunciation of the standard of care, it can ultimately be said that the domestic context at least attempts to provide a clearer theoretical approach compared to the Italian one. However, both share challenges of a possible return to a paternalistic stance, since the balance between medical and patient's contribution is not clear in either of the legal systems.

73. Cass.civ. Sez. III Sent. 19-09-2019, n.23328. The same approach was also expressed in an earlier judgment in Cass. Civ. Sez. III Sent. 04/02/2016, n. 2177. In this judgment, it was specified that IC needs to be based on the disclosure of detailed information and must be oriented towards the provision of a full knowledge of the nature and extent of the surgical intervention, of its risks, of its possible positive and negative outcomes. It is also specified that it is not sufficient to require from the patient a mere signature on a generic paper, but the patients' understanding needs to be pursued via tailoring the information in a way suitable for the subjectivity of patients. However, once again the issue of standard of disclosure is left unspecified.

74. *Montgomery* at [87]

Degree of disclosure

A further key issue to be comparatively analysed is the degree of information disclosure. This is a clear point of difference between the two legal systems. When Italian law specifies the characteristics of the disclosure process, it mentions a ‘complete’⁷⁵ disclosure of information. However, it is not clear whether complete means full disclosure or whether there is any room for a more tailored approach that considers the patient’s needs and circumstances. Although in the same section the Act mentions the importance of sharing information that a patient can understand, this does not in any way safeguard against a process of information disclosure whose content is tailored around a doctor-centred stance, more than a patient-centred one. In addition, the right to refuse IC cannot go sufficiently far to safeguard patient-centredness, but can only promote the possibility of a refusal of information from the patient’s side altogether. The Italian approach is crucially different from their *Montgomery*⁷⁶ counterpart where the materiality test clearly outlines the importance of both medical expertise and patients’ contributions⁷⁷, and in no way seems to suggest that complete disclosure is the norm. In the latter context, the degree of disclosure is very much dependent on the circumstances of the case and the needs of patients.⁷⁸

Such uncertainty concerning the degree of disclosure also risks leading to a possible return to a doctor-centred approach, and with it an undermining of the ‘good intentions’ behind IC.

Ultimately, when it comes to the definition of a standard of disclosure, both legal systems share the same challenge. The balance between the doctors’ involvement and patients’ involvement is clearly left unresolved in both legal systems. Conversely, when it comes to the degree of information disclosure, the approach appears to be markedly different. The Italian system calls for a process of complete disclosure, without specifying what this actually entails, whereas *Montgomery* highlights the importance of a more patient-tailored approach.

The lack of a clear safeguard of IC in both legal systems. Having analysed some preliminary comparative aspects of IC in both legal systems, this section delves into a key shared challenge: the gulf between the ‘good intentions’ of IC and the ‘law in practice’. In other words, the gap between the enunciation of principles of medical partnership and autonomy, and the lack of a clear safeguard of these. This, crucially, calls for a wider reflection on IC, if this key patient right is to become more than an ‘empty promise’.

The key reason why, in both systems, IC risks being an ‘empty promise’ is evidenced by the lack of a clear safeguarding of IC per se. The ‘*San Martino bis* judgment’ analysed above tried to go further than *Montgomery*, attempting to outline five hypotheses in which IC could be protected, and hence the circumstances in which a successful claim

75. Art 1, s. 3.

76. *Montgomery* at [89]

77. See on this point: M Dunn, K W M Fulford, J Herring, A Handa, ‘Between the Reasonable and the Particular’, p. 110.

78. *Montgomery* at [89]

for violation of IC can be brought. However, the only hypothesis mentioned in which IC per se might be safeguarded is likely to be very rare and difficult to satisfy.⁷⁹ This also does not exempt the claimant from the burden of proving the existence of harm⁸⁰ connected to the violation of IC, rendering the idea of a protection of IC per se an illusion.

The same challenge is evident in England, Wales, and Scotland and is mostly related to how the law of negligence is structured. As has been highlighted above, the inherent limitations of proving factual and legal causation imply that practically IC is only safeguarded when a harm to patient arises, beyond harm to autonomy. A violation of IC per se is, even in the domestic context, not considered to be significant enough for a successful claim in negligence to arise.

What this means in practice is that there is little, if any, room for the ‘good intentions’ stated in both *Montgomery* and within the Italian legislation and case law⁸¹ to be translated into robust legal protection. Both legal systems have clearly embarked on a journey where patient-centredness is valued, at least in theory, more and more via IC. However, as outlined above, the crucial challenge that both legal systems face stands in the difficulty of translating these ‘good intentions’ into reality through the possibility of a successful legal claim for patients.

The existence of such a gap calls for further research on IC, particularly regarding how to enhance its safeguarding in court. It is not the intention of this article to outline what exact shape a legal reform should take, but to suggest that this should embrace a clear focus: a protection of the principle of medical partnership and autonomy. Research should also consider the implications of any revised approach for the National Health Service (NHS), particularly its costs,⁸² and the risk that this might feed a ‘fear of the law’⁸³ culture among clinicians. In addition, whether or not legal reforms are pursued, this should also be coupled with a reflection on possible policy changes. Professional

79. G Navone, ‘La responsabilita’’, p. 1394.

80. See also on this point: A Palmieri, ‘Il “restatement” della terza sezione in tema di consenso informato tra continuita col passato e innovazioni (di segno negativo per il paziente)’, *Foro it*, 1 (2020), Gli speciali, c. 78.

81. G Navone, ‘La responsabilita’’, p. 1405.

82. It should be borne in mind that this can additionally fuel a risk of a ‘flood’ of claims that can further negatively impact the limited resources of the NHS. The latest Annual report of NHS resolution for 2019/2020 resolution already shows that ‘The total value of clinical negligence claims under the CNST scheme incurred as a result of incidents in 2019/20 was £8.3 billion, down from £8.8 billion the previous year’. See: NHS Resolution, Annual report and accounts 2019-2020, (2020), available at: https://resolution.nhs.uk/wp-content/uploads/2020/07/NHS-Resolution-2019_20-Annual-report-and-accounts-WEB.pdf (accessed 29 April 2021), p. 103.

83. The existence of the risk of a ‘fear of the law’, or rather a ‘defensive’ approach on the side of clinicians, has been supported in literature. See on this point: O Ortashi, J Virdee, R Hassan, T Mutrynowski, F Abu-Zidan, ‘The Practice of Defensive Medicine among Hospital Doctors in the United Kingdom’, *BMC Medical Ethics*, 14 (2013), p. 42; A O’ Dowd, ‘Doctors Increasingly Practice ‘defensive’ Medicine for Fear of Litigation says Regulator’, *BMJ*, 350 (2015), p. h87.

guidelines will need to play a vital role in this context. In light of the publication of the GMC 2020 guidelines on consent⁸⁴ and the core relevance attributed to IC in this guidance, there are also signs that a slow, yet positive cultural change is occurring, where IC is valued not as a tick-box exercise or a one-off event⁸⁵ but as a process which concretely hears and values every patient's journey.

Conclusion

This article has embarked on a comparative exercise between Italy and England, Wales, and Scotland on the law surrounding IC. It has outlined that both legal systems share a desire to value IC as a tool to endorse patient-centred practices (autonomy) and the relevance of medical partnership, which have been here framed as the 'good intentions' behind IC. The Supreme Court judgment in *Montgomery* and the Italian law n. 219/2017 are good examples of this approach. This can be clearly summarised with reference to the same Italian law, which states that the time spent in a fruitful conversation with the patient is all part of medical care.⁸⁶

However, the 'good intentions' of valuing patient autonomy and medical partnerships through IC are crucially marked by the inherent limitations surrounding this area of the law. In the domestic context, there is still a pervasive influence played by the previous doctor-centred standard of care in *Bolam*, which is ill-placed to safeguard IC. The Italian legislation is also not clear on the standard of disclosure, since it does not expressly mention how this standard is going to be addressed. It also raises concerns about the 'complete' disclosure process and the risk of this amounting to an overly inflexible approach. Both legal systems also face the inevitable challenge of the lack of a means to redress a violation of IC *per se*, when this is not connected with the existence of a harm.

In light of such challenges, it is of key importance to brainstorm new ways to better translate into practice the 'good intentions' behind IC in order for these to become more than an 'empty promise'. Ultimately, if both medical partnerships and patient autonomy are to be safeguarded in practice – as they should be – new, clearer directions need to be explored by both lawmakers and policymakers.

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84. GMC, Decision making and consent (2020), a guideline that highlighted the importance of the doctor–patient relationship as a form of ongoing support. In this respect, the role attributed to the process of sharing information through IC is deemed vital.

85. The relevance of IC as a process is also stated in *Montgomery* at [90]

86. S.8, law n. 219/2017.

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