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# Responsiveness and the Role of Rights in Medical Law: Lessons from Montgomery<sup>‡</sup>

TT Arvind\* and Aisling McMahon<sup>†</sup>

## Abstract:

Over time, medical law has moved away from paternalism in favour of an approach grounded in patients' rights. Using *Montgomery v Lanarkshire Health Board* (2015) as a case-study, we offer a deeper analysis of this emerging approach. We argue that patients' rights should be evaluated in terms of their contribution to making medical law more socially responsive, by developing it to give effect to social needs and aspirations pertaining to healthcare. Although rights can play an important role in achieving social responsiveness, they also carry the risk of entrenching approaches unrepresentative of patients' actual needs and empirical realities. This is evident in *Montgomery*, where the law, despite being derived from GMC guidance, has effects which differ significantly from the GMC's goals. Drawing on socio-legal literature, we outline a new approach for guiding the use of rights in medical law focused on the functional consequences of rights in facilitating patients' aspirations, and the capacity of rights to respond to social and institutional contexts in which medical interactions occurs. We conclude by showing how this approach, applied to informed consent, would produce a different and arguably superior duty, providing a sounder basis for responding to patient needs.

**Keywords:** Autonomy; Informed Consent; Montgomery; Risk Disclosure; Rights.

## INTRODUCTION

For much of the twentieth century, patients played a relatively marginal role in medical law's standard-setting processes. The focus was on doctors:<sup>1</sup> the manner in which they defined patients' needs, the therapeutic approaches their professional practices saw as having value, and the standards of conduct generally accepted in their professional norms. This has now changed. Over the past two decades, the courts have brought the patient back into medical law. Patients and patients' rights—including Convention rights as well as common law duties—have come to play a central role in the way medical law thinks about its task; and courts routinely have regard not just to professional norms and standards, but also to patients' rights and the core needs and entitlements those rights protect, in developing medical law.<sup>2</sup>

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<sup>1</sup> The issues we discuss apply not just to 'doctors' in the strict sense, but to all healthcare professionals involved in making treatment decisions—including, in some cases, nurses, occupational health therapists, and other medical professionals. We use the term 'doctors' for convenience.

<sup>2</sup> Patients' rights, as used in the literature, refers both to common law rights, statutory rights (such as those contained in the Patient Rights (Scotland) Act 2011), rights derived from human rights law (which, in the UK context, usually refers to the rights contained in the ECHR), and rights contained in internal documents such as the NHS Constitution for England (available at <https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england>) or the Charter of Patient Rights and Responsibilities

In theory, this should have strong resonances with the traditional underpinnings of medical law and ethics. Medical lawyers have long argued for a move away from deference,<sup>3</sup> and for centring medical law on the patient's need for healthcare. Despite this, however, there has been disquiet about whether medical law's new emphasis on rights is entirely a good thing, or whether it may be in danger of going too far. Jonathan Montgomery, for example, has argued that the new approach might 'demoralise' medical practice, reducing practitioners' scope for moral reflection and action,<sup>4</sup> and even herald a move away from the very concept of a 'patient' as traditionally understood.<sup>5</sup> Coggon and Miola have suggested that the conception of autonomy underlying these changes may prove to be excessively libertarian, and lead to a near-abandonment of patients by the law.<sup>6</sup> Brazier has asked whether the newfound emphasis on patients' rights needs to be balanced by asking if they also have responsibilities.<sup>7</sup>

Our argument in this article is that the unease with rights reflected in this body of critical work reflects the challenges of using rights as a tool to make medical law more 'socially responsive' – that is to say, capable of responding to, and keeping in step with, social needs and priorities. A socially responsive medical law would see itself as a 'facilitator of response to social needs and aspirations'<sup>8</sup> pertaining to healthcare, and a participant in the task of making the health system better able to 'anticipate and adapt to existing and future health needs, thus contributing to better health outcomes.'<sup>9</sup> It would, accordingly, seek to develop in a manner that recognises and gives effect to those needs and aspirations, rather than simply with reference to precedent and established legal patterns of thought, and its development would have as much regard to social and institutional needs, constraints, and contexts as it would to purely normative frameworks.<sup>10</sup> In an area as institutionally complex as healthcare, this requires the law to be grounded in a nuanced understanding of the social and institutional contexts in which doctor-patient interaction takes place, and the impact those contexts have on both doctors and patients. This understanding, we suggest, is frequently absent in theories of patients' rights which, in consequence, are prone to relying on models of behaviour and motivations that are at variance with the empirical reality of doctor-patient interaction. Remedying this requires a shift in the way we think about rights and their relevance to medical law, requiring us in particular to contextualise those rights to a greater extent than is currently the norm, and to pay closer attention to their *functional* (and not merely ethical) implications.

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NHS Scotland (2019) (available at <https://www.gov.scot/publications/charter-patient-rights-responsibilities-2/>). The rights that are potentially relevant to the specific context we discuss—namely, medical treatment decisions—include the right to patient participation, the right to information on treatment and risks, the right to be treated with dignity and respect, the right to bodily integrity, and so on. A fuller discussion of this topic is, however, beyond the scope of this article.

<sup>3</sup> M Braizer and J Miola, 'Bye Bye Bolam: A Medical Litigation Revolution?' (2000) 8 *Medical Law Review* 85-114, 112, 114.

<sup>4</sup> J Montgomery, 'Law and the demoralisation of medicine' (2006) 26 *LS* 185.

<sup>5</sup> J Montgomery, 'Patient No Longer? What Next in Healthcare Law?' (2017) 70 *CLP* 73.

<sup>6</sup> J Coggon and J Miola, 'Autonomy, Liberty, and Medical Decision-Making' (2011) 70 *CLJ* 523; A Maclean, 'Autonomy, Consent and Persuasion' (2006) 13 *EJHL* 321.

<sup>7</sup> M Brazier, 'Do no harm—do patients have responsibilities too?' (2006) 65 *CLJ* 397.

<sup>8</sup> P Nonet and P Selznick, *Law and Society in Transition: Towards Responsive Law* (New York: Harper & Row, 1978), 14-15.

<sup>9</sup> T Mirzoev and S Kane, 'What is health systems responsiveness? Review of existing knowledge and proposed conceptual framework' (2017) 2 *BMJ Global Health* 2017 e000486.

<sup>10</sup> Nonet and Selznick termed this approach 'autonomous' law as distinct from 'responsive' law. See Nonet and Selznick, n 8 above.

We develop our argument through an in-depth study of the decision of the UK Supreme Court in *Montgomery v Lanarkshire Health Board*,<sup>11</sup> which established a new legal approach to informed consent. We focus on *Montgomery* because it is a particularly clear instantiation of the trends we have discussed.<sup>12</sup> The impetus behind *Montgomery*, as Part 1 discusses in greater detail, was the feeling that the law on informed consent was too doctor-centric, and out of step with the needs of modern patients.<sup>13</sup> Modern patients expect and deserve equality and parity of respect and treatment from doctors,<sup>14</sup> not paternalism. *Montgomery*, accordingly, sought to sweep the old law away and replace it with a new patient-centred material risk test. Despite this goal, we show that significant divergences remain between the law and the social and professional expectations to which it sought to respond. Drawing on clinical literature as well as empirical research into patient preferences and doctors' priorities, we demonstrate that the decision in *Montgomery* is more consumerist and individualist in its approach to doctor-patient interaction than social and professional norms are, and that it prioritises factors which do not reflect patients' actual needs.

Part 2 argues that this divergence reflects a fundamental weakness in the courts' approach to developing medical law. As we show in Part 2, social responsiveness requires rules to be developed in a way that, firstly, relates the normative positions embedded in rules and concepts to social needs and to the hurdles and challenges that might prevent the needs from being realised; and, secondly, embeds an institutional propensity towards responsive outcomes in medical practice. Neither of these is straightforward. Concepts, and especially open-textured evaluative concepts such as 'autonomy' and 'consent', acquire much of their content and evaluative significance from the social and institutional environments in which they function. Transposing them across institutional boundaries and into a different institutional environment—for example, from the legal setting to the clinical setting—can radically alter their content and the manner in which they operate, unless it is done with sensitivity to, and awareness of, these institutional differences. As we show in Part 3, the failure to have regard to these issues has had a non-trivial impact on how the doctor-patient relationship has developed in medical law. In *Montgomery* itself, the result was that the law, despite having been derived from professional guidance issued by the GMC, has effects which differ significantly from the GMC's goals, including potentially granting a higher degree of protection to less vulnerable patients than to more vulnerable patients.

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<sup>11</sup> *Montgomery v Lanarkshire Health Board* [2015] UKSC 11

<sup>12</sup> In case selection, a 'pathway' case is a particularly appropriate focus for research whose purpose (as with this article) is to confirm, disconfirm, or refine a causal hypothesis formulated by the researchers (in this instance, our hypothesis that institutional issues and the mechanics of responsiveness play a significant causative role in determining the effectiveness of the courts' attempt to responsively adapt medical law to give patients a greater role). See J Gerring, *Case Study Research: Principles and Practice* (Cambridge: Cambridge University Press, 2016, 2<sup>nd</sup> edn) 98-116 and 39-55; J Gerring and L Cojocar, 'Selecting Cases for Intensive Analysis: A Diversity of Goals and Methods' (2016) 45 *Sociological Methods and Research* 392, 402-403, 405-406. It is well-established that a single case study can be a useful way of diagnosing the factors underlying a phenomenon, not least because it enables researchers to construct a nuanced and much richer picture of the phenomenon. See J Gerring, 'What is a case study and what is it good for?' (2004) 98 *American Political Science Review* 341; J Gerring 'Single-Outcome Studies: A Methodological Primer' (2006) 21 *International Sociology* 707.

<sup>13</sup> [2015] UKSC 11 [75]-[78], [81].

<sup>14</sup> See the discussion of patient expectations in NW Dickert & NE Kass, 'Understanding respect: learning from patients' (2009) 35 *Journal of Medical Ethics* 419; F Lateef, 'Patient expectations and the paradigm shift of care in emergency medicine' (2011) 4 *Journal of Emergency Trauma Shock* 163.

Part 4 uses this to consider the broader question with which we began, namely, how medical law can use patients' rights to address patient needs in a way that aligns with, rather than goes against, the many contexts of modern healthcare. Drawing on the socio-legal literature on responsive law and professional regulation, we argue that the starting point must lie in ensuring that the use of rights is guided by an empirically grounded understanding of, firstly, the underlying social needs and, secondly, of the social and institutional contexts in which medical interaction takes place and the hurdles these pose to the realisation of those needs. These, we suggest, must then be combined with a more systematic evaluation of the different conceptual frameworks available for thinking about approaches to address those hurdles and meet the underlying needs. Closer engagement with empirical research and studies within medical ethics are an important part of this process. However, they also require shifts in how medical law thinks about the issues it faces, creating a more symbiotic relationship between law and professional norms. We show how this approach, if applied to informed consent, would produce a very different type of duty, which would arguably produce superior results in practice and provide a sounder basis for understanding and responding to patient needs.

## I. INFORMED CONSENT IN LAW AND SOCIETY

### A. *Consent in Montgomery*

Few areas of law illustrate the judicial shift away from paternalism and deference,<sup>15</sup> and the growing importance of patients' rights, as well as the law in relation to informed consent. For much of the 20<sup>th</sup> century, the law of consent to medical treatment was grounded in a paternalistic view of the doctor-patient relationship. The making of treatment decisions was a matter of medical judgment, exercised by doctors who were trusted to use their superior expertise in their patients' best interests. Patient involvement was largely confined to acquiescing to the doctor's advice: patients were informed of the doctor's proposed treatment and asked to consent to it but there was limited role for patient participation.

Although informed consent now has a broad connotation, it first developed in reaction to abuses within medical practice,<sup>16</sup> including not just the notorious example of medical research in Nazi Germany, but also evidence of experiments carried out in the UK and US in the 1970s without the subjects' knowledge.<sup>17</sup> Informed consent emphasised autonomy, but this was a consequence of its role in protecting patients against coercion and exploitation, rather than in limiting paternalism.<sup>18</sup> Judicial approaches to 'informed consent' in therapeutic decision-making continued to treat the question of how much involvement patients should have in decisions as a matter of professional judgment. In *Sidaway*,<sup>19</sup> for example, a majority of the House of Lords held that although doctors had to disclose risks when obtaining informed consent, the question of what needed to be disclosed was governed by the *Bolam*<sup>20</sup> test. This,

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<sup>15</sup> This was a gradual move from earlier cases which gave considerable deference to professional views, epitomised in *Bolam v Friern Hospital Management Committee* [1957] WLR 582, to cases including *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871; *Gold v Haringey Health Authority* [1988] QB 481; *Pearce v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118; *Chester v Afshar* [2004] UKHL 41; *Birch v University College London Hospital NHS Foundation Trust* [2008] EWHC 2237.

<sup>16</sup> J Miola, *Medical Ethics and Medical Law A Symbiotic Relationship* (Hart Publishing, Oxford, 2007)

<sup>17</sup> O Corrigan, 'Empty ethics: the problem with informed consent' (2003) 25 *Sociology of Health and Illness* 768, 771-772; R Faden and TL Beauchamp, *The History and Theory of Informed Consent* (Oxford University Press, Oxford 1986).

<sup>18</sup> Corrigan, *ibid*, 788.

<sup>19</sup> *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871.

<sup>20</sup> *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582, 587. The equivalent case in Scotland is *Hunter v Hanley* 1955 SC 200.

in effect, required only that decisions were grounded in the views of an informed body of professionals. Although several subsequent cases did give a role to patient preferences,<sup>21</sup> they were not easy to reconcile with *Sidaway*,<sup>22</sup> and they rarely took an expressly rights-based approach.

In *Montgomery*, the Supreme Court moved decisively away from this legacy. Overruling *Sidaway*, it held that paternalism was no longer appropriate. Society had changed, and so had medical practice. A new approach grounded in patients' rights was needed to meet the needs and expectations of modern patients. As the remainder of this section will show, however, despite its laudable goal, the model of decision-making adopted in *Montgomery* when applied in practice in fact deviates significantly both from the way doctors and patients view their relationship and from the priorities and needs of patients, for reasons inherent in the approach the courts took.

The facts of *Montgomery* can be stated quite simply. Nadine Montgomery was pregnant. She was also diabetic. This meant she risked having a larger baby. She was told about this risk, which was particularly worrisome to her given her short stature, but she was not told that there was a 9-10% risk of shoulder dystocia—a situation where the baby is unable to pass through the pelvis, potentially leading to further complications.<sup>23</sup> The non-disclosure of this risk was intentional. Her obstetrician, Dr McLellan, felt that if she were aware of the risk, she would opt for a caesarean which would not be in her maternal interest.<sup>24</sup> Tragically, this risk eventuated, leading to her son suffering from cerebral palsy due to oxygen deprivation during delivery and Erb's palsy.<sup>25</sup> Evidence showed that she would have elected to have a caesarean section had she known of the risk of shoulder dystocia, and her son would have been born uninjured.<sup>26</sup>

Montgomery sued Dr McLellan for failing to disclose this risk.<sup>27</sup> She was unsuccessful at first instance and on appeal. The Supreme Court, however, allowed her claim. Overruling *Sidaway*, it held that Dr McLellan was negligent for not disclosing a material risk to her. Changes in society and medical practice meant that *Sidaway* had fallen out of step with professional and social norms, as well as the modern doctor-patient relationship.<sup>28</sup> The GMC's 2008 guidance on consent envisaged doctors and patients making decisions together in a patient-centred process of shared decision-making.<sup>29</sup> Responding to this required a new test consciously

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<sup>21</sup> These include: *Gold v Haringey Health Authority* [1988] QB 481; *Pearce v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118 (CA); *Chester v Afshar* [2004] UKHL 41.

<sup>22</sup> See e.g. the remarks of Cranston J in *Birch v University College London Hospital NHS Foundation Trust* [2008] EWHC 2237 (QB), [73].

<sup>23</sup> [2015] UKSC 11 [8]-[13].

<sup>24</sup> [2015] UKSC 11 [113]-[115].

<sup>25</sup> See [2015] UKSC 11 [22] for further details. The extent of the interventions and trauma arising during the birth and delivery are described by Nadine Montgomery in: 'Birthrights names Nadine Montgomery as charity's first Patron' (19<sup>th</sup> September, 2019) available at <https://www.birthrights.org.uk/2019/09/19/birthrights-names-nadine-montgomery-as-charitys-first-patron/>

<sup>26</sup> [2015] UKSC 11 [22].

<sup>27</sup> At first instance, the primary claim was that the management of Montgomery's labour was negligent. See *Montgomery v Lanarkshire Health Board* [2010] CSOH 104.

<sup>28</sup> *Montgomery*, n 11 above [75]-[78], [81].

<sup>29</sup> General Medical Council, *Consent: patients and doctors making decisions together* (General Medical Council, Manchester, 2008), available at <[www.gmc-uk.org/guidance](http://www.gmc-uk.org/guidance)>.

modelled on this guidance,<sup>30</sup> and a greater focus on patients' rights.<sup>31</sup> The Supreme Court accordingly repudiated the medical paternalism of *Sidaway* in favour of patient autonomy.<sup>32</sup>

The mechanism through which they did so combines patients' rights with consumer choice. The Court held that *Sidaway* was grounded in viewing decisions on risk-disclosure as entailing clinical judgment, exercised based on professional practices.<sup>33</sup> But the court highlighted that 'providers and recipients' of 'healthcare services' no longer viewed their relationship in this way:

[P]atients are now widely regarded as persons holding rights, rather than as the passive recipients of the care of the medical profession. They are also widely treated as consumers exercising choices: a viewpoint which has underpinned some of the developments in the provision of healthcare services.<sup>34</sup>

This combination means that every patient has a right to decide whether to incur a given risk,<sup>35</sup> which they may exercise on medical or non-medical grounds.<sup>36</sup> Disclosure enables them to make this choice. Doctors are, accordingly, obliged to disclose material risks because patients have the right to choose whether or not to incur a particular risk, and not simply because established medical practice requires disclosure.<sup>37</sup>

As a result of *Montgomery*, because disclosure is a matter of patients' rights, its scope is determined by law rather than professional practice.<sup>38</sup> What must be disclosed is, therefore, a question for the courts to determine, not the medical profession. Doctors must take reasonable care to disclose material risks to the patient, with materiality determined not with reference to what a reasonable *practitioner* would regard as significant, but what a reasonable *patient* would regard as significant,<sup>39</sup> thus placing the primary focus on patients' priorities rather than scientific facts:

The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.<sup>40</sup>

Materiality is also sensitive to facts and to the patient's characteristics, rather than statistical percentages.<sup>41</sup> The doctor's role involves dialogue to ensure the patient understands their condition and the treatments available.<sup>42</sup> However, obtaining a signature on a consent form is not adequate, nor is bombarding the patient with technical information.

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<sup>30</sup> *Montgomery*, n 11 above, [93].

<sup>31</sup> *ibid* [80].

<sup>32</sup> *ibid* [81].

<sup>33</sup> *ibid* [74].

<sup>34</sup> *ibid* [75].

<sup>35</sup> *ibid* [82].

<sup>36</sup> *ibid* [83].

<sup>37</sup> *ibid* [82]-[83].

<sup>38</sup> *ibid* [83].

<sup>39</sup> *ibid* [82], [87].

<sup>40</sup> *ibid* [87].

<sup>41</sup> *ibid* [89].

<sup>42</sup> *ibid* [90].

## B. Consumerism and patient needs

In framing its response in these terms, the Supreme Court expressly tried to follow the GMC's lead and keep the law in step with shifting social and professional norms.<sup>43</sup> The weight the Court placed on 'choice' and 'autonomy', however, means that it—unlike the GMC—could be read as setting up an absolute dichotomy between, on the one hand, paternalistic models of active doctors and passive patients and, on the other, consumerist models of active, autonomous patients exercising free choice after evaluating a targeted set of risks and benefits disclosed by their doctors; and as coming down in favour of the latter consumerist model.

Consumerism was not the only factor highlighted in *Montgomery*. The Supreme Court also discussed the importance of other, non-consumerist factors such as dialogue and the subjective dimensions of materiality. This dichotomised reading is not, therefore, inevitable. Nevertheless, as we demonstrate later on in this article (Part III), it is a natural reading of *Montgomery* when seen in the broader context of how consent, choice, and autonomy are approached in private law, and it has begun to exercise a strong influence on cases following *Montgomery*. Our focus in this section is on demonstrating that viewing the making of treatment decisions in terms of this dichotomy, and choosing the consumerist model because of that view, are problematic. Consumer decision-making is not ordinarily a shared or mutual process, in sharp contrast to the model of 'shared decision making' which underlies the GMC's guidance (a point we develop more fully in Part III-A). The choice is the consumer's alone, and the service provider's role is simply to provide any information the consumer might require in order to make a choice. The consumer is assumed to have the ability to process and evaluate this information autonomously, and come to a satisfactory conclusion based on their preferences. These elements are fundamental to consumerism but, as we show in this section, empirical studies of doctors and patients suggest that they neither reflect social perceptions of doctors' responsibilities, nor do they meet patients' expectations and needs.

Firstly, surveys of patients show that although some patients do value the provision of information and view the doctor-patient relationship in consumerist terms, this is far from universal and varies considerably with age and ethnicity. The English national GP patient survey, for example, suggests that involvement in decisions about care is much more important to patients over 65 than to patients under 35, and is less prevalent among ethnic minorities.<sup>44</sup> What does emerge as a universal concern, however, is the importance to patients of feeling of that their problems are taken seriously, and that they are being treated with care and concern. Courteous, respectful, dignified treatment and the availability of staff matter more to patients than having a say in treatment decisions; and a lack of respect and dignity tends to lead to far greater dissatisfaction with their treatment than having less of a say.<sup>45</sup> Conveying an attitude of respect, in particular, is a far greater determinant of trust than being given a say: patients appear to prefer to leave at least some aspects of their health-care decisions to medical professionals, as long as they feel able to trust the professionals in question.<sup>46</sup>

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<sup>43</sup> General Medical Council, n 29 above.

<sup>44</sup> JE Croker et al, 'Factors affecting patients' trust and confidence in GPs: evidence from the English national GP patient survey' (2013) 3 *BMJ Open*.

<sup>45</sup> S Joffe, M Manocchia, JC Weeks, and PD Cleary, 'What do patients value in their hospital care? An empirical perspective on autonomy centred bioethics' (2003) 29 *JME* 103, 106.

<sup>46</sup> B McKinstry, 'Do patients wish to be involved in decision making in the consultation? A cross sectional survey with video vignettes' (2000) 321 *BMJ* 867; Joffe et al, n 45 above, 106.



Secondly, surveys of patients also suggest that patients frequently find it difficult to emotionally process information at clinical consultations,<sup>47</sup> creating a greater need for doctors to act as more than just information-givers. These issues acquire particular salience where the patient is in a vulnerable position when making treatment decisions, for instance patients who are in pain or fearful for their health and lives.<sup>48</sup> A post-*Montgomery* GMC survey of doctors' attitudes to consent highlighted how they felt they could assist patients who struggled to grapple with odds and percentages or to assess risk. Fraught, stressful situations exacerbate problems posed by the unfamiliarity of this type of information.<sup>49</sup> Doctors were therefore concerned by approaches which treated doctors as a source of information no different from Google.<sup>50</sup> Patients' attitudes towards information are similar to doctors', with their decisions embedded less in the information provided to them than in their emotional, cultural, and social relationship to the world around them, including their trust in medical institutions, clinicians, and even the welfare state.<sup>51</sup>

Thirdly, surveys also demonstrate that doctors and patients understand autonomy in the medical context in non-consumerist terms. A study conducted by Stiggelbout et al examined six moral theories of autonomy, and surveyed doctors and patients to determine which of these theories described their attitudes.<sup>52</sup> They found support not just for the liberal individualist concept of autonomy, but also for the idea of autonomy as entailing 'critical reflection' on decisions and the preferences underlying them. A survey by Page, similarly, found that when faced with a choice between different ethical principles, non-maleficence and justice were valued far more than autonomy as guides to ethical decision-making.<sup>53</sup> A 2017 survey for the GMC showed that doctors recognised the importance of disclosing risks to patients, but see it as part of a full dialogue, encompassing common and rare risks.<sup>54</sup>

These studies show, therefore, that *Montgomery's* consumerist model of autonomy fails to reflect what doctors and patients actually value, and serves neither patients' expectations nor clinical priorities. In particular, it leaves little room for the dimensions of trust and reliance which patients also value. This stands to reason. Treatment decisions differ from ordinary consumer decisions in two fundamental ways.<sup>55</sup> Firstly, the value and costs of medical treatment extends beyond consumer surpluses and opportunity costs. Patients undergoing medical treatment face risks which could have a detrimental effect on their health and life. For this reason, a far broader range of factors play a role in patients' decision-making, including

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<sup>47</sup> GN Samuel, S Dheensa, B Farsides, A Fenwick and A Lucassen, 'Healthcare professionals' and patients' perspectives on consent to clinical genetic testing: moving towards a more relational approach' (2017) 18 BMC Medical Ethics 47, 6.

<sup>48</sup> See BA Brody, 'Making informed consent meaningful' (2001) 23 IRB Ethics and Human Research 1–5 which highlights how anxiety, desperation or depression may lead to an incomplete understanding of information given.

<sup>49</sup> Community Vision, *Doctors' Attitudes to Consent and Shared Decision Making: Full Research Report for the GMC* (June 2017) at <[https://www.gmc-uk.org/Doctors\\_attitudes\\_to\\_consent\\_and\\_shared\\_decision\\_making\\_FINAL\\_research\\_report.pdf](https://www.gmc-uk.org/Doctors_attitudes_to_consent_and_shared_decision_making_FINAL_research_report.pdf) 72137875.pdf >, 27.

<sup>50</sup> Community Vision, *ibid*, 27.

<sup>51</sup> Samuel et al, n 47 above, 6-7.

<sup>52</sup> AM Stiggelbout et al, 'Ideals of patient autonomy in clinical decision making: a study on the development of a scale to assess patients' and physicians' views' (2004) 30 JME 268.

<sup>53</sup> K Page, 'The four principles: Can they be measured and do they predict ethical decision making?' (2012) 13 BMC Medical Ethics 10, 5.

<sup>54</sup> Community Vision, n 49 above, 4.

<sup>55</sup> RD Turow, 'Expanding the horizon of our obligations in the Clinician-Patient Relationship' (2017) 47(4) Hastings Center Report 32, 37.

the impact of their decisions on others.<sup>56</sup> And whilst a consumer purchasing (say) a kitchen appliance will generally be able to wait and consider their options, patients undergoing a non-elective procedure are unlikely to have the time to give considerable thought to their options. To describe patients as ‘consumers exercising choices’ as *Montgomery* did and to link reliance on doctors with ‘passivity’ is empirically unsound, because patients’ reasons for trusting a doctor’s guidance typically have little to do with passivity.

Secondly, whilst the ideal type of the self-aware, informed, perfectly confident patient-consumer does approximate to empirical reality in some transactions, in others, the relationship between doctors and patients is characterised by significant structural asymmetries, a very high degree of epistemic uncertainty in relation to why particular risks eventuate sometimes and not others, and a very limited ability to take steps to prevent the eventuation of these risks. These factors place patients’ rights to have their concerns heard and addressed in a different category from a consumer’s right to information, and point to the fact that therapeutic decision-making involves far more complex processes than consumer transactions. It is far from obvious that a patient should be deemed to have accepted risk as a consumer is.<sup>57</sup>

## II. DIAGNOSING THE ISSUE: AUTONOMY, RIGHTS AND THE CHALLENGE OF RESPONSIVENESS

At first glance, the issues discussed in the previous section present a paradox. *Montgomery* expressly sought to align the law with medical practice and the GMC’s guidance, which built on decades of research into patients’ roles in treatment decisions. Why, then, has *Montgomery* adopted an approach that differs fundamentally from the needs and expectations of both doctors and patients? This paradox is compounded when we examine the reaction of the medical profession to *Montgomery*. Professional bodies have worried that *Montgomery* will lead to a bureaucratised, routinised approach to consent.<sup>58</sup> In post-*Montgomery* guidance, the Royal College of Surgeons expressed concern that consent might come to be seen as a ‘tick the box’ criterion focused on legal compliance, where doctors say ‘it is the law that I tell you this and that we have this conversation’, rather than a culture of respecting patients’ interests through shared decision-making.<sup>59</sup> The GMC, too, is revising its guidance on consent in the light of the anxiety which *Montgomery* caused among sections of the medical profession aware of the ruling.<sup>60</sup> Why has *Montgomery* had this effect, when it sought to give legal force to the profession’s own standards, as set out in the GMC guidance?

These problems, as we argue in this section, arise from the fact that medical law has in recent years come to be dominated by a decontextualized approach to rights, which attaches greater weight to the normative and conceptual dimensions of the doctor-patient relationship than to its empirical dimensions. As we discuss below (section A), this approach, which we term the

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<sup>56</sup> A Petersen, *The politics of bioethics* (New York: Routledge, 2007); R Gilbar ‘Communicating genetic information in the family: the familial relationship as the forgotten factor’ (2007) 33 *JME* 390.

<sup>57</sup> Samuel et al, n 47 above, cite over a dozen studies which demonstrate the limits of an information-focused concept of consent.

<sup>58</sup> Devaney, et al, note that “A worrying consequence of the judgment could be that consent forms are now made more intricate and detailed, and that practitioners will spend more time listing every possible risk and alternative on the form in order to safeguard themselves against the threat of litigation.” S Devaney, C Purshouse, E Cave, R Heywood, J Miola and N Reinach “The far-reaching implications of *Montgomery* for risk disclosure in practice” (2019) 24(1) *Journal of Patient Safety and Risk Management* 25–29, 28.

<sup>59</sup> Royal College of Surgeons, ‘Informed Consent – Episode 1’ (Transcript) available at <https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/good-practice-guides/consent/>

<sup>60</sup> General Medical Council, ‘Review of our consent guidance’ available at <[https://www.gmc-uk.org/guidance/news\\_consultation/30001.asp](https://www.gmc-uk.org/guidance/news_consultation/30001.asp)>.

‘internalist’ approach,<sup>61</sup> suffers from a number of limitations in the context of medical law. Addressing these limitations requires a shift of approach, involving taking account of a much broader spectrum of contextual factors. In particular, it requires the courts to have close regard to the functional suitability of the legal rules and duties they frame for the full range of social and institutional contexts in which medical interaction takes place (section B).

#### A. *Internalism and the problem of conceptual allure*

From a legal point of view, responding to social change necessarily involves reworking existing legal concepts and categories. This process, in turn, necessitates choices by judges and jurists in relation to the concepts and categories that will be pressed into service to meet social needs, and the manner in which they will be reworked to address those needs. Critically, however, the effectiveness of the response depends on the suitability of these choices. In internalist legal scholarship, reworking is typically assessed with reference to its *normative* suitability, that is to say, with reference to whether the concept appears to capture features of the relationship that a particular theoretical approach treats as having special normative significance. From the point of view of social responsiveness, however, an equally important issue is the *functional* suitability of the concept or category in question.

Functional suitability is particularly important in relation to abstract legal concepts, such as ‘autonomy’, which are foundational to rights-based accounts of law. As one of us has discussed elsewhere, in law these abstract concepts function as ‘ideal types’ in the Weberian sense: constructs which are purely theoretical to the point of being utopian, and which do not and cannot exist in the empirical world.<sup>62</sup> Ideal types radically simplify the complex phenomena they represent and, through doing so, create reductionist models of reality.<sup>63</sup> This simplification can be useful in a legal context—for example, by highlighting (and, hence, prioritising) a particular interest while stripping out (and, hence, deprioritising) other interests. However, it also carries dangers. In her work on legal change, Jenny Steele has shown that certain legal concepts have an allure, or inherent appeal, because they:

may very neatly capture a way of approaching a complex problem; or they may carry inherent normative appeal [...] An alluring concept is not only a good representation of what is needed; it also appeals in some other way. Perhaps it carries its own explanation implicitly with it, possibly even by making an appeal to common or shared morality.<sup>64</sup>

There is, however, an important downside to the allure of concepts, in that the concept’s normative appeal may lead to:

the temptation to neglect the underlying interests and outcomes that are inevitably involved. Thus, the ‘allure’ of concepts may be as dazzling and as dangerous as it is attractive [...] We tend to think that the forms of words we use actually are what is

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<sup>61</sup> In socio-legal literature, this approach is usually called ‘autonomous law’: see e.g. Nonet and Selznick, n 8 above. We have used the term ‘internalist’ instead, in part because that term is more commonly used in private law theory, but more fundamentally to avoid confusion with the very different ethical and philosophical idea of autonomy, whose role in medical law is also an important theme in this article.

<sup>62</sup> M Weber, *Economy and Society: An Outline of Interpretive Sociology* (E Fischhoff tr, Berkeley: University of California Press, 1978), 19-22.

<sup>63</sup> D Sheehan and TT Arvind, ‘Private Law Theory and Taxonomy: Reframing the Debate’ (2015) 35 *480*, 490-492.

<sup>64</sup> J Steele, ‘Alluring concepts’, Paper presented at the Symposium on Fossilization and Innovation in Law, Newcastle University, 11-12 July 2016, available at [https://pure.york.ac.uk/portal/files/58892586/Alluring\\_Concepts\\_july.docx](https://pure.york.ac.uk/portal/files/58892586/Alluring_Concepts_july.docx).

being developed or decided by the law: the general begins to rule over the factual and particular.

Internalist approaches provide little by way of defence against this downside. From an internalist perspective, using an ideal type such as ‘autonomy’ as the primary legal construct to deal with a social phenomenon is justified by its inherent normativity rather than its social utility: ‘autonomy’ highlights a certain mode of interacting which the law believes to be normatively superior. This reliance on inner normativity makes the approach particularly vulnerable to being ‘dazzled’ by the allure of concepts, with little if any attention being paid to the social consequences of using ‘autonomy’ as the primary conceptual device to deal with a particular social phenomenon.

In contrast, in an approach grounded in social responsiveness the central focus relates not to inner normativity, but to the social usefulness of deploying a particular concept in a particular context. To rely on an ideal type is to implicitly make an evaluative judgment that the form of reductionism implicit in that ideal type is an appropriate way of dealing with the underlying social problem or need. This requires express engagement with the underlying social need, and with the impact on that need of a particular legal construct. From this perspective, using ‘autonomy’ as the primary legal construct to deal with a phenomenon is only justifiable if and to the extent it helps us understand dimensions of the phenomenon that requires resolution, or sheds light on how we might resolve it.

This is not to suggest that ideal-typical constructs like autonomy do not matter. The point is, rather, that they must be seen in terms of their contribution to social responsiveness. Autonomy, for example, helps us see, usefully, that ‘wellbeing’ is a subjective rather than wholly objective notion whose meaning is inextricably tied to the patient’s personal values, and that any system which treats it as an objective concept that can be determined by doctors exercising purely scientific expertise fails to advance actual wellbeing. The danger, however, arises if its allure leads it to be deployed regardless of whether its use in a particular context makes a contribution to meeting patients’ needs and aspirations pertaining to healthcare. This is arguably exactly what happened in *Montgomery*, leading the Supreme Court to adopt a consumerist understanding of doctor-patient interaction which, as discussed in Part 1, diverges significantly from the needs of both doctors and patients.

### B. *Functional suitability and the role of context*

Internalist approaches, such as that taken in *Montgomery*, have their defenders, particularly among theorists of private law. Nevertheless, there are serious reasons to question whether they are desirable in an area like medical law, which is characterised both by a broad consensus that the central concern of medical law is, and ought to remain, patients’ wellbeing and their need for healthcare, and by a highly complex social and institutional environment which exercises considerable influence over the form and outcome of patients’ interaction with the health system. Weber pointed out that because the ideal types are reductionist and non-empirical, they should be used heuristically rather than normatively: their importance stems from their utility in analysing and dealing with social phenomena rather than from their ability to offer immediate prescriptions through their reductionism.<sup>65</sup> This also means that anyone seeking to use ideal-typical constructs must consider the *discrepancy* between those constructs and the empirical world they model.<sup>66</sup>

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<sup>65</sup> Weber, n 62 above, 20.

<sup>66</sup> Weber, n 62 above, 21.

Applied to law, this suggests that reworking concepts to make the law more socially responsive requires close attention to be paid to the overarching concept's functional suitability—the evaluative biases inherent in it, and the potential consequences of entrenching those evaluative biases into the law—as well as to empirical discrepancies—the ways in which the real world differs from the world of the ideal-typical construct, and the dimensions of social interaction from which the law's reliance on that construct deflects attention. This requires the court to consider three sets of questions:

- Firstly, what, precisely, is the court trying to be responsive to? What are the needs they seek to adapt the law to meet, and what is it about the present state of the law that prevents those needs from being met?
- Secondly, what are the concepts that the court could draw on to embed a sensitivity to those needs into the law? What are the evaluative biases inherent in those concepts? Do those biases adequately reflect the underlying need? Do they create a potential for a mismatch, either with that need or with some other position that the law does not seek to alter?
- Thirdly, how well do these concepts align with the institutional context in which doctor-patient interaction takes place? Do they provide a basis for embedding responsive outcomes in the everyday functioning of healthcare organisations, and other relevant institutions?

As we argue in Part III, the reliance placed on autonomy in *Montgomery* reflects a failure to ask these questions. In the first instance, *Montgomery* reflects a failure to recognise that the issue underlying informed consent in the modern sense is no longer merely defending an individual against a doctor's failure to respect their interests but, more fundamentally, dealing with the epistemic uncertainty that characterises much of modern medicine. As a result, whilst the Supreme Court in formulating a response was drawn to autonomy—a concept that has obvious legal allure—it failed to take account of the fact that the GMC's approach which it sought to follow was in fact built on an entirely different normative basis of shared decision-making (section A).

Secondly, it reflects a failure to take account of the asymmetries of information, social position, and institutional authority between doctors, hospitals, and different types of patients. *Montgomery*'s reasoning treats the relationship between doctors and patients as one of equality. It fails to capture the nuance which embeds such relationships, and the differing forms such relationships can take. As a result, it knits together an understanding of consent which is as concerned with protecting the defendant as the claimant, and an understanding of autonomy which sees it as being as much about assuming responsibility for risk as about respect for a patient's inherent dignity. Yet when seen in its social context, the doctor-patient relationship is frequently asymmetric, not least in each's ability to evaluate the risks, benefits, and information relevant to treatment decisions. *Montgomery* thus has the potential to produce results which are normatively deeply problematic in a range of contexts. In particular, decisions of lower courts applying *Montgomery*, as well as the language of *Montgomery* itself, suggest that in its present form, it will grant a higher degree of protection to less vulnerable patients than to more vulnerable patients (section B).

Thirdly, it reflects a failure to take account of the fact that effective responsiveness requires not just a deeper understanding of the nature of the issue which creates the need for legal intervention, but also a recognition that the legal concepts employed by the law must be capable of responding to that issue in a way that delivers the desired outcome not just when applied *post hoc* in litigation, but also when applied to ordinary decision-making within the everyday

institutional context of the medical profession. In this respect, it is important to keep in mind that the role of courts is somewhat limited by their institutional powers and structure, requiring an element of caution in developing the law, in order to ensure that the outcome they intend is achieved. Courts are tied to case-specific reasoning and generic (rather than sector-specific) standards, and lack the freedom to engage in praise, education, and support instead of sanctions.<sup>67</sup> Nor can they, within the confines of private law, create intermediary institutions or choose to regulate processes to the exclusion of outcomes.<sup>68</sup> This makes it critically important that the chosen concepts serve as vehicles of institutional dialogue between law, on the one hand, and members of the medical profession, professional regulators, healthcare organisations such as NHS trusts and hospitals, and the other organisations that make up the NHS, on the other—or, to put it differently, that they provide an adequate basis for law to discharge what Atiyah called its ‘hortatory’ function—encouraging individuals and organisations to conduct themselves in a manner that fulfils the law’s requirements—in relation to doctors and healthcare organisations.<sup>69</sup> The conceptual language deployed in *Montgomery* fails to do this, thereby running the risk of triggering consequences that are far from benign (section C).

### III. LOST IN TRANSLATION: EPISTEMIC UNCERTAINTY AND THE LIMITS OF ‘PATIENT RIGHTS’

#### A. *Epistemic uncertainty and shared decision-making*

Let us start with the first set of questions, namely, what the underlying problem is to which informed consent is a response in the context of therapeutic decision-making, and what conceptual resources are available to the court to deal with that problem.

In its modern form, the use of informed consent in this context is a response to the epistemic uncertainty inherent in the making of treatment decisions. Every treatment carries risks of adverse consequences, even without any negligence on the part of doctors. It is not possible to predict whether a given risk will eventuate, nor is it possible to eliminate the chance of it eventuating. Because uncertainty itself cannot be controlled, both clinical ethics and law deal with the problem of epistemic uncertainty by regulating the process by which treatment decisions are made. The focus has been on demarcating the roles of doctors and patients in deciding what risks to undertake, instituting safeguards to protect the patient’s interests, and identifying where responsibility for policing those safeguards should lie.

Until the 1980s, a significant amount of trust was placed in medical paternalism, with doctors trusted to make most decisions in the best interests of their patients. *Sidaway*, discussed above, marks the high point of this approach in law. In the 1990s, however, the medical profession began to move away from paternalism in favour of ‘shared decision-making’, where treatment decisions are made in partnership with patients. The shift was influenced by a greater awareness of the ethical importance of autonomy and of patients as rights-holders. But purely clinical issues also played a role. Of particular importance was the growing realisation that therapeutic decisions reflected more uncertainty than conventionally appreciated. Evidence-based medicine showed that many conditions frequently had a range of possible treatment options,

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<sup>67</sup> See esp I Ayers and J Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (Oxford: Oxford University Press, 1992) 91-94; J Braithwaite, *Regulatory Capitalism* (Cheltenham: Edward Elgar, 2008) 35-51.

<sup>68</sup> As most theories of ‘reflexive’ regulation would envisage. See e.g. G Teubner, ‘Substantive and Reflexive Elements in Modern Law’ (1983) 17 *Law and Society Review* 239.

<sup>69</sup> P Atiyah, ‘From Principles to Pragmatism: Changes in the Function of the Judicial Process and the Law’ (1980) 65 *Iowa Law Review* 1249.

each with its own set of compromises between possible risks and therapeutic benefits, and each carrying its own uncertainties.<sup>70</sup> Often, no option could objectively be said to be better than others. Variations in treatment practices were discovered which did not appear to produce differences in outcomes,<sup>71</sup> or where the evidence was too limited to judge the relative effectiveness of different treatment options.<sup>72</sup>

These epistemic uncertainties challenged the idea that doctors' expertise was sufficient to make treatment decisions, and led to the view that choices must be made with the full participation of the patient, who alone lived with the consequences of treatment.<sup>73</sup> By 2008, the GMC's guidance on consent envisaged doctors and patients making decisions together in a patient-centred process of shared decision-making.<sup>74</sup> Informed consent was no longer simply about obtaining patients' assent to decisions doctors made.<sup>75</sup> Doctors were expected to engage in a process of dialogue whose focus was tailored to each patient's characteristics and needs, and to ensure that treatment decisions reflected the patient's preferences on risks and outcomes.

The clinical literature, in consequence, takes a far more nuanced approach to patient involvement than *Montgomery's* simple dichotomy between paternalism and passivity, and autonomy and consumer choice. In the leading model, derived from the work of Emanuel and Emanuel<sup>76</sup> and Roter<sup>77</sup> (Table 1 below), four prototypes of the doctor-patient relationship are identified, mapped along two axes representing, respectively, the relative strength of the doctor's and patient's power.

**Table 1: Models of patient involvement in making treatment decisions**

		Strength of the doctor's power	
		Low	High
Strength of the patient's power	Low	Default (indecision)	Paternalism
	High	Consumerism	Mutuality (shared decision-making)

<sup>70</sup> G Elwyn, B Elwyn, and T Miron-Shatz, 'Measuring decision quality: Irresolvable difficulties and an alternative proposal' in A Edwards and G Elwyn (eds), *Shared Decision-Making in Health Care: Achieving evidence-based patient choice* (Oxford: OUP, 2<sup>nd</sup> edn, 2009), 144.

<sup>71</sup> C Charles, A Gafni, and T Whelan, 'Decision-making in the physician-patient encounter: revisiting the shared treatment decision-making model' (1999) 49 *Social Science & Medicine* 651, 653.

<sup>72</sup> V Entwistle and M O'Donnell, 'Evidence-based health care: What role for patients?' in A Edwards and G Elwyn (eds), *Evidence-based Patient Choice: Inevitable or Impossible?* (Oxford: Oxford University Press, 2001) 42.

<sup>73</sup> Charles et al, n 71 above.

<sup>74</sup> General Medical Council, *Consent: patients and doctors making decisions together* (General Medical Council, Manchester, 2008) at <http://www.gmc-uk.org/guidance>.

<sup>75</sup> General Medical Council, *Consent*, *ibid.*.

<sup>76</sup> See EJ Emanuel and LL Emanuel, 'Four Models of the Physician-Patient Relationship' (1992) 267 *JAMA* 2221.

<sup>77</sup> D Roter, 'The enduring and evolving nature of the patient-physician relationship' (2000) 39 *Patient Education and Counseling* 5, 6.

As this model shows, consumerism is not the same as shared decision-making. The key difference lies in their respective approaches to dealing with epistemic uncertainty. Consumerism deals with epistemic uncertainty by distancing doctors from the decision, placing both power over the decision and responsibility for its consequences with the patient. Patient autonomy in this model is synonymous with patients having exclusive control. The role of doctors is merely to supply information about options, risks, and benefits. Doctors do not assist in making the decision and, provided they execute the patient's decision faithfully, they are wholly absolved from responsibility for bad decisions or poor outcomes.<sup>78</sup>

Shared decision-making, in contrast, deals with epistemic uncertainty by making decision-making a joint task, from which neither the doctor nor the patient is distanced. The doctor-patient relationship it envisages is one of partnership. Choices are based on a combination of the doctor's knowledge and the patient's values, and the doctor acts as an advisor or counsellor to assist the patient in relating the treatment options to the patient's values. Doctors and patients achieve a consensus on the outcome,<sup>79</sup> through dialogue to explore and articulate which of the patient's values, goals, and preferences are most salient to the treatment decision, and which option best reflects those values and preferences.<sup>80</sup>

Shared decision-making does not, therefore, entail shifting responsibility for the decision to the patient. Giving the patient information does not exhaust the doctor's role, and the process is not seen in terms of a stark dichotomy between 'doctor choice' and 'patient choice.'<sup>81</sup> Patients' self-understanding of their interests play a central role in the final decision,<sup>82</sup> but both doctors and patients are seen as being experts—doctors in the issue's biomedical dimensions, and patients in how it affects the achievement of their aspirations.<sup>83</sup>

This reflects a deeper philosophical difference. If consumerism embodies a *monist* approach, in which autonomy is the sole consideration from which norms and values are derived,<sup>84</sup> then shared decision-making is grounded in *plural* values, which are closely related to those that undergird human rights.<sup>85</sup> Doctors' obligations spring from the patient's inherent dignity, integrity, and privacy, and the idea that the power doctors hold makes it incumbent on them to justify the trust placed in them and exercise a high degree of sensitivity to their patients' goals, needs, and vulnerability.<sup>86</sup> Health care organisations, too, owe institutional obligations to patients and doctors to facilitate the interactions, practices, and processes on which shared decision-making is predicated.<sup>87</sup> The underlying vision it reflects is that of a multipartite therapeutic alliance, rooted in a social ethic of participation (rather than the liberal ethic of autonomy that forms the basis of the consumerist model), and underpinned by a shared commitment to the health and well-being of the individual.<sup>88</sup> This sits uneasily with the vision

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<sup>78</sup> Emanuel and Emanuel, n 76 above.

<sup>79</sup> M Stewart et al, *Patient-centred Medicine: Transforming the Clinical Method* (London: Radcliffe, 3<sup>rd</sup> ed, 2014) 107.

<sup>80</sup> Roter, n 77 above, 6-7.

<sup>81</sup> HWM van Laarhoven, I Henselmans, and HC De Haes, 'To Treat or Not to Treat: Who Should Decide?' (2014) 19 *The Oncologist* 433.

<sup>82</sup> Emanuel and Emanuel, n 76 above, 2222.

<sup>83</sup> D Tuckett et al, *Meetings between experts: An approach to sharing ideas in medical consultations* (London: Tavistock, 1985).

<sup>84</sup> J Brännmark, 'Patients as Rights Holders' (2017) 47(4) *Hastings Center Report* 32, 37.

<sup>85</sup> *ibid* 37-38.

<sup>86</sup> *ibid* 35, 38.

<sup>87</sup> *ibid* 36.

<sup>88</sup> H Teff, 'Consent to Medical Procedures: Paternalism, Self-Determination or Therapeutic Alliance?' (1985) 101 *LQR* 432.



of autonomous individuals with clearly and narrowly specified responsibilities that undergirds the rights-based approach and, arguably, lies at the heart of *Montgomery*.

*Montgomery* uses the language of consumer choice rather than shared decision-making. A first indication that this is not simply a case of words poorly chosen is the judgment's overwhelming emphasis on the provision of information by the doctor to the patient. The judgment adds some nuance to this role, in that the doctor is expected to be selective and not bombard the patient with information. Nevertheless, it has a wholly different character to the doctor's role in shared decision-making, which places great weight on doctors' role in helping patients work out how to relate their values and preferences to a decision on undergoing a procedure. This is neither simply information-transfer, nor is it a transfer of decision-making to the doctor. The GMC's 2013 guidance on doctors' duties, which the Court noted in *Montgomery*, states that doctors should:

Work in *partnership* with patients. Listen to, and respond to, their concerns and preferences. Give patients the information they want or need in a way they can understand. Respect patients' right to reach decisions *with you* about their treatment and care.<sup>89</sup> (emphasis added)

*Montgomery*'s account of doctor-patient interaction misses this crucial dimension of partnership. The judgment quotes the GMC's guidance on the importance of patient values,<sup>90</sup> and acknowledges patients' rights to decide based on their own values.<sup>91</sup> Nevertheless, the actual operative section of the judgment, which sets out the actual legal content of the duty the case imposes on doctors, the judgment appears to default to the position that those values will typically be a consideration that influence a patient's unilateral decision on whether to consent to the treatment, rather than being a focus of the doctor-patient dialogue.<sup>92</sup> Lords Kerr and Reed describe the purpose of dialogue as being:

to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision.<sup>93</sup>

There is little sense here of the role dialogue can play to support the patient in working out how best to relate their values and preferences to the treatment options. The lack of focus on this dimension of dialogue can undoubtedly be attributed in part to the focus of the arguments in the case on risk disclosure, rather than on the other dimensions of dialogue. Nevertheless, the result is a separation between the dimensions of dialogue focused on risk disclosure, and the broader dialogue of values that underpins shared decision-making. This separation fits far more closely with consumerism than it does with shared decision-making, where the doctor is necessarily viewed as a caring, but non-paternalistic, expert counsellor.

A second indication is the extent of responsibility placed by *Montgomery* on patients. The Supreme Court stressed that it was important to ensure that the law:

instead of treating patients as placing themselves in the hands of their doctors (and then being prone to sue their doctors in the event of a disappointing outcome), treats them 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*

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<sup>89</sup> *Montgomery*, n 11 above, [5].

<sup>90</sup> *Ibid* [77]-[78] (Lords Kerr and Reed JJSC).

<sup>91</sup> *ibid* [45]-[46] (Lords Kerr and Reed JJSC), [115] (Baroness Hale DPSC).

<sup>92</sup> See eg the excerpt from Lord Scarman's dissent in *Sidaway* quoted by Lords Kerr and Reed (*ibid* [45]).

<sup>93</sup> *ibid* [90].

*risks affecting their own lives, and living with the consequences of their choices.*<sup>94</sup>  
(emphasis added)

The emphasis on transferring risk from doctors to patients is typical of consumerism, which is characterised both by the transfer of risk following a choice, and a form of *caveat emptor*.<sup>95</sup> Individuals are informed of their risks and given the opportunity to take steps to reduce it to their satisfaction; if the risk then eventuates, any blame for the choice rests solely with them.<sup>96</sup> Such a model, unlike shared decision-making, assigns a distanced role to doctors and health-care organisations, with little broader responsibility beyond imparting relevant information to the patient and then stepping aside to let the patient make the decision and live with its consequences, precisely like any domestic supplier.<sup>97</sup> Isolated, rational decision-making of this type fits a consumer model where the service-provider's responsibilities are exhausted by providing sufficient accurate information to let the consumer make a utility-maximising decision, but it is not compatible with the collective responsibility that is fundamental to shared-decision making.<sup>98</sup>

### *B. Passive subjects and active choices: The social context of autonomy*

A central reason for the divergence between law and clinical practice in *Montgomery* is that 'consent' as a concept has a very different significance in the two contexts. In terms of *normative* theory, consent is a rich and nuanced concept both in private law generally<sup>99</sup> and in the specific context of medical law.<sup>100</sup> Yet, as commentators on private law have long recognised, consent as a concept in legal *doctrine* lacks most of these normative features. As a private law concept, as distinct from an ethical doctrine,<sup>101</sup> consent is as much about protecting defendants as it is about vindicating the claimant's moral autonomy. It is associated not just with contracts, but also with voluntary assumptions of responsibility, the *volenti* defence, and so on. The private law roots of much of medical law mean that the understanding of consent as an instrument to protect not just patients but also doctors is deeply entrenched in medical law. Although consent prevents encroachments on the patient's bodily integrity,<sup>102</sup> it also provides a defence for doctors against claims which would otherwise fall within the tort of battery or constitute a criminal offence, thus protecting them against litigation.<sup>103</sup> In *Re W*,<sup>104</sup> Lord Donaldson MR likened consent to a 'flak jacket' protecting doctors against actions in negligence. The effect, as Prainsack has pointed out, is to increase the agency of some while decreasing the agency of others,<sup>105</sup> and the law regularly holds parties to have 'consented' even if their actual conduct lacked many or most of the features that moral or ethical theory would

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<sup>94</sup> *Montgomery*, n 11 above, [81].

<sup>95</sup> *Roter*, n 77 above, 7.

<sup>96</sup> B Prainsack, *Personalized Medicine: Empowered Patients in the 21<sup>st</sup> Century?* (New York: NYU Press, 2017)82.

<sup>97</sup> K Hoeyer and N Lynøe, 'Motivating donors to genetic research? Anthropological reasons to rethink the role of informed consent' (2006) 9 *Medical Health Care Philosophy* 13, 18-19.

<sup>98</sup> B Prainsack, n 96 above, 140-143.

<sup>99</sup> See eg D Beylveveld and R Brownsword, *Consent in the Law* (Oxford: Hart Publishing, 2007).

<sup>100</sup> See eg A Maclean, *Autonomy, Informed Consent, and Medical Law: A relational challenge* (Cambridge: Cambridge University Press, 2009).

<sup>101</sup> See the discussion of relationship between private law and ethical issues in Miola, n 16 above, Chapter 2 and 3.

<sup>102</sup> See SHE Harmon and A McMahon, 'From Consent to Authorisation and the Transformative Potential of Solidarity' (2014) 22 *Medical Law Review* 572, 590.

<sup>103</sup> *ibid* 590.

<sup>104</sup> [1994] 4 All ER 627.

<sup>105</sup> Prainsack, n 96 above, 79.

associate with consent.<sup>106</sup> As a legal concept, it requires not participation in the making of a decision but submission to a decision made by another;<sup>107</sup> and courts in assessing whether a party has given ‘informed’ consent are not assessing whether a party was given the opportunity to fully participate in the making of a decision, but whether the party understood the decision to which they were submitting. Clinical practice, in contrast, sees consent precisely as a measure of participation, rooted in values of trustworthiness, openness, and honesty.<sup>108</sup> Consequently, whereas clinical practice can conceive of degrees of consent, and forms or varieties of consent, consent is necessarily a binary concept in private law: one has submitted to a determination, or one has not submitted. Whether that determination was made unilaterally or in a joint process is irrelevant to consent: participation and consent are wholly separate and wholly individuated concepts.

The limitations of this approach are exacerbated by the fact that patients and doctors are rarely equal. Doctor-patient interaction takes place in a social context characterised by relationships of power, trust, and dependence, which have a significant impact on the practical ability of patients to exercise autonomous choice.<sup>109</sup> As scholars of clinical ethics have long been aware, conceptions of consent rooted primarily in autonomy are *inherently* limited in their ability to deal with inequality. Two assumptions underlie these models: firstly, that patients who are given scientific information on the benefits and risks of treatment can make decisions for themselves and, secondly, that ‘physicians should not have an investment in the decision-making process or in the decision made.’<sup>110</sup> Both assumptions are questionable, promoting a contractual understanding of the obligations of doctors and healthcare institutions which is at variance with how doctors and patients see their relationship—as not contractual, but built on trust.<sup>111</sup>

Although the pursuer in *Montgomery* had much less need to rely on her doctor’s expertise than a typical patient would have, she was an atypical patient: she had a molecular biology background, she worked as a hospital specialist with a pharmaceutical company, and her mother and sister were general medical practitioners. *Britten v Tayside Health Board*<sup>112</sup> involved a more typical patient. The patient in *Britten* had not been warned that the treatment he received might cause a relapse in his bipolar disorder. Other treatments would have avoided the risk. The Court held that the patient could not recover, as he had failed to establish causation. This was because, on the balance of probabilities, it was likely that the patient would have followed the doctor’s recommendation even if the risk had been disclosed.

Underlying this is the problem which Jonathan Montgomery has described as the law’s failure to take seriously the idea of ‘patients as citizens’, and instead defaulting to treating them as ‘passive recipients of altruistic care.’<sup>113</sup> The paradoxical result is that as the law stands, more assertive and less vulnerable patients are given more protection by the law: because they are more likely to be assertive and challenge the doctor’s advice, they are more able to prove causation. More vulnerable patients, who are arguably normatively most in need of legal protection, are less likely to be able to prove causation, because they are more likely to repose

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<sup>106</sup> A Robertson, ‘The Limits of Voluntariness in Contract’ (2005) 29 Melbourne University Law Review 179.

<sup>107</sup> For a full argument on the limits of private law concepts of consent in the context of contract, see MJ Radin, *Boilerplate: The Fine Print, Vanishing Rights, and the Rule of Law* (Princeton: Princeton University Press, 2012).

<sup>108</sup> Samuel et al, n 47 above, 2.

<sup>109</sup> Corrigan, n 17 above, 788.

<sup>110</sup> C Charles, A Gafni, and T Whelan, n 71 above, 657.

<sup>111</sup> Turog, n 55 above, 40.

<sup>112</sup> [2016] SC DUN 75.

<sup>113</sup> Montgomery, n 5, 34-35.

trust in doctors and accept their advice. *Montgomery* thus reproduces a much-criticised feature of *Sidaway*:<sup>114</sup> namely, the fact that it gave far greater control to certain categories of patients. It is hard to see how such a position can be defended, and it sits at best uneasily with the justifications for the shift put forward by the Supreme Court in *Montgomery*, but it reflects deeper issues with the law's approach to consent. The Australian experience with causation under the very similar rule in *Rogers v Whitaker*,<sup>115</sup> which influenced the Supreme Court in *Montgomery*, lends considerable support to the idea that this is a necessary consequence of the approach to informed consent that undergirds *Montgomery*.<sup>116</sup> This has non-trivial implications. In pre-*Montgomery* surveys, practitioners acknowledged that they regularly guided patients towards particular outcomes;<sup>117</sup> yet the availability of a remedy under *Montgomery* has little connection with whether the doctor's guidance reflected a genuine attempt to assist the patient in relating their values to available treatment options.

The task of causation in relation to shared decision-making properly ought to be to identify situations where the harm was a product of epistemic uncertainty rather than a failure to create a truly joint decision—for example, if a joint decision would have been the same as the actual decision. What causation actually does in *Montgomery*, however, is to dilute the obligation to work to ensure that a decision is actually a joint product of doctor and patient. Recent work by Devaney et al has shown that courts pre-*Montgomery* had been willing to relax causation principles to protect patients, for example if patients could show they would have delayed procedures if they had been properly informed of risks, even if they could not prove they would have refused the treatment.<sup>118</sup> Yet in their view, post-*Montgomery* English courts have been 'less generous to patients in the approach they have adopted to causation'.<sup>119</sup> They argue for caution in using causation as a control device on informed consent claims as has happened in the Australian approach,<sup>120</sup> because it 'runs the risk of undermining all that *Montgomery* purports to bring in terms of a more sympathetic standard of disclosure.'<sup>121</sup>

This reflects an inherent problem with autonomy which, despite its conceptual allure, is in fact functionally unsuitable for the role *Montgomery* assigns it because of its inability to capture elements of reliance and trust,<sup>122</sup> and its tendency to draw the focus away from the obligations doctors and hospitals owe to patients.<sup>123</sup> As Brody<sup>124</sup> has pointed out, this is because autonomy elides the distinction between intentionality (that a decision reflects the patient's values, not someone else's) and voluntariness (that the decision was genuinely the patient's, and not something they were induced to choose by someone). This distinction is of crucial importance to understanding the actual nature of the normative issues in relation to informed consent, as cases like *Britten* demonstrate. The breach in *Britten* related to intentionality: that the doctor failed to work with the patient to find a decision that reflected his values. Had *Britten*—or, for

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<sup>114</sup> [1985] AC 871, 895 (Lord Diplock). For a critical analysis of this case see: M Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law?' (1987) 7 LS 169-93. It is worth noting that *Montgomery* acknowledges this criticism (see esp [58]), but ends up adopting a test that replicates it.

<sup>115</sup> (1992) 175 CLR 479 (HCA).

<sup>116</sup> See in particular *Rosenberg v Percival* [2001] HCA 18, (2002) 205 CLR 434, and its relationship with *Chappel v Hart* (1998) 195 CLR 232 (HCA).

<sup>117</sup> R Heywood, A Macaskill, and Kevin Williams, 'Informed Consent in Hospital Practice: Health Professionals' Perspectives and Legal Reflections' (2010) 18 Medical Law Review 152.

<sup>118</sup> Devaney et al, n 58 above, 27

<sup>119</sup> *Ibid*, 27.

<sup>120</sup> See also: MK Smith and T Carter, 'Montgomery, informed consent and causation of harm: lessons from Australia or a uniquely English approach to patient autonomy?' (2018) 44 JME 384-388.

<sup>121</sup> Devaney et al, n 58 above, 27,

<sup>122</sup> O O'Neill, *Autonomy and Trust in Bioethics* (Cambridge: Cambridge University Press, 2002), 24-30.

<sup>123</sup> *ibid* 79-85.

<sup>124</sup> Brody, n 48 above, 1-2.

that matter, the Australian cases following *Rogers v Whitaker*— been understood in this way, causation would have posed far less of a challenge for vulnerable patients than it actually did. Such an approach would, arguably, also have provided a better framework for dealing with *Montgomery* itself.

C. *Law, society, and institutional dialogue: A failure to communicate?*

The previous sections have given us a clearer sense of the underlying issue, and of the conceptual frameworks that can help form the basis of a legal response. Actually framing a response, however, requires taking account not just of the social context, but also of the institutional context, and of the relationship between legal and social institutions. This not only affects the powers of patients and doctors, but also influences how decisions are made and options evaluated, in ways that materially affect the effectiveness of patient-centred processes.<sup>125</sup> Consider, for example, the making of an evaluative judgment, based on a particular conceptual framework such as ‘risk’ or ‘consent’. As the discussion in the previous section has shown, the use of the same *word* in law and medicine can mask the fact that the two domains are working with different *conceptions* of the phenomenon underlying the word. Consent, for example, is an open-textured concept—a ‘mere legal shell’ which has to be ‘filled out with the aid of moral principles’ before it can be applied.<sup>126</sup> The meaning and significance an actor assigns to an open-textured concept is strongly influenced by the institutional environment in which its meaning and significance are interpreted.<sup>127</sup> It will almost inevitably have multiple meanings in different interpretative communities,<sup>128</sup> unless those communities share common points of reference (which law and medicine typically will not).

This is true not just of consent, but also of concepts like materiality. As used in *Montgomery*, materiality entails making a multi-layered assessment involving, firstly, constructing a reasonable person ‘in the patient’s position’ and, secondly, assessing whether that reasonable person would regard particular risk as ‘significant’. This involves a hybrid of subjective and objective tests: the law assesses what a *particular* patient would attach significance to while also imposing objective criteria on that particular patient by asking what a *reasonable* person in that position would feel.<sup>129</sup> The difficulty of this hybrid test is exacerbated by the fact that in medicine, risk is primarily an actuarial concept, assessed using techniques such as probabilities and decision trees.<sup>130</sup> Cultural conceptions affect *attitudes* to risk, but not risk itself.<sup>131</sup> In contrast, although law embeds a number of different conceptions of risk, actuarial risk plays a minimal role.<sup>132</sup> The legal understanding of materiality of risk will in consequence necessarily differ from the medical understanding unless there is engagement and shared thinking on materiality across the two domains.<sup>133</sup> Engagement and shared thinking are, however, made considerably harder when the law is based on a consideration which, like the

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<sup>125</sup> See e.g. G Elwyn et al, “‘Many miles to go...’: a systematic review of the implementation of patient decision support interventions into routine clinical practice” (2013) 13 BMC Medical Informatics and Decision Making S14; WA Nelson and T Walsh, ‘Ensuring patient-centred care’ (2014) 29(4) Healthcare Executive 40.

<sup>126</sup> HLA Hart, *The Concept of Law* (Oxford: Oxford University Press, 1961) 199-200.

<sup>127</sup> For further discussion of the significance of open-textured principles within an institutional context, see A McMahon, *The Morality Provisions in the European Patent System: An Institutional Examination* (PhD Thesis, University of Edinburgh 2016), chapter 2.

<sup>128</sup> See P Drahos, ‘Biotechnology Patents, Markets and Morality’ (1999) 21 EIPR 441-449.

<sup>129</sup> *Thefault v Johnston* [2017] EWHC 497 (QB).

<sup>130</sup> For an overview of decision trees, see A Schwartz and G Bergus, *Medical Decision Making: A Physician's Guide* (Cambridge: Cambridge University Press, 2008) 107-110.

<sup>131</sup> Schwartz and Bergus, n 130 above, 59-61.

<sup>132</sup> See generally J Steele, *Risk and Legal Theory* (Oxford: Hart, 2004).

<sup>133</sup> For an analogous point on the difference between legal and moral reasoning, see N MacCormick, *Practical reason in Law and Morality* (Oxford: OUP, 2008) 172.

version of autonomy in *Montgomery*, is at variance with how doctors and patients view their relationship. The result is a high degree of uncertainty for doctors on what the law requires of them in an individual case.

This has a particularly strong impact in an environment like healthcare, which is characterised by a high degree not just of professionalization, but also professional fragmentation through the absence of a single overarching professional body with oversight over all relevant professions. A key characteristic of professions is their ability to control and regulate themselves through professional standards, codes of conduct, and other such norms prescribed by professional bodies.<sup>134</sup> When the social character of the relationship between professionals and the public changes, the law is faced not just with shifting social expectations, but also with shifting professional norms, which almost inevitably also evolve in response to these changes but not always symbiotically with or even in the same direction as social expectations. *Montgomery* instantiates this, because the issue of informed consent has been one to which professional bodies have devoted considerable time, and because the responses to *Montgomery* have brought out divisions not just between lawyers and the medical profession, but also between the medical profession's regulatory bodies and medical practitioners.

The result is an institutional gap, whose existence makes the legal assessment of medical judgment problematic. Although the medical sphere is institutionally different from the legal sphere, medicine cannot ignore the law. It must therefore find a way of adapting to the law. Institutional theorists describe the resulting process as 'isomorphism',<sup>135</sup> a 'constraining process which forces one unit in a population to resemble other units that face the same set of environmental constraints.'<sup>136</sup> Where the institutional environments in questions are not sufficiently similar to replicate or anticipate each other's interpretation of open-textured concepts (as medicine and law are not), 'soft' harmonisation is difficult to achieve. Instead, a *coercive* form of isomorphism occurs, where homogenisation results from pressure exerted on an organisation by external organisations, either because it depends on them or because of cultural expectations within broader society.<sup>137</sup>

Coercive isomorphism will not always work, however. It can have adverse consequences even if it is well intentioned. This is partly because of the stakes involved. Where the liability and reputation of practitioners and their organisations are placed at risk, they may tend towards approaches that seek to 'second guess' the likely judicial assessment of materiality, but without the institutionally embedded interpretative thought-styles that exist within law.<sup>138</sup> As Helmke and Levitsky have shown, under such circumstances institutional divergences can result in the two institutions being *accommodating*, where the medical community as the weaker institution recognises that it lacks the ability to influence law, a stronger institution, and seeks instead to mitigate its effects. Alternately, they may become *competing*, where the medical profession tries to alter or even subvert the effect the legal rules were designed to have. Either relationship

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<sup>134</sup> See E Freidson, *Professionalism: The third logic* (London: Polity Press, 2001). 'Profession' is a heavily contested concept within sociology, which several scholars questioning whether the category is a useful one. This article, however, uses the phrase as a legal category rather than a sociological category, to describe a set of social institutions which, for historical reasons, have self-run bodies which set their own standards, to which the law has historically had regard.

<sup>135</sup> P DiMaggio and W Powell, 'The Iron Cage Revisited: Institutional Isomorphism and Collective Rationality in Organizational Fields' (1983) 48 *American Sociological Review* 147. For further discussion, see [self-identifying reference removed].

<sup>136</sup> DiMaggio and Powell, n 135 above, 149.

<sup>137</sup> *ibid* 149-150.

<sup>138</sup> On the significance of thought styles, see M Douglas, *How Institutions Think* (Syracuse: Syracuse University Press, 1986).

can, over time, undermine both the legitimacy of the legal system and perceptions as to the desirability of the outcomes it seeks to promote. A proper balance requires institutions to be *complementary*, such that each seeks to support the other.<sup>139</sup> Achieving this is not straightforward, however, unless the law takes express account of the need for institutional dialogue, and selects conceptual frameworks based on their transplantability into the context of medical practice and their ability to support not just law's adjudicatory function but, more fundamentally, its hortatory function.<sup>140</sup>

These challenges are exacerbated by two other factors. The first is that doctors in general do not know the law. Surveys carried out before *Montgomery* showed that the medical profession frequently either did not know or misunderstood what the law required of them in obtaining informed consent,<sup>141</sup> and a GMC survey of doctors in 2017 showed very low awareness of *Montgomery*.<sup>142</sup> Secondly, the manner in which doctors reason about ethical decisions differs fundamentally from legal reasoning. Studies of ethical decision-making by doctors have shown that we do not yet fully understand how they use ethical principles in making decisions, nor how more specific situational factors influence their use of ethical principles in making decisions, nor even the types of reasoning they deploy to deal with these challenges.<sup>143</sup>

A second dimension arises from the fact that decision-making in the modern health system is in very large part *organisationally* governed. Like much of private law, *Montgomery* assumes that doctor-patient interaction takes place exclusively between individuals—the individual doctor and individual patient—free from organisational constraints. In modern healthcare, however, doctors and patients do not deal with each other as mere individuals. They deal with each other in the context of complex, all-encompassing institutional structures, policies, and procedures—including the many layers of trusts and bodies within the NHS each with their own policies—and in large teams covering multiple specialisms. Hospitals, managers, trusts, and their rules and processes play a central role in the medical system, and all but minor treatments are typically carried out by referral to a team in a hospital or specialist care facility.

*Montgomery*, however, does not consider organisations or their role in decision-making, save in passing: its model of decision-making assumes interaction between disaffiliated individuals, unconstrained by any broader institutional or organisational context.<sup>144</sup> The failure to acknowledge or engage with the role of organisations is problematic, because organisational goals and motivations are not the same as the goals and motivations of individual doctors. *Montgomery* envisages a situation where the making of decisions is influenced by either therapeutic grounds or value grounds, and it assigns the former wholly to the doctor's domain, and the latter wholly to the patient's domain. The doctor's duty is breached where a doctor trespasses on the patient's domain—either directly by making a value choice that the patient should have been allowed to make, as Dr. McLellan did in *Montgomery* itself, or indirectly by failing to alert the patient to a value choice by not disclosing a material risk.

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<sup>139</sup> G Helmke and S Levitsky, 'Informal institutions and comparative politics: A research agenda' (2004) 2 *Perspectives on Politics* 735.

<sup>140</sup> Atiyah, n 69 above.

<sup>141</sup> L Fisher-Jeffes, C Barton, and F Finlay, 'Clinicians' knowledge of informed consent' (2007) 33 *JME* 181.

<sup>142</sup> *Community Vision*, n 49 above, 4.

<sup>143</sup> Page, n 53 above, 6-7.

<sup>144</sup> Decision-making is also embedded within complex inter-personal relations, which are discussed within relational accounts of autonomy. See especially C Mackenzie and N Stoljar (eds), *Relational autonomy: feminist perspectives on autonomy, agency and the social self* (New York: Oxford University Press, 2000). See also V Entwistle, 'Supporting Patient Autonomy: The Importance of Clinician-patient Relationships' (2010) 25 *Journal of General Internal Medicine* 741.

Organisations, however, make decisions not merely on value or therapeutic grounds, but also on *operational* grounds—and it is arguably these operational grounds that are most salient in large, complex organisations with a powerful and deeply embedded managerial class. For such an organisation, a key priority is to seek legitimacy for its approach to making treatment decisions, in order to fend off liability and protect the standing of the organisation. Due to their nature, however, operational considerations—unlike therapeutic and value considerations—are blind to the requirements and characteristics of the individual case.

The divergence between the goals and motivations of healthcare organisations and those of the medical profession has long been of concern to professional bodies.<sup>145</sup> GMC surveys of doctors suggest that organisational policies hamper shared decision-making, for example the limited time doctors are given with patients; the limited time available for training on communication and other soft skills required for effective dialogue with patients; and resource constraints under which treatments agreed between patients and doctors are denied due to limited budgets.<sup>146</sup> Cultural issues also matter. Does the spirit of the healthcare organisation’s policies and procedures reflect an atomised understanding of individuals dealing with each other through legalised, socially disembedded processes? Or are they suffused with the social and ethical expectations patients have of doctors?<sup>147</sup>

This affects the models of decision-making discussed in Table 1, because it creates the possibility of situations where both doctors and patients have little power. Table 1 suggests that the outcome in such cases is ‘indecision’. In the world of the NHS, however, ‘indecision’ is not a therapeutic option. A doctor treating a patient within the NHS does not have the option of stating: “No decision was made on how to treat the patient’s condition.” Even if the decision that is made is to leave the patient’s condition untreated, or to maintain the status quo, that is a treatment decision, not indecision. In reality, the outcome in such situations is proceduralism—determination by routinised processes which are influenced more by organisational priorities than professional norms. The paternalism/consumerism dichotomy of *Montgomery* focuses on only one dimension of decision-making, namely, *individual* discretion and the relative power of doctors and patients. Yet there is also a second dimension, whose focus is on the distribution of power between individuals and organisations. Shared decision-making represents a situation where organisational procedures play a relatively weak role, facilitating rather than constraining individual action. In contrast, where procedures and processes play a controlling rather than facilitatory role, doctors as much as patients are left in a state of ‘powerless discretion’, in Sarfatti Larson’s evocative phrase.<sup>148</sup>

Indeed, case law since *Montgomery* demonstrates the limits of the law in constraining proceduralism. In *A v East Kent Hospitals*,<sup>149</sup> for example, one of the clinicians involved had made extensive use of ‘decision trees’—a tool that uses statistical probabilities in deciding how to evaluate a situation—in making decisions as to what risks were material.<sup>150</sup> Such a tool is a far cry from the principled, supportive discussions that shared decision-making envisages, but

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<sup>145</sup> See e.g. World Medical Association, Declaration of Seoul on Professional Autonomy and Clinical Independence (59th WMA General Assembly, Seoul, Korea, October 2008) at <https://www.wma.net/policies-post/wma-declaration-of-seoul-on-professional-autonomy-and-clinical-independence/>.

<sup>146</sup> Community Vision, n 49 above, 19-22.

<sup>147</sup> WA Nelson, JJ Donnellan, and G Elwyn, ‘Implementing shared decision making: An organizational imperative’ in G Elwyn, A Edwards, and R Thompson (eds), *Shared Decision-Making in Health Care: Achieving evidence-based patient choice* (Oxford: Oxford University Press, 3<sup>rd</sup> edn, 2016).

<sup>148</sup> M Sarfatti Larson, *The Rise of Professionalism: A Sociological Analysis* (Berkeley: University of California Press, 1978) 237.

<sup>149</sup> [2015] EWHC 1038 (QB)

<sup>150</sup> Schwartz and Bergus, n 130 above, 107-110.



it is typical of how doctors function in a heavily regulated organisational environment. The same is true of other aspects of risk-communication, such as the use of standardised information, in accessible formats such as podcasts and apps, to explain risks and treatment options to patients, which although organisationally attractive run the risk of being too generic to be useful.

The ruling in *Montgomery* provides the court with no conceptual tools to deal with the broader question of the responsibility of medical institutions to individuals—doctors as well as patients—who place their trust in them.<sup>151</sup> This explains the otherwise puzzling reaction of professional bodies to *Montgomery*. The gap between legal and medical understandings of consent and risk creates a strong possibility that the law’s influence on medical practice will tend towards unidirectional, coercive isomorphism rather than soft harmonisation. In such a situation, the formal institutions of law and the informal institutions constituted by practices and guidelines of hospitals and professional bodies are likely to be accommodating or competing, rather than complementary, in the sense discussed by Helmke and Levitsky.<sup>152</sup> The resulting lack of control, coupled with the power of healthcare organisations over the doctor-patient relationship, creates conditions favouring policies oriented towards liability management rather than a holistic consideration of the patient’s best interests. *Montgomery*’s consumerist focus, and the *caveat emptor* mentality which come with this, only compounds the problem. In this, again, it highlights that social responsiveness depends on a far deeper contextual engagement with empirical realities and broader contexts of decision-making than private law typically shows.

#### IV. RECONCEPTUALISING THE PROBLEM: THE ROLE OF FUNCTIONAL COMPLEMENTARITY

The previous sections have argued that the issues with *Montgomery* reflect deep-running problems in the common law system. Yet given that the common law is likely to continue to play a key role in dealing with healthcare, absent a dramatic overhaul of the legal system the task must be to work to address these problems within the institutional confines of the common law. As this article has argued, the answer to this issue lies in rethinking the way in which the common law engages with social expectations. *Montgomery* provides an excellent illustration both of why the current approach to achieving a responsive medical law is so deeply problematic, and what form a new approach might take. At its heart, social responsiveness requires the law to take its starting point in patient needs—that is to say, in what they expect and require from healthcare organisations and from the doctor-patient relationship—rather than the law’s construction of what their responsibility should be, and to translate them into rules that embed a propensity to producing those outcomes in the functioning of healthcare institutions. Judicial responses to changing social needs, however, fall almost without exception into two broad archetypes. The first, which in a regulatory context would be classed as a form of ‘command and control’, involves shaping independent responses to underlying social shifts, grounded in distinctively legal values and principles rather than in the social perceptions. The second, which, in a regulatory context would be treated as a form of self-regulation, involves leaving the issue to be regulated by professional norms, either by incorporating these norms into the law or by keeping the law to *de minimis* standards, leaving more intrusive regulation to professional bodies. Informed consent instantiates this dichotomy, in as much as *Montgomery* marks a decisive shift from the latter approach (taken in *Sidaway*) to the former. Yet neither approach in and of itself can offer adequate support to build a more

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<sup>151</sup> K Hoeyer and N Lynøe, ‘Motivating donors to genetic research? Anthropological reasons to rethink the role of informed consent’ (2006) 9 *Medicine, Health Care and Philosophy* 13, 21.

<sup>152</sup> Helmke and Levitsky, n 139 above.

responsive medical law. Both approaches suffer from a shared underlying weakness inherent in seeking off-the-shelf solutions from the law's existing stock of concepts and frameworks—namely, that the law will create norms that are neither adequate nor effective at dealing with the underlying issues.

From this perspective, the issues we have identified with *Montgomery* are a consequence of the fact that despite its attempt to mirror professional norms articulated by the GMC, *Montgomery* remains embedded within a 'command and control' approach. Professional norms, in this approach, only have utility to the extent that they are transposed into the law; yet once transposed into the law, they become legal norms for the law to develop and apply, detached from the relevant profession. The high degree of juridification this produces is the cause of the issues we have discussed in this article. As we have shown, *Montgomery*'s emphasis on autonomy, its espousal of a consumerist model of the doctor-patient relationship, and the lack of consideration given to the institutional influences on doctor-patient interaction limit the extent of protection it gives patients as well as its ability to exert a positive influence on clinical practice. Each of these failings is a consequence of the legal misinterpretation of a professional norm. Yet, whilst such a high degree of juridification is problematic, so too is a high degree of de-juridification, as the experience of *Sidaway*'s attempt at permissive self-regulation demonstrates.

Our criticisms should not, however, be read as a rejection of *Montgomery*'s attempt to meld legal norms with professional norms nor should they be read as suggesting that the law should refrain from seeking to be socially responsive. As we have shown in the preceding sections, the difficulties with *Montgomery* arise not because the law sought to regulate medical discretion in a socially responsive way, but because it adopted rules which diverge from the normative frameworks used in medical practice while also failing to reflect the needs and priorities of patients. The issues we have pointed to in this article are problematic only if autonomy, consumerism, and risk-disclosure come to be entrenched as *the* key evaluative considerations underpinning the law, and if legal engagement with professional norms continues to be seen in terms of a dichotomy between self-regulation and command and control, rather than as an attempt to recognise and legally support the full range of considerations that underpin shared decision-making. Examining how the law might chart a path away from this position provides considerable insight not only into how the law of informed consent can be developed, but also a more general template for how tort law can more effectively seek to be responsive.

The first step on this path lies in understanding the reasons for the divergence between the *Montgomery* rule and the principle of shared decision-making underlying the GMC's guidance. The preceding section argued that the causes of this divergence lie in the challenge of transposing open-textured norms from one institutional context (in this case, medicine) to a very different institutional context (in this case, law). Because norms acquire their content and evaluative significance from the surrounding institutional context within which they are applied/adjudicated upon, their effect changes dramatically in the course of this transposition.

This problem is not unique to medical law. It applies to all cases where the law seeks to engage with social needs and expectations, and it is closely related to the phenomenon comparative lawyers term the 'transplant effect'. The transplant effect reflects the challenges posed by importing a norm from one jurisdiction to another jurisdiction with a very different institutional setting.<sup>153</sup> Its consequence is that laws reflecting the traditions or assumptions of one

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<sup>153</sup> TT Arvind, 'The "Transplant Effect" in Harmonization' (2010) 59 ICLQ 65, 81.

jurisdiction assume a new character and effect when they are transplanted to another jurisdiction, much as a grape varietal transplanted to a different *terroir* becomes a new wine.<sup>154</sup>

Mitigating these effects requires two shifts in the way courts approach responsiveness. The first is understanding that although they are often articulated in the language of ethical philosophy, in social practice as in law, normative and ethical categories are primarily used as *heuristic* devices.<sup>155</sup> Professional codes, and social expectations more generally, are rarely based on a fully theorised philosophical understanding of the norms they embed, nor could they be. Their aim is not to embody definitive values as much as it is to achieve particular outcomes and patterns of conduct in interaction. The second is that engaging effectively with them requires not a simple transposition of the rules into law but an approach grounded in *functional* suitability and functional complementarity, in which the law draws on its own reservoir of concepts and principles to create legal rules designed to achieve outcomes which parallel or complement those that underlie the social norms in question. Law, in such an approach, is neither operating within a ‘command and control’ framework, nor is it relinquishing the regulatory role as thoroughly as it does in a pure ‘self-regulation’ framework. Instead, it seeks to work to complement other social institutions, by providing institutional capacity which these approaches do not have and by ensuring that the approaches themselves recognise and respond to social expectations in a way that reflects the value those expectations have in law (and not, for example, an attitude of condescension that is at variance with legal values).

This requires close attention to the social context of professional interaction and the social expectations which members of the public have (discussed in Sections I and II), and to the institutional framework within which the profession functions (discussed in section III). From this perspective, we can identify three gaps left by *Montgomery*, which the law now needs to focus on resolving. The first is that consent in law is radically different from consent as understood in professional medical ethics guidance; and if the law remains grounded exclusively in an autonomy-based understanding of consent, it will be inherently incapable of supporting the professional bodies’ goal of embedding patient-centric shared decision-making into every context where treatment decisions are made. The second is that a test of risk grounded in materiality is not inherently suited to encouraging or facilitating the level of institutional communication necessary for law to effectively perform its hortatory function.<sup>156</sup> On the contrary, it carries a real danger of having the opposite effect. The third is the lack of engagement with the role of healthcare organisations in controlling how doctors and patients interact, and the resources available to doctors to engage effectively with shared decision-making.

Addressing these issues is not complicated, but will require reconceptualising the nature of the duty owed to patients. In effect, *Montgomery* was articulated too narrowly, in terms of a duty to disclose material risks. Disclosing risks, however, is only one aspect of the GMC guidance on consent. Focusing on it to the exclusion of other aspects of the guidance limits the law’s ability to encourage shared decision-making and support the GMC’s goal of ensuring patient participation in the process by which treatment decisions are made. If the law is to be aligned with the GMC’s guidance, the courts must begin by recognising this broader context. The duty under the GMC on doctors is not simply a duty to disclose risks, but a duty to ensure and facilitate participation by patients in the process by which treatment decisions are made. And,

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<sup>154</sup> *ibid* 66.

<sup>155</sup> TT Arvind, ‘Paradigms lost or paradigms regained? Legal revolutions and the path of the law’ in S. Worthington, A Robertson, and G. Virgo (eds.), *Revolution and Evolution in Private Law* (Oxford: Hart Publishing 2018) 68-71.

<sup>156</sup> Atiyah, n 69 above.

to deal with the institutional issues discussed above, the duty must be imposed independently on both doctors and healthcare organisations. Above all, it must ensure that the significance of the guiding role of doctors – not just in the *provision* of information, but in the *weighing* of that information – remains at the heart of the law.

For doctors, such a duty will require them to engage fully in the patient-centred, partnership-oriented process envisaged by shared decision-making. Their duty will not be discharged by simply disclosing material risks. Instead, it will extend to assessing whether they worked with the patient to explore the patient's values and goals, identify the ones most salient to the treatment decision, and advise the patient on the extent to which different options reflect those values and goals. The focus will, accordingly, be where it belongs from the patient's point of view—on the actual role their values and goals play in the final decision, the degree of respect and consideration given to those values, and the extent to which the doctor treats decision-making as a two-way process governed by the patient's values and the doctor's technical expertise.

For healthcare organisations, such a duty will require them to orient their policies, procedures, and structures to facilitate participation, rather than merely seeking to manage operational risks. Assessing their compliance with this duty will entail looking at the facilities they provide to doctors, including physical facilities as well as training and time, and the organisational culture created by their rules and policies. Critically, grounding the duty in private law will avoid the problem, much discussed in the literature, of judges deferring to resource allocation decisions made by healthcare bodies.<sup>157</sup> Such deference is a characteristic of judicial review, not private law.

There are several reasons why such a reconceptualisation is necessary. Firstly, the binary nature of consent is deeply entrenched in private law—arguably, too deeply to permit incorporating the more nuanced participation-based significance it has come to have in medical ethics. From the perspective of ensuring functional complementarity, the law can only recognise the significance of participation if it moves away from the terminology of consent to a conceptual framework that permits it to evaluate patients' involvement, and to do so as a matter of degree rather than presence or absence. Participation as a concept does this; risk-disclosure, consumerist autonomy, and consent do not.

Secondly, a duty to facilitate participation is also normatively richer than a mere duty to disclose material risks when obtaining consent, and gives more room to incorporate the broader range of normative considerations that underpin shared decision-making. A duty conceptualised in terms of participation is inherently capable of assessing both intentionality and voluntariness in the sense discussed in section II,<sup>158</sup> and to draw on the broader normative considerations of dignity, integrity, and trust identified by Brännmark as central to shared decision-making when assessing the adequacy of participation.<sup>159</sup> Of its nature, therefore, it is far less vulnerable to the consumerism that has had unfortunate consequences in the post-*Montgomery* case law; and it provides a better basis for institutional dialogue than a test of material risk, because it maps far more closely onto the evaluative considerations that actually underlie shared decision-making than the concept of material risk does. Grounding the duty in participation rather than disclosure also avoids the unfortunate issues in proving causation that, in both Australian law and post-*Montgomery* cases, have led to the law being inherently

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<sup>157</sup> K Syrett, *Law, Legitimacy and the Rationing of Health Care* (Cambridge: Cambridge University Press, 2007).

<sup>158</sup> Brody, n 48 above.

<sup>159</sup> Brännmark, n 84 above.

predisposed to giving a higher degree of protection to assertive patients than to more vulnerable patients.<sup>160</sup>

Thirdly, shared decision-making views the interaction between doctors and patients as a *collaborative* endeavour. An approach grounded in risk-disclosure does not. Relational theorists of private law have long pointed out the difficulties in reading an ‘ethic of care’ into risk-based understandings of duties of care for precisely this reason.<sup>161</sup> Yet a collaborative relationship is fundamental to shared decision-making, and a broadened duty will therefore provide a far better degree of support for it than a narrower duty to disclose does.

Such a reconceptualisation will represent an incremental development of *Montgomery* rather than a radical departure. A fundamental aspect of common law incrementalism is the ability to retheorise a precedent as setting out a specific instance of a broader general rule. In *Montgomery*, the failure to disclose the risk of shoulder dystocia was simply the most salient breach of the duty to ensure and facilitate participation. The fact that *Montgomery* was articulated in terms of a duty to disclose material risks is not, therefore, in any way incompatible with the broader duty we propose. Such a duty would subsume and extend the duty in *Montgomery*, rather than abrogate it.

Similarly, a duty to facilitate participation is not any more incompatible with the structure of the tort of negligence than *Montgomery* itself. The doctrinal structure of the rule in *Montgomery* is already distinctive within negligence. It is foundational to negligence that the standard of care is set with reference to a reasonable person in the position of the *defendant*. *Montgomery* breaks fundamentally with this structure by setting the standard of care with reference to a reasonable person in the position of the *claimant*. *Montgomery* also departs from the ordinary structure of negligence by grounding the duty of care in the patient’s legal rights. As even the most ardently rights-based theorists of tort law acknowledge, rights are usually of no more than peripheral importance to negligence.

This divergence is arguably necessary. In assisting with treatment decisions, doctors are operating at a higher level of epistemic uncertainty than other types of professional activities. A civil engineer or a chartered accountant can deal with the majority of risks by acting with due care and skill. There are few unforeseeable and untameable risks. This is not true of medical treatment. It is often impossible to prevent risks from eventuating, and it is difficult to be certain about the nature of the harm that will result if they do eventuate. This uncertainty makes a *sui generis* approach to duties and standards of care necessary, as *Montgomery* has already realised. Reconceptualising the duty as one to ensure and facilitate participation does not materially increase the divergence that already exists between informed consent and the rest of the tort of negligence.

Moreover, the approach of functional suitability is not restricted to informed consent. As we have discussed above, the problems posed by *Montgomery* are simply one instance of the growing disquiet in medical law about the impact of the judicial espousal of an approach grounded almost exclusively in patient rights and the prioritisation of autonomy. The approach we have identified in this article offers an alternative way of dealing with the challenges posed by modern healthcare which, by directly engaging with the normative underpinnings of the social expectations in question and placing them in dialogue with legal norms, represents a

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<sup>160</sup> See the discussion in Section II above.

<sup>161</sup> J Steele, ‘Duty of Care and Ethic of Care: Irreconcilable Difference?’ in J Richardson & E Rackley (eds), *Feminist Perspectives on Tort Law* (Abingdon: Routledge, 2012).

more complete, considered, and effective discharge of the judicial role in keeping medical law in step with the needs of society.

## **V. CONCLUSIONS: SOCIAL RESPONSIVENESS AND THE CHALLENGE FOR MEDICAL LAW**

*Montgomery* is a significant case. It matters not only because of its importance within the law of informed consent to medical treatment, but also for the light it sheds on a set of critical challenges that medical law faces today. As we have shown in this article, medical law sits at the intersection of three very different frameworks—the clinical, the ethical, and the legal—each of which is characterised by a different set of institutional priorities and institutionally embedded ways of conceptualising problems and identifying solutions. The outcome in *Montgomery* underscores the extent to which these different institutional contexts influence and alter the significance of concepts—a significance which is all too often disguised by the use of common words to describe very different concepts—and the consequences that a choice of functionally unsuitable concepts transplanted across these frameworks have for the efficacy of the law. All these parallel concerns which other commentators have expressed in relation to medical law, as we discussed in the introduction to this article.

As we have sought to argue here, these challenges are far from insurmountable, but they require the courts to take a broader view of the manner in which they engage with social needs, and approach the task of incrementally developing the common law. As *Montgomery* also demonstrates, although rights-based approaches to medical law have accomplished much, particularly in moving medical law beyond paternalism, they are more limited when it comes to the fostering institutional dialogue of the type that is increasingly necessary in modern healthcare. Simply transposing professional norms into the law, as *Montgomery* did, is a tempting option in an era of responsive law, but it holds dangers. As *Montgomery* evidences, a transposition runs the risk of radically and inadvertently changing the norms in question in the course of their transposition into a very different institutional context, and of failing to transpose aspects of the norm that are fundamental to its intended operation.

This article has argued for a different approach, where the law focuses on functional complementarity: seeking to understand the full breadth of the underlying social need, the role which any relevant social expectation would play in the context in which it originated, and drawing on its reservoir of concepts, rules, standards, and principles to structure actions and remedies in a way that closely replicates and supports that role. In doing so, the role of institutional contexts must also be acknowledged, engaged with and closely accounted for in any normative change suggested. The gap between the world of law, the world of medical professionals, and the world of the members of society who deal with them is inherently a large one, but it can be bridged if the task of adapting legal rules to a changing context is approached in the right way.