

Innovation, informed consent, health research and the Supreme Court: Montgomery v Lanarkshire – a brave new world?

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"Innovation, Informed Consent, Health Research and the Supreme Court: Montgomery v Lanarkshire- A brave new world?"

Introduction

The informed consent process and its application in the context of health research has long been a source of controversy and of academic debate. Consent is something which is fundamentally important in safeguarding individual human rights and also demonstrating respect for broader societal obligations when regulating the research process. It has long been at the heart of international statements and policies in relation to health research from Nuremberg to Helsinki and beyond (Biggs 2009). But while its importance as a rhetorical principle is undoubted how it applies practically has been questioned. However a recent UK Supreme Court case rise to new provides new challenges for researchers and research regulatory bodies alike in structuring approaches to informed consent. The Supreme Court decision in *Montgomery v Lanarkshire* ([2015] UKSC11) has been hailed as a landmark, not least because the Court enshrines the doctrine of informed consent formally into English law for the first time in relation to medical treatment and in the process has apparently departed from the *Bolam* test, that of the responsible body of professional medical practice itself being the critical factor in determining the level of information provided. If in the light of *Montgomery* informed consent is an obligation in relation to English law concerning treatment then surely in the context of innovative treatment and health research it would be impossible to recognise a lower standard of disclosure. This is particularly the case given that an individual who is a participant in clinical research can be seen as acting

fundamentally in the public interest and for the public benefit. So could this case ultimately prove a watershed moment in relation to clinical research shifting the axis of control over information disclosure and the consent process itself in the future to the research participant and away from the researcher or research organisation?

First, the paper explores the concept of “informed consent” in clinical research as seen through international, Council of Europe and EU instruments. Secondly, it considers consent in relation to clinical research and the position before *Montgomery* focusing upon the questions of disclosing risks, dialogue and the consent process and withholding information on therapeutic grounds. Thirdly it discusses the decision in *Montgomery* and what might be the impact of this decision in the health research context. It asks whether *Montgomery* itself can be seen as ushering in a brave new world of informed consent or whether in fact there is much more which would need to be done to achieve that goal.

Respecting informed consent in health research

One of the challenges in understanding the nature of the consent process in the research context is the sheer breadth of what constitutes “health research”. For the purposes of regulation of health research in England and Wales and the operation of the Health Research Authority(discussed below) section 110(3) of the Care Act 2014 provides that

“ Health research is research into matters relating to people’s physical or mental health; but a reference to health research does not include a reference to anything authorised under the Animals (Scientific Procedures) Act 1986”

This is a huge definition. It also illustrates as well the changing approach to research. The language has changed. In the past the focus was on clinical research or medical research and this language is still reflected in older rights declarations however more modern statements and policy guidance is increasingly utilizing the word “health” (eg DOH 2005).

The importance of respecting consent as part of respect for individual autonomy in relation to health care is emphasised in many international statements of human rights (Plomer 2005). The Declaration of Helsinki, the major international rights statement concerning medical research, provides in relation to consent

In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject’s freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed (Declaration of Helsinki, para 26).

Article 8 of the European Convention of Human Rights which concerns the right of individual privacy has been interpreted by the European Court of Human Rights as safeguarding decision making autonomy(see e.g. *Pretty v UK* Application 2346/02 (2002) 66 BMLR 147 (ECtHR), at

para 63). This is nonetheless a general statement of human rights. More recent human rights Conventions however provide more explicit engagement with the notion of informed consent in the health research context. So for example, the Council of Europe Convention on Human Rights and Biomedicine provides in Article 5 that

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

Article 16 that

“Research on a person may only be undertaken if all the following conditions are met:

- i there is no alternative of comparable effectiveness to research on humans;
- ii the risks which may be incurred by that person are not disproportionate to the potential benefits of the research;
- iii the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability;
- iv the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection;
- v the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time

Critically here are the words “expressly”, “specifically” and “is documented”. First, consider expressly. While in the context of medical treatment implied consent is recognized in various contexts this does not apply in the context of research. Secondly, “specifically”- namely that the consent relates to the specific research project. However while the UK is bound by the ECHR itself it has never become a signatory of the Bioethics Convention. Indeed were it to do so this would lead to considerable problems given the move to the use of specific consent not least in the contexts of genetic databases or “biobanks”. Obtaining consent for undertaking an

experimental procedure has different implications for obtaining consent for material and information to be stored in a genetic database or biobank. The first is a one-off transaction, the risks and implications are in relation to that particular research project. The second, in contrast, involves information and material being obtained and stored and used over a longer period for a range of studies. In relation to many biobanks an approach of “generic” consent has been adopted in relation to the use of the material and information (Kaye 2004). Individuals may consent to the material/information being used by the biobank rather than it being used in relation to a specific project. Individual control may be effectively removed in relation to particular projects. This has notable practical advantages for researchers in not having to go back and re-consent in relation to such procedures. However it means that effectively participants cede control of material may be used for future purposes.

Consent and Health Research in England and Wales: The position prior to Montgomery

At domestic level consent is regarded as an integral part of the research ethics process in England and Wales today and is emphasized in research ethics guidelines (e.g. Declaration of Helsinki; Department of Health, 2005, para 2.2.7). However the precise mechanics of what informed consent means in English law in relation to health research have, to date, remained uncertain.

This is at least in part due to the piecemeal legal regulatory structure which still applies in the context of health research. Although there have been research ethics governance guidelines operational across the NHS since the early 1990's there is still no comprehensive overarching legal regulation of the research process (McHale 2013). Instead regulation is a combination of statutory and common law provisions and as we shall see this gives rise to some considerable uncertainty. There is now a statutory regulator, the Health Research Authority. Its roles include the co-ordination and standardization of practice in relation to clinical research (Care Act 2014). Some specific areas of health research and innovation are also subject to separate legal regulation for example the Medicines for Human Use Clinical Trials Regulations (2004) (S.I. 2004/1031) which implements the EU Clinical Trials Directive into English law. The Regulations provided the first explicit statutory requirement in relation to informed consent in relation to health research. It provides that research participants give informed consent to their involvement in drug trials. Informed consent in this context is defined as being a decision which is 'taken freely after being duly informed of its nature, significance, implications and risks'. In addition following the Interim Bristol Royal Infirmary Report (Bristol 1998) and that of the inquiry into the unauthorised retention of human organs and tissue at Alder Hey Hospital in Liverpool (Alder Hey 2001). This was swiftly followed in the light of the scandals in relation to unauthorised retention of human material by the implementation of the Human Tissue Act 2004 (Price 2005). While consent is a fundamental issue here nonetheless the 2004 Act provides for the need for "appropriate consent" in relation to consent regarding the use of human material for a range of purposes including clinical research. The Act does not however talk in terms of informed consent in relation to clinical research. It does however provide that a Code of Practice must be produced in relation to consent and in addition consent and information provision does remain an

important part of the subsequent Codes of Practice produced by the Human Tissue Authority (Human Tissue Act 2004, s 27 and HTA Codes, Code 1 Consent and Code 9 Research, 2014). But what is lacking is any clear comprehensive overarching legal framework addressing consent and clinical research. Moreover in some instances consent may not be needed at all before inclusion of a person's human material in a research project. So for example controversially section 1(9) and schedule 1 of the Human Tissue Act 2004 provide that material may be used without consent in relation to research where it has been anonymised and subject to research ethics committee approval.

While in the research context guidelines refer to "informed consent" in fact there was no general principle of informed consent in relation to health research in English law. Save for those areas mentioned above to ascertain the legal position concerning informed consent and health research we therefore have to look at existing fundamental principles of English law in the areas of criminal law and civil law and those very limited situations in which specific statutory provisions also apply. First, failure to provide information such that consent is given may give rise to a prosecution in criminal law for assault or battery or in the case of surgical interventions it can give rise to a prosecution for an assault occasioning actual bodily harm or grievous bodily harm under the Offences Against the Person Act 1861. Such prosecutions are however rare not least given the burden of proof in criminal offences which is one of beyond reasonable doubt. Section 5 of the Human Tissue Act 2004 also makes it a specific offence to use human material without consent having been obtained, although to date it appears that no prosecution has been brought under this provision.

In practice failure to obtain informed consent is more likely to give rise to liability in civil law. First, failure to obtain consent in a situation concerning research involving any “touching”, the obvious example would be that of a surgical procedure may give rise to liability in the tort of battery. To establish battery the claimant needs to prove that the touching was without consent. In the context of consent to treatment it was held in *Chatterson v Gerson* ([1981] 1 All ER 257) that a health professional is only required to provide a patient with a general explanation in broad terms of the nature of a procedure to avoid liability in battery. In such circumstances it is not necessary to disclose specific risks. However it remains uncertain as to whether the English courts would be prepared to take the same approach in relation to disclosure of information in the context of research. Comparisons can be drawn with the approach taken by the court in the Canadian case of *Halushka v University of Saskatchewan* ([1965] 53 DLR (2d) 436.) In this case, Hall J stated that:

The subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent. It has been suggested that such an approach should be employed in relation to both patients and volunteers.

It has been argued that such a broader approach to information disclosure in the context of claims in the tort of battery should apply in England in relation to such non-therapeutic procedures as in the context of health research (McHale, 2010). Given health research in general, and clinical trials in particular are activities which are undertaken in the public interest through the public interest in developing new therapies and treatments then surely the position of the volunteer in such a trial should be safeguarded through full and frank disclosure of all applicable risks. It is argued that this should also apply to a patient acting as a volunteer in a trial or innovative treatment since while their inclusion might be for therapeutic purposes it can also be strongly

seen as benefitting the broader public interest by ensuring that such information is obtained. Whilst this principle has been long established in Canada to date it appears that there has been no attempt to advance such arguments in the English courts. The first reason for this may be a matter of public policy. Currently were this to be the case it would work against the trend in English law to limit liability in battery (see e.g. Tan Keng Feng 1987, Brazier, 1987). Secondly, an action in battery inevitably has its limits. Extension of liability in battery would also only be applicable in relation to certain forms of health research, those concerning unconsented touching- thus actions concerning trials involving e.g. most medicinal products would still need as the law currently stands to be brought in negligence. Nonetheless it is suggested that the possibility of the extension of English law in this area should be subject to serious consideration by the courts.

At present the emphasis in relation to informed consent litigation in the UK has been in relation to the tort of negligence. In contrast to the tort of battery where it is only necessary to establish unconsented touching in negligence the litigant needs to establish duty, breach of duty and finally that this breach of duty has caused the resultant harm. While in relation to research establishing a duty of care itself is likely to be comparatively straightforward. It is likely that the courts will assume that the relationship of researcher and research participant will give rise to a duty of care. However the second part of the cause of action, demonstrating that there has been a breach of duty is unlikely to be so unproblematic. To prove breach of duty it is necessary to show that a researcher has fallen below the standard of care required. In negligence the standard of care has been referable to that of the *Bolam test* (*Bolam v. Friern Hospital Management Committee* [1957] 2 All ER 118) namely whether an individual was negligent would be

ascertained by reference to what would be appropriate by a responsible body of medical practitioners. However the test in relation to informed consent has long been much more problematic. In the House of Lords decision in *Sidaway v. Bethlem Royal Hospital Governors* ([1985] 2 WLR 503) the dissenting judge, Lord Scarman, adopted an “informed consent” approach drawing upon United States of America jurisprudence and setting out a test rooted in what information a prudent patient would want to know. In contrast the majority of the House of Lords based the standard of disclosure upon the *Bolam* test. Lord Diplock relied entirely upon the *Bolam* test thus leaving a great deal of discretion in the hands of the profession. However a broader and more nuanced approach was taken by other members of the court. Lord Bridge said that a judge could disagree with the evidence given to him where a disclosure was such that “no reasonably prudent medical man would fail to make it”. He suggested that such a situation would be an:

operation involving a substantial risk of grave adverse consequences, as for example, [a] 10 per cent risk of stroke from the operation . . . In such a case, in the absence of some cogent clinical reason why the patient should not be informed, a doctor . . . could hardly fail to appreciate the necessity for an appropriate warning.

Lord Templeman stated that there could be a distinction between general risks that would normally be known to the patient and special risks that might be required to be disclosed. However he emphasized that it was for the court itself to determine negligence. In the years which followed *Sidaway*, the courts were generally unwilling to hold that the information disclosed was insufficient such that this constituted negligence and indeed initially confined *Sidaway* to the more restrictive approach taken by Lord Diplock. It took over a decade for a broader approach to be taken (Jones 1999). In *Pearce v. United Bristol NHS Trust* ([1999] PIQR P53. (CA)) Lord Woolf in the Court of Appeal stated that

if there is a significant risk which would affect the judgement of a reasonable patient then in the normal course it is the responsibility of a doctor to inform the patient of that significant risk, if the information is needed so that the patient can determine for him or herself as to what course she should adopt.

Subsequently Lord Steyn in *Chester v Afshar* ([2005] 1 AC 234) stated that

A surgeon owes a legal duty to a patient to warn him or her in general terms of possible serious risks involved in the procedure. The only qualification is that there may be wholly exceptional cases where objectively in the best interests of the patient the surgeon may be excused from giving a warning. This is, however, irrelevant in the present case. In modern law medical paternalism no longer rules and a patient has a prima facie right to be informed by a surgeon of a small, but well established, risk of serious injury as a result of surgery.

In later cases the courts confirmed that while there may be an obligation to inform there was no responsibility on the clinician to ensure that the patient understood the information given (*Al Hamwi v. Johnston and Another* [2005] E.W.H.C. 206; Miola, 2006). It was not until *Montgomery* however that the Supreme Court were given the opportunity after more than thirty years to reconsider *Sidaway* and ultimately to reframe the law.

Montgomery v Lanarkshire: Informed consent, negligence and the lessons for research

It is against this backdrop of a notably uncertain legal position in relation to nature of informed consent in the research context that we need to consider the implications of the UK Supreme

Court decision of *Montgomery v Lanarkshire* ([2015] UKSC 11). The facts in this case do not concern clinical research. Instead they relate to the approach taken to information provided in relation to the pregnancy and birth of a son to Mrs Montgomery. Mrs Montgomery was pregnant with her first child. She is a petite woman just over 5 feet in height. She suffers from diabetes and as a result was likely to give birth to a baby which was larger than normal. An obstetrician and gynaecologist, Dr McLenan, monitored her pregnancy. A major risk in diabetic pregnancies is that of a condition known as “shoulder dystocia” namely the risk that the shoulders of the baby will be too wide to pass to enable a standard vaginal delivery without medical assistance with consequent risk of material and fetal abnormality. There was a 9% risk of shoulder dystocia. In addition, there was a further risk to the fetus of a broken shoulder and damage to the nerve roots. While such injury may be limited it can also lead to permanent disability, leaving the child with a useless arm. In cases of shoulder dystocia involving diabetic mothers the risk of such brachial plexus injury, is about 0.2%. There are some instances where the umbilical cord becomes trapped against the woman’s pelvis and, in such a situation, there is a small risk of less than 0.1% that where the umbilical cord is occluded prolonged hypoxia may result leading to cerebral palsy or death. While Mrs Montgomery was told that she would have a larger than usual baby she was not told the risk of shoulder dystocia. She was not offered a caesarean section as the anticipated birth weight of the baby was lower than the weight at which her consultant would have normally offered such a procedure. Mrs Montgomery said if she had known of the risk of shoulder dystocia, she would have wanted an explanation and what the risks were and if it was a significant risk, she would have asked for a caesarean section. During birth the baby became stuck due to shoulder dystocia. In the period of some 12 minutes from the head of the baby emerging and the subsequent delivery, the umbilical cord was completely or partially

occluded depriving him of oxygen. The baby was subsequently diagnosed as suffering from cerebral palsy of a form caused by the deprivation of oxygen (this affects all 4 limbs) and a brachial plexus injury resulting in Erb's palsy (ie paralysis of the arm). Had Mrs Montgomery had an elective caesarean section, her son would have been born uninjured. The court was faced with the question as to what information should have been provided in relation to the risks of harm to the baby.

Some thirty years before in the Court of Appeal in *Sidaway* the Court had stated that there was no doctrine of informed consent in English law. In *Montgomery* such an approach was finally discarded to the vaults of legal history as the Supreme Court confirmed that informed consent was indeed definitely now part of English law. The Supreme Court emphasized that following the Human Rights Act 1998 courts are very aware of the fact that the common law reflects fundamental values which include the right of self-determination including Article 8 of the European Convention on Human Right which safeguards the right to privacy (per Lords Kerr and Reid, [2015] UKSC 11, para 87). They went onto say that the law was taking an approach such that

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 risks affecting their own lives, and living with the consequences of their choices” (per Lords Kerr and Reid, [2015] UKSC 11, para 81)

This is a clear statement of respect for individuals as autonomous decision-makers with autonomy safeguarded by principles of fundamental human rights. Nonetheless it needs to be

stressed at the outset is that it is a negligence case. The principles discussed here apply to this cause of action only at present and only reframe English law to that extent, although as is highlighted below longer term it may have broader ramifications.

One particularly notable aspect of the judgment in *Montgomery* is that the Supreme Court finally moves away from the *Bolam* test, (*Bolam v Friern Hospital Management Company* [1957] 1 WLR 582) the standard of care in negligence set in terms of what a responsible body of medical practice which underpins standard clinical negligence actions and makes clear that it does not apply in this context of disclosure of risks in relation to informed consent ([2015] UKSC11, para 83). Instead they build upon the judgments of Lord Scarman in *Sidaway* and Lord Woolf MR in *Pearce*, as well as the notable decision of the High Court of Australia in *Rogers v Whitaker* ((1992) 175 CLR 479, Miola 2009). As Lord Kerr and Reid stated

“It follows that the analysis of the law by the majority in *Sidaway* is unsatisfactory, in so far as it treated the doctor’s duty to advise her patient of the risks of proposed treatment as falling within the scope of the *Bolam* test, subject to two qualifications of that general principle, neither of which is fundamentally consistent with that test”, ([2015] UKSC11, para 86)).

The test in relation to information disclosure is therefore now:

The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. 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” (Lords Kerr and Reid, [2015] UKSC 11, at para 87).

What then will the implications of this be generally and in research in particular? Could it be said that some major risks should now be automatically disclosed? While doctors should clearly communicate with their patients, what time scale will this involve? What precise degree of informed consent process will be practicable? In the research context it can be argued that there should indeed be time and space devoted to ensuring that risks should be disclosed, it also highlights the need for researchers to truly engage with participants. These issues are explored in turn.

Disclosing Risks in the Context of Research

What are the implications of the decision of *Montgomery v Lanarkshire* in relation to the disclosure of risks in the context of research? The test is one of a reasonable person in the patient's position but not simply a reasonable person. The court makes clear that reference needs to be made to what information this *particular* patient would regard as significant. It should be noted that this is a negligence action and the duty is one of reasonable care - not an absolute duty. Not all risks have to be disclosed. Instead here the court is talking about "material" risks. This will inevitably be context dependent. As Lords Kerr and Reid stated

it follows from this approach that the assessment of whether a risk is material cannot be reduced to percentages. The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for example, the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient" (Lords Kerr and Reid, [2015] UKSC11, para 89).

Here the Supreme Court is itself building upon the approach taken by the General Medical Council in successive Good Medical Practice guidance since the late 1990s of what is essentially a very patient-focused approach to disclosure (GMC 2008; GMC 2013; Montgomery and Montgomery 2016).

One issue is that while the test for disclosure has been reframed that this will remain a negligence action and both sides will be adducing evidence to determine whether there has been a breach of a duty of care. In so doing there needs to be a reasonableness test assessment.

Writing about *Montgomery* in the context of treatment Heywood suggests that

“negligence is still only a standard of reasonableness and it would transcend that to expect doctors to disclose every conceivable course of action available. To interpret the duty in this way would be to stretch it too far and could cause resultant harm to the effective provision of healthcare. Further it would be destructive to the exercise of clinical discretion which is still an important element of the doctor-patient relationship and which should not be viewed as being completely eroded as a result of the decision (Heywood, 2015, at page 10).

Reasonableness may be determined on an individual basis but in determining this inevitably evidence as to what would be a responsible body of professional practice would be relevant. Expert witnesses will be brought before the courts. The legitimacy of the approach taken will be determined by reference to evidence. A further issue raised by Heywood is in relation to disclosure of “excessive information which patients may not necessarily need or worse still want” (Heywood, 2015, page 10). Caution is needed here. Inevitably levels of need of information will be subjective. Moreover there are dangers in assuming that individuals will not necessarily want information. Much may depend upon how information is communicated to

them. There has also been a gradual movement over the last two decades to make available more information about risks of various established treatments. So for example, in relation to pharmaceuticals there are already thanks to EU pharmaceutical regulation patient information leaflets providing long lists of risks and potential side-effects (Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67 (as amended) Articles 54-57). The internet is an increasing source of information concerning the risks of treatment and indeed these are also highlighted by sites such as NHS Choices (<http://www.nhs.uk/Conditions/Pages/hub.aspx>). But while in relation to established treatments there are identifiable risks which can be disclosed the whole essence of health research from experimental surgical techniques to drug trials etc. is inevitably fraught with greater uncertainty. In such a situation it is argued that full and frank disclosure of known risks is critical to ensure that the individual makes an effective and valid decision. This has to come as part of an explanation of the health research process itself and why it is different than the consent process in a standard treatment context where the uncertainties involved are necessarily of a different magnitude.

Dialogue in Informed Consent In Research after Montgomery

Montgomery also impacts upon the dialogue in the consent process itself. Simply providing information as such may not necessarily equate with “informed consent”. Information may be given but individuals may simply not understand it. Some notable commentators have indeed

questioned the extent to which informed consent can ever be effectively realised (Mason and O'Neill 2007; O'Neill 2003). Other commentators such as Thornton, have been sceptical as to the reality of consent and have suggested that the best which may be achieved is partly informed consent (Thornton, 1994). In the context of health services research has been argued by Cassell and Young that a traditional model of informed consent does not operate effectively and that we need to look at other models such as "community consent" (Cassell and Young, 2002). The present author cautions against the danger of such approaches. To cast informed consent as some form of utopia to which we will inevitably be doomed to fail has worrying practical consequences and can fundamentally undermine individual autonomy. Moreover comprehension of information at least to some extent is related to the manner in which information is communicated. This is something else which in a further shift in judicial approach is highlighted in the Supreme Court in *Montgomery*. The Supreme Court makes clear that the clinician will need to make the information comprehensible and also ensure that the patient understands it. Emphasis is placed upon the need for dialogue. So e.g. Lords Kerr and Reid state that

.....the doctor's advisory role involves dialogue, the aim of which is 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. This role will only be performed effectively if the information provided is comprehensible. The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form. (Lords Kerr and Reid, [2015] UKSC 11 para 90).

This suggests that this judgment has implicitly overruled the earlier lower court decision in *Al Hamni v Johnston and North West London Hospitals NHS Trust*. In the research setting this would suggest that time will need to be taken to ensure that research subjects do truly understand

the information which has been provided to them. At present research governance guidelines provide that the information provided to research participants must include information sheets containing information which includes risks, etc. Clearly simply signing a consent form is not enough, and indeed this has been recognized for many years. So for example in *Re T*, Lord Donaldson MR stated:

They will be wholly ineffective . . . if the patient is incapable of understanding them, they are not explained to him and there is no good evidence (apart from the patient's signature) that he had that understanding and fully appreciated the significance of signing it. ([1992] 4 All ER 649, 668)

Signing a consent form does not mean that a research participant has given consent which would be effective in English law, rather that there is evidence that consent has been given- but no more than that. Some explanation was always required. What is interesting about *Montgomery* is that this formally stated need for dialogue and comprehension takes us one stage further. So how will this translate out in the context of health research itself? We have already moved from the individual being characterized as the research subject to research participant from a passive recipient/involve to an active role in the research process. To fully participate this will need a real dialogue. How will this work in practice?

Meaningful dialogue involves time being spent in obtaining consent and moreover for the person obtaining consent needs to have the necessary degree of expertise both in terms of knowledge and also communication skills to undertake such a dialogue. Such a dialogue involves time and time costs. As Reid has commented in relation to the decision in *Montgomery* extra resources devoted to the consent process may be difficult for some NHS bodies to find (Reid 2015). That doesn't mean that they shouldn't be provided but in a cash-strapped NHS this demonstrates some

of the problems in reality faced by clinicians and researchers. Nonetheless others might argue that in the research context such additional costs in terms of time and effort could be built into funding bids where research is funded by research councils or where research is supported by the private sector through commercial organisations they in turn should foot the bill.

There can also be different dimensions in the consent process concerning research as opposed to a standard treatment context. Take for example, the removal of a tumour on therapeutic grounds and decision to allow the use of that tumour tissue for research purposes. This will involve consent in relation to the initial procedure and its risks but also at the same time consent in relation to the subsequent use of that material. The former as we have seen will lead to discussion in relation to risks of the procedure itself but the latter use and consent process gives rises to other related and interesting questions concerning what information needs to be provided before an individual can truly be said to have consented. Is consent in relation to the tumour's use one off consent in relation to a specific research project and for that project alone? Here consent would thus not only be needed under the law of negligence but subsequent use of that tissue for research purposes would require 'appropriate consent' under the Human Tissue Act 2004(s.s 2 and 3). But what if it is intended to store the tissue and use it for more than one research project. Can in such a situation an individual give "generic" consent for its later use by researchers? In relation to genetic databases and longer term storage and use of information and data there has been already considerable debate as to the validity of informed generic rather than specific consent (McHale, 2004, Kaye, 2004, McHale et al 2007, McHale et Price 2009, Nuffield). Generic consent is the notion that individuals can provide broad general consent for subsequent use of e.g. tissue samples in a database by a range of different researchers over a

considerable period of time. Specific consent, as the name suggests relates to specific consent given for a particular use at a given time. Can generic consent survive a consent environment as framed in *Montgomery*? *Montgomery* is rooting informed consent in individual human rights. It is recognizing the particular characteristics of the individual in relation to information disclosure which is truly rooted in specificity of decision making, which is fundamentally seen as part of human rights and of Article 8 of the ECHR. Will researchers be able to rely on one-off generic consent or will use of stored material have to be subject to on-going dialogues with researchers as to how they might want their own human material, samples and data utilized? Is the next step then inevitably a broader human rights based approach to informed consent? This issue is returned to below.

Withholding information from research participants in the consent process on “therapeutic grounds”

In the Supreme Court the emphasis is upon autonomy. However as Farrell and Brazier note

“While affirming the importance of respect for patient autonomy the Court did recognize that patient autonomy should not trump all considerations impacting medical treatment and care.” (Farrell and Brazier, 2015).

One element of the *Montgomery* judgement which is likely to continue to prove very controversial in the future is that of the inclusion of the notion of a “therapeutic privilege”. Essentially the idea of a therapeutic privilege is that of information being withheld from a patient because it could otherwise have an adverse effect on them. Before *Montgomery* it might have been thought that this concept, utilized in US jurisdictions before being discussed in *Sidaway*, might be today regarded as fundamentally outdated, a product of a more paternalistic era. But despite this it was recognized by the Supreme Court in *Montgomery*, holding that:

The doctor is however entitled to withhold from the patient information as to a risk if he reasonably considers that its disclosure would be seriously detrimental to the patient’s health. The doctor is also excused from conferring with the patient in circumstances of necessity, as for example where the patient requires treatment urgently but is unconscious or otherwise unable to make a decision. It is unnecessary for the purposes of this case to consider in detail the scope of those exceptions. (Lords Kerr and Reid, [2015] UKSC 11)

So does this mean that while the Supreme Court are respecting individual decision making autonomy on the one hand they are fundamentally undermining it on the other? Let’s deal with the second part of this exception first. If the patient is unconscious then this falls under the question of decision making capacity rather than information provision as such and cannot be seen as an exception at all to informed consent, rather a totally different legal issue. The same surely applies to the other part of this subcategory where the patient is “otherwise unable to make a decision” informed consent simply cannot arise here. However the first part of the exception is something which can be seen as having the potential to drive a coach and horses through informed consent. The Supreme Court was clearly cognizant of some of these dangers. Lords

Kerr and Reid commented in the case that

It is important that the therapeutic exception should not be abused. It is a limited exception to the general principle that the patient should make the decision whether to undergo a proposed course of treatment: it is not intended to subvert that principle by enabling the doctor to prevent the patient from making an informed choice where she is liable to make a choice which the doctor considers to be contrary to her best interests” (Lords Kerr and Reid, [2015] UKSC 11 at para 91).

But even if such a limited approach is taken could this be realistically utilized in the context of a clinical trial or experimental treatment? Surely this is one step too far. The validity of this exception itself is something which is exceedingly controversial. It can be seen as a retreat to paternalism. Moreover the notion of extending this out in the context of research or innovative treatment must be surely unacceptable. Those involved in trials and innovative treatment are clearly acting in the broader public interest- the information obtained as a result of those procedures will benefit society as a whole.

Health Research, human rights and informed consent after Montgomery: A brave new world?

Informed consent as Lady Hale emphasized in the Supreme Court in *Montgomery* is indeed now part of English law. This case has attracted much attention from academics and clinicians alike it is limited in scope (Heywood 2015). But this is still informed consent rooted in negligence as a cause of action, duty, breach of duty and causation still have to be established. It is evolution rather than revolution, developing from earlier case law in the area as Heywood, Farrell and Brazier have highlighted (Heywod 2015, Farrell and Brazier 2015). Nonetheless the Supreme Court judgment in *Montgomery* will clearly have a notable impact in relation to any future

negligence case concerning failure to inform a research participant in a case where harm has resulted. Information needs to be given not just in the form of a standard information sheet but in the form of a dialogue with the individual research participant themselves to ascertain what information they would want to be provided for them. As noted above this may of course be particularly challenging given that in the context of research by its very nature this can give rise to degree of uncertainty as to what precisely are the real risks that harm may result. The extent to which the notion of therapeutic privilege could moreover ever be said to be applicable in relation to research remain exceedingly questionable. If as this judgment suggests consent will become an increasingly become a specific personalised process this is sharply at odds with provisions such as those of s 1(7-9) and schedule 1 of the Human Tissue Act which allow use of human material where approved by a research ethics committee without consent, the application of the consent in relation to the Data Protection Act 1998 and the use of clinical information by eg cancer registries and for other research purposes under section 251 of the NHS Act 2006 without specific patient consent (Case 2002, Taylor and Taylor 2014, Taylor 2011, Taylor and Townsend 2010). The fact that the public interest overrides consent in some forms of research while others are covered by detailed informed consent processes strikes what is an increasingly discordant note.

But could and should the Supreme Court have gone one step further? It is notable that both Lord Steyn obiter in *Chester v Afshar* and now the Supreme Court in *Montgomery* are rooting informed consent in principles of fundamental human rights and in *Montgomery* Article 8 of the ECHR itself. What they have not done however is truly developed a new cause of action as such. Article 8 is utilized to safeguard individual decision making autonomy. Duties to comply with

the human rights are specifically placed upon public bodies but to date we still remain constrained by existing causes of action- in a case such as *Montgomery* to obtain redress the action still needs to be pleaded in negligence.

In relation to research as we have seen respect for individual decision making autonomy and the consequent respect and protection of the rights of the research participant is inherent in international and European human rights declarations yet at domestic level there is no clear statutory basis for safeguarding informed consent, simply a series of piecemeal legal structures. This is in itself surely something for the Health Research Authority to consider and take forward in the future. But it also goes beyond the remit of that Authority. At EU level questions such as the specificity of informed consent are left to member states in existing EU Clinical Trials Directive (Directive 2001/20/EC) and also in the new EU Clinical Trials Regulation (Regulation EU No 536/2014). This too is perhaps not a matter which should simply be devolved in this way. Health research is increasingly a globalized activity. If we are serious about respecting human rights in relation to informed consent in clinical research these issues need to be revisited at domestic and at international level. Thus *Montgomery v Lanarkshire* while an important staging post in the development of principles of informed consent in English law in general and in the context of health research in particular is not a brave new world rather it represents steady evolution. The “brave new world” would have been to step outside negligence and to entirely reframe consent in relation to health care through the prism of autonomy based human rights itself. This would give rise to new possibilities and notable new challenges in reframing research regulation. Nonetheless this is unlikely at least in the near future, It will need some very bold and indeed a very brave judges to move the law forward, to wholly recast the informed consent

process in relation to health care in general and health care research in particular in the mould of fundamental human rights and as a new freestanding cause of action.

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