The Montgomery judgment and pharmacist consultations

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There is little awareness among pharmacists of the existence of the Montgomery judgment or its potential implications for medicines-related consultations. Nina Barnett and Claudia Carr therefore undertook a survey of pharmacists in England to create a baseline for current knowledge about informed consent in the context of medicines-related consultations.

Nadine Montgomery suffered complications while in labour, as a result of which her son was born with severe disability. She suffered from a medical condition (diabetes) known to her obstetrician, who failed to advise her of the risks associated with her particular condition and her labour and the alternative of a caesarean rather than vaginal delivery. Mrs Montgomery sought damages (financial compensation) from the Health Board for the injuries caused to her son.

In the Scottish lower courts, Mrs Montgomery was unsuccessful, as the courts applied the Bolam test of duty of care (where clinicians’ actions are measured against the action of a reasonable body of their peers) and found that the obstetrician had acted accordingly. Consequently, the Health Board was not liable for the damage caused to her son. However, on appeal, the Supreme Court rejected the application of Bolam to information disclosure. The court ruled in favour of Mrs Montgomery, who was awarded significant damages for the injury caused to her son. This was on the basis that Mrs Montgomery’s consent was not informed and therefore the obstetrician was negligent.

Following Montgomery, the new test for risk disclosure is expressed as follows: “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 treatment.”

The test of materiality (referred to above) has two aspects, firstly, “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” and secondly “whether the doctor is or should reasonably be aware that the patient would attach significance to it.”

Box 1. Summary of the Montgomery judgment

The judgment of the Supreme Court in the case of Montgomery v Lanarkshire Health Board (Scotland) 2015 was received by the academic and health community with the consensus view that while the case heralded a new era of standards of risk disclosure, once stripped back, it confirmed the death knell for paternalism in clinical practice. It is now indisputable that the patient sits at the heart of the decision-making process where treatment choices are concerned, and decisions are made in partnership with the healthcare professional.

This article will explore the nature and context of this patient autonomy and in so doing will examine why a Supreme Court case that concerned alleged negligence in obstetric care sets new standards of risk disclosure, which apply equally to all healthcare professionals who treat patients, including pharmacists. At first glance, it may be hard to appreciate the connection between a case of alleged negligent obstetric management and treatment with medicines by pharmacists but the judgment makes very clear that the duty of care for information disclosure is equally applicable to all healthcare professionals.

To fully appreciate the judgment, it is necessary to briefly review the facts (see Box 1). The court’s decision makes clear that a number of different healthcare professionals are now involved in providing patients with both treatment and advice either individually or as part of a team, “with the consequence that although this judgment is concerned particularly with doctors, it is also relevant to other healthcare professionals.”
In the NHS, treatments offered commonly relate either to surgical procedures or prescription of medicines – with over £16 million spent on medicines by NHS England in 2015/2016. Pharmacists have been involved with all aspects of medicines-related care for at least three decades and more recently, there has been an increase in the number of clinical, patient-facing pharmacy roles, with the advent of pharmacist prescribing, care home support and roles in general practice. However, a search of the legal databases (Lexis, Westlaw) and medicines-related databases (Medline, Embase) revealed no cases of pharmacy challenge relating to informed consent despite pharmacists’ patient-facing roles. Recent discussion in the pharmacy literature has highlighted the potential for improvements to medicines-related consultation to take account of the requirements for informed consent.

From a legal perspective, one of the authors (CC) was concerned that healthcare professionals in general were not being sufficiently proactive in incorporating the recommendations of the judgment into daily practice. The other author (NB), in conversation with national pharmacy colleagues, identified that there was little awareness of the existence of the judgment or its potential implications for medicines-related consultations. It was therefore decided that there was value in undertaking a survey of pharmacists in England to create a baseline for current knowledge about informed consent in the context of medicines-related consultations.

**Method**

A survey was devised using SurveyMonkey to explore the awareness of pharmacy staff of the requirements and the legislation for informed consent. The survey was piloted in one of the author’s (NB) local NHS hospital trusts (London North West Healthcare NHS Trust) within the pharmacy department. Feedback received from participants and interpretation of responses led to changes to the questions. The updated survey was then circulated through the Medicines Use and Safety Network, which provides access to pharmacy staff based in primary and secondary care NHS organisations, in May 2017. Only 100 responses could be collected due to the limitations of the free service offered by SurveyMonkey. These 100 respondents provided data for the survey, which was completed over a 24-hour period between 23–24 May 2017.

**Results**

Questions 1 and 2 provided information on respondents’ profession and level of experience. The majority (96%) of the 100 respondents were pharmacists and the remainder were pharmacy technicians. More than three-quarters of respondents (81%) considered themselves to be “experienced” or “very experienced”, with 13% stating they were “somewhat experienced” and 6% “novices”.

Question 3 asked: “Thinking about the last patient you spoke to about taking a new medicine, what did you discuss?” Of the 97 respondents to this question, over 73% asked the patient what they wanted to know about their medication; however, only 30% of respondents asked the patient what was important to them about taking their medicines (see Figure 1).

- 9% asked if they had had it before
- 82% directed patient to instructions on the label and on the package insert
- 81% checked allergies then told the patient about the dose, frequency, duration, warnings and storage
- 72% asked what they wanted to know about their medicine
- 58% asked what is important to them about taking their medicines
- 7% other (please specify)

In response to question 4: “Thinking about the last patient you spoke to about side-effects of a medicine, how did you decide what to tell them?” 33% of the 99 respondents asked the patient what side-effects they were worried about, while only 20% asked the patient what side-effects would be important to them (see Figure 2). Other free-text responses included “playing down” side-effects as they can affect patients differently, discussing the likelihood of side-effects, their duration and how to manage them, signposting to NHS websites, using additional leaflets for support, and asking the patient what questions they had about their medicines.

The majority (88%) of the 99 respondents to question 5: “In your opinion, what does a patient need to be able to give informed consent to taking a medicine?” thought that telling the patient about common and serious side-effects was needed, 86% thought that telling patients how to take their medicines was required, and 62% considered that asking patients what is important to them...
was needed (see Figure 3). There were a number of additional free-text responses to this question. These included ensuring the patient had capacity, checking understanding, the aim of treatment, the evidence for taking the medicine, the risks associated with not taking the medicine and asking how the patient feels about taking the medicine.

Over half of the respondents (53%, n=97) had not heard of, or had no real knowledge of, the case of Bolam v Friern Hospital and this was also the response from nearly three-quarters (74%) of the 100 respondents regarding the case of Montgomery v Lanarkshire Health Board. While just over one-third of respondents (36%, n=97) felt they knew the current requirements for informed consent nearly three-quarters of respondents (73%, n=100) did not know what ‘material risk’ meant in relation to advising patients about medication side-effects. Most respondents (96%, n=100) felt they would benefit from further learning about the law in relation to informed consent and medicine.

Discussion

This is the first survey of pharmacists exploring informed consent and the implications of the Montgomery judgment on medicines-related consultations. It is encouraging to see that 73% of respondents reported asking patients what they want to know about their medicine;12 however, patients may not necessarily know the questions to ask.13 The patient can only know the questions to ask if fully informed about the existing medication and alternatives and the consultation is patient-centred, i.e. focusing on what is important to this particular patient. Only once this is achieved can a consultation be “Montgomery compliant”.

Discussion of side-effects is common in some areas of pharmacy practice when dispensing a medicine. In our survey, 88% of respondents suggested that informed consent required discussing common and serious side-effects with the patient, and 62% of respondents considered that asking patients about what was important to them about taking the medicine was part of informed consent. These results raise some concerns regarding discussion of the risk of side-effects, which appear to be based solely on the likelihood of the side-effect occurring. It appears that pharmacists may be taking a more paternalistic ‘Bolam-based’ approach to consultations. This is not in accordance with the Montgomery judgment, which takes a more holistic approach. Consultations should now focus on a ‘value-based’ practice,14 which values the perspective of patients and clinicians equally, supporting person-centred, collaborative care in clinical practice.

Only 7% of respondents stated that they were very familiar with the Montgomery case and the judgment, and over half had not heard of the case. While there is no obligation on pharmacists to ensure they are familiar with the law, like any other healthcare professional, they should be aware of information that is so well accepted that it should be adopted.15 On this basis, we would argue that there is a need to ensure that pharmacists are compliant with Montgomery in order that patients are able to provide informed consent. However, it is a positive sign that although the majority of pharmacists were not aware of what would amount to either a material risk or informed consent, the vast majority wanted further education on the subject.

The majority of academic commentary on Montgomery suggests that although it was time that informed consent was now patient-centred, the previous existence of the GMC guidelines meant this was nothing new. The GMC provides guidance on best practice between doctor and patient,16 referred to by the Supreme Court in the Montgomery judgment.17 The emphasis is on working in partnership together – a principle that has reflected patient autonomy for several years. The GMC guidance emphasises the need to create a dialogue with the patient, discussing options and “set-

![Figure 2. Question 4: Thinking about the last patient you spoke to about side-effects of a medicine, how did you decide what to tell them about? (Tick all that apply)](prescriber.co.uk)
ANALYSIS | Montgomery judgment

...including the option to have no treatment.”

Later guidance states: “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.”

In 2016, in light of the Supreme Court judgment, the Royal College of Surgeons updated their guidance to include the Montgomery standard, and we suggest that the General Pharmaceutical Council (GPhC) guidance from May 2017 (and therefore post-Montgomery) would benefit from inclusion of the implications of the Montgomery judgment and informed consent. The Academy of Medical Royal Colleges is developing guidance at present, which could contribute to updated GPhC guidance.

Comment

The standard of care for risk disclosure set out by Montgomery must be adhered to, as failure to do so exposes the pharmacist to the risk of breaching their duty of care to the patient, with resulting negligence. Assuming the patient has capacity to consent, that patient is entitled to decide for themselves which available treatment to undergo, and the pharmacist’s duty relates directly to treatment from the patient’s and not the pharmacist’s perspective.

Thus far, the pharmacist, like every other healthcare professional post-Montgomery, is under a duty to take reasonable care to ensure the patient is advised of any risks associated with the medication being prescribed. This relates to either a risk that the patient would be likely to attach significance to or a risk that the pharmacist should reasonably be aware that the patient would attach significance to.

A good illustration of a risk being significant to a particular patient can be seen in the Australian case of Rogers v Whittaker, where a patient should have been warned of the 1 in 14,000 risk of sight loss in the left eye following surgery. While the risk was clearly extremely low, this was important (“material” is the term used in the Montgomery judgment) to the patient, as she was already blind in the right eye. This highlights the need to understand the patient’s specific circumstances to tailor information about side-effects that are relevant, as well as common or serious.

But the judgment goes further, as it requires not only the risks of the medication to be discussed, but the benefits as well. Materiality includes discussion of not only the percentage risk but also the effect that that medication would have on the patient’s life and the alternatives that are available. This is illustrated in Box 2, which outlines a case scenario demonstrating a lack of informed consent in a medicine-related context.

However, the only way informed consent can be achieved is through dialogue that recognises the individuality of the patient. The Montgomery judgment states that dialogue is required so that “the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives.” In addition, dialogue can “only be performed effectively if the information provided is comprehensible” and cannot be achieved by “bombarding the patient with technical information which she cannot be expected to grasp.” Thus, using a two-page “consultation checklist” to promote safe use of an anticoagulant for a patient with aphasia would not be consistent with Montgomery. The pharmacist would be required to provide information that is understandable and appropriate to the patient.

There is a very clear recognition within the Montgomery judgment that, with the ability to access more information via the internet, patient support groups and leaflets, the patient is no longer uninformed and entirely dependent on the pharmacist for initial information. Therefore, the pharmacist has a duty to discover what the patient already knows and to supplement this understanding with information relevant to the patient and their situation. Use of a consultation structure promotes this dialogue. The “Four Es” (Explore, Educate, Empower, Enable), describes a four-stage process including exploring what the patient already knows and providing education in response to this to empower the patient to make an informed decision.

Limitations

This was a small survey using a convenience sample of respondents from hospital and primary care pharmacy. It should be repeated with community phar...
macists and a larger, random cohort. The survey questions have face validity but the answers may not be representative as they relate to what respondents think they would do or remember, and to their last patient rather than a wide spectrum of patients. However, this work provides some pilot data that suggests that pharmacy staff may be in need of further education around the current law of informed consent.

The way forward
In order to address the key changes following the Montgomery judgment, pharmacy staff would benefit from using a person-centred approach to consultations. This can be delivered through pharmacy consultations using a structured approach. A coaching approach to consultations can support a more person-centred conversation, and can be applied to medication review, optimising polypharmacy and safe deprescribing, all of which require informed consent.

Conclusion
The results of this small study suggest that pharmacy practice in consultations about medicines may need to change as a result of the Montgomery judgment. It is apparent that other professional bodies in healthcare are addressing the Montgomery standard and the need for clear dialogue with patients. The Montgomery guidelines are largely unknown to the respondents of this study, who were all either pharmacists or pharmacy technicians. The results suggest that there is a possibility that pharmacists are not Montgomery compliant and thus their patients have not provided informed consent. It follows that pharmacists, who historically have not attracted clinical negligence claims, may be at risk of breaching their duty of care to their patients, which could expose pharmacy staff to the risk of future legal action.

The decision in the Montgomery case is here to stay and marks a significant development in the jurisprudential development of informed consent and risk disclosure. The judgment, while ostensibly concerned with obstetrics, has been applied by the courts to several other medical cases and considered in others. It may not be too long before it also concerns pharmacy.

References
4. Sokol D. Let’s raise a glass to the ordinary sensible patient BMJ 2015;351:h3956. doi: https://doi.org/10.1136/bmj.h3956
5. Bolam v Friern Hospital Management Committee [1957] 1 WLR 582.
7. Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11, para 75.

Ali goes to see his pharmacist Camilla. He has hypertension and Camilla prescribes him lisinopril. Camilla does not discuss the potential side-effects with him and other antihypertensive medication could be considered for Ali.

Ali is self-employed and bidding for a lucrative contract. He is also a 100m sprinter in trials for a place in the GB team. After starting his lisinopril, he develops dry cough and fatigue. The fatigue is so severe that he cannot run or work. He is unable to bid for the lucrative contract, and his business suffers. Is Camilla negligent?

In order to establish negligence, Ali will need to prove:

- A duty of care + breach of duty of care + causation* = negligence

It is easily proved that Camilla has a duty of care to Ali. To determine whether Camilla has breached her duty of care by failing to advise Ali of these risks, it is necessary to apply the Montgomery test: “Has Camilla taken reasonable care to ensure that Ali was aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatment?” In this particular case, would a reasonable person in Ali’s position be likely to have attached significance to the risk of dry cough and fatigue taking lisinopril for hypertension? Was Camilla aware, or was it reasonable to suggest that she should have been aware, that Ali would attach significance to it?

If Camilla had engaged Ali in conversation, she is likely to have heard about his business commitment and athletics trial; aspects of his life that satisfy the materiality test in Montgomery. She could then have discussed the risks, benefits and alternatives with him.

By failing to do this, Camilla has breached her duty of care to Ali. In order to claim damages for the loss he has sustained, he needs to prove causation. Did Camilla’s negligent act (failing to give advice about the risks) cause Ali’s injuries (potential loss to business, pain and suffering, potential lost opportunity) and were these foreseeable? In this case, although some aspects may be challenging to prove, causation is likely to be satisfied. If Camilla is found to be negligent in failing to advise of the risks associated with the medicine, compensation would be paid to Ali.

*Is the negligent act the cause of the patient’s injuries?

Box 2. A case scenario providing an example of lack of informed consent in a medicine-related context
15. The unreported case of Crawford v Board of Governors of Charing Cross Hospital. The Times 8 December 1953.
19. Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11, para 78.
26. Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11, para 90.
27. Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11, para 76.
34. Diamond v Royal Devon and Exeter NHS Foundation Trust [2017] EWHC 1295.

**Declaration of interests**

Nina Barnett specialises in teaching, communication skills and working with older people for private and public organisations, but has not presented on specific medications. For more information contact ninabarnett@nhs.net.

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