QJM: An International Journal of Medicine, 2020, 721–725

doi: 10.1093/qjmed/hcaa082
Advance Access Publication Date: 19 March 2020
Original paper

ORIGINAL PAPER

The effect of the Montgomery judgment on settled claims against the National Health Service due to failure to inform before giving consent to treatment

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Summary

Background: A landmark legal judgment in March 2015 (Montgomery) changed the test for determining negligence due to failing to inform patients before consent, by moving away from asking what a reasonable doctor should disclose and asking instead what a reasonable patient would expect to know.
Aim: We sought to determine the effect Montgomery has had on settled claims due to failure to inform compared with claims for other reasons and whether legal firms are adding contributory claims of failure to inform to other principal allegations of negligence.
Methods: A Freedom of Information request to NHS Resolution provided data on the number of settled claims against the NHS (2005–19) for any cause and where failure to inform before consent was the principal or contributory cause. Time-series regression was used to compare trends before and after 31 March 2015.
Results: The trend in claims/year increased 4-fold for failure to inform (an increase of 9.8/year before 2015 vs. 39.5/year after 2015, $P < 0.01$), 2.7-fold when failure to inform was the principal cause (7.9/year vs. 21.2/year, $P = 0.02$) and 9.9-fold as a contributory cause (1.9/year vs. 18.3/year, $P < 0.01$). There was no material difference in claims due to other causes (334/year vs. 318/year, $P = 0.84$).
Conclusions: Montgomery has led to a substantial increase in settled claims of failure to inform before consent, with no coincident change in claims for other causes. The increase in contributory compared with principal causes suggests that lawyers are using the judgment to increase the chances of a successful claim against the NHS.

Introduction

Failure to inform patients before they give their consent to treatment is considered a failure in the duty of medical care.[1] Such failures usually go unnoticed when outcomes are good, but become scrutinized when complications arise. There is evidence that the cost of settling NHS legal claims due to a failure to inform before consent is increasing in the UK.[2]

It is uncertain whether this increase is part of a general pattern of increasing litigation for all causes of alleged negligence or whether it is specific to failure to inform before consent in the wake of the Montgomery judgment in March 2015. In this

Received: 30 January 2020; **Revised (in revised form):** 17 February 2020

landmark case (Montgomery-v-Lanarkshire),[3] a 5-ft tall woman with diabetes, delivered her son vaginally, but complications developed due to shoulder dystocia resulting in cerebral palsy. She claimed she would have requested a cesarean section, had she known of the risks linking diabetes, large babies and small mothers. The UK Supreme Court ruled in her favor.

The court established that in seeking consent, patients should be informed of any material risk that a reasonable person in that patient's position would regard as significant and ruled that the test of materiality be based on what patients would expect to be told, not on what doctors think patients should be told. This effectively replaced the Bolam test that had stood for decades in determining negligence. If the Bolam test is used, a doctor is deemed not to be negligent if he or she has acted in accordance with a practice accepted as proper by a body of responsible doctors skilled in the field. The Montgomery judgment rejected Bolam and replaced it with a test of what a reasonable patient, or indeed the actual patient, would expect to know.[4] In order for a consent case to succeed it needs to meet the legal test in demonstrating both that (i) the patient would not have gone ahead with the procedure at the time it was performed had the risk been disclosed and (ii) a harm was suffered as a result of the procedure.[5]

The lack of clarity over what may or may not be construed as a material risk by a patient makes it almost impossible to completely inform a patient before consent and easier to win legal claims of failure to inform. There are concerns that law firms may now be exploiting the judgment, by adding contributory claims of failure to inform before consent to principal claims for other reasons to increase the chances of success.[6]

The uncertainty over the effect of Montgomery on settled claims due to failure to inform compared with claims for other reasons, and whether legal firms are adding contributory claims to other principal allegations, prompted us to file a Freedom of Information request to NHS Resolution and examine the data over the past 14 years.

Materials and Methods

A Freedom of Information request (#3884) was submitted to NHS Resolution, in September 2019, for data on settled claims against the NHS each year for the period 1 April 2005 to 31 March 2019. We sought the total number and cost of settled claims across all NHS Hospitals and for all medical or surgical specialties where the primary (principal) or secondary (contributory) cause was a failure to inform before consent to treatment, coded as 'Primary cause Fail to Warn- Informed Consent' and 'Secondary cause Fail to Warn—Informed Consent'; hereafter referred to as failure to inform (principal) and failure to inform (contributory), respectively. We also sought the total number and cost of settled claims across the NHS regardless of cause and determined the total number and cost without failure to inform, by subtraction.

Plots of the annual number and cost of settled claims were constructed for failure to inform (principal and contributory combined and each separately) and for other causes. Using a single group interrupted time-series regression analysis, we compared the regression slopes before 31 March 2015 with those after 1 April 2015 (hereafter simplified to before and after March 2015, the year and month of the Montgomery judgment), to determine the annual rate of change before and after the ruling and the net change at this date. Ratios of the rates of change (after/before March 2015) were calculated together with 95% confidence intervals. We adjusted costs (total and cost per settled claim) for inflation using the Consumer price inflation index including owner occupiers' housing costs (CPIH) index, adjusting all costs to 2019 quarter 1 values.[7] Stata version 15 was used for all analyses.

Results

The data comprised 69 942 cases of settled claims, across 47 specialties, at a total cost of £15 311 203 494 to the NHS over 14 years. There were 2301 claims due to a failure to inform before consent at a total cost of £396 013 764.

Figure 1 shows that the annual trend in settled claims per year before March 2015 compared with that after March 2015 increased due to (i) failure to inform (principal and contributory causes combined), (ii) failure to inform (principal) and (iii) failure to inform (contributory). There was no change in trend for other causes (iv). Table 1 gives the average annual change in the number of settled claims before and after March 2015. There was a 4-fold increase (2.8–5.3, $P < 0.01$) for failure to inform (principal and contributory), a 2.7-fold increase (1.3–4.0, $P < 0.01$) for failure to inform (principal) and a 9.9-fold increase (8.5–11.2, $P < 0.01$) for failure to inform (contributory).

Figure 2 shows that the annual trend in the cost of settled claims per year before compared with after March 2015, increased for failure to inform as well as for other causes. There were no statistically significant changes in the costs per claim for failure to inform; $P = 0.25$ for principal and contributory, $P = 0.56$ for principal alone and $P = 0.55$ for contributory alone (Supplementary Table S1), but there was an increase in the cost per claim (£18 400/year, $P < 0.01$) for other causes.

Supplementary Table S2 gives the total cost of claims over the 14 years of this study due to a failure to inform before consent, according to discipline for specialties with at least five settled claims during that period. The highest cost specialties were general surgery, orthopedics, obstetrics, gynecology and cardiac surgery.

Discussion

The results of this study show that the 2015 Montgomery judgment was followed by a substantial rise in the annual rate of settled claims due to a failure to inform before consent to treatment (about a 4-fold increase), whilst the rate of increase in settled claims for other reasons has not changed. The rate of increase was greater where failure to inform was a contributory cause (9.9-fold increase) compared with it being the principal cause (2.7-fold increase), suggesting that, since Montgomery, legal firms are adding contributory claims to improve the chances of a successful settlement when the primary claim is not consent related.

Overall litigation costs against the NHS have increased steadily since 2005, and the costs of failure to inform are a relatively small proportion of this but the net financial impact of the Montgomery judgment is still substantial; in the 4 years before Montgomery, NHS costs due to settled claims for failure to inform increased from £25 million/year to £28 million/year and in the subsequent 4 years to £62 million/year. The increase has not been due to an increase in the cost per claim, which has remained steady (about £200 000/claim each year) but due to the increase in the number of claims. The data probably underestimate the true cost, because they do not include resources used to investigate complaints that never become claims or claims that fail to settle.

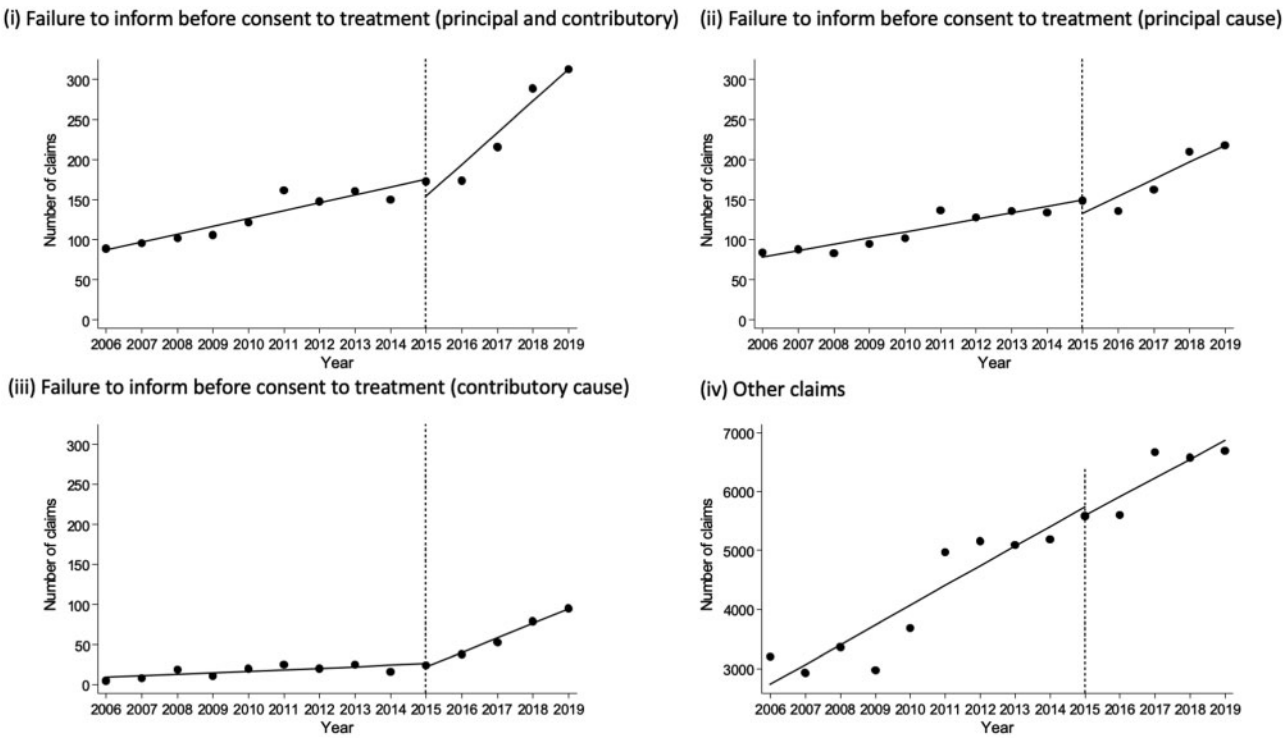

Figure 1. Number of settled claims against the NHS per year according to cause before and after the Montgomery judgment (marked by dotted vertical line).

Table 1. Number and cost of settled claims against the NHS according to cause, before and after the March 2015 Montgomery judgment

	Annual change		Difference		
	Before 2015[a]	After 2015[b]	Absolute	Relative	P-value
Number of claims					
Failure to inform (principal plus contributory)	9.8 (6.7–12.9)	39.5 (27.4–51.6)	29.7 (17.2–42.2)	4.0 (2.8–5.3)	<0.01
Failure to inform (principal)	7.9 (5.7–10.1)	21.2 (10.8–31.6)	13.3 (2.6–23.9)	2.7 (1.3–4.0)	0.02
Failure to inform (contributory)	1.9 (0.1–3.6)	18.3 (16.6–20.0)	16.5 (14.0–18.9)	9.9 (8.5–11.2)	<0.01
Other causes	334 (225–442)	318 (197–440)	−15.2 (−178–148)	1.0 (0.5–1.4)	0.84
Inflation adjusted total cost of claims (£ millions)					
Failure to inform (principal plus contributory)	1.8 (0.2–3.4)	9.0 (5.2–12.9)	7·3 (3.1–11.4)	5.1 (2.8–7.4)	<0.01
Failure to inform (principal)	1.0 (−0.6–2.7)	4.0 (1.6–6.3)	2·9 (0.1–5.8)	3.8 (1.1–6.6)	0.04
Failure to inform (contributory)	0.7 (0.2–1.3)	5.1 (2.6–7.5)	4·3 (1.8–6.9)	6.9 (3.4–10.3)	<0.01
Other causes	77.0 (47.7–106)	187 (123–250)	110 (40.0–179)	2.4 (1.8–3.1)	<0.01

[a]1 April 2005 to 31 March 2015.
[b]1 April 2015 to 31 March 2019.

Following the Montgomery judgment, there was speculation over whether the ruling would open the flood gates for litigation[8] and several publications followed citing subsequent cases in which the ruling was used to secure a settlement and also cases where it failed.[9] For example, In Spencer v Hillingdon NHS Trust[10] a patient suffered a pulmonary embolism after a hernia operation. He did not seek treatment immediately because he had not been warned of the risk or symptoms. The judge considered the Montgomery ruling and found, even though this was a post-procedure event, that there had been a failure to inform and a breach of the duty of care. Several attempts to introduce a consent-based claim to cases that were under way before the ruling[11,12] have succeeded and others have settled even before litigation ever started, because the claims were regarded as unanswerable in the light of Montgomery.[6] Other attempts have failed. For example, In Mrs A v East Kent Hospitals University NHS Foundation Trust[13] the claimant's baby, who was conceived using intracytoplasmic sperm injection, had a chromosomal abnormality. The claimant alleged that the trust was negligent in failing to advise of this possibility. The court determined that the risk was not material, because neither a reasonable patient nor the patient herself would have attached significance to it. Such anecdotal reports may give the impression of a balanced approach to the ruling but do not reflect the true overall picture. Our results show a clear surge in claims and cost, which looks set to continue. The NHS has become the target of a legal ruling that, whilst reasonable in the circumstances of the Montgomery case, has had serious unintended consequences.

A difficulty with the Montgomery judgment is that it is based on a determination of whether a risk is material to a particular patient. The problem with any test of materiality is that it lacks

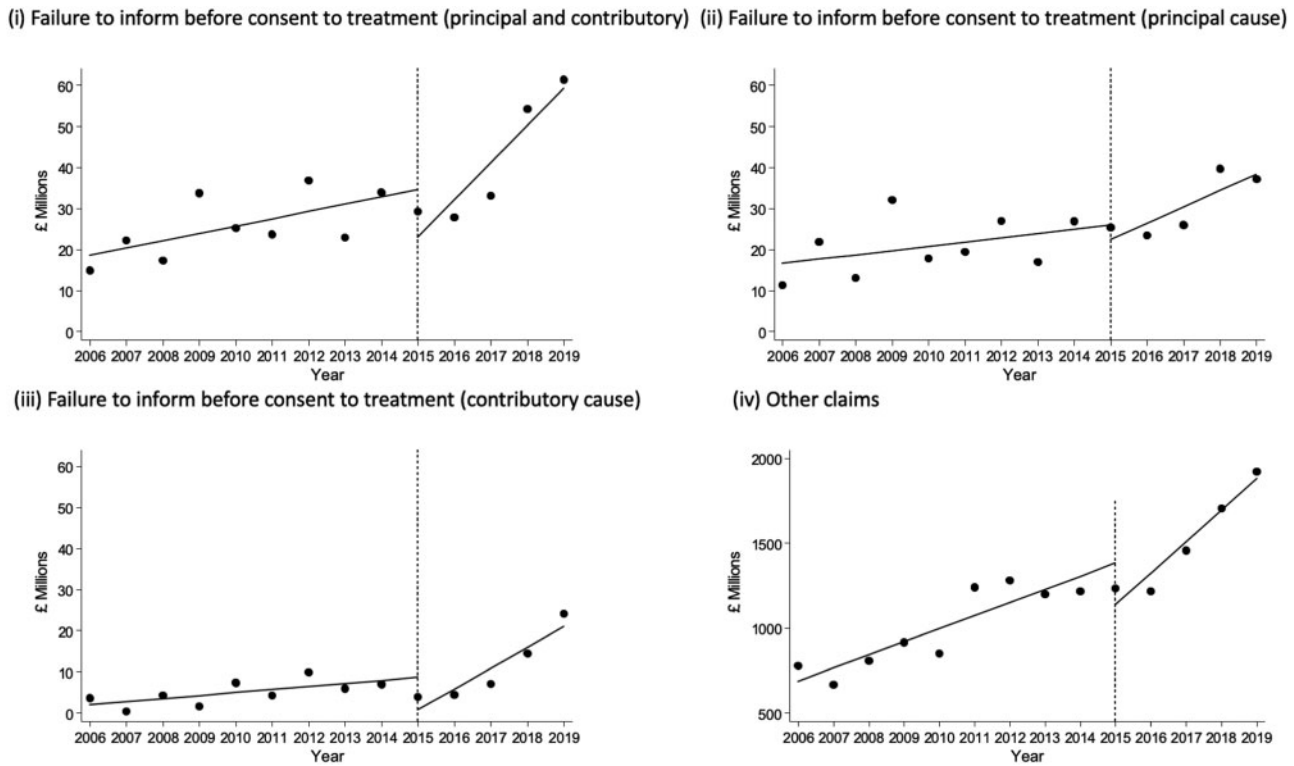

Figure 2. Cost of settled claims against the NHS per year (adjusted for inflation) according to cause before and after the Montgomery judgment (marked by dotted vertical line).

objectivity and puts doctors and their hospitals in the difficult position of having to work out whether a patient would find a particular risk relevant in their decision-making, even when the risk is potentially very small. For example, coronary angiography is usually performed from the radial artery in the wrist because, compared with the femoral artery in the groin, there is about a 30% lower risk of bleeding and death following the procedure.[14] However, radial procedures carry a very rare risk of hand damage, which theoretically could cause permanent injury. The incidence is unknown, probably less than 1 in 10 000 and certainly less than the risk of not surviving the procedure (about 1 in 1000) but it is rarely mentioned in a discussion with a patient before consent. However, it is possible that a patient may prefer a higher risk of death, using the femoral approach, than the remote possibility of hand damage, if for example they play the violin, and would claim for failure to inform in the event of hand injury. One can imagine other scenarios in other disciplines where individual lifestyles, hobbies and professions could be used to support a claim that a remote risk is material, even when evidence-based practice would support a lower-risk approach to a procedure.

The results of this study may encourage attempts to find a more objective approach to the test of materiality, so doctors can practice with a clearer framework of what needs to be disclosed before patients' consent is sought to a medical or surgical treatment. Perhaps a bolder approach is needed. For example, a no-fault compensation scheme in the event of a complication, as exists in New Zealand.[15] The UK Criminal Injuries Compensation Authority Scheme is another model that could be used, where claimants do not need to prove that the government was negligent in preventing a crime and damages are prespecified in the event of injury.[16] It is the proof of negligence and calculating the value that often requires legal input. About 40% (£155 million) of costs paid by the NHS in settled claims due to failure to inform were for claimant or defence legal fees (2005–19). This does not include legal fees for claims that fail. A no-fault compensation scheme would largely avoid these legal costs, saving time and anxiety, although it risks increasing claims and overall cost.

Whatever modification may be made to the legal framework, there is merit in hospitals improving the process of delivering information and doing more to encourage a dialogue before consent to treatment is given. Modern communication methods such as internet-accessible animations in languages patients understand have been shown to increase understanding of benefits and risks in elective and urgent clinical settings.[17] Information can be delivered early following a treatment recommendation giving patients time to consider, reflect and question the procedures being offered and possible alternatives before they are asked to give their consent. An audit trail of the process should be created so claims of failing to disclose can be properly examined.

A limitation of this study is uncertainty over the extent to which claims that were settled due to a failure to inform were due to an omission in disclosing common risks that any patient would expect to be told regarding a procedure or rare risks that were only in retrospect regarded as material. The sharp rises in the number of claims due to a failure to inform before consent following the Montgomery judgment suggests, but does not prove, it had a causal role. The observation that there was no change in the rate of rise of claims for other reasons and that the analyses either side of March 2015 were specified in advance, makes a noncausal explanation unlikely.

The Supreme Court recognized, in its concluding statements in 2015 (paragraphs 92–93),[3] that the ruling it imposed could result in an increase in litigation and that the outcome of such

litigation may be less predictable. They argued, however, that 'an approach which results in patients being aware that the outcome of treatment is uncertain and potentially dangerous, and in their taking responsibility for the ultimate choice to undergo that treatment, may be less likely to encourage recriminations and litigation, in the event of an adverse outcome, than an approach which requires patients to rely on their doctors to determine whether a risk inherent in a particular form of treatment should be incurred'. The Court believed there would be less litigation, but in fact there has been more.

Conclusion

The Montgomery judgment changed the legal test for determining what is sufficient disclosure before consent is given to treatment, by moving away from asking what a reasonable doctor would warn about and asking instead what a reasonable patient would expect to know. This ruling coincided with a substantial increase in settled claims against the NHS for alleged failure to inform and a particular surge in claims where this was added as a contributory cause of negligence, with no comparable increase in claims for other causes. These findings support the need for a revised system that would better serve the interests of both patient and doctor.

Supplementary material

Supplementary material is available at *QJMED* online.

Acknowledgments

We thank Tim Shurlock for help with data acquisition and Nicholas Wald for his comments on the manuscript.

Declaration of interests

D.S.W. set up and leads Explain my Procedure™ an online platform for viewing animations describing the benefits, risks and alternatives of medical procedures (www.explainmyprocedure.com).

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