



Hilary Term
[2015] UKSC 11

On appeal from: [2013] CSIH 3; [2010] CSIH 104

JUDGMENT

Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland)

before

Lord Neuberger, President
Lady Hale, Deputy President
Lord Kerr
Lord Clarke
Lord Wilson
Lord Reed
Lord Hodge

JUDGMENT GIVEN ON

11 March 2015

Heard on 22 and 23 July 2014

Appellant

James Badenoch QC
Colin J MacAulay QC
Lauren Sutherland
(Instructed by
Balfour+Manson LLP)

Respondent

Rory Anderson QC
Neil R Mackenzie

(Instructed by NHS
National Services Scotland
Central Legal Office)

*Intervener (General
Medical Council)*

Andrew Smith QC

(Instructed by GMC
Legal)

LORD KERR AND LORD REED: (with whom Lord Neuberger, Lord Clarke, Lord Wilson and Lord Hodge agree)

Introduction

1. Nadine Montgomery gave birth to a baby boy on 1 October 1999 at Bellshill Maternity Hospital, Lanarkshire. As a result of complications during the delivery, the baby was born with severe disabilities. In these proceedings Mrs Montgomery seeks damages on behalf of her son for the injuries which he sustained. She attributes those injuries to negligence on the part of Dr Dina McLellan, a consultant obstetrician and gynaecologist employed by Lanarkshire Health Board, who was responsible for Mrs Montgomery's care during her pregnancy and labour. She also delivered the baby.
2. Before the Court of Session, two distinct grounds of negligence were advanced on behalf of Mrs Montgomery. The first concerned her ante-natal care. It was contended that she ought to have been given advice about the risk of shoulder dystocia (the inability of the baby's shoulders to pass through the pelvis) which would be involved in vaginal birth, and of the alternative possibility of delivery by elective caesarean section. The second branch of the case concerned the management of labour. It was contended that Dr McLellan had negligently failed to perform a caesarean section in response to abnormalities indicated by cardiotocograph ("CTG") traces.
3. The Lord Ordinary, Lord Bannatyne, rejected both grounds of fault: [2010] CSOH 104. In relation to the first ground, he based his decision primarily on expert evidence of medical practice, following the approach laid down by the majority in *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871. He also concluded that, even if Mrs Montgomery had been given advice about the risk of serious harm to her baby as a consequence of shoulder dystocia, it would have made no difference in any event, since she would not have elected to have her baby delivered by caesarean section. That decision was upheld by the Inner House (Lord Eassie, Lord Hardie and Lord Emslie): [2013] CSIH 3; 2013 SC 245.
4. The appeal to this court has focused on the first ground of fault. The court has been invited to depart from the decision of the House of Lords in *Sidaway* and to re-consider the duty of a doctor towards a patient in relation to advice about treatment. The court has also been invited to reverse the findings of the Lord Ordinary in relation to causation, either on the basis that his treatment

of the evidence was plainly wrong, or on the basis that, instead of applying a conventional test of “but for” causation, he should instead have applied the approach adopted in the case of *Chester v Afshar* [2004] UKHL 41; [2005] 1 AC 134.

5. Before considering those issues, we shall explain in greater detail the relevant facts and the approach adopted by the courts below.

The facts

6. Mrs Montgomery studied molecular biology at Glasgow University and graduated with a BSc. She then worked for a pharmaceutical company as a hospital specialist. She was described by the Lord Ordinary as “a clearly highly intelligent person”. Her mother and sister are both general medical practitioners.
7. In 1999 Mrs Montgomery was expecting her first baby. She is of small stature, being just over five feet in height. She suffers from insulin dependent diabetes mellitus. Women suffering from diabetes are likely to have babies that are larger than normal, and there can be a particular concentration of weight on the babies’ shoulders. Because of her diabetes, Mrs Montgomery’s was regarded as a high risk pregnancy requiring intensive monitoring. She therefore attended the combined obstetric and diabetic clinic at Bellshill Maternity Hospital, under the care of Dr McLellan, throughout her pregnancy.
8. The widest part of a baby’s body is usually the head. If the head successfully descends through the birth canal, in a normal birth the rest of the body will descend uneventfully. Since the widest part of the body of a baby whose mother is diabetic may be the shoulders the head may descend but the shoulders can be too wide to pass through the mother’s pelvis without medical intervention. This phenomenon, known as shoulder dystocia, is the prime concern in diabetic pregnancies which proceed to labour. It was described by Dr Philip Owen, an expert witness who gave evidence on behalf of the Board, as “a major obstetric emergency associated with a short and long term neonatal and maternal morbidity [and] an associated neonatal mortality”.
9. That evidence is consistent with guidance issued by the Royal College of Obstetricians and Gynaecologists, which states that there can be a high perinatal mortality and morbidity associated with the condition, even when it

is managed appropriately. Maternal morbidity is also increased: in 11% of cases of shoulder dystocia there is postpartum haemorrhage, and in 3.8% fourth degree perineal tears. The guidance advises that help should be summoned immediately when shoulder dystocia occurs. When the mother is in hospital this should include assistance from midwives, an obstetrician, a paediatric resuscitation team and an anaesthetist.

10. According to the evidence in this case, about 70% of cases of shoulder dystocia can be resolved by what is known as a “McRoberts” manoeuvre. This involves two midwives or nurses taking hold of the mother’s legs and forcing her knees up towards her shoulders, so as to widen the pelvic inlet by means of hyperflexion. An attempt can also be made to manoeuvre the baby by suprapubic pressure. This procedure involves the doctor making a fist with both hands and applying pressure above the mother’s pubis, in order to dislodge the baby’s shoulder and push the baby down into the pelvis. Another procedure which may be attempted is a “Zavanelli” manoeuvre. This involves pushing the baby’s head back into the birth canal, to the uterus, so as to be able to perform an emergency caesarean section. Another possible procedure is a symphysiotomy. This is a surgical procedure which involves cutting through the pubic symphysis (the joint uniting the pubic bones), so as to allow the two halves of the pelvis to be separated.
11. According to Dr McLellan’s evidence, in some cases the mother may be entirely unaware that shoulder dystocia has occurred. It is clear, however, that when shoulder dystocia happens and the mother knows of it, dealing with it is, at least, an unpleasant and frightening experience for her. It also gives rise to a variety of risks to her health.
12. Shoulder dystocia also presents risks to the baby. The physical manoeuvres and manipulations required to free the baby can cause it to suffer a broken shoulder or an avulsion of the brachial plexus – the nerve roots which connect the baby’s arm to the spinal cord. An injury of the latter type may be transient or it may, as in the present case, result in permanent disability, leaving the child with a useless arm. The risk of a brachial plexus injury, in cases of shoulder dystocia involving diabetic mothers, is about 0.2%. In a very small percentage of cases of shoulder dystocia, the umbilical cord becomes trapped against the mother’s pelvis. If, in consequence, the cord becomes occluded, this can cause the baby to suffer from prolonged hypoxia, resulting in cerebral palsy or death. The risk of this happening is less than 0.1%.
13. Mrs Montgomery was told that she was having a larger than usual baby. But she was not told about the risks of her experiencing mechanical problems during labour. In particular she was not told about the risk of shoulder

dystocia. It is agreed that that risk was 9-10% in the case of diabetic mothers. Unsurprisingly, Dr McLellan accepted that this was a high risk. But, despite the risk, she said that her practice was not to spend a lot of time, or indeed any time at all, discussing potential risks of shoulder dystocia. She explained that this was because, in her estimation, the risk of a grave problem for the baby resulting from shoulder dystocia was very small. She considered, therefore, that if the condition was mentioned, “most women will actually say, ‘I’d rather have a caesarean section’”. She went on to say that “if you were to mention shoulder dystocia to every [diabetic] patient, if you were to mention to any mother who faces labour that there is a very small risk of the baby dying in labour, then everyone would ask for a caesarean section, and it’s not in the maternal interests for women to have caesarean sections”.

14. During her fortnightly attendances at the clinic, Mrs Montgomery underwent ultrasound examinations to assess foetal size and growth. The final ultrasound examination was on 15 September 1999, at 36 weeks gestation. Dr McLellan decided that Mrs Montgomery should not have a further ultrasound examination at 38 weeks, because she felt that Mrs Montgomery was becoming anxious as a result of the information revealed by the scans about the size of her baby. That sense of anxiety related to her ability to deliver the baby vaginally.
15. Based on the 36 weeks ultrasound, Dr McLellan estimated that the foetal weight at birth would be 3.9 kilograms. She made that estimate on the assumption that the baby would be born at 38 weeks. This is important because Dr McLellan gave evidence that, if she had thought that the baby’s weight was likely to be greater than 4 kilograms, she would have offered Mrs Montgomery a caesarean section. In keeping with general practice Dr McLellan would customarily offer a caesarean section to diabetic mothers where the estimated birth weight is 4.5 kilograms. She decided to reduce that threshold to 4 kilograms in Mrs Montgomery’s case because of her small stature.
16. As Dr McLellan was aware, estimating birth weight by ultrasound has a margin of error of plus or minus 10%. But she decided to leave this out of account, stating that “if you do that you would be sectioning virtually all diabetics”. By the time of the 36-week examination, Dr McLellan had already made arrangements for Mrs Montgomery’s labour to be induced at 38 weeks and 5 days. She accepted in evidence that she should have estimated the baby’s birth weight as at 38 weeks and 5 days, rather than 38 weeks, and that the estimated birth weight would then have been over 4 kilograms which was, of course, beyond the threshold that she herself had set. In the event, the baby was born on the planned date and weighed 4.25 kilograms.

17. At the 36-week appointment, Dr McLellan noted that Mrs Montgomery was “worried about [the] size of [the] baby”. In her evidence, she accepted that Mrs Montgomery had expressed concern at that appointment about the size of the foetus and about the risk that the baby might be too big to be delivered vaginally. Dr McLellan also accepted that it was possible that Mrs Montgomery had expressed similar concerns previously. Certainly, she said, such concerns had been mentioned more than once. She stated that Mrs Montgomery had not asked her “specifically about exact risks”. Had Mrs Montgomery done so, Dr McLellan said that she would have advised her about the risk of shoulder dystocia, and also about the risk of cephalopelvic disproportion (the baby’s head becoming stuck). In the absence of such specific questioning, Dr McLellan had not mentioned the risk of shoulder dystocia, because, as we have already observed, it was her view that the risk of serious injury to the baby was very slight. In accordance with her practice in cases where she felt (in her words) that it was “fair to allow somebody to deliver vaginally”, Dr McLellan advised Mrs Montgomery that she would be able to deliver vaginally, and that if difficulties were encountered during labour then recourse would be had to a caesarean section. Mrs Montgomery accepted that advice. But if she had requested an elective caesarean section, she would have been given one.

18. Mrs Montgomery said in evidence that if she had been told of the risk of shoulder dystocia, she would have wanted Dr McLellan to explain to her what it meant and what the possible risks of the outcomes could be. If she had considered that it was a significant risk to her (and, in light of what she had subsequently learned, she would have assessed it as such) she would have asked the doctor to perform a caesarean section.

19. As we have explained, Dr McLellan gave evidence that diabetic patients who had been advised of the risk of shoulder dystocia would invariably choose the alternative of delivery by caesarean section. She also gave evidence that Mrs Montgomery in particular would have made such an election:

“since I felt the risk of her baby having a significant enough shoulder dystocia to cause even a nerve palsy or severe hypoxic damage to the baby was low I didn’t raise it with her, and had I raised it with her then yes, she would have no doubt requested a caesarean section, as would any diabetic today.”

20. Mrs Montgomery’s labour was induced by the administration of hormones, as Dr McLellan had planned. After several hours, labour became arrested. The strength of the contractions was then augmented by the administration of further hormones over a further period of several hours, so as to overcome

whatever was delaying progress towards vaginal delivery. When the baby's head nevertheless failed to descend naturally, Dr McLellan used forceps. At 5.45 pm the baby's shoulder became impacted at a point when half of his head was outside the perineum.

21. Dr McLellan had never dealt with that situation before. She described it as very stressful for Mrs Montgomery and for all the staff in theatre, including herself. Mr Peter Stewart, an expert witness led in support of Mrs Montgomery's case, described the situation as every obstetrician's nightmare. An anaesthetist gave Mrs Montgomery a general anaesthetic so as to enable the Zavanelli manoeuvre (ie pushing the baby back into the uterus, in order to perform an emergency caesarean section) to be attempted. Dr McLellan decided however that she had no other option but to try to complete the delivery. She pulled the baby's head with "significant traction" to complete the delivery of the head. In order to release the shoulders, she attempted to perform a symphysiotomy, and succeeded to some extent in cutting through the joint. No scalpels with fixed blades were available, however, and the blades she used became detached before the division of the joint had been completed. Eventually, "with just a huge adrenalin surge", Dr McLellan succeeded in pulling the baby free, and delivery was achieved at 5.57 pm.
22. During the 12 minutes between the baby's head appearing and the delivery, the umbilical cord was completely or partially occluded, depriving him of oxygen. After his birth, he was diagnosed as suffering from cerebral palsy of a dyskinetic type, which had been caused by the deprivation of oxygen. He also suffered a brachial plexus injury resulting in Erb's palsy (ie paralysis of the arm). All four of his limbs are affected by the cerebral palsy. If Mrs Montgomery had had an elective caesarean section her son would have been born uninjured.
23. Mr Stewart gave evidence that Dr McLellan's failure to inform Mrs Montgomery of the risk of shoulder dystocia was contrary to proper medical practice, whether or not Mrs Montgomery had asked about the risks associated with vaginal delivery. In cross-examination, however, counsel for the defender put the following question to him:

"And if Dr McLellan had said your baby appears to be on the 95th centile or whatever, so it's borderline large, it's the top end of the normal size, its largish ... We know that you are diabetic. We know you are whatever height you are, we've estimated the size as best we can all the way through, there are risks but I don't think the baby is so big that vaginal delivery is beyond

you and I think we should try for vaginal delivery and if anything comes up we will go to caesarean section. Now if that was the general tenor of the discussion, could you criticise that? I know it's very vague and it's very difficult because it's another hypothesis, Mr Stewart and I appreciate that but yes I would ... are you able to answer that question?"

24. Mr Stewart replied that he was “able to go along with that, with the caveat that you would then say to the patient, ‘Are you happy with that decision?’”. Professor James Neilson, another expert witness led in support of Mrs Montgomery’s case, gave evidence that, if she expressed concerns about the size of her baby, then it was proper practice to discuss the potential problems that could arise because of the baby’s size. That discussion would have included the risk of shoulder dystocia, and the option of an elective caesarean section.
25. Dr Owen gave evidence that what had been said by Dr McLellan was an adequate response to Mrs Montgomery’s expressions of concern about the size of her baby and her ability to deliver vaginally. Another expert witness led on behalf of the Board, Dr Gerald Mason, considered that it was reasonable not to have discussed shoulder dystocia with Mrs Montgomery, as the risks of a serious outcome for the baby were so small. Like Dr McLellan, he considered that, if doctors were to warn women at risk of shoulder dystocia, “you would actually make most women simply request caesarean section”. He accepted however that if a patient asked about risks then the doctor was bound to respond.

The judgments of the courts below

26. The Lord Ordinary was invited by counsel to accept that Mrs Montgomery should have been informed of the risk of shoulder dystocia if vaginal delivery was proposed and that she should have been advised about the alternative of delivery by caesarean section. He rejected that contention. Following the approach in *Sidaway*, he decided that whether a doctor’s omission to warn a patient of inherent risks of proposed treatment constituted a breach of the duty of care was normally to be determined by the application of the test in *Hunter v Hanley* 1955 SC 200, 206 or the equivalent *Bolam* test (*Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582, 587). It therefore depended on whether the omission was accepted as proper by a responsible body of medical opinion. In light of the expert evidence given on behalf of the Board (and Dr Stewart’s evidence in cross-examination), which could not be rejected as incapable of standing up to rational analysis (cf

Bolitho v City and Hackney Health Authority [1998] AC 232, 241-243), that test was not met.

27. The Lord Ordinary accepted, following the speech of Lord Bridge in *Sidaway*, that there might be circumstances, where the proposed treatment involved a substantial risk of grave adverse consequences, in which a judge could conclude, notwithstanding any practice to the contrary, that a patient's right to decide whether to consent to the treatment was so obvious that no prudent medical practitioner could fail to warn of the risk, save in an emergency or where there was some other cogent clinical reason for non-disclosure. The Lord Ordinary was referred to the way in which the matter had been put by Lord Woolf MR in *Pearce v United Bristol Healthcare NHS Trust* [1999] PIQR P 53, para 21: was there a significant risk which would affect the judgment of a reasonable patient? That did not, in the Lord Ordinary's judgment, alter the test in *Sidaway* because he considered that, in order to be significant, a risk must be a substantial risk of grave adverse consequences.
28. The circumstances of the present case did not in his view fall within the scope of that exception. Although there was a significant risk of shoulder dystocia, that did not in itself require a warning, since "in the vast majority of ... cases ... shoulder dystocia was dealt with by simple procedures and the chance of a severe injury to the baby was tiny". The Lord Ordinary declined to follow the approach adopted in *Jones v North West Strategic Health Authority* [2010] EWHC 178 (QB), [2010] Med LR 90, a case on similar facts where it had been held that the risk of shoulder dystocia was in itself sufficiently serious for the expectant mother to be entitled to be informed.
29. The Lord Ordinary also accepted, again following the speech of Lord Bridge in *Sidaway*, that a doctor must, when questioned specifically by a patient about risks involved in a particular treatment proposed, answer truthfully and as fully as the questioner requires. He held however that there had been no breach of that duty. He rejected Mrs Montgomery's evidence that she had asked Dr McLellan about the risks inherent in vaginal delivery and about other options. He accepted that Mrs Montgomery had raised concerns with Dr McLellan about her ability to deliver such a large baby vaginally: indeed, that was not in dispute. But the expression of such concerns did not in his opinion result in any duty to explain the risks involved. In order for a duty to explain the risks to arise, Mrs Montgomery would have had to have "raised questions of specific risks" involved in vaginal delivery.
30. In her appeal to the Inner House of the Court of Session, Mrs Montgomery again argued that she ought to have been informed of the risk of shoulder

dystocia, and should have been offered and advised about the alternative of delivery by caesarean section. The reclaiming motion was refused for reasons set out in an opinion delivered by Lord Eassie.

31. Lord Eassie rejected the argument that there had been, in recent judicial authority (in particular, *Pearce v United Bristol Healthcare NHS Trust*), a departure from the approach adopted in *Sidaway*, so as to require a medical practitioner to inform the patient of any significant risk which would affect the judgment of a reasonable patient. The decision in *Sidaway* was understood by Lord Eassie as normally requiring only of a doctor, in advising a patient of risks, to follow the practice of a responsible body of medical practitioners. He accepted, in the light of the opinion of Lord Bridge in *Sidaway*, and the later case of *Bolitho v City and Hackney Health Authority* [1998] AC 232, that there might be exceptional cases in which the court should not regard as determinative medical practice as to what should be conveyed to the patient where the risk was so obviously substantial that the court could say that no practitioner could reasonably omit to warn the patient. This was not such a case, however. The relevant risk was not the possibility of shoulder dystocia occurring but the much smaller risk of a grave adverse outcome.
32. The second limb of Mrs Montgomery's case in relation to the advice that she should have received was founded, as we have explained, on the observation of Lord Bridge in *Sidaway* that when questioned specifically by a patient about risks, it is the doctor's duty to answer truthfully and as fully as the questioner requires. The Lord Ordinary had rejected Mrs Montgomery's evidence that she had repeatedly asked Dr McLellan about the risks of vaginal delivery. But it was argued on her behalf that her undisputed expression to her doctor of concerns about the size of her baby, and her ability to deliver the baby vaginally, was in substance a request for information about the risks involved in her delivering the baby vaginally, and was equally apt to trigger a duty to advise of the risks.
33. This argument was also rejected. Lord Eassie stated that "communication of general anxieties or concerns, in a manner which does not clearly call for the full and honest disclosure of factual information in reply, falls short of qualifying under Lord Bridge's observation". Mrs Montgomery's concerns had been of a general nature only. Unlike specific questioning, general concerns set no obvious parameters for a required response. "Too much in the way of information ... may only serve to confuse or alarm the patient, and it is therefore very much a question for the experienced practitioner to decide, in accordance with normal and proper practice, where the line should be drawn in a given case".

34. Since the Lord Ordinary and the Extra Division both found that Dr McLellan owed no duty to Mrs Montgomery to advise her of any risk associated with vaginal delivery, the question of how Mrs Montgomery might have reacted, if she had been advised of the risks, did not arise. Both the Lord Ordinary and the Extra Division nevertheless dealt with the matter. The relevant question, as they saw it, was whether Mrs Montgomery had established that, had she been advised of the very small risks of grave adverse consequences arising from shoulder dystocia, she would have chosen to have a caesarean section and thus avoided the injury to the baby.
35. The Lord Ordinary described the evidence in relation to this matter as being in fairly short compass, and said that “it is as follows”. He then quoted the passage in Mrs Montgomery’s evidence which we have narrated at para 18. Mrs Montgomery was not challenged on this evidence. Notwithstanding that, the Lord Ordinary did not accept her evidence. He considered that because (1) the risk of a grave adverse outcome from shoulder dystocia was “minimal”, (2) the risks of an elective caesarean section would also have been explained to her, (3) Dr McLellan would have continued to advocate a vaginal delivery, and (4) Mrs Montgomery said in evidence that she was “not arrogant enough to demand a caesarean section” when it had not been offered to her, she would not have elected to have that procedure, even if she knew of the risks of shoulder dystocia.
36. Before the Extra Division, counsel pointed out that the Lord Ordinary had purported to narrate the entire evidence bearing on this issue, but had omitted any reference to the evidence given by Dr McLellan that had she raised the risk of shoulder dystocia with Mrs Montgomery, “then yes, she would have no doubt requested a caesarean section, as would any diabetic today”. Lord Eassie considered however that this evidence was given in the context of a discussion about “professional practice in the matter of advising of the risks of shoulder dystocia, rather than a focused consideration of the likely attitude and response of the pursuer as a particular individual”. The fact that the Lord Ordinary did not refer to this evidence did not, in Lord Eassie’s view, betoken a failure to take into account material and significant evidence. As Lord Simonds had observed in *Thomas v Thomas* 1947 SC (HL) 45, 61; [1947] AC 484, 492, an appellate court was “entitled and bound, unless there is compelling reason to the contrary, to assume that [the trial judge] has taken the whole of the evidence into his consideration”.
37. An alternative argument was advanced on behalf of Mrs Montgomery on the issue of causation. It was submitted that the response which the patient would have given to advice about risks, had she received it, should not be determinative. It was sufficient that a risk of grave adverse consequences, of which there was *ex hypothesi* a duty to advise, had in fact materialised. This

submission was based on the House of Lords decision in *Chester v Afshar*. That was a case where the patient had undergone elective surgery which carried a small risk of cauda equina syndrome, about which she had not been advised. She developed the condition. The judge at first instance found that, had the claimant been advised of the risk, as she ought to have been, she would have sought advice on alternatives and the operation would not have taken place when it did. She might have agreed to surgery at a future date, in which event the operation would have involved the same small risk of cauda equina syndrome. The House of Lords held by a majority that causation was established.

38. The Lord Ordinary declined to apply the approach adopted in *Chester v Afshar*, on the basis that the instant case was materially different on its facts. Lord Eassie also distinguished *Chester* from the present case. The birth of a baby could not be deferred: one was “not in the area of truly elective surgery”. Moreover, there was a specific, positive finding that Mrs Montgomery would not have elected to undergo a caesarean section if she had been warned about the risk of shoulder dystocia.

Sidaway

39. In *Maynard v West Midlands Regional Health Authority* [1984] 1 WLR 634, 638, the House of Lords approved the dictum of Lord President Clyde in *Hunter v Hanley* 1955 SC 200, 205, that the true test for establishing negligence in diagnosis or treatment on the part of a doctor is whether she has been proved to be guilty of such failure as no doctor of ordinary skill would be guilty of if acting with ordinary care. Lord Scarman, in a speech with which the other members of the House agreed, stated (*ibid*):

“A case which is based on an allegation that a fully considered decision of two consultants in the field of their special skill was negligent clearly presents certain difficulties of proof. It is not enough to show that there is a body of competent professional opinion which considers that theirs was a wrong decision, if there also exists a body of professional opinion, equally competent, which supports the decision as reasonable in the circumstances. It is not enough to show that subsequent events show that the operation need never have been performed, if at the time the decision to operate was taken it was reasonable in the sense that a responsible body of medical opinion would have accepted it as proper.”

40. In that part of his speech, Lord Scarman followed the approach adopted in *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582, a case concerned with advice as well as with diagnosis and treatment, where McNair J directed the jury that a doctor was not guilty of negligence if she had acted in accordance with a practice accepted as proper by a responsible body of medical practitioners skilled in that particular art. The question whether the same approach should be applied (as it had been, in *Bolam* itself) in relation to a failure to advise a patient of risks involved in treatment was considered by the House of Lords in *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* which was, of course, decided in 1985, two years after the *Maynard* decision.

41. In *Sidaway's* case this question was approached by the members of the House in different ways, but with a measure of overlap. At one end of the spectrum was Lord Diplock, who considered that any alleged breach of a doctor's duty of care towards his patient, whether it related to diagnosis, treatment or advice, should be determined by applying the *Bolam* test:

“The merit of the *Bolam* test is that the criterion of the duty of care owed by a doctor to his patient is whether he has acted in accordance with a practice accepted as proper by a body of responsible and skilled medical opinion To decide what risks the existence of which a patient should be voluntarily warned and the terms in which such warning, if any, should be given, having regard to the effect that the warning may have, is as much an exercise of professional skill and judgment as any other part of the doctor's comprehensive duty of care to the individual patient, and expert medical evidence on this matter should be treated in just the same way. The *Bolam* test should be applied.” (pp 893, 895)

42. Lord Diplock provided some reassurance to members of the judiciary:

“But when it comes to warning about risks, the kind of training and experience that a judge will have undergone at the Bar makes it natural for him to say (correctly) it is my right to decide whether any particular thing is done to my body, and I want to be fully informed of any risks there may be involved of which I am not already aware from my general knowledge as a highly educated man of experience, so that I may form my own judgment as to whether to refuse the advised treatment or not.

No doubt if the patient in fact manifested this attitude by means of questioning, the doctor would tell him whatever it was the patient wanted to know ...” (p 895)

There was on the other hand no obligation to provide patients with unsolicited information about risks:

“The only effect that mention of risks can have on the patient's mind, if it has any at all, can be in the direction of deterring the patient from undergoing the treatment which in the expert opinion of the doctor it is in the patient's interest to undergo.” (p 895)

43. At the other end of the spectrum was the speech of Lord Scarman, who took as his starting point “the patient’s right to make his own decision, which may be seen as a basic human right protected by the common law” (p 882). From that starting point, he inferred:

“If, therefore, the failure to warn a patient of the risks inherent in the operation which is recommended does constitute a failure to respect the patient’s right to make his own decision, I can see no reason in principle why, if the risk materialises and injury or damage is caused, the law should not recognise and enforce a right in the patient to compensation by way of damages.” (pp 884-885)

44. In other words, if (1) the patient suffers damage, (2) as a result of an undisclosed risk, (3) which would have been disclosed by a doctor exercising reasonable care to respect her patient’s right to decide whether to incur the risk, and (4) the patient would have avoided the injury if the risk had been disclosed, then the patient will in principle have a cause of action based on negligence.

45. Lord Scarman pointed out that the decision whether to consent to the treatment proposed did not depend solely on medical considerations:

“The doctor's concern is with health and the relief of pain. These are the medical objectives. But a patient may well have in mind circumstances, objectives, and values which he may reasonably not make known to the doctor but which may lead

him to a different decision from that suggested by a purely medical opinion.” (pp 885-886)

46. This is an important point. The relative importance attached by patients to quality as against length of life, or to physical appearance or bodily integrity as against the relief of pain, will vary from one patient to another. Countless other examples could be given of the ways in which the views or circumstances of an individual patient may affect their attitude towards a proposed form of treatment and the reasonable alternatives. The doctor cannot form an objective, “medical” view of these matters, and is therefore not in a position to take the “right” decision as a matter of clinical judgment.
47. In Lord Scarman’s view, if one considered the scope of the doctor's duty by beginning with the right of the patient to make her own decision whether she would or would not undergo the treatment proposed, it followed that the doctor was under a duty to inform the patient of the material risks inherent in the treatment. A risk was material, for these purposes, if a reasonably prudent patient in the situation of the patient would think it significant. The doctor could however avoid liability for injury resulting from the occurrence of an undisclosed risk if she could show that she reasonably believed that communication to the patient of the existence of the risk would be detrimental to the health (including the mental health) of her patient.
48. It followed from that approach that medical evidence would normally be required in order to establish the magnitude of a risk and the seriousness of the possible injury if it should occur. Medical evidence would also be necessary to assist the court to decide whether a doctor who withheld information because of a concern about its effect upon the patient’s health was justified in that assessment. The determination of the scope of the doctor’s duty, and the question whether she had acted in breach of her duty, were however ultimately legal rather than medical in character.
49. Lord Scarman summarised his conclusions as follows (pp 889-890):

“To the extent that I have indicated I think that English law must recognise a duty of the doctor to warn his patient of risk inherent in the treatment which he is proposing; and especially so, if the treatment be surgery. The critical limitation is that the duty is confined to material risk. The test of materiality is whether in the circumstances of the particular case the court is satisfied that a reasonable person in the patient's position would be likely to attach significance to the risk. Even if the risk be

material, the doctor will not be liable if upon a reasonable assessment of his patient's condition he takes the view that a warning would be detrimental to his patient's health.”

50. Lord Bridge of Harwich, with whom Lord Keith of Kinkel agreed, accepted that a conscious adult patient of sound mind is entitled to decide for herself whether or not she will submit to a particular course of treatment proposed by the doctor. He recognised the logical force of the North American doctrine of informed consent, but regarded it as impractical in application. Like Lord Diplock, he emphasised patients’ lack of medical knowledge, their vulnerability to making irrational judgments, and the role of “clinical judgment” in assessing how best to communicate to the patient the significant factors necessary to enable the patient to make an informed decision (p 899).
51. Lord Bridge was also unwilling to accept without qualification the distinction drawn by the Supreme Court of Canada, in *Reibl v Hughes* [1980] 2 SCR 880, between cases where the question is whether the doctor treated the patient in accordance with acceptable professional standards and cases concerned with the patient’s right to know what risks are involved in undergoing treatment. In Lord Bridge’s view, “a decision what degree of disclosure of risks is best calculated to assist a particular patient to make a rational choice as to whether or not to undergo a particular treatment must primarily be a matter of clinical judgment” (p 900). It followed that the question whether non-disclosure of risks was a breach of the doctor’s duty of care was an issue “to be decided *primarily* on the basis of expert medical evidence, applying the *Bolam* test” (p 900; emphasis supplied).
52. Nevertheless, his Lordship qualified his adherence to the *Bolam* test in this context in a way which narrowed the gap between his position and that of Lord Scarman:

“But even in a case where, as here, no expert witness in the relevant medical field condemns the non-disclosure as being in conflict with accepted and responsible medical practice, I am of opinion that the judge might in certain circumstances come to the conclusion that disclosure of a particular risk was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it. The kind of case I have in mind would be an operation involving a substantial risk of grave adverse consequences, as, for example, the ten per cent risk of a stroke from the operation which was the subject of the Canadian case of *Reibl v Hughes*, 114 DLR (3d) 1. In such a case, in the absence of some cogent

clinical reason why the patient should not be informed, a doctor, recognising and respecting his patient's right of decision, could hardly fail to appreciate the necessity for an appropriate warning.” (p 900)

53. In relation to this passage, attention has tended to focus on the words “a substantial risk of grave adverse consequences”; and, in the present case, it was on those words that both the Lord Ordinary and the Extra Division concentrated. It is however important to note that Lord Bridge was merely giving an example (“The kind of case I have in mind would be ...”) to illustrate the general proposition that “disclosure of a particular risk [may be] so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it”. In relation to that proposition, it is also important to note, having regard to the last sentence in the passage quoted, that the standard is that of a doctor who recognises and respects his patient’s right of decision and is exercising reasonable care (ie is “reasonably prudent”). Reading the passage as a whole, therefore, the question for the judge is whether disclosure of a risk was so obviously necessary to an informed choice on the part of the patient that no doctor who recognised and respected his patient’s right of decision and was exercising reasonable care would fail to make it. So understood, Lord Bridge might be thought to arrive at a position not far distant from that of Lord Scarman.

54. Lord Bridge also said (at p 898):

“I should perhaps add at this point, although the issue does not strictly arise in this appeal, that, when questioned specifically by a patient of apparently sound mind about risks involved in a particular treatment proposed, the doctor's duty must, in my opinion, be to answer both truthfully and as fully as the questioner requires.”

55. Lord Templeman implicitly rejected the *Bolam* test, and approached the issue on the basis of an orthodox common law analysis. He noted, like Lord Diplock and Lord Bridge, the imbalance between the knowledge and objectivity of the doctor and the ignorance and subjectivity of the patient, but accepted that it was the right of the patient to decide whether or not to submit to treatment recommended by the doctor, and even to make an unbalanced and irrational judgment (p 904). In contract, it followed from the patient’s right to decide whether to accept proposed treatment that “the doctor impliedly contracts to provide information which is adequate to enable the patient to reach a balanced judgment, subject always to the doctor’s own obligation to say and do nothing which the doctor is satisfied will be harmful

to the patient” (p 904). The obligation of the doctor “to have regard to the best interests of the patient but at the same time to make available to the patient sufficient information to enable the patient to reach a balanced judgment” (pp 904-905) also arose as a matter of a duty of care. Lord Templeman’s formulation of the doctor’s duty was, like Lord Scarman’s, not confined to the disclosure of risks: the discussion of “the possible methods of treatment” (p 904), and therefore of reasonable alternatives to the treatment recommended, is also necessary if the patient is to reach a balanced judgment.

56. Lord Templeman thus arrived, by a different route, at an outcome not very different from that of Lord Scarman. Although Lord Scarman drew on the language of human rights, his reasoning was in substance the same as Lord Templeman’s: the doctor’s duty of care followed from the patient’s right to decide whether to undergo the treatment recommended.
57. It would therefore be wrong to regard *Sidaway* as an unqualified endorsement of the application of the *Bolam* test to the giving of advice about treatment. Only Lord Diplock adopted that position. On his approach, the only situation, other than one covered by the *Bolam* test, in which a doctor would be under a duty to provide information to a patient would be in response to questioning by the patient.
58. The significance attached in *Sidaway* to a patient’s failure to question the doctor is however profoundly unsatisfactory. In the first place, as Sedley LJ commented in *Wyatt v Curtis* [2003] EWCA Civ 1779, there is something unreal about placing the onus of asking upon a patient who may not know that there is anything to ask about. It is indeed a reversal of logic: the more a patient knows about the risks she faces, the easier it is for her to ask specific questions about those risks, so as to impose on her doctor a duty to provide information; but it is those who lack such knowledge, and who are in consequence unable to pose such questions and instead express their anxiety in more general terms, who are in the greatest need of information. Ironically, the ignorance which such patients seek to have dispelled disqualifies them from obtaining the information they desire. Secondly, this approach leads to the drawing of excessively fine distinctions between questioning, on the one hand, and expressions of concern falling short of questioning, on the other hand: a problem illustrated by the present case. Thirdly, an approach which requires the patient to question the doctor disregards the social and psychological realities of the relationship between a patient and her doctor, whether in the time-pressured setting of a GP’s surgery, or in the setting of a hospital. Few patients do not feel intimidated or inhibited to some degree.

59. There is also a logical difficulty inherent in this exception to the *Bolam* test, as the High Court of Australia pointed out in *Rogers v Whitaker* (1992) 175 CLR 479, 486-487. Why should the patient's asking a question make any difference in negligence, if medical opinion determines whether the duty of care requires that the risk should be disclosed? The patient's desire for the information, even if made known to the doctor, does not alter medical opinion. The exception, in other words, is logically destructive of the supposed rule. Medical opinion might of course accept that the information should be disclosed in response to questioning, but there would then be no exception to the *Bolam* test.
60. Lord Bridge's other qualification of the *Bolam* test achieves an uneasy compromise, describing the issue as one to be decided "primarily" by applying the *Bolam* test, but allowing the judge to decide "that disclosure of a particular risk was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it", the reasonably prudent medical man being "a doctor, recognising and respecting his patient's right of decision".
61. Superficially, this resembles the qualification of the *Bolam* test subsequently stated by Lord Browne-Wilkinson in *Bolitho v City and Hackney Health Authority* [1998] AC 232, 243: that notwithstanding the views of medical experts, the court may conclude that their opinion is incapable of withstanding logical analysis. Lord Browne-Wilkinson however expressly confined his observations to cases of diagnosis and treatment, as distinct from disclosure of risk. In cases of the former kind, the court is concerned with matters of medical skill and judgment, and does not usually find a doctor guilty of negligence if she has followed a practice accepted as proper by a responsible body of doctors skilled in the relevant field. That is however subject to Lord Browne-Wilkinson's qualification where the court is satisfied that the professional practice in question does not meet a reasonable standard of care. In cases concerned with advice, on the other hand, the application of the *Bolam* test is predicated on the view that the advice to be given to the patient is an aspect of treatment, falling within the scope of clinical judgment. The "informed choice" qualification rests on a fundamentally different premise: it is predicated on the view that the patient is entitled to be told of risks where that is necessary for her to make an informed decision whether to incur them.
62. The inherent instability of Lord Bridge's qualification of the *Bolam* test has been reflected in a tendency among some judges to construe it restrictively, as in the present case, by focusing on the particular words used by Lord Bridge when describing the kind of case he had in mind ("a substantial risk of grave adverse consequences"), and even on the particular example he gave

(which involved a 10% risk of a stroke), rather than on the principle which the example was intended to illustrate.

The subsequent case law

63. In the present case, as in earlier cases, the Court of Session applied the *Bolam* test, subject to the qualifications derived from Lord Bridge's speech. In England and Wales, on the other hand, although *Sidaway's* case remains binding, lower courts have tacitly ceased to apply the *Bolam* test in relation to the advice given by doctors to their patients, and have effectively adopted the approach of Lord Scarman.

64. The case of *Pearce v United Bristol Healthcare NHS Trust* [1999] PIQR P 53 is particularly significant in this context. The case concerned an expectant mother whose baby had gone over term. Her consultant obstetrician took the view that the appropriate course was for her to have a normal delivery when nature took its course, rather than a caesarean section at an earlier date, and advised her accordingly. In the event, the baby died *in utero*. The question was whether the mother ought to have been warned of that risk. In a judgment with which Roch and Mummery LJ agreed, Lord Woolf MR said (para 21):

“In a case where it is being alleged that a plaintiff has been deprived of the opportunity to make a proper decision as to what course he or she should take in relation to treatment, it seems to me to be the law, as indicated in the cases to which I have just referred, that if there is a significant risk which would affect the judgment 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 he or she should adopt.”

65. In support of that approach, the Master of the Rolls referred in particular to the passage from Lord Bridge's speech in *Sidaway* which we have quoted at para 52. In Lord Bridge's formulation, as we have explained, the question for the judge was whether disclosure of a risk was so obviously necessary to an informed choice on the part of the patient that no doctor who recognised and respected his patient's right of decision and was exercising reasonable care would fail to make it. In our view, the Master of the Rolls was correct to consider that “a significant risk which would affect the judgment of a reasonable patient” would meet that test. Lord Woolf's approach is also consistent with that adopted in *Sidaway* by Lord Templeman (“information

which is adequate to enable the patient to reach a balanced judgment”), as well as with the test favoured by Lord Scarman (“that a reasonable person in the patient's position would be likely to attach significance to the risk”). It does not, on the other hand, have anything to do with the *Bolam* test.

66. The Extra Division correctly pointed out in the present case that Lord Woolf spoke of a “significant” risk, whereas Lord Bridge, when describing the kind of case he had in mind, had referred to a “substantial” risk. In so far as “significant” and “substantial” have different shades of meaning, “significant” is the more apt adjective. Lord Bridge accepted that a risk had to be disclosed where it was “obviously necessary to an informed choice”; and the relevance of a risk to the patient’s decision does not depend solely upon its magnitude, or upon a medical assessment of its significance.
67. The point is illustrated by the case of *Wyatt v Curtis* [2003] EWCA Civ 1779, which concerned the risk of around 1% that chickenpox during pregnancy might result in significant brain damage. The Court of Appeal applied the law as stated in *Pearce*, observing that it was no less binding on the court than *Sidaway*. Sedley LJ stated:

“Lord Woolf’s formulation refines Lord Bridge's test by recognising that what is substantial and what is grave are questions on which the doctor's and the patient's perception may differ, and in relation to which the doctor must therefore have regard to what may be the patient's perception. To the doctor, a chance in a hundred that the patient's chickenpox may produce an abnormality in the foetus may well be an insubstantial chance, and an abnormality may in any case not be grave. To the patient, a new risk which (as I read the judge's appraisal of the expert evidence) doubles, or at least enhances, the background risk of a potentially catastrophic abnormality may well be both substantial and grave, or at least sufficiently real for her to want to make an informed decision about it.”
(para 16)

68. It is also relevant to note the judgments in *Chester v Afshar*. The case was concerned with causation, but it contains relevant observations in relation to the duty of a doctor to advise a patient of risks involved in proposed treatment. Lord Bingham of Cornhill said that the doctor in question had been under a duty to warn the patient of a small (1%-2%) risk that the proposed operation might lead to a seriously adverse result. The rationale of the duty, he said, was “to enable adult patients of sound mind to make for themselves decisions intimately affecting their own lives and bodies” (para 5). Lord

Steyn cited with approval para 21 of Lord Woolf MR's judgment in *Pearce*. Lord Walker of Gestingthorpe referred to a duty to advise the patient, a warning of risks being an aspect of the advice (para 92). He also observed at para 92 that during the 20 years which had elapsed since *Sidaway's* case, the importance of personal autonomy had been more and more widely recognised. He added at para 98 that, in making a decision which might have a profound effect on her health and well-being, a patient was entitled to information and advice about possible alternative or variant treatments.

69. In more recent case law the English courts have generally treated Lord Woolf MR's statement in *Pearce* as the standard formulation of the duty to disclose information to patients, although some unease has on occasion been expressed about the difficulty of reconciling that approach with the speeches of Lord Diplock and Lord Bridge in *Sidaway's* case (see, for example, *Birch v University College London Hospital NHS Foundation Trust* [2008] EWHC 2237 (QB)). Significantly, the guidance issued by the Department of Health and the General Medical Council has treated *Chester v Afshar* as the leading authority.

Comparative law

70. The court has been referred to case law from a number of other major common law jurisdictions. It is unnecessary to discuss it in detail. It is sufficient to note that the Supreme Court of Canada has adhered in its more recent case law to the approach adopted in *Reibl v Hughes*, and that its approach to the duty of care has been followed elsewhere, for example by the High Court of Australia in *Rogers v Whitaker* (1992) 175 CLR 479 and subsequent cases.
71. The judgment of Mason CJ, Brennan, Dawson, Toohey and McHugh JJ in *Rogers v Whitaker* identifies the basic flaw involved in approaching all aspects of a doctor's duty of care in the same way:

“Whether a medical practitioner carries out a particular form of treatment in accordance with the appropriate standard of care is a question in the resolution of which responsible professional opinion will have an influential, often a decisive, role to play; *whether* the patient has been given all the relevant information to choose between undergoing and not undergoing the treatment is a question of a different order. Generally speaking, it is not a question the answer to which depends upon medical standards or practices. Except in those cases where there is a

particular danger that the provision of all relevant information will harm an unusually nervous, disturbed or volatile patient, no special medical skill is involved in disclosing the information, including the risks attending the proposed treatment.” (pp 489-490: original emphasis)

72. The High Court of Australia in *Rogers* also reformulated the test of the materiality of a risk so as to encompass the situation in which, as the doctor knows or ought to know, the actual patient would be likely to attach greater significance to a risk than the hypothetical reasonable patient might do:

“a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.” (p 490)

73. That is undoubtedly right: the doctor's duty of care takes its precise content from the needs, concerns and circumstances of the individual patient, to the extent that they are or ought to be known to the doctor. In *Rogers v Whitaker* itself, for example, the risk was of blindness in one eye; but the plaintiff was already blind in the other eye, giving the risk a greater significance than it would otherwise have had. In addition, she had asked anxiously about risks. Expressions of concern by the patient, as well as specific questions, are plainly relevant. As Gummow J observed in *Rosenberg v Percival* (2001) 205 CLR 434, 459, courts should not be too quick to discard the second limb (ie the possibility that the medical practitioner was or ought reasonably to have been aware that the particular patient, if warned of the risk, would be likely to attach significance to it) merely because it emerges that the patient did not ask certain kinds of questions.

Conclusions on the duty of disclosure

74. The Hippocratic Corpus advises physicians to reveal nothing to the patient of her present or future condition, “for many patients through this cause have taken a turn for the worse” (*Decorum*, XVI). Around two millennia later, in *Sidaway's* case Lord Templeman said that “the provision of too much information may prejudice the attainment of the objective of restoring the patient's health” (p 904); and similar observations were made by Lord Diplock and Lord Bridge. On that view, if the optimisation of the patient's health is treated as an overriding objective, then it is unsurprising that the

disclosure of information to a patient should be regarded as an aspect of medical care, and that the extent to which disclosure is appropriate should therefore be treated as a matter of clinical judgment, the appropriate standards being set by the medical profession.

75. Since *Sidaway*, however, it has become increasingly clear that the paradigm of the doctor-patient relationship implicit in the speeches in that case has ceased to reflect the reality and complexity of the way in which healthcare services are provided, or the way in which the providers and recipients of such services view their relationship. One development which is particularly significant in the present context is that patients 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. In addition, a wider range of healthcare professionals now provide treatment and advice of one kind or another to members of the public, either as individuals, or as members of a team drawn from different professional backgrounds (with the consequence that, although this judgment is concerned particularly with doctors, it is also relevant, *mutatis mutandis*, to other healthcare providers). The treatment which they can offer is now understood to depend not only upon their clinical judgment, but upon bureaucratic decisions as to such matters as resource allocation, cost-containment and hospital administration: decisions which are taken by non-medical professionals. Such decisions are generally understood within a framework of institutional rather than personal responsibilities, and are in principle susceptible to challenge under public law rather than, or in addition to, the law of delict or tort.

76. Other changes in society, and in the provision of healthcare services, should also be borne in mind. One which is particularly relevant in the present context is that it has become far easier, and far more common, for members of the public to obtain information about symptoms, investigations, treatment options, risks and side-effects via such media as the internet (where, although the information available is of variable quality, reliable sources of information can readily be found), patient support groups, and leaflets issued by healthcare institutions. The labelling of pharmaceutical products and the provision of information sheets is a further example, which is of particular significance because it is required by laws premised on the ability of the citizen to comprehend the information provided. It would therefore be a mistake to view patients as uninformed, incapable of understanding medical matters, or wholly dependent upon a flow of information from doctors. The idea that patients were medically uninformed and incapable of understanding medical matters was always a questionable generalisation, as Lord Diplock implicitly acknowledged by making an exception for highly educated men of

experience. To make it the default assumption on which the law is to be based is now manifestly untenable.

77. These developments in society are reflected in professional practice. The court has been referred in particular to the guidance given to doctors by the General Medical Council, who participated as interveners in the present appeal. One of the documents currently in force (*Good Medical Practice* (2013)) states, under the heading “The duties of a doctor registered with the General Medical Council”:

“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.”

78. Another current document (*Consent: patients and doctors making decisions together* (2008)) describes a basic model of partnership between doctor and patient:

“The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept their advice. The patient weighs up the potential benefits, risks and burdens of the various options as well as any non-clinical issues that are relevant to them. The patient decides whether to accept any of the options and, if so, which one.” (para 5)

In relation to risks, in particular, the document advises that the doctor must tell patients if treatment might result in a serious adverse outcome, even if the risk is very small, and should also tell patients about less serious complications if they occur frequently (para 32). The submissions on behalf of the General Medical Council acknowledged, in relation to these documents, that an approach based upon the informed involvement of patients in their treatment, rather than their being passive and potentially reluctant recipients, can have therapeutic benefits, and is regarded as an integral aspect of professionalism in treatment.

79. Earlier editions of these documents (*Good Medical Practice* (1998), and *Seeking patients' consent: The ethical considerations* (1998)), in force at the time of the events with which this case is concerned, were broadly to similar effect. No reference was made to them however in the proceedings before the Court of Session.
80. In addition to these developments in society and in medical practice, there have also been developments in the law. Under the stimulus of the Human Rights Act 1998, the courts have become increasingly conscious of the extent to which the common law reflects fundamental values. As Lord Scarman pointed out in *Sidaway's* case, these include the value of self-determination (see, for example, *S (An Infant) v S* [1972] AC 24, 43 per Lord Reid; *McCull v Strathclyde Regional Council* 1983 SC 225, 241; *Airedale NHS Trust v Bland* [1993] AC 789, 864 per Lord Goff of Chieveley). As well as underlying aspects of the common law, that value also underlies the right to respect for private life protected by article 8 of the European Convention on Human Rights. The resulting duty to involve the patient in decisions relating to her treatment has been recognised in judgments of the European Court of Human Rights, such as *Glass v United Kingdom* (2004) EHRR 341 and *Tysiack v Poland* (2007) 45 EHRR 947, as well as in a number of decisions of courts in the United Kingdom. The same value is also reflected more specifically in other international instruments: see, in particular, article 5 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, concluded by the member states of the Council of Europe, other states and the European Community at Oviedo on 4 April 1997.
81. The social and legal developments which we have mentioned point away from a model of the relationship between the doctor and the patient based upon medical paternalism. They also point away from a model based upon a view of the patient as being entirely dependent on information provided by the doctor. What they point towards is an approach to the law which, 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.
82. In the law of negligence, this approach entails a duty on the part of doctors to take reasonable care to ensure that a patient is aware of material risks of injury that are inherent in treatment. This can be understood, within the traditional framework of negligence, as a duty of care to avoid exposing a

person to a risk of injury which she would otherwise have avoided, but it is also the counterpart of the patient's entitlement to decide whether or not to incur that risk. The existence of that entitlement, and the fact that its exercise does not depend exclusively on medical considerations, are important. They point to a fundamental distinction between, on the one hand, the doctor's role when considering possible investigatory or treatment options and, on the other, her role in discussing with the patient any recommended treatment and possible alternatives, and the risks of injury which may be involved.

83. The former role is an exercise of professional skill and judgment: what risks of injury are involved in an operation, for example, is a matter falling within the expertise of members of the medical profession. But it is a *non sequitur* to conclude that the question whether a risk of injury, or the availability of an alternative form of treatment, ought to be discussed with the patient is also a matter of purely professional judgment. The doctor's advisory role cannot be regarded as solely an exercise of medical skill without leaving out of account the patient's entitlement to decide on the risks to her health which she is willing to run (a decision which may be influenced by non-medical considerations). Responsibility for determining the nature and extent of a person's rights rests with the courts, not with the medical professions.
84. Furthermore, because the extent to which a doctor may be inclined to discuss risks with a patient is not determined by medical learning or experience, the application of the *Bolam* test to this question is liable to result in the sanctioning of differences in practice which are attributable not to divergent schools of thought in medical science, but merely to divergent attitudes among doctors as to the degree of respect owed to their patients.
85. A person can of course decide that she does not wish to be informed of risks of injury (just as a person may choose to ignore the information leaflet enclosed with her medicine); and a doctor is not obliged to discuss the risks inherent in treatment with a person who makes it clear that she would prefer not to discuss the matter. Deciding whether a person is so disinclined may involve the doctor making a judgment; but it is not a judgment which is dependent on medical expertise. It is also true that the doctor must necessarily make a judgment as to how best to explain the risks to the patient, and that providing an effective explanation may require skill. But the skill and judgment required are not of the kind with which the *Bolam* test is concerned; and the need for that kind of skill and judgment does not entail that the question whether to explain the risks at all is normally a matter for the judgment of the doctor. That is not to say that the doctor is required to make disclosures to her patient if, in the reasonable exercise of medical judgment, she considers that it would be detrimental to the health of her patient to do

so; but the “therapeutic exception”, as it has been called, cannot provide the basis of the general rule.

86. 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. It is unsurprising that courts have found difficulty in the subsequent application of *Sidaway*, and that the courts in England and Wales have in reality departed from it; a position which was effectively endorsed, particularly by Lord Steyn, in *Chester v Afshar*. There is no reason to perpetuate the application of the *Bolam* test in this context any longer.
87. The correct position, in relation to the risks of injury involved in treatment, can now be seen to be substantially that adopted in *Sidaway* by Lord Scarman, and by Lord Woolf MR in *Pearce*, subject to the refinement made by the High Court of Australia in *Rogers v Whitaker*, which we have discussed at paras 77-73. An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. 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.
88. 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.
89. Three further points should be made. First, 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.

90. Secondly, 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.
91. Thirdly, 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.
92. There are, of course, arguments which can be advanced against this approach: for example, that some patients would rather trust their doctors than be informed of all the ways in which their treatment might go wrong; that it is impossible to discuss the risks associated with a medical procedure within the time typically available for a healthcare consultation; that the requirements imposed are liable to result in defensive practices and an increase in litigation; and that the outcome of such litigation may be less predictable.
93. The first of these points has been addressed in para 85 above. In relation to the second, the guidance issued by the General Medical Council has long required a broadly similar approach. It is nevertheless necessary to impose legal obligations, so that even those doctors who have less skill or inclination for communication, or who are more hurried, are obliged to pause and engage in the discussion which the law requires. This may not be welcomed by some healthcare providers; but the reasoning of the House of Lords in *Donoghue v Stevenson* [1932] AC 562 was no doubt received in a similar way by the manufacturers of bottled drinks. The approach which we have described has long been operated in other jurisdictions, where healthcare practice presumably adjusted to its requirements. In relation to the third point, in so far as the law contributes to the incidence of litigation, 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. In relation to the fourth point, we would accept that a departure from the *Bolam* test will reduce the predictability of the outcome of litigation, given the difficulty of overcoming that test in contested proceedings. It appears to us however that a degree of unpredictability can be tolerated as the consequence of protecting patients from exposure to risks of injury which they would otherwise have chosen to avoid. The more fundamental response to such points, however, is that respect for the dignity of patients requires no less.

The disclosure of risks in the present case

94. Approaching the present case on this basis, there can be no doubt that it was incumbent on Dr McLellan to advise Mrs Montgomery of the risk of shoulder dystocia if she were to have her baby by vaginal delivery, and to discuss with her the alternative of delivery by caesarean section. The Court of Session focused upon the consequent risk that the baby might suffer a grave injury, a risk which was relatively small. The risk of shoulder dystocia, on the other hand, was substantial: on the evidence, around 9-10%. Applying the approach which we have described, the exercise of reasonable care undoubtedly required that it should be disclosed. Quite apart from the risk of injury to the baby (a risk of about 1 in 500 of a brachial plexus injury, and a much smaller risk of a more severe injury, such as cerebral palsy, or death), it is apparent from the evidence (summarised at paras 8-12 and 21 above) that shoulder dystocia is itself a major obstetric emergency, requiring procedures which may be traumatic for the mother, and involving significant risks to her health. No woman would, for example, be likely to face the possibility of a fourth degree tear, a Zavanelli manoeuvre or a symphysiotomy with equanimity. The contrast of the risk involved in an elective caesarean section, for the mother extremely small and for the baby virtually non-existent, is stark and illustrates clearly the need for Mrs Montgomery to be advised of the possibility, because of her particular circumstances, of shoulder dystocia. This conclusion is reinforced by Dr McLellan's own evidence (summarised at paras 13 and 19 above), that she was aware that the risk of shoulder dystocia was likely to affect the decision of a patient in Mrs Montgomery's position, and that Mrs Montgomery herself was anxious about her ability to deliver the baby vaginally.
95. There is no question in this case of Dr McLellan's being entitled to withhold information about the risk because its disclosure would be harmful to her patient's health. Although her evidence indicates that it was her policy to

withhold information about the risk of shoulder dystocia from her patients because they would otherwise request caesarean sections, the “therapeutic exception” is not intended to enable doctors to prevent their patients from taking an informed decision. Rather, it is the doctor’s responsibility to explain to her patient why she considers that one of the available treatment options is medically preferable to the others, having taken care to ensure that her patient is aware of the considerations for and against each of them.

Causation

96. As we have explained, the Lord Ordinary found that, even if Mrs Montgomery had been informed of the risk of shoulder dystocia and had been told of the alternative of a caesarean section, she would not have elected to undergo that procedure. That finding was upheld by the Extra Division.

97. This court has reiterated in a number of recent cases, including *McGraddie v McGraddie* [2013] UKSC 58; 2014 SC (UKSC) 12; [2013] 1 WLR 2477 and *Henderson v Foxworth Investments Ltd* [2014] UKSC 41; 2014 SLT 775; [2014] 1 WLR 2600, that appellate courts should exercise restraint in reversing findings of fact made at first instance. As was said in *Henderson’s* case at para 67,

“in the absence of some other identifiable error, such as (without attempting an exhaustive account) a material error of law, or the making of a critical finding of fact which has no basis in the evidence, or a demonstrable misunderstanding of relevant evidence, or a demonstrable failure to consider relevant evidence, an appellate court will interfere with the findings of fact made by a trial judge only if it is satisfied that his decision cannot reasonably be explained or justified.”

It is in addition only in comparatively rare cases that this court interferes with concurrent findings of fact by lower courts. As Lord Jauncey of Tullichettle explained in *Higgins v J & C M Smith (Whiteinch) Ltd* 1990 SC (HL) 63, 82:

“Where there are concurrent findings of fact in the courts below generally this House will interfere with those findings only where it can be shown that both courts were clearly wrong.”

98. As has been observed in the Australian case law, the issue of causation, where an undisclosed risk has materialised, is closely tied to the identification of the

particular risk which ought to have been disclosed. In the present case, the Lord Ordinary focused on the risk of a severe injury to the baby, and said, in relation to causation:

“I have already said that the real risk of grave consequences arising should shoulder dystocia occur were very small indeed. Given the very small risks the first question must be for the court: has the pursuer established on the basis of the ‘but for’ test, a link between the failure to advise her of *said risks* and damage to the child. Or to put the matter another way, has the pursuer established that had she been advised of *the said risks* she would have chosen a caesarean section and thus avoided the damage to the child?” (emphasis supplied)

99. As we have explained, the Lord Ordinary described the evidence in relation to that matter as being in short compass, and said that “it is as follows”. He then quoted the passage in Mrs Montgomery’s evidence which we have narrated at para 18. Having rejected that evidence as unreliable, he accordingly found that causation had not been established.
100. Like the Lord Ordinary, the Extra Division approached the question of causation on the basis that the relevant issue was “what [Mrs Montgomery] would have done if advised of the risk of grave consequences arising should shoulder dystocia occur”, rather than what she would have done if advised of the risk of shoulder dystocia, and of the potential consequences of that complication. As we have explained, counsel pointed out that the Lord Ordinary had purported to narrate the entire evidence bearing on the issue, but had omitted any reference to the evidence given by Dr McLellan that had she raised the risk of shoulder dystocia with Mrs Montgomery, “then yes, she would have no doubt requested a caesarean section, as would any diabetic today” (para 19 above). The Extra Division observed that that evidence had been given in the context of a discussion about professional practice in relation to advising of the risks of shoulder dystocia, rather than a focused consideration of the likely attitude and response of Mrs Montgomery.
101. That particular piece of evidence did not however stand alone. It was consistent with the evidence given by Dr McLellan to the effect that diabetic women in general would request an elective caesarean section if made aware of the risk of shoulder dystocia (para 13 above). Her position was that it was precisely because most women would elect to have a caesarean section if informed of the risk of shoulder dystocia (contrary, in her view, to their best interests), that she withheld that information from them. That was also consistent with the evidence of the Board’s expert witness, Dr Gerald Mason,

that if doctors were to warn women at risk of shoulder dystocia, “you would actually make most women simply request caesarean section” (para 25 above).

102. The Lord Ordinary’s failure to refer to any of this evidence does not in our view fall within the scope of Lord Simonds’s dictum in *Thomas v Thomas* 1947 SC (HL) 45, 61, that an appellate court is “entitled and bound, unless there is compelling reason to the contrary, to assume that [the trial judge] has taken the whole of the evidence into his consideration”. That is an important observation, but it is subject to the qualification, “unless there is compelling reason to the contrary”. In the present case, the Lord Ordinary not only failed to refer to any of this evidence, but also made the positive statement that “The evidence in relation to the [issue of causation] is in fairly short compass. It is as follows ...” before quoting only the passage from the evidence of Mrs Montgomery. The apparent implication of that statement was that there was no other relevant evidence. Those circumstances constitute a compelling reason for concluding that there was a failure by the Lord Ordinary to consider relevant evidence; a failure which also affected the decision of the Extra Division.
103. More fundamentally, however, the consequence of our holding that there was a duty to advise Mrs Montgomery of the risk of shoulder dystocia, and to discuss with her the potential implications and the options open to her, is that the issue of causation has to be considered on a different footing from that on which it was approached by the Lord Ordinary and the Extra Division. They had in mind the supposed reaction of Mrs Montgomery if she had been advised of the minimal risk of a grave consequence. The question should properly have been addressed as to Mrs Montgomery’s likely reaction if she had been told of the risk of shoulder dystocia. On that question, we have Dr McLellan’s unequivocal view that Mrs Montgomery would have elected to have a caesarean section. The question of causation must also be considered on the hypothesis of a discussion which is conducted without the patient’s being pressurised to accept her doctor’s recommendation. In these circumstances, there is really no basis on which to conclude that Mrs Montgomery, if she had been advised of the risk of shoulder dystocia, would have chosen to proceed with a vaginal delivery.
104. Approaching the issue of causation in that way, we have therefore concluded that the evidence points clearly in one direction. We have mentioned the passages in the evidence of Mrs Montgomery, Dr McLellan and Dr Mason in which the likely response of Mrs Montgomery, or of women in her position in general, if advised of the risk of shoulder dystocia, was discussed. We have also mentioned Dr McLellan’s evidence that Mrs Montgomery had been anxious about her ability to deliver the baby vaginally, and had expressed her

concerns to Dr McLellan more than once. Although the Lord Ordinary expressed serious reservations about the extent to which Mrs Montgomery's evidence had been affected by hindsight, he had no such misgivings about Dr McLellan: she was found to be "an impressive witness" in relation to the informed consent aspect of the case, and her evidence was "credible and reliable". In the light of that assessment, and having regard to her evidence in particular, the only conclusion that we can reasonably reach is that, had she advised Mrs Montgomery of the risk of shoulder dystocia and discussed with her dispassionately the potential consequences, and the alternative of an elective caesarean section, Mrs Montgomery would probably have elected to be delivered of her baby by caesarean section. It is not in dispute that the baby would then have been born unharmed.

105. It is unnecessary in these circumstances to consider whether, if Mrs Montgomery could not establish "but for" causation, she might nevertheless establish causation on some other basis in the light of *Chester v Afshar*.

Conclusion

106. For these reasons, we would allow the appeal.

LADY HALE:

107. In the third (2010) edition of their leading work on *Principles of Medical Law*, Andrew Grubb, Judith Laing and Jean McHale confidently announced that a detailed analysis of the different speeches of the House of Lords in *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871 was no longer necessary. A combination of the 2008 Guidance provided by the General Medical Council, the decision of the Court of Appeal in *Pearce v United Bristol Healthcare NHS Trust* [1999] PIQR P 53 and the decision of the House of Lords in *Chester v Afshar* [2005] 1 AC 134 meant that it could now be stated "with a reasonable degree of confidence" that the need for informed consent was firmly part of English law (para 8.70). This case has provided us with the opportunity, not only to confirm that confident statement, but also to make it clear that the same principles apply in Scotland.
108. It is now well recognised that the interest which the law of negligence protects is a person's interest in their own physical and psychiatric integrity, an important feature of which is their autonomy, their freedom to decide what shall and shall not be done with their body (the unwanted pregnancy cases

are an example: see *Rees v Darlington Memorial Hospital NHS Trust* [2003] UKHL 52, [2004] 1 AC 309). Thus, as Jonathan Herring puts it in *Medical Law and Ethics* (2012), 4th ed, p 170), “the issue is not whether enough information was given to ensure consent to the procedure, but whether there was enough information given so that the doctor was not acting negligently and giving due protection to the patient’s right of autonomy”.

109. An important consequence of this is that it is not possible to consider a particular medical procedure in isolation from its alternatives. Most decisions about medical care are not simple yes/no answers. There are choices to be made, arguments for and against each of the options to be considered, and sufficient information must be given so that this can be done: see the approach of the General Medical Council in *Consent: patients and doctors making decisions together* (2008), para 5, quoted by Lord Kerr and Lord Reed at para 77 and approved by them at paras 83 to 85.
110. Pregnancy is a particularly powerful illustration. Once a woman is pregnant, the foetus has somehow to be delivered. Leaving it inside her is not an option. The principal choice is between vaginal delivery and caesarean section. One is, of course, the normal and “natural” way of giving birth; the other used to be a way of saving the baby’s life at the expense of the mother’s. Now, the risks to both mother and child from a caesarean section are so low that the National Institute for Health and Clinical Excellence (NICE clinical guideline 132, [new 2011] [para 1.2.9.5]) clearly states that “For women requesting a CS, if after discussion and offer of support (including perinatal mental health support for women with anxiety about childbirth), a vaginal birth is still not an acceptable option, offer a planned CS”.
111. That is not necessarily to say that the doctors have to volunteer the pros and cons of each option in every case, but they clearly should do so in any case where either the mother or the child is at heightened risk from a vaginal delivery. In this day and age, we are not only concerned about risks to the baby. We are equally, if not more, concerned about risks to the mother. And those include the risks associated with giving birth, as well as any after-effects. One of the problems in this case was that for too long the focus was on the risks to the baby, without also taking into account what the mother might face in the process of giving birth.
112. It was well recognised in 1999 that an insulin-dependent diabetic mother could have a larger than average baby. This brings with it a 9 to 10% risk of “mechanical problems” in labour, either that the baby’s head will fail to descend or, worse still, that it will descend but the baby’s shoulders will be too broad to follow the head through the birth canal and will therefore get

stuck. Desperate manoeuvres are then required to deliver the baby. As the Royal College of Obstetricians and Gynaecologists state in their Guideline No 42 on *Shoulder Dystocia* (2005),

“There can be a high perinatal mortality and morbidity associated with the condition, even when it is managed appropriately. Maternal morbidity is also increased, particularly postpartum haemorrhage (11%) and fourth-degree perineal tears (3.8%), and their incidence remains unchanged by the manoeuvres required to effect delivery.”

No-one suggests that this was not equally well known in 1999. The risk of permanent injury to the baby is less than the risk of injury to the mother, but it includes a very small risk of catastrophic injury resulting from the deprivation of oxygen during delivery, as occurred in this case.

113. These are risks which any reasonable mother would wish to take into account in deciding whether to opt for a vaginal delivery or a caesarean section. No doubt in doing so she would take serious account of her doctor's estimation of the likelihood of these risks emerging in her case. But it is not difficult to understand why the medical evidence in this case was that, if offered a caesarean section, any insulin dependent pregnant woman would take it. What could be the benefits of vaginal delivery which would outweigh avoiding the risks to both mother and child?
114. We do not have a full transcript of the evidence, but in the extracts we do have Dr McLellan referred to explaining to a mother who requested a caesarean section “why it may not be in the mother's best interest” and later expressed the view that “it's not in the maternal interests for women to have caesarean sections”. Whatever Dr McLellan may have had in mind, this does not look like a purely medical judgment. It looks like a judgment that vaginal delivery is in some way morally preferable to a caesarean section: so much so that it justifies depriving the pregnant woman of the information needed for her to make a free choice in the matter. Giving birth vaginally is indeed a unique and wonderful experience, but it has not been suggested that it inevitably leads to a closer and better relationship between mother and child than does a caesarean section.
115. In any event, once the argument departs from purely medical considerations and involves value judgments of this sort, it becomes clear, as Lord Kerr and Lord Reed conclude at para 85, that the *Bolam* test, of conduct supported by a responsible body of medical opinion, becomes quite inapposite. A patient

is entitled to take into account her own values, her own assessment of the comparative merits of giving birth in the “natural” and traditional way and of giving birth by caesarean section, whatever medical opinion may say, alongside the medical evaluation of the risks to herself and her baby. She may place great value on giving birth in the natural way and be prepared to take the risks to herself and her baby which this entails. The medical profession must respect her choice, unless she lacks the legal capacity to decide (*St George’s Healthcare NHS Trust v S* [1999] Fam 26). There is no good reason why the same should not apply in reverse, if she is prepared to forgo the joys of natural childbirth in order to avoid some not insignificant risks to herself or her baby. She cannot force her doctor to offer treatment which he or she considers futile or inappropriate. But she is at least entitled to the information which will enable her to take a proper part in that decision.

116. As NICE (2011) puts it, “Pregnant women should be offered evidence-based information and support to enable them to make informed decisions about their care and treatment” (para 1.1.1.1). Gone are the days when it was thought that, on becoming pregnant, a woman lost, not only her capacity, but also her right to act as a genuinely autonomous human being.
117. These additional observations, dealing with the specific example of pregnancy and childbirth, are merely a footnote to the comprehensive judgment of Lord Kerr and Lord Reed, with which I entirely agree. Were anyone to be able to detect a difference between us, I would instantly defer to their way of putting it. I would allow this appeal.