Legal and psychological considerations for obtaining informed consent for reverse total shoulder arthroplasty

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Abstract

This paper seeks to outline recent legal developments and requirements pertinent to obtaining informed consent. We argue that this is of particular relevance to patients considering a reverse total shoulder arthroplasty, due to the high complication rate associated with this procedure. By examining the cognitive processes involved in decision-making, and other clinician-related factors such as delivery of information, gender bias and conflict of interest, we explore some of the barriers that can undermine the processes of shared decision-making and obtaining genuine informed consent. We argue that these issues highlight the importance for surgeons in understanding the cognitive processes and other influential factors involved in patients' comprehension and decision-making. We recommend, based on strong evidence, that decision aids could prove useful in overcoming such challenges and could provide one way of mitigating the ethical, professional and legal consequences of failing to obtain proper informed consent. They are not widely used in orthopaedics at present, although it would be in the interests of both the surgeon and patient for such measures to be explored.

Keywords

cognitive processes, decision aids, decision-making, duty of care, heuristics, informed consent, legal considerations, medical negligence, reverse total shoulder replacement, risks

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Introduction

This review examines the issues that arise for surgeons obtaining informed consent from patients to proceed with reverse total shoulder arthroplasty (RTSA). This issue is particularly pertinent because RTSA has become increasingly popular since its introduction, despite evidence of higher complication rates compared to other orthopaedic procedures.¹

The review will consider some of the particular challenges that may arise in obtaining valid consent to perform RTSA, including:

- a review of the evidence highlighting the incidence of RTSA and its complication rates;
- analysis of the professional guidance and legal authorities on explaining risks to patients, following a recent UK Supreme Court decision on informed consent;

- consideration of various patient-specific and surgeon-specific factors that may affect shared decision-making and informed consent in relation to the RTSA; and
- consideration of ways in which the process of shared decision-making and informed consent could be improved in an orthopaedic context.

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Background

The RTSA is a procedure that has been specifically designed and developed for patients with large or massive rotator cuff tears, where conventional total shoulder arthroplasty (TSA) may not be appropriate.² RTSA has become increasingly common; evidence from the USA suggests that it accounted for more than 40% of all total shoulder arthroplasties in 2011,³ and the Swedish Shoulder Arthroplasty Register shows a year-on-year increase in its use over the last decade, with it currently accounting for 36% of all total shoulder arthroplasties⁴ (Fig. 1).

Industry reports show a dramatically increasing trend in reverse shoulder device sales.¹ This increase in RTSA forms part of a wider trend of increasing numbers of total shoulder arthroplasties,^{1,5} which is speculated to be a result of the availability of RTSA in the USA from 2003.¹

Indications for the use of RTSA continue to evolve.⁶ For example, it is being increasingly used for the treatment of proximal humeral fractures in the USA; a study by Acevedo et al. demonstrated a significant increase in its use for fractures by newly trained orthopaedic surgeons, rising in incidence in use for fracture from 2% to 4% during 2005 to 2007 to 38% in 2012.⁷

The RTSA can result in excellent pain relief and highly satisfactory functional improvements.² However, it has also been associated with higher complication rates compared to conventional arthroplasty, with complications including scapular notching, infection, instability and acromial fractures.^{8,9}

In a systematic review in 2011, Zumstein et al. found a complication rate of 24% in patients with a minimum

follow-up of 24 months,⁹ while Wierks et al. found a complication rate of 24.7% with a mean follow-up time of 44 months¹⁰ and Ek et al. found a complication rate of 37.5% in a group of patients aged under 65 years, with a mean follow-up time of 93 months.¹¹ RTSA has been associated with a significantly higher infection rate than anatomic TSA, with an incidence of infection after primary RTSA of approximately 5%⁷ and higher hospital re-admission rates compared to TSA.¹²

These complication rates compare unfavourably with those for other total joint procedures; a 2015 study by Waterman et al. of 2004 patients who received TSA (including RTSA) found a 30-day complication rate of 3.64%.¹³ An older study by Bohsali et al. found that mean complication rates for TSR ranged from 10% to 16% over a wide range of follow-up periods.¹⁴ By comparison, an investigation into incidence rates for postoperative mortality and complications among over 15,000 patients who underwent primary unilateral total knee arthroplasty found a 30-day complication rate of 5.6%.¹⁵ This rate is similar to that found for primary total hip arthroplasty, with one study reporting an orthopaedic complication rate of 3% and a medical complication rate of 4.9%.¹⁶

There is some evidence that the increase in incidence of RTSA may result in surgeons becoming better at performing the procedure. A study by Walch et al. of two consecutive series of 240 RTSAs evaluated whether the increase in surgeon experience modified the indications, clinical and radiographic results and complication rate.¹⁷ The study, which involved the same two surgeons in each series, found that the postoperative complication rate decreased from 19% to 10.8% with increased experience, and the rate of revision arthroplasty decreased from 22.5% to 9.1%. It was concluded that experience significantly modified patient selection, results and complications.

The relatively high complication rate for RTSA presents a challenge for the surgeon in explaining the risks of the procedure to patients and engaging effectively in a discussion with the patient to obtain informed consent to proceed with surgery. The issue is not helped by the fact that there is a general lack of evidence and inconsistency in reporting of RTSA outcomes⁷ and, in particular, a shortage of evidence regarding long-term outcomes.^{18,19} These uncertainties will inevitably impact upon the possibility of obtaining true informed consent. Given the increasing numbers of RTSA being performed, this issue will only become more salient.

Figure 1. Data from the Swedish Shoulder Arthroplasty Register illustrate the increase in the use of primary reverse total shoulder arthroplasties as a percentage of total number of primary arthroplasties. RTSA, reverse total shoulder arthroplasty.

UK Professional Guidance and Legal Authorities

A medical professional must obtain valid consent before performing a physical examination or treatment

on a person.²⁰ Any consent to treatment will be invalid unless it is given voluntarily by a suitably informed patient.²⁰ Grasping the risks involved in proceeding with a treatment will form a key part of patient understanding. Accordingly, any failure to obtain informed consent presents serious ethical, professional and legal issues.

Explaining risks: professional standards

There are a wide range of factors that will affect whether informed consent has been obtained. It is now an established ethical and professional principle that surgeons must work in partnership with patients, and a key aspect of this partnership model is an open exchange of information.²¹

At a basic level, the relevant professional guidance provides that a surgeon must tailor his or her approach to discussions with patients according to:

- the patient's needs, wishes and priorities;
- the patient's level of knowledge about, and understanding of, their condition, prognosis and treatment options;
- the nature of their condition;
- the complexity of the treatment; and
- the nature and level of risk associated with the investigation or treatment.²⁰

When considering the suitability of a treatment with a patient and discussing it alongside any alternatives, there will be a range of considerations in deciding what information to give to the patient. A surgeon must give patients the information they want or need about the potential risks, benefits and burdens, and the likelihood of success, for each option.²¹ Surgeons are expected to discuss such issues with patients, giving them an opportunity to explain their views, raise concerns and ask questions, and should seek to check that they have understood the information provided. Patients' questions must be answered honestly and, as far as is practical, as fully as the patient wishes.²¹ If an investigation or treatment might result in a serious adverse outcome, even if the likelihood is very small, the surgeon must explain this to the patient.¹² Moreover, information about risks must be given in a balanced way, together with the expected benefits, in a way that avoids bias.²¹

Explaining risks: legal authorities

If valid informed consent has not been given (whether as a result of a failure to adequately explain risks or otherwise), the patient may have a legal claim against the surgeon. If the patient suffers harm as a result of valid consent not being obtained, he or she may be able

to bring a claim in negligence against the surgeon and his or her employer. This is costly for the National Health Service (NHS); out of 1473 successful adult orthopaedic claims against English health trusts between 2000 and 2006, Atrey et al. identified 78 where an inadequate consent process was the reason for litigation (and many others where inadequate disclosure of complication risks was implicated in the case). These 78 cases cost the NHS a total of £7,049,514.²²

The issue of whether a patient's consent is 'valid' is ultimately a legal question for determination by the courts. Historically, the courts have favoured an approach to negligence (and therefore to the question of whether the surgeon has fallen short of the standard required) involving a determination of whether the surgeon has been proven to be guilty of such failure that no surgeon of ordinary skill would be guilty of if acting with ordinary care.²³ This so-called 'Bolam test' is based on the principle that a surgeon cannot breach the relevant standard of care if the practice in question can be supported by a responsible body of professional opinion.

The Bolam approach was upheld in one of the key cases on advising patients of the risks involved in treatment, *Sidaway v Bethlem Royal Hospital*.²⁴ One of the judge's opinions, however, which disagreed with the majority opinion (a dissenting judgment), foreshadowed later developments that would focus on other factors relevant to consent to medical treatment (necessitating a greater level of information to be given to the patient, as a matter of principle).

Although the Bolam test remained binding in England and Wales, the courts have, more recently, effectively abandoned a strict application of this test and, instead, have adopted the more cooperative and expansive approach outlined by the dissenting judgment in *Sidaway*.

A significant development in the focus on sharing information on risks was taken in *Pearce v United Bristol Healthcare NHS Trust*.²⁵ This case involved a pregnant woman whose consultant obstetrician advised that the patient should have a normal delivery, rather than an earlier caesarean. The baby died *in utero* and the question for the court was whether the mother ought to have been warned of that risk. The court held that a doctor must inform patients of any significant risks that would affect the judgment of a reasonable patient, if that information is needed so that the patient can determine for him or herself what to do.

More recently, in *Chester v Afshar*,²⁶ the court decided that a surgeon had a duty to advise a patient of the risks involved in proposed surgery for a lumbar disc protrusion and, in particular, to warn of a small (1% to 2%) risk that the surgery might lead

to a seriously adverse outcome (in this case, significant nerve damage and partial paralysis). The court considered that a small but 'well-established' risk of such an outcome was significant, such that the surgeon had a duty to bring it to the patient's attention.

A recent Supreme Court decision has clarified and restated the law regarding the extent to which surgeons are required to explain treatment risks to patients: *Montgomery v Lanarkshire Health Board*²⁷ (this case is Scottish, though the judgment has subsequently been accepted by the English courts as a valid restatement of the law in England and Wales). In *Montgomery*, the court considered advice given by a consultant obstetrician to an expectant mother in 1999, regarding the method of delivery. The patient, Mrs Montgomery, was of small stature and had insulin dependent diabetes. It was accepted that there is an increased risk of shoulder dystocia, a major obstetric emergency, if the mother is insulin dependent, as a result of the potentially larger size of the baby. In Mrs Montgomery's case, there was a 9% to 10% risk of shoulder dystocia occurring.

The court found that Mrs Montgomery had expressed concern about the size of the baby but had not specifically asked her consultant about the risks. Dr McLellan said that she would have explained the risks of shoulder dystocia, if asked, but that she believed that Mrs Montgomery would have wanted a caesarian section and the consultant did not consider that this was in the patient's best interests.

The court highlighted a general shift in the surgeon-patient relationship and acknowledged that the existing legal authorities no longer 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'.²⁷ It found in favour of Mrs Montgomery, overturning the previous appeal.

The court stated that a doctor has 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 given circumstances, a reasonable person in the patient's position would be likely to attach significance to the risk, or whether the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.

The legal test for explaining risks to patients, as stated by the Supreme Court in *Montgomery*, now broadly mirrors the professional guidance issued by the General Medical Council.²⁸

The *Montgomery* decision makes clear that the test for materiality involves both an objective element (by referring to a reasonable person in the patient's

position) and a patient-specific element (by referring to the circumstances of the particular case and whether the surgeon considers the patient in question would be likely to attach significance to a particular risk).

Considerations for RTSA

It is clear that, under the relevant professional guidance and in light of *Montgomery*, the risks inherent in RTSA must be explained to the patient as part of the process for obtaining informed consent or as part of a more general process for explaining treatment options. This is because it is highly likely that a reasonable person in the position of a patient considering elective surgery would view the complication rates for RTSA to be a material risk.

The question that remains is how far the surgeon needs to go in satisfying him or herself that the patient is not only aware of the risks of RTSA, but understands the risks in the context of the wider discussion about treatment options (including the option of doing nothing), and the benefits, risks and burdens of each option in the round.⁷

Shared Decision-Making and Obtaining Informed Consent

Despite an evolution towards more patient-centred models of care over the last couple of decades,²⁹ barriers to informed decision-making and informed consent still exist. Despite the current emphasis on patient-centred care, patients are not always fully involved in clinical decision-making; in fact, many patients, even those who are well-educated, align themselves with socially-sanctioned roles and defer to surgeons, who may themselves be authoritarian in manner.³⁰

Shared decision-making has been defined as 'an approach where clinicians and patients make decisions together using the best available evidence'.³¹ Despite an established acceptance of the benefits of shared decision-making in orthopaedics, the practice is not used widely among orthopaedic surgeons.³² The consequences of inadequately facilitating this process can, as described above, be devastating for patients, surgeons and trusts. Despite this, Muslow et al. found that 'surgical patients are often poorly informed about their condition and treatment, and are ill-equipped to make autonomous decisions affecting their care. Furthermore, surgeons' appreciation of their patients' information needs appear to be poor, and methodologies to improve and assess this understanding are rarely used'.³³

When considering the degree to which a patient's consent is 'informed', it is important for the surgeon to be aware of how the patient might experience and

process information around risks and complications. Maintaining an awareness of how people reason should be regarded as an important clinical skill with its basis in psychology.³⁴

Cognitive processes, understanding and informed consent

Risk is generally regarded as being the product of the probability and severity of a given outcome, and a patient must understand both to give informed consent. It is not adequate for a patient to just understand the percentage risk of a given complication; they must also understand what that complication means in terms of the effect on their health and functional status in the short and longer term.³⁵ However, patients' understanding of surgical procedures can often be poor.³³ There are a variety of patient-specific factors that can jeopardise a patient's understanding, and consequently the process of informed consent and shared decision-making, regardless of how well the surgeon communicates risks. This is especially worrying, given that a patient's comprehension of relevant issues tends to be presumed but is not usually formally assessed.³³

A body of evidence illustrates the fact that people often simplify the decision-making process by using mental short cuts;³⁶ known as heuristics, these short-cuts can lead to overestimates and underestimates of risk.³⁵ As an example, the availability heuristic means that one is more likely to perceive an event as more probable if it is easily brought to mind; for example, there is likely to be heightened public concern around rail safety following a recent railway accident, even though statistically one is more likely to be killed when travelling by car.³⁵ People are more likely to rely on heuristics if the message comes from somebody who is articulate, who they regard highly and think to have good motives,³⁷ which would describe the way many surgeons are regarded by their patients. This has clear implications for medical decision-making and the process of obtaining informed consent.³⁵

The extent of a patient's trust in their surgeon will also affect the degree to which they comply with the surgeon's judgment,³⁸ thus making them more likely to agree to a suggested procedure without necessarily weighing up all of the information and making an objective decision. The surgeon-patient relationship will always be asymmetrical as a result of the disparity in roles and the surgeon's experience and training,³⁹ and surgeons must be aware when discussing and recommending procedures of the influence this might have on a patient's decision-making. This is particularly important given that patients have been shown to make assumptions about their surgeon's competence based on heuristic judgments which form more from

the quality of the surgeon-patient interaction (e.g. if the patient feels listened to) than from the detailed content of the information that the surgeon provides.⁴⁰

It has been demonstrated that the cognitive avoidance associated with denial can create another barrier to a patient's comprehension of medical information.⁴¹ Patients have also been shown to exhibit a tendency towards optimism bias, whereby they perceive risks to themselves as being lower than risks to others.⁴² This implies that they are more likely to place themselves in the group of 75% who will not experience complications, as opposed to the group of 25% who will; this could be another factor in a patient's decision to consent to RTSA, despite its high complication rate. Because RTSA has typically been used in older people, it is interesting to note that older people have been demonstrated to show a greater optimism bias than younger people.⁴³

Another way in which a patient's decision-making, and thus consent-giving, may be affected is by the process described in fuzzy trace theory (FTT). FTT asserts that patients, and people generally, base their judgments, decisions and behaviours primarily on what they understand to be the gist, or the bottom line meaning, of the information they are given, as opposed to a verbatim recollection of the information.⁴⁴ This understanding is influenced by factors such as their emotional state, education and cultural background.⁴⁴ Reyna gives the example of an individual told she has a 22.2% chance of getting breast cancer; this might be considered low because it is more unlikely to occur than it is likely, or high in that others of the same age have a lower probability of developing breast cancer. Although the individual might understand and remember the numerical fact, she is more likely to be affected by the affective interpretation of the information: 'that's really bad; the risk is high' or 'that's ok, the risk is not that high.'⁴⁴ The implication of this for surgeons is that the way they frame risk information is important because it can influence a patient's understanding, and the patient may decide whether to proceed with surgery based on the gist of the information they are given.

Other studies have demonstrated the influence of a doctor's framing of information.³⁵ For example, Redelmeier et al. showed that a patient's decision-making is likely to be affected by risk probability being presented either as a percentage chance of survival, or as a percentage chance of mortality.³⁴ Surgeons must also ensure that they understand and explain statistical information and numbers in a way that is accessible to patients⁷ because additional barriers to a patient's understanding can be created by 'statistical illiteracy', whereby both patient and surgeon might struggle to accurately interpret statistical information.⁴⁵

There has also been evidence to suggest that patients forget information given to them around risks, even in the short term,⁴⁶ and FTT posits that representations of gist remain more stable in an individual's memory over time than verbatim representations.⁴⁷ This again underlines the potential for barriers to obtaining true informed consent.

Gender bias

A patient's potential to make a truly informed decision might also be undermined as a result of gender bias. Borkhoff et al. found that women's opportunities to receive the information necessary for informed decision-making were undermined by the fact that orthopaedic surgeons provided them with less medical information and encouragement to participate in the decision-making process than they did men.⁴⁸ Other studies have shown that gender bias can affect the likelihood of an orthopaedic surgeon recommending particular procedures to patients,^{49–51} thereby jeopardising the obtaining of informed consent through inadequate discussion of alternative options.

Conflict of interest

Another factor that may potentially affect the surgeon's approach in recommending a procedure is conflict of interest. Financial and nonfinancial conflicts of interest in medicine and surgery can skew decision-making in ways that could be detrimental to patient care.⁵² Such conflicts can arise when a surgeon's 'secondary interests,' such as financial gain, professional advancement or recognition, pose an actual or potential conflict with primary duties (e.g. to promote the welfare of patients).⁵³

Such a conflict could manifest itself if, for example, a surgeon was to knowingly favour a particular device because of a financial relationship with its manufacturer.⁵² However, there are subtler ways in which an actual or potential conflict of interest may arise, for example, through unconscious bias; there is evidence from social science that behaviour can be influenced even by gifts of negligible value without the recipient necessarily being aware.⁵⁴

The implementation of DePuy's Articular Surface Replacement (ASR) hip highlights the harmful effects of conflicts of interest in surgery.^{52,55} The ASR hip was implicated in a range of health problems, including infection, pain, inflammation and heart palpitations.⁵² A number of conflicts of interest in its use were identified. For example, DePuy offered surgeons financial inducements to use the ASR, which could have had an impact on their decision-making, and these were not, at least in every case, disclosed to patients, who may have considered this relevant in their own decision-making.⁵²

To seek to avoid a repeat of the ASR case, Johnson and Rogers outline a number of strategies that may be adopted to mitigate the effect of conflicts of interest in surgery. Disclosure is one possibility that is generally advocated and Johnson and Rogers consider that a surgeon's disclosure to their patients is likely essential for obtaining fully informed consent. Alternative courses of action are available, such as recusal from the decision-making process or from the consent process, or a requirement for a financially conflicted surgeon to recommend that patients receive a second opinion from a surgeon who is not conflicted (although each of these options is not without its own problems).⁵¹

A key issue in the consent process for surgeons discussing RTSA will therefore be to consider conflicts of interest, disclose any conflicts to the patient, answer any questions the patient may have openly and honestly, and review whether further action may be merited, such as offering a second opinion.

Improving shared decision-making and informed consent

Given the importance and challenges of ensuring a patient's understanding to obtain informed consent, and the challenges that surgeons face when doing so, it is essential that surgeons consider how they frame and explain procedures.

It has been suggested that, as a result of a patient's inability to retain information around risk, written information should be given as part of the informed consent process.⁴⁶ However, a review study by Muslow et al. found the evidence for the effectiveness of patient information leaflets in improving patient understanding to be lacking; contributing factors included inadequate information in the leaflets or leaflets being difficult to read.³² The study did, however, uncover a body of evidence reporting the benefits of multimedia interventions, such as videos and animations, on surgical patients' recall.

Decision aids can provide another way of helping patients make decisions in an informed way, and can use a variety of different formats, including written documents, videos, animations or computer programmes.³³ More than simply giving information, decision aids explicitly state the decision in question, providing evidence-based information around the possible treatment options. They are intended to assist patients in considering the values-sensitive nature of their decision and the value they place on risks, benefits and scientific uncertainties, sometimes giving sufficient detail that patients can imagine how they might experience the physical, emotional and social consequences of each option.⁵⁶

A Cochrane Review⁵⁶ found that decision aids were effective in increasing patient knowledge, and this effect increased in relation to the level of detail given. Expressed probabilities in decision aids led more patients to accurately perceive risks, and aids with explicit values clarification led to patients being more likely to make a decision in line with their own values. They found that patients felt less conflicted and were less passive in their decision-making. Aids also positively affected communication between patients and surgeons and resulted in more patients choosing more conservative options over major elective invasive surgery. An interesting area for future research would be to examine whether such aids might affect patients' decisions to proceed with RTSA. Presently, such shared decision-making aids are not routinely used in orthopaedic practice⁵⁷ but, given the seriousness of, and the barriers to, informed consent discussed in the present review, widening their use could prove valuable, particularly when considering procedures with high complication rates, such as the RTSA.

Conclusions

The present review has outlined recent legal developments and requirements pertinent to obtaining informed consent. This is of particular relevance to patients considering a RTSA, due to the high complication rate associated with this procedure. There are a number of barriers that can undermine the processes of shared decision-making and obtaining informed consent, and these highlight the importance for surgeons to understand the cognitive processes and other influential factors involved in patients' comprehension and decision-making. Decision aids could prove useful in helping to overcome such problems, although currently they are not widely used in orthopaedics. It would, however, be in the interests of both the surgeon and patient for such measures to be explored. From the surgeon's perspective, such measures may mitigate the ethical, professional and legal consequences of failing to obtain proper informed consent.

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