An audit of consent for allograft use in elective orthopaedic surgery

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ABSTRACT

INTRODUCTION Patients receiving musculoskeletal allografts may be at risk of postoperative infection. The General Medical Council guidelines on consent highlight the importance of providing patients with the information they want or need on any proposed investigation or treatment, including any potential adverse outcomes. With the increased cost of defending medicolegal claims, it is paramount that adequate, clear informed patient consent be documented.

METHODS We retrospectively examined the patterns of informed consent for allograft bone use during elective orthopaedic procedures in a large unit with an onsite bone bank. The initial audit included patients operated over the course of 1 year. Following a feedback session, a re-audit was performed to identify improvements in practice.

RESULTS The case mix of both studies was very similar. Revision hip arthroplasty surgery constituted the major subgroup requiring allograft (48%), followed by foot and ankle surgery (16.3%) and revision knee arthroplasty surgery (11.4%). On the initial audit, 17/45 cases (38%) had either adequate preoperative documentation of the outpatient discussion or an appropriately completed consent form on the planned use of allograft. On the re-audit, 44/78 cases (56%) had adequate pre-operative documentation. There was little correlation between how frequently a surgeon used allograft and the adequacy of consent (Correlation coefficient -0.12).

CONCLUSIONS Although the risk of disease transmission with allograft may be variable, informed consent for allograft should be a routine part of preoperative discussions in elective orthopaedic surgery. Regular audit and feedback sessions may further improve consent documentation, alongside the targeting of high volume/low compliance surgeons.

KEYWORDS

Allograft – Informed consent – Documentation – Orthopaedics

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Orthopaedic surgeons often need to use bone grafts or substitutes to aid bone healing, whether in trauma surgery or to correct bone defects. While autografts can be used, the amount of bone available from a patient's own body is limited, and harvesting can be associated with donor-site morbidity. Due to this, approximately one-third of the bone grafts used in North America, for example, are allograft.¹ Bone allografting is an essential adjunct to elective orthopaedic surgery. It can provide large quantities of graft, is less time-consuming and reduces donor site morbidity versus autograft techniques.

There is some debate about the infection risk following allograft, however. Some authors have claimed the risk is as high as 12.8% with the use of massive allografts,² and 12.2% with femoral head allografts,³ while others have reported lower rates. A prospective bone bank study using frozen femoral heads reported an infection rate of 6.9%, with none of the infections attributable to allograft.⁴ A study of 861 patients undergoing anterior cruciate ligament

reconstruction concluded that there was no significant difference in the infection rate of patients treated with tendon autograft or allograft.⁵

The use of bone allograft is widespread in revision arthroplasty surgery, spine surgery and foot and ankle surgery. There has been a 70% increase in revision knee and hip arthroplasty between 2005 and 2010 in the UK alone, and rates of revision arthroplasty are predicted to expand exponentially over the coming years.⁶ The total cost of orthopaedic claims has also risen, at an increase of 60% between 2009 and 2012 versus a 12% rise in overall NHS litigation claims over the same time period.^{7,8} The NHSLA claims database shows a significant number of claims where consent is an issue. Latest risk management standards from this authority state that a lack of adequate, clear information for patients, due to issues over verbal or written communication, is a major factor in claims involving consent. An analysis of NHSLA orthopaedic surgery claims between 1995 and 2006 by Khan *et al* concluded that spine

and lower-limb surgery have the most claims relating to elective surgery.⁹

A study Bhattacharyya *et al* of US malpractice claims over 24 years found no cases of proven inadequate consent in emergency surgery versus 24 cases in elective surgery.¹⁰ The General Medical Council (GMC) guidelines on consent state: "You must give patients the information they want or need about the purpose of any proposed investigation or treatment and what it will involve."¹¹ They further note that we, as surgeons, "must" discuss the risks and identify adverse outcomes that may result from the proposed options. Furthermore, the patient's notes should include details of tissues removed, added or altered.¹² At the consent discussion, information on the procedure and its implications should be provided.¹²

There are also ethical issues over using allograft products in patients that have not necessarily been defined in law. In one study, 77% of religious leaders surveyed said that patients should be informed of the constituents of the biological products and consent obtained.¹³

We conducted an audit our unit's 'adequacy' of consent for the elective use of bone allograft in orthopaedic procedures.

Methods

The study was carried out in a large elective orthopaedic unit with an onsite bone bank. The initial audit included consecutive patients operated on in the unit over the course of 1 year, of whom 68 received a femoral head allograft. In all, 45 complete sets of case notes were available for review. For each patient, the preoperative clinical notes, consent forms and operative clinical notes were reviewed for adequate discussion and documentation over the use of allograft. A breakdown of the availability of the various components of the notes is shown in Table 1. Data from the Belfast Orthopaedic Information System (BOIS), the perioperative system used in the unit, was also reviewed to fill any gaps in the data.

Table 1 Demographics characteristics and the adequacy of consent. All values n, unless otherwise stated.

	Audit 1 (n=45)	Adequacy	Audit 2 (n=78)	Adequacy
Mean age (years [range])	69 (12–94)		63 (15–90)	
Females	27		40	
Clinical note available	41	9/41 (22%)	72	28/72 (39%)
Operative note available	43	41/43 (95%)	77	74/77 (96%)
Consent available	44	12/44 (27%)	71	16/71 (23%)
Preoperative consent		17/45 (38%)		44/78 (56%)

Subsequently, an education session was arranged to raise awareness of the issues and highlight the role of the local bone bank. The findings of the audit were also presented to the orthopaedic consultants and registrars.

After 2 years, a re-audit of 78 cases involving the use of allograft was carried out to identify any improvements in the adequacy of consent. As with the original audit, the preoperative clinical note, consent form, operative note and BOIS data were reviewed for each patient (Table 1).

Consent was deemed 'adequate' if the use of allograft had been documented in either the surgeon's outpatient preoperative clinical note or appropriately on the patients' signed consent form. The standards used for the audit were: a preoperative clinical note to detail the conversation of consent on allograft use; a consent form to confirm informed consent on use of allograft; and the type of graft used detailed in all theatre notes.

To assess whether surgeons who use allograft more frequently had better consenting habits, a Pearson Product-Moment Correlation was performed using Microsoft Excel (Microsoft, Richmond, WA, USA).

Results

The case mix of the two audits was very similar (Table 2 and Figure 1). Revision hip arthroplasty was the major subgroup requiring allograft (48%), followed by foot and ankle surgery (16.3%), revision knee arthroplasty (11.4%) and spinal surgery (9.8%). Allograft was also used for the treatment of non-union (5.6%) and for bone lesions that required curettage and bone grafting (6.5%). In the initial audit, nine cases required two or more femoral heads, while 28 cases needed two or more femoral heads in the second audit (Figure 2).

Consent

On the initial audit, consultants completed 25/44 consent forms, while 10 were completed by registrars, 9 by senior house officers and two were completed by non-consultant career grade doctors. Four (40%) of the forms completed by registrars were adequate, versus only five (22%) of those completed by consultants.

Table 2 Surgeries requiring femoral head allograft

	Audit 1 (n=45)	Audit 2 (n=78)	Total (n=123)
Revision hip	18	41	59 (48.0%)
Revision knee	6	8	14 (11.4%)
Primary hip	0	2	2 (1.6%)
Spinal surgery	8	4	12 (9.8%)
Foot and ankle Surgery	6	14	20 (16.3%)
Non-union	2	5	7 (5.6%)
Bone lesion	4	4	8 (6.5%)
Physal surgery	1	0	1 (0.8%)

The second audit revealed that consultants completed 34/71 consent forms, while registrars completed 37. The adequacy rate was very similar between the two groups, at 24% and 22%, respectively. Steps have since been taken to educate all registrars rotating through the unit about the importance of appropriate consenting for allograft procedures. The findings were also discussed at the departmental consultant body meeting.

Documenting allograft use

On the initial audit, nine (22%) of 45 clinical notes had documentation on the preoperative clinical consult that detailed the consent procedure on the planned use of allograft (Table 1). Twelve (27%) of 40 consent forms had an appropriate patient consent form. In all, 17 (38%) cases had adequate preoperative documentation of the outpatient discussion or on an appropriately completed consent form on the planned use of allograft.

The second audit showed that 28 (39%) of 78 cases had documentation of a discussion on the planned use of allograft, while 16 (23%) of 71 consent forms had documented the planned use of allograft. In all, 44 (56%) of 78 cases had documentation of an adequate pre-operative discussion on the use of allograft.

On both the first and second audit, there was a high rate of documentation of the use of allograft in the operative notes, at 95% and 96%, respectively.

There was little correlation between how frequently a surgeon used allograft and adequacy of consent (correlation coefficient = -0.12)

Discussion

Surgeons are required to discuss treatment options with patients, including the associated risks.^{11,12} While there is some debate about the risk of using fresh-frozen femoral head allograft,²⁻⁴ any risk of disease transmission or infection should be discussed with the patient before surgery and clearly documented. There is also a strong ethical case for discussion of allograft use, as some patient groups may

have religious reasons for withholding consent.¹³ While these discussions may take place in cases where consent is not documented, it would be difficult to subsequently defend the use of allograft without a written record. It is also recognised that there will always be cases where the decision to use allograft will have to be taken intraoperatively, and it would not be possible to obtain consent in advance.

Previous studies have indicated that there is poor documentation of consent for patients receiving allograft. Porter *et al* reported that only 47 (32%) of 148 patients had preoperative discussions over the risks and benefits of allograft documented with a signed preoperative consent form.¹⁴ We had similar experience in our study. The results of our initial audit demonstrated that an adequate written record was made in only 38% of cases. After a feedback session, this improved to 56%, with the improvement most marked for consultants. Registrars taking consent in the re-audit may have been appointed to a higher surgical training scheme after the initial feedback session, which may account for their relatively poor results. Interestingly, there was no correlation between the frequency with which a surgeon uses allograft and their documentation of discussions with patients.

In this study, we also examined consent forms and clinic notes. An analysis of 28 malpractice claims across a range of medical specialties demonstrated that a documented conversation of informed consent in the outpatient clinic lead to a successful defence in the majority of cases.¹⁰ That review also stated that taking the time to obtain consent in the outpatient clinic, rather than on the ward just before surgery, significantly reduced the risk of litigation over consent. We believe that best practice would include explicit documentation of allograft use in the outpatient notes, as well as on the consent form. In our study, this was performed in 38% of cases on the initial audit and in 56% on the follow-up audit.

Regular audit and feedback sessions are likely to bring about further improvements in documentation of the consent process. Additional improvements may be gained by targeting high volume/low compliance surgeons.

Conclusions

We have demonstrated that, although there are considerable deficiencies in the process of documenting discussions over the use of bone allograft in surgery, feedback and re-auditing may improve documentation. At present, there is no explicit duty to record a discussion over the use of allograft. However, this is implicit in the advice given to doctors by regulatory bodies. There is also a strong ethical case for discussing the use of allograft with patients, where possible, before surgery.

References

1. De Long WG, Jr., Einhorn TA, Koval K *et al*. Bone grafts and bone graft substitutes in orthopaedic trauma surgery. A critical analysis. *J Bone Joint Surg Am* 2007; **89**: 649–658.
2. Mankin HJ, Hornicek FJ, Raskin KA. Infection in massive bone allografts. *Clin Orthop Relat Res* 2005; 210–216.
3. Sutherland AG, Raafat A, Yates P *et al*. Infection associated with the use of allograft bone from the north east Scotland Bone Bank. *J Hosp Infect* 1997; **35**: 215–222.
4. Kappe T, Cakir B, Mattes T *et al*. Infections after bone allograft surgery: a prospective study by a hospital bone bank using frozen femoral heads from living donors. *Cell Tissue Bank* 2010; **11**: 253–259.
5. Greenberg DD, Robertson M, Vallurupalli S *et al*. Allograft compared with autograft infection rates in primary anterior cruciate ligament reconstruction. *J Bone Joint Surg Am* 2010; **92**: 2,402–2,408.
6. Briggs T. *Getting It Right First Time. Improving the Quality of Orthopaedic Care within the National Health Service in England*. Stanmore: 2012.
7. The National Health Service Litigation Authority. *Report and Accounts 2011–12*. London: The Stationery Office; 2012.
8. Annual Reports. NHS Litigation Authority. <http://www.nhs.uk/AboutUs/Pages/AnnualReport.aspx> (cited January 2016).
9. Khan IH, Jamil W, Lynn SM *et al*. Analysis of NHS LA claims in orthopedic surgery. *Orthopedics* 2012; **35**: e726–e731.
10. Bhattacharyya T, Yeon H, Harris MB. The medical-legal aspects of informed consent in orthopaedic surgery. *J Bone Joint Surg Am* 2005; **87**: 2,395–2,400.
11. Consent: patients and doctors making decisions together. General Medical Council. http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp (cited November 2015).
12. Good Surgical Practice. The Royal College of Surgeons of England. <https://www.rcseng.ac.uk/surgeons/surgical-standards/professionalism-surgery/gsp> (cited November 2015).
13. Enoch S, Shaaban H, Dunn KW. Informed consent should be obtained from patients to use products (skin substitutes) and dressings containing biological material. *J Med Ethics* 2005; **31**: 2–6.
14. Porter SE, Stull D, Kneisl JS *et al*. Informed consent is not routinely documented for procedures using allografts. *Clin Orthop Relat Res* 2004; 287–290.