The Journal of Foot & Ankle Surgery 57 (2018) 81–85

Contents lists available at ScienceDirect

The Journal of Foot & Ankle Surgery

journal homepage: www.jfas.org

Improving the Consent Process in Foot and Ankle Surgery With the Use of Personalized Patient Literature

Nicholas Howard, MRCS [1], Christopher Cowan, MBChB [2], Raju Ahluwalia, FRCS [3], Andrew Wright, FRCS [4], Michael Hennessy, FRCS [5], Gillian Jackson, FRCS [5], Simon Platt, FRCS [5]

[1]*Specialist Trainee Trauma and Orthopaedics, Orthopaedic Department, Arrowe Park Hospital, Wirral University Teaching Hospital NHS Trust, Wirral, UK*
[2]*Core Trainee Trauma and Orthopaedics, Orthopaedic Department, Arrowe Park Hospital, Wirral University Teaching Hospital NHS Trust, Wirral, UK*
[3]*Fellow Trauma and Orthopaedic Surgeon, Orthopaedic Department, Arrowe Park Hospital, Wirral University Teaching Hospital NHS Trust, Wirral, UK*
[4]*North West Orthopaedic Specialist Trainee, Royal Preston Hospital, Sharoe Green Lane North, Fulwood, Preston, UK*
[5]*Consultant Trauma and Orthopaedic Surgeon, Orthopaedic Department, Arrowe Park Hospital, Wirral University Teaching Hospital NHS Trust, Wirral, UK*

ARTICLE INFO

Level of Clinical Evidence: 2

Keywords:
clinical governance
foot and ankle
informed consent
recall
risk management
risks
surgery

ABSTRACT

A patient-specific letter was introduced to the consent process to observe the effect, if any, on information recall and satisfaction for patients undergoing elective foot and ankle surgery. The patients attending the clinic were written a personalized letter—this was a simple personalized letter that outlined their treatment options, the proposed management plan, likely treatment course, and the benefits, risks, and likely period required for recovery. The personalized letter system was compared with the 2 existing methods of consent process: signing for consent at their outpatient encounter at which they were scheduled for surgery and a separate consent clinic without the personalized letter. A total of 111 patients (87 females, 24 males) undergoing elective foot and ankle surgery were assessed on the day of surgery for recall of the procedure, risks, postoperative course, and satisfaction with the consent process. Patients receiving a personalized letter recalled more than those who had attended a routine preoperative consent clinic visit and significantly more than those who had provided consent at their last clinic visit. Patient satisfaction with the consent process was also greater in the personalized group. Our results suggest that the consent process is improved using routine preoperative consent clinics and, most notably, with patient-specific information to improve patient recall and satisfaction.

Informed consent reflects a process, not just a signature on a form. It represents the discussion of relevant facts with time and opportunity for potential participants to ask questions to ensure they have adequate information to grant informed consent (1). It is, however, questionable whether informed consent is ever completely achieved, and litigation relating to consent has become more prevalent (2).

Our findings could not be more timely given the Supreme Court Judgment in March 2015 (3). The Montgomery ruling now requires a physician 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."

Previously, consent was considered implicit by patients merely presenting themselves on the day of the procedure. Today, we are morally, ethically, and legally bound to provide adequate information, to explain the procedure and other alternatives for treatment, and to specify the associated risks and benefits, including the likely outcome if the patient does not accept the treatment (1–4).

The UK Department of Health guidelines and General Medical Council guidance on consent have stated that valid consent revolves around sharing and discussing information, with an emphasis on the side effects, complications, and other risks that should be discussed and documented (4,5). No doubt exists that the patient must be considered an integral part of the modern informed consent process.

At present, no clear definition exists regarding what constitutes adequate information. However, it has been accepted as what "a reasonable person in the patient's situation would need to make an appropriate decision" (5). In the United Kingdom, an expectation exists that all patients are provided with informative literature regarding their condition and also the procedure they will undergo (6). However, previous studies have

Financial Disclosure: None reported.
Conflict of Interest: None reported.
Address correspondence to: Nicholas Howard, MRCS, Orthopaedic Department, Arrowe Park Hospital, Wirral University Teaching Hospital NHS Trust, Arrowe Park Road, Wirral, Merseyside CH49 5PE, UK.
E-mail address: nick.howard@doctors.org.uk (N. Howard).

1067-2516/$ - see front matter
https://doi.org/10.1053/j.jfas.2017.08.011

Table 1
Group details

Group	Description
A	Operating department practitioner decision to schedule and standardized consent form completed
	Information leaflet
	Standard clinic letter
B	Operating department practitioner decision to schedule and standardized consent form completed
	Information leaflet
	Standard clinic letter
	Additional consent clinic with discussion and confirmation of consent
C	Operating department decision to schedule and standardized consent form completed
	Information leaflet
	Standard clinic letter
	Additional consent clinic with discussion and confirmation of consent
	Personalized letter

reported that providing more detailed and complete information has no advantage compared with a simple explanation in terms of patient anxiety and comprehension of a proposed surgical procedure (7).

Our pragmatic study compared the robustness of clinical consent within the National Health Service framework. The effect on patient recall using 3 different methods of consenting was tested. Three patient groups were included (Table 1). The purpose of the present study was to determine whether patient comprehension and satisfaction could be improved using a simple personalized letter confirming the treatment options, management plan, and likely treatment course. Objective assessment of patient recall was measured just before surgery. Specifically, we assessed patient recall of the procedure, likely postoperative course, risks of the proposed surgery, and satisfaction with the consent process.

Patients and Methods

After internal review board approval, the present study was instigated to assess the practice of our foot and ankle unit and whether the consent process could be improved. A total of 111 consecutive patients aged ≥18 years admitted for elective foot and ankle surgery agreed to complete a preoperative questionnaire on the day of surgery. All elective foot and ankle procedures were included, thereby encompassing a range of cases and complexity. The patients included had previously discussed their planned procedure and signed a consent form, with informed consent presumed on this basis. Competency was assessed at the bedside when discussing the questionnaire. The study was double blinded to both patients and the staff who took consent. The patients were not randomized but followed the existing method of consent at that time.

A power analysis was performed before the study to determine the number of patients needed to show a significant difference. With a power calculation of 0.80, 16 patients in each group would have been sufficient to show a 20% improvement in recall between the groups. The exclusion criteria included patient refusal or an inability to complete the questionnaire preoperatively (poor vision, language barrier, or mental impairment) and those aged <18 years.

The patient demographics were similar in all 3 groups, with 78% of patients included being female. More than 50% of those included in all groups were aged >50 years. Overall, 29% of patients had not continued education beyond General Certificate of Secondary Education level (age 16 years). A lower percentage of patients in group B had remained in education after General Certificate of Secondary Education (age 16), 41% compared with 71% and 88%, which we could not explain. Patient age stratified by group is shown in Fig. 1.

The patients were not aware that they would be asked to recall the information regarding their surgery provided at the time of consent. All the patients were provided with their consent form, standard clinic letter, and an information leaflet designed by the hospital with the goal of explaining the proposed procedure in layman's terms at the point at which written consent was taken. These leaflets described the risks and benefits of the proposed surgery and had previously completed local internal review and governance. The consent forms used were standardized and included the generic risks relevant to all foot and ankle surgery and adjusted accordingly for the planned procedure with any additional specific risks.

Group A underwent the written consent process at their last outpatient clinic with provision of an operation-specific hospital information leaflet and confirmation of consent on the morning of surgery. They received their outpatient clinic letter and a copy of the consent form.

Group B underwent the consent process at a preadmission consent clinic visit in the week before surgery. A senior surgeon was present and reviewed all the patients, including obtaining written consent. The patients were provided with an information leaflet, clinic letter from previous outpatient visit, and a copy of their consent form, just as for group A.

Group C underwent a development of the existing consent processes. Patients in this group also attended a preadmission consent clinic visit in the week before surgery. At this visit, the senior surgeon responsible for obtaining written consent from the patient dictated a letter to the patient as a written record and explanation of their surgery and particular risks. This letter was dictated in front of the patient. The letter included an explanation of the procedure, complications, risks, and benefits in layman's terms. It included advice concerning alternative treatments and the consequence of taking no action. The risks were graded as common, less common, and rare. The main focus of the letter, in contrast to the standard clinic letter, was to explain the planned surgery in simpler language and to explain any technical terms. The letter was then sent to the patients before their surgery. They were also provided with the same standard hospital leaflet regarding their surgery and a copy of their consent form.

All included patients completed a preoperative questionnaire on the morning of surgery administered by an independent blinded observer before any contact with the surgical team after providing verbal consent for the process. The questions focused on their planned procedure, postoperative instructions, and possible complications to assess their recall of the consent process. The questions regarding the postoperative instructions assessed parameters such as the period of non-weightbearing and time unable to drive. A copy of the questionnaire is provided in the Appendix.

After completion of the questionnaire, all the patients were then seen by the surgical team and provided confirmation of consent. Any patient unable to recall a single risk were taken through the consent process again.

Statistical Analysis

The independent observer conducted the data analysis. A comparison of patients' recall of instructions and of the visual analog scale scores for patient satisfaction was performed using a 2-tailed Student's *t* test. Some results have been are expressed as percentages because

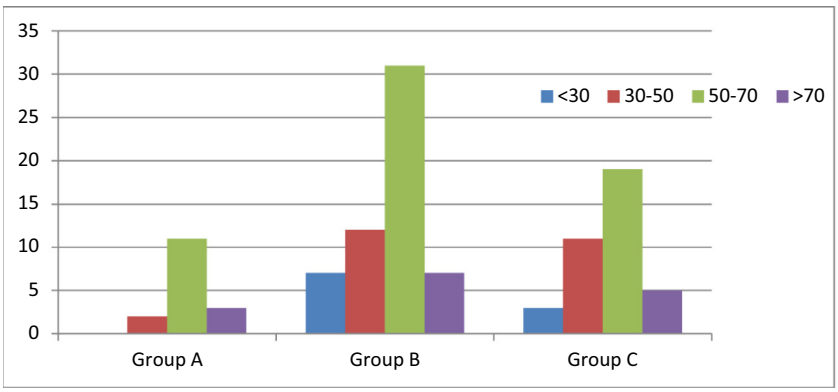

Fig. 1. Bar graph showing patient age stratified by group.