Delivering high quality documentation on operative consent forms: a UK major trauma center Quality Improvement Project

Dorian Hobday, MBBS, MRCS*, Zulfiqar Chaudhry, MBBS, MRCS, Dardan Popova, MBBS, Ted Welman, MBBS, MRCS, Gurjinderpal S. Pahal, MBBS, FRCS, Matthew Stodell, MBBS, FRCS

Background: Royal College of Surgeons guidelines exist on the importance of full, accurate and legible completion of consent forms as a key part of the process of gaining informed consent. In addition to this, consent forms serve as an important medico-legal document to protect clinicians and patients should problems arise. It is therefore in all parties’ interests that they are correctly completed. It was noted that consent forms within the Royal London Hospital Plastic Surgery department were often not correctly completed. A Quality Improvement Project was undertaken to improve the completion of consent forms within the department.

Materials and methods: Common problem areas on consent forms were identified and Quality Improvement (QI) methodology was used to design the study including selection of appropriate outcome, process and balancing measures. Baseline information on completion of: (1) patient details, (2) consultant details, (3) legibility, (4) use of abbreviations in description of operation/complications, and (5) patient signatures was collected. Four weekly interventions were made which were accompanied by 4 further data collection cycles. A further audit took place 4 months following the completion of the project to establish whether improvements had been sustained.

Results: Over the 5 QI data collection cycles the average completion of the 3 outcome measures rose from 59% to 93% and 4 months later was sustained at 91%. Outcome measure 1 (legibility of documentation) rose from 62% to 100%. Outcome measure 2 (omission of abbreviations) rose from 33% to 79%. Outcome measure 3 (patient signature) rose from 81% to 100%.

Conclusion: This Quality Improvement Project led to a significant and sustained improvement in quality of completion of consent forms within the department with the most marked improvement in omission of abbreviations. This quality improvement methodology could easily be adapted for other surgical specialties.

Keywords: Quality improvement, Informed consent, Consent form

In 2018–2019 the NHS paid out 2.4 billion in clinical negligence claims which equates to ~2% of the entire NHS budget in England[1]. Between 2007 and 2017 the annual number of clinical negligence claims has quadrupled over the same period[2]. In 2016 the Royal College of Surgeons warned that trusts are at risk of a significant increase in the cost of litigation pay outs in the wake of a 2015 landmark judgment in the case of Montgomery versus Lanarkshire Health board. Before this ruling it had been the case that it was up to doctors to decide what risks should be communicated to patients when taking consent, but the court in the Montgomery case changed this to hold that doctors must ensure that patients are aware of any and all risks that an individual patient might consider significant[3].

Aside from the medico-legal aspect of taking informed consent it is its importance in terms of satisfying 3 of the 4 core principles of medical ethics[4]. Patients have a right to fully understand the risks, benefits and alternatives to a proposed surgical procedure and their autonomy in making their decision should be fully supported by the clinician. As such it is clear that ensuring quality in the discussion that constitutes the taking of informed consent, as well as in the documentation of said consent is strongly in the interests of both patient and clinician.

This is, however, often difficult to achieve in practice: “The NHS is under huge pressure and seeing more patients than ever. It’s not hard to see how in many hospitals gaining a patient’s consent has become a paper tick-box exercise, hurriedly done in the minutes before a patient is wheeled into theater for their procedure. Operating lists and consultation clinics are packed leaving little time for these important consent discussions”[5]. Royal College of Surgeons guidelines state that details of the consent process should be documented both in the consent form as well as in the medical notes[6]. However, it is often the case that the only documentation of this important discussion is the consent form itself, which increases the onus on the consent form being adequately and accurately completed.

Despite these guidelines and the above detailed hardening of the medicolegal environment around informed consent, it was noted within our department that consent forms were often not correctly
Materials and methods

Our Quality Improvement Project (QIP) has been reported in line with the Standards for Quality Improvement Reporting Excellence (SQUIRE) criteria using the model of Improvement methodology “Quality Improvement Essentials Toolkit” as provided by the Institute for Healthcare Improvement[6]. We carried out a baseline audit to assess the quality of consent form completion (QCFC) and discussed factors that may influence QCFC. Barriers to QCFC were identified which included: lack of education on how to complete consent forms, lack of understanding of the importance of consent forms as medicolegal documents, time pressure when completing consent forms, prevailing culture within the department (positive or negative) and the influence of seniors (positive or negative). Ideas about potential influencers and change interventions were compiled and are illustrated on our driver diagram (Fig. 1).

Working from the basis that a consent form should be something that a patient can fully understand; that is, legible and free from medical jargon, and something that it can be demonstrated that the patient has actually consented to; that is, clearly signed, written their name and dated, the following outcome measures were selected:

(1) Documentation on consent forms being legible. (Overall legibility of each consent form was assessed by 2 members of the team. If their opinion differed as to whether a form was clearly legible a third member of the team assessed and the decision was based on this third assessment.)

(2) The consent form being free from abbreviations in the description of the name of the proposed procedure/the risks and benefits of the proposed procedure.

(3) The patient having signed, written their name below the signature and dated the consent form.

A process measure was “full completion of responsible health professional details,” as though not essential, an improvement in completion of this field would likely reflect an overall improvement in QCFC. A balancing measure was “completion of patient demographics” including full name, date of birth and hospital number, as any deterioration in this field of the consent form would cause problems identifying patients perioperatively. Information was also collected on the abbreviations used on the consent forms.

Following a baseline audit of 23 consent forms to facilitate planning of the project, data from 20 randomly selected consent form 1 (adults) or consent form 2 (paediatrics) completed by the plastics surgery team was collected and analyzed once weekly for a 5-week period. The sum of consent forms assessed during the QIP period was thus 100 forms. All data was free of patient specific information and concerned only the quality of completion of the consent forms. Information was collated in a specially designed spread sheet with outcome, process and balancing measures captured on run-charts.

Four PDSA (plan, do, study, act) cycles were completed with each cycle including observational assessment of the effectiveness of a PDSA intervention. The quality improvement team consisted of 4 trainee doctors and 1 plastic surgery consultant who acted as mentor. The Quality Improvement (QI) team had weekly discussions to review the impact of each intervention and to plan the next intervention. Communication between PDSA cycles was via instant messaging.

The first intervention was a poster of a consent form (to scale) which was filled out as an example of a badly completed form with labels to highlight the deficiencies (Fig. 2). These posters were put up in key areas where department staff most commonly take consent, namely the plastic surgery trauma clinic and the plastic surgery speciality room in A&E. Another poster was also put up in the departmental doctor’s office where the team congregate daily. The poster was designed to be simple, eye catching,
and to provoke thought by begging a question without directly articulating it, namely: “Do you make any of these mistakes when you are taking consent?”

The second intervention was an instant message sent to the departmental group whose members comprise all core surgery trainees, all registrars and some consultants (who had joined the group on a voluntary basis). This message briefly explained the motivation behind the project and aimed to educate on QCFC by reminding of the moral duty associated with taking informed consent as well as the RCS and General Medical Council.

Figure 2. Poster.

Figure 3. Instant message.
guidelines on consent (Fig. 3)\(^7\). This intervention was designed to directly reach the vast majority of the team, and to target the team members most commonly completing consent forms—namely those at core trainee and registrar level.

The third intervention was an email sent to all members of the plastic surgery department from the consultant lead of the QIP (Fig. 4). As well as core trainees and registrars this included all consultants, clinical nurse specialists and the plastics trauma coordinator. The idea behind this was firstly to reach 100% of the plastic surgery team, secondly to make ancillary team members aware of the need for QCFC so they may be empowered to flag when consent forms were not being correctly completed and thirdly to give the message of the project additional weight from the email being sent by a consultant.

The fourth intervention was a second instant message sent to the departmental group detailing gains made by the project, including a graph to visually illustrate the progression of the QCFC measures (Fig. 5). The tone was that of positive encouragement stating gains had been made but that there was room for further improvement. The idea behind the positive tone of the message was to encourage further investment in the project. The inclusion of the graph was not only to illustrate the gains but also to make it very clear how closely performance was being tracked in order to gently pressurize the team to try and do better.

Consideration was given to the potential benefit of presenting the QIP in person and giving a short teaching session on QCFC, as there is no doubt that personal interaction can be a catalyst to behavioral change. This was however not done as daily morning handover is only attended by ~25% of the team including just one on call consultant. The only time that the majority of the plastic surgery team are present in the same room is at departmental audit meetings and unfortunately there were no meetings that coincided with the QIP period. For this reason, an “in person” intervention was deemed to be unlikely to have much effect.

**Results**

**Baseline audit**

In the baseline audit of 23 consent forms it was revealed that only 62% of the forms were legible, only 33% were free from abbreviations and 81% had the patient signature + name + date of signature fully completed. The mean of these outcome measures was 59%.

**Outcome, process, and balancing measures**

Over the 5 QI data collection cycles the average completion of the three outcome measures rose from 59% to 93% (graph 1) and on reaudit 4 months later was sustained at 91% (graph 2).

Outcome measure 1 (legibility of documentation) rose from 62% to 100% and on reaudit four months later was sustained at 100%. Outcome measure 2 (omission of abbreviations) rose from 33% to 79% and on reaudit 4 months later was sustained at 79%. Outcome measure 3 (patient signature, name and dating)
rose from 81% to 100% and on re-audit 4 months later had reduced to 94%.

Balancing measure (documentation of patient details) started at 100% and remained at 100% throughout the QI and reaudit period (graph 3). Process measure (consultant details) rose from 90% to 100% (graph 4) but on reaudit 4 months later had reduced to 74%.

### Use of abbreviations

The most common abbreviations used on consent forms were MUA—manipulation under anesthesia and ORIF—open reduction and internal fixation. Of more concern, there was one instance of an abbreviation of the side the operation was to be performed on: L—left. Further details on abbreviations used can be found in Table 1.

### PDSA cycles

The PDSA interventions with greatest impact were (i) posters illustrating common mistakes on consent forms and (ii) email from consultant project lead. It was unexpected that the intervention with the greatest impact was the poster as at this point in time the project had not been widely publicized within the department. This gain may be reflective of a strong visual message or it may simply be that at this stage there were the greatest gains to be made. The wide degree of variation in legibility and patient signing/dating the form in weeks 2 and 3 may be due to fluctuations in which specific team members fill in a large number of consent forms in a given week secondary to the nature of an on-call rota. A full description of each PDSA and their effect on QIP are given in Table 2. There were no external incidents that impacted on the project.

### Discussion

#### Main study findings

This QIP achieved its chosen aim of improving the completion of the 3 outcome measures to over 90% which was accompanied with an increase in the process measure of documentation of responsible health professional. In addition, the balancing measure of documenting patient demographics remained at 100% throughout the project. On reaudit 4 months later these gains were largely sustained with the average of the 3 outcome measures remaining over 90%.

### Table 1

| Abbreviation | Meaning                                | No. Times Occurred |
|--------------|----------------------------------------|--------------------|
| MUA          | Manipulation under anesthesia           | 15                 |
| ORIF         | Open reduction and internal fixation    | 8                  |
| ELA          | Examination under anesthesia            | 6                  |
| SSG          | Split thickness skin graft              | 3                  |
| L            | Left                                   | 1                  |
| EDC          | Extensor digitorum communis            | 1                  |
| EDM          | Extensor digitii minimi                 | 1                  |
| CRPS         | Chronic regional pain syndrome          | 1                  |
| #            | Fracture                                | 1                  |
| UDN          | Ulnar digital nerve                     | 1                  |
| RDN          | Radial digital nerve                    | 1                  |

### Table 2

| Week | Intervention                                                                 | Effect of Intervention                                      |
|------|-------------------------------------------------------------------------------|-------------------------------------------------------------|
| 1    | Poster
Color A3 poster in areas where most patient consents are taken: Plastics trauma clinic room and Plastics A&E room, and in Plastics doctors office. [Figure X] | Largest overall improvement (mean +18% improvement) with improvements in all 3 outcome measures |
| 2    | Instant message #1
Message from QIP team to all house officers, all registrars and some consultants including education on consent process and reinforcement + inclusion of poster message from week 1 | Largest improvement in avoidance of abbreviations, though worsening of legibility meant mean improvement of outcome measures smallest at +3% |
| 3    | Consultant email
Email from QIP consultant lead to entire plastics department including all consultants | Continued steady improvement in 2 of 3 outcome measures—2nd greatest mean improvement of outcome measures +8% |
| 4    | Instant message #2
Message from QIP team to all house officers, all registrars and some consultants with graph illustrating progression/gains made by project and highlighting areas still in need of improvement | Legibility improvements sustained, fluctuations in other 2 outcome measures—mean improvement of outcome measures +5% |

QIP indicates Quality Improvement Project.

### Strengths and weaknesses of the project

A strength of the program was the adherence to model of Improvement methodology. Choice of measurements were guided by SMART criteria\(^6\). Strict weekly data collection meant that the findings are underpinned with a moderately large and complete dataset.

Limitations include the relatively short study period. The study could also have been strengthened by a larger data set both pre-interventions (to establish the baseline) and throughout the QIP. We were, however, limited by the total number of consents taken within the department on a weekly basis (which stands at around 25–40). As mentioned previously, the team members mainly taking consent varies to some degree week by week due to the nature of an on-call rota which may have affected the results.

### Post quality improvement project

A further intervention outside the QIP period took place in the form of presentation of the project at the departmental audit meeting 1 month following completion of the QIP. This meeting was attended by ~60% of departmental staff. Presentation of the project served as a reminder of its message but, perhaps more importantly, a lively discussion ensued involving a number of consultants as well as the junior staff on the subject of consent, with strong support for the idea of QCFC being shown by the consultants in attendance. This “buy in” from other seniors within the department may have helped create a further culture shift towards the taking of consent being perceived not as a tick box exercise but as an important process that should be given the time and care it merits.

Two months following completion of the QIP it was expected that ~25% of the surgeons at core trainee/registrar level would...
rotate away from the department which may have led to a deterioriation in the newly improved culture around QCFC. However, due to the advent of the coronavirus-19 pandemic the department kept all its staff, albeit with the majority of them temporarily redeployed to critical care. The effect of this service disruption on QCFC at the time of reaudit is hard to quantify — on the one hand the message of this QIP has been hugely overshadowed by the pandemic and subsequent redeployment, but on the other hand it has meant the department retained all the staff who are aware of the QIP and its message.

When staff do eventually rotate to other jobs, we advocate inclusion of a teaching session on QCFC as part of the induction process for new staff joining the department.

Conclusion

Our QI program has shown significant and sustained gains in quality of consent form completion. These improvements, and the discussion that the project has provoked within the plastic surgery department, are likely reflective of improvements in the process of taking consent which is of benefit to patients and clinicians alike.

High quality consent form completion is common to all areas of surgery and the quality improvement methodology applied here could easily be adapted to other specialities.

Ethical approval

As this study does not involve patient data, ethical approval was not required or sought. This was a hospital-based initiative to improve consent form completion in our trust. We confirm that this quality improvement project is exempt from full ethics form submission. No identifiable patient demographic was collected. All data was made anonymous. No funding or sponsorship was provided. The paper was prepared according to Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) September 15, 2015.

Sources of funding

The authors received no funding for the undertaking of this study.

Author contribution

D.H.: study design, data collection and analysis, drafting and review of paper. Z.C.: study design, data collection and analysis, review of paper. D.P.: study design, data collection and analysis, review of paper. T.W.: study design, data collection and analysis, review of paper. S.G.: study design and review of paper (Senior Author).

Conflicts of interest disclosure

The authors declare that they have no financial conflict of interest with regard to the content of this report.

Research registration unique identifying number (UIN)

ClinicalTrials.gov Identifier: NCT04493866.

Guarantor

Dorian Hobday.

References

[1] Yau CWH, Leigh B, Liberati E, et al. Clinical Negligence Costs: taking action to safeguard NHS sustainability. BMJ 2020;368:m552.
[2] House of Commons Committee of public accounts. Managing the costs of clinical negligence in hospital trusts. Fifth report of session 2017–2019. Available at: https://publications.parliament.uk/pa/cm201719/cmselect/cmpubacc/397/397.pdf. Accessed July 4, 2020.
[3] Royal College of Surgeons report: surgeons warn NHS failing to implement patient consent rules, risks facing increase in litigation pay-outs. 2016. Available at: https://www.rcseng.ac.uk/news-and-events/media-centre/press-releases/surgeons-warn-nhs-failing-to-implement-patient-consent-rules/. Accessed July 4, 2020.
[4] Gillon R. Defending the four principles approach as a good basis for good medical practice and therefore for good medical ethics. J Med Ethics 2015;41:111–6.
[5] Royal College of Surgeons Guidelines on Good Surgical Practice Sept 2014 section 3.5.1 “Consent”. Available at: https://www.rcseng.ac.uk/standards-and-research/gsp/domain-3/3-5-1-consent/. Accessed July 4, 2020.
[6] Institute for Healthcare Improvement. Quality Improvement Essentials Toolkit. Available at: http://www.ihi.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx. Accessed July 4, 2020.
[7] General Medical Council: consent: patients and doctors making decisions together. Sections 44-49. 2008. Available at: https://www.gmc-uk.org/ethical-guidanceethical-guidance-for-doctors/consent/part-2-making-decisions-about-investigations-and-treatment#paragraph-51. Accessed July 3, 2020.
[8] Doran GT. There’s a SMART Way to write management’s goals and objectives. Manag Rev 1981;70:35–6.