



Original research

Improving the quality of operative notes for laparoscopic cholecystectomy: Assessing the impact of a standardized operation note proforma



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HIGHLIGHTS

- An operation note proforma significantly increased compliance with guidelines for laparoscopic cholecystectomy.
- Procedure-specific proformas, can help to produce more complete and medico-legally robust operation notes.
- Proformas have been successfully validated in general and gynaecological surgery.
- To our knowledge this is the first demonstration of proforma use in general surgery.

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ABSTRACT

Introduction: Operative notes are the recognized standard for documenting the details of an operation yet key procedural details are frequently missing. With the aim of improving standards, based on the Royal College of Surgeons (RCS) and Dutch Society of Surgery (DSS) Guidelines, we introduced an operation note proforma for use following laparoscopic cholecystectomy in a tertiary centre in the UK. **Methods:** This study audited 130 consecutive laparoscopic cholecystectomy operation notes against accepted guidelines across three hospital sites within the same NHS Trust. Following analysis of these operation notes a standardized operation note proforma was designed and introduced across the Trust, which included all items from the DSS and RCS guidelines in the form of keyword prompts or simple yes/no responses. A further 128 operation notes were analysed. Guideline compliance was compared pre- and post-introduction of the proforma. Non-parametric data were analysed using Fisher's exact and Mann–Whitney U tests. Statistical significance was set at $p < 0.05$.

Results: On a global assessment of operation note completeness against all guideline items, introduction of an operation note proforma significantly improved documentation rates for both DSS guidelines ($p < 0.001$) and RCS guidelines ($p < 0.001$).

Discussion: We have demonstrated that the introduction of a procedure-specific proforma to assist with writing the post-operative note following laparoscopic cholecystectomy can result in significant improvements in documentation of generic and procedure-specific items that should be recorded for every operation. Procedure-specific proformas, based on established guidelines can help to produce more complete and medico-legally robust operation notes.

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1. Introduction

Operative notes are the recognized standard for documenting the details of an operation. They allow the communication of intraoperative events to other healthcare professionals, which can

significantly impact upon future clinical decisions and operative procedures. Accurate and complete documentation has been correlated with good clinical care [1]. Furthermore, operative reports have an important role in medico-legal conflicts [2] as well as quality assurance.

Despite their importance the quality of operative reports is often poor with critical aspects of the procedure frequently missing [3]. The National Confidential Enquiry into Peri-Operative Deaths has

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identified documentation deficiencies as an increased risk for litigation and identified an urgent need for improvement [4]. The Royal College of Surgeons (RCS) has established generic guidelines outlining the minimum information required within operative notes [5], and standardization using procedure-specific operation notes has been shown to significantly improve adherence to these guidelines for hip hemi-arthroplasty [6].

Laparoscopic cholecystectomy is the most commonly performed minimally invasive surgical procedure in the UK, with over 50,000 procedures performed annually [7] and is associated with a relatively high incidence of complications [11], which are often only clinically apparent in the post-operative period [8], therefore clear and accurate operative notes are essential for the reviewing clinician. Further, a delay in recognition of complications correlates with the subsequent risk of litigation [9]. The Dutch Society of Surgery, incorporating previous guidelines from several international societies [10,11], has published specific guidance detailing a stepwise protocol for safe laparoscopic cholecystectomy [12]. Nonetheless, poor documentation of each step of this protocol has been demonstrated, including deficiencies in recording of trocar insertion, establishment of the critical view of safety, and gall bladder condition [13]. Poor or illegible documentation of surgical procedures often results in complications being indefensible in the face of litigation [14,15].

The aim of this study was to review the quality of laparoscopic cholecystectomy operative notes from both the emergency and elective setting across a single NHS Trust that included three teaching hospital sites. Notes were reviewed against the Royal College of Surgeons general guidelines and specific laparoscopic cholecystectomy guidance from the Dutch Society of Surgery. After identifying deficiencies in compliance with numerous key areas of these guidelines a standardized operation note proforma was developed, with the aim of creating a tool that would facilitate improved adherence to standards of documentation [Appendix I]. This proforma was then introduced across the hospital Trust and its impact assessed.

2. Methods

2.1. Study design and intervention

Ethical approval was obtained from the clinical audit department of the Oxford University Hospitals Surgery and Oncology Division, and the audit was registered with Datix ID 2914. From April–November 2013, 130 consecutive operation notes on adults >18 years undergoing laparoscopic cholecystectomy were identified using Janus™ audit software and retrieved from the Surgical Emergency Unit, John Radcliffe Hospital, Oxford (emergency setting), Horton Hospital, Banbury (elective setting) and Churchill Hospital, Oxford (elective setting). Following analysis of these operation notes a standardized operation note proforma was designed (supplement 1) which included all items from the DSS and RCS guidelines in the form of keyword prompts or requiring simple yes/no responses, with white space for further details to be recorded. This proforma was disseminated around all three hospital sites, and a further review of operation notes following laparoscopic cholecystectomy was carried out from February–August 2014, for which 128 consecutive operation notes were retrieved.

2.2. Data extraction

A standardized data extraction proforma was created based on the Dutch Society of Surgery (DSS) guidelines for operation documentation post laparoscopic cholecystectomy, which identify six key steps: (1) Introduction of trocars under direct vision; (2)

Condition of the gallbladder; (3) Establishment of the critical view of safety; (4) Placement of the clips; (5) Haemostasis of the liver bed and (6) Removal of trocars under vision. Additionally, iatrogenic gallbladder perforation with leak of bile and gallstones is an important problem that is often not recorded [16,19]. Therefore a seventh step was also recorded: (7) Iatrogenic gallbladder damage.

‘Condition of the gallbladder’ was defined as a description of the presence or absence of acute/chronic inflammation or adhesions. Critical view of safety was defined as “completely unfolding Calot’s triangle by mobilizing the gallbladder neck from the gallbladder bed of the liver before clipping and transecting the cystic artery and duct”. ‘Adequate placing of the clips’ was defined as “clips encircling the entire tubular structure”, and ‘adequate haemostasis of the liver bed’ was defined as “either checking actively by pulling up the liver by lifting of the gallbladder or pushing up the liver edge by means of an instrument”. Finally, ‘Iatrogenic gallbladder damage’ was defined as a statement that confirmed or refuted the occurrence of bile or stone spillage into the peritoneal cavity.

Data were also extracted based on the RCS guidance for operation notes across nine domains: (1) Date and time; (2) Elective/Emergency procedure; (3) Name of operating surgeon and assistant; (4) Procedure performed; (5) Incision utilized; (6) Operative findings; (7) Details of closure technique; (8) Post-operative care instructions and (9) Signature.

Data were extracted by two authors working independently. To ensure inter-observer agreement the data extraction form was first trialled on a random selection of 10% of operation notes for analysis by both investigators, with results checked for consistency. Each item was rated as either “described” (1) or “not described” (0). To minimize bias, blinding of data extraction to details of location, urgency, operating surgeon and patient identifiable information was conducted by a third author.

2.3. Outcomes

There were two primary end points in this study: (1) Degree of compliance with Dutch society of Surgeons guidance; (2) Degree of compliance with RCS guidance.

There were three secondary end points: (1) Variation in completeness of operative note according to seniority of surgeon writing the operation note (registrar, consultant); (2) Variation in completeness of operative note according to setting (elective, emergency); (3) Variation in completeness of operative note according to time of day when the operation note was written (day [defined as 08:00–17:00], evening [17:00–midnight], night [midnight–0800]).

2.4. Statistical analysis

Results were compared pre- and post-introduction of the proforma. Non-parametric data were analysed using Fisher’s exact and Mann–Whitney U tests. Statistical significance was set at $p < 0.05$.

3. Results

3.1. Uptake

Uptake of the operation note proforma, which was disseminated around all three hospital sites was high, with 124/128 (97%) operation notes retrieved written using the template.

3.2. Compliance with DSS guidelines

Fig. 1 summarises the degree of compliance with DSS guidelines before and after introduction of the proforma. There were

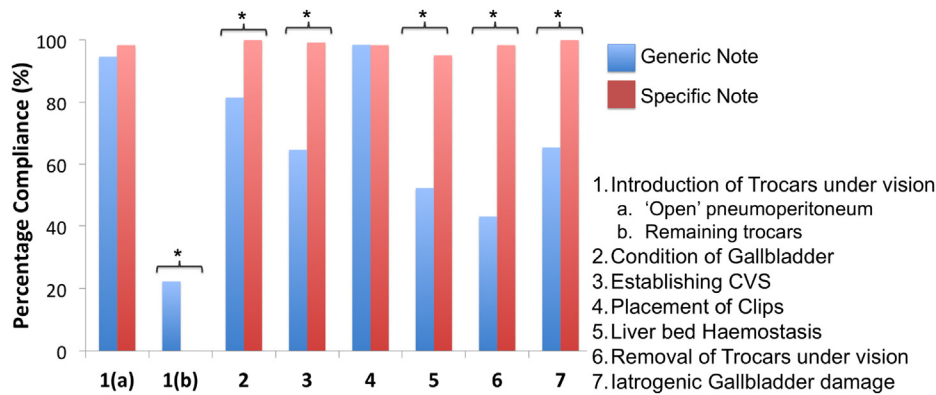


Fig. 1. Documentation of procedure-specific items. $p < 0.05$ denoted by *.

statistically significant improvements in documentation rates for the following items: (2) Condition of gall bladder; (3) Establishment of critical view of safety; (5) Liver bed haemostasis; (6) Removal of trocars under vision ($p < 0.05$). In addition there was a significant improvement for our additional item (7) Iatrogenic gall bladder damage ($p < 0.05$). Documentation completion rates remained high for two further items (1a) Introduction of trocars under vision for open pneumoperitoneum (97%) and (4) Placement of clips (96%) ($p < 0.05$). There was a significant decrease in recording of (1b) Placement of the remaining trocars under vision ($p < 0.05$).

3.3. Compliance with RCS guidelines

Table 1 summarises compliance with the RCS guidelines. Following introduction of the proforma there were statistically significant improvements in documentation rates for the following domains: Time; operative setting (elective or emergency); name of surgeon; complications and signature ($p < 0.05$). There was a fall in recording rates for date of operation from 99% to 89% ($p < 0.05$). High rates of documentation were maintained after proforma introduction for: Name of procedure, operative findings, incision, details of closure and post-operative instructions.

On a global assessment of operation note completeness against all guideline items, introduction of an operation note proforma significantly improved documentation rates for both DSS guidelines ($p < 0.001$) and RCS guidelines ($p < 0.001$).

3.4. Secondary outcomes

There was a significant positive correlation between increasing seniority of author (registrar versus consultant) and completeness

of operation note ($p < 0.001$) for the old freetext operation note. This correlation was no longer significant following introduction of the operation specific proforma ($p = 0.07$). There were no significant variations in note completeness between operative setting (emergency vs. elective) or time of day before and after introduction of the proforma (all NS).

4. Discussion

We have demonstrated that the introduction of a procedure-specific proforma to assist with writing the post-operative note following laparoscopic cholecystectomy can result in significant improvements in documentation of both generic and procedure-specific items that should be recorded for every operation. Previous studies have demonstrated poor compliance of operation notes with the DSS guidelines for laparoscopic cholecystectomy when written without the assistance of a proforma [12,16]. In addition, procedure-specific proformas have been shown to improve compliance with documentation guidelines for hip hemiarthroplasty [6] and Caesarean section, with potentially beneficial consequences for medical litigation rates [17]. To our knowledge this is the first study to demonstrate improved guideline compliance for laparoscopic cholecystectomy with the use of a proforma.

Wauben et al. have previously observed differences in operative documentation completeness between residents and attendings for laparoscopic cholecystectomy (with better performance amongst residents in their series) and have suggested that a procedure-specific template based on established guidelines could improve the quality of operation notes [18]. Borchert et al. have highlighted that there is little formal teaching of operation note writing during surgical training [19], and the use of proformas can assist more junior surgeons in documenting a complete record of the operation.

We believe that the use of procedure-specific proformas, based on established guidelines for minimum documentation data sets can have a useful role in facilitating the production of more complete and medico-legally robust operation notes. Our proforma has proved popular with surgeons, as demonstrated by its high usage levels across three hospital sites (97%). With guidelines increasingly being used to define standards for clinical practice in medical litigation [20] it is vital that we make the process of authoring guideline-compliant operation notes straightforward, through innovations including proformas.

Potential limitations of using proformas include logistical considerations in ensuring ready access to the proforma at all locations where an operation is performed, and reluctance amongst surgeons to alter their established documentation practices. In addition the role of photographic demonstration of key steps, including

Table 1
Percentage of operation notes which recorded items in the RCS operation note guidelines. $p < 0.05$ denoted by*.

Item	Generic note (%)	Specific note (%)
Date	99*	89
Time	25	82*
Elective/Emergency	3	95*
Name of Surgeon	93	99*
Name of Procedure	100	97
Operative Findings	98	100
Incision (s) Utilised	100	96
Complications	49	83*
Details of Closure	100	100
Post-op Instructions	99	98
Signature	88	96*

establishing the critical view of safety, may be of use in making operative documentation more legally watertight in the future [21]. This manuscript was authored in compliance with SQUIRE 2.0 standards for quality improvement reporting excellence [22].

Ethical approval

Ethical approval given by Oxford University Hospitals clinical audit department and registered on Datix. ID number 2914.

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Author contribution

David Thomson: Study design, Data collection, Data analysis, Manuscript writing, Editing and final approval of manuscript.

Matt Baldwin: Study design, Data collection, Data analysis, Editing and final approval of manuscript.

Maria Bellini: Data collection, Data analysis, Editing and final approval of manuscript.

Michael Silva: Study design, Data analysis, Manuscript writing, Editing and final approval of manuscript.

Conflicts of interest

None to declare.

Guarantor

Guarantor: David Thomson.

Appendix A. Supplementary data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.ijssu.2016.01.037>.

References

- [1] T.F. Lyons, B.C. Payne, The relationship of physicians' medical recording performance to their medical care performance, *Med. Care* 12 (1974) 714–720.
- [2] M. Gomey, Accurate medical records your primary line of defence, *Health Care Risk Rep.* 10 (1998) 1.
- [3] I. Edhemovic, W.J. Temple, C.J. de Gara, G.C. Stuart, The computer synoptic operative report—a leap forward in the science of surgery, *Ann. Surg. Oncol.* 11 (2004) 941–947.
- [4] National Confidential Enquiry into Perioperative Deaths, NCEPOD, London, 2002, p. 65.
- [5] The Royal College of Surgeons of England, Good Surgical Practice, The Royal College of Surgeons of England, London, 2008.
- [6] A.W. Barritt, L. Clark, A.M. Cohen, N. Hosangadi-Jayedev, P.A. Gibb, Improving the quality of procedure-specific operation reports in orthopaedic surgery, *Ann. R. Coll. Surg. Engl.* 92 (2010) 159–162.
- [7] J.A. Gossage, M.J. Forshaw, Prevalence on outcome of litigation claims in England after laparoscopic cholecystectomy, *Int. J. Clin. Pract.* 64 (13) (2010) 1832–1836.
- [8] P.R. de Reuver, J. Wind, J.E. Cremers, O.R. Busch, T.M. van Gulik, D.J. Gouma, Litigation after laparoscopic cholecystectomy: an evaluation of the Dutch arbitration system for medical malpractice, *J. Am. Coll. Surg.* 206 (2008) 328–334.
- [9] P.G. Roy, Z.F. Soonawalla, H.W. Grant, Medicolegal costs of bile duct injuries incurred during laparoscopic cholecystectomy, *J. Int. Hepato-Pancreato-Biliary Assoc.* 11 (2009) 130–134.
- [10] E.A.M. Neugebauer, S. Sauerland, A. Fingerhut, B. Millat, G.F. Buess, EAES Guidelines for Endoscopic Surgery, Springer, Berlin, 2006.
- [11] Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), SAGES Guidelines for the Clinical Application of Laparoscopic Biliary Tract Surgery, Society of American Gastrointestinal and Endoscopic Surgeons, Los Angeles: SAGES, 2010.
- [12] Dutch Society of Surgery, Advice: Guideline Laparoscopic Cholecystectomy, DSS, Amsterdam, 2006.
- [13] L.S.G.L. Wauben, W.M.U. Grevenstein, R.H.M. Goossens, F.H. van der Meulen, J.F. Lange, Operative notes do not reflect reality in laparoscopic cholecystectomy, *Br. J. Surg.* 98 (2011) 1431–1436.
- [14] R.B. Vukmir, Medical malpractice: managing the risk, *Med. Law* 23 (2004) 495–513.
- [15] T. Sathesh-Kumar, A.P. Saklani, R. Vinayagam, R.L. Blackett, Spilled gall stones during laparoscopic cholecystectomy: a review of the literature, *Postgrad. Med. J.* 80 (2004) 77–79.
- [16] L.S.G. Wauben, R.H.M. Goossens, J.F. Lange, Evaluation of operative notes concerning laparoscopic cholecystectomy: are standards being met? *World J. Surg.* 34 (2010) 903–909.
- [17] J.D.M. Nicopoullos, S. Karrar, A. Gour, K. Panter, Significant improvement in quality of caesarean section documentation with dedicated operative proforma, *J. Obstetrics Gynecol.* 23 (2003) 381–386.
- [18] L.S. Wauben, R.H. Goossens, J.F. Lange, Differences between attendings' and residents' operative notes for laparoscopic cholecystectomy, *World J. Surg.* 37 (2013) 1841–1850.
- [19] D. Borchert, R. Harshen, M. Kemps, M. Lavelle, Operative notes teaching: re-discovery of an effective teaching tool in surgical training, *Internet J. Surg.* 8 (2005) 1.
- [20] B. Hurwitz, How does evidence based guidance influence determinations of medical negligence? *Br. Med. J.* 329 (2004) 1024–1028.
- [21] K.T. Buddingh, Documenting correct assessment of biliary anatomy during laparoscopic cholecystectomy, *Surg. Endosc.* 26 (2012) 79–85.
- [22] G. Ogrinc, et al., SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process, *BMJ Qual. Saf.* (2015 Sep 14) (Epub ahead of print).