Current use of procedure specific consent forms for laparoscopic cholecystectomy

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ABSTRACT

INTRODUCTION Procedure specific consent forms (PSCFs) have been shown to improve consenting practice for a standardised list of complications. The aim of this study was to assess the current usage and quality of PSCFs in the National Health Service (NHS) for cholecystectomy, specifically comparing the listed complications with those mentioned on the NHS website.

METHODS A freedom of information request was sent to all NHS trusts asking whether they perform laparoscopic cholecystectomy and whether they have a PSCF for this. A copy of the PSCF was also requested. Complications stated on these forms were compared with those on the NHS Choices website.

RESULTS Overall, 162 (88%) of the 185 trusts responded, with 121 of these performing cholecystectomies. Among these, 20 (17%) currently use PSCFs; all provided a copy. Five (25%) of the PSCFs contained all eight risks mentioned on the NHS website. The number of risks listed varied from 4 to 18 per form. Only bile duct injury was listed on every PSCF. The least frequently mentioned complication (45% of forms) was the risk from general anaesthetic.

CONCLUSIONS This study suggests that too few trusts are using PSCFs and that those PSCFs that are in use contain too little detail on the risks of cholecystectomy. The listed risks and incidences on each PSCF were highly variable. More trusts should begin to use PSCFs during the informed consent process and each PSCF should include a nationally standardised list of potential complications to act as a prompt for discussion (and documentation) of risk.

KEYWORDS

Consent form – Informed consent – Cholecystectomy

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Gallstone disease is highly prevalent in the UK, with approximately 15% of adults thought to be affected.¹ Surgery is indicated for symptomatic patients or those with a complication related to gallstones, making cholecystectomy one of the most commonly performed procedures in the UK.¹ Although considered generally safe, complications do occur and range from minor short-term problems (such as minor wound infections) to major life-changing ones (such as major bile duct injury requiring reconstruction) but all of these may affect a patient's future quality of life to varying degrees.

For this reason, it is essential that the patient and clinician have a clear discussion about the risks and benefits of the procedure. Regarding cholecystectomy, the benefits are variable depending on the patient's indication for surgery; the complications that occur are much more consistent (although the likelihood of each may change according to circumstances). The National Health Service (NHS) website provides information for patients on the risks of cholecystectomy. These include: infection; bleeding; bile leakage (1% of cases); injury to bile duct (0.2% of cases); injury to the intestine; bowel and blood vessels (0.1% of cases); deep vein thrombosis; risks from general anaesthetic; and

postcholecystectomy syndrome (including abdominal pain, indigestion, diarrhoea, jaundice and fever).² Similar information (albeit with more complications included) is available from the American College of Surgeons.³

Informed consent is essential prior to any surgical procedure. It requires patients to have appropriate information on what the procedure involves, alternative treatments, and the likely outcomes of having and not having treatment.⁴ Aside from being fundamental to good patient care (as part of the General Medical Council guidance on good medical practice),⁵ it is also highly important in the event of medicolegal action. The information necessary for consent should be ideally communicated to the patient (and recorded as such) at various stages before the procedure. Nevertheless, the consent form is often relied on as a uniform document to confirm that a discussion has taken place, and that both the surgeon and the patient are content that all of the necessary information has been provided.

In order to ensure that consent is informed, all of the complications listed on the NHS website should be the minimum standard of information discussed (and documented) as potential adverse events when patients are considering cholecystectomy. Handwritten consent forms may be illegible or

miss key information. For this reason, procedure specific forms have been recommended as a method for improvement in consenting practice.^{6,7} To date, there are no published data on the usage and quality of procedure specific consent forms (PSCFs) for cholecystectomy. The aim of this study was to assess the uniformity and quality of PSCFs for laparoscopic cholecystectomy in the UK.

Methods

A list of NHS trusts was created using an internet search. All trusts that were identifiable as providing solely disease specific, paediatric or community care were excluded. A freedom of information request was sent to each trust asking whether laparoscopic cholecystectomy is performed at the trust and whether the trust uses a preprinted cholecystectomy consent form. A copy of the PSCF was also requested.

The Freedom of Information Act required all contacted trusts to respond within 30 days. Any trusts that had not responded by this time were sent a follow-up email. The primary outcome measure was concordance in terms of complications associated with cholecystectomy listed on the NHS Choices website. (For postcholecystectomy syndrome, this meant mentioning at least one of the five individual specified symptoms [ie abdominal pain, indigestion, diarrhoea, jaundice or fever].) Secondary outcomes were the incidences of complications quoted on consent forms and other risks mentioned. Synonyms or any terms that were deemed the 'lay' equivalent were grouped together (eg 'visceral injury' and 'damage to bowel').

Results

Of the 185 contacted trusts, 162 (88%) responded. Three-quarters of these ($n=121$, 75%) perform laparoscopic cholecystectomy. Twenty (17%) of the trusts performing cholecystectomies use PSCFs and all of these emailed a copy of it. The number of risks mentioned on each PSCF varied (range: 4–18), as did the content. In total, 22 different risks were mentioned (Table 1).

Between four and eight of the eight risks on the NHS Choices website were mentioned on each PSCF (mean: 6.5, median: 6); five PSCFs (20%) contained all eight risks. The only complication mentioned on every form was damage to the bile duct. The risk from general anaesthetic was the least commonly mentioned complication ($n=9$, 45%). Seventeen forms (85%) also mentioned a chance of conversion to open surgery, ten (50%) a possible need for intraoperative cholangiography and three (15%) a possible need for bile duct exploration. The incidence of a complication occurring was quoted infrequently and was inconsistent between forms (Table 2).

Discussion

There were two key findings in this study. First, even though the literature repeatedly shows the benefits of PSCFs, only a minority of trusts are currently using them for laparoscopic cholecystectomy. Second, where PSCFs are used, the

Table 1 List of all risks mentioned on received procedure specific consent forms

Complication	Number of forms
Adhesions	1 (5%)
*Anaesthetic risks	9 (45%)
*Bile duct injury	20 (100%)
*Bile leakage	19 (95%)
*Bleeding	19 (95%)
Cholecystostomy	1 (5%)
Death	1 (5%)
Haematoma	1 (5%)
Hernia	8 (40%)
*Infection	18 (90%)
Need for further procedures	1 (5%)
Numbness	1 (5%)
Pain	7 (35%)
Pancreatitis	1 (5%)
Peritonitis	2 (10%)
Poor wound healing	1 (5%)
Retained stone	10 (50%)
*Postcholecystectomy syndrome (any symptom)	11 (55%)
Scars	6 (30%)
Surgical emphysema	2 (10%)
Urinary retention	1 (5%)
*Venous thromboembolism	13 (65%)
*Visceral injury	17 (85%)
*Mentioned on the National Health Service website	

information included on them is highly variable (in terms of the number of risks mentioned and quoted incidences) and in three-quarters, key risks were omitted. These two findings have important implications. The infrequent use of PSCFs suggests that the majority of trusts are relying on handwritten consent forms completed by the surgeon (or the surgeon's team), which are unreliable in terms of both what is discussed and what is documented.⁸ Worryingly, however, most PSCFs in use currently omit key complications, which implies that not enough information is provided during the consent process.

Informed consent is a process and signing the consent form is only one element. Despite this, the consent form is often relied on as a prompt to ensure that all key complications are mentioned to the patient. It also serves as documentation that a discussion regarding the benefits, risks and alternatives to the procedure has occurred, and that both the surgeon and the patient are happy to proceed, and if patients are provided with a copy of the consent form, they can use it for further reference after the consultation. Where PSCFs

Table 2 Incidences quoted on consent forms for complications mentioned on the National Health Service (NHS) website

Complication	Number of forms quoting incidence	Mean incidence on forms (range)	Incidence on NHS website
Infection	1 (5%)	5%	–
Bleeding	0 (0%)	–	–
Bile leakage	6 (30%)	1.8% (1–5%)	1%
Injury to bile duct	10 (50%)	0.425% (0.02–2%)	0.2%
Injury to intestine, bowel and blood vessels	5 (25%)	0.444% (0.02–1.5%)	0.1%
Deep vein thrombosis	1 (5%)	1%	–
Risks from general anaesthetic	0 (0%)	–	–
Postcholecystectomy syndrome	1 (5%)	10%	–

are used but miss details on certain complications, it may mean that those risks have not been discussed with the patient and so have not been included in the consent process. This is likely to be confounded by the fact that patients could assume that the information provided on PSCFs is accurate and complete.

A lack of detail can have serious repercussions for both the patient and the surgeon. If patients do not have all of the information required to make an informed choice, they could be putting themselves at risk of suffering from an adverse outcome of which they were unaware. Surgeons, on the other hand, could be opening themselves up to medico-legal scrutiny by bringing the completeness of the consenting process into question. For the most commonly mentioned risk on the received PSCFs (bile duct injury), litigation is frequent⁹ and monetary compensation in the UK has been noted up to £216,000 (reflecting the significant adverse impact on quality of life),¹⁰ providing an example of the importance that both the surgeon and the patient understand the risks involved.

A literature review on PubMed did not reveal any other studies looking at current PSCFs for cholecystectomy. The only similar study for any general surgical procedure (by the same authors as this study) assessed PSCFs for inguinal hernia repairs and found similar results.¹¹ The British Orthopaedic Association and British Association of Urological Surgeons have successfully implemented national standardised consent forms, which have had a positive impact on the consent process.^{12–15}

The high response rate in our survey is almost certainly due to the compulsory requirement for government organisations to respond to freedom of information requests, and makes the study valid and reliable. It cannot be guaranteed that the non-responding trusts did not differ in some way from those that did respond but as the request for information did not include the reason for the request, there is unlikely to be any bias with regard to which trusts responded.

The NHS Choices website was used as the standard list for comparison as it is generic, easily accessible and likely to be considered a reliable reference for patients undergoing

surgery. While the risks mentioned in other sources may differ, the issue of variability of current PSCFs will remain unchanged.

A limitation of our study is that it is not known whether clinicians using the PSCFs amended them to include all of the risks listed on the NHS website or whether other risks were discussed and documented elsewhere (eg clinic letters). Furthermore, this study did not examine the quality of handwritten forms in trusts not using PSCFs and the assumption that these are poor is based solely on previously published literature.^{6–8} With regard to the quoted incidences of complications, it is possible that these reflect the individual organisation's outcomes although this is unlikely given the lack of current follow-up for cholecystectomies in the UK.

This study highlights a need for improvement in consenting practice for a high volume procedure in the UK. A randomised controlled trial published in 2018 showed that the introduction of a PSCF for cholecystectomies improved the documentation of standard complications.¹⁶ The problem is that the PSCFs currently in use vary widely in terms of the complications mentioned and the quoted incidence of each, and they often miss key information. A change is therefore needed to ensure that all PSCFs meet a minimum standard in line with the published literature and information available through national bodies. This could be achieved with the introduction of a national standardised consent form. Ongoing audit into the type of complications and their frequency would be useful (both nationally and locally) to allow regular update of the PSCFs.

Finally, consideration should be given to the 2015 *Montgomery v Lanarkshire Health Board* judgement and its subsequent impact on the consent process. Whereas it was previously acceptable to mention the standard risks of a procedure so long as this complied with what other experts would say, since 2015 the material risks unique to that person must be considered and discussed.¹⁷ This means that a single list of complications is unlikely to be adequate for every patient (and at any rate, incidences are likely to vary with changing patient and procedural factors). This does not make PSCFs obsolete but perhaps changes the perspective

in that the listed complications should be viewed as a minimum standard rather than an exhaustive list.

Consent forms could be changed to include a list of all complications (ie those mentioned on the NHS Choices website) together with free text space for additional information or amendments relevant to that specific patient or case. This would ensure that the consent process is unique for each patient (ie focusing on the material risks) and avoids the omission of key information applicable to everyone (which can occur with handwritten forms).

Conclusions

This study suggests that too few trusts are using PSCFs and that those that are in use contain too little detail on the potential risks of cholecystectomy. The listed risks and their quoted incidences vary greatly between trusts. Our recommendation is that more trusts should use PSCFs during the informed consent process and each PSCF should include a nationally standardised list of potential complications to act as a prompt for discussion (and documentation) of risk.

Stating a list of complications in writing or verbally to the patient does not make consent valid: it is only validated by an individualised discussion that ensures understanding of what is involved and what might occur. Conversely, just because all the recognised complications were not written down, does not mean they were not discussed or that the consent given was not valid. Nevertheless, the printed standardised list does act as a prompt to discuss the risks and should be regarded as the minimum standard of information that must be communicated (albeit in an appropriate, personalised way for the individual patient).

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