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Patient-reporting improves estimates of postoperative complication rates: a prospective cohort study in gynaecological oncology

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Background: Most studies use hospital data to calculate postoperative complication rates (PCRs). We report on improving PCR estimates through use of patient-reporting.

Methods: A prospective cohort study of major surgery performed at 10 UK gynaecological cancer centres was undertaken. Hospitals entered the data contemporaneously into an online database. Patients were sent follow-up letters to capture postoperative complications. Grade II–V (Clavien–Dindo classification) patient-reported postoperative complications were verified from hospital records. Postoperative complication rate was defined as the proportion of surgeries with a Grade II–V postoperative complication.

Results: Patient replies were received for 1462 (68%) of 2152 surgeries undertaken between April 2010 and February 2012. Overall, 452 Grade II–V (402 II, 50 III–V) complications were reported in 379 of the 1462 surgeries. This included 172 surgeries with 200 hospital-reported complications and 231 with 280 patient-reported complications. All (100% concordance) 36 Grade III–V and 158 of 280 (56.4% concordance) Grade II patient-reported complications were verified on hospital case-note review. The PCR using hospital-reported data was 11.8% (172 out of 1462; 95% CI 11–14), patient-reported was 15.8% (231 out of 1462; 95% CI 14–17.8), hospital and verified

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patient-reported was 19.4% (283 out of 1462; 95% CI 17.4–21.4) and all data were 25.9% (379 out of 1462; 95% CI 24–28). After excluding Grade II complications, the hospital and patient verified Grade III–V PCR was 3.3% (48 out of 1462; 95% CI 2.5–4.3).

Conclusion: This is the first prospective study of postoperative complications we are aware of in gynaecological oncology to include the patient-reported data. Patient-reporting is invaluable for obtaining complete information on postoperative complications. Primary care case-note review is likely to improve verification rates of patient-reported Grade II complications.

There is growing interest in using patient-reported outcomes as benchmarking standards for surgery, with complications one of the many measures being explored. Data on complications can be collected in a variety of ways. The most common method is retrospective case-note review, which provides first-hand information on the clinical course and complications experienced by the patient while in hospital. However, it is time consuming and subject to recording bias. Prospective data collection is an alternative used in clinical audits such as the UK National Cardiac Surgery Register (Bridgewater, 2010). Prospectively collected data on a limited number of surrogate complication measures such as return to theatre and readmission are also available as part of Hospital Episode Statistics (HES; <http://www.hesonline.nhs.uk>), an administrative database used in the National Health Service, UK. With all approaches, there is under reporting as a result of poor compliance with completing audit data, incorrect coding of procedures (Cockbain *et al*, 2012) and treatment of patients for complications in primary care or in institutions other than the hospital where the initial surgery was performed.

One strategy for overcoming some of these biases is to use patient-reported complication data. This is distinct from the patient-reported outcomes measures (PROMs) that are used to evaluate the effects of treatments including surgery (Guldberg *et al*, 2012). Patient-reported outcomes measures are quality of life measures of patient experience, focused on those outcomes that matter to patients (person-focused) (McHorney, 1997). They cover the domains of physical, emotional and social health (Howell *et al*, 2013) and complement disease focused outcomes such as survival, mortality and surgical complications.

Currently, there is limited literature on the additional value of patient-reported complications following surgery. We are only aware of three studies (Dushey *et al*, 2011; Alazzawi *et al*, 2012; Greenbaum *et al*, 2012) examining concordance of clinical and patient-reported complications, in elective hip and knee replacement surgery. These suggest variable rates of correct reporting for different complications with good concordance for clearly defined complications such as deep vein thrombosis (DVT) and pulmonary embolism (PE) and poor concordance for those less clearly defined such as ‘major bleeding’.

We report on whether patient-reporting of complications in the multicentre prospective audit, the United Kingdom Gynaecological Oncology Surgical Outcomes and Complications (UKGOSOC) was able to improve the estimation of postoperative morbidity resulting from gynaecological cancer surgery. Our research questions for this study were (1) What is the concordance between patient-reported and hospital-reported postoperative complications? (2) What is the difference in the estimates of overall postoperative morbidity according to data source? (3) What is the sensitivity of hospital- and patient-reporting for detection of postoperative complications? (4) What is the most feasible questionnaire format for collecting patient-reported data on postoperative complications?

MATERIALS AND METHODS

Ten gynaecological cancer centres in the United Kingdom participated in UKGOSOC. This included eight centres from

England, one from Wales and one from Scotland. Eligible surgeries were defined as all major procedures undertaken on a gynaecological oncology theatre list. In addition to cancer surgery, this included surgery for benign conditions in women with a complicated surgical history or high suspicion of cancer and risk-reducing surgery in women at risk of familial gynaecological cancer. While all operative laparoscopy was included, diagnostic procedures and surgery for complications were excluded.

A surgical complication was defined as ‘an undesirable and unintended result of an operation affecting the patient that occurs as a direct result of the operation’ (Sokol and Wilson, 2008). Postoperative complications were defined as those occurring following the surgery and individual complications were defined as per Supplementary Table 1.

Data on surgery and the postoperative course in hospital were entered by the clinicians onto a central online database. Access to the system was restricted to users nominated by the audit lead in each centre who were given individual unique usernames and passwords. The surgeon entered the details of the surgery, co-morbidity and any intraoperative complications usually in theatre. The hospital-reported postoperative complications were entered by the clinical team contemporaneously as they occurred on the ward and while entering discharge details. The system was set up in such a way that any data once entered by the hospital team could not be amended unless they contacted the coordinating centre (CC).

Ethics approval was sought from the Joint UCL/UCLH Committees on the Ethics of Human Research in June 2008, which advised that the project was considered to be an audit, not requiring ethical review. Women were provided written information about the study. Consent was obtained to include their personal identifiers on the central database so that follow-up letters (FULs) could be sent postoperatively from the CC at University College London ~8 weeks following the surgery. Women had the option of only allowing their anonymised data to be entered, in which case they were not included in the central follow-up from the CC. The list of women eligible for follow-up was checked by the respective clinical teams before mailing to ensure no letters were sent to deceased patients or those still in hospital.

Initially an open, free-text question was used to collect patient-reported data. Women were asked, ‘Have you had a complication following your gynaecological surgery? If so, please give details’ (Supplementary document 1). Women were also requested to provide their telephone numbers to allow for clarifications. Interim analysis of the FUL was undertaken in July 2011 to elucidate the common postoperative complications experienced by women so that a closed format questionnaire could be developed to capture data in a uniform manner that could be easily interpreted and analysed. A list of 11 common postoperative complications was derived, which included wound breakdown, infections, pelvic/abdominal abscess/haematoma, heavy vaginal bleeding, lymphoedema, lymphocyst, constipation, other bowel problems, bladder problems (including incontinence and urinary retention), DVT and PE. Every complication was briefly described and the questions included a subset on management (whether readmission or reoperation had been necessary). Space was provided after each

question for the patient to add any additional details if they so wished. Women were also asked questions about the main language spoken in their home, whether the questionnaire was in a language that they could easily understand, and their educational status. The responses were kept to simple 'yes/no' answers, with a view to minimise free text. Initially, two formats of the questionnaire were designed. These were then circulated among eight non-medical female colleagues and two lay volunteers. They were asked to comment on the questions and the format of the questionnaire. In the first format, women were asked if they had suffered a particular complication from the surgery. Following the main question, space was provided to enter details regarding the management. In the second format, the main question was followed by a subset of specific questions regarding management with yes/no answers. Seven out of the ten women who had been asked to evaluate the questionnaire preferred the second format as the questionnaire though longer than the first was easier to complete with minimum writing required. Hence, this latter format was adopted (Supplementary document 2).

All replies were entered on the central audit database. The data were cleaned and analysed by a single clinician (RI), a fully trained obstetrician and gynaecologist. The same researcher contacted all women for clarification of equivocal replies. The postoperative complications were classified according to the Clavien and Dindo system in which complications are graded from I to V (with two subsets each in Grades III and IV), based on their severity and the intervention required (Dindo *et al*, 2004; Table 1). Hernias that had been managed conservatively were included under Grade II rather than Grade I. Grade I complications being the least severe (not requiring any specific pharmacological/surgical/radiological intervention) were excluded from future analysis as it was felt these could be subject to individual variation. Clinical teams were contacted for individual confirmation of all Grade II–V postoperative complications not previously reported by the hospital. Patient-reported readmissions, reoperations and admissions to intensive care were forwarded as soon as the replies were received and all other patient-reported complications were forwarded at quarterly intervals.

The postoperative complication rate (PCR) was calculated as the proportion of eligible surgeries with a Grade II–V postoperative complication. Concordance was calculated as proportion of Grade II–V patient-reported complications that were verified by the hospital clinician.

RESULTS

The audit consisted of a pilot phase from 1 April 2010 to 31 January 2011 that included 3 centres and a main phase from 1 February 2011 to 29 February 2012 that included all 10 centres. In all, 2575 surgical procedures were undertaken in women who had provided personal identifiers. Follow-up letters were not sent following 423 surgeries, which included 24 where the women had died and 399 with missing or incomplete addresses. The remaining 2152 were sent FUL and replies were received for 1462 (68%) surgeries (Figure 1).

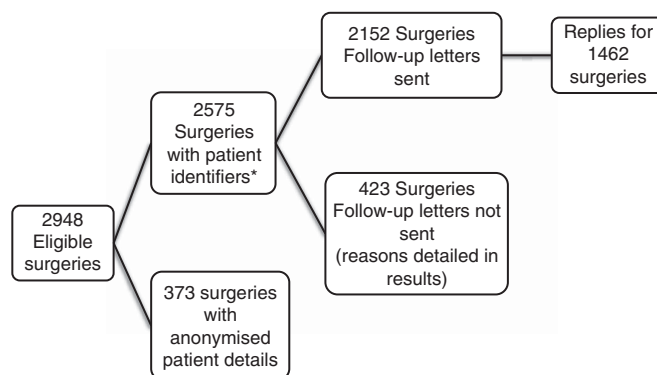
Median age at surgery was 63 years (IQR 53–72). The final diagnosis in the 1462 surgeries included ovarian cancer in 481, uterine cancer in 427, cervical cancer in 80, vulval cancer in 79 and benign pathology in 395.

In 256 of 265 (97%) questionnaire format replies, women reported that English was the main language spoken at home. Of the remaining nine (3%) only two women reported having difficulty understanding English and requiring help to complete the questionnaire. In all, 30% of the women had left school before 15 years of age and 15% had completed a bachelor's degree (Table 2).

Table 1. Clavien and Dindo's classification of complications

Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions
	Allowed therapeutic regimens are drugs such as antiemetics, antipyretics, analgesics, diuretics, electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and TPN are also included
Grade III	Requiring surgical, endoscopic or radiological intervention
IIIa	Intervention not under general anaesthesia
IIIb	Intervention under general anaesthesia
Grade IV	Life-threatening complication (including CNS complications – excludes TIA) requiring IC/ICU management
IVa	Single organ dysfunction (including dialysis)
IVb	Multiorgan dysfunction
Grade V	Death of a patient

Abbreviations: CNS=central nervous system; IC=intensive care; ICU=intensive care management; TIA=transient ischaemic attack; TPN=total parenteral nutrition. Source: Dindo *et al* (2004).



*Surgeries where women had given consent to include their identifiers to receive follow-up letters.

Figure 1. Response to follow-up letters.

Hospital-reported complications. In 172 of these 1462 surgeries, hospitals reported 200 Grade II–V postoperative complications. The commonest complications reported were infections (51, 26%), wound breakdown (48, 24%), ileus (13, 7%) and bladder-related complications (13, 7%).

Patient-reported complications

Free-text format FUL. In 1787 of the 2152 surgeries (1 November 2010 to 31 December 2011), FUL was sent using the free-text format (Figure 2a). Replies were received for 1197 (67%). There were 289 patient-reported complications in 265 surgeries. In all, 91 were excluded as they were Grade I postoperative complications (67), intra-operative (four) or related to chemo/radiotherapy or care in hospital (20).

Patient-reported Grade II–V complications: There were 198 complications related to 188 surgeries, which included 26 readmissions, 22 reoperations, four complications requiring management in intensive care and two perioperative deaths. The

Table 2. Demographics of women who underwent surgery

	Number	Median (IQR)
Age	1462	63 years (53–72)
Diagnosis		%
Ovarian ^a	481	33
Uterine ^b	427	29
Cervical	80	6
Vulval ^c	79	5
Benign	395	27
Total	1462	
Main language spoken at home^d (n = 265)		
English	256	97
Other ^e	9	3
Questionnaire in a language that could be understood^d (n = 265)		
Yes	263	99
No	2	1
Help required to complete questionnaire^d (n = 265)		
Yes	2	1
No	263	99
Educational status^d (n = 265)		
Finished school at or before 15 years of age	79	30
Completed GCSEs, O levels or equivalent	67	25
Completed A levels or equivalent	21	8
Completed further education but not a degree	45	17
Completed a bachelor's degree/master's degree/PhD	41	15
Other (please specify)	5	2
Missing	7	3
Total	265	
Abbreviations: IQR = interquartile range; GCSE = General Certificate of Secondary Education.		
^a Includes primary ovarian, fallopian tube, primary peritoneal, non-gynae primary, unknown primary and synchronous cancers.		
^b Includes primary endometrial cancer, carcinosarcomas and uterine sarcomas.		
^c Includes primary vulval and vaginal cancers.		
^d Limited to women who completed the questionnaire format of follow-up letters.		
^e Five Welsh, two Polish, one Greek and one French.		

commonest patient-reported complications were wound breakdown, infections (mostly urinary tract and chest infections) and lymphocysts/lymphoedema (Table 3). In all, 57 (53 surgeries) of the 198 patient-reported complications had already been reported by the hospitals.

Patient-only-reported complications: The remaining 141 complications (135 surgeries) were reported solely on FUL. They included 125 Grade II, 2 Grade IIIa, 9 Grade IIIb and 3 Grade IVa complications (Table 3). In reply to the FUL, the family members of two patients informed the CC of their relatives' perioperative deaths (Grade V), one due to cardiac failure and the other due to bowel perforation. In this subgroup of patient-only-reported complications, the commonest complications were wound breakdown, infections and lymphocysts/lymphoedema (Table 3).

Hospital-only-reported complications: For this cohort, there were an additional 113 Grade II–V complications in 104 surgeries reported by hospitals but not reported by patients on FUL, with the commonest being infections followed by wound breakdown and lymphocysts/lymphoedema. This included 10 readmissions, 3 reoperations and 3 admissions to intensive care (Table 3).

Patient comments: Women were able to add comments on the FULs. In all, 3 of 1197 women commented that they were unsure of what was meant by a 'complication'. One woman also felt that the question had been 'too poorly defined to answer'.

Questionnaire format FUL. Following 365 surgeries between January and February 2012, FUL was sent using the closed questionnaire format (Figure 2b). In all, 265 (72%) replies were received. In all, 217 complications were reported in 165 surgeries. Ninety-nine complications were excluded as they were Grade I (94), intra-operative complications (4), incorrectly reported Grade II complication (1) and not related to surgery (1). The latter was one where the family had reported death of the patient due to progression of cancer, as a postoperative complication.

Patient-reported Grade II–V complications: The remaining 117 Grade II–V postoperative complications (101 surgeries) included 9 readmissions, 2 reoperations and 2 requiring intensive care management (Table 4). The commonest patient-reported complications were infection, wound breakdown and lymphocyst/lymphoedema. Six of the complications had already been reported by the hospitals.

Patient-only-reported complications: The 111 complications (96 surgeries) reported only on FUL included 108 Grade II, 1 Grade IIIa, 1 Grade IIIb and 1 Grade IVa. In this subgroup, once again the commonest complications were infection, wound breakdown and lymphocyst/lymphoedema (Table 4).

Hospital-only-reported complications: For this cohort, there were an additional 24 complications in 21 surgeries that were reported by the hospitals but not by patients with the commonest being infections, bladder problems and wound breakdown. This included three readmissions, three reoperations and one admission to intensive care (Table 4).

Patient comments: Women were asked to for their views on how the questionnaire could be improved. Two women felt inclusion of 'Gynaecological Cancer Research Centre' in the return address (printed at the back of the envelope), breached confidentiality about their diagnosis. The other comments included the question on educational status being inappropriate, request for larger print size and for the questionnaire to be sent soon after surgery to avoid surgical complications being confused with those related to chemo/radiotherapy.

Concordance of complications

Grade III–V complications. There were 36 patient-reported complications with significant sequelae such as reoperations, admissions to intensive care and perioperative deaths of which 17 had been previously reported by the hospitals. The Grade of the remaining patient-only-reported 19 complications was confirmed by the clinician resulting in 100% concordance for complication Grade. The details of 1 of these 19 patient-only-reported complications were found to be incorrect. This was a case of patient-reported vault dehiscence requiring resuturing in theatre when in fact the vault was intact and only an examination under anaesthesia had been performed. This resulted in 97.2% (35 out of 36) concordance for complication type for Grade III–V patient-reported complications.

Grade II complications. There were 280 patient-reported Grade II complications of which 46 had been previously reported by the hospitals. The remaining 234 patient-only-reported complications were forwarded to the respective centres for the clinicians to verify from hospital records. Case notes for 221 (94.4%) of these complications were checked and the complication grade and type was confirmed for 113. These included 34 infections (25 urinary tract infections, 5 pyrexia of unknown origin, 1 each of chest infection, cellulitis, gastroenteritis and *Clostridium difficile*

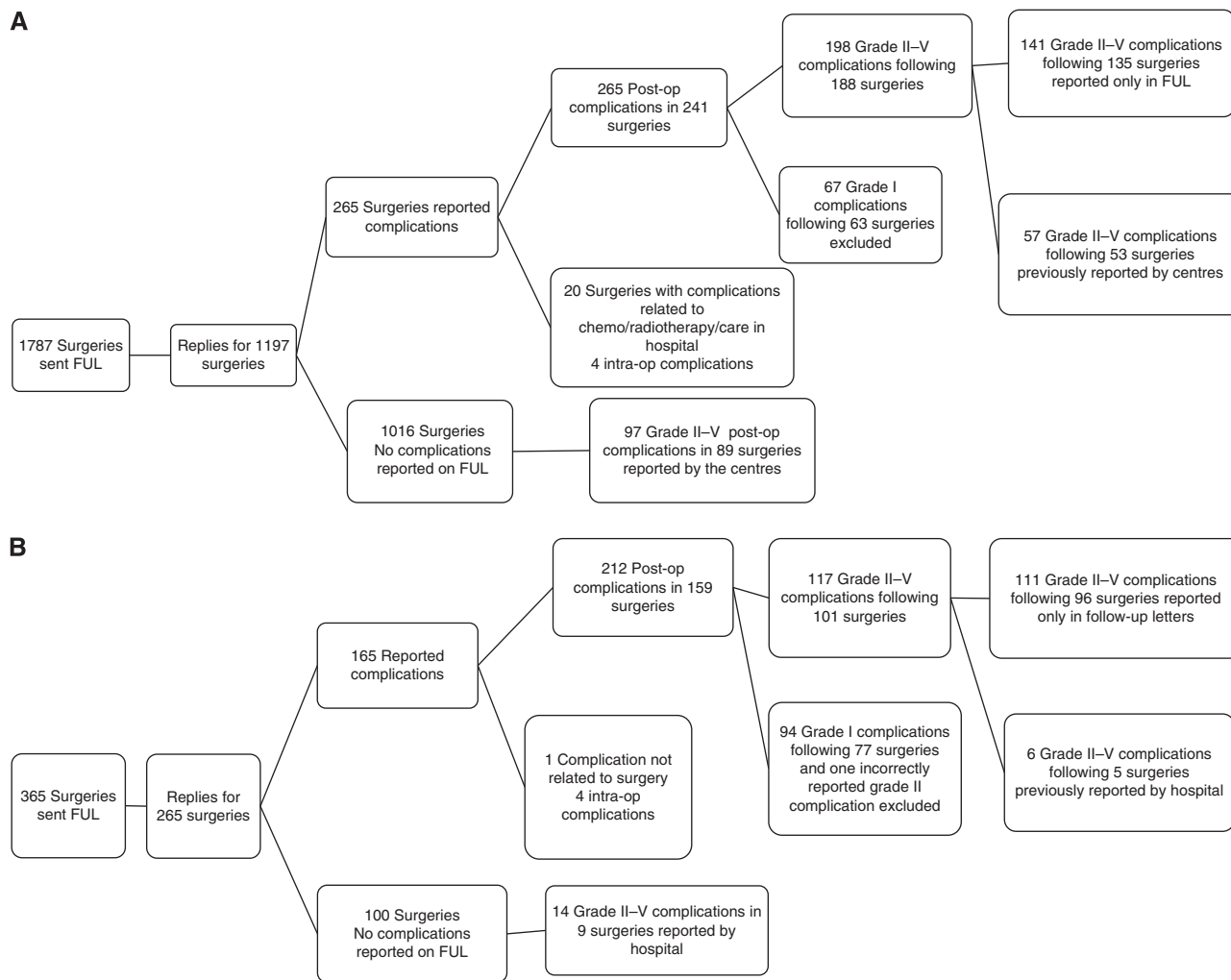


Figure 2. Patient-reported postoperative complications. (A) Follow-up letters (FULs) that used free-text format. (B) FULs that used questionnaire format.

diarrhoea), 33 wound breakdowns, 9 lymphoedema, 6 lymphocysts, 5 haematomas, 4 DVTs, 4 PEs, 3 secondary haemorrhages, 3 readmissions to hospital with vomiting and abdominal pains (no obvious cause found), 2 cases of ileus, 2 cases of severe constipation, 2 hernias, 1 case each of dural tap, colovaginal fistula, urinary retention, pressure sore, haematemesis (secondary to stress ulcer) and allergic reaction to antibiotics. One case of PE had been wrongly reported by the patient as a postoperative complication when in fact it had occurred before surgery and therefore was excluded. The concordance for complication Grade for patient-reported Grade II complications was 56.4% ($\{46 + 112 = 158\} / 280$). Excluding the incorrectly reported PE, 279 patient-reported Grade II complications were included in further analysis.

In the case of allergic reaction, the patient had reported allergy to antibiotics when in fact the allergy was transfusion-related to pooled platelets. There was also a case of readmission for diarrhoea which was confirmed by the clinician. Although the complication type was correctly reported, the causative agent was not *Clostridium difficile* as reported by the patient. This resulted in 55.7% (156 out of 280) concordance for complication type for patient-reported Grade II complications.

The centres were unable to confirm the remaining 108 Grade II complications, which included 43 wound breakdowns, 39 infections (25 urinary tract infections, 8 chest and 6 pyrexia of unknown origin), 9 lymphoedema (5 treated with compression stocking and

4 treated with physiotherapy), 5 lymphocysts (drained in the outpatients department), 4 bowel-related complications (2 cases of severe constipation requiring readmission and enemas, 1 case of ileus requiring nasogastric tube insertion, 1 case of bowel obstruction requiring readmission and steroids), 3 bladder-related complications (2 cases of urinary retention requiring recatheterisation and 1 case of extreme urge incontinence requiring treatment by urologists), 2 hernias, 1 case each of neuropathic pain, depression and pressure sores.

Postoperative complication rate. A postoperative Grade II–V complication was reported in 379 of the 1462 surgeries. This included a total of 452 (402 Grade II that includes 4 hernias, 50 Grade III–V) complications. Of the 379 surgeries with a reported postoperative Grade II–V complication, 172 had at least one hospital-reported complication, 231 had at least 1 patient-reported complication of which 124 were verified and 107 were not (Table 5).

On hospital-reporting, the proportion of surgeries with a postoperative complication was 11.8% (172 out of 1462; 95% CI 11–14) and on patient-only-reporting it was 15.8% (231 out of 1462; 95% CI 14–17.8). Using hospital and hospital verified FUL data, this rate increased to 19.4% (283 out of 1462; 95% CI 17.4–21.4). Using hospital and all FUL data, the rate was 25.9% (379 out of 1462; 95% CI 24–28).

Table 3. Grade II–V postoperative complications from follow-up letters which used free-text format

Complication category	Patient-reported complications – all (only reported by patient)						Only reported by hospital	Overall total
	Total	Grade II	Grade IIIa	Grade IIIb	Grade IVa	Grade V		
Wound breakdown	73 (54)	63 (47)		9 (6)	1 (1)		22	95
Infection	42 (32)	42 (32)					35	77
Lymphocyst/Lymphoedema	19 (18)	19 (18)					8	27
Abscess/Haematoma	8 (4)	5 (3)	2 (1)	1			4	12
Bladder problems	5 (4)	5 (4)					6	11
Ileus	5 (2)	5 (2)					6	11
Bowel obstruction	2 (1)	1		1 (1)			3	5
Bowel perforation	1 (1)					1 (1)	0	1
Bowel – other	4 (2)	4 (2)					2	6
Fistula	4 (1)			4 (1)			2	6
Primary haemorrhage	4 (1)			3	1 (1)		1	5
Secondary haemorrhage	2	2					4	6
Deep vein thrombosis	2 (2)	2 (2)					1	3
Pulmonary embolism	2 (2)	2 (2)					2	4
Cardiac	3 (1)	2				1 (1)	4	7
Respiratory	2 (2)		1 (1)		1 (1)		4	6
Neurological	3 (2)	3 (2)					1	4
Hernia	3 (3)	3 (3)					0	3
Anastomotic leak	2			2			0	2
Psychiatric	1 (1)	1 (1)					1	2
Other complications	11 (8)	8 (7)		2 (1)	1		7	18
Total	198 (141)	167 (125)	3 (2)	22 (9)	4 (3)	2 (2)	113	311

Complications reported by both hospital and patients = all patients reported – those only reported by patient. Readmissions = 26 (21 patient-only-reported, 5 patient- and hospital-reported) + 10 hospital-only-reported. Reoperations = 22 (9 patient-only-reported, 13 patient- and hospital-reported) + 3 hospital-only-reported. Admissions to intensive care = 4 (3 patient-only-reported, 1 patient- and hospital-reported) + 3 hospital-only-reported. Perioperative deaths = 2 (both patient-only-reported).

Excluding Grade II complications, the hospital-reported Grade III–V PCR was 2.0% (29 out of 1462; 95% CI 1.4–2.8). Using hospital and hospital-verified FUL data, this rate increased to 3.3% (48 out of 1462; 95% CI 2.5–4.3). Since all the Grade III–V patient-only-reported complications had been confirmed and found to be correct, this rate was the same when all FUL data were included.

Post-op complication rate for cancer surgery. The hospital-reported Grade II–V PCR for gynaecological cancer surgery (1067), after excluding surgery for benign disease (395), was 14% (146 out of 1067; 95% CI 12–17). Using hospital and hospital verified FUL data, this rate increased to 21.5% (229 out of 1067; 95% CI 19–24). Using hospital and all FUL data, the rate was 27% (289 out of 1067; 95% CI 25–30).

Excluding Grade II complications, the hospital-reported Grade III–V PCR for gynaecological cancer surgery (1067) was 2.3% (24 out of 1067; 95% CI 1.5–3.3). Using hospital and hospital verified FUL data, this rate increased to 3.5% (37 out of 1067; 95% CI 2.5–4.7). Again, since all the Grade III–V patient-only-reported complications had been confirmed and found to be correct, this rate was the same when all FUL data were included.

Sensitivity for detection of postoperative complications. The sensitivity of hospital-reporting for detection of all 379 surgeries with Grade II–V postoperative complications was 44% (200 out of 452; 95% CI 40–49) and that of patient-reporting was 70% (315 out

of 452; 95% CI 65–74) (Table 6). When the free-text format was used for FUL, sensitivity for hospital-reporting was 55% (95% CI 49–60) and 64% (95% CI 58–69) for patient-reporting. With the questionnaire format, sensitivity of hospital-reporting of complications was 21% (95% CI 15–29) with patient-reporting being 83% (95% CI 76–88).

Excluding the 121 (108 Grade II and 13 notes not checked) complications not confirmed by the hospital, the sensitivity for patient-reporting was 59% (194 out of 331; 95% CI 53–64) using both questionnaire formats and for hospital-reporting was 60% (200 out of 331; 95% CI 55–66) (Table 6).

Grade II complications accounted for 402 (89%) (279 patient-reported, 123 hospital-only-reported) out of the total 452 complications. Excluding these, the overall sensitivity of hospital-reporting for detection of Grade III–V postoperative complications was 62% (31 out of 50; 95% CI 48–74) and patient-reporting was 72% (36 out of 50; 95% CI 58–83) (Table 6).

Types of postoperative complications reported by hospital and patients. Hospital-reporting appeared better for cardiac complications, ileus, bladder complications, bowel obstruction and respiratory complications. Patients were better at reporting hernia, wound breakdown, DVT, lymphocysts/lymphoedema, neurological complications and pelvic/abdominal abscess/haematoma. Both hospital and patients had similar reporting rates for anastomotic leak, fistula, primary haemorrhage, bowel perforation and

Table 4. Grade II–V postoperative complications from follow-up letters which used questionnaire format

Complication category	Patient-reported complications – all (only reported by patient)						Overall Total
	Total	Grade II	Grade IIIa	Grade IIIb	Grade IVa	Only reported by hospital	
Infection	44 (43)	43 (43)			1	5	49
Wound breakdown	41 (38)	40 (37)		1 (1)		4	45
Lymphocyst/Lymphoedema	12 (12)	12 (12)				0	12
Bladder problems	1	1				5	6
Ileus	1 (1)	1 (1)				4	5
Bowel obstruction	1 (1)	1 (1)				1	2
Bowel perforation						1	1
Bowel – other	3 (3)	3 (3)				2	5
Fistula	1 (1)	1 (1)				0	1
Secondary haemorrhage	4 (3)	3 (3)		1		0	4
Abscess/Haematoma	2 (2)	2 (2)				0	2
Deep vein thrombosis	2 (2)	2 (2)				0	2
Pulmonary embolism	1 (1)	1 (1)				0	1
Hernia	1 (1)	1(1)				0	1
Ureteric obstruction	1 (1)		1 (1)			0	1
Other complications	2 (2)	1 (1)			1 (1)	2	4
Total	117 (111)	112 (108)	1 (1)	2 (1)	2 (1)	24	141

Complications reported by both hospital and patients = all patients reported – those only reported by patient. Readmissions = 9 (9 patient-only-reported) + 3 hospital-only-reported. Reoperations = 2 (1 patient-only-reported, 1 patient- and hospital-reported) + 3 hospital-only-reported. Admissions to intensive care = 2 (1 patient-only-reported, 1 patient- and hospital-reported) + 1 hospital-only-reported.

Table 5. Proportion of surgeries with a post-operative complication

Highest grade of complication	Post-operative complications					
	Hospital-reported	Patient-reported			Total	Hospital and patient verified
Verified on hospital notes review		Not verified on hospital notes review				
II	143	105	107	212	235	331
III–V	29	19	0	19	48	48
Total surgery	172	124	107	231	283	379

psychiatric complications (Supplementary Table 2). The numbers were too small for any formal statistical comparisons.

DISCUSSION

To our knowledge, this is the first study to use both hospital- and patient-reported information to estimate the overall postoperative morbidity in gynaecological oncology surgery. Concordance of patient-reported complications with hospital case-note review was 100% for Grade III–V and 56.4% for Grade II postoperative complications. The hospital-reported postoperative Grade II–V complication rate for major surgery undertaken in gynaecological oncology centres of 11.8% increased to 19.4% if hospital verified patient-reported complications were also included and 25.9% on

inclusion of all patient-reported complications. The hospital and patient verified Grade III–V PCR was 3.3%. Overall, sensitivity for patient-reporting was 70% and hospital-reporting was 44%. During the study, a closed format questionnaire was developed that enabled more accurate capture of complication rates. The questionnaire and the process set-up in UKGOSOC could therefore better inform future data capture of complications in gynaecological oncology surgery.

Patients reported a higher proportion of the overall 452 Grade II–V complications when compared with hospitals (55.8% vs 44.2%). A survey of patients following radical prostatectomy also noted that patients reported more complications in comparison with previous hospital/clinician reported rates (Fowler *et al*, 1993). However, the sensitivity of patient- and hospital-reporting was similar (59% vs 60%) when the 121 Grade II complications not

Table 6. Sensitivity of patient- and hospital-reporting for Grade II–V postoperative complications

Data source	No. of Grade II–V complications	Sensitivity (95% CI)	
		Patient-reporting	Hospital-reporting
All Grade II–V complications			
Patient-reporting using free-text format			
Patient-reported alone	141	64% (58–69)	55% (49–60)
Patient- and Hospital-reported	57		
Hospital-reported alone	113		
Total	311		
Patient-reporting using questionnaire format			
Patient-reported alone	111	83% (76–88)	21% (15–29)
Patient- and Hospital-reported	6		
Hospital-reported alone	24		
Total	141		
Patient-reporting using both formats			
Patient-reported alone	252	70% (65–74)	44% (40–49)
Patient- and Hospital-reported	63		
Hospital-reported alone	137		
Total	452		
Patient-reporting using both formats excluding complications not confirmed by the hospital (n = 121^a)			
Patient-reported alone	131	59% (53–64)	60% (55–66)
Patient- and Hospital-reported	63		
Hospital-reported alone	137		
Total	331		
Grade III–V complications only			
Patient-reporting using both formats			
Patient-reported alone	19	72% (58–83)	62% (48–74)
Patient- and Hospital-reported	17		
Hospital-reported alone	14		
Total	50		

^a108 Grade II, 13 notes not checked.

confirmed on hospital case-note review were excluded. Patients were better at reporting complications that had occurred following discharge such as wound breakdown, pelvic abscess/haematoma, DVT, lymphocysts/lymphoedema and hernias while hospitals seemed better at reporting complications that had occurred during the hospital stay such as ileus, bowel obstruction, bladder (e.g. urinary retention), cardiac (e.g. atrial fibrillation) and respiratory complications (e.g. pulmonary oedema).

Hospital notes of 94.8% (240 out of 253) of those with patient-reported complications previously undocumented by the clinical staff were reviewed. The clinical team confirmed all Grade III–V patient-reported complications. This probably reflects the fact that these were complications with significant sequelae requiring secondary care management. Grade II complications such as infections treated with antibiotics and lymphoedema treated with compression stockings and physiotherapy were less likely (concordance 56.4%) to be confirmed. While it is unlikely that patients incorrectly reported use of antibiotics or compression stockings, the possibility cannot be entirely ruled out. However, the more likely explanation is that the surgical teams did not manage these complications. A significant proportion was probably

managed in primary care. The wording of patient consent meant that the coordinating centre team was unable to request review of primary care records. In addition, some of the readmissions are likely to have involved local hospitals, different from where the initial surgery had been performed. Both these issues were noted in the elective hip and knee replacement studies in which about half of the surgical complications were managed outside the institution where the initial surgery was undertaken (Dushey *et al*, 2011; Greenbaum *et al*, 2012) and would have been missed if only clinician-reported data were used. Logistic issues may also have contributed to clinicians not entering some of the post discharge Grade II–V complications that they were aware of. As it is medical treatment that defines a complication as Grade II, the issue of variation in threshold for prescription of antibiotics for postoperative infections also needs to be considered.

The open free-text format for collecting patient data proved time consuming to analyse, requiring a clinician's input to decipher and enter the complications into the database. A minority of women did not understand what was meant by a complication and some women mentioned complications related to non-surgical

treatments or detailed problems related to their care in hospital. The structured questionnaire (closed) format for patient-reporting developed in the course of the study allowed easier interpretation and grading of the complications. It comprises specific questions pertaining to the management of 11 common postoperative complications that were highlighted on analysis of the free-text format of FULs. Every question included a brief description of the complication with management options clearly specified. Simple Yes/No answers also probably made completion easier for women. The closed format also decreased the number of replies with complications not related to surgery. The proportion of replies reporting a complication was higher with this format (63% vs 22%) when compared with the free-text format. However, a large proportion (44% vs 25%) were Grade I complications, with the commonest being constipation requiring diet changes/laxatives and urinary incontinence not requiring any medication. This was probably related to the inclusion of specific questions regarding bowel and bladder problems. At present, there is no nationally agreed list of complications that could be used to audit surgical outcomes in gynaecological oncology. It might be feasible to shorten the list of complications in the closed format from eleven to five or six core complications for use in future local and/or national audits. The reliability of this approach would however have to be tested in a further prospective study.

In our study, the overall response rate was 68% with a similar rate (72% vs 68%) associated with the use of a closed vs free-text format for postal follow-up. Studies investigating patient-reported postoperative complications following elective surgery have reported response rates ranging from 80% (hip and knee replacement surgery), 73% for hernia repair and 65% for varicose vein surgery (Alazzawi *et al*, 2012; Greenbaum *et al*, 2012; Grosse Frie *et al*, 2012). These studies also used a questionnaire format containing questions regarding specific postoperative complications and simple yes/no answers. It is likely that response rates could have been improved by sending reminders to non-responders.

Strengths of our study included the size, multicentre design and prospective online data collection by clinical teams, 68% patient response rate, the same clinician (a general obstetrician and gynaecologist) undertaking all patient interviews where data were equivocal, hospital case-note review of patient-only-reported complications and central-independent data analysis. The main limitation was that the coordinating centre could not contact the primary care teams to verify complications that were not managed by the surgical team. Only those women who had provided telephone numbers could be contacted directly for clarification. In the absence of a validated questionnaire on postoperative complications in gynaecological oncology, we designed one to capture more accurate and precise information regarding complications. Although it was piloted and women provided feedback on its content, it requires further validation in future studies. In common with all questionnaire studies, one could speculate that women were more likely to respond to the questionnaire if they had experienced a complication.

Finally though the intention was to send the FULs 8 weeks postoperatively this was not always possible due to delays in receiving updates from the hospitals regarding any patients who might have died or were terminally ill. The latter step was essential to avoid causing unnecessary distress to family members. Despite this, four (0.2%) FULs were sent to deceased patients and one of the families complained prompting a written apology. Delays in sending the FUL probably contributed to recall bias causing some women to confuse surgical complications with side effects from chemo/radiotherapy (commenced usually within 6 weeks of surgery).

There is growing interest in using PROMs to assess outcomes of cancer treatment (Howell *et al*, 2013). The PROMs are designed to

assess the quality of life and long-term disability from treatment and not surgical complications in particular. A recent study (Andikyan *et al*, 2012) in gynaecological cancer looked at the feasibility of capturing patient-reported symptoms electronically in the immediate 6-week postoperative period following major surgery. The authors concluded that this method was highly acceptable to the women and provided useful information regarding problems experienced by patients which could be helpful to the clinicians in providing timely and appropriate interventions where required. The Royal College of Obstetricians and Gynaecologists (RCOG) recently published a scientific impact paper evaluating the use of PROMs in gynaecology and gynaecological oncology (RCOG, 2012). It is envisaged that in future PROMs will routinely be collected in the United Kingdom for all gynaecological cancer patients. Linking or combining our follow-up questionnaire to PROMs would be a cost-effective method of collecting data on postoperative complications.

Conclusions. Follow-up letters provide valuable additional information on complications experienced by women following gynaecological cancer surgery and both hospital and patient reporting are essential to obtain a complete picture. Future studies on surgical complications should endeavour to use both data sources and include primary care record verification of unconfirmed patient-reported Grade II complications.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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