BMJ Open

Which clinical scenarios do surgeons record as complications? A benchmarking study of seven hospitals

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2014-007500
Article Type:	Research
Date Submitted by the Author:	22-Dec-2014
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Primary Subject Heading:	Surgery
Secondary Subject Heading:	Qualitative research
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Adult surgery < SURGERY, Adverse events < THERAPEUTICS

Benchmarking of surgical complications:

Comparing apples and oranges

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Word count: 2618

Keywords: Complication, Registration, Surgery, Benchmarking

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Funding: none

Conflicts of interest: none

Abstract

Background

The trend to develop national benchmarking data, including those regarding complications in hospitalized surgical patients is growing. To obtain high-quality benchmarking data a reliable and uniform registration by the participating surgical departments is required. Several studies show considerable variability regarding the definition of a complication and regarding the application of this definition.

Objectives

To investigate agreement and potential differences in the application and interpretation of the definition among surgical departments of various hospitals.

Design

Twenty-four cases were formulated including general, trauma, gastrointestinal and vascular surgery and based on points of discussion about the definition and ambiguities regarding complication registration as encountered in daily practice. The cases were presented to the surgical staff and residents in seven Dutch hospitals using an electronic response system.

Results

In total 134 participants responded. Interpretation differences were particularly found regarding: 1) complications considered as logical consequences of a surgical procedure; 2) complications occurring after radiological interventions; 3) severity criteria as when to consider a complication as a '(probably) permanent damage or function loss' 4) registering a cancelled operation as a complication; and 5) patients with serial complications during hospital stay.

Conclusion The definition of surgical complications as currently applied in the Netherlands does not ensure a uniform complication registration. Improvement of this registration system is mandatory before benchmarking of these findings in the public domain is appropriate. Modifications of the

current definition of a surgical complication and improved consensus about specific clinical situations and training of surgeons might improve the quality of benchmarking.

Strengths and limitations

Limitations

- Arbitrary choices of clinical problem situations for the cases.
- Representatively for all hospitals outside the Netherlands.

Strengths

- The participating hospitals included a mix of the different hospital types: university medical centres, tertiary and general hospitals.
- Global issues of reliability of benchmarking of hospital data and the issue of differences in interpretation of definitions are addressed.

Introduction

The trend to develop national benchmarking data, including those regarding complications suffered by surgical patients during their hospital stay or shortly after discharge is ongoing. For example, the national benchmarking by the NSQIP institutions (the American College of Surgeons National Surgical Quality Improvement Program) appears to be improving morbidity and mortality over time.[1] In order to obtain high quality benchmarking data, it is necessary to correct for underreporting of complications, and for differences in case mix as well as in the level of complexity of the interventions.[2] The validity of benchmarking data also depends on the quality control of these data.[3,4] High-quality data requires reliable and uniform registration by the participating surgical departments. This includes that at least, for identical situations, all hospitals should register the same complications with the same degree of severity. Santford et al. already showed that variations in definition and methods of retrieval greatly influence what is rated as a complication in patients undergoing a pacreatoduodenectomy.[5] This is especially true for complications of a lower severity level.

Other studies have shown that there is still variability about the definition of a complication or regarding the interpretation of this definition.[6-8] Should we define a complication as an *undesirable* event following surgical medical care? By this definition an operative scar would also be a complication.[6] Or do we perhaps consider a complication to be an *unexpected* result? Is damage of an intra-abdominal organ – for example injury to the spleen during pancreatic surgery – a complication, or only if this negatively affects the patient outcome, for example when an accidental splenectomy is performed with the patient has to follow a vaccination programme?

In the Netherlands, the currently used definition of a surgical complication consists of three essential components (specified by the Association of Surgeons of the Netherlands (NVvH) and the Dutch Association of Medical Specialists):[9,10]

A complication is an unintended and undesirable event or state that:

1. Occurs during or following a medical specialist intervention that negatively affects the patient's health such that this requires their medical treatment to be adapted, or such that irreparable damage is caused,

2. Is established either during in-hospital treatment or during immediate follow-up, up to a period of 30 days after discharge

3. Is the result of the actual medical specialist intervention, the chances of the complication occurring, and the presence or absence of culpability are not relevant

It is unclear whether this definition is interpreted and applied in the same way among different surgical departments and by all surgeons within a surgical department. Therefore we investigated the agreement in the registration of complications within and among the surgical departments of hospitals in The Netherlands.

Methods

Example cases

An inventory study was carried out in a convenience sample of seven hospitals. Two surgeons formulated 24 cases based on critical points of discussion, definitions and ambiguities regarding the registration of complications taken from their experience during complication registration from daily practice (Appendix).

The questions were divided into the following six main categories:

1. Definition.

   Whether this is a complication according to the definition of a 'complication' as defined by the Association of Surgeons of the Netherlands.

2. Other specialty.

   Whether complications of a patient admitted at the surgical department were included in the registry if these occurred as a result of an other specialty but within the well-defined postoperative period of registration (during admission and a the 30-day period after discharge)

3. Severity.

   Determining the grade of severity of the complication, categorized using the four-level grade scale based on Clavien and Dindo grading system;[11] Severity 0) temporary health disadvantage without treatment 1) recovering without (re)operation; 2) recovery after (re)operation; 3) (probably) permanent damage or function loss; and 4) death.

4. Intra-operative damage.

   Whether complications that occurred intra-operatively were registered.

5. Cancellation of operations.

   Whether physicians registered cancelled operations as a complication.

6. Serial complications and transfers

   The registration of complications of patients with severe and serial medical problems and transferred from other hospitals.

Each category was represented by at least three questions. Since some cases were relevant for several categories; these cases were also assigned to several categories and analysed as such.

Procedure

Medical professionals (surgeons, fellows and residents) working at the surgical departments of seven hospitals participated in the study. These hospitals included two university medical centres, four tertiary referral hospitals and one general teaching hospital. The 24 cases were presented at a random order in the format of a multiple-choice quiz to the members of the surgical staff and residents. The

responses were registered using electronic voting devices (Turning Technologies LLC, Youngstown, OH, USA).

The participants were first asked about their position (attending surgeon, fellow, resident) and specialty/subspecialty (gastrointestinal/oncology, vascular surgery, trauma surgery, or not applicable). The approved definition of a complication was not shown to the participants before the session and they were not allowed to ask any questions for clarification during the presentation of the cases. The potential responses to the 24 example cases were either dichotomous or categorical. Participants were given 10 seconds to respond to each case and the time available was shown on a screen. The number of participants that voted for each case was recorded.

Data analysis

Data was analysed for each hospital, per case and per category. The dichotomous answers were used to calculate the proportion of participants (in percent) who responded to the case with 'yes, I register this as a complication' and the total number of participants for that case. Proportions close to 100% were defined as unanimity in the interpretation of a particular case as a complication; the same applied for numbers close to 0% for cases not being considered as a complication. For each question, the average (with its range) percentage of 'yes' responses was calculated over all hospitals, weighted for the number of participants per hospital. The results of the example cases that had a categorical range of responses were analysed separately. Analysis of responses related to function (staff versus residents) were performed by Chi-squared test. A $p<0.05$ was considered statistically significant.

Results

General characteristics of participants and hospitals

The number of participants in the seven hospitals was 134. The distribution over different functions and subspecialties is shown in table 1. More than 50% of participants practiced at a university medical

centre, almost 40% in a tertiary referral hospital and around 10% in a general training hospital. About 40% of the participants were attending surgeons. The largest subspecialty was gastrointestinal oncology, represented by almost 35%, while 25% of participants indicated not having any specific subspecialty.

Table 1: Participants per hospital

Hospital		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**Total**
Number		34	17	14	7	12	17	36	134
Function									
	Staff member	16	4	4	2	8	5	14	53
	Surgical trainee/fellow	4	3	0	0	1	1	3	12
	Residents	12	9	7	5	3	6	13	55
	Missing data	*2*	*1*	*3*	*0*	*0*	*2*	*6*	*14*
Specialty									
	Gastrointestinal/oncology	14	4	2	0	4	6	16	46
	Vascular surgery	8	3	1	0	2	1	3	18
	Trauma surgery	5	3	1	3	4	3	3	22
	None	5	5	7	4	2	3	10	36
	Missing data	*2*	*2*	*3*	*0*	*0*	*1*	*4*	*12*

Results per category

Category 1: Definition

Figure 1 shows the percentage of 'yes' responses per hospital in the category 'Definition'. For 6 out of 16 example cases (fig. 1; cases 1 through 6), the agreement between hospitals was more than 80% on average, whereas agreement in case 16 was below 20%. For some of the other cases, either the variation *among* hospitals was extremely high, ranging from 9-100% in case 15 (fig. 1), or there was no agreement *within* hospitals (range 18-58%), as shown for case 13.

The highest agreement was found for complications such as post-operative wound infections or anastomotic leaks. The lowest agreement was found in cases with complications that might often directly be related to the surgical procedure, such as gastroparesis after a gastrectomy or ongoing bowel paralysis following adhesiolysis.

Category 2: Complication related to other specialty

For 2 out of the 3 cases in this category, cases 17 and 18 (fig. 2) a 'complication in the ICU' and 'complication on a non-surgical nursing ward', 98% of participants agreed that both cases should be registered as a complication (ranges 70-100% and 83-100%, respectively). On the other hand, a groin haemorrhage following percutaneous intervention by a radiologist (fig, 2: case 19) was reported as a complication with a wide variation ranging from 50-82% of the participants. (Figure 2).

Category 3: Severity

We also found differences in responses with regard to the severity assigned to a complication (categorical variables not shown in figure 2, table 1: cases 3,8,10,14, 23,24). A complication that occurs during surgery but that is repaired during that same operation would generally not be registered as complication with severity grade: "*recovery after (re)operation*" (case 14; average 0%, range 0-14.3%). In 2 cases (3, 14) participants were asked whether a complication would be registered with a severity grade " *(probably) permanent damage or function loss*". The percentage of participants who judged this as correct varied widely per hospital (17-62% for case 14 and 67-100% for case 3). The construction of an intentionally temporary ileostomy performed during a surgical intervention after a complication (case 24) was considered to be registered with severity "*(probably) permanent damage or function loss*" by only 0-41% of the participants.

Category 4: Intra-operative damage

Damage to the spleen (requiring splenectomy; fig. 2, case 3), followed by a vaccination programme for the patient, was considered by an average of 95% of participants (range 86-100%) as a complication. However, only 32% of surgeons would register damage during a surgical procedure, such as an accidental intestinal perforation (fig. 2, cases 14) with subsequent closure of the defect, as a complication (range 0-50%).

Category 5: Cancelled operations

Whether or not a cancellation of an operation is registered as a complication varied widely between participants and hospitals. Cancellation for medical reasons (case 22) would be registered as a complication by 0 to 40% of the participants. If the reason for cancellation was identified during the 'time out' procedure this percentage was higher; 25-93% (case 20). Operations cancelled due to logistic reasons, for example due to the urgency of other emergency surgery patients (fig. 2, case 21), showed a large variation among hospitals, e.g. (range 8-80%) .

Category 6: Serial complications and transfers

On average, more than 70% of the participants would register one or more complications (incl. during the further clinical course) if a patient with complications had been transferred from another hospital (fig. 2, case 9; range 55-86%). Of all participants, an average of 55% would not register existing complications upon admission, but would register any subsequent complications that occurred during hospitalisation in the receiving hospital (not shown). In the cases with serial complications, about half of the participants (range 25-73%) would register all complications during hospitalisation, while the other half (range 27-67%) would register only some of them (not shown).

Staff versus residents

Responses to 19 cases showed no significant differences between staff and residents, whereas three cases (1, 8, 10) did show significant differences in responses. Staff would register a hypocalcaemia after thyroidectomy significantly more often as a complication than residents (case 8; p=0.002), as well as post-discharge abdominal pain after a laparoscopic colectomy (case 10; p=0.015). Finally, residents would register more complications after hemicolectomy (case 1; p<0.001).

Discussion

Despite a uniform definition for surgical complications, the present study showed there is limited consensus both among and within hospitals as to which event should be considered as a complication and should therefore be registered, which is an prerequisite for adequate hospital benchmarking. This is particularly important in the current era of reporting and comparing the quality of healthcare, for example using Hospital Mortality Ratios like the HSMR,[12,13] or the national and international complication registrations for heart surgery in adults (LCRHV; www.nvtnet.nl), or the NSQIP.[1,5]

The present study showed enormous differences in the use of the current definition of a complication. In order to improve uniform interpretation, three different aspects of the definition might require revision:

First, surgeons could consider some results of care to be 'calculated risks'.[14] Based on the findings in this study, a result should be registered as a complication only if this result is undesirable for the patient and negatively affects the patient (e.g. vaccination following accidental splenectomy).[6]

Second, this study found no consensus as to registering complications related to other specialties. Despite this divergence, working in multidisciplinary teams has become increasingly more important in healthcare[15]. Some years ago, the report entitled "*To err is human"* also argued in favour of teamwork, a concept that might be able to prevent a large number of avoidable complications.[16] A more consistent registration of all complications is advocated, meaning that all complications developed under the responsibility of the surgical department should be registered, regardless of which specialty is responsible.

Third, although complications might indicate something about the results of care, they do not inform about the process or any underlying, unintended incidents. Complication registration provides better awareness of the actions of individuals or departments and of trends in complications.[17] The definition should therefore be applied as literally as possible, without interpretation or desire for self-protection. Only in retrospect we should consider whether or not the results were avoidable. For such complications we can refer back to the processes.[18] Results of a previous study suggest that

differences in interpretation of definitions might be more important than the differences in the definition itself.[19] Even if the same way of reviewing medical records and definition of complication is used, important differences in complication rates may occur.[20] This study describes several cases that call for agreement among surgeons. For example the impact of serial complications should be addressed.[21,22] Several studies describe extensive training in the use of the complication registration, resulting in better patient outcomes over time.[23-25] Educating and training surgeons to familiarise themselves with the definition, and encouraging them to acquire knowledge about national agreements with regard to specific situations may help achieve a more uniform registration.

Strengths and limitations

This study used real-life situations from daily clinical practice in one country to show that there are clear judgement differences between surgeons which demonstrates that there is room for improvement in complication registration. Because the choice of clinical problem situations for the cases was arbitrary, some problem situations may well have been left out. However, this would not have changed the main conclusion of the study. For some complications, the discussion remains regarding whether or not they should be considered as permanent (e.g. in the case of vocal cord paralysis or an ileostomy intended to be temporary), because it is not known beforehand. For intraoperative complications it is unclear whether these should be considered as a re-operation.[26] Finally, one could argue whether the seven participating hospitals were representative of all hospitals in the Netherlands. Nevertheless, the participating hospitals did include a mix of the different hospital types: university medical centres, tertiary and general hospitals.

Conclusion

Given the considerable differences in interpretation of the current definition of a complication, it is unlikely that uniform registration of complications is actually possible. This uniformity may be

increased by additions to the current definition, by more agreement about specific clinical situations, and by training of surgeons, thereby improving comparisons at both local and national levels. This seems a prerequisite before such data can be used at the public domain and function as one of the parameters for the quality of healthcare.

Acknowledgements

We thank all surgeons, fellows and residents of the surgical departments of the seven hospitals that participated in the study. We also thank Anne van Wijngaarden for assisting in the data collection.

Contributorship

All authors have made substantial contributions to the manuscript and have had the opportunity to read and comment upon the present manuscript:

•Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work

A Visser: Design, aquisition, analyses, interpretation

DT Ubbink: Analyses, Interpretation

DJ Gouma: Design, Interpretation

JC Goslings: Design, Interpretation

•Drafting the work or revising it critically for important intellectual content:

A Visser: Draft

DT Ubbink: Revision

DJ Gouma: Revision

JC Goslings: Revision

•Final approval of the version to be published:

A Visser, DT Ubbink, DJ Gouma and JC Goslings

•Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved:

A Visser, DT Ubbink, DJ Gouma and JC Goslings

Data sharing

This research does not have unpublished data.

Figure 1: Agreement within and between hospitals: 'definition' category.

The questions are ordered from the highest to the lowest average percentage of 'yes' responses per case per hospital

Figure 2: Agreement within and between hospitals: other categories.

The questions are ordered from the highest to the lowest average percentage of 'yes' responses per category per case per hospital. The cases can appear in more than one category.

Appendix: Cases

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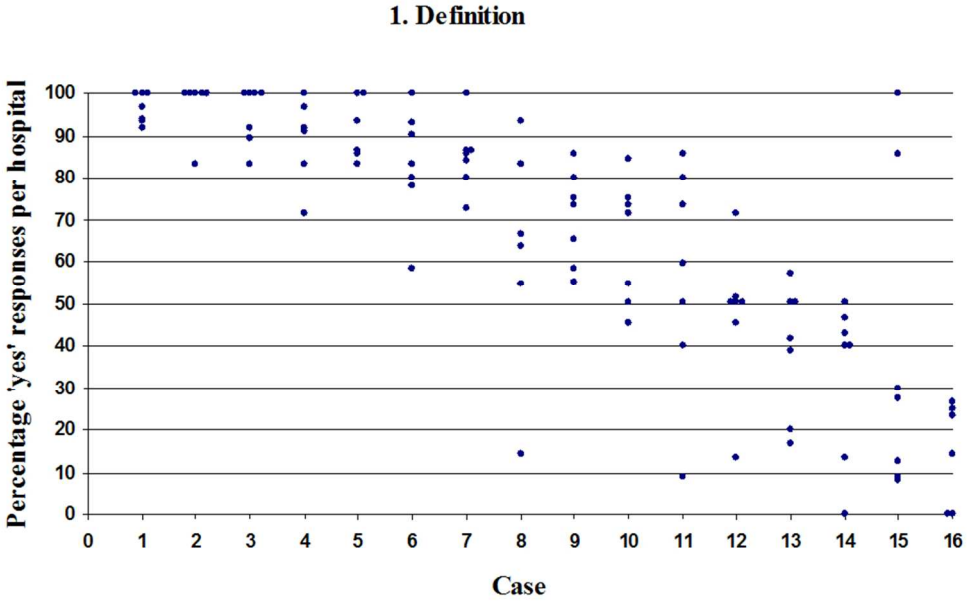

Figure 1: Agreement within and between hospitals: 'definition' category.
The questions are ordered from the highest to the lowest average percentage of 'yes' responses per case per hospital

262x165mm (96 x 96 DPI)

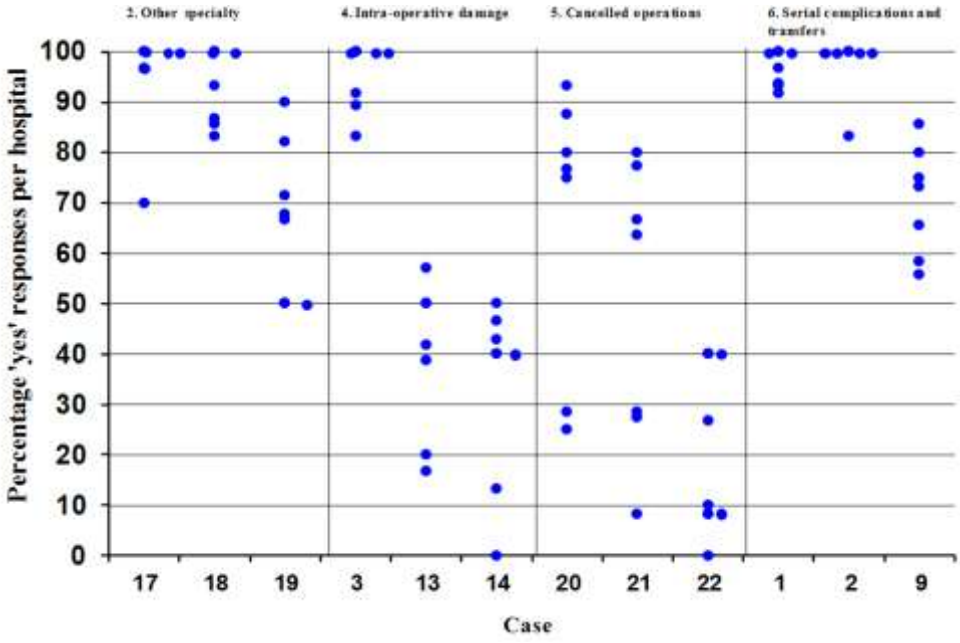

Figure 2: Agreement within and between hospitals: other categories.
The questions are ordered from the highest to the lowest average percentage of 'yes' responses per category per case per hospital. The cases can appear in more than one category.

278x177mm (96 x 96 DPI)

Appendix: Cases

Case	Outcome measure	N	Category
1. After a left hemicolectomy, a patient suffers a postoperative anastomotic leak and an intra-abdominal abscess. How many complications would you enter into the complication registry?	0 (No) / 1 (Yes) / 2 (Yes)	132	1 6
2. A patient is admitted with bilateral multiple rib fractures and haemothorax. During clinical course patient develops new episode of respiratory insufficiency with pneumonia, requiring re-intubation. Also delirium and UTI, which are treated. Which complication(s) do you register?	None / Resp. & UTI / Resp. & UTI & delirium / Resp. & UTI & delirium & pneumonia	109	1 6
3. During surgery, the patient's spleen is accidentally damaged, requiring splenectomy. This means that the patient must take part in a vaccination programme.	No Yes; temporary / Yes; re-op / Yes; permanent	127	1 3 4
4. A patient is operated for a perforated appendix. The wound is not left open but is aligned with 2 stitches. The wound becomes infected.	No / Yes	115	1
5. A patient underwent a right hemicolectomy. The patient developed a wound abscess which is treated conservatively.	No / Yes	126	1
6. After a high-energy trauma a patient is surgically treated for a crural fracture with step-off of the lower leg with a metal rod. 2 hours after the operation the patient develops a compartment syndrome, which is treated with fasciotomy.	No / Yes	130	1
7. Patient undergoes an aorta valve replacement. During hospitalisation he suffers abdominal pain for which the surgeon performs an ileocaecal resection. During the postoperative l course the patient suffers congestive heart failure due to AF which is treated with medication. The patient dies on the surgery ward.	No / Yes	128	1
8. A patient undergoes a total thyroidectomy. Hypocalcaemia develops postoperatively.	No Yes; Temporary / Yes; permanent	129	1 3
9. A patient underwent sigmoid resection in another hospital and is transferred with abdominal sepsis. During hospitalisation the patient develops an intra-abdominal abscess which is treated with percutaneous drainage. Which complication do you register?	None / Sepsis / Abd. abscess / Both	126	1 6
10. A patient undergoes a laparoscopic colectomy. 5 days after discharge from hospital, the patient presents to the emergency department with abdominal pain and is admitted for observation.	No Yes; Temporary	126	1 3
11. A patient with 'body packer' syndrome undergoes a laparotomy during which 13 packets are removed via enterotomy. During the postoperative clinical course the patient develops ileus and is discharged after 22 days.	No / Yes	128	1
12. A day after undergoing daycare laparoscopic cholecystectomy, a patient presents to the emergency department with continuous abdominal pain and vomiting. The patient is diagnosed with choledocholithiasis and admitted to hospital where an ERCP is performed.	No / Yes	126	1
13. After a high-energy trauma a patient is surgically treated for a crural fracture with step-off of the lower leg with a metal rod. During the operation the patient develops compartment syndrome which is treated with fasciotomy.	No / Yes	129	1 4
14. During an operation to repair an incisional hernia, the patient's small intestine is accidentally damaged. The defect is repaired immediately during the same operation. The postoperative clinical course is uncomplicated.	No / Yes; temporary / Yes; re-operation	126	1 3 4
15. A patient has undergone surgery to remove an adrenal tumour by means of laparotomy. The patient is discharged after one week in good condition. 6 weeks later, the patient presents to the outpatient department with abdominal pain and is readmitted with bowel obstruction due to adhesions.	No / Yes	92	1
16. A patient is admitted and underwent a gastrectomy. It takes 6 days after the operation before gastric emptying occurs.	No / Yes	132	1
17. Following surgery for acute appendicitis, the patient occupies a 'borrowed' bed at the orthopaedics department. During this period the patient suffers morphine toxicity.	No / Yes	129	2
18. During placement of a central venous catheter in a surgical patient in the ICU, the patient develops pneumothorax which requires placement of a thorax drain.	No / Yes	126	2
19. A patient undergoes a PTA (by the interventional radiologist). Following the intervention, a large haematoma develops in the groin at the puncture site.	No / Yes	126	2
20. In the operating theatre, the surgeon performs the 'time out'. It appears that all equipment is not sterile. The patient is sent back to the ward and is operated on a day later.	No / Yes	130	5
21. A patient is admitted for elective surgery for a fractured ankle. A day before the operation, it is cancelled due to priority being given to more emergency patients.	No / Yes	127	5
22. A patient is admitted for elective surgery for a fractured ankle. A day before the operation, it is cancelled because the ankle is still too swollen.	No / Yes	126	5
23. The patient has undergone a left hemithyroidectomy. After the operation the patient is found to have vocal cord paralysis. What severity do you register for this complication?	Temporary / Permanent	124	3
24. A patient undergoes a hemicolectomy. After 5 days the patient suffers an anastomotic leak for which an ileostomy is constructed. What is the severity of this complication?	Re-op / Permanent	125	3

N.B. The questions are ordered from the highest to the lowest average percentage of 'yes' responses per category per case. The example cases were presented to participants in random order.

BMJ Open

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Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2014-007500.R1
Article Type:	Research
Date Submitted by the Author:	19-Mar-2015
Complete List of Authors:	Visser, Annelies; AMC, Surgery Ubbink, Dirk; Academic Medical Center, Quality Assurance and Process Innovation; Academic Medical Center, University of Amsterdam, Department of Surgery Gouma, Dirk; Academic Medical Center, University of Amsterdam, Department of Surgery Goslings, J.C.; Academic Medical Center, University of Amsterdam, Department of Surgery
Primary Subject Heading:	Surgery
Secondary Subject Heading:	Qualitative research
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Adult surgery < SURGERY, Adverse events < THERAPEUTICS

Which clinical scenario's do surgeons record as complications?

A benchmarking study of seven hospitals

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Word count: 3268

Keywords: Complication, Registration, Surgery, Benchmarking

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Funding: none

Conflicts of interest: none

Abstract

Objectives

To investigate agreement and potential differences in the application and interpretation of the definition among surgical departments of various hospitals.

Design

Twenty-four cases were formulated including general, trauma, gastrointestinal and vascular surgery and based on points of discussion about the definition and ambiguities regarding complication registration as encountered in daily practice. The cases were presented to the surgical staff and residents in seven Dutch hospitals using the national registration system of complications and an electronic response system.

Results

In total 134 participants responded. Interpretation differences were particularly found regarding: 1) complications considered as logical consequences of a surgical procedure; 2) complications occurring after radiological interventions; 3) severity criteria as when to consider a complication as a '(probably) permanent damage or function loss' 4) registering a cancelled operation as a complication; and 5) patients with serial complications during hospital stay.

Conclusion The definition of surgical complications as currently applied in the Netherlands does not ensure a uniform complication registration. Improvement of this registration system is mandatory before benchmarking of these findings in the public domain is appropriate. Modifications of the current definition of a surgical complication and improved consensus about specific clinical situations and training of surgeons might improve the quality of benchmarking.

Strengths and limitations

Limitations

- Arbitrary choices of clinical problem situations for the cases.

- Representatively for all hospitals outside the Netherlands.

Strengths

- The participating hospitals included a mix of the different hospital types: university medical centres, tertiary and general hospitals.
- Global issues of reliability of benchmarking of hospital data and the issue of differences in interpretation of definitions are addressed.

Introduction

The trend to develop national benchmarking data, including those regarding complications suffered by surgical patients during their hospital stay or shortly after discharge is ongoing. For example, the national benchmarking by the NSQIP institutions (the American College of Surgeons National Surgical Quality Improvement Program) appears to be improving morbidity and mortality over time.[1] In order to obtain high quality benchmarking data, it is necessary to correct for underreporting of complications, and for differences in case mix as well as in the level of complexity of the interventions.[2] The validity of benchmarking data also depends on the quality control of these data.[3,4] High-quality data requires reliable and uniform registration by the participating surgical departments. This includes that at least, for identical situations, all hospitals should register the same complications with the same degree of severity. Santford et al. already showed that variations in definition and methods of retrieval greatly influence what is rated as a complication in patients undergoing a pacreatoduodenectomy.[5] This is especially true for complications of a lower severity level.

Other studies have shown that there is still variability about the definition of a complication or regarding the interpretation of this definition.[6-8] Should we define a complication as an *undesirable* event following surgical medical care? By this definition an operative scar would also be a complication.[6] Or do we perhaps consider a complication to be an *unexpected* result? Is damage of an intra-abdominal organ – for example injury to the spleen during pancreatic surgery – a complication, or only if this negatively affects the patient outcome, for example when an accidental splenectomy is performed with the patient has to follow a vaccination programme?

In the Netherlands, the currently used definition of a surgical complication consists of three essential components (specified by the Association of Surgeons of the Netherlands (NVvH) and the Dutch Association of Medical Specialists already in 1999).[9,10]

A complication is an unintended and undesirable event or state that:

1. Occurs during or following a medical specialist intervention that negatively affects the patient's health such that this requires their medical treatment to be adapted, or such that irreparable damage is caused,

2. Is established either during in-hospital treatment or during immediate follow-up, up to a period of 30 days after discharge

3. Is the result of the actual medical specialist intervention, the chances of the complication occurring, and the presence or absence of culpability are not relevant

Registration of complications is regulated by the Association of Surgeons in the Netherlands already in 1999 and accepted in all hospitals in the Netherlands. The focus of present study was to investigate whether complication data in the Netherlands can be compared among surgical departments. Although the association of Surgeons of the Netherlands specified a national definition of a complication it remains unclear whether this definition is interpreted and applied in the same way.Therefore we investigated the agreement in the registration of complications within and among the surgical departments of hospitals in The Netherlands.

Methods

Example cases

An inventory study was carried out in a convenience sample of seven hospitals. Two surgeons formulated 24 cases based on critical points of discussion, definitions and ambiguities regarding the registration of complications taken from their experience during complication registration from daily practice (Appendix).

The questions were divided into the following six main categories. The specifications of the categories enabled us to be more specific about potential points of improvement, while realizing that some cases could be included in more categories

1. Definition.

   Whether this is a complication according to the definition of a 'complication' as defined by the Association of Surgeons of the Netherlands.

2. Other specialty.

   Whether complications of a patient admitted at the surgical department were included in the registry if these occurred as a result of an other specialty but within the well-defined postoperative period of registration. Part 2 of the definition describes the period of responsibility for the surgeon during admission and a the 30-day period after discharge. For example if the patient had to be admitted at the ICU after surgery or treated by an interventional radiologist during surgical admission, the surgeon is still responsible for registering complications.

3. Severity.

   Determining the grade of severity of the complication, categorized using the four-level grade scale based on Clavien and Dindo grading system;[11] Severity 0) temporary health disadvantage without treatment 1) recovering without (re)operation; 2) recovery after (re)operation; 3) (probably) permanent damage or function loss; and 4) death.

4. Intra-operative damage.

   Whether complications that occurred intra-operatively were registered.

5. Cancellation of operations.

   Whether physicians registered cancelled operations as a complication. Independent on the reason for cancelation such as other emergency operations. The cancelation of an operation meets the criteria of a complication if this unintended and undesirable event requires medical treatment to be adapted, or irreparable damage is caused. (part 1 of the definition).

6. Serial complications and transfers

The registration of complications in patients with severe and serial medical problems and transferred from other hospitals. The issue here is whether the surgeon is responsible for registering these medical problems and the (serial) complications following during the responsibility period (part 2 of the definition).

Each category was represented by at least three questions. Since some cases were relevant for several categories; these cases were also assigned to several categories and analysed as such.

Procedure

Medical professionals (surgeons, fellows and residents) working at the surgical departments of seven hospitals participated in the study. These hospitals included two university medical centres, four tertiary referral hospitals and one general teaching hospital. The cases were presented to the members of the surgical staff and residents at a time interval approved by the different departments (e.g. at the end of a daily change of shift, or during a session on complication registration or research meeting).The 24 cases were presented at a random order in the format of a multiple-choice quiz. The responses were registered using electronic voting devices (Turning Technologies LLC, Youngstown, OH, USA).

The participants were first asked about their position (attending surgeon, fellow, resident) and specialty/subspecialty (gastrointestinal/oncology, vascular surgery, trauma surgery, or not applicable). The approved definition of a complication was not shown to the participants before the session and they were not allowed to ask any questions for clarification during the presentation of the cases. The potential responses to the 24 example cases were either dichotomous or categorical. Participants were given 10 seconds to respond to each case and the time available was shown on a screen. The number of participants that voted for each case was recorded.

Data analysis

Data was analysed for each hospital, per case and per category. The dichotomous answers were used to calculate the proportion of participants (in percent) who responded to the case with 'yes, I register this as a complication' and the total number of participants for that case. Proportions close to 100% were defined as unanimity in the interpretation of a particular case as a complication; the same applied for numbers close to 0% for cases not being considered as a complication. For each question, the average (with its range) percentage of 'yes' responses was calculated over all hospitals, weighted for the number of participants per hospital. The results of the example cases that had a categorical range of responses were analysed separately. Analysis of responses related to function (staff versus residents) were performed by Chi-squared test. A $p<0.05$ was considered statistically significant.

Results

General characteristics of participants and hospitals

The number of participants in the seven hospitals was 134. The response rate was nearly 100% because all staff and resident present participated. The appendix shows the number of responses per case. Cases 2 and 15 were the first and last cases presented to the departments (response rate: resp. 81% and 69%). The reason for the lower response rate in these cases can be explained by the fact that some surgeons arrived later at the meeting or had to leave earlier due to other scheduled activities. The distribution over different functions and subspecialties is shown in table 1. More than 50% of participants practiced at a university medical centre, almost 40% in a tertiary referral hospital and around 10% in a general training hospital. About 40% of the participants were attending surgeons. The largest subspecialty was gastrointestinal oncology, represented by almost 35%, while 25% of participants indicated not having any specific subspecialty.

Table 1: Participants per hospital

Hospital		1	2	3	4	5	6	7	Total
Number		34	17	14	7	12	17	36	134
Function									
	Staff member	16	4	4	2	8	5	14	53
	Surgical trainee/fellow	4	3	0	0	1	1	3	12
	Residents	12	9	7	5	3	6	13	55
	Missing data	*2*	*1*	*3*	*0*	*0*	*2*	*6*	*14*
Specialty									
	Gastrointestinal/oncology	14	4	2	0	4	6	16	46
	Vascular surgery	8	3	1	0	2	1	3	18
	Trauma surgery	5	3	1	3	4	3	3	22
	None	5	5	7	4	2	3	10	36
	Missing data	*2*	*2*	*3*	*0*	*0*	*1*	*4*	*12*

Results per category

Category 1: Definition

Figure 1 shows the percentage of 'yes' responses per hospital in the category 'Definition'. For 6 out of 16 example cases (fig. 1; cases 1 through 6), the agreement between hospitals was more than 80% on average, whereas agreement in case 16 was below 20%. For some of the other cases, either the variation *among* hospitals was extremely high, ranging from 9-100% in case 15 (fig. 1), or there was no agreement *within* hospitals (range 18-58%), as shown for case 13.

The highest agreement was found for complications such as post-operative wound infections or anastomotic leaks. The lowest agreement was found in cases with complications that might often directly be related to the surgical procedure, such as gastroparesis after a gastrectomy or ongoing bowel paralysis following adhesiolysis.

Category 2: Complication related to other specialty

For 2 out of the 3 cases in this category, cases 17 and 18 (fig. 2) a 'complication in the ICU' and 'complication on a non-surgical nursing ward', 98% of participants agreed that both cases should be registered as a complication (ranges 70-100% and 83-100%, respectively). On the other hand, a groin

haemorrhage following percutaneous intervention by a radiologist (fig, 2: case 19) was reported as a complication with a limited variation ranging from 50-82% of the participants. (Figure 2).

Category 3: Severity

We also found differences in responses with regard to the severity assigned to a complication (categorical variables not shown in figure 2, table 1: cases 3,8,10,14, 23,24). A complication that occurs during surgery but that is repaired during that same operation would generally not be registered as complication with severity grade: "*recovery after (re)operation*" (case 14; average 0%, range 0-14.3%). In 2 cases (3, 14) participants were asked whether a complication would be registered with a severity grade " *(probably) permanent damage or function loss*". The percentage of participants who judged this as correct varied per hospital (17-62% for case 14 and 67-100% for case 3). The construction of an intentionally temporary ileostomy performed during a surgical intervention after a complication (case 24) was considered to be registered with severity "*(probably) permanent damage or function loss*" by only 0-41% of the participants.

Category 4: Intra-operative damage

Damage to the spleen (requiring splenectomy; fig. 2, case 3), followed by a vaccination programme for the patient, was considered by an average of 95% of participants (range 86-100%) as a complication. However, only 32% of surgeons would register damage during a surgical procedure, such as an accidental intestinal perforation (fig. 2, cases 14) with subsequent closure of the defect, as a complication (range 0-50%).

Category 5: Cancelled operations

Whether or not a cancellation of an operation is registered as a complication varied between participants and hospitals. Cancellation for medical reasons (case 22) would be registered as a

complication by 0 to 40% of the participants. If the reason for cancellation was identified during the 'time out' procedure this percentage was higher; 25-93% (case 20). Operations cancelled due to logistic reasons, for example due to the urgency of other emergency surgery patients (fig. 2, case 21), showed a variation among hospitals, e.g. (range 8-80%) .

Category 6: Serial complications and transfers

On average, more than 70% of the participants would register one or more complications (incl. during the further clinical course) if a patient with complications had been transferred from another hospital (fig. 2, case 9; range 55-86%). Of all participants, an average of 55% would not register existing complications upon admission, but would register any subsequent complications that occurred during hospitalisation in the receiving hospital (not shown). In the cases with serial complications, about half of the participants (range 25-73%) would register all complications during hospitalisation, while the other half (range 27-67%) would register only some of them (not shown).

Staff versus residents

Responses to 19 cases showed no significant differences between staff and residents, whereas three cases (1, 8, 10) did show significant differences in responses. Staff would register a hypocalcaemia after thyroidectomy significantly more often as a complication than residents (case 8; p=0.002), as well as post-discharge abdominal pain after a laparoscopic colectomy (case 10; p=0.015). Finally, residents would register more complications after hemicolectomy (case 1; p<0.001).

Discussion

Despite a uniform definition for surgical complications, the present study showed there is limited consensus both among and within hospitals as to which event should be considered as a complication and should therefore be registered, which is an prerequisite for adequate hospital benchmarking. This

is particularly important in the current era of reporting and comparing the quality of healthcare, for example using Hospital Mortality Ratios like the HSMR,[12,13] or the national and international complication registrations for heart surgery in adults (LCRHV; www.nvtnet.nl), or the NSQIP.[1,5] The present study showed enormous differences in the use of the current definition of a complication. In order to improve uniform interpretation, three different aspects of the definition might require revision:

First, surgeons could consider some results of care to be 'calculated risks'.[14] Based on the findings in this study, a result should be registered as a complication only if this result is undesirable for the patient and negatively affects the patient (e.g. vaccination following accidental splenectomy).[6]

Second, this study found limited consensus as to registering complications related to other specialties. Despite this divergence, working in multidisciplinary teams has become increasingly more important in healthcare[15]. Some years ago, the report entitled "*To err is human"* also argued in favour of teamwork, a concept that might be able to prevent a large number of avoidable complications.[16] For example GI-surgeons form a multidisciplinary GI-oncology team with gastroenterologist, medical oncologists and radiologists or, vascular surgeons with interventional radiologists, trauma surgeons with orthopaedic surgeons and neurosurgeons in a trauma unit. A more consistent registration of all complications is advocated, meaning that all complications developed under the responsibility of the surgical department should be registered, regardless of which specialty is responsible.

Third, although complications might indicate something about the results of care, they do not inform about the process or any underlying, unintended incidents. Complication registration provides better awareness of the actions of individuals or departments and of trends in complications.[17] The definition should therefore be applied as literally as possible, without interpretation or desire for self-protection. These three aspects should be added to the three parts of the definition; part 1: *undesirable result for the patient*, part 2: *all complications under responsibility of the Surgical Department,* part 3: *whithout interpretation or self-protection.*

Only in retrospect we should consider whether or not the results were avoidable. For such complications we can refer back to the processes.[18] Results of a previous study suggest that differences in interpretation of definitions might be more important than the differences in the definition itself.[19] Even if the same way of reviewing medical records and definition of complication is used, important differences in complication rates may occur.[20] This study describes several cases that call for agreement among surgeons. For example the impact of serial complications should be addressed.[21,22] Several studies describe extensive training in the use of the complication registration, resulting in better patient outcomes over time.[23-25] Educating and training surgeons to familiarise themselves with the definition, and encouraging them to acquire knowledge about national agreements with regard to specific situations may help achieve a more uniform registration.

Strengths and limitations

This study used real-life situations from daily clinical practice in one country to show that there are clear judgement differences between surgeons which demonstrates that there is room for improvement in complication registration. Because the choice of clinical problem situations for the cases was arbitrary, some problem situations may well have been left out. However, this would not have changed the main conclusion of the study. For some complications, the discussion remains regarding whether or not they should be considered as permanent (e.g. in the case of vocal cord paralysis or an ileostomy intended to be temporary), because it is not known beforehand. For intraoperative complications it is unclear whether these should be considered as a re-operation.[26] Furthermore, one could argue whether the seven participating hospitals were representative of all hospitals in the Netherlands. Nevertheless, the participating hospitals did include a mix of the different hospital types: university medical centres, tertiary and general hospitals.

The national surgical complication registration used in the Netherlands since 1999 to register surgical complications contains all complications of the department of surgery (general, vascular, trauma and gastrointestinal). The residents of the department register the complications during hospitalisation and after discharge. These patients and their complications are plenary discussed during hand-offs by senior surgeons and residents. Therefore we chose the mixed sample of specialties, as these were all involved in the registration process. The different grades were also important, to assess possible differences in grading interpretations among the surgeons. Given the fact that the whole team of surgeons and residents attending the hand-offs was involved in the registration, they were all included, which added up to the numbers described in this study.

Nowadays academic hospitals seem more subspecialty-driven, but this represents only a small part of all surgical care. The smaller hospitals do not have specialized units as most university hospitals. Most subspecialties indeed have their specific registration system, such as the national audits for colorectal, pancreatic, and oesophageal surgery. A generic registration still is of importance for general departments of surgery in these smaller hospitals. We also do realize this might change in the next decades. Moreover, complication registration is an outcome-driven registration. It enables us to review trends in complications, such as an increasing postoperative infection rate. These trends should be reviewed and analysed on the higher level of general surgery because the processes or actions for improvement may transcend the subspecialty.

Finally, nowadays benchmarking criteria may not be based of self-reported outcomes but outcome data gathered by 'coders'. Coders may take over the surgeons' task of recording complications, for example using trigger tools. This is even more important in the multidisciplinary units in the future. The agreement between surgeons and coders is the first step toward benchmarking. To this end, interpretation differences regarding specific clinical situations should be reconciled and regulated by the professional society first.

Conclusion

Given the considerable differences in interpretation of the current definition of a complication, it is unlikely that uniform registration of complications is actually possible. This uniformity may be increased by additions to the current definition, by more agreement about specific clinical situations, and by training of surgeons, thereby improving comparisons at both local and national levels. This seems a prerequisite before such data can be used at the public domain and function as one of the parameters for the quality of healthcare.

Acknowledgements

We thank all surgeons, fellows and residents of the surgical departments of the seven hospitals that participated in the study. We also thank Anne van Wijngaarden for assisting in the data collection.

Figure 1: Agreement within and between hospitals: 'definition' category.

The questions are ordered from the highest to the lowest average percentage of 'yes' responses per case per hospital

Figure 2: Agreement within and between hospitals: other categories.

The questions are ordered from the highest to the lowest average percentage of 'yes' responses per category per case per hospital. The cases can appear in more than one category.

Appendix: Cases

a. Contributorshipstatement

All authors have made substantial contributions to the manuscript and have had the opportunity to read and comment upon the present manuscript. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work

A Visser: Design, aquisition, analyses, interpretation

DT Ubbink: Analyses, Interpretation

DJ Gouma: Design, Interpretation

JC Goslings: Design, Interpretation

b. Competing interests

There are no competing interest.

c. Funding

There are no funders to report for this research.

d. Data sharing statement

This research does not have unpublished data.

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Appendix: Cases

Case	Outcome measure	N	Category
1. After a left hemicolectomy, a patient suffers a postoperative anastomotic leak and an intra-abdominal abscess. How many complications would you enter into the complication registry?	0 (No) / 1 (Yes) / 2 (Yes)	132	Definition (1) Serial/transfer (6)
2. A patient is admitted with bilateral multiple rib fractures and haemothorax. During clinical course patient develops new episode of respiratory insufficiency with pneumonia, requiring re-intubation. Also delirium and UTI, which are treated. Which complication(s) do you register?	None / Resp. & UTI / Resp. & UTI & delirium / Resp. & UTI & delirium & pneumonia	109	Definition (1) Serial/transfer (6)
3. During surgery, the patient's spleen is accidentally damaged, requiring splenectomy. This means that the patient must take part in a vaccination programme.	No Yes; temporary / Yes; re-op / Yes; permanent	127	Definition (1) Severity (3) Intra-op (4)
4. A patient is operated for a perforated appendix. The wound is not left open but is aligned with 2 stitches. The wound becomes infected.	No / Yes	115	Definition (1)
5. A patient underwent a right hemicolectomy. The patient developed a wound abscess which is treated conservatively.	No / Yes	126	Definition (1)
6. After a high-energy trauma a patient is surgically treated for a crural fracture with step-off of the lower leg with a metal rod. 2 hours after the operation the patient develops a compartment syndrome, which is treated with fasciotomy.	No / Yes	130	Definition (1)
7. Patient undergoes an aorta valve replacement. During hospitalisation he suffers abdominal pain for which the surgeon performs an ileocaecal resection. During the postoperative l course the patient suffers congestive heart failure due to AF which is treated with medication. The patient dies on the surgery ward.	No / Yes	128	Definition (1)
8. A patient undergoes a total thyroidectomy. Hypocalcaemia develops postoperatively.	No Yes; Temporary / Yes; permanent	129	Definition (1) Severity (3)
9. A patient underwent sigmoid resection in another hospital and is transferred with abdominal sepsis. During hospitalisation the patient develops an intra-abdominal abscess which is treated with percutaneous drainage. Which complication do you register?	None / Sepsis / Abd. abscess / Both	126	Definition (1) Serial/transfer (6)
10. A patient undergoes a laparoscopic colectomy. 5 days after discharge from hospital, the patient presents to the emergency department with abdominal pain and is admitted for observation.	No Yes; Temporary	126	Definition (1) Severity (3)
11. A patient with 'body packer' syndrome undergoes a laparotomy during which 13 packets are removed via enterotomy. During the postoperative clinical course the patient develops ileus and is discharged after 22 days.	No / Yes	128	Definition (1)
12. A day after undergoing daycare laparoscopic cholecystectomy, a patient presents to the emergency department with continuous abdominal pain and vomiting. The patient is diagnosed with choledocholithiasis and admitted to hospital where an ERCP is performed.	No / Yes	126	Definition (1)
13. After a high-energy trauma a patient is surgically treated for a crural fracture with step-off of the lower leg with a metal rod. During the operation the patient develops compartment syndrome which is treated with fasciotomy.	No / Yes	129	Definition (1) Intra-op (4)
14. During an operation to repair an incisional hernia, the patient's small intestine is accidentally damaged. The defect is repaired immediately during the same operation. The postoperative clinical course is uncomplicated.	No / Yes; temporary / Yes; re-operation	126	Definition (1) Severity (3) Intra-op (4)
15. A patient has undergone surgery to remove an adrenal tumour by means of laparotomy. The patient is discharged after one week in good condition. 6 weeks later, the patient presents to the outpatient department with abdominal pain and is readmitted with bowel obstruction due to adhesions.	No / Yes	92	Definition (1)
16. A patient is admitted and underwent a gastrectomy. It takes 6 days after the operation before gastric emptying occurs.	No / Yes	132	Definition (1)
17. Following surgery for acute appendicitis, the patient occupies a 'borrowed' bed at the orthopaedics department. During this period the patient suffers morphine toxicity.	No / Yes	129	Specialty (2)
18. During placement of a central venous catheter in a surgical patient in the ICU, the patient develops pneumothorax which requires placement of a thorax drain.	No / Yes	126	Specialty (2)
19. A patient undergoes a PTA (by the interventional radiologist). Following the intervention, a large haematoma develops in the groin at the puncture site.	No / Yes	126	Specialty (2)
20. In the operating theatre, the surgeon performs the 'time out'. It appears that all equipment is not sterile. The patient is sent back to the ward and is operated on a day later.	No / Yes	130	Cancellation (5)
21. A patient is admitted for elective surgery for a fractured ankle. A day before the operation, it is cancelled due to priority being given to more emergency patients.	No / Yes	127	Cancellation (5)
22. A patient is admitted for elective surgery for a fractured ankle. A day before the operation, it is cancelled because the ankle is still too swollen.	No / Yes	126	Cancellation (5)
23. The patient has undergone a left hemithyroidectomy. After the operation the patient is found to have vocal cord paralysis. What severity do you register for this complication?	Temporary / Permanent	124	Severity (3)
24. A patient undergoes a hemicolectomy. After 5 days the patient suffers an anastomotic leak for which an ileostomy is constructed. What is the severity of this complication?	Re-op / Permanent	125	Severity (3)

N.B. The questions are ordered from the highest to the lowest average percentage of 'yes' responses per category per case. The example cases were presented to participants in random order.