



Universiteit  
Leiden  
The Netherlands

## **Implementing patient safety in laparoscopic surgery: quality assessment and process analysis**

Blikkendaal, M.D.

### **Citation**

Blikkendaal, M. D. (2018, May 23). *Implementing patient safety in laparoscopic surgery: quality assessment and process analysis*. Retrieved from <https://hdl.handle.net/1887/62352>

Version: Not Applicable (or Unknown)

License: [Licence agreement concerning inclusion of doctoral thesis in the Institutional Repository of the University of Leiden](#)

Downloaded from: <https://hdl.handle.net/1887/62352>

**Note:** To cite this publication please use the final published version (if applicable).

Cover Page



Universiteit Leiden



The handle <http://hdl.handle.net/1887/62352> holds various files of this Leiden University dissertation.

**Author:** Blikkendaal, M.D.

**Title:** Implementing patient safety in laparoscopic surgery: quality assessment and process analysis

**Issue Date:** 2018-05-23





# Chapter 2

## **Achieving consensus on the definition of conversion to laparotomy: a Delphi study among general surgeons, gynecologists, and urologists**

Mathijs D. Blikkendaal  
Andries R. H. Twijnstra  
Anne M. Stiggelbout  
Harrie P. Beerlage  
Willem A. Bemelman  
Frank Willem Jansen

## Abstract

**Background:** In laparoscopic surgery, conversion to laparotomy is associated with worse clinical outcomes, especially if the conversion is due to a complication. Although apparently important, no commonly used definition of conversion exists. The aim of this study was to achieve multidisciplinary consensus on a uniform definition of conversion.

**Methods:** On the basis of definitions currently used in the literature, a web-based Delphi consensus study was conducted among members of all four Dutch endoscopic societies. The rate of agreement (RoA) was calculated; a RoA of >70% suggested consensus.

**Results:** The survey was completed by 268 respondents in the first Delphi round (response rate, 45.6%); 43% were general surgeons, 49% gynecologists, and 8% urologists. Average  $\pm$  standard deviation laparoscopic experience was  $12.5 \pm 7.2$  years. On the basis of the results of round 1, a consensus definition was compiled. Conversion to laparotomy is an intraoperative switch from a laparoscopic to an open abdominal approach that meets the criteria of one of the two subtypes: strategic conversion, a standard laparotomy that is made directly after the assessment of the feasibility of completing the procedure laparoscopically and because of anticipated operative difficulty or logistic considerations; and reactive conversion, the need for a laparotomy because of a complication or (extension of an incision) because of (anticipated) operative difficulty after a considerable amount of dissection (i.e., >15 min in time). A laparotomy after a diagnostic laparoscopy (i.e., to assess the curability of the disease) should not be considered a conversion. In the second Delphi round, a RoA of 90% was achieved with this definition.

**Conclusions:** After two Delphi rounds, consensus on a uniform multidisciplinary definition of conversion was achieved within a representative group of general surgeons, gynecologists, and urologists. An unambiguous interpretation will result in a more reliable clinical registration of conversion and scientific evaluation of the feasibility of a laparoscopic procedure.

## Introduction

Inherent to laparoscopic surgery is a risk of conversion to conventional laparotomy. This risk depends on a combination of indication, disease and patient characteristics, and surgeon skill. In the past, the conversion rate was used to determine the feasibility of the laparoscopic approach [1, 2]. Nowadays, this rate could more specifically be used as a means of evaluation [3]. In general, compared to a procedure completed laparoscopically, a conversion is associated with worse outcomes, such as a longer length of surgery, more postoperative complications, and a longer hospital stay [4, 5]. The outcomes after a conversion due to a complication (reactive) are significantly worse in comparison to those after a strategic conversion in order to prevent an intraoperative complication in case of anticipated operative difficulty (e.g., dense adhesions, underlying or additional pathology) [6, 7].

To date, a uniform registration of conversions is not common practice. Moreover, some consider each laparotomy during a laparoscopic procedure a conversion [8], while others consider only a laparotomy due to an intraoperative complication [9, 10] or an incision larger than 7 cm to be a conversion [11, 12]. As a result of this inconsistency, comparison between centers, procedures, and the literature is not reliable, and any observed difference is likely to be explained by the lack of an unambiguous and generally accepted definition. This is increasingly recognized, and it is frequently stated that a unified and consistent definition of conversion must be obtained [4, 5, 13].

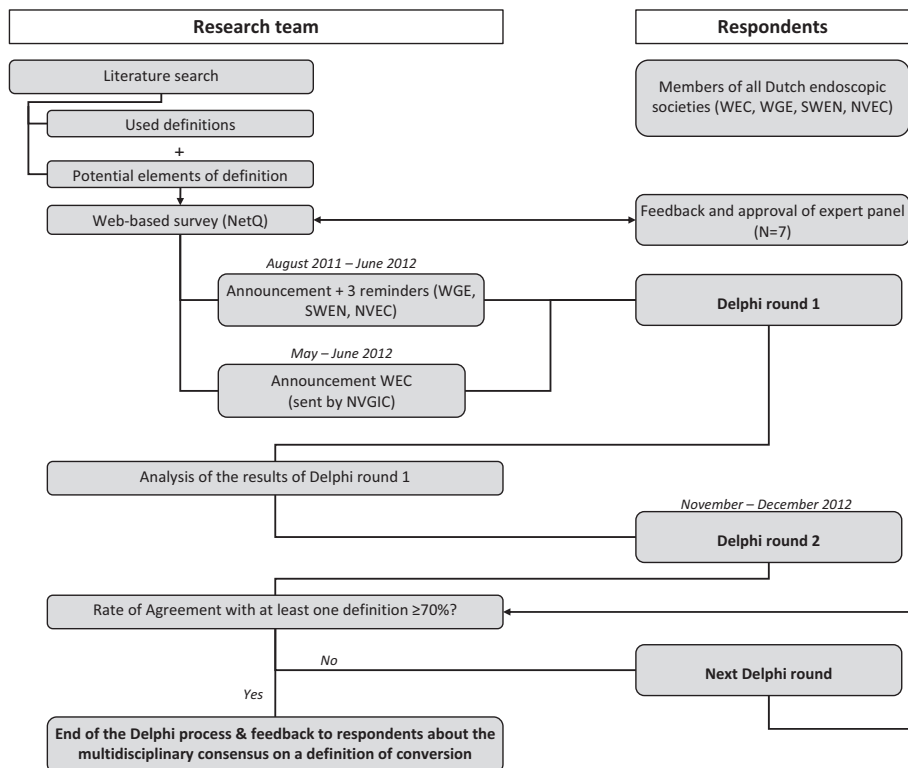
In general, a good definition has to be clear, easy to interpret, and complete, thereby covering every situation and even the (rare) exceptions. This can be obtained by stating the *genus* and *differentia* and by taking into account the five rules of Copi and Cohen [14]: focus on essential features, avoid circularity, capture the correct extension, avoid figurative or obscure language, and be affirmative rather than negative. Only when such a definition exists and is used consistently can conversion be a reliable means of evaluation, can it be used for reliable comparison between surgeons and/or clinics, and can it provide reliable grounds for the comparison of procedures that are performed now and in the future.

The goal of this study was to achieve multidisciplinary consensus on a generally applicable definition of conversion in laparoscopic surgery by means of the Delphi approach.

## Materials and methods

### Study design

On the basis of definitions of conversion that are currently used in the literature, a Delphi consensus study was conducted. The Delphi technique is a widely used consensus method that allows a large group of individuals to achieve consensus on a complex problem effectively by structuring the group communication process [15]. In repeated rounds, the respondents are polled individually and (quasi-)anonymously, with self-administered surveys [16, 17]. In each subsequent round, the results of the previous round are provided, thus enabling the range of answers to converge toward a consensus. This process is repeated until an acceptable level of consensus is reached. The data were collected between August 2011 and December 2012. An overview of the study design is presented in Figure 2.1.



**Figure 2.1** Flow chart of the Delphi technique used in this study to achieve multidisciplinary consensus on a generally applicable definition of conversion in laparoscopic surgery.

WEC = Working group Endoscopic Surgery, part of Dutch Society for Gastrointestinal Surgery, WGE = Working group Gynecologic Endoscopy, SWEN = Foundation Working group Endourology, NVEC = Dutch Society of Endoscopic Surgery, NVGIC = Dutch Society for Gastrointestinal Surgery.

## Survey

Through the design of the web-based survey, the possible outcome was twofold. Ideally, an acceptable level of agreement with a definition that is currently used in the literature would already exist or would be established by the Delphi procedure. If not, on the basis of the (dis)agreement of the respondents with elements that could be present in a definition, a new definition could be compiled and introduced in the subsequent round or rounds. In this way, we tried to obtain an optimal balance between objectivity and the effectiveness of the Delphi process.

The survey consisted of four parts (see Appendix 2.1). Part I asked the respondents to state the definition of conversion they used in their daily practice (free text). These definitions were categorized on the basis of the presence of essential elements in the definition of conversion by two persons independently. Part II included the different elements that potentially could be present in a (new) definition of conversion. They were isolated from the definitions that are currently used in the literature. This part enquired after the current use of each specific element and provided some clinical scenarios. The scenarios had to be marked as a laparoscopic or laparoscopic-assisted procedure, or as a strategic or reactive conversion. The questions in this part were individually routed according to the answers provided. Part III consisted of definitions that are currently used in the literature. These were both definitions that were stated in studies covering the same topic and a selection of definitions used in recent observational studies with conversion or conversion rate as an outcome measure. The respondents were asked to state their agreement with each definition on a 5-point Likert scale, from -2 (strongly disagree) to +2 (strongly agree). Additionally, the respondents were able to indicate whether they were of the opinion that the definition would be useful in daily practice. To avoid bias, we did not provide any references of the definitions in the survey. The last part included physician demographics and characteristics of their surgical practices.

## Selection of experts

A panel of senior laparoscopists with extensive experience in advanced procedures (three general surgeons, three gynecologists, and one urologist) was consulted beforehand to provide feedback on the survey. After incorporating their comments and obtaining their approval, we e-mailed the survey using an online survey tool (NetQ) to the members all four endoscopic societies: Working Group Endoscopic Surgery [WEC, part of the Dutch Society for Gastrointestinal Surgery (NVGIC); general surgeons], Working Group Gynecologic Endoscopy (WGE), Foundation Working group Endourology (SWEN), and the Dutch Society of Endoscopic Surgery (NVEC; multidisciplinary). Additionally, three reminders were sent to those who did not respond or who did not fully complete the survey. Double responses that were the result



of membership in multiple societies and data of partially completed surveys were discarded. The response rate was based on the number of fully completed surveys.

All answers were collected and analyzed by Microsoft Excel and SPSS software, version 20. A Pearson chi-square test was used to compare proportions, and p values of <.05 were considered statistically significant. The rate of agreement (RoA) was calculated by subtracting the number of respondents who (strongly) disagree from those who (strongly) agree and by dividing that by the total number of respondents:

$$\text{RoA} = \frac{(\text{strongly})\text{agree} - (\text{strongly})\text{disagree}}{(\text{strongly})\text{agree} + (\text{strongly})\text{disagree} + \text{indifferent}} \times 100\%$$

A RoA of >70% suggests consensus on the definition, and a RoA of ≤70% justifies rejection of the definition [18]. With respect to questions with dichotomous answers, 80% in one category was defined as the cutoff for consensus [19]. To avoid reduction in response rate with repeated questions due to respondent fatigue, in subsequent rounds, only questions were asked on which no consensus existed. The complete process ceased when consensus on a definition was obtained [18].

## Results

### Respondents

The response rate in the first round was 45.6% (268 completed surveys from 588 potential responders). Of the respondents, 43% were general surgeons (n = 116), 49% were gynecologists (n = 131), and 8% were urologists (n = 21). The denominator consisted of 275 general surgeons [member of WEC (approximation) and/or NVEC], 282 gynecologists (member of WGE and/or NVEC), and 31 urologists (member of SWEN and/or NVEC). Half of all respondents worked in a university-affiliated teaching hospital, 20% in a tertiary referral/university center, and 29% in a nonteaching hospital. The majority performed advanced laparoscopic procedures (general surgeons 94%, gynecologists 67%, urologists 95%). Over half of the respondents (53%) had performed laparoscopic procedures for >10 years; another 34% for 5–10 years (average ± standard deviation experience, 12.5 ± 7.2 years). Approximately two-thirds (64%) performed >50 laparoscopic procedures annually, and 24% performed 25–50 procedures per year. With respect to open procedures, 45% performed >50 annually, and another 28% performed 25–50 procedures annually. More than two-thirds (71%) used a conversion registration that is at least annually discussed or presented in a report.

## Delphi round 1: elements potentially present in a definition of conversion

The definition of conversion that the respondents currently applied (answered as free text) were categorized on the presence of specific elements (Table 2.1). The most common element present in the definition was a deviation from the plan of the procedure: 51% stated a switch from laparoscopy to laparotomy has to be unplanned in order to be considered as a conversion. Furthermore, 45% responded that a conversion can be performed at any time during a laparoscopic procedure, while a minority (6%) was of the opinion at least some laparoscopic dissection had to be done before laparotomy. A reason for the conversion was

**Table 2.1** Categorization of the presence of specific elements in the free-text definitions supplied by the respondents (part 1 of the survey, N = 267)

Characteristic	n (%)
Reason	108 (40)
Strategic and reactive	50 (19)
Only strategic	24 (9)
Only reactive	4 (1)
Any	29 (11)
No progression	1 (0)
Schedule	
Unplanned	137 (51)
Time	136 (51)
Intraoperative	120 (45)
Early vs. late	1 (0)
During the therapeutic part of the procedure	15 (6)
Incision	28 (10)
Standard	14 (5)
Any	8 (3)
Specific (midline, Pfannestiel, etc.)	5 (2)
Length	20 (7)
Larger than specimen	9 (3)
Larger than planned	6 (2)
Larger than trocar	1 (0)
Larger than hand-assistance	2 (1)
Larger than abdominal equivalent	1 (0)
Larger than 7 cm	1 (0)
Assisted	
Distinction between totally laparoscopic and laparoscopic-assisted or hand-assisted	10 (4)
Technique	9 (3)
No optics / no instruments	6 (2)
No pneumoperitoneum	2 (1)
No optics and no pneumoperitoneum	1 (0)

present in 40% of the supplied free-text definitions. Most frequently a subdivision between strategic and reactive (i.e., after an intraoperative complication) reasons for conversion was made (19%).

In the next part of the survey, when specifically asked, overall, 56% ( $n = 149$ ) responded that they stated the reason for the conversion (reactive or strategic) in their registration of conversions (47% among general surgeons, 60% among gynecologists, and 71% among urologists,  $p = .04$ ). The most common grounds for this subdivision were “additional insight in the indication” (74%) and “difference in morbidity” (54%). In five out of the seven clinical scenarios, between 93 and 97% of the respondents agreed on the type of conversion (either strategic or reactive) (Table 2.2). Only regarding a conversion due to anesthesiologic problems (42% reactive; 53% strategic) and a conversion due to technical failure of the equipment (50% reactive; 46% strategic) did no consensus exist on the type of conversion (equal among specialties,  $p = .892$  and  $p = .835$ , respectively).

**Table 2.2 Clinical scenarios regarding type of conversion ( $n = 149$ ): a laparotomy is performed during a laparoscopic procedure. How would you register the laparotomy if it was due to...**

	Strategic		Reactive		No conversion	
	Round 1 (%)	Round 2 (%) <sup>a</sup>	Round 1 (%)	Round 2 (%) <sup>a</sup>	Round 1 (%)	Round 2 (%) <sup>a</sup>
... a large iatrogenic bleeding?	3		97		1	
... visibility / mobility problems?	97		1		2	
... an internal organ lesion?	3		93		4	
... extensive intra-abdominal adhesions?	95		3		3	
... underlying / additional pathology?	95		1		5	
... anesthesiologic problems?	53	49	42	50	5	1
... technical failure of the equipment?	46	35	50	64	3	1

<sup>a</sup> Only responses on which no consensus was achieved were asked again in the second round.

With respect to the moment of conversion, it seemed clear that if during the preoperative briefing it was decided to perform a standard laparotomy instead of a laparoscopic procedure, it was not considered a conversion (94%). Similarly, a planned switch to a laparotomy after a diagnostic laparoscopy (i.e., to assess the curability of the disease) was not considered a conversion (90%). On the other hand, an unplanned switch to a laparotomy directly after the assessment of the feasibility of completing the procedure laparoscopically (e.g., in case of underlying/additional pathology) was considered a conversion by 64% of the respondents (general surgeons 72%, gynecologists 59%, urologists 57%,  $p = .088$ ).

Regarding the incision used, 66% responded that every type of abdominal incision potentially could be registered as a conversion. Among the others, 25% stated an incision for conversion should be similar to the incision required for the laparotomic equivalent of the same procedure.

With respect to the registration of an extension of a port site, overall, 17% (n = 46) indicated that they use the term *laparoscopic assisted* (general surgeons 31%, gynecologists 7%, and urologists 5%,  $p < .001$ ). Among these respondents, a variation was observed within the presented clinical scenarios regarding the registration of an extended port site: “an incision larger than usual,” 41% laparoscopic, 48% laparoscopic assisted; “any incision for specimen retrieval,” 54% laparoscopic, 46% *laparoscopic assisted*; and “an incision as large as the conventional open approach for retrieval of the specimen,” 54% laparoscopic assisted, 35% conversion (n = 46 for all). Of those who did indicate that they did not use the term *laparoscopic assisted* (83%, n = 219), 94% did not consider an incision for specimen retrieval to be a conversion. However, an incision as large as the conventional open approach for retrieval of the specimen would be registered as a conversion by 52% of these respondents.

### **Delphi round 1: RoA with the definitions currently used in the literature**

Although none of the definitions that were found in the literature was identical, we were able to group those that contained the same essential elements into nine different definitions (Table 2.3) [1, 8, 9, 12, 13, 20-23]. On the basis of the Likert scale, the calculated RoA for each definition ranged between -10 and +85% (Table 2.3). Two of these (Kolkman et al. [21] [75%] and Leonard et al. [1] [85%]) resulted in a RoA of >70%. Among the different specialties, both these RoAs did not differ (76% general surgeons, 72% gynecologists, 90% urologists,  $p = .614$ ; 89% general surgeons, 82% gynecologists, 86% urologists,  $p = .564$ ).

### **Delphi round 2**

In concordance with the Delphi method, questions on which no consensus was achieved were asked again in the second round, together with a summary of the results of the first round. During the interim analysis of the results of round 1, it was found that both definitions that received a RoA of >70% were not able to discriminate indifferently in all situations between strategic or reactive conversion and no conversion. Because this was regarded as an important requirement for a uniform definition [14], a more specific definition, entirely based on the above-mentioned results of the first round, was compiled (Table 2.4). Because 17 respondents stated that they were not willing to participate in subsequent rounds, the second Delphi round was sent to 251 persons, of whom 191 fully completed the survey (response rate 76.1%).

**Table 2.3** Different elements present in the definitions of conversion that we identified in the literature

Definition of conversion	Reason	Schedule / time	Type of incision	Length of incision	Specimen retrieval	RoA	
						Round 1 (N = 268)	Round 2 (N = 191)
Any incision made earlier than initially planned to complete the procedure [13]		X	X			-12%	
Open abdominal access through a more than 7-cm long skin incision [12]				X		-6%	
Any laparotomy other than extension of a port to remove the specimen [23]			X		X	15%	
A vertical incision greater than necessary for specimen retrieval [22]			X	X	X	10%	
Any laparotomy procedure performed for any reason [8]	X		X			16%	
A case that could not be completed endoscopically as planned [21]		X				75%	67%
The need for a standard laparotomy at any time during the procedure, either because of complications or technical difficulties [1]	X	X	X			85%	91%
Failure of the planned procedure [20]		X				28%	
A substitution of laparoscopy by laparotomy for intraoperative complications [9]	X	X				61%	

In the last 2 columns, the rate of agreement (RoA) with each of these definitions is shown.  $\text{RoA} = [(\text{Agreement} - \text{Disagreement}) / (\text{Agreement} + \text{Disagreement} + \text{Indifferent})] \times 100\%$ . A RoA of  $>70\%$  allows acceptance of the recommendation, and a RoA of  $\leq 70\%$  justifies rejection of the recommendation [18].

The respondents were asked again to provide their agreement with the two definitions with the highest RoA from round 1 (respectively, 68 and 91% in round 2; Table 2.3). Additionally, the newly compiled definition was added. This definition resulted in a RoA of 90% (Table 2.4).

The latter was the preferred definition by 60% of the respondents, and in its current form, 93% considered this compiled definition applicable as a multidisciplinary definition. The definition of Leonard et al. [1] (Table 2.3) was preferred by 31% and was considered applicable by 87%. Therefore, after the second round, the compiled definition was adopted for consensus.

Within the 34% who did suggest the use of a separate definition for a laparoscopic-assisted procedure (n = 64), 53% preferred “any incision larger than required for laparoscopic

equipment and not being a conversion,” while 42% suggested the definition used by Dindo et al. [7] (“a small-target incision for specimen retrieval”).

The Delphi process was ceased after two rounds because consensus on a multidisciplinary applicable definition was achieved (Table 2.4).

**Table 2.4 Definition of conversion that was compiled entirely based on the results of round 1 (RoA 90% in round 2)**

Conversion to laparotomy is an intraoperative switch from a laparoscopic to an open abdominal approach that meets the criteria of 1 of the 2 subtypes:

- Strategic conversion is a standard laparotomy that is made directly after the assessment of the feasibility of completing the procedure laparoscopically<sup>a</sup> and because of anticipated operative difficulty or logistic considerations
- Reactive conversion is the need for a laparotomy because of a complication or (extension of an incision) because of (anticipated) operative difficulty after a considerable amount of dissection (i.e., >15 min in time)

<sup>a</sup> A laparotomy after a diagnostic laparoscopy (i.e., to assess the disease) should not be considered a conversion.

## Discussion

Consensus on a uniform and multidisciplinary applicable definition was achieved after two Delphi rounds (Table 2.4). This definition received a very high RoA in Delphi round 2 (90%), was preferred by most respondents, and was considered applicable in its current form. The survey was performed within a representative group of laparoscopically experienced general surgeons, gynecologists, and urologists in the Netherlands (N = 268).

Because a converted laparoscopic procedure is associated with worse or similar outcomes compared to an initially primary laparotomy, conversion has received much attention as a means to evaluate the feasibility of newly introduced laparoscopic techniques. Nevertheless, most laparoscopic surgeons are of the opinion that conversion is inherent to laparoscopy and should not be regarded as a complication [6, 24, 25]. If laparoscopy fails, the surgeon always has the possibility to switch to the conventional abdominal approach. Still, the conversion rate can also be used as a means to evaluate indication, patient selection, and surgeon experience and skills [3, 13, 26]. However, proper evaluation and comparison is not possible until a clear, uniform, and generally accepted definition of conversion is used.

Only in the field of laparoscopic colorectal surgery have both the associated differences in morbidity and the definition of conversion been subject to research [4-7, 13, 27]. Gervaz et al. [5] found that only 30% of the studies stated the definition of conversion that was used. Shawki et al. [13] tried to obtain consensus on a definition within a group of laparoscopic

colorectal surgeons. In their survey, 68% agreed on the definition “any incision made earlier than initially planned to complete the procedure.” However, in our opinion, although this definition is brief and concise, it leaves too much room for interpretation, lacks the differentiation between strategic and reactive conversions, and is only valid for colorectal procedures. In general, all these studies concluded that no consistent definition was currently used in the literature, and to our knowledge, in the international literature no uniform multidisciplinary definition of conversion has yet been obtained. These findings support the need to compile a uniform multidisciplinary applicable definition. This definition was entirely based on the results of round 1, which was completed by a large and broad group of experienced laparoscopists. Furthermore, the response rate of 46% was considered acceptable, both compared to the average response rate in other survey studies and especially compared to the response rate in the only other study on this subject (29%) [13, 28]. Therefore, the validity of the responses appears to be high, and the definition on which we achieved consensus seems widely supported.

Having taken into account the rules of Copi and Cohen [14], the first part of the consensus definition (Table 2.4) consists of the *genus*: the essence of each conversion is the switch from a laparoscopic to an open abdominal approach during the procedure. Then, because of the difference in morbidity, two subtypes with each a specific set of *differentia* are defined. In order to qualify as a strategic conversion, the laparotomy must be made before extensive dissection is done and before the decision is made that the procedure can be performed entirely laparoscopically. Furthermore, the laparotomy must be standard—that is, the type of incision that would be used for a conventional primary open abdominal approach. Reasons could be either anticipated operative difficulty (e.g., extensive adhesions, a large immobile structure) or logistic considerations (e.g., time constraints due to a busy operating schedule). This implies that a conversion performed at this stage of the procedure and because of a complication (e.g., a vessel or bowel injury) cannot be marked as strategic. It has to be noted that a laparotomy after a true diagnostic laparoscopy (i.e., to assess the curability of the disease, thereby preventing the patient from a laparotomy in case no therapeutic steps can/have to be performed) should not be registered as a conversion.

The first *differentium* of a reactive conversion is the need for a laparotomy. In other words, there is a necessity for the laparotomy, and it could be each type of abdominal incision. Second, one reason for this type of conversion could be the presence of a complication requiring laparotomy. In the absence of a complication, another reason could be either anticipated or experienced operative difficulty that is discovered after a considerable amount of dissection. Given the associated morbidity described in the literature, an evidence-based cutoff would be 15 min of dissection (starting after establishment of the pneumoperitoneum) [29]. This allows some dissection, thus enabling an optimal assessment of the feasibility of

completing the procedure laparoscopically. Although conversion should be regarded a safety step [26], a switch to laparotomy after a considerable amount of laparoscopic operating time because of a lack of progress indirectly implies that an inadequate judgment has been made during the assessment of the feasibility of completing the procedure laparoscopically, and that during some part of the procedure, an unnecessary combined risk of complications existed. It is important to realize that (extension of) an incision for specimen retrieval does not meet the criteria of either subtype and therefore should not be registered as a conversion. Importantly, because the researcher must maintain a subject-neutral role in the Delphi method, it was safeguarded that only elements on which already consensus existed after the first Delphi round were included in this compiled definition.

During Delphi round 1, in five out of the seven clinical scenarios, the type of conversion was already interpreted in concordance with the consensus definition (Table 2.2). Only the subdivisions of a conversion due to anesthesiologic problems and due to technical failure of the equipment were answered as “indifferent.” Applying the consensus definition to these scenarios, the differentiation between the type of conversion in case of anesthesiologic reasons depends entirely on the moment the decision is made. If the decision to convert is made during the assessment of the feasibility of completing the procedure laparoscopically, it should be regarded as a strategic conversion. However, if at first both the anesthetist and the surgeon judged a laparoscopic procedure to be feasible and after a considerable amount of dissection time (i.e., >15 min) ventilation problems and/or insufficient Trendelenburg or visualization of the operating field are experienced, it should be regarded as a reactive conversion. Similarly, because technical failure of the equipment that results in a conversion is regarded a complication [30], this should be interpreted as a reactive conversion.

The most important implication of a uniform and multidisciplinary used definition will be a more reliable comparison of (new) laparoscopic procedures. Additionally, given the differences in morbidity associated with the type of conversion, a subdivision into strategic and reactive conversions will provide detailed insight into the advantages or disadvantages of the procedure under research. Moreover, patient informed consent will improve as well.

Consensus on the registration of an incision for specimen retrieval and the definition of a laparoscopic-assisted procedure was not achieved. Although subject to debate, we are of the opinion that, in line with proper registration of converted procedures, laparoscopic procedures that require an incision for specimen retrieval should be adequately categorized. Most importantly, this will enable future research on technological developments that could make the (enlarged) incision for specimen retrieval superfluous. Only by adding a proper registration of laparoscopic-assisted procedures as well can the true morbidity associated with totally laparoscopic procedures be elucidated.



The size of the expert panel (N = 268) may be considered rather large, which is partially explained by the multidisciplinary design of the study. The reasons for approaching members of all endoscopic societies in the Netherlands were simultaneously to conduct this study and to create awareness among clinicians about this subject, as well as to create a final definition within an entire group of specialists performing (advanced) laparoscopic surgery. A panel consisting of 15–30 persons could have been prone to selection bias and would have resulted in a definition that should have been communicated to the entire field of laparoscopic surgeons as a top-down approach. A downside of a large panel is the fact that it is harder to reach consensus. The fact that we were able to reach consensus even within this large panel supports the proposed definition. On the other hand, it is stated that “the output of the Delphi method is only as good as the experts selected for the panel.” One could argue if every member of an endoscopic society should be considered an expert. However, the demographics show that this group is a rather experienced group, the majority of which performs advanced procedures. Furthermore, the compiled definition was preferred by 60% of the respondents, followed by the definition of Leonard et al. [1] (31%) (RoA 90 vs. 91%). Although only twice as many respondents preferred the compiled definition, in our opinion, these figures reflect a nuance in preference because these two definitions are very similar to each other, and both differentiate between a strategic and a reactive conversion. Therefore, we adopted the most preferred definition for consensus instead of performing a third Delphi round. Additionally, it was likely that the secondary questions on which no agreement of >80% was achieved would not converge significantly toward a consensus in subsequent rounds.

In conclusion, after two Delphi rounds, a high level of consensus within a representative group of general surgeons, gynecologists, and urologists was achieved on a uniform multidisciplinary definition differentiating between a strategic and a reactive conversion (Table 2.4). An unambiguous interpretation will consequently result in a more reliable clinical registration of conversion and scientific evaluation of the feasibility of a surgical procedure, provided that this definition becomes obligatory to be adopted in laparoscopic surgery.

## **Acknowledgments**

The authors would like to thank all the respondents for their time to complete the survey. Additionally, we would like to thank Dr. C. de Kroon and Dr. C. van Meir (gynecologists) and Dr. E. Consten and Dr. P. Tanis (general surgeons) for their presence in the pilot group, and S. Hofwijk (medical student) for her help in categorizing the free-text definitions of all respondents as an independent second observer.

## References

- Leonard F, Chopin N, Borghese B, Fotso A, Foulot H, Coste J, et al. Total laparoscopic hysterectomy: preoperative risk factors for conversion to laparotomy. *J Minim Invasive Gynecol.* 2005;12:312-317
- Hunter RW, McCartney AJ. Can laparoscopic assisted hysterectomy safely replace abdominal hysterectomy? *Br J Obstet Gynaecol.* 1993;100:932-934
- Twijnstra AR, Blikkendaal MD, van Zwet EW, Jansen FW. Clinical relevance of conversion rate and its evaluation in laparoscopic hysterectomy. *J Minim Invasive Gynecol.* 2013;20:64-72
- Chew MH, Ng KH, Fook-Chong MC, Eu KW. Redefining conversion in laparoscopic colectomy and its influence on outcomes: analysis of 418 cases from a single institution. *World J Surg.* 2011;35:178-185
- Gervaz P, Pikarsky A, Utech M, Secic M, Efron J, Belin B, et al. Converted laparoscopic colorectal surgery. *Surg Endosc.* 2001;15:827-832
- Yang C, Wexner SD, Safar B, Jobanputra S, Jin H, Li VK, et al. Conversion in laparoscopic surgery: does intraoperative complication influence outcome? *Surg Endosc.* 2009;23:2454-2458
- Dindo D, Schafer M, Muller MK, Clavien PA, Hahnloser D. Laparoscopy for small bowel obstruction: the reason for conversion matters. *Surg Endosc.* 2010;24:792-797
- David-Montefiore E, Rouzier R, Chapron C, Darai E, Collegiale d'Obstetrique et Gynecologie de Paris-Ile de F. Surgical routes and complications of hysterectomy for benign disorders: a prospective observational study in French university hospitals. *Hum Reprod.* 2007;22:260-265
- Seracchioli R, Venturoli S, Vianello F, Govoni F, Cantarelli M, Gualerzi B, et al. Total laparoscopic hysterectomy compared with abdominal hysterectomy in the presence of a large uterus. *J Am Assoc Gynecol Laparosc.* 2002;9:333-338
- Malzoni M, Perniola G, Perniola F, Imperato F. Optimizing the total laparoscopic hysterectomy procedure for benign uterine pathology. *J Am Assoc Gynecol Laparosc.* 2004;11:211-218
- Sesti F, Calonzi F, Ruggeri V, Pietropolli A, Piccione E. A comparison of vaginal, laparoscopic-assisted vaginal, and minilaparotomy hysterectomies for enlarged myomatous uteri. *Int J Gynaecol Obstet.* 2008;103:227-231
- Tan J, Sun Y, Zhong B, Dai H, Wang D. A randomized, controlled study comparing minilaparotomy versus isobaric gasless laparoscopic assisted minilaparotomy myomectomy for removal of large uterine myomas: short-term outcomes. *Eur J Obstet Gynecol Reprod Biol.* 2009;145:104-108
- Shawki S, Bashankaev B, Denoya P, Seo C, Weiss EG, Wexner SD. What is the definition of "conversion" in laparoscopic colorectal surgery? *Surg Endosc.* 2009;23:2321-2326
- Copi IM, Cohen C. Introduction to Logic. 12<sup>th</sup> edn, Pearson Education Inc., Upper Saddle River; 2005
- Linstone H, Turoff M. The Delphi Method: Techniques and Applications. In: Linstone HA, Turoff M (eds) <http://is.njit.edu/pubs/delphibook/delphibook.pdf>, Reading, Mass. Addison-Wesley Pub. Co., Advanced Book Program; 2002.
- Fink A, Kosecoff J, Chassin M, Brook RH. Consensus Methods - Characteristics and Guidelines for Use. *Am J Public Health.* 1984;74:979-983
- Jones J, Hunter D. Consensus methods for medical and health services research. *BMJ.* 1995;311:376-380
- Janssen PF, Brolmann HAM, Huirne JAF. Recommendations to Prevent Urinary Tract Injuries During Laparoscopic Hysterectomy: A Systematic Delphi Procedure Among Experts. *J Minim Invas Gyn.* 2011;18:314-321

19. Keeney S, Hasson F, McKenna H. Consulting the oracle: ten lessons from using the Delphi technique in nursing research. *J Adv Nurs*. 2006;53:205-212
20. Garry R, Fountain J, Brown J, Manca A, Mason S, Sculpher M, et al. EVALUATE hysterectomy trial: a multicentre randomised trial comparing abdominal, vaginal and laparoscopic methods of hysterectomy. *Health Technol Assess*. 2004;8:1-154
21. Kolkman W, Engels LE, Smeets MJ, Jansen FW. Teach the teachers: an observational study on mentor traineeship in gynecological laparoscopic surgery. *Gynecol Obstet Invest*. 2007;64:1-7
22. Neudecker J, Klein F, Bittner R, Carus T, Stroux A, Schwenk W, et al. Short-term outcomes from a prospective randomized trial comparing laparoscopic and open surgery for colorectal cancer. *Br J Surg*. 2009;96:1458-1467
23. Seamon LG, Cohn DE, Henretta MS, Kim KH, Carlson MJ, Phillips GS, et al. Minimally invasive comprehensive surgical staging for endometrial cancer: Robotics or laparoscopy? *Gynecol Oncol*. 2009;113:36-41
24. Atkinson SW. Results of eVALuate study of hysterectomy techniques: conversion to open surgery should not be regarded as major complication. *BMJ*. 2004;328:642; author reply 643
25. Chapron C, Querleu D, Bruhat MA, Madelenat P, Fernandez H, Pierre F, et al. Surgical complications of diagnostic and operative gynaecological laparoscopy: a series of 29,966 cases. *Hum Reprod*. 1998;13:867-872
26. Lengyel BI, Azagury D, Varban O, Panizales MT, Steinberg J, Brooks DC, et al. Laparoscopic cholecystectomy after a quarter century: why do we still convert? *Surg Endosc*. 2012;26:508-513
27. Offodile AC, Balik E, Hoffman A, Moon V, Baxter R, Grieco M, et al. Is there a role for a strict incision length criterion for determining conversions during laparoscopic colorectal resection? *Surg Innov*. 2010;17:120-126
28. Archer T. Characteristics Associated with Increasing the Response Rates of Web-Based Surveys. <http://pareonline.net/pdf/v12n12.pdf>, Practical Assessment Research & Evaluation; 2007
29. Slim K, Pezet D, Riff Y, Clark E, Chipponi J. High morbidity rate after converted laparoscopic colorectal surgery. *Br J Surg*. 1995;82:1406-1408
30. Twijnstra AR, Zeeman GG, Jansen FW. A novel approach to registration of adverse outcomes in obstetrics and gynaecology: a feasibility study. *Qual Saf Health Care*. 2010;19:132-137

## Appendix 2.1

The original questions used for this manuscript were translated from Dutch. Included are all answers that were given (in percentages).

### Round 1 (N = 268)

#### Part I:

Q1: What is the definition of conversion you are currently applying in your daily practice?

A: Free text (see Table 2.1)

Part II – Specific elements that could be present in a (new) definition of conversion (*some questions were individually routed according to the given answers*):

Q2: Regarding the registration of a conversion in the patient file: Do you differentiate between a laparotomy because of a complication ('reactive') and a laparotomy due to the inability to complete the procedure laparoscopically ('strategic')?

A: - Yes (56%) → (routing to Q3)  
- No (44%) → (routing to Q5)

Q3: "A laparotomy is performed during a laparoscopic procedure. How would you register the laparotomy, in case it was due to ..."

A:

	Strategic	Reactive	No conversion
... a large iatrogenic bleeding?	3%	97%	1%
... visibility / mobility problems?	97%	1%	2%
... an internal organ lesion?	3%	93%	4%
... extensive intra-abdominal adhesions?	95%	3%	3%
... underlying / additional pathology?	95%	1%	5%
... anesthesiologic problems?	53%	42%	5%
... technical failure of the equipment?	46%	50%	3%

Q4: Please mark why you differentiate between strategic and reactive conversion in your registration (multiple answers possible)

- A:
- Difference in associated morbidity (54%)
  - Recommendation in the multidisciplinary guideline Minimally Invasive Surgery (42%)
  - Provides insight in the indication (74%)
  - Provides insight in the skills of the surgeon (23%)
  - Strategic conversion is a diagnostic laparoscopy followed by a laparotomy (21%)
  - Means of evaluation / Quality indicator (31%)
  - Other, .... (10%)

(routing to Q7)

Q5: *“A laparotomy is performed during a laparoscopic procedure. How would you register the laparotomy, in case it was due to ...”*

A:

	Conversion	No conversion
... a large iatrogenic bleeding?	98%	2%
... underlying / additional pathology?	84%	16%
... anesthesiologic problems?	93%	7%
... technical failure of the equipment?	97%	3%

Q6: Please mark why you don't differentiate between strategic and reactive conversion in your registration (multiple answers possible)

- A:
- No difference in associated morbidity (21%)
  - Superfluous (31%)
  - Strategic conversion are a diagnostic laparoscopy followed by a laparotomy (26%)
  - Other, .... (34%)

Q7: “How would you register a laparoscopically (planned) procedure, when ...”

A:

	Conversion	No conversion
... during the preoperative briefing it is decided to perform a laparotomy?	6%	94%
... directly following the diagnostic laparoscopy a switch to laparotomy is made (as planned)?	10%	90%
... following the diagnostic laparoscopy a switch to laparotomy is made because of underlying / additional pathology ( <u>not</u> as planned)?	64%	36%

Q8: In what percentage of your laparoscopic procedures an extra incision or enlargement of an existing port site is made because of specimen retrieval?

- A:
- Never (5%)
  - 1–5% (27%)
  - 5–10% (21%)
  - 10–15% (12%)
  - >15% (32%)
  - Other, ... (3%)

Q9: Do you use the term ‘laparoscopic-assisted’ with regard to the registration of an abdominal incision for specimen retrieval?

- A:
- Yes (17%) → (routing to Q10)
  - No (83%) → (routing to Q11)

Q10: Indicate how you would register the following clinical scenarios

A:

	Laparoscopic	Laparoscopic-assisted	(Strategic) conversion
If a larger than commonly used incision is necessary to complete this fully laparoscopic procedure	41%	48%	11%
If an incision for specimen retrieval is necessary	54%	46%	0%
If after the laparoscopic part of the procedure an incision as large as the conventional open approach for retrieval of the specimen is necessary	11%	54%	35%
If the specimen is morcellated	93%	4%	2%

(routing to Q12)

Q11: Indicate how you would register the following clinical scenarios

A:

	Conversion	No conversion
If an incision for specimen retrieval is necessary	6%	94%
If an incision as large as the conventional open approach for retrieval of the specimen is necessary	52%	48%

Q12: Which type of abdominal incision could potentially be registered as a conversion?  
(multiple answers possible)

- A:
- Midline incision (15%)
  - Pfannenstiel incision (12%)
  - Lateral flank (McBurney, etc.) (9%)
  - Every type of abdominal incision (66%)
  - Similar to the incision required for the laparotomic equivalent of the same procedure (25%)
  - Other, .... (3%)

Part III – Agreement with definitions currently used in the literature:

Q13: Please indicate to what extent you agree with the definitions of conversion used in the literature. Additionally, you can indicate if you are of the opinion that the definition could be useful in daily practice.

A:

	Strongly disagree	Disagree	Neither agree/ nor disagree	Agree	Strongly agree	Useful
Any incision made earlier than initially planned to complete the procedure	13%	35%	15%	19%	13%	14%
Open abdominal access through a more than 7-cm long skin incision	12%	32%	18%	26%	9%	6%
Any laparotomy other than extension of a port to remove the specimen	10%	28%	10%	30%	17%	15%
A vertical incision greater than necessary for specimen retrieval	10%	25%	19%	30%	12%	7%
Any laparotomy procedure performed for any reason	11%	22%	18%	26%	19%	12%
A case that could not be completed endoscopically as planned	3%	6%	7%	42%	35%	27%
The need for a standard laparotomy at any time during the procedure, either because of complications or technical difficulties	2%	4%	3%	35%	42%	42%
Failure of the planned procedure	7%	18%	22%	31%	18%	12%
A substitution of laparoscopy by laparotomy for intraoperative complications	3%	9%	15%	39%	29%	13%

(For calculated RoAs, please see Table 2.3 in the manuscript)



Part IV – Demographics:

Q14: In what type of hospital are you currently working?

- A:
- Non-teaching hospital (29%)
  - University-affiliated teaching hospital (51%)
  - Tertiary referral / university center (20%)

Q15: Which specialism do you perform?

- A:
- General surgeon (43%)
  - Gynecologist (49%)
  - Urologist (8%)

Q16: Which procedures do you regularly perform laparoscopically?

A:

General surgeons		Gynecologists		Urologists	
Cholecystectomy	99%	Sterilization	98%	Varicocelelectomy	25%
Appendectomy	99%	Cystectomy	91%	Ureterostomy	45%
Inguinal hernia repair	65%	Adnexectomy	98%	Pyelothomy	65%
Bariatric surgery	20%	Ectopic pregnancy	90%	Cystectomy	20%
Colorectal surgery	90%	Hysterectomy	66%	Adrenalectomy	40%
Nissen fundoplication	41%	Myomectomy	26%	(Radical) prostatectomy	60%
Adrenalectomy	22%	Endometriosis resection	46%	Nephrectomy	90%
Nephrectomy	5%	Other, ...	16%	Other...	65%
Other, ...	20%				

Q17: Are conversions centrally registered (on behalf of an annual discussion or report)?

- A:
- Yes (71%)
  - No (29%)

Q18: How many years are you currently working as a specialist?

- A: Free text (0–5 years: 30%. 5–10 years: 24%. >10 years: 46%)

Q19: How many years of experience with laparoscopy do you have?

A: Free text (0–5 years: 13%. 5–10 years: 34%. >10 years: 53%)

Q20: How many laparoscopic procedures do you perform annually?

- A:
- <10 (1%)
  - 10–25 (11%)
  - 25–50 (24%)
  - 50–100 (29%)
  - >100 (35%)
  - Other, ... (0%)

Q21: How many open abdominal procedures do you perform annually?

- A:
- <10 (8%)
  - 10–25 (19%)
  - 25–50 (28%)
  - 50–100 (30%)
  - >100 (15%)
  - Other, ... (0%)

**Round 2 (N = 191)**

Part I:

Q1: The previous round resulted in two definitions with a very high Rate of Agreement (RoA). All other definitions resulted in a considerably lower RoA (-12% to 61%). Please indicate again to what extent you agree with these definitions.

A:

	Strongly disagree	Disagree	Neither agree/ nor disagree	Agree	Strongly agree
The need for a standard laparotomy at any time during the procedure, either because of complications or technical difficulties (RoA 85%)	1%	4%	1%	31%	64%
A case that could not be completed endoscopically as planned (RoA 75%)	2%	10%	8%	51%	29%

*(For calculated RoAs, please see Table 2.3 in the manuscript)*

Q2: During the interim analysis of the results of Round 1 it was found that above mentioned definitions were not able to discriminate indifferently in all situations between ‘(strategic or reactive) conversion’ and ‘no conversion’. Since this is regarded an important requirement for a uniform definition, a more specific definition, entirely based on the results of the first round, was compiled. Please indicate to what extent you agree with this definition.

A:

	Strongly disagree	Disagree	Neither agree/ nor disagree	Agree	Strongly agree
Conversion to laparotomy is an intraoperative switch from a laparoscopic to an open abdominal approach that meets the criteria of one of the two subtypes:	1%	3%	4%	47%	46%
<ul style="list-style-type: none"> <li>Strategic conversion: a standard laparotomy that is made directly after the assessment of the feasibility of completing the procedure laparoscopically* and because of anticipated operative difficulty or logistic considerations</li> <li>Reactive conversion: the need for a laparotomy because of a complication or (extension of an incision) because of (anticipated) operative difficulty after a considerable amount of dissection (i.e. in time &gt;15 minutes)</li> </ul>					
* A laparotomy after a diagnostic laparoscopy (i.e. to assess the curability of the disease) should not be considered as a conversion					

(For calculated RoA, please see Table 2.3 in the manuscript)

Q3: With which of the three above mentioned definitions you agree most?

- A:
- |   |  |       |
|---|--|-------|
| 1 | The need for a standard laparotomy at any time during the procedure, either because of complications or technical difficulties                             | (31%) |
| 2 | A case that could not be completed endoscopically as planned   | (9%)  |
| 3 | Conversion to laparotomy is an intraoperative switch from a laparoscopic to an open abdominal approach that meets the criteria of one of the two subtypes: | (60%) |
- Strategic conversion: a standard laparotomy that is made directly after the assessment of the feasibility of completing the procedure laparoscopically\* and because of anticipated operative difficulty or logistic considerations
  - Reactive conversion: the need for a laparotomy because of a complication or (extension of an incision) because of (anticipated) operative difficulty after a considerable amount of dissection (i.e. in time >15 minutes)
- \* A laparotomy after a diagnostic laparoscopy (i.e. to assess the curability of the disease) should not be considered as a conversion

Q4: Concerning the definition with which you agree the most: Do you consider this definition in its current form to be applicable as a multidisciplinary definition? (if no, multiple answers possible)

A:	1. The need ...	2. A case ...	3. Conversion to ...
• Yes	87%	76%	93%
• No, not specific enough	2%	12%	3%
• No, incomplete	3%	6%	2%
• No, too much room for interpretation	5%	12%	2%
• No, unclear	0%	0%	0%
• No, other ...	3%	0%	2%

Q5: During the previous round, it seemed that consensus already existed on the registration of the type of conversion in five out of the seven clinical scenarios (strategic conversion: visibility / mobility problems (97%), extensive intra-abdominal adhesions (95%), underlying / additional pathology (95%); reactive conversion: a large iatrogenic bleeding (97%), an internal organ lesion (93%)).

*“A laparotomy is performed during a laparoscopic procedure. How would you register the laparotomy, in case it was due to ...”*

A:

	Strategic	Reactive	No conversion
... anesthesiologic problems?	49%	50%	1%
... technical failure of the equipment?	35%	64%	1%

Q6: During the previous round, 30% of the respondents indicated they make an extra incision or enlargement of an existing port site because of specimen retrieval in 1–5% of their procedures and 61% in >5% of their procedures. Furthermore, 18% of the respondents indicated they register this type of procedures as ‘laparoscopic-assisted’.

Are you of the opinion that also for the registration of this type of procedures a (separate) definition is necessary?

- A:
- Yes, this type should also be specified in the definition of conversion (4%)
  - Yes, this type should be specified in a separate definition (34%)  
→ (routing to Q7)
  - No, this type is similar to ‘conversion’ (3%)
  - No, this type is completely different from conversion (and its definition) (58%)
  - No opinion (2%)

Q7: Which definition of ‘laparoscopic-assisted’ procedures do you prefer?

- A:
- Any incision larger than required for laparoscopic equipment and not being a conversion (53%)
  - A small-target incision for specimen retrieval (Dindo, Surg Endosc, 2009) (42%)
  - Other, ... (5%)