

Development of a Surgical Competency Assessment Tool for Sentinel Lymph Node Dissection by Minimally Invasive Surgery for Endometrial Cancer

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Disclosure Statement

Andreas Obermair reports grants and personal fees from SurgicalPerformance PTY LTD, grants from Medtronic, outside the submitted work;

Nadeem Abu-Rustum reports grants from Stryker/Novadaq, outside the submitted work;

Michael Frumovitz reports grants from Astra Zeneca, grants from Tesaro/GSK, grants and personal fees from Stryker, grants from Biom'Up, outside the submitted work;

Mario Leitao reports other from Intuitive Surgical , other from Ethicon, partial grant support from NIH/NCI Memorial Sloan Kettering Cancer Center Support, outside the submitted work;

Thomas Ind reports personal fees from Medtronic, personal fees from Intuitive surgical, outside the submitted work;

Rainer Kimmig reports personal fees from Intuitive Surgical Inc., personal fees from Medtronic, personal fees from Medcaroid, outside the submitted work; and President of SERGS and Council Member of IGCS;

Henrik Falconer reports personal fees from Intuitive Surgical Inc, outside the submitted work;

Jan Persson reports personal fees from Intuitive surgical, outside the submitted work;

Alon Altman reports grants and other from Astrazeneca, other from GSK, grants and other from Merck, other from Sanofi, grants from Pfizer, grants from Clovis, grants from CancerCare Manitoba Foundation, grants from Canadian Clinical Trials group, outside the submitted work;

All other authors declare they have nothing to disclose.

Contributors

Kristen Moloney, Andreas Obermair, Monika Janda and George Hanna contributed to the design of the trial.

Kristen Moloney, Andreas Obermair and Monika Janda contributed to manuscript writing.

All authors contributed to data acquisition, interpretation of data, revising the draft for intellectual content, final approval of the version to be published, agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy and integrity of any part of the work were appropriately investigated and resolved.

Funding Sources

None

Trial Registration

N/A

Previous Presentations

N/A

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Data Access, Responsibility and Analysis

Kristen Moloney had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Manuscript Word Count: 2960

Abstract Word Count: 379

1) Condensation:

A Competency Assessment Tool for surgical quality assurance of sentinel node dissection in endometrial cancer has been developed and validated through a Delphi process.

2) **Short Title:** Surgical Competency Assessment of Sentinel Node Dissection.

3) AJOG at a Glance:**A.** Why was the study conducted?

Variation in surgical technique may influence delivery of surgical interventions and outcomes in surgical clinical trials. This study was conducted to minimize variation of the surgical technique of sentinel node dissection in endometrial cancer.

B. What are the key findings?

In this study, 35 international gynecological oncology experts, identified and validated through a Delphi process and consensus the mandatory, optional and prohibited steps of sentinel lymph node dissection.

C. What does this study add to what is already known?

Prior to this study important and measurable surgical quality criteria for sentinel node dissection were lacking. The results of this study describe specific steps and assessment criteria for use in surgeon selection for clinical trials, prospective surgical quality assurance and educational assessment of future surgeons.

Abstract

Background: Sentinel node dissection is widely practiced by gynecological oncologists for the minimally invasive surgical staging of patients with endometrial cancer. Variation in surgical technique may potentially impact on diagnostic accuracy and surgical outcomes, thus posing barriers to comparing outcomes of sentinel lymph node dissection across institutions or clinical trial sites. Standardization of surgical technique and tools for assessment of surgical quality in sentinel lymph node dissection are lacking but critical to the conduct of such trials.

Objective: To identify the mandatory, optional and prohibited steps of sentinel lymph node dissection in endometrial cancer and to develop and validate a competency assessment tool for use in surgical quality assurance.

Study Design: A three-round Delphi methodology was applied from 2019 to 2020. Thirty-five expert gynecological oncology surgeons from sixteen countries participated. Semi-structured interviews were conducted in round one to identify key steps and tasks (hierarchical task analysis) which were rated mandatory, optional or prohibited in rounds two and three using questionnaires. Using the surgical steps for which consensus was achieved, a competency assessment tool was developed and subjected to assessments of validity and reliability.

Results: Seventy per cent (70%) consensus agreement determined the specific mandatory, optional and prohibited steps of sentinel lymph node dissection for endometrial cancer. These standardized surgical steps informed the development of a competency assessment tool. Eighty per cent of participating surgeons were above 40 years of age and 24 of 35 (68%) participants practiced gynecological oncology for 10 years or longer. Consensus agreement identified 21 mandatory, nine optional and three prohibited steps to complete a sentinel lymph node dissection. Using the

competency assessment tool to rate highly skilled, inconsistent and poor quality of surgery in three preselected videos, there was clear separation in the rating of the skill level displayed with mean skills summary scores differing significantly between the three videos (F score = 89.4; $p < 0.001$). Internal consistency of the items was high (Cronbach $\alpha = 0.88$).

Conclusions: The specific mandatory, optional and prohibited steps of sentinel lymph node dissection in endometrial cancer have been identified and validated based on consensus amongst a large number of international experts. A competency assessment tool is now available and can be used for surgeon selection in clinical trials and for ongoing, prospective quality assurance in routine clinical care.

Keywords or short phrases:

Sentinel Node Dissection

Endometrial cancer

Surgical Quality Assurance

Competency Assessment

Introduction

Surgical trials pose methodological challenges¹ because surgeon training, experience, and skills will influence the delivery of surgical interventions, leading to variability of health practices and outcomes². Surgical quality assurance (QA) can aid adherence to pre-defined standards and outcome measures and enable reliable comparison across multiple clinical trial sites³⁻⁷.

Clinical management guidelines for endometrial cancer seemingly confined to the uterus prescribe a total hysterectomy, bilateral salpingo-oophorectomy (THBSO) for removal of the primary tumour and pathological assessment of pelvic +/- aortic lymph nodes to establish the stage of disease ('staging')⁸. Information regarding lymph node involvement is prognostic and may guide postoperative treatment decisions⁸⁻¹⁰. In the past, surgical staging typically entailed a full or limited pelvic/paraortic lymph node dissection (LND). This staging practice was informed by results of observational, clinicopathologic studies^{11,12} and then adopted by the International Federation of Gynecology and Obstetrics in 1988¹³. Subsequent prospective studies have failed to demonstrate differences in survival outcomes¹⁴⁻¹⁶. Currently, surgical staging is performed by practice of Sentinel Lymph Node Dissection (SLND)¹⁷. According to the Sentinel Lymph Node (SLN) concept, tumour cells metastasise to one or two lymph nodes first, before involving further lymph nodes^{9,18}. The presumed benefits of SLND include increased surgical staging precision, identifying fewer lymph nodes (more likely to harbor metastases) while sparing removal of other regional lymph nodes that are not involved¹⁹. Sentinel nodes are examined histopathologically using enhanced pathology techniques (ultrastaging) to detect metastases that may have been missed by traditional Haematoxylin & Eosin sectioning of non-SLN²⁰. Evidence shows that SLND obtains

accurate information about lymph node status²⁰ such that many clinicians now elect SLND in place of a full lymphadenectomy²¹.

With the rapid and global adoption of SLND²¹ comes variability of surgical technique. In the past, local institutional guidelines were developed to minimize variation in outcomes^{22,23}. However, these algorithms are insufficient to facilitate harmonization of the detailed surgical technique across a group of surgeons. There remains a need to define the precise surgical steps required to accomplish satisfactory bilateral SLND; assess a surgeon's proficiency before he/she can enroll patients into clinical trials; and assist with ongoing surgical quality assurance²⁴.

The purpose of this study was to establish a consensus on the specific mandatory, optional and prohibited steps of SLND in endometrial cancer, as well as develop a competency assessment tool (CAT). This CAT facilitates assessment of surgical quality in clinical trials aiding in both selection of surgeons and prospective QA.

Materials and Methods

Study participants

Participants were expert gynecological oncology surgeons from five continents currently performing SLND, henceforth referred to as "the group". Experts were recruited using snowball sampling, i.e. first contacting surgeons known to perform SLND per scientific reports or presentations in peer reviewed forums, and then asking these surgeons to nominate other experts. Participant characteristics were summarized using descriptive statistics.

Standardization of SLND

A four-round Delphi methodology was applied in order to achieve standardization of SLND steps and tasks. The Delphi method is a forecasting process framework.

Several rounds of questionnaires are sent out to experts; the responses are

aggregated, de-identified and shared with the group after each round. Experts can adjust their answers in subsequent rounds, based on their interpretation of the group response provided to them. Over these multiple rounds of questionnaires, the Delphi method seeks to reach the best response through consensus²⁵.

Study data

Study data was collected and managed on a secure, web-based REDCap electronic database hosted at The University of Queensland^{26,27}.

Delphi Consensus Process and Hierarchical Task Analysis

Round one: The first Delphi round comprised semi-structured interviews conducted by phone or video conferencing. After providing written informed consent, interviewees described their opinion about the mandatory, optional and unwarranted steps taken in performing SLND for endometrial cancer (“In your view, what are the mandatory, optional and unwarranted steps of a SLND procedure; including tracer injection technique and timing, uterine manipulation?”).

The interviews were conducted individually over 30-60 minutes and were audio recorded. The recordings were transcribed and thematically analysed by two reviewers (KM, AO). Each reviewer independently identified important and recurring codes (e.g. uterine manipulation, identifying anatomy, trouble shooting, etc.). Codes were then compared to confirm the important themes. The reviewers jointly examined codes and themes and interpreted the data. Where discordance in coding was identified, themes were refined through discussions between the two reviewers. Interviews were conducted until saturation in variations of technique and no new codes emerged. Key steps and tasks of SLND were identified by a process of hierarchical task analysis.

Round two-to-four: Delphi-rounds two-to-four comprised the consensus process.

Following the interview responses, an initial questionnaire was devised that included all of the variations identified in the interviews. Members of the group were invited to indicate their agreement or disagreement with variations. In accordance with other published work the consensus agreement level was set at 70%^{4,28}. Variations where consensus was reached were iteratively moved into an operation guide; those with <70% agreement remained for a subsequent survey round.

Operation Guide

A SLND operation guide was created including the mandatory, optional and prohibited/unwarranted steps that reached 70% agreement level.

Competency Assessment Tool (CAT)

Development

The final CAT was limited to the intraoperative phase of SLND. A score of one to four was allocated to each step – ‘skillful’, ‘adequate’, ‘inconsistent’, ‘lacking/deficient’; for troubleshooting steps ‘not applicable’ was also offered.

Content validity

Three surgical videos were selected having been agreed by KM and AO to represent poor, inconsistent or optimal technique of SLND according to the ratings conferred by application of the CAT. The videos featured the 11 surgical steps of SLND assessed by the CAT, but did not include tracer preparation and injection, surgical trouble shooting or pathological assessment of tissues. Content validity was assessed by review of the CAT by KM and AO who discussed each step of the CAT in detail, before watching those individual steps performed with various skill levels across the three surgical videos and confirming that the CAT items adequately described the skill required as expressed by the Delphi consensus.

Contrast validity and internal reliability

Contrast validity²⁹ was assessed via invitation of the group members to utilize the CAT in rating the three pre-selected (known-group) videos representing three distinct performance levels. Due to the occurrence of some cells with a cell size <5, Fisher's exact tests were performed to assess if the proportion of experts who rated each of the three videos as 'skillful', 'adequate', 'inconsistent', 'lacking/deficient' differed according to the quality of the video. An average CAT score (possible range 11-44) was computed for each video. One-way ANOVA modelling determined if the overall CAT score assigned by the SLND experts to each video differed significantly. The summary score was also used to assess the internal consistency (Cronbach alpha) of the CAT.

Human research ethics approval was obtained via the University of Queensland (HREC 2019001699).

Results

Thirty-five international gynecological oncology surgeons and experts in SLND from 16 countries were identified and agreed to participate. Some demographic data was not available for five participants, but 28 surgeons were above 40 years of age (80%) and 27 were male (77%) (Table 1). Twenty-four surgeons had practiced gynecological oncology for more than 10 years (69%), and 21 had performed SLND for > five years (60%). Nineteen surgeons (54%) reported that their institution had an endometrial cancer SLND standard protocol. Twenty-one surgeons (60%) performed more than 50 SLNDs annually, excluding those performed for cancer of the vulva. Participating surgeons reported using between one and eight methods to learn SLND; most commonly being self-taught (46%), learning from research papers (43%) or being trained by a senior colleague (31%).

Standardization of Sentinel Node Dissection (SLND)

Delphi Round One (Hierarchical Task Analysis)

Saturation in variation of SLND technique was reached after 25 interviews. Analysis of the transcripts allocated themes into four phases, including: preoperative (dye selection and preparation, injection); intraoperative (pelvic dissection, identification of key anatomical structures, definition and dissection of sentinel node, extraction of tissue); trouble shooting; and a postoperative (pathology) phase. Task variations were defined as management of specific surgical steps in different ways. In total 107 task variations were identified across the interviews (Table 2).

Delphi Rounds Two – Three (Consensus Process)

The first survey (Delphi round two) featured 107 task variations identified in the interviews and was completed by all 35 participants (Supplementary Table 1). The second survey (Delphi round three) was informed by the results of the first survey and 33 of 35 participants responded (Supplementary Table 2). Over rounds two and three, >70% consensus was achieved in 33 of the 107 (30.8%) task variations^{4,28} on mandatory, optional and prohibited steps of SLND. Of the variations that reached consensus, 21 were classified as mandatory, nine optional and three prohibited. For example, in round two, 79% of participants agreed that “a transperitoneal approach of injecting dye into the uterus” should be prohibited; while 75% of participants agreed that “the internal iliac artery must be identified for sentinel node mapping” was mandatory. An operation guide consisting of the final list of steps for which consensus was obtained is provided in Table 3.

There was consensus that the tracer of choice must be Indocyanine Green (ICG) but adding other tracers is optional. There was consensus that ICG should be injected into the cervix. There was no consensus about the dilution of ICG (between 0.5 mg/l

and 1.5 mg/ml), the total volume injected or timing of injection (before or after establishing a pneumoperitoneum). The use of a uterine manipulator was considered optional, but if used, it should be inserted after tracer injection. There was consensus that dividing the round ligament and the infundibulopelvic ligament can be performed either before or after SLND. The pelvic structures and spaces that should be demonstrated for SLND include external and internal iliac vessels, ureter, obliterated umbilical ligament and the paravesical space. The direction of the SLND was considered optional (starting close to the cervix or dissecting towards the cervix). The group agreed that the sentinel node should be defined as the most proximal node irrespective of the nodal station in which the node is found. Eighteen participants felt that mapping of presacral nodes should be optional (56.3%). There was lack of consensus on a side-specific lymphadenectomy if no nodes are mapped on one side. Participants agreed that the sentinel node should be a single mapped node with or without its next station (second echelon node(s)). A majority of participants (59.4%) but less than required for consensus, agreed that excising all mapped nodes should be avoided. There was consensus that specimen extraction should be within a containment device; that ex-vivo fluorescence should be used to prove the sentinel node; that labelling of the sentinel node should be according to laterality and nodal station; and enhanced pathology techniques for ultrastaging of sentinel nodes should be used.

Contrast validity and internal reliability: Twenty-seven (77.1%) Delphi participants were involved in rating the quality of surgery of the three preselected videos using the CAT (Figure 1). For each of the 10 initial surgical steps, there was clear separation in the rating of the skill level displayed between the three videos (Table 4). For example, while 78% of experts rated the “optimal technique video” as skillfully

performing the dissection of the iliac vessels, only 19% and 0% of experts rated the “inconsistent technique video” and “poor technique video” as skillful (Fishers exact test = 56.0; $p < 0.001$). For the last step (“completion of SLND in one hemipelvis before proceeding to the contralateral side”), 25 of the 27 group members rated this step as not applicable. Overall, the mean skills summary score differed significantly between the three videos from 35.6 (SD =4.7) for the “optimal technique video”, to 25.3 (SD=5.9) for the “inconsistent technique video” and 17.7 (SD=4.1) for the “poor technique video” (One-way ANOVA F score = 89.4; $p < 0.001$). Internal consistency of the items was high (Cronbach $\alpha = 0.88$).

Structured Discussion/Comment

Principle findings

We report the creation of a competency assessment tool (CAT), derived by consensus amongst a large number of international experts, describing the mandatory, optional and prohibited steps of a SLND procedure for endometrial cancer. The CAT is validated by gynecological oncology surgeons and can be used by trial governance committees as a decision aide for surgeon selection and for ongoing QA in surgical clinical trials.

Results

While several local health service protocols^{23,30,31} suggest specific steps for a SLND, the present publication summarizes an operating consensus based on the opinion of a considerable number of international experts in SLND. In brief, there was consensus that ICG should be used as the tracer and that if a surgeon wishes to use a tracer other than ICG, it should only be used in addition to ICG. Hysteroscopic or transabdominal injection was considered inadequate. For the first time, this paper describes the need for surgeons to identify key anatomical landmarks during a

SLND, whereas other landmarks are not mandatory to be demonstrated (e.g. obturator nerve). Consensus was also achieved about definition of the sentinel node, as the node closest to the uterus, regardless of whether it is located at the lateral pelvic wall, the aortic/caval or the presacral area. There was also agreement that the number of sentinel nodes removed should be kept to a minimum. There was no consensus on the mandatory need for a completion lymphadenectomy on the ipsilateral side if a sentinel node was not mapped, most likely because patient and uterine factors known at the time of surgery could suggest that a full lymph node dissection may not be warranted in some patients. Consensus was reached on the need to extract nodes through a containment system, on the need for ex-vivo green fluorescence to prove the sentinel node, on specimen labelling and on pathologic ultrastaging.

Clinical implications

Despite the benefits of SLND, including shorter operating times compared to a LND, it remains unknown in what ways SLND impacts patient outcomes, the need for postoperative radiation treatment or chemotherapy, recovery from surgery and quality of life, the incidence of adverse events and survival²⁴. As described by the IDEAL Collaboration for surgical innovations³², just because a new surgical procedure appears promising, recovery is quick, or the incidence of complications seems to be decreased, there is still a need to evaluate novel surgical procedures for safety and effectiveness³³. Such surgical trials rely on the standardized delivery of the intervention (with minimal variation) to allow a meaningful and reliable comparison between intervention and control groups across multiple surgeons or trial sites. In the context of SLND, variability in technique and failure to identify sentinel nodes could translate into the need for frozen section assessment of the

uterus, acceptance of unknown nodal status, or may increase the risk of an “empty package”³⁴, all of which may confound the results of SLND efficacy trials. Depending on local protocols, some patients may even require re-staging, a full ipsilateral LND²³, or might warrant adjuvant chemotherapy or radiation treatment based on uterine risk factors. These scenarios may have significant impact on short and long-term patient and trial outcomes. With the availability of the CAT, institutions or clinical trialists can define quality standards of SLND and measure individual surgical performance against an agreed standard.

Research implications

In the past, significant efforts were made by chief investigators and trial management committees to minimize variability in surgical technique and outcomes, including limiting the trial to sites with a high surgical volume. Recently, principal investigators additionally completed a site visit and all surgeons were observed in-person^{20,35} or unedited videos were reviewed to confirm standardization of the technique³⁶. In other trials, participating surgeons were required to have completed a minimum number of procedures, before the initiation of enrollment^{37,38}. While these measures were valuable within institutions, volume, minimal number or observation of one surgery may be inaccurate without application of a standardized assessment tool.

The CAT development undertaken in this study follows similar efforts in other surgical specialties. In general surgery, a recent systematic review reporting on QA in randomised controlled trials of laparoscopic colorectal surgery identified three distinct categories of surgical QA measures: (i) trial entry criteria for surgeons and centres; (ii) standardization of surgical techniques; and (iii) continuous monitoring of surgeons and/or units³⁹. A CAT was developed, validated and implemented to assess technical surgical performance in the context of a summative assessment

process for the National Training Programme in Laparoscopic Colorectal Surgery (Lapco)⁴⁰. Subsequently both the ROMIO^{6,41} and COLOR III⁴ investigators have described standardization of surgical interventions followed by development and assessment of objective surgical QA tools for use in oesophagogastric and colorectal trials respectively.

Strengths and Limitations

The strengths of our study include the large number of international experts who identified the mandatory, optional and prohibited steps of SLND based on consensus. In addition, the CAT was able to demonstrate contrast validity and internal reliability. Predictive clinical validity can only be determined with accumulation of clinical outcomes after using the CAT in SLND clinical trials and educational programs, as has been demonstrated for a colorectal CAT in both the Lapco program and the Australasian Laparoscopic Cancer of Rectum (ALaCaRT) trial^{42,43}.

Conclusion

In this paper we describe a method to standardize SLND for the staging of endometrial cancer developed through a consensus process amongst experts in the SLND procedure. The output from this work includes a list of mandatory and prohibited steps of a SLND that independent assessors can use to check for both surgical proficiency as well as if the SLND has been performed in accordance to an agreed standard. The value of this work is found in the specific steps of SLND, and in the QA criteria developed as part of this process - both will help with selection of prospective surgeons into surgical trials evaluating SLND. The goal is to assist with shortening the learning curve⁴⁴ but also to control for the heterogeneity in surgical performance that could override the true efficacy⁴.

Acknowledgments

We thank all participants for their expertise in developing this tool. We also thank Vanessa Behan, Queensland Centre for Gynaecological Cancer Research, University of Queensland, Centre for Clinical Research, QLD Australia for administrative support with the project. All those acknowledged have nothing to disclose.

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Table 1: Participating surgeons demographic characteristics

| Variables | | n= 35 (%) |
|---|---|----------------------------|
| Age (years) | 31-41 | 4 (11) |
| | 41-50 | 15 (43) |
| | 51-60 | 14 (40) |
| | >61 | 1 (3) |
| Gender | Female | 8 (23) |
| | Male | 27 (77) |
| Continent | Europe | 10 (29) |
| | North America | 9 (26) |
| | Australia | 10 (29) |
| | Asia | 4 (11) |
| | South America | 2 (6) |
| Does your Institution have its own Sentinel Node Mapping protocol in Endometrial Cancer? | No | 14 (40) |
| | Yes | 19 (54) |
| How did you learn to perform sentinel node biopsies? | Self-taught | 16 (46) |
| | Learnt from Research papers | 15 (43) |
| | Standard Operating Procedures/ Protocols | 11 (31) |
| | Taught by Senior colleague/s | 11 (31) |
| | Videos | 10 (29) |

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| | Trained by surgeon/s overseas | 7 (20) |
| | Formal course/s | 4 (11) |
| | Other | 7 (20) |
| How many years Gynonc? (years) | Less than 10 | 11 (31) |
| | 10-19 | 14 (40) |
| | 20-29 | 9 (26) |
| | 30 or more | 1 (3) |
| How many years performed SLND? (years) | Less than 5 | 13 (37) |
| | 5-9 | 8 (23) |
| | 10 or more | 11 (31) |
| Number of SLND | Less than 50 | 14 (40) |
| | 50-99 | 10 (29) |
| | 100 or more | 6 (17) |

Table 2: Hierarchical task analysis including task variations

| Phase | Theme | Sub-themes | No. of sub tasks/task variations |
|----------------|--|---|---|
| Peri-operative | Tracer Injection | Choice of tracing agent Site of injection Tracer Concentration Total volume of injected Injection technique | 34 |
| | Uterine Manipulation | Use of manipulator at all Timing of manipulator insertion Type of uterine manipulator | 9 |
| | Sequence of Initial Steps | Timing of entry Timing of adhesiolysis Timing of staging inspection | 7 |
| Operative | Preparation /opening spaces | Transperitoneal identification of channels Pelvic Side wall spaces | 10 |
| | Identifying anatomy, lymphatic channels and sentinel nodes | Anatomical structure Methods of locating nodes | 24 |

| | | | |
|-----------------|---|---|---|
| | Excision and confirmation of mapped nodes | Defining the SLN Technique of nodal excision Mode of ex vivo SLN confirmation | 7 |
| | Specimen retrieval | Mode of containment | 5 |
| Troubleshooting | Action plan for no nodes mapped | | 5 |
| Post-Operative | Specimen labelling | Anatomical site Laterality | 4 |
| | Pathology processing | | 2 |

Table 3: Operation Guide

Final consensus on mandatory and prohibited steps of SLND by minimally invasive surgery in Endometrial Cancer.

| Surgical Step | Descriptor | Consensus recommendation |
|-------------------------------|--|---------------------------------|
| Tracer | ICG | Mandatory |
| Injection location | Ectocervix in two or four positions | Mandatory |
| Injection technique | Superficial injection into the ectocervix | Mandatory |
| | Transperitoneal injection into the uterus | Prohibited |
| | Hysteroscopic injection into the uterus | Prohibited |
| | Surgeon appreciation of resistance at tracer injection | Mandatory |
| Injection needle | Gauge between 20G and 25G | Mandatory |
| | Length sufficient to ensure easy and accurate access to the cervix | Mandatory |
| Uterine manipulator | If being used, insert uterine manipulator after tracer injection | Mandatory |
| White light inspection | Prior to SLN mapping, conduct an inspection of the pelvic areas | Mandatory |
| External vessels | Identify the external iliac vessels | Mandatory |
| Internal iliac artery | Identify the internal iliac artery | Mandatory |

| | | |
|--|---|-----------------------------------|
| Ureter | Identify the ureter | Mandatory |
| Obliterated umbilical ligament | Identify the obliterated umbilical ligament | Mandatory |
| Paravesical space | Open the paravesical space | Mandatory |
| Start the SLN mapping | Begin at the level of the uterine artery and continue dissection LATERALLY away from the uterus | Mandatory |
| Dissection technique | Use blunt or electrosurgical technique | Mandatory |
| | Avoid disrupting lymphatic channels during dissection | Mandatory |
| | Ensure isolation of node from local anatomy | Mandatory |
| Definition of the Sentinel Node | <p>A sentinel node is defined as ...</p> <ul style="list-style-type: none"> • The <u>most proximal node</u>¹, irrespective of the nodal station in which the node is found • A <u>single mapped node</u> or a single node plus its next station echelon node(s). | <p>Mandatory</p> <p>Mandatory</p> |
| SLN dissection | SLN dissection should be completed in one hemipelvis before proceeding to the contralateral side | Mandatory |

¹ The most proximal node is defined as the node closest to the uterus, regardless of location.

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| Troubleshooting | <p>Troubleshooting when no nodes are mapping includes any one, or combination of, the following:</p> <p>Wait; undertake dissection on the contralateral side before returning to original side</p> <p>Extend retroperitoneal dissection to encompass common, pre-sacral and/or paraaortic areas</p> <p>Re-inject ICG</p> <p>Undertake a side-specific lymphadenectomy</p> | Mandatory |
| Specimen extraction | Removal of nodes without using a containment device | Prohibited |
| Prove of sentinel node | Use ex-vivo green fluorescence to prove the sentinel node | Mandatory |
| Specimen labelling | <p>Label specimens according to laterality (right/left) AND nodal station (obturator/external iliac/internal iliac/presacral/common iliac/aortic/caval)</p> | Mandatory |
| Ultrastaging | Use enhanced pathology techniques, such as immunohistochemistry, for ultrastaging of sentinel nodes | Mandatory |

Table 4: Assessment of contrast validity

| | Poor Video | Inconsistent Video | Optimal Video | Fishers exact test |
|-----------------------------------|---------------|-----------------------|------------------|-----------------------|
| White light inspection | 1 (4) | 6 (22) | 22 (81) | 47.1; p<0.00 |
| External vessels | 0 (0) | 5 (19) | 21 (78) | 56.0; p<0.001 |
| Internal iliac artery | 0 (0) | 2 (7) | 22 (82) | 75.3; p<0.001 |
| Ureter | 0 (0) | 6 (22) | 20 (74) | 70.6; p<0.001 |
| Paravesical space | 0 (0) | 4 (15) | 19 (70) | 58.9; p<0.001 |
| Obliterated umbilical ligament | 0 (0) | 2 (7.4) | 19 (70) | 60.3; p<0.001 |
| Dissection technique | 1 (4) | 2 (7.4) | 16 (59) | 36.9; p<0.001 |
| Proof of sentinel node | 6 (22) | 2 (7.4) | 20 (74) | 33.6; p<0.001 |
| Specimen extraction | 0 (0) | 9 (33) | 21 (78) | 84.2; p<0.001 |
| SLN mapping | 1 (3.7) | 5 (19) | 10 (37) | 15.9; p=0.03 |

n (%) of reviewers who rated the performance as skilful

Figure 1: SLND Competency Assessment Tool

Supplementary Table 1: Results of Delphi Round Two (Questionnaire 1)
Level of consensus on steps (mandatory optional, prohibited) to complete a SLND.

| Domain | Meaning | Level of Consensus/Response |
|---------------------------------|--|--|
| Choice of Tracing Agent | ICG should be used as the tracer | Mandatory 87.9% Optional 12.1% Prohibited 0% |
| | Blue dye (Iso-sulfan, methylene, patent blue) should be used as the tracer | Mandatory 0% Optional 75.8% Prohibited 24.2% |
| | Radio-technetium should be used as the tracer | Mandatory 0% Optional 63.6% Prohibited 36.4% |
| Site of Tracer Injection | Inject dye into the ectocervix in four positions | Mandatory 9.1% Optional 69.7% Prohibited 21.2% |
| | Inject dye into the ectocervix in two positions | Mandatory 69.7% Optional 21.2% Prohibited 9.1% |
| | Inject dye into the uterus (abdomino-pelvic approach) | Mandatory 0% Optional 21.2% Prohibited 78.8% |

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| | Inject dye into the uterus – fundal (hysteroscopic approach) | Mandatory 0% Optional 27.3% Prohibited 72.7% |
| Tracer Concentration | ICG – 1.25mg/ml (dilute 25mg of ICG with 20ml sterile water) | Mandatory 59.4% Optional 37.5% Prohibited 3.1% |
| | ICG – 0.5mg/ml | Mandatory 6.3% Optional 40.6% Prohibited 53.1% |
| | Blue dye - neat | Mandatory 6.3% Optional 56.3% Prohibited 37.5% |
| Total Volume Injected | 4ml | Mandatory 50.0% Optional 40.6% Prohibited 9.4% |
| | 2ml | Mandatory 28.1% Optional 46.9% Prohibited 25.0% |
| | 1ml | Mandatory 3.1% Optional 25.0% Prohibited 71.9% |
| Injection Depth | Deep Only | Mandatory 6.3% Optional 21.9% |

| | | |
|---------------------------|--|---|
| | | Prohibited 71.9% |
| | Superficial (submucosal) Only | Mandatory 18.8% Optional 40.6% Prohibited 40.6% |
| | Deep AND Superficial | Mandatory 56.3% Optional 37.5% Prohibited 6.3% |
| Syringe Size | 1ml | Mandatory 28.1% Optional 40.6% Prohibited 31.3% |
| | 2ml | Mandatory 12.5% Optional 56.3% Prohibited 31.3% |
| | 5ml | Mandatory 21.9% Optional 40.6% Prohibited 37.5% |
| | 10ml | Mandatory 3.1% Optional 28.1% Prohibited 68.8% |
| Needle and syringe | Change needle and syringe after each injection | Mandatory 12.5% Optional 50.0% Prohibited 37.5% |
| Injection Pace | Inject slowly | Mandatory 65.6% |

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|--|-----------------------------------|--|
| | | Optional 21.9% Prohibited 12.5% |
| | Pace of injection does not matter | Mandatory 18.8% Optional 21.9% Prohibited 59.4% |
| | Aim for feeling of 'resistance' | Mandatory 62.5% Optional 28.1% Prohibited 9.4% |
| | Aim to achieve submucosal 'bleb' | Mandatory 40.6% Optional 50.0% Prohibited 9.4% |
| What is Your Preferred Needle Diameter/Gauge? | Free text | 5G 3.1% (1) 18G 6.2% (2) 20G 12.5% (4) 21G 9.4% (3) 22G 18.8% (6) 23G 6.2% (2) 24G 9.4% (3) 25G 25% (8) 27G 9.4% (3) |
| What is Your Preferred Needle Length? | | As long as possible 50.0% As short as possible 12.5% It does not matter 37.5% |

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|--|--|---|
| Uterine Manipulation | Use a uterine manipulator | Mandatory 15.6% Optional 71.9% Prohibited 12.5% |
| | DO NOT use a uterine manipulator | Mandatory 15.6% Optional 59.4% Prohibited 25.0% |
| | Insert uterine manipulator BEFORE tracer injection | Mandatory 0% Optional 9.4% Prohibited 90.6% |
| | Insert uterine manipulator AFTER tracer injection | Mandatory 65.6% Optional 21.9% Prohibited 12.5% |
| Timing of Laparoscopic/Robotic Entry | Inject tracer BEFORE abdominal entry/pneumoperitoneum obtained | Mandatory 37.5% Optional 50.0% Prohibited 12.5% |
| | Inject tracer AFTER abdominal entry/pneumoperitoneum obtained | Mandatory 13.3% Optional 60.0% Prohibited 26.7% |
| Ensure Access to Pelvic Side Walls/Nodal Stations | Mobilise adhesions BEFORE tracer injection | Mandatory 21.9% Optional 46.9% Prohibited 31.3% |

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| | Mobilise adhesions AFTER tracer injection | Mandatory 37.5% Optional 34.4% Prohibited 28.1% |
| Confirm No Macroscopic Disease Outside Uterus | Undertake abdomino-pelvic inspection with white light BEFORE tracer injection | Mandatory 46.9% Optional 43.8% Prohibited 9.4% |
| | Undertake abdomino-pelvic inspection with white light AFTER tracer injection | Mandatory 46.9% Optional 43.8% Prohibited 9.4% |
| | Undertake abdomino-pelvic inspection with white light IRRESPECTIVE of timing of tracer injection | Mandatory 59.4% Optional 28.1% Prohibited 12.5% |
| Transperitoneal Inspection Using Your Preferred Technique to Identify Lymphatic Channels | Pelvic side walls | Mandatory 93.8% Optional 3.1% Prohibited 3.1% |
| | Common iliac/pre-sacral areas | Mandatory 68.8% Optional 25.0% Prohibited 6.3% |
| | Para-aortic area | Mandatory 53.1% |

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| | | Optional 40.6% Prohibited 6.3% |
| Commence Dissection by Opening Pelvic Side Walls | Divide round ligament | Mandatory 28.1% Optional 56.3% Prohibited 15.6% |
| | Preserve round ligament | Mandatory 15.6% Optional 75.0% Prohibited 9.4% |
| | Secure and divide infundibulo-pelvic ligament | Mandatory 6.3% Optional 65.6% Prohibited 28.1% |
| | Preserve infundibulo- pelvic ligament | Mandatory 34.4% Optional 59.4% Prohibited 6.3% |
| | Open para-vesical space | Mandatory 71.9% Optional 25.0% Prohibited 3.1% |
| | Open para-rectal space | Mandatory 68.8% Optional 28.1% Prohibited 3.1% |
| Identifying Anatomy, Lymphatic Channels and Sentinel Nodes: | Ureter | Mandatory 93.8% Optional 12.5% Prohibited 0% |

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| These structures should be mandatory/optional identified or should not be identified (prohibited/unwarranted) during sentinel lymph node dissection | Obliterated umbilical artery/ligament | Mandatory 87.5% Optional 12.5% Prohibited 0% |
| | Superior vesical artery | Mandatory 28.1% Optional 62.5% Prohibited 9.4% |
| | Uterine artery (medial aspect) | Mandatory 34.4% Optional 65.6% Prohibited 0% |
| | Uterine artery (lateral aspect) | Mandatory 37.5% Optional 56.3% Prohibited 6.3% |
| | External iliac artery and vein | Mandatory 100% Optional 0% Prohibited 0% |
| | Internal iliac artery and vein | Mandatory 75.0% Optional 21.9% Prohibited 3.1% |
| | Obturator nerve | Mandatory 65.6% Optional 31.3% Prohibited 3.1% |
| | Start at the level of the uterine artery and | Mandatory 9.4% Optional 62.5% |

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|---|--|---|
| Identifying Anatomy, Lymphatic Channels and Sentinel Nodes: The sentinel node is mapped... | continue medially TOWARDS the uterus | Prohibited 28.1% |
| | Start at the level of the uterine artery and continue laterally/distally AWAY from the uterus | Mandatory 65.6% Optional 21.9% Prohibited 12.5% |
| | Start at the level of the uterine artery and continue towards the presacral areas | Mandatory 21.9% Optional 56.3% Prohibited 21.9% |
| | Start at the most highlighted node and dissect proximally (TOWARDS cervix) | Mandatory 15.6% Optional 59.4% Prohibited 25.0% |
| | Start at the most highlighted node and dissect proximally (AWAY from the cervix) | Mandatory 28.1% Optional 40.6% Prohibited 31.3% |
| | It is important to avoid disruption of lymphatic channels during dissection | Mandatory 81.3% Optional 15.6% Prohibited 3.1% |
| | Retroperitoneal dissection should be blunt only | Mandatory 9.4% Optional 59.4% |

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|--|---|---|
| | | Prohibited 31.3% |
| | Retroperitoneal dissection can compromise blunt and electrosurgical techniques | Mandatory 50.0% Optional 37.5% Prohibited 12.5% |
| Identifying Anatomy, Lymphatic Channels and Sentinel Nodes: In each hemi- pelvis, the sentinel node that you remove is... | A single mapped node | Mandatory 43.8% Optional 40.6% Prohibited 15.6% |
| | The first (most proximal to the uterus) node identifiable in the channel pathway | Mandatory 81.3% Optional 9.4% Prohibited 9.4% |
| | Any node that demonstrates uptake (i.e. 'maps') with tracing agent | Mandatory 9.4% Optional 40.6% Prohibited 50.0% |
| | All mapped nodes in the pelvis should be excised | Mandatory 15.6% Optional 25.0% Prohibited 59.4% |
| | The importance of mapping presacral nodes(s) is | Mandatory 28.1% Optional 56.3% Prohibited 15.6% |

| | | |
|---|--|---|
| | The importance of mapping nodes(s) on the lateral pelvic wall is | Mandatory 53.1% Optional 37.5% Prohibited 9.4% |
| | The importance of mapping node(s) in the aortic/caval areas is | Mandatory 21.9% Optional 65.6% Prohibited 12.5% |
| Excision and Confirmation of Mapped Nodes: Mapped nodes should be excised using these techniques | Isolation from local anatomy | Mandatory 87.5% Optional 9.4% Prohibited 3.1% |
| | Firm but gentle traction | Mandatory 62.5% Optional 28.1% Prohibited 9.4% |
| | Blunt dissection | Mandatory 34.4% Optional 62.5% Prohibited 0% |
| | Electrosurgery | Mandatory 31.3% Optional 68.8% Prohibited 0% |
| | Application of haemostatic clips | Mandatory 0% Optional 84.4% Prohibited 15.6% |
| | Dissection/excision should be completed in one | Mandatory 53.1% Optional 37.5% |

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|--|---|--|
| | hemi-pelvis before proceeding to contralateral side | Prohibited 9.4% |
| Excision and Confirmation of Mapped Nodes: During surgery, excised tissue should be confirmed as nodal using these techniques | Ex-vivo green fluorescence (if using ICG) | Mandatory 77.4% Optional 22.6% Prohibited 0% |
| | Macroscopic inspection, palpation or incision | Mandatory 56.3% Optional 37.5% Prohibited 6.3% |
| | Fresh frozen section | Mandatory 6.3% Optional 46.9% Prohibited 46.9% |
| Specimen Retrieval: Contained removal of sentinel nodal tissue can be undertaken using these methods | Endocatch bag via port | Mandatory 37.5% Optional 59.4% Prohibited 3.1% |
| | Finger of sterile glove via port | Mandatory 6.3% Optional 78.1% Prohibited 15.6% |
| | Laparoscopic 'cup forceps' | Mandatory 6.3% Optional 43.8% Prohibited 50.0% |

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|--|--|---|
| | Endocatch bag via colpotomy | Mandatory 3.1% Optional 68.8% Prohibited 28.1% |
| | Removal of nodes through port without protection | Mandatory 0% Optional 21.9% Prohibited 78.1% |
| Sentinel Node Specimens: Labelling of specimen(s) | Obturator, external iliac, common iliac, aortic/caval | Mandatory 75.0% Optional 21.9% Prohibited 3.1% |
| | Lateral pelvis, presacral | Mandatory 50.0% Optional 28.1% Prohibited 21.9% |
| | Pelvic, aortic | Mandatory 50.0% Optional 18.8% Prohibited 31.2% |
| | Right, left | Mandatory 68.8% Optional 6.3% Prohibited 0% |
| Sentinel Node Specimens: Pathology processing of sentinel nodes | Pathological ultrastaging using immunohistochemistry | Mandatory 93.8% Optional 6.3% Prohibited 0% |
| | Standard H.E. staining | Mandatory 53.1% Optional 21.9% |

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|--|--|---|
| | | Prohibited 25.0% |
| Troubleshooting Action Plan for 'no nodes mapped' | Reinject tracing agent | Mandatory 18.8% Optional 62.5% Prohibited 18.8% |
| | Wait – undertake dissection on contralateral hemi-pelvis before returning to original side | Mandatory 31.3% Optional 65.6% Prohibited 3.1% |
| | Extend retro-peritoneal dissection to encompass common/presacral and para-aortic areas | Mandatory 34.4% Optional 59.4% Prohibited 6.3% |
| | Undertake a side-specific lymphadenectomy | Mandatory 62.5% Optional 37.5% Prohibited 0% |

Supplementary Table 2: Results of Delphi Round Three (Questionnaire 2)
Level of consensus on steps (mandatory optional, prohibited) to complete a SLND.

| Domain | Level of Consensus/Response |
|---|---|
| Indigo-Cyanine Green (ICG) MUST be used for SLN Mapping in Endometrial Cancer. Adding blue dye or radiolabelled technetium is optional | Agree 75.8% Disagree 24.2% |
| Injection of ICG should be into the ectocervix in two or four positions | Agree 87.9% Disagree 12.1% |
| ICG Dilution 1.5mg/ml (dilute 25mg of ICG with 20ml sterile water). (In the survey, 59.4% of respondents answered mandatory; 37.5% optional; 3.1% prohibited/unwarranted) Based on those results, please select | Mandatory 57.6% Optional 42.4% |
| ICG Dilution 0.5mg/ml. (In the first survey, 6.3% of respondents answered mandatory; 40.6% optional; 53.1% prohibited/unwarranted) Based on those results, please select final response | Optional 51.5% Prohibited 48.5% |
| Injection of ICG into the cervix should be done with a 20 to 25G needle (In the first survey, 20 to 25G needle diameter was within the 10-90th percentile responses) | Agree 97.0% Disagree 3.0% |
| Total volume of ICG injection should be 2ml total (In the first survey round, 28.1% of respondents answered mandatory, 46.9% answered optional; 25.0% answered prohibited/unwarranted) | Mandatory 18.2% Optional 60.6% Prohibited 21.2% |

| | |
|--|--|
| Total volume of ICG injection should be 4ml total (In the first survey, 50% of respondents answered mandatory, 40.6% optional; 9.4% prohibited/unwarranted) | Mandatory 39.4% Optional 57.6% Prohibited 3.0% |
| A 1ml syringe be used for ICG injection | Agree 54.5% Disagree 45.5% |
| A 2ml syringe be used for ICG injection | Agree 54.5% Disagree 45.5% |
| A 5ml syringe be used for ICG injection | Agree 48.5% Disagree 51.5% |
| Superficial injection of ICG into the cervix is mandatory. A deep injection is optional | Agree 63.6% Disagree 36.4% |
| The needle and syringe used to inject ICG should be changed after each injection (In the first survey, 12.5% of respondents answered mandatory; 50.0% optional; 37.5% prohibited/unwarranted) | Mandatory 9.1% Optional 66.7% Prohibited 24.2% |
| The surgeon should inject ICG slowly (In the first survey, 65.6% of respondents stated slow injection is mandatory; 21.9% optional; 12.5% prohibited/unwarranted) each hemipelvis, the sentinel node that you remove is... | Mandatory 66.7% Optional 30.3% Prohibited 3.0% |
| The pace of injection does not matter (In the first survey, 18.8% of respondents answered mandatory; 21.9% optional; 59.4% prohibited/unwarranted) | Mandatory 9.1% Optional 36.4% Prohibited 54.5% |

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| The surgeon should aim for feeling of resistance (In the first survey, 62.5% of respondents answered mandatory; 28.1% optional; 9.4% prohibited/unwarranted) | Mandatory 78.8% Optional 18.2% Prohibited 3.0% |
| The surgeon should aim to achieve sub-mucosal bleb (In the first survey, 40.6% of respondents answered mandatory; 50.0% optional; 9.4% prohibited/unwarranted) | Mandatory 45.5% Optional 48.5% Prohibited 6.1% |
| The needle used to inject ICG should be long enough to ensure easy and accurate access to the injection sites on the ectocervix | Agree 100% Disagree 0% |
| ICG should be injected | BEFORE establishing a pneumoperitoneum 39.4% AFTER establishing a pneumoperitoneum 24.2% EITHER before or after establishing a pneumoperitoneum 36.4% |
| If using a uterine manipulator, it is mandatory to insert it AFTER ICG injection | Agree 90.6% Disagree 9.4% |
| It is important to mobilise pelvic adhesions | BEFORE ICG injection 24.2% AFTER ICG injection 33.3% EITHER before or after ICG injection 42.4% |

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| Is it necessary to undertake a staging inspection of abdomino-pelvic surfaces with white light | BEFORE ICG injection 24.2% AFTER ICG injection 27.3% EITHER before or after ICG injection 48.5% |
| Identifying lymphatic channels and nodes: It is OPTIONAL to undertake near-infrared transperitoneal inspection of the common iliac, pre-sacral and para-aortic areas prior to commencing the dissection | Agree 63.6% Disagree 36.4% |
| Preserving or dividing of the round ligament for SLN mapping is OPTIONAL | Agree 93.9% Disagree 6.1% |
| Preserving or dividing of the IP ligament for SLN mapping is OPTIONAL | Agree 90.9% Disagree 9.1% |
| The pararectal space should be opened (In the first survey, 68.8% of respondents answered mandatory; 28.1% optional; 3.1% prohibited/unwarranted) | Mandatory 66.7% Optional 33.3% Prohibited 0% |
| The superior vesical artery should be identified (mandatory/optional) or should not be identified (prohibited/unwarranted) during sentinel lymph node detection (In the first survey, 28.1% of respondents answered mandatory; 62.5% optional; 9.4% prohibited/unwarranted) | Mandatory 39.4% Optional 60.6% Prohibited 0% |
| The uterine artery (medial to the ureter) should be identified (mandatory/optional) or should not be identified | Mandatory 18.2% Optional 78.8% |

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| <p>(prohibited/unwarranted) during sentinel lymph node detection (In the first survey, 34.4% of respondents answered mandatory; 65.6% optional; 0% prohibited/unwarranted)</p> | <p>Prohibited 3.0%</p> |
| <p>The uterine artery (lateral to the ureter) should be identified (mandatory/optional) or should not be identified (prohibited/unwarranted) during sentinel lymph node detection (In the first survey, 37.5% of respondents answered mandatory; 56.3% optional; 6.2% prohibited/unwarranted)</p> | <p>Mandatory 39.4%</p> <p>Optional 60.6%</p> <p>Prohibited 0%</p> |
| <p>The obturator nerve should be identified (mandatory/optional) or should not be identified (prohibited/unwarranted) during sentinel lymph node detection (In the first survey, 65.6% of respondents answered mandatory; 31.3% optional; 3.1% prohibited/unwarranted)</p> | <p>Mandatory 66.7%</p> <p>Optional 30.3%</p> <p>Prohibited 3.0%</p> |
| <p>Start SLN mapping at the level of the uterine artery and continue medially TOWARDS uterus (In the first survey round, 9.4% of respondents answered mandatory; 62.5% optional; 28.1% prohibited/unwarranted)</p> | <p>Mandatory 0%</p> <p>Optional 72.7%</p> <p>Prohibited 27.3%</p> |
| <p>Start SLN mapping at the level of the uterine artery and continue laterally AWAY from the uterus (In the first survey</p> | <p>Mandatory 66.7%</p> <p>Optional 33.3%</p> <p>Prohibited 0%</p> |

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| round, 65.6% of respondents answered mandatory; 21.9% optional; 12.5% prohibited/unwarranted) | |
| Start SLN mapping at the level of the uterine artery and continue towards the presacral areas (In the first survey round, 21.9% of respondents answered mandatory; 56.3% optional; 21.9% prohibited/unwarranted) | Mandatory 12.1% Optional 78.8% Prohibited 9.1% |
| Start SLN mapping at the most highlighted node and dissect proximally (TOWARDS cervix) (In the first survey round, 15.6% of respondents answered mandatory; 59.4% optional; 25.0% prohibited/unwarranted) | Mandatory 6.1% Optional 72.7% Prohibited 21.2% |
| Start SLN mapping at the most highlighted node and dissect cephalad (AWAY from the cervix) (In the first survey round, 28.1% of respondents answered mandatory; 40.6% optional; 31.3% prohibited/unwarranted) | Mandatory 0% Optional 75.8% Prohibited 24.2% |
| Retroperitoneal dissection CAN involve blunt or electro-surgical dissection techniques, gentle traction and/or clips | Agree 97.0% Disagree 3.0% |
| The most proximal node, irrespective of the nodal station in which the node is found (e.g. obturator, external iliac, para-aortic) | Agree 90.9% Disagree 9.1% |
| A sentinel node(s) should be defined as.... | Single mapped node 65.6% The most proximal node plus the next station |

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| | <p>(station 2) echelon nodes</p> <p>9.4%</p> <p>All mapped (green) nodes</p> <p>25.0%</p> |
| <p>Sentinel lymph node dissection/excision should be completed in one hemi-pelvis before proceeding to the contralateral side (In the first survey, 53.1% of respondents answered mandatory; 37.5% optional; 9.4% prohibited/unwarranted)</p> | <p>Agree 87.5%</p> <p>Disagree 12.5%</p> |
| <p>Troubleshooting when 'no nodes are mapped' In the event that no nodes are mapped, activating any combination of the following troubleshooting strategies is OPTIONAL: -</p> <p>Wait. Undertake dissection on the contralateral side before returning to original side - Extend retroperitoneal dissection to encompass common, pre-sacral and/or paraaortic areas - Re-inject ICG - Undertake a side-specific lymphadenectomy</p> | <p>Agree 97.0%</p> <p>Disagree 3.0%</p> |
| <p>Specimen extraction It is MANDATORY to extract sentinel nodes using any of the following containment techniques: endo-catch bag finger of sterile glove, laparoscopic 'cup forceps' contained extraction via port, contained extraction via colpotomy</p> | <p>Agree 97.0%</p> <p>Disagree 3.0%</p> |

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| Specimen labelling It is MANDATORY to label sentinel nodal tissue according to laterality (right/left) and nodal station (obturator/external iliac/internal iliac/presacral/common iliac/aortic/caval) | Agree 100% Disagree 0% |
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