

# Telephone call for post-discharge surveillance: validation and application of tool for video-assisted surgery

*Vigilância pós-alta por telefone: validação e aplicação de instrumento para cirurgias vídeo-assistidas*  
*Vigilancia después del alta por teléfono: validación y aplicación de instrumento para la cirugía asistida por vídeo*

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## ABSTRACT

**Objective:** to validate an instrument for post-discharge surveillance by telephone for video assisted surgeries. **Method:** a multi-method study with development, validation and application of the instrument. The validation was performed by experts considering the relevance, clarity and completeness of the contents in the calculation of the content validity index and valid questions that demonstrated 80% agreement. For the application of the instrument, the sample consisted of 68 women undergoing video-assisted surgery, and we conducted a descriptive analysis. **Results:** there was disagreement among experts in the first evaluation, and the instrument was redesigned obtaining agreement in the second evaluation. The response rate to the telephone contact was 88.2% (60/68). Complaints of abdominal pain, bleeding and incisional edema were more frequent. No patients presented with infection. **Conclusion:** the questionnaire was validated and applied and is available for use.

Key words: Laparoscopy; Epidemiological Surveillance; Validation Studies.

## RESUMO

**Objetivo:** validar instrumento para vigilância pós-alta por contato telefônico de cirurgias vídeo-assistidas. **Método:** estudo multi-métodos com elaboração, validação e aplicação de instrumento. A validação foi realizada por peritos considerando pertinência, clareza e abrangência do conteúdo, sob cálculo do índice de validade de conteúdo, sendo válidas as questões com 80% de concordância. Para aplicação do instrumento, a amostra foi composta por 68 mulheres submetidas à cirurgia vídeo-assistidas sendo realizada análise descritiva. **Resultados:** houve discordância entre peritos na primeira avaliação e o instrumento foi reformulado obtendo-se concordância na segunda avaliação. A taxa de resposta ao contato telefônico foi de 88,2% (60/68). Queixas de dor abdominal, sangramento e edema incisional foram mais frequentes. Nenhuma apresentou infecção. **Conclusão:** o instrumento foi validado, aplicado e encontra-se disponível para utilização.

**Descritores:** Laparoscopia; Vigilância Epidemiológica; Estudos de Validação.

## RESUMEN

**Objetivo:** validar un instrumento para la vigilancia después del alta por teléfono para la cirugía asistida por vídeo. **Método:** estudio multimétodo de desarrollo, validación y aplicación de la instrumento. La validación fue realizada por expertos que consideran la pertinencia, claridad e integridad de los contenidos, en el cálculo del índice de validez de contenido y preguntas válidas que encontró 80% de concordancia. Para la aplicación del instrumento, la muestra consistió en 68 mujeres sometidas a cirugía asistida-video y llevó a cabo un análisis descriptivo. **Resultados:** no hubo acuerdo entre los expertos en la primera evaluación y el instrumento fue rediseñado obtener un acuerdo en la segunda evaluación. La tasa de respuesta al contacto telefónico fue del 88,2% (60/68). Las quejas de dolor abdominal, hemorragia y edema incisional fueron más frecuentes. Ninguno presentó infección. **Conclusión:** el cuestionario fue validado, aplica y está disponible para su uso.

**Palabras clave:** Laparoscopia; Vigilancia Epidemiológica; Estudios de Validación.

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## INTRODUCTION

Surgical site infection (SSI) is an important public health issue among the infections related to health care based on its high incidence and associated repercussions<sup>(1-2)</sup>. It was considered to be the most common infection and a cause of substantial health costs, accounting for 70% of deaths in affected patients<sup>(3-4)</sup>. The SSIs are those involving tissue, organ or cavities manipulated during surgery<sup>(2)</sup>, and approximately 60% are preventable<sup>(3)</sup>. Minimally invasive surgery requiring a short hospital stay and the choice of outpatient surgeries have increased. According to the Centers for Disease Control and Prevention (CDC)<sup>(5)</sup>, the occurrence of SSI should be monitored not only during hospitalization but also after discharge for a period of 30 days or up to one year in the case of implants. New definitions of SSI criteria, adopted by the CDC<sup>(6)</sup> and the Epidemiological Surveillance Center of São Paulo<sup>(7)</sup>, suggest a post discharge surveillance of 30-90 days for deep incisional SSI or body or space for some procedures, including laparoscopic procedures<sup>(7)</sup>.

In video-assisted surgery, lower risk of infection than that in the corresponding open surgery has been described<sup>(8-9)</sup>. However, post-discharge surveillance still faces obstacles in implementation in many institutions<sup>(10)</sup>, which can result in the underreporting of cases of SSI<sup>(3)</sup>. If complications are minimal, the patient may not seek health services, or medical care cannot investigate and report the infection to the institution where the procedure was performed. The SSI notification is fundamental in health care, translates as an important indicator of quality of patient care, and is required for hospital accreditation and inspection by the regional epidemiological surveillance services, both state and federal<sup>(11)</sup>. Additionally, by identifying the epidemiology and risk factors, surveillance provides grants for infection control activities and feedback to health teams involved<sup>(10)</sup>, which may result in reducing surgical site infection rates by 33-88% in patients<sup>(12)</sup>.

There are various methods of surveillance<sup>(10)</sup>, and the most common are questionnaires sent to patients and surgeons, telephone interviews and monitoring or follow up<sup>(11)</sup>. One method is not more efficient than another because all have advantages and disadvantages. Therefore, it is advised to use two or more approach strategies for more accurate rates of infection<sup>(13)</sup>. To ensure the quality and reliability of the data, the surveillance methods should have standardized and well-defined criteria. Validation is the only way to determine the accuracy of responses and monitoring data<sup>(14)</sup>. In the literature, we found a non-validated questionnaire for a telephone interview with a patient undergoing cesarean section<sup>(13,15)</sup>. The objective of this study was to construct, validate and implement a tool for research by telephone and determine the signs and symptoms suggestive of SSI in video-assisted surgeries.

## METHOD

The study was conducted in a public teaching hospital located in the interior of São Paulo state that is a regional referral center for women's health. The study was approved

by the Ethics Committee (Opinion No 1201/2011; CAAE: 1102.0.146.000-11). Participants were targeted and received an informed consent form, prepared in duplicate in accordance with the Brazilian Resolution 196/96 CONEP in effect at the time of the survey.

The study used the sequential multi-study method<sup>(16)</sup> and was developed in two stages. First, the methodological development for instrument validation was based on Pasquali's model<sup>(17-18)</sup> following a three-axis procedure: theoretical, empirical and analytical. In the second stage that involved a cross-sectional study<sup>(19-20)</sup> with a quantitative approach, the validated instrument was applied to a defined sample.

### First stage - establishment and instrument validation

#### *Instrument development*

The instrument was developed based on the literature on the topic and also considering the experience of the researchers. The first version, developed in 2011, was composed of 35 questions divided into two sections: 1) characterization of the subject with 10 questions containing the serial number, identification, age, date of birth, hospital record number, address, clinical diagnosis, name of surgery, date of procedure, phone numbers, telephone contact (date of the first, second and third attempts) and best time to connect; 2) telephone contact with 25 issues at the time of contact, time elapsed after surgery, initial approach and presentation of the work and issues related to the SSI in the immediate postoperative period and late - existence of hyperthermia checked with or without a thermometer, drug ingestion, aspects of surgical site (redness, increased temperature, edema at the site of intervention, characteristic of the secretion), healing of the surgical incision, vaginal bleeding after surgery, odor and time of bleeding, need for medical care after surgery, prescription after returning to the doctor if necessary, need for hospitalization, open questions about the patient placements and observations from the interviewer.

#### *Test pilot*

To identify possible gaps and verify aspects of the approach to the patient, we conducted a pilot test with the primary instrument by applying it to five patients undergoing laparoscopic surgery in 2012. Only one patient had signs of inflammation that did not meet the case definition criteria. The instrument was reformulated according to the needs identified by researchers, making it more practical for application.

#### *Validation content*

Validity may be defined as the ability of an instrument to accurately measure what is to be measured (i.e., the studied phenomenon)<sup>(21-24)</sup>. In this study, the content validation was performed corresponding to the meticulous analysis of the content of the instrument initially developed to verify that the proposed items constitute a representative sample of the subject to be measured<sup>(21-23)</sup>.

Five<sup>(25)</sup> experts, professionals involved in education and health care, were chosen based on their experience and expertise in the area being studied<sup>(26)</sup>: a nurse from a hospital infection

control committee with expertise in the monitoring, assistance and follow-up of surgical patients after discharge; a nurse doctor with experience in care, teaching and research with an emphasis on elderly health; a nurse post-doctor with experience in teaching and research in infections related to health care, public health, patient safety, epidemiology, reprocessing products for health and biosecurity; a nurse doctor experienced in assistance and education aimed at the control and transmission of pathogens, biosafety, and biological occupational hazard; and a medical doctor experienced in care and education in public health, pthiology, surveillance and epidemiology.

A cover letter to explain the research objectives and instructions for how to proceed in evaluating the instrument was created for the experts. A guide was prepared to clarify the content that we wished to obtain in each sub-item of each instrument section. Both documents, together with the instrument to be assessed, were delivered to the experts in person or by mail after prior contact.

The redesigned instrument was sent to the group of experts to examine whether the proposed items had validity for clarity, relevance and comprehensiveness. We used the following definitions: clarity - property assessing whether the wording of the items proposed is adequate and understandable, exactly expresses the intended measure and can be evaluated by the judges as: unclear, no opinion or clear<sup>(27-28)</sup>; relevance - property assessing whether the items actually reflect the concepts involved, whether they are relevant and appropriate to achieve the objectives proposed by the research and may be considered by judges as: not relevant, no opinion or relevant<sup>(27,28)</sup> comprehensiveness - property that evaluates the instrument as a whole, analyzing whether all sections contain the proper items and all sizes were included and can be evaluated by the judges as: not comprehensive, no opinion or comprehensive<sup>(27-28)</sup>.

Based on the results of the evaluations of all experts, we conducted a data analysis and evaluated the suitability of the instrument returning. The questionnaire then underwent a second evaluation. Then, the validated instrument was administered to three patients undergoing video-assisted surgery for final testing and was considered adjusted for use.

### Data analysis

We calculated the content validity index (CVI) for each item present on the instrument in regard to relevance and clarity and for each of the two sections of the instrument with respect to the comprehensiveness. A degree of agreement among experts greater than or equal to 80%<sup>(23,26)</sup> was the criterion for relevance and clarity.

### Second stage - instrument application

The final version of the validated instrument was applied to patients undergoing elective gynecological laparoscopy or hysteroscopy who agreed to participate and whose telephone address was recorded during the hospitalization for the surgical intervention. Loss of follow-up occurred after three phone contacts on different days to the patient. Thus, the initial sample consisted of 68 patients in the period from March to June 2013.

To define the surgical site infection as superficial incisional, deep incisional and organ or space, we used the criteria described by the National Health Surveillance Agency (Anvisa)<sup>(29)</sup>.

## RESULTS

### First stage

The CVI or percentage of agreement adopted in this study was 80%. Items with a CVI less than 80% on relevance or clarity or both were reformulated or deleted as suggested by the experts, and the instrument was resubmitted for evaluation. An item (1.5) had agreement less than 80% on relevance, but this item was kept due to the importance of knowing the address if it were necessary to contact the patient. Two items (1.7 and 2.3) had agreement less than 80% on clarity, one of which (1.7) was excluded from the instrument and the other (2.3.) was reformulated according to the suggestions of the experts (Table 1).

**Box 1 -** Version proposal and resulting pre-final version of the first evaluation by experts of items 1.5, 1.7 and 2.3, Campinas, São Paulo, Brazil, 2012

Item	VERSION PROPOSAL	VERSION PRE-FINAL
1.5	Address	Maintained
1.7	Scheduling: outpatient scheduled	Removed
2.3	Note: For physical-clinical needs, confirming the outpatient scheduled with the doctor and/or scheduling a new telephone contact for follow up.	Note: For physical-clinical needs, the responsible for telephone contact communicates to the Hospital Infection Control Commission.

After the first evaluation by the experts, the instrument was reformulated. In the first section, it was necessary to add an item (1.6) for the clinical diagnosis of the patient because it was considered important to know if there was a relationship between this diagnosis and the occurrence of SSI. We also added three items; two of them (1.7 and 1.8.), for the name of the surgical procedure and the date of the procedure, respectively, were already collected at the time of first contact and delivery of the informed consent form. There was no place for notes in the instrument. Accordingly, we added a third option "any time" in item (1.11) for participants who had no preference for a specific time to be contacted. In the second section of the instrument, we added three items (2.2.7, 2.2.8 and 2.2.9) referring to hysteroscopy because the need to include questions specifically directed to this type of surgical procedure was found to be more effective because of the possibility of endometritis in patients submitted to it. We also included an item (2.3) for the observations of the interviewer, if there was a need to write them, for better organization.

In the second evaluation by the experts, the two sections had 100% agreement and were maintained, resulting in the

final version of the instrument with 40 questions, 11 regarding socio-demographic characteristics of the subject and 29 regarding the telephone contact.

### Second stage

Of the 68 patients who underwent hysteroscopy and/or gynecological laparoscopy and were addressed during hospitalization for participation in the research, the validated instrument was applied to 60 (88.2%) patients from March to June 2013. The telephone call was conducted between 30 and 35 days in 71.6% of cases, followed by 25.0% within 36 to 40 days and 3.4% of the cases more than 40 days after surgery.

One-third of female participants (33.3%) were in the age group 30-39 years old, followed by groups 40-49 years and 50-59 years with 18.3% each. Most participants resided in Campinas, SP (48.3%). The main reason for the diagnosis and surgery was endometrial polyp (48.3%), followed by primary infertility and endometriosis (6.7% each). The surgeries were performed via hysteroscopy and laparoscopy (70.0% and 30.0%, respectively).

Among the 42 patients who underwent hysteroscopy, 33.4% (14/42) reported vaginal bleeding after surgery; 1 (7.1%) reported no bleeding odor, 1 (7.1%) reported a blood characteristic odor and 85.7% (12/42) reported a menstrual odor. In regard to the duration of the bleeding, 7.1% (1/42) reported having bleeding for 15 days, 21.4% (3/42) for 7 days, 7.1% (1/42) for 6 days, 14.3% (2/42) for 5 days, 21.4% (3/42) for 4 days, 7.1% (1/42) for 3 days, 14.3% (2/42) for 2 days and 7.1% (1/42) for 1 month. Two patients, one with bleeding for 4 days and another 5 days, had menstrual bleeding. The patient who had bleeding for a month went to the doctor who prescribed a contraceptive to stop the bleeding. The patient who had bleeding for fifteen days did not complain of other complications or signs suggestive of infection.

Of the 18 patients who underwent laparoscopy, none presented with redness or warmth at the sites of surgical incision; 5.6% (1/18) reported localized edema in all incisions related to the removal of stitches lasting 7 days. Because this sign occurred alone, the edema was considered an adverse event caused by local trauma. Regarding the output discharge, 16.7% (3/18) reported bloody, yellowish and clear discharge, respectively, only in the umbilicus incision on the day of surgery or the first postoperative day, which lasted 1-3 days. One patient reported that the "yellowish" discharge on the first postoperative day had evolved from dehiscence of the incision in the umbilicus and healed after four days.

Of the total 60 patients interviewed, only 1 (1.2%) reported inconclusive fever postoperatively because the temperature was not measured with a thermometer. She reported to have felt very cold and did not need to take medicine for fever. As the patient did not show any other signs indicative of infection, the diagnosis of SSI was discarded. Six patients (10%) sought private medical care at basic health units or at the institution where the procedure was performed. The visits were scheduled for the following reasons: return visit, leg pain, prolonged bleeding, bleeding and abdominal pain due to pneumoperitoneum. Five patients (8.3%) were prescribed analgesic or anti-inflammatory drugs for home use, and 1 (1.7%) had to be readmitted for pain treatment. In the last item of the questionnaire (where the

patients were able to present their comments), 13.4% (8/60) had pain complaints and reported having the flu, but there were no reported signs or symptoms indicative of SSI, other than those addressed in the questions of the instrument.

### DISCUSSION

Video-assisted surgeries are increasing every year in various surgical specialties. As hospital stays decrease, there is higher turnover of patients and procedures, which demands greater attention and time from health professionals for post-discharge surveillance. This increased demand has contributed, in addition to with the expansion of post-discharge surveillance time to 90 days in particular with surgical procedures<sup>(6-7)</sup>, to instigate discussion on the impact of this type of surveillance on the rate of infection in hospitals<sup>(30)</sup>, the application and effectiveness of various methods<sup>(13,31-32)</sup>, and the time for surveillance<sup>(15,33)</sup>.

We developed a data collection instrument to investigate the signs and symptoms of SSI by telephone, which was intended to direct the interview to collect epidemiological data, conduct surveillance and avoid underreporting of adverse events. The initial instrument was developed as a questionnaire with open and closed questions, and there was disagreement among the experts on the first assessment followed by approval of the revised version from their suggestions. The validation process was necessary to determine the key elements that should be evaluated in post-operative patients using accurate and reliable information, as none of the studies reviewed<sup>(13,15,31-32)</sup> presented a validated instrument. Additionally, there was a lack of appropriate instruments for SSI research in video-assisted surgeries. The application of an instrument for the active search of cases of post hysteroscopy and laparoscopy infection Aids the planning of patient safety initiatives, lowers the cost of service and increases the accuracy in epidemiological surveillance.

To diagnose SSI, we used the criteria described by Anvisa<sup>(29)</sup> of surgical site infections: superficial incisional, deep incisional and organ/space. Surgeries that did not correspond to the definition of surgery given by Anvisa, which consists of the presence of incision and suture, were not exempt from notification. These situations included endometritis after episiotomy, curettage and hysteroscopy.

None of the signs and symptoms reported by the patients met the criteria for the case definition of SSI, and the reported signs and symptoms were considered adverse events inherent in the procedure or isolated complaints. A patient reported "yellowish, purulent" secretion (item 2.2.5.1 answer number 2) during hospitalization, followed by the umbilicus suture dehiscence after suture removal. In this case, a second call was performed after the scheduled doctor's appointment when the patient reported to have the yellow discharge, and the patient reported clear, odorless discharge with no local inflammatory signs and did not receive antibiotics. After discussion with professional experts in infection control, the secretion was determined to not be purulent and the possibility of SSI in this patient was discarded. Such situations are foreseen in the CDC recommendations<sup>(5)</sup> among those who do not qualify as having the SSI criteria: "A stitch abscess alone (minimal inflammation and discharge confined to

the points of suture penetration)". An important point is that despite the efforts of researchers to create appropriate and easy to understand questions, this item may have caused confusion, and therefore, we suggest that it be reviewed in the future. However, regardless of the need to correct the wording, most of the items, including this item, obtained a CVI greater than or equal to 80% and were considered to have valid content<sup>(2,3)</sup>.

The method of post-discharge surveillance by telephone showed a response rate close to 90.0%, similar to another national study designed to follow patients who underwent cesarean delivery<sup>(15)</sup>. International studies have reported 74.8%<sup>(13)</sup> and 78.4%<sup>(31)</sup> response rates for telephone interviews. The interaction of the professional responsible for this surveillance with the patient during their stay favored the contact to search for signs and symptoms suggestive of SSI.

This study did not aim for economic cost-effectiveness in the use of the instrument or implementation of this method of surveillance. Noy and Creedy<sup>(13)</sup> declared that performing post-discharge surveillance with multiple methods may be considered cost-effective because the surveillance can be adapted to suit the resources available in the institution and to the various types of surgical procedures with higher risk of infection. The authors<sup>(13)</sup> conducted telephone interviews with mothers after cesarean sections with an average duration of 3 minutes lead, which they considered to be cost-effective due to the high response rate. Other studies have also recommended the method to be applicable<sup>(32)</sup> and effective<sup>(31)</sup>.

The limitations of the study involved a small sample size and the possibility of recall bias of patients, considering that the interviews were not made within 30 days of surgery but after this period. Elaborate research instruments, even if validated, may be subject to adjustments and adaptations to the reality in which they will be applied. This study used content validation, and other validation methods should be applied in future research to ensure that the instrument reach the ultimate goal for which it was built.

## CONCLUSION

In this study, an instrument developed to research surgical site infections in gynecological video-assisted surgery was validated and applied and is available for use.

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