Ministry of Health

Department of Quality
Directorate General of Health Planning

Recommendation for the Prevention of Retained Sponges, Instruments or Other Material in a Surgical Site.

The retention of sponges , instruments or other material in surgical sites can cause severe harm.

The retention of sponges, instruments or other material in a surgical site poses as an important sentinel event(1) that can and must be prevented. Presently in our country, some hospitals have already implemented preventative measures to contrast the occurrences of such events. This present recommendation is intended to serve as an operative model to be implemented in all health structures countrywide.

Recommendation #2, March 2008
This document in its present version has been prepared by the Ministry of Health and with the Coordination of the Regions and Autonomous Provinces for Patient Safety.

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Attachment 1 - Prevention of Retained Sponges, Instruments or Other Material in Surgical Site Form

1. Premise

The retention of sponges, instruments and other material in surgical site represents an important event noted and represented in literature.

1.1 Incidence

Although official data of this incidence is not available, it is estimated that this phenomenon occurs 1 in every 1000-3000 surgical procedures per annum(2). Some factors which obstacle the reporting of such events is most likely due to the frequent lack of symptoms, inadequate documentation of the diagnostic cases, difficulties in diagnosis and the lack of encouragement to report events in question spontaneously.

1.2 Type of Material Retained

Material most frequently retained are sponges (clinical condition defined in literature as "Gossypiboma "[1] or "Textiloma") or surgical instruments, for example needles, scalpels, electrical-surgical adaptors, tongs or their parts.(3)

1.3 Site of Surgery

The majority of events reported in literature deal with abdominal and thoracic surgery and as well with childbirth.

1.4 Risk Factors

The principle risk factors reported in literature are (4-7)[2]:

- Surgical procedure performed in emergency
- Unexpected changes and therefore not programmed in the procedures during surgery
- Obesity
- Surgery that requires more that one surgical team
- Complexity of operation
- Fatigue of the surgical team
- Situations that favour counting error (ex. gauze stuck together)
- Lack of a procedure for the systematic count of instruments and gauzes
- No checkpoint of all materials and medical devices at the end of surgery

1.5 Diagnosis Times

The time lapse between surgery and the time of diagnosis can be extremely varied (days, months, years) and it is dependent on the site and the type of reaction provoked from the foreign object. In fact, the diagnosis can be accidental in asymptomatic patients or with pseudotumor syndrome, as well, it may necessitate the prompt diagnosis and further surgery in cases in which there are acute reactions with local or systematic symptoms(2).

1.6 Outcome

Retained foreign objects can cause a wide range of clinical outcomes ranging from asymptomatic cases to cases with severe complications, such as intestinal perforations, sepsis, organ damage leading to death; in fact, it is estimated a mortality rate of 11% to 35% (3,5).

2. Objectives

To prevent the retention of gauze, instruments and other foreign objects in surgical site.

3. Areas of Application

This recommendation applies to

- all operating rooms
- all healthcare operators involved in surgical activity

4. Actions

4.1 Procedure for the systematic count of surgical material and a control of its integrity

What
The procedure must be applied to gauzes, scalpels, needles and all other materials, also for single instruments used in the course of the surgery.

When
The **count** must be performed in the following phases: 1. before beginning surgery (initial count) 2. during surgery, before closing a cavity that is internally located in another cavity 3. before stitching a wound 4. when mending the skin or at the end of the procedure 5. at the possible shift change of nurses and or surgeons that are head of the equip A **verification of status/integrity of instruments** must be conducted in the following phases: 1. when a sterile package is opened 2. when it is passed to the surgeon for use 3. when it is returned after use by the surgeon

Who
The count and the check of the conditions of the instruments must be carried out be the nursing personnel (instrumentalists, operating room nurses) or by support staff responsible specifically for surgical counts. The surgeon verifies that the count has been performed and that the total of gauze used and remaining correspond to the number received prior and during surgery. To be noted that the current law states that consequent of omission of surgical count or the removal of foreign objects from surgical site, attributes responsibility to the entire surgical team (Sentence of the Court of Cassation/Court of Appeal IV penal section: May 26, 2004 n.39062; May 18,2005 n. 18568; June16, 2005 n.22579).

How
• the counting procedure must be performed out loud • the counting procedure must be carried out by two operators simultaneously (operating room nurses , support staff) • relative to the initial count of gauzes, verify that the number written on the package actually corresponds to the number inside the package, by counting every gauze individually, writing the number on the appropriate form: the initial count establishes the base for succeeding counts • all instruments, gauzes or other material added during the course of the surgery must be immediately counted and registered in the operating documentation • the count must always be documented and signed on the specific form provided by the healthcare trust and be included with the surgery documentation, as in the model proposed (see attachment 1) • all the material that arrives and returns from the operating table must be checked in its integrity • Containers must be used for the sterile gauzes used for the surgery, differentiated in respect to containers that collect other gauzes or other material for the operating room. • Avoid medicating at the end of the operation with gauzes that contains barium in order to prevent false positive in the event a radiography check is needed.

In the event that the surgical count does not balance, or rather there seems to be material or instruments uncounted for, one must:
• proceed to recount the gauzes • report event to surgeon • inspect surgical site • inspect surrounding operating area (pavement, all the bins for waste and used instruments) • perform an operating radiography with the relative reading, before bringing the patient out of the operating room • record events and all procedures performed in the patient's operating documentation.

The **work ambience** inside an operating room must encourage free flowing and effective communication which entails the entire surgical team, in order that all team members are in the optimal conditions to communicate any doubts regarding potential counting discrepancies.

4.2 Technology for Limiting the Consequences of Material Retention in Surgical Site

Where the counting procedure is not sufficient, in addition to counting, it is recommended during surgery to use gauze exclusively containing Barium or other appropriate materials able to be effectively identified if required.

For high risk patients (emergency surgical procedures, unexpected changes and unforeseen procedures during surgery, obesity) it is suggested, where possible, radiographic screening before the patient exits the operating room, in order to identify radiopaque objects and gauzes, even though, to date there is a lack of analysis on the efficacy of such measures, which in turn could be burdened by false negatives(2)

Furthermore, object of assessment are the new technologies used for limiting the containment of material, such as "electronic tagging" of surgical material, however at the present moment there does not exist sufficient evidence to consent its widespread use .

4.3. New Risk Reducing Technology

With regards to new technology which may used to facilitate surgical counts (ex. inventory control instruments, bar coding etc.), to date there is a lack of scientific evidence available to support its efficacy (3).

5. Implementation of Recommendation in Healthcare Structures

Health management is responsible for the development and implementation of this present recommendation.
Healthcare management which decide not to use this present recommendation must make available their own standardized procedure for surgical counts with the scope to reduce the risk of retained foreign objects in surgical sites.
Considering the organizational differences and in particular the heterogeneity of the operating equip amongst the various regions and healthcare structures, this present recommendation must be adapted taking into account such specific situations.

5.1 Monitoring the Implementation of the Recommendation

It is recommended to actively monitor the compliance to the procedures regarding surgical counts foreseen by the healthcare trust and to keep documentation of such inspections performed.

5.2 Activation of Monitoring Protocol of Sentinel Events

The healthcare trust must encourage the reporting of sentinel events by specific procedures set forth by the trust itself.
The sentinel event "*Instruments or other material retained in surgical site which require successive surgery or further procedures*" must be reported according to monitoring protocol of sentinel events as set forth by the Ministry of Health (1).

6. Training/ Continuing Education

Training Programmes must be foreseen and provided by the healthcare structure which also include training in surgical counts (gauzes, instruments and other surgical material) for personnel working in the operating room.
The training programs must include case studies which will play a role in increasing the staff's knowledge and the possible consequences related to this topic. With regards to such initiatives, placing importance in promoting a work environment which promotes collaboration and open communication amongst staff, is needed

7. Recommendation Update

This recommendation will be object of periodic reviews and will be updated based on emerging evidence and results of its application in clinical practice.

Suggestions for the Improvement in Efficacy of this Recommendation

With the scope to improve this recommendation in clinical practice, healthcare facilities are encouraged to submit suggestions and comments, answering the questions posed in the attached questionnaire "Together to Improve the Prevention of Sentinel Events".

8. Bibliography

1 *Ministero della Salute* *http://www.ministerosalute.it/dettaglio/pdFocus.jsp?area=programmazionequalita&colore=3&id=305*

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8 *AORN, Standards, Recommended Practices, and Guidelines; 2005; 307-*

This present Recommendation has been elaborated by the Third Office - Quality of the Healthcare Activities and Services (Alessandro Ghirardini, Roberta Andrioli, Rosetta Cardone, Susanna Ciampalini, Giorgio Leomporra, Giuseppe Murolo, Claudio Seraschi) of the General Directorate of Healthcare Planning , LEA, Ethical System Principals, and with the technical support of all team members involved in "Valutazione degli approcci metodologici in tema di Rischio clinico" and in particular Luciana Bevilacqua, Enrica Capitoni and Piera Poletti.

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Federazione Nazionale Medici Chirurghi e Odontoiatri (FNMOCeO)

- Federazione Nazionale Collegi Infermieri Professionali Assistenti Sanitari e Vigilatrici di Infanzia (IPASVI)
- Federazione Nazionale dei Collegi delle Ostetriche (FNCO)
- Associazione Infermieri di Camera Operatoria (AICO)
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- Società Italiana di Chirurgia (SIC)
- Società Italiana di Igiene e Medicina Preventiva (SITI)
- Società Italiana per la Qualità dell'Assistenza Sanitaria (SIQUAS)
- Società Italiana di Radiologia Medica (SIRM)
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Attachment 1 – Form for the prevention of the retention of sponges, tools or other material in a surgical site

Patient's Full Name:_____________________________________
Date of Birth ____
Date of Surgery____
Chief Surgeon____
Type of surgery to be performed: ______________________________

	Phase Count*					**Elements added****				**TOT**
	1	2	3	4	5	+	+	+	+	
Sponges - Laparotomic										
Sponges - Lunghette										
Needles										
Cotton Swabs										
Scalpel										
Instruments										
……..										
Signature 1st nurse/ other employee										
Signature 2nd nurse/ other employee										

* Count phases

1. before beginning surgery (initial count)
2. during surgery, before closing a cavity that is internally located in another cavity
3. before stitching a wound
4. when mending the skin or at the end of the procedure
5. at the possible shift change of nurses and or surgeons of the operating team (final count)

** the count of all elements/articles (instruments, gauzes or other material) not foreseen and added during the course of the surgery.

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