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Original Article

Assessment of protocols for surgical-site preparation in a regional network of hospitals[1]

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Surgical-site infection is a preventable adverse event. Implementation of good practices for correct surgical-site preparation can contribute to lessen this safety problem. The objective of this study was to describe the presence and quality of protocols on surgical-site preparation in the Murcia (Spain) regional network of public hospitals. The indicator "existence of protocol for surgical-site preparation" was assessed, as well as the formal quality (expected attributes) and contents (compared to current evidence-based recommendations) of existing documents. Seven of the nine hospitals have a protocol for surgical-site preparation. Opportunities to improve have been identified in relation to the protocols' formal quality and contents. Recommendations related to skin asepsis are incomplete and those related to hair removal contradict existing evidence. Most hospitals have protocols for surgical-site preparation; however, there is great room for improvement, in relation to their expected attributes and to the inclusion of evidence-based recommendations.

Descriptors: Quality Assurance, Health Care; Guidelines as Topic; Evidence-based Practice; Infection Control; Hospitals, Public; Safety Management; Nursing Assessment.

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Avaliação da normatização da preparação pré-cirúrgica em uma rede regional de hospitais

A infecção do sítio cirúrgico é evento adverso, possível de prevenir mediante a implementação de boas práticas de preparação pré-cirúrgica. Este estudo teve por objetivo descrever a existência e qualidade da protocolização da preparação pré-cirúrgica em uma rede regional de hospitais públicos de Múrcia, Espanha. Avaliou-se o indicador Existência de protocolo/norma de preparação pré-cirúrgica, analisando-se a qualidade formal (atributos) e de conteúdo (presença de recomendações baseadas em evidência) dos documentos existentes. Sete (de nove) hospitais comprovaram que tinham protocolos de preparação pré-cirúrgica. Identificaram-se oportunidades de melhoria da qualidade formal e de conteúdo dos protocolos. As recomendações sobre assepsia estavam incompletas na maioria dos documentos, e aquelas de eliminação do pelo mostraram-se contrárias à evidência. A preparação pré-cirúrgica está protocolizada na maioria dos hospitais, mas a qualidade dos protocolos é deficiente, assim como a padronização das práticas baseadas em evidência.

Descritores: Garantia da Qualidade dos Cuidados de Saúde; Guias como Assunto; Prática Clínica Baseada em Evidências; Controle de Infecções; Hospitais Públicos; Gerenciamento de Segurança; Avaliação em Enfermagem.

Evaluación de la normalización de la preparación prequirúrgica en una red regional de hospitales

La infección del sitio quirúrgico es un evento adverso prevenible mediante la implementación de buenas prácticas de preparación prequirúrgica. El objetivo del presente estudio fue describir la existencia y calidad de protocolización de la preparación prequirúrgica en la red regional de hospitales públicos de Murcia (España). Se evaluó el indicador "Existencia de protocolo/norma de preparación prequirúrgica", analizando la calidad formal (atributos) y de contenido (presencia de recomendaciones basadas en evidencia) de los documentos existentes. Siete (de nueve) hospitales acreditaron tener protocolos de preparación prequirúrgica. Existen oportunidades de mejora en la calidad formal y de contenido. Las recomendaciones sobre asepsia son incompletas en la mayoría de los documentos, y las de eliminación del vello contrarias a la evidencia. La preparación prequirúrgica está protocolizada en la mayoría de hospitales, pero la calidad de los protocolos es deficiente, así como la normalización de prácticas basadas en evidencia.

Descriptores: Garantía de la Calidad de Atención de Salud; Guías como Asunto; Práctica Clínica Basada en la Evidencia; Control de Infecciones; Hospitales Públicos; Administración de la Seguridad; Evaluación en Enfermería.

Introduction

Concerns with surgical-site infection have been linked with surgical practice since its primordial times until today. Although preventive evidence-based knowledge exists today, as well as better equipment, antibiotics, cleaning and sterilization techniques, an important number of surgical procedures that are not supposed to cause patient damage display infection-related adverse events[1-2].

In this sense, EPINE 2010 (Prevalence Study of Nosocomial Infections in Spanish Hospitals)[3], in which 278 hospitals participated, estimated an acquired infection prevalence of 6.8% at these centers, and one

study[4] highlighted that the third most frequent type is surgical site infection. This finding is consistent with other epidemiological studies in other countries, with detected the alarming problem of surgical site infections and their unwanted repercussions on the increase in morbidity and mortality levels and health care costs[5-8].

The risk of surgical site infection (SSI) involves multiple factors. Intrinsic (host-related) factors include, for example, malnutrition and protein depletion, extreme ages, severity of baseline diseases like diabetes, cancer, chronic vascular disease, obesity and smoking[9-10]. On the other hand, extrinsic factors (related to the surgery and hospital environment) can be the duration of surgical washing, extended hospitalization, shaving, surgery duration, skin antisepsis, prophylactic antibiotics and sterilization[9-10]. Although some of these factors cannot be modified (e.g. patient's age), others can be controlled or eliminated through an excellent care process focused on prevention (e.g. skin antisepsis, antibiotic prophylaxis, etc.).

Therefore, international entities like the Center for Disease Control and Prevention (CDC)[11], the National Institute of Clinical Evidence (NICE)[12] and the National Quality Forum (NQF)[13] have reviewed existing evidence on the theme and recommended good preventive practices to reduce both the risk and the number of SSIs. These entities agree that one of the processes that has demonstrated its effectiveness for SSI prevention, basically the nursing team's responsibility, is the pre-surgical preparation of skin and mucosa. As this complete process includes several coordinated activities, its standardization through the design or planning of the care process and the institutional implementation of standards and protocols can be a key structural factor to encourage professionals' adherence to these practices and consequently, to improve safety in hospitals[13].

Thus, one of the patient safety indicators our group constructed and validated in 2007, through an agreement with the Spanish Ministry of Health and Consumption, establishes that hospitals should have implemented standards and protocols for the pre-surgical preparation of skin and mucosa[14]. It remains unknown, however, how many hospitals have implemented pre-surgical preparation protocols. Moreover, like any protocol, the effectiveness of this care quality improvement intervention depends on the quality of the protocol itself and its correct implementation. These aspects can be assessed through a review of the formal (desirable attributes of clinical protocols) and content (presence of evidence-based recommendations) quality of its documents.

The goals of this study were to: (1) describe the existence of pre-surgical preparation standards or protocols in a regional public hospital network; and (2) assess existing protocols, considering their formal quality and the quality of their contents with regard to published scientific recommendations. Assessing these aspects permits the identification of hospitals with good SSI prevention practices regarding skin and mucosa preparation, and contributes to prove the validity of the documents used, as low-quality protocols can be ineffective as an improvement strategy.

Method

An observational, cross-sectional and descriptive study was accomplished. The quality of pre-surgical skin and mucosa protocols was described in a regional hospital network. This study is part of the project "Measurement of best-practice indicators for patient safety", developed in 2008 in the Spanish Region of Murcia.

The study context comprises all public hospitals in the region. Out of nine existing hospitals, one is large (500 beds or more), four medium (between 200 and 499 beds) and four small (less than 200 beds).

As a measurement instrument, the structural indicator "Existence of a surgical skin and mucosa preparation protocol/standard" was used, whose construction and validation were described in a previous report[14]. The measurement method was auditing. The investigators contacted each hospital's board, requesting, if this activity had been standardized, a copy of its pre-surgical skin and mucosa preparation protocol.

In addition, the formal quality of existing protocols was valued according to the following aspects, which are part of the EMCA Program's[15] protocol assessment tool (a tool that measures the presence of desirable attributes in clinical protocols[16]): flexibility, reliability, documentation, manageability, structural clarity, programmed review and interprofessional process.

The analysis of content quality was based on the set of evidence-based recommendations by the CDC, NICE and NQF[11-13] Although these entities' recommendations include the entire preoperative phase, for this study, only those related to skin and mucosa preparation were selected, which resulted in six CDC[11], three NICE[12] and one NQF[13] recommendation.

First, a trained nurse reviewed the documents, followed by two experts in Health Service Quality Management.

Compliance with the patient safety indicator "Existence of a surgical skin and mucosa preparation

protocol/standard" is described in the nine participating hospitals.

In addition, the formal and content quality of the documents the hospitals forwarded are described, highlighting the frequency at which the documents present the desired formal characteristics and evidence-based recommendations.

Regarding content quality, data analysis comprised two phases: 1) description of protocol contents in function of what they should contain, i.e. whether they adapted to evidence-based recommendations on best pre-surgical preparation practices; and 2) description of protocol contents not present in international recommendations.

Results

Participating hospitals and existence of protocols

The nine public hospitals located in the Region of Murcia (1 large, 4 medium and 4 small hospitals) participated. In seven of them (1 large, 4 medium and 2 small), a pre-surgical preparation standard/protocol existed, and a copy of the documents was provided. Two small hospitals did not believe they had protocoled this activity; at one of them, only one aspect was specified (need to shave skin hair) in trauma and gynecology surgeries.

Formal characteristics of forwarded documents

The document title takes different forms. Four of them are entitled "protocols" (Hospitals 1L, 3M, 4M, and 7S in Table 1), while the remainder are "preoperative nursing procedures and/or care", y "pre-surgical preparation of skin and mucosa". Concerning the formal quality (Table 1), the best protocol was found at the large hospital (1L), which complied with 7 out of 10 criteria. In general and as a positive aspect, the documents' good structural clarity can be highlighted, as all of them contained the recommendations in the form of algorithm, specifying their sequence from the day before until the time of the surgery. In this sense, three documents also contained illustrations, specifically skin preparation graphs according to the type of surgery. On the other hand, however, the documents are not easy to use due to the lack of an index and page numbers in most documents. In three publications, the information source for the recommendations or bibliography was not documented. The most recent protocol was issued in 2008, the eldest in 2003, and the remainder between 2005 y 2006, but three did not specify the issue/review/publication date. In only two documents external expert review was used (which enhances their reliability), and none of them considered exceptions to the recommendations' application or professionals or users' opinion. One of them contains a checklist the nursing staff needs to fill out, and another facilitates the monitoring of compliance through indicators, aimed at measuring both protocol use and effectiveness to reduce SSI rates.

Table 1 – Distribution of compliance with formal quality indicators in skin and mucosa preparation protocols at seven public hospitals in the Region of Murcia, Spain, 2008

Desirable attribute	Formal criterion	Hospitals							
		1L	2M	3M	4M	5M	6S	7S	Total
Structural clarity	1. Includes diagrams and/or algorithms	+	+	+	+	+	+	+	7/7
	2. Includes illustrations	-	+	-	+	+	-	-	3/7
Manageability of use	3. Index	+	-	-	-	-	-	+	2/7
	4. Numbered pages	+	-	+	+	-	-	-	3/7
Documentation	5. Includes bibliography or information sources	+	+	-	+	-	+	-	4/7
Programmed review	6. Issue/update/publication date	+	-	-	+	-	+	+	4/7
	7. Established date for review or validity period	+	+	-	-	-	+	-	3/7
Reliability	8. Expert review	+	+	-	-	-	-	-	2/7
Flexibility	9. Considers exceptions to the application of recommendations.	-	-	-	-	-	-	-	0/7
Interprofessional process	10. Considered professionals or users' opinion	-	-	-	-	-	-	-	0/7
Total		7/10	5/10	2/10	5/10	2/10	4/10	3/10	

L: Large (≥500 beds); M: Medium (200-499 beds); S: Small (<200 beds)

Content quality of forwarded skin and mucosa preparation documents

The evidence-based recommendations reviewed by the entities considered in this study consider that the surgical preparation process of skin and mucosa comprises two groups of activities: skin asepsis and correct hair elimination. Nevertheless, none of the forwarded documents fully complies with CDC[11], NICE[12], or specific NQF[13] recommendations, which denounces the insufficient content quality of the assessed protocols.

The most present recommendations in the documents were "Shower or bath with antiseptic soap before the surgery" (3/7 documents) and "Use of appropriate antiseptic agent in the surgery zone" (5/7 documents), both related to skin antisepsis. Only one of the seven documents, however, correctly specifies the technique to be used for washing the anatomic region of the surgery and which should be accomplished before applying the antiseptic, in accordance with CDC specifications and recommendations 2 and 4 in Table 2.

With regard to hair elimination, the reviewed evidence appoints four important aspects: 1- Not eliminating hair systematically, only if its interferes in the surgery (present in 1/7 documents); 2- if the hair needs to be eliminated, do it immediately before the intervention (present in 1/7 documents); 3- Not using switchblades or shaving the skin (present in 0/7 documents); 4- Using an electric razor (present inn 2/7 documents); and 5- Using a single-use head in electric razors (present in 0/7 documents). The complete description of protocol contents in function of evidence-based recommendations is displayed in Table 2.

In addition, somewhere in the protocol, six of the seven hospitals recommend "shaving" or using an "electric shaving machine", which is exactly the opposite of best practices.

Table 2 – Distribution of compliance with CDC, NICE and NQF recommendations in skin and mucosa preparation protocols at seven public hospitals in the Region of Murcia, Spain, 2008

CDC* NICE† and NQF‡ recommendations	Hospitals							
	1L	2M	3M	4M	5M	6S	7S	Total
1. Shower or bath with antiseptic agents at least during the night before the surgery *(or with soap during the previous day).†	+	+	D_1	D_1	D_1	+	D_1	3/7
2. Wash and carefully clean the anatomic region of the surgery and its surroundings to remove gross contamination before preparing the skin with antiseptic.†	-	-	+	-	-	-	-	1/7
3. Use an appropriate antiseptic agent for skin preparation. †	+	-	-	+	+	+	+	5/7
4. Antiseptic application technique: in concentric circles from the center to the sides. The prepared area should be sufficiently large to permit larger incisions or create new incisions or draining sites, if necessary.†	-	-	D_2	+	-	-	D_3	1/7
5. Do not eliminate the hair systematically,* but only if it interferes in the surgery.†‡	-	-	-	-	-	+	-	1/7
6. If the hair has to be eliminated, do it immediately before the surgery.†‡	+	-	-	-	-	-	-	1/7
7. If the hair has to be eliminated, use an electric razor.* †‡	+	-	-	-	-	+	-	2/7
8. If the hair has to be eliminated, use an electric razor with a single-use head.*	-	-	-	-	-	-	-	0/7
9. If the hair has to be eliminated, do not use switchblades to eliminate the hair or a shaving machine.*‡	-	-	-	-	-	-	-	0/7

L: Large (≥500beds); M: Medium (200-499 beds); S: Small (<200 beds); D_1: Specifies neither soap nor antiseptic agent; D_2: Does not specify movements from the center to the sides; D_3: Does not specify circular movements.

* Recommendation from Center for Disease Control and Prevention (CDC)

† Recommendation from National Institute for Health and Clinical Excellence (NICE)

‡ Recommendation from National Quality Forum (NQF)

Additional contents included in the documents analyzed

The reviewed documents also include additional recommendations not addressed in evidence on best practices for pre-surgical skin and mucosa preparation. All of them include the recommendation, for patient preparation, to verify and execute, if the physician has prescribed this, some type of specific preparation for the intervention (cleaning enemas, measuring, weighing…), administer antibiotic prophylaxis and removing personal objects (jewelry, rings), dental prostheses, earphones, etc. Five of these seven hospitals also recommend cut nails without nail polish, as this is important to observe patients' oxygenation. Three hospitals also refer to tying the hair (or using a cap), advising the patients to use the toilet before taking them to the surgery room and inserting catheters and probes as indicated. The full description of variations in these recommendations among the documents is present in Table 3.

Table 3 – Distribution of presence of additional recommendations to prevent Surgical Site Infection that are not evidence-based or not related to skin and mucosa preparation, in the protocols of seven hospitals in the Region of Murcia (Spain), 2008

Additional recommendations	Hospitals							
	1L	2M	3M	4M	5M	6S	7S	Total
1. Administering antibiotic prophylaxis.	+	+	+	+	+	+	+	7/7
2. Verifying and executing, if prescribed by the physician, some type of specific preparation for the intervention (cleaning enemas, measuring, weighing, etc.).	+	+	+	+	+	+	+	7/7
3. Removing personal objects (jewelry, rings), dental prostheses, ear phones, etc.	+	+	+	+	+	+	+	7/7
4. Cut nails without nail polish.	+	+	-	+	+	+	-	5/7
5. Determining vital signs.	+	+	+	+	-	-	+	5/7
6. Tied hair (or with cap).	+	-	+	-	+	-	-	3/7
7. Advise the patient to use the bathroom before taking him/her to the surgery room.	+	+	-	+	-	-	-	3/7
8. Insert catheters and probes as indicated.	-	+	-	+	-	-	+	3/7

L: Large (≥500 beds); M: Medium (200-499 beds); S: Small (<200 beds)

The documents also include general patient safety recommendations during hospitalization for surgical interventions. The most prevalent recommendations are: 1-putting patients in the best possible physical and mental conditions to reduce surgical risks (7/7 documents); 2-informing patients and families about routine hospital procedures and solving their questions (7/7 documents); and 3-writing down procedures in nursing records (7/7 documents). Other recommendations are specified in Table 4.

Table 4 – Additional recommendations for patient safety in general in the analyzed protocols from public hospitals in the Region of Murcia, Spain, 2008

Additional recommendations	Hospitals							
	1L	2M	3M	4M	5M	6S	7S	Total
1. Putting patients in the best physical and mental conditions to reduce surgical risks.	+	+	+	+	+	+	+	7/7
2. Informing patients and their families about routine hospital procedures and solving their questions.	+	+	+	+	+	+	+	7/7
3. Writing down the procedure in the nursing records.	+	+	+	+	+	+	+	7/7
4. Reducing patient anxiety.	+	+	+	+	-	-	+	5/7
5. Maintaining the safety of patients and families.	+	+	-	+	-	-	-	3/7
6. Requesting the signing of the informed consent form.	+	+	-	+	-	-	-	3/7
7. Maintaining the safety of health staff.	–	+	-	+	-	-	-	2/7

L: Large (≥500 beds); M: Medium (200-499 beds); S: Small (<200 beds)

Discussion

This study provides information on best practices in SSI prevention in hospitals, specifically concerning the existence and quality of pre-surgical preparation protocols. In accordance with the most recent evidence, standardizing this phase of the care process can be key to prevent SSI[13], and this paper describes the situation in a Spanish public hospital network.

Protocols are disseminated at most of the hospitals assessed, but two of the four small hospitals that participated did not believe they had explicit standards for pre-surgical skin and mucosa preparation. Future studies that use larger hospital samples can statistically prove needs to further sensitize small hospitals as to the importance of this process. Hospitals that have not standardized these activities should interpret the results as an opportunity to improve this aspect, motivating internal activities to design or plan their care process (always based on evidence-based clinical guidelines or recommendations)[11-13], so as to facilitate their professionals' adherence to best practices and enhance the quality of patient care and safety.

Like any structural element at health services, however, although protocols are useful instruments to reduce variations and guarantee satisfactory results, their existence permits but does not necessarily guarantee care quality[17]. For protocols to be useful and

effective tools, their formal quality (desirable attributes, such as structural clarity, manageability of use, documentation, programmed review, flexibility, etc.)[16], and content quality (precise and valid recommendations that correspond to the theme of the protocol) should be good and they should be used correctly[15]. Assessing the former two aspects, as done in this study, can indicate their potential use, as protocols of bad formal and content quality tend to be hard or problematic to put in practice[15,18].

As for the ease of use (structural clarity and manageability), the presence of algorithms in all protocols, associated with illustrations in three cases, is a positive point in the documents. All documents should contain page numbers and an index though, which would facilitate their use by nurses.

The formal attribute "programmed review", which includes expressing the issue and review date, is important due to permanent changes in scientific information and the need to update recommendations. In our case, despite the acceptable range of the document issue date (2003 to 2008), the absence of the issue and review data (or validity period) in some documents is a sign of alert on update problems, further reinforced by the protocols' deficient contents.

Another flaw that could be related to content quality is the lack of external expert review documentation in some documents. The problem of absent bibliography in some documents is important because exact theoretical foundations are absolutely determining for the validity of recommendations in the protocol. Not specifying this information can severely hamper the credibility of the document and its use[16,18], which can raise doubts on whether the approach was appropriate, which would definitively affect its validity.

In fact, perhaps the most relevant result of this original study was the identification of severe shortages in the documents' contents (e.g. they do not usually recommend: the correct antiseptic application technique; non-systematic hair elimination; non-use of switchblades or shaving machines; etc.), which can impair their use and effectiveness[18]. In general, best-practice recommendations are associated with skin asepsis and correct hair elimination. While the CDC is most specific on cleaning[11], all other entities in this review agree on recommendations about not eliminating body hair systematically and, if necessary, using an electric razor[11-13].

Concerning skin asepsis, showering or bathing at least the day before is a common recommendation, but four documents did not take care to recommend the use of soap or an antiseptic agent, in line with CDC and NICE specifications[11-12]. Moreover, another opportunity for improvement is to specify the need to wash the anatomic region before applying the antiseptic and the adequate antiseptic application technique[11]. These aspects may be accomplished, despite their absence from the protocols, or these instructions may be included in the protocol corresponding to each type of intervention, although this is not the most adequate way to proceed.

Surprisingly, in six out of seven documents, "shaving" the patient was recommended somewhere, which goes against best practices for SSI prevention. At most hospitals, shaving is a technique that has been implanted for a long time in patient skin preparation[19-21] and, therefore, this standard is introduced almost automatically when the protocol is elaborated, without introducing the new and safer techniques in this context, such as chemical depilation or the use of a sole-use electrical razor. Besides, shaving supposes lower material costs for hospitals than the use of the latter techniques; nevertheless, this cost can be negligible in comparison with the large sums of money that can be saved by investing in the improvement of SSI prevention[22-23]. Moreover, the NQF specifies that electrical razors should not shave[13] but cut the hair, as the former can also increase infection risks. "Electrical shaving machines" were mentioned at the two hospitals that recommended electrical equipment.

In addition, the hospitals present another group of recommendations that could be interesting, although they have not been scientifically studied or directly related with skin and mucosa preparation when preparing patients before entering the surgery room (Tables 2 and 3). These recommendations include interesting points in pre-surgical care and reflect the relation between skin and mucosa preparation and other interventions to prevent SSI (such as antibiotic prophylaxis).

These study results are limited to the hospitals under assessment, but pre-surgical preparation protocols have been internationally indicated to any institution that performs surgeries[13]. Although they are part of health service managers' primary responsibilities, the standardization of this process should be elaborated in cooperation with clinical professionals from the center and with patients as, at bottom, the aim of the standards is to attend to their needs and expectations.

It should be kept in mind that skin and mucosa preparation is a structural indicator and, as such, facilitates but does not guarantee good care practices[17].

Therefore, it would be important, after guaranteeing a correct protocol, to complement the assessment through the monitoring of protocol use and its effectiveness to improve care outcomes.

Conclusion

Pre-surgical preparations protocols are part of best practices at most of the hospitals assessed. Institutions that do not comply with this indicator should prioritize the solution of this potential safety problem. Nevertheless, the formal and content quality of the document can clearly be improved, which could indicate problems in the use and effectiveness of existing activity standards. Recommendations on hair elimination most lack updates through evidence-based information, as they even recommend practices that increase infection risks. This reveals a clear need to improve the planning of the care process studied, so as to reach better results in terms of patient safety quality and quantity. Prioritizing these efforts can be useful to reduce the unwanted effects of surgical site infections.

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