Forum Risk Management

Arezzo,
Martedi 25 novembre 2025

GdL 5: Individuazione delle idonee misure per la prevenzione del rischio

Michele Tancredi Loiudice – Alessandro Bonsignore

UOS Rischio clinico e sicurezza delle cure
Università di Genova

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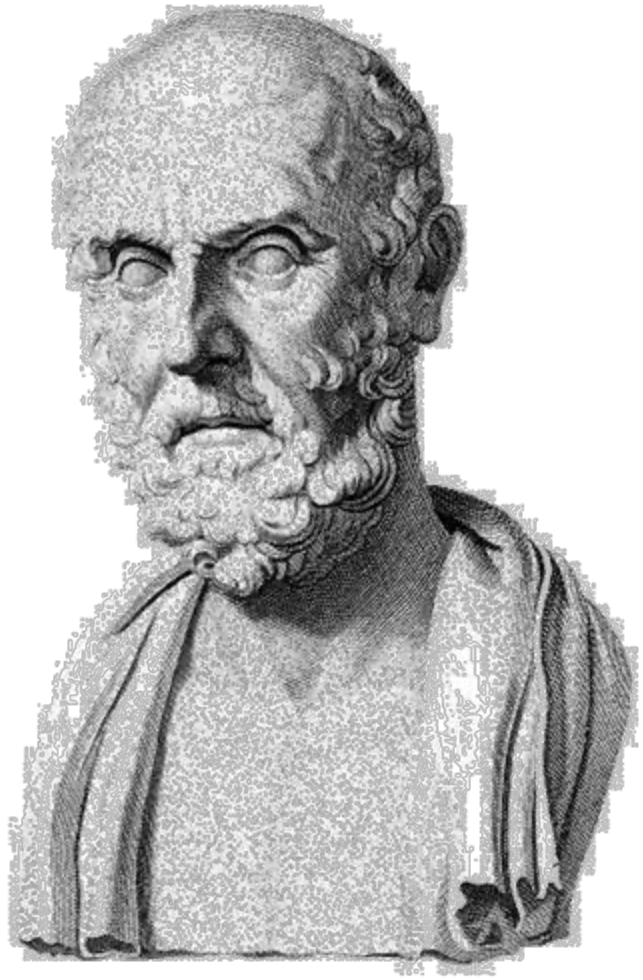
PRIMUM NON NOCERE

Non si sa se Ippocrate abbia effettivamente scritto nel suo giuramento "mi asterrò dal recar danno e offesa"

e l'origine stessa dell'allocuzione «Primum non nocere, secundum cavere, tertium sanare» «In primo luogo non fare del male, come seconda cosa agisci in sicurezza, infine favorisci la guarigione» a lui attribuita, è stata messa in discussione



Origin and Uses of *Primum Non Nocere*—
Above All, Do No Harm!

Cedric M. Smith, MD, FCP

J Clin Pharmacol 2005;45:371-377

UN APPROCCIO REALISTICO

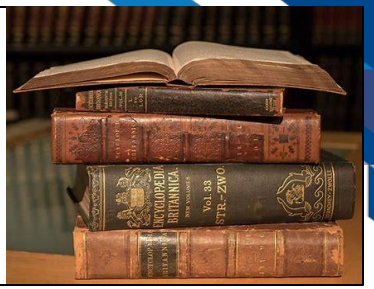
"Omnia venenum sunt: nec sine veneno quicquam existit. Dosis sola facit, ut venenum non fit"

"Tutto è veleno, e nulla esiste senza veleno. Solo la dose fa in modo che il veleno non faccia effetto."

Responsio ad quasdam accusationes calumnias suorum aemulorum et obtrectatorum. Defensio III. Descriptionis & designationis nouorum Receptorum
- Paracelso

Il rischio è insito nella natura dell'attività sanitaria

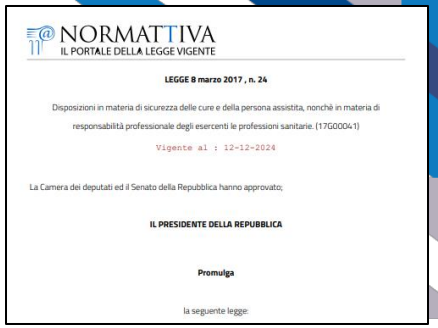
LE PAROLE CONTANO



RIDUCIBILE	EVITABILE
• Che si può ridurre, nel senso di ricondurre o di portare a una determinata Condizione: *effetto r. al suo principio*; *ragazzo riottoso, difficilmente r. all'obbedienza*.	• Che può essere evitato: male, danno, errore evitabile.

LEGGE 8 MARZO 2017, N. 24

«DISPOSIZIONI IN MATERIA DI SICUREZZA DELLE CURE E DELLA PERSONA ASSISTITA, NONCHÈ IN MATERIA DI RESPONSABILITÀ PROFESSIONALE DEGLI ESERCENTI LE PROFESSIONI SANITARIE»


NORMATTIVA
IL PORTALE DELLA LEGGE VIGENTE

LEGGE 8 marzo 2017 , n. 24

Disposizioni in materia di sicurezza delle cure e della persona assistita, nonchè in materia di responsabilità professionale degli esercenti le professioni sanitarie. (17G00041)

Vigente al : 12-12-2024

La Camera dei deputati ed il Senato della Repubblica hanno approvato;

IL PRESIDENTE DELLA REPUBBLICA

Promulga

la seguente legge:

Art. 5 legge 24/2017: Gli esercenti le professioni sanitarie, nell'esecuzione delle prestazioni sanitarie con finalità preventive, diagnostiche, terapeutiche, palliative, riabilitative e di medicina legale, si attengono, salve le specificità del caso concreto, **alle raccomandazioni previste dalle linee guida pubblicate ai sensi del comma 3** (…). In mancanza delle suddette raccomandazioni, gli esercenti le professioni sanitarie si attengono alle **buone pratiche clinico-assistenziali**.

DEFINIZIONI: LINEE GUIDA

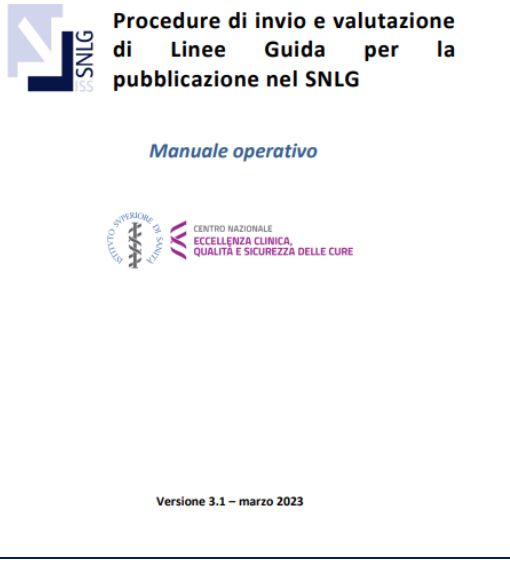
*Le Linee Guida (LG) di pratica clinica sono uno strumento di **supporto decisionale** finalizzato a consentire che, fra opzioni alternative, sia **adottata** quella che offre un **migliore** bilancio fra benefici ed effetti indesiderati, tenendo conto della esplicita e sistematica valutazione delle prove disponibili, commisurandola alle circostanze peculiari del caso concreto e condividendola-laddove possibile- con il paziente o i caregivers*

Manuale Operativo - ISS

DEFINIZIONI: BUONE PRATICHE CLINICO-ASSISTENZIALI

Tutte le pratiche clinico-assistenziali generalmente ritenute efficaci, sicure ed appropriate dalla comunità scientifica internazionale perché basate su solide prove di efficacia o su un generale consenso sulle pratiche consolidate negli anni

Manuale Operativo - ISS



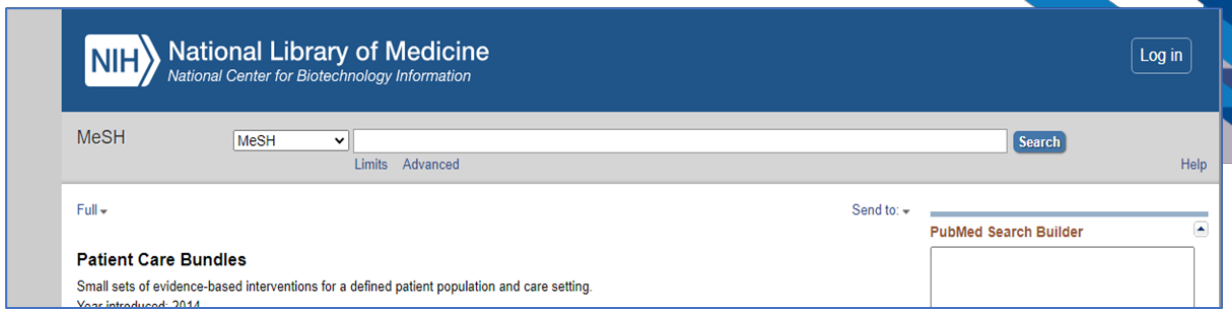
DEFINIZIONI: BUONE PRATICHE PER LA SICUREZZA

Il Decreto ministeriale 29 settembre 2017 istituisce **l'Osservatorio nazionale delle buone pratiche sulla sicurezza nella sanità** di cui all'articolo 3 legge n. 24 del 2017; definisce le funzioni dell'Osservatorio, riportando il termine "*buone pratiche per la sicurezza*" nella denominazione dell'Osservatorio; tra le sue **attività** vi è quella di **individuazione delle idonee misure per la prevenzione e gestione del rischio sanitario** e quella di **monitoraggio delle buone pratiche per la sicurezza delle cure**.

Il Legislatore ha impiegato il concetto di buona pratica, senza fornirne alcuna specifica definizione

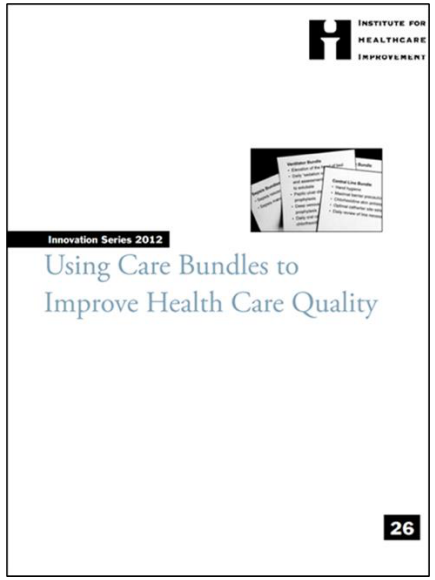
L'Osservatorio nel 2018, pubblicando un proprio glossario, le ha qualificate come "*pratiche, interventi, comportamenti che abbiano come finalità il miglioramento della sicurezza per i pazienti e/o la riduzione dei rischi e dei danni al paziente derivanti dall'assistenza sanitaria (o, più in generale, dovuti all'esposizione al sistema sanitario)", c*omprendendo, quindi, comportamenti e indicazioni, codificati o meno, volti alla prevenzione e gestione del rischio sanitario.

DEFINIZIONI: BUNDLE



Nella letteratura scientifica si presentano sia indicazioni da applicarsi ad una molteplicità di processi sanitari:

- es. i *Bundle* (trad. **set di interventi per la sicurezza**): un insieme contenuto (da 3 a 5) di elementi (interventi, comportamenti e/o pratiche evidence-based) rivolti ad una specifica tipologia di pazienti e setting di cura, che, applicati congiuntamente e in modo adeguato, migliorano la qualità e l'esito dei processi con un effetto maggiore di quello che gli stessi determinerebbero, se ogni attività fosse attuata separatamente



OSSERVATORIO NAZIONALE DELLE BUONE PRATICHE SULLA SICUREZZA NELLA SANITÀ

L'Osservatorio

- *Conferma la necessità che, alle* ***Linee Guida, si affianchi un numero significativo di Buone Pratiche*** *che forniscano indicazioni agli esercenti le professioni sanitarie;*
- ***Propone il termine di "Insieme di interventi per la Sicurezza"*** *(traduzione del termine Bundle) quale* ***format utile per l'elaborazione e individuazione di indicazioni per la riduzione del rischio*** *e per la loro successiva diffusione, implementazione e monitoraggio*

ESISTONO BUONE PRATICHE PER LA SICUREZZA PER RIDURRE LE INFEZIONI CORRELATE ALL'ASSISTENZA?

BUNDLE PER PREVENIRE LE INFEZIONI: POLMONITI ASSOCIATE A VENTILAZIONE MECCANICA

VAP

Su 38 studi considerati, 4 studi hanno indicato una bassa riduzione della VAP, in 22 studi si è riscontrato un declino della VAP superiore al 36% e in dieci la diminuzione è stata superiore al 65%

Mastrogianni, M., Katsoulas, T., Galanis, P., Korompeli, A., & Myrianthefs, P. (2023). The impact of care bundles on ventilator-associated pneumonia (VAP) prevention in adult ICUs: a systematic review. Antibiotics, 12(2), 227.

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antibiotics MDPI

Systematic Review

The Impact of Care Bundles on Ventilator-Associated Pneumonia (VAP) Prevention in Adult ICUs: A Systematic Review

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Abstract: Ventilator-associated pneumonia (VAP) remains a common risk in mechanically ventilated patients. Different care bundles have been proposed to succeed VAP reduction. We aimed to identify the combined interventions that have been used to by ICUs worldwide from the implementation of "Institute for Healthcare Improvement Ventilator Bundle", i.e., from December 2004. A search was performed on the PubMed, Scopus and Science Direct databases. Finally, 38 studies met our inclusion criteria. The most common interventions monitored in the care bundles were sedation and weaning protocols, semi-recumbent positioning, oral and hand hygiene, peptic ulcer disease and deep venus thrombosis prophylaxis, subglottic suctioning, and cuff pressure control. Head-of-bed elevation was implemented by almost all studies, followed by oral hygiene, which was the second extensively used intervention. Four studies indicated a low VAP reduction, while 22 studies found an over 36% VAP decline, and in ten of them, the decrease was over 65%. Four of these studies indicated zero or nearly zero after intervention VAP rates. The studies with the highest VAP reduction adopted the "IHI Ventilator Bundle" combined with adequate endotracheal tube cuff pressure and subglottic suctioning. Multifaced techniques can lead to VAP reduction at a great extent. Multidisciplinary measures combined with long-lasting education programs and measurement of bundle's compliance should be the gold standard combination.

Keywords: ventilator-associated pneumonia; care bundles; intensive care units; prevention

check for updates

Citation: Mastrogianni, M.; Katsoulas, T.; Galanis, P.; Korompeli, A.; Myrianthefs, P. The Impact of Care Bundles on Ventilator-Associated Pneumonia (VAP) Prevention in Adult ICUs: A Systematic Review. *Antibiotics* **2023**, *12*, 227. https://doi.org/10.3390/antibiotics12020227

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1. Introduction

Ventilator-associated pneumonia (VAP) is one of the main types of infection in critically ill mechanically ventilated patients, leading to increased mortality, morbidity, hospital stay, economic and psychological costs for patients and their families [1–4]. During the last two decades, many guidelines have been proposed to reduce the incidence of VAP. It has been scientifically proven that interventions must be combined in order to be useful [5–7]. Bundle is a set of individual components, combined to make a set of quality indicators for a specific system, procedure, or treatment [8]. These interventions must be all implemented together to achieve significantly better results [9].

In 1983, the CDC published the guidelines for the prevention of nosocomial pneumonia, which were specialized for VAP in 2003 [9]. In December 2004, the Institute for Healthcare Improvement (IHI), during the promotion of the "100,000 Lives Campaign", inserted the "IHI Ventilator Bundle", consisting of four elements: (1) elevation of the head of bed (HOB) to 30°–45°; (2) daily "sedation vacation" and assessment of readiness to

BUNDLE PER PREVENIRE LE INFEZIONI: INFEZIONI SITO CHIRURGICO SSI

I tassi di SSI sono diminuiti da 11,0 a 4,1% dopo l'implementazione del pacchetto di intervento

Weiser, M. R., Gonen, M., Usiak, S., Pottinger, T., Samedy, P., Patel, D., ... & Yeung, K. (2018). Effectiveness of a multidisciplinary patient care bundle for reducing surgical-site infections. Journal of British Surgery, 105(12), 1680-1687.

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Original article

Effectiveness of a multidisciplinary patient care bundle for reducing surgical-site infections

M. R. Weiser[1], M. Gonen[2], S. Usiak[3], T. Pottinger[4], P. Samedy[4], D. Patel[4], S. Seo[5], J. J. Smith[1], J. G. Guillem[1], L. Temple[1], G. M. Nash[1], P. B. Paty[1], A. Baldwin-Medsker[6], C. E. Cheavers[4], J. Eagan[3] and J. Garcia-Aguilar[1], on behalf of the Memorial Sloan Kettering Multidisciplinary Surgical-Site Infection Reduction Team

[1]Department of Surgery, [2]Department of Epidemiology and Biostatistics, [3]Infection Control Program, [4]Division of Quality and Safety, [5]Department of Medicine and [6]Department of Nursing, Memorial Sloan Kettering Cancer Center, New York, USA

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Background: Surgical-site infection (SSI) is associated with significant healthcare costs. To reduce the high rate of SSI among patients undergoing colorectal surgery at a cancer centre, a comprehensive care bundle was implemented and its efficacy tested.

Methods: A pragmatic study involving three phases (baseline, implementation and sustainability) was conducted on patients treated consecutively between 2013 and 2016. The intervention included 13 components related to: bowel preparation; oral and intravenous antibiotic selection and administration; skin preparation, disinfection and hygiene; maintenance of normothermia during surgery; and use of clean instruments for closure. SSI risk was evaluated by means of a preoperative calculator, and effectiveness was assessed using interrupted time-series regression.

Results: In a population with a mean BMI of 30 kg/m^2, diabetes mellitus in 17·5 per cent, and smoking history in 49·3 per cent, SSI rates declined from 11·0 to 4·1 per cent following implementation of the intervention bundle ($P = 0·001$). The greatest reductions in SSI rates occurred in patients at intermediate or high risk of SSI: from 10·3 to 4·7 per cent ($P = 0·006$) and from 19 to 2 per cent ($P < 0·001$) respectively. Wound care modifications were very different in the implementation phase (43·2 *versus* 24·9 per cent baseline), including use of an overlying surface vacuum dressing (17·2 from 1·4 per cent baseline) or leaving wounds partially open (13·2 from 6·7 per cent baseline). As a result, the biggest difference was in wound-related rather than organ-space SSI. The median length of hospital stay decreased from 7 (i.q.r. 5–10) to 6 (5–9) days ($P = 0·002$). The greatest reduction in hospital stay was seen in patients at high risk of SSI: from 8 to 6 days ($P < 0·001$). SSI rates remained low (4·5 per cent) in the sustainability phase.

Conclusion: Meaningful reductions in SSI can be achieved by implementing a multidisciplinary care bundle at a hospital-wide level.

Paper accepted 3 May 2018
Published online 4 July 2018 in Wiley Online Library (www.bjs.co.uk). **DOI:** 10.1002/bjs.10896

Introduction

Surgical-site infection (SSI) accounts for more than one-third of all inpatient infectious events[1]. SSI can manifest as wound erythema and discharge when it is superficial, or as sepsis when it is deep and involves fascia or an intra-abdominal organ space. Along with added morbidity and delayed convalescence, SSI places considerable financial strain on the healthcare system[2,3] owing to prolonged hospital care, readmission and disability[4–6]. Treatments include opening a surgical incision, antibiotics, or an invasive procedure to drain an abscess or debride tissue. A perioperative mortality rate for SSI of 3 per cent has been reported, with 75 per cent of associated deaths directly attributable to the SSI[7].

SSI is a direct consequence of surgery, and some instances may be preventable. Intensive quality improvement initiatives have been developed in the USA, including the Surgical Infection Prevention Project[8] and the Surgical Care Improvement Project (SCIP)[9]. These initiatives were first implemented for high-risk procedures such

BUNDLE PER PREVENIRE LE INFEZIONI: CLABSI

Il tasso medio CLABSI è sceso da 2,2/1000 giorni di linea centrale (picco di 5,2/1000 giorni di linea centrale nel quarto trimestre 2008) durante il periodo pre-intervento a 0,5/1000 giorni di linea centrale (0/1000 giorni di linea centrale da luglio 2012 a luglio 2014) durante il periodo post-intervento.

Entesari-Tatafi, D., Orford, N., Bailey, M. J., Chonghaile, M. N. I., Lamb-Jenkins, J., & Athan, E. (2015). Effectiveness of a care bundle to reduce central line-associated bloodstream infections. Medical Journal of Australia, 202(5), 247-249.

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Effectiveness of a care bundle to reduce central line-associated bloodstream infections

The central line-associated bloodstream infections rate ... decreased from 2.2 in the pre-intervention period to 0.5 in the post-intervention period

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doi: 10.5694/mja14.01644

Abstract

Objective: To determine the effectiveness of a care bundle, with a novel line maintenance procedure, in reducing the rate of central line-associated bloodstream infection (CLABSI) in the intensive care unit (ICU).

Design, participants and setting: Before-and-after study using CLABSI data reported to the Victorian Healthcare Associated Infection Surveillance System (VICNISS), in adult patients admitted to a tertiary adult ICU in regional Victoria between 1 July 2006 and 30 June 2014. VICNISS-reported CLABSI cases were reviewed for verification. An intervention was implemented in 2009.

Intervention: The care bundle introduced in 2009 included a previously established line insertion procedure and a novel line maintenance procedure comprising Biopatch, daily 2% chlorhexidine body wash, daily ICU central line review, and liaison nurse follow-up of central lines.

Main outcome measures: CLABSI rate (cases per 1000 central line days).

Results: The average CLABSI rate fell from 2.2/1000 central line days (peak of 5.2/1000 central line days in quarter 4, 2008) during the pre-intervention period to 0.5/1000 central line days (0/1000 central line days from July 2012 to July 2014) during the post-intervention period.

Conclusion: Our study suggests that this care bundle, using a novel maintenance procedure, can effectively reduce the CLABSI rate and maintain it at zero out to 2 years.

Central line-associated bloodstream infections (CLABSIs) are an important source of morbidity, mortality and cost.[1] About 4000 CLABSIs occur in Australian intensive care units (ICUs) each year, with an estimated nationwide cost of $36.26 million and a mortality rate of 4%–20%.[2,3] The importance placed on CLABSI and its prevention has prompted standardised monitoring for quality assurance and innovation of preventive strategies.[3,4,5] Care bundles focused on improving line insertion procedure have proven successful overseas.[3,6] Local implementation of a similar care bundle to that used overseas across New South Wales proved successful, and prompted the Australian and New Zealand Intensive Care Society CLABSI Prevention Project.[7,8] Despite these interventions, CLABSI rates range from 0.9 to 3.6 per 1000 central line days.[4,7,9-20]

The Victorian Healthcare Associated Infection Surveillance System (VICNISS) collects standardised ICU CLABSI rates for the state of Victoria.[21] Since 2006, the University Hospital Geelong (UHG) ICU has reported CLABSI rates to VICNISS.

An elevated reported CLABSI rate at UHG in 2007 and 2008 (3.8 and 3.6, respectively, compared with the state average of 2.7 per 1000 central line days)[22] prompted development and introduction of a CLABSI prevention care bundle. Our care bundle used an effective line insertion procedure identified from previous studies,[3,4,7] but also incorporated a novel maintenance procedure. In this article, we report the effectiveness of this care bundle in a tertiary ICU in Victoria.

Methods

We undertook a before-and-after study, retrospectively accessing the pre-intervention data, at an adult, tertiary, 19-bed ICU that admits medical, surgical and cardiac surgical patients. Ethics approval was obtained from the Barwon Health Research Review Committee. This project was performed as part of the authors' usual roles and no funding or subsidy was received. All of us had full access to the study data.

Intervention

The care bundle was based on the Australian and New Zealand Intensive Care Society CLABSI prevention project,[8] comprehensive literature review and collaboration between UHG ICU, UHG Infection Control Services and other key stakeholders. The final care bundle (Appendix 1) included standard line insertion procedure consistent with that described previously,[4,7] bedside audit by an observer with stopping rules, and a novel line maintenance procedure that included placement of a Biopatch (Johnson and Johnson), sterile line access, daily 2% chlorhexidine body wash, daily central venous catheter (CVC) review with early line removal, and liaison nurse follow-up of all CVCs present at discharge.

Study procedure

All adult patients admitted to UHG ICU between 1 July 2006 and 30 June 2014 were captured in this study. The care bundle was introduced in 2009, dividing patients into a pre-intervention period (1 July 2006 to 31 December 2009) and a post-intervention period (1 January 2010 to 30 June 2014). Case identification of CLABSI was based on the VICNISS dataset and review of blood cultures. All VICNISS-reported CLABSI cases were reviewed by one of us (DE) to confirm that they fulfilled the current VICNISS definition (Appendix 2). This definition is consistent with the internationally accepted O'Grady definition that has been previously applied.[7,23]

All confirmed CLABSIs were included in the analysis, irrespective of whether line insertion occurred in the ICU. Cohort demographic, basic clinical and microbiological data were collected from the hospital electronic database. Patient medical records of all VICNISS-reported CLABSI cases were reviewed to confirm CLABSI definition and collect additional clinical information. Finally, all positive

BUNDLE PER PREVENIRE LE INFEZIONI: CAUTI

L'incidenza e i tassi di CAUTI sono stati rispettivamente del 5,8% e 6,1 per 1000 giorni di catetere urinario e dell'1,5% e 1,8 per 1000 giorni di catetere urinario. C'era una differenza statisticamente significativa tra i tassi CAUTI pre-bundle e post-bundle.

Düzkaya, D. S., Bozkurt, G., Uysal, G., & Yakut, T. (2016). The effects of bundles on catheter-associated urinary tract infections in the pediatric intensive care unit. Clinical Nurse Specialist, 30(6), 341-346.

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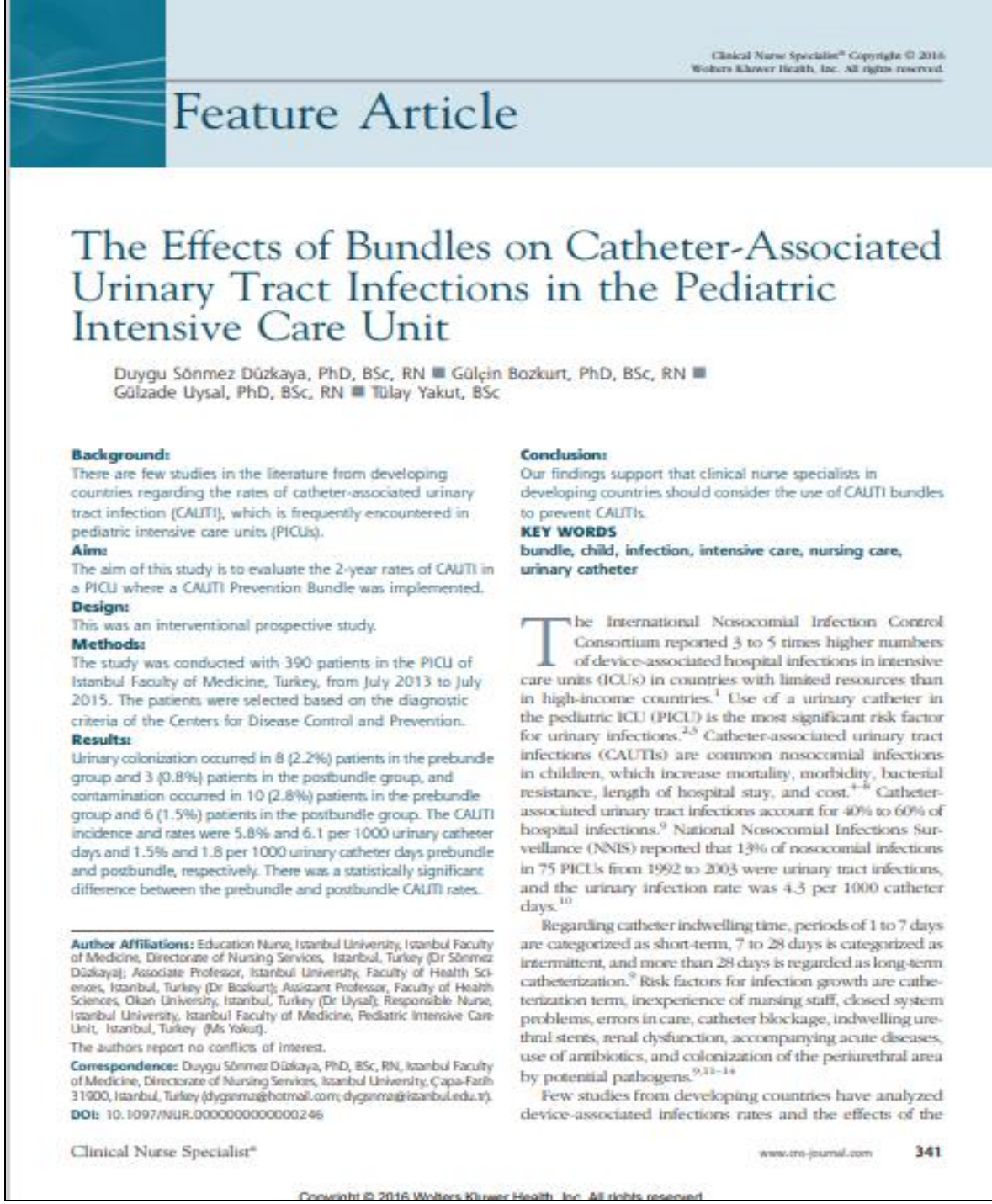

Feature Article

The Effects of Bundles on Catheter-Associated Urinary Tract Infections in the Pediatric Intensive Care Unit

Duygu Sönmez Düzkaya, PhD, BSc, RN ■ Gülçin Bozkurt, PhD, BSc, RN ■ Gülzade Uysal, PhD, BSc, RN ■ Tülay Yakut, BSc

Background: There are few studies in the literature from developing countries regarding the rates of catheter-associated urinary tract infection (CAUTI), which is frequently encountered in pediatric intensive care units (PICUs).

Aim: The aim of this study is to evaluate the 2-year rates of CAUTI in a PICU where a CAUTI Prevention Bundle was implemented.

Design: This was an interventional prospective study.

Methods: The study was conducted with 390 patients in the PICU of Istanbul Faculty of Medicine, Turkey, from July 2013 to July 2015. The patients were selected based on the diagnostic criteria of the Centers for Disease Control and Prevention.

Results: Urinary colonization occurred in 8 (2.2%) patients in the prebundle group and 3 (0.8%) patients in the postbundle group, and contamination occurred in 10 (2.8%) patients in the prebundle group and 6 (1.5%) patients in the postbundle group. The CAUTI incidence and rates were 5.8% and 6.1 per 1000 urinary catheter days and 1.5% and 1.8 per 1000 urinary catheter days prebundle and postbundle, respectively. There was a statistically significant difference between the prebundle and postbundle CAUTI rates.

Conclusion: Our findings support that clinical nurse specialists in developing countries should consider the use of CAUTI bundles to prevent CAUTIs.

KEY WORDS
bundle, child, infection, intensive care, nursing care, urinary catheter

The International Nosocomial Infection Control Consortium reported 3 to 5 times higher numbers of device-associated hospital infections in intensive care units (ICUs) in countries with limited resources than in high-income countries.[1] Use of a urinary catheter in the pediatric ICU (PICU) is the most significant risk factor for urinary infections.[2,3] Catheter-associated urinary tract infections (CAUTIs) are common nosocomial infections in children, which increase mortality, morbidity, bacterial resistance, length of hospital stay, and cost.[4–8] Catheter-associated urinary tract infections account for 40% to 60% of hospital infections.[9] National Nosocomial Infections Surveillance (NNIS) reported that 13% of nosocomial infections in 75 PICUs from 1992 to 2003 were urinary tract infections, and the urinary infection rate was 4.3 per 1000 catheter days.[10]

Regarding catheter indwelling time, periods of 1 to 7 days are categorized as short-term, 7 to 28 days is categorized as intermittent, and more than 28 days is regarded as long-term catheterization.[9] Risk factors for infection growth are catheterization term, inexperience of nursing staff, closed system problems, errors in care, catheter blockage, indwelling urethral stents, renal dysfunction, accompanying acute diseases, use of antibiotics, and colonization of the periurethral area by potential pathogens.[9,11–14]

Few studies from developing countries have analyzed device-associated infections rates and the effects of the

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The authors report no conflicts of interest.

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DOI: 10.1097/NUR.0000000000000246

BUNDLE PER PREVENIRE LE INFEZIONI: SEPSIS

La mortalità intraospedaliera per SEPSI è stata del 54,0% da luglio 2005 ad aprile 2006, del 41,1% da maggio a dicembre 2006, del 39,3% nel 2007, del 41,4% nel 2008 e del 16,2% nel 2009

Shiramizo, S. C. P. L., Marra, A. R., Durao, M. S., Paes, A. T., Edmond, M. B., & Pavao dos Santos, O. F. (2011). Decreasing mortality in severe sepsis and septic shock patients by implementing a sepsis bundle in a hospital setting. PloS one, 6(11), e26790.

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Decreasing Mortality in Severe Sepsis and Septic Shock Patients by Implementing a Sepsis Bundle in a Hospital Setting

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Abstract

Background: The Surviving Sepsis Campaign (SSC) guidelines for the management of severe sepsis (SS) and septic shock (SSh) have been recommended to reduce morbidity and mortality.

Materials and Methods: A quasi-experimental study was conducted in a medical-surgical ICU. Multiple interventions to optimize SS and SSh shock patients' clinical outcomes were performed by applying sepsis bundles (6- and 24-hour) in May 2006. We compared bundle compliance and patient outcomes before (July 2005-April 2006) and after (May 2006-December 2009) implementation of the interventions.

Results: A total of 564 SS and SSh patients were identified. Prior to the intervention, compliance with the 6 hour-sepsis resuscitation bundle was only 6%. After the intervention, compliance was as follows: 8.2% from May to December 2006, 9.3% in 2007, 21.1% in 2008 and 13.7% in 2009. For the 24 hour-management bundle, baseline compliance was 15.0%. After the intervention, compliance was 15.1% from May to December 2006, 21.4% in 2007, 27.8% in 2008 and 44.4% in 2009. The in-hospital mortality was 54.0% from July 2005 to April 2006, 41.1% from May to December 2006, 39.3% in 2007, 41.4% in 2008 and 16.2% in 2009.

Conclusion: These results suggest reducing SS and SSh patient mortality is a complex process that involves multiple performance measures and interventions.

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Introduction

Severe sepsis and septic shock are the major causes of admission and death in intensive care units (ICUs). The sepsis syndromes are lethal and expensive conditions, with hospital mortality rates for severe sepsis ranging between 30% and 50% [1,2]. In the United States, this results in an estimated 751,000 cases and 215,000 deaths annually [1]. In Brazil, the incidence density is 57 per 1,000 patient-days and the mortality rate of patients with severe sepsis and septic shock is 47.3% and 52.2%, respectively [3].

In 2004, the Surviving Sepsis Campaign (SSC) introduced guidelines for the management of severe sepsis and septic shock, as well as strategies for bedside implementation [4,5]. The treatment recommendations were organized in two bundles: a resuscitation bundle (6 tasks to begin immediately and to be accomplished within 6 hours) and a management bundle (4 tasks to be completed within 24 hours). The 6-hour resuscitation bundle includes the lactate determination, early cultures and antibiotic therapy as soon as possible, and "early goal directed therapy" (EGDT) [2]. The first 24-hour management bundle includes optimization of glycemic control, respiratory inspiratory plateau pressure, and determination of the need for corticosteroids and drotrecogin alfa (activated). EGDT is simply a protocol derived from components that have long been recommended as standard care for the septic patient to optimize hemodynamics. Of note, we did not use packed red blood cells as a resuscitation fluid nor did we use dobutamine as a standard of care for all septic shock patients.

The aims of this study were to determine the rate of compliance with 6-hour and 24-hour sepsis bundles, and to determine the impact of compliance on hospital mortality in patients with severe sepsis and septic shock.

Methods

This study was conducted in the ICU of a tertiary care, private hospital in São Paulo, Brazil. This open model ICU is a 38-bed medical-surgical unit where approximately 2,200 patients are admitted each year.

APPLICAZIONE DELLE MISURE SPECIFICHE

La Joint Commission International richiede nelle strutture accreditate alcuni bundles come quello:

1. Per la prevenzione della infezione del torrente ematico associata a cateterismo venoso centrale (CLABSI)
2. Per la prevenzione della polmonite associata alla ventilazione assistita (VAP)
3. Per la prevenzione dell'infezione del tratto urinario associata a catetere vescicale (CAUTI)
4. Per la prevenzione dell'infezione del sito chirurgico (SSI)
5. Per la prevenzione della sepsi severa (SEPSIS)

ESEMPI DI MODALITÀ DI VERIFICA DELLE MISURE SPECIFICHE

Hand hygiene performed before catheter insertion	☐
Aseptic technique followed/Sterile equipment used	☐
Maximal barrier precautions followed (Gown, Gloves, Mask etc)	☐
Proper disinfection of insertion site done	☐
Application of lubricant or anaesthetic gel	☐
Catheter gently inserted	☐
Replace if a break in asepsis occurs	☐
Proper securing of catheter in the bladder	☐
Catheterization is documented/labelled (Date, Time & Personnel)	☐
Comments if any:	

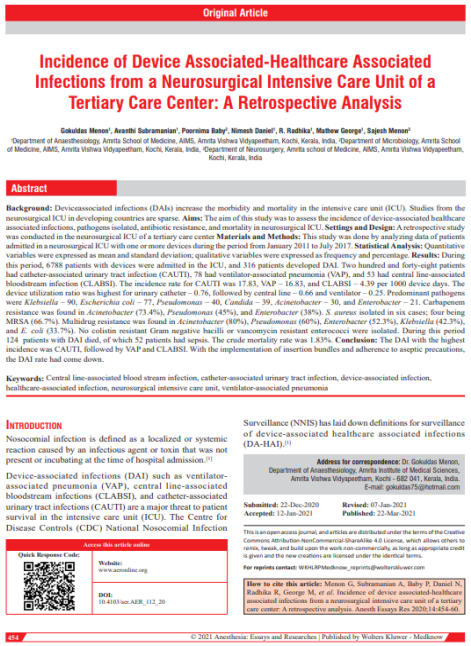
Urinary catheter bundle follow-up:	Day 1		
	Shift 1	Shift 2	Shift 3
Proper fixing of catheter on thigh			
Urobag not touching the floor			
Urine flow should remain unobstructed			
Perform routine hygienic meatal care			
Handwashing done after catheter/urobag manipulation			
Maintaining closed drainage system			
Urobag emptied every 6 hours			
Proper disinfection of sample collection site			
Urine aspirated for culture using sterile needle & syringe			
Specimen transported to lab within 2 hours of collection			
Sterility maintained throughout the procedure			
Handwashing done after removal of gloves			

Figure 3: Urinary catheter insertion bundle checklist and follow-up

Hand hygiene performed before intubation	☐
Aseptic technique followed	☐
Sterile/disinfected equipment used	☐
Maximal barrier precautions followed (Gown, Gloves, Mask etc)	☐
Oral suction done before insertion	☐
ET-Tube gently inserted	☐
Used sterile suction catheter & gloves for each ET-suctioning	☐
Checked cuff pressure and & dislocation of ET-Tube	☐
Proper securing of ET-Tube done	☐
Comments if any:	

Ventilator bundle follow-up:	Day 1		
	Shift 1	Shift 2	Shift 3
Head end elevation (30-45°)			
Antiseptic oral care			
Daily sedation vacation			
PUO prophylaxis			
DVT prophylaxis			
Assessment of readiness to extubate			

Figure 4: Intubation bundle checklist and follow-up



Original Article

Incidence of Device Associated-Healthcare Associated Infections from a Neurosurgical Intensive Care Unit of a Tertiary Care Center: A Retrospective Analysis

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Abstract

Background: Deviceassociated infections (DAIs) increase the morbidity and mortality in the intensive care unit (ICU). Studies from the neurosurgical ICU in developing countries are sparse. **Aims:** The aim of this study was to assess the incidence of device-associated healthcare associated infections, pathogens isolated, antibiotic resistance, and mortality in neurosurgical ICU. **Settings and Design:** A retrospective study was conducted in the neurosurgical ICU of a tertiary care center **Materials and Methods:** This study was done by analyzing data of patients admitted in a neurosurgical ICU with one or more devices during the period from January 2011 to July 2017. **Statistical Analysis:** Quantitative variables were expressed as mean and standard deviation; qualitative variables were expressed as frequency and percentage. **Results:** During this period, 6788 patients with devices were admitted in the ICU, and 316 patients developed DAI. Two hundred and forty-eight patients had catheter-associated urinary tract infection (CAUTI), 78 had ventilator-associated pneumonia (VAP), and 53 had central line-associated bloodstream infection (CLABSI). The incidence rate for CAUTI was 17.83, VAP – 16.83, and CLABSI – 4.39 per 1000 device days. The device utilization ratio was highest for urinary catheter – 0.76, followed by central line – 0.66 and ventilator – 0.25. Predominant pathogens were *Klebsiella* – 90, *Escherichia coli* – 77, *Pseudomonas* – 40, *Candida* – 39, *Acinetobacter* – 30, and *Enterobacter* – 21. Carbapenem resistance was found in *Acinetobacter* (73.4%), *Pseudomonas* (45%), and *Enterobacter* (38%). *S. aureus* isolated in six cases; four being MRSA (66.7%). Multidrug resistance was found in *Acinetobacter* (80%), *Pseudomonas* (60%), *Enterobacter* (52.3%), *Klebsiella* (42.3%), and *E. coli* (33.7%). No colistin resistant Gram negative bacilli or vancomycin resistant enterococci were isolated. During this period 124 patients with DAI died, of which 52 patients had sepsis. The crude mortality rate was 1.83%. **Conclusion:** The DAI with the highest incidence was CAUTI, followed by VAP and CLABSI. With the implementation of insertion bundles and adherence to aseptic precautions, the DAI rate had come down.

Keywords: Central line-associated blood stream infection, catheter-associated urinary tract infection, device-associated infection, healthcare-associated infection, neurosurgical intensive care unit, ventilator-associated pneumonia

Introduction

Nosocomial infection is defined as a localized or systemic reaction caused by an infectious agent or toxin that was not present or incubating at the time of hospital admission.[1]

Device-associated infections (DAI) such as ventilator-associated pneumonia (VAP), central line-associated bloodstream infections (CLABSI), and catheter-associated urinary tract infections (CAUTI) are a major threat to patient survival in the intensive care unit (ICU). The Centre for Disease Controls (CDC) National Nosocomial Infection Surveillance (NNIS) has laid down definitions for surveillance of device-associated healthcare associated infections (DA-HAI).[1]

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Hand hygiene performed before catheter insertion & manipulating the catheter	☐
Maximal barrier precautions followed (Gown, Gloves, Mask etc)	☐
Chlorhexidine skin antisepsis done	☐
Optimal catheter site selection (preferably subclavian)	☐
Catheter insertion is documented/labelled (Date, Time & Personnel)	☐
Antiseptic dressing done	☐
Comments if any:	

Central line bundle follow-up:	Day 1		
	Shift 1	Shift 2	Shift 3
Hand hygiene performed before & after manipulating			
Hub cleaning done before accessing the catheter			
Daily review of catheter insertion site			

Interventions to improve CLABSI rates (ICMR-CDC)

1. Hands on training for nurses on appropriate handling of central lines
2. Silent observation by House surgeons to monitor the management of central lines based on modified central line care checklist.
3. Re-training of nurses based on the observations by House surgeons
4. Blue sheet – to cover the central lines

Figure 5: Central line insertion bundle checklist and follow-up

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MISURE DI GESTIONE GENERALI PER LA RIDUZIONE DELLE INFEZIONI

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Effectiveness of hand washing and disinfection methods in removing transient bacteria after patient nursing

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SUMMARY

The effectiveness of various hand washing and disinfection methods in removing transient skin bacteria was studied in hospital after dry or moist contamination of the hands when nursing burn patients. The results were compared with those of laboratory tests with volunteers. A fairly good correlation of the bacterial reductions existed between hospital and laboratory tests. All other methods removed *Staph. aureus* from the hands more effectively than liquid soap. Gram-negative bacilli were more easily removed than staphylococci, even with soap wash alone.

In hospital, none of the washing and disinfection methods always removed all patient-borne bacteria from the hands. After dry or moist contamination and subsequent washing with soap only, colonies of *Staph. aureus* were often detected in finger-print samples. Staphylococci were more often completely removed by a 4% chlorhexidine detergent scrub and alcoholic solutions (either with or without previous soap wash) than by liquid soap, hexachlorophene or iodophor preparations. Gram-negative bacilli were more easily removed by all the washing and disinfection methods. After moist contamination, Gram-negative bacilli were more often completely removed from the hands by ethanol than by other treatments.

The results of the present study emphasize the importance of always using gloves when nursing a profuse spreader of bacteria or one who must be protected from infection.

INTRODUCTION

The main goal of hand washing in hospital is to cut the route or transmission of pathogenic micro-organisms to patients. Usually the removal of transient microbes is sufficient, although in special circumstances the reduction of resident bacteria is of additional advantage. The effectiveness of some disinfectants in removing various transient bacteria has been studied in a simplified test design after artificial contamination of the hands (Lowbury, Lilly & Bull, 1964; Mittermeyer & Rotter, 1975; Lilly & Lowbury, 1978). Such studies, however, overlook many variables common in everyday hospital practice. In hospital, prolonged use of soaps or disinfectants, high hand washing frequency, differences in the skin of hospital staff or other factors may yield results unlike those obtained in tests with volun-

0022-1724/80/0089-1979 $01.00

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PeerJ

The role of textiles as fomites in the healthcare environment: a review of the infection control risk

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ABSTRACT

Background. Infectious diseases are a significant threat in both healthcare and community settings. Healthcare associated infections (HCAIs) in particular are a leading cause of complications during hospitalisation. Contamination of the healthcare environment is recognised as a source of infectious disease yet the significance of porous surfaces including healthcare textiles as fomites is not well understood. It is currently assumed there is little infection risk from textiles due to a lack of direct epidemiological evidence. Decontamination of healthcare textiles is achieved with heat and/or detergents by commercial or in-house laundering with the exception of healthcare worker uniforms which are laundered domestically in some countries. The emergence of the COVID-19 pandemic has increased the need for rigorous infection control including effective decontamination of potential fomites in the healthcare environment. This article aims to review the evidence for the role of textiles in the transmission of infection, outline current procedures for laundering healthcare textiles and review studies evaluating the decontamination efficacy of domestic and industrial laundering.

Methodology. Pubmed, Google Scholar and Web of Science were searched for publications pertaining to the survival and transmission of microorganisms on textiles with a particular focus on the healthcare environment.

Results. A number of studies indicate that microorganisms survive on textiles for extended periods of time and can transfer on to skin and other surfaces suggesting it is biologically plausible that HCAIs and other infectious diseases can be transmitted directly through contact with contaminated textiles. Accordingly, there are a number of case studies that link small outbreaks with inadequate laundering or infection control processes surrounding healthcare laundry. Studies have also demonstrated the survival of potential pathogens during laundering of healthcare textiles, which may increase the risk of infection supporting the data published on specific outbreak case studies.

Conclusions. There are no large-scale epidemiological studies demonstrating a direct link between HCAIs and contaminated textiles yet evidence of outbreaks from published case studies should not be disregarded. Adequate microbial decontamination of linen and infection control procedures during laundering are required to minimise the risk of infection from healthcare textiles. Domestic laundering of healthcare worker uniforms is a particular concern due to the lack of control and monitoring of decontamination, offering a route for potential pathogens to enter the clinical environment. Industrial laundering of healthcare worker uniforms provides greater assurances of adequate decontamination compared to domestic laundering, due to the

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Additional Information and Declarations can be found on page 26

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Expert Commentary

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Hospital design for better infection control

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ABSTRACT

The physical design and infrastructure of a hospital or institution is an essential component of its infection control measure. Thus is must be a prerequisite to take these into consideration from the initial conception and planning stages of the building. The balance between designing a hospital to be an open, accessible and public place and the control to reduce the spread of infections diseases is a necessity. At Singapore General Hospital, many lessons were learnt during the SARS outbreak pertaining to this. During and subsequent to the SARS outbreak, many changes evolved in the hospital to enable us to handle and face any emerging infectious situation with calm, confidence and the knowledge that staff and patients will be in good stead.

This paper will share some of our experiences as well as challenges

Key Words: Emerging infection, infection control measures

INTRODUCTION

When the statutes of the hospital of St John Bridgewater were developed in 1219, Bishop Joscelin of Bath commented -, "No lepers, lunatics or persons having the following sickness or other contagious diseases are to be admitted to the house, and if any such be admitted by mistake, they are to be expelled as soon as possible".[1] Hospitals and healthcare institutions have certainly come a long way from the days of Bishop Joscelin. We are not as drastic in our sentiments today and we do not expel patients with infectious diseases. In fact, we admit them to suitably planned facilities and rooms and ensure that they do not cause unnecessary hazards to staff and other hospital users.

The physical design of a hospital is an essential component of its infection control measures to minimize the risk of transmission of any infectious disease. When historical and traditional hospitals were built, there were minimal concerns of new emerging infectious diseases. Today, with a more progressive outlook, it is the fundamental requirement to adopt a holistic view of the design and management of hospitals. Designing hospitals to be open, public spaces can make it difficult to control the spread of infectious diseases. The ease of travel and transportation today helps people cross borders easily. They can harbor, carry or catch infectious agents readily. During the Severe Acute Respiratory Syndrome (SARS) outbreak it became clear that the multiple public entrances in hospitals make it difficult, and often costly, to control entry and thus infiltration of infectious diseases.[2,3]

Only a few hospitals have an adequate supply of isolation and negative pressure rooms in wards, emergency departments (EDs) and Intensive Care Units (ICUs). While hospitals may not have complete control over host factors and agents, they are still responsible for the environment that surrounds the patients. By controlling and ensuring adequate sanitization of the environment of the host, hospital authorities can reduce the incidence of hospital acquired infections.

A decision on hospital buildings must be based on multiple factors besides cost, like fire protection, strength of construction material, hygiene, building health, environmental protection, sound isolation, energy saving, durability and utilization rate, among others. Even after initial completion of the hospital building, systematic data collection and feedback for addition, modification and upgrading of the infrastructure must be ongoing.[4] Built-in flexibility in design is becoming more crucial, mainly because technology is quickly obsolete and patient population is constantly changing. For example, single rooms may be more useful to have as they can be converted to isolation rooms more readily during an outbreak. Healthcare buildings are a complex environment with a need for specialized areas like high wear and tear areas, circulation areas, wards, specialized theatres and hazardous material chain of disposition. Choice of material

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ESEMPI DI MODALITÀ DI VERIFICA DELLE MISURE GENERALI: LAVAGGIO DELLE MANI CON SAPONE

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Soap/Handrub Consumption Survey

Measuring the Consumption of Products in Association with the Implementation of WHO Multimodal Hand Hygiene Improvement Strategy

Purpose

This tool provides a simple template to measure the consumption of products (e.g. soap and alcohol-based handrubs) associated with implementing a hand hygiene improvement strategy.

Measuring the consumption of these products is an indirect method of monitoring hand hygiene performance. This indicator can help to assess the uptake of the intervention as a whole and provides an overall indication of its success. It also provides the opportunity to control stock levels over the short- and medium-term and to help estimate likely increases in requirements, particularly relating to alcohol-based handrub.

Method

In general, the data collection method and the area in which data are collected (selected wards or the entire health-care facility) should not be changed so as to obtain comparable data at different moments in time.

A simple way to collect data is through the central purchasing unit, if this exists, by regularly reviewing the order forms (monthly) for the selected product (e.g. alcohol-based handrub solutions). Alternatively, the information could be retrieved from the pharmacy or the service in charge of the distribution of the products to the wards. It is important to identify a method which fits the purchase/distribution procedure at the facility level and is optimal in terms of time investment and reliability of the information.

Measurement of consumption should be repeated at the end of each month; if this is not feasible, it should be undertaken at time intervals that are better suited to the purchase/distribution cycle in the hospital/ward. The grid for information collection included in this document offers the possibility to record data by month up to a period of 6 months. A new form should be filled in for every 6-month period. If monthly data are not available, cumulative data corresponding to longer periods (e.g. 3 or 6 months) should be entered. This measurement will contribute to the development of a plan for long-term procurement sustainability of products and monitoring of usage.

Calculations of consumption made on the basis of purchased or distributed products may be biased by the amount of product still in stock (i.e. not all products may have been used). Please ensure that the amount in stock is subtracted to calculate the real product consumption. It is important to indicate whether the amount reported corresponds to the purchased or to the used product.

If you use different products (e.g. different alcohol-based handrub formulations), please fill in one form for each product. A separate grid is used to register the use of soap.

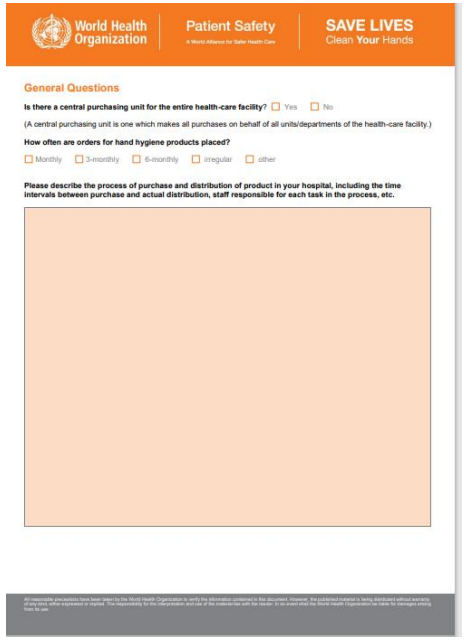
Units of products may differ in volume and weight. Please indicate the number of units used (e.g. number of bottles) and the equivalent number of litres or total weight of the product.

Any variation in workforce or number of beds needs to be recorded; this also holds true for a sudden increase in beds (e.g., the opening of a new ward may drastically influence product consumption).

Feedback

- The attached protocol forms are for measurement of consumption over a 6-month period.
- The forms should be filled in monthly, preferably at the end of each month.
- At the end of the 6-month period, product consumption can be tabulated for the whole facility or the respective departments/wards.
- An increasing consumption trend indicates the success of the hand hygiene intervention.
- Static or declining trends post-implementation need to be examined closely. They may be linked to lack of product availability, distribution delays or interruptions, or other reasons.

Revised August 2009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General Questions

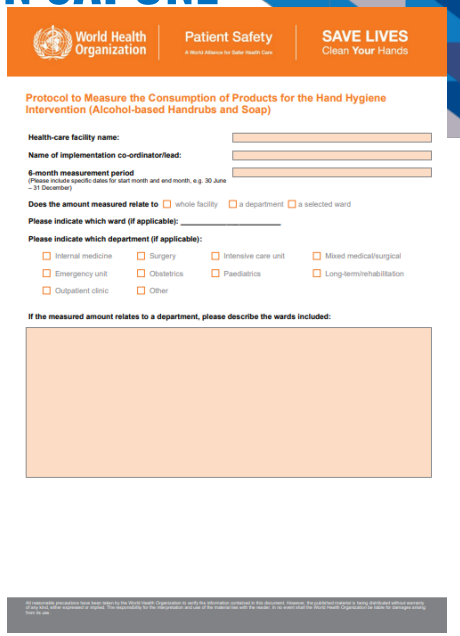
Is there a central purchasing unit for the entire health-care facility? ☐ Yes ☐ No

(A central purchasing unit is one which makes all purchases on behalf of all units/departments of the health-care facility.)

How often are orders for hand hygiene products placed?

☐ Monthly ☐ 3-monthly ☐ 6-monthly ☐ irregular ☐ other

Please describe the process of purchase and distribution of product in your hospital, including the time intervals between purchase and actual distribution, staff responsible for each task in the process, etc.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Protocol to Measure the Consumption of Products for the Hand Hygiene Intervention (Alcohol-based Handrubs and Soap)

Health-care facility name:

Name of implementation co-ordinator/lead:

6-month measurement period
(Please include specific dates for start month and end month, e.g. 30 June – 31 December)

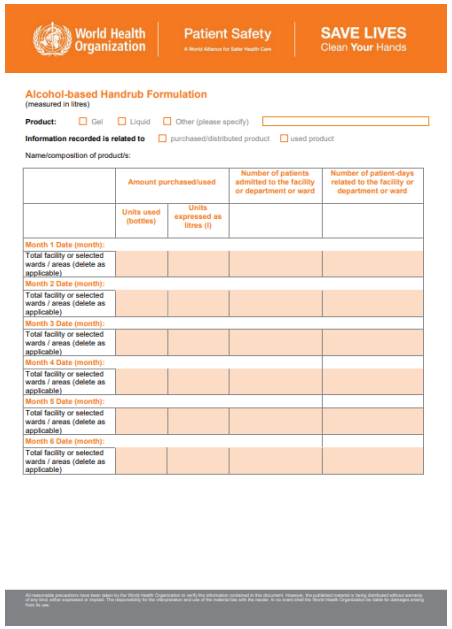
Does the amount measured relate to ☐ whole facility ☐ a department ☐ a selected ward

Please indicate which ward (if applicable): _____

Please indicate which department (if applicable):

☐ Internal medicine ☐ Surgery ☐ Intensive care unit ☐ Mixed medical/surgical
☐ Emergency unit ☐ Obstetrics ☐ Paediatrics ☐ Long-term/rehabilitation
☐ Outpatient clinic ☐ Other

If the measured amount relates to a department, please describe the wards included: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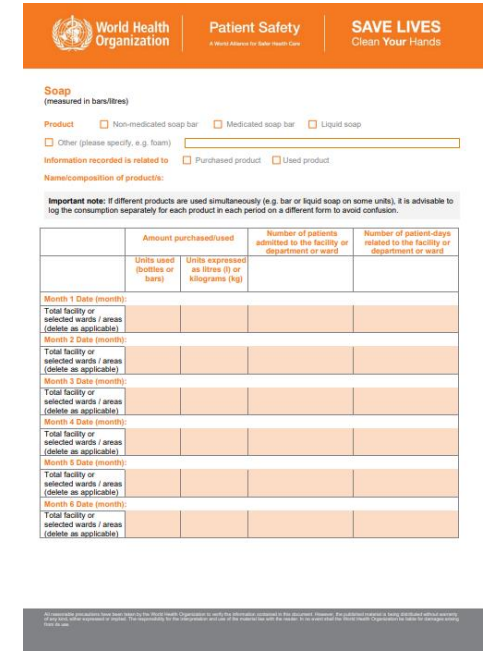
Alcohol-based Handrub Formulation
(measured in litres)

Product: ☐ Gel ☐ Liquid ☐ Other (please specify)

Information recorded is related to ☐ purchased/distributed product ☐ used product

Name/composition of product/s:

	Amount purchased/used		Number of patients admitted to the facility or department or ward	Number of patient-days related to the facility or department or ward
	Units used (bottles)	Units expressed as litres (l)		
Month 1 Date (month):				
Total facility or selected wards / areas (delete as applicable)				
Month 2 Date (month):				
Total facility or selected wards / areas (delete as applicable)				
Month 3 Date (month):				
Total facility or selected wards / areas (delete as applicable)				
Month 4 Date (month):				
Total facility or selected wards / areas (delete as applicable)				
Month 5 Date (month):				
Total facility or selected wards / areas (delete as applicable)				
Month 6 Date (month):				
Total facility or selected wards / areas (delete as applicable)				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Soap
(measured in bars/litres)

Product ☐ Non-medicated soap bar ☐ Medicated soap bar ☐ Liquid soap
☐ Other (please specify, e.g. foam)

Information recorded is related to ☐ Purchased product ☐ Used product

Name/composition of product/s:

Important note: If different products are used simultaneously (e.g. bar or liquid soap on some units), it is advisable to log the consumption separately for each product in each period on a different form to avoid confusion.

	Amount purchased/used		Number of patients admitted to the facility or department or ward	Number of patient-days related to the facility or department or ward
	Units used (bottles or bars)	Units expressed as litres (l) or kilograms (kg)		
Month 1 Date (month):				
Total facility or selected wards / areas (delete as applicable)				
Month 2 Date (month):				
Total facility or selected wards / areas (delete as applicable)				
Month 3 Date (month):				
Total facility or selected wards / areas (delete as applicable)				
Month 4 Date (month):				
Total facility or selected wards / areas (delete as applicable)				
Month 5 Date (month):				
Total facility or selected wards / areas (delete as applicable)				
Month 6 Date (month):				
Total facility or selected wards / areas (delete as applicable)				

ESEMPI DI MODALITÀ DI VERIFICA DELLE MISURE GENERALI: LAVAGGIO DELLE MANI OSSERVATORE

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Observation Form

Facility:		**Period Number*:**		**Session Number*:**	
Service:		**Date:** (dd/mm/yy)	/ /	**Observer:** (initials)	
Ward:		**Start/End time:** (hh:mm)	: / :	**Page N°:**	
Department:		**Session duration:** (mm)		**City**:**	
Country:**					

Prof.cat			Prof.cat			Prof.cat			Prof.cat		
Code			Code			Code			Code		
N°			N°			N°			N°		
Opp.	**Indication**	**HH Action**	**Opp.**	**Indication**	**HH Action**	**Opp.**	**Indication**	**HH Action**	**Opp.**	**Indication**	**HH Action**
1	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	1	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	1	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	1	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
2	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	2	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	2	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	2	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
3	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	3	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	3	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	3	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
4	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	4	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	4	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	4	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
5	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	5	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	5	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	5	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
6	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	6	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	6	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	6	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
7	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	7	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	7	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	7	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
8	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	8	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	8	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	8	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves

* To be completed by the data manager.
** **Optional**, to be used if appropriate, according to the local needs and regulations.

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General Recommendations
(refer to the Hand Hygiene Technical Reference Manual)

1. In the context of open and direct observations, the observer introduces him/herself to the health-care worker and to the patient when appropriate, explains his/her task and proposes immediate informal feed back.
2. The health-care worker, belonging to one of the main four following professional categories (see below), is observed during the delivery of health-care activities to patients.
3. Detected and observed data should be recorded with a pencil in order to be immediately corrected if needed.
4. The top of the form (header) is completed before starting data collection (excepted end time and session duration).
5. The session should last no more than 20 minutes (± 10 minutes according to the observed activity); the end time and the session duration are to be completed at the end of the observation session.
6. The observer may observe up to three health-care workers simultaneously, if the density of hand hygiene opportunities permits.
7. Each column of the grid to record hand hygiene practices is intended to be dedicated to a specific professional category. Therefore numerous health-care workers may be sequentially included during one session in the column dedicated to their category. Alternatively each column may be dedicated to a single health-care worker only of whom the professional category should be indicated.
8. As soon as you detect an indication for hand hygiene, count an opportunity in the appropriate column and cross the square corresponding to the indication(s) you detected. Then complete all the indications that apply and the related hand hygiene actions observed or missed.
9. Each opportunity refers to one line in each column; each line is independent from one column to another.
10. Cross items in squares (several may apply for one opportunity) or circles (only a single item may apply at one moment).
11. When several indications fall in one opportunity, each one must be recorded by crossing the squares.
12. Performed or missed actions must always be registered within the context of an opportunity.
13. Glove use may be recorded only when the hand hygiene action is missed while the health-care worker is wearing gloves.

Short description of items

Facility:	to complete according to the local nomenclature	
Service:	to complete according to the local nomenclature	
Ward:	to complete according to the local nomenclature	
Department:	to complete according to the following standardized nomenclature:	
	medical, including dermatology, neurology, haematology, oncology, etc.	surgery, including neurosurgery, urology, EENT, ophthalmology, etc.
	mixed (medical & surgical), including gynaecology	obstetrics, including related surgery
	paediatrics, including related surgery	intensive care & resuscitation
	emergency unit	long term care & rehabilitation
	ambulatory care, including related surgery	other (to specify)
Period N°:	1) pre- / 2) post-intervention; and then according to the institutional counter.	
Date:	day (dd) / month (mm) / year (yy).	
Start/end time:	hour (hh) / minute (mm).	
Session duration:	difference between start and end time, resulting in minutes of observation.	
Session N°:	attributed at the moment of data entry for analysis.	
Observer:	observer's initials (the observer is responsible for the data collection and for checking their accuracy before submitting the form for analysis.	
Page N°:	to write only when more than one form is used for one session.	
Prof.cat:	according to the following classification:	
	1. nurse / midwife	1.1 nurse, 1.2 midwife, 1.3 student.
	2. auxiliary	
	3. medical doctor	3.1 in internal medicine, 3.2 surgeon, 3.3 anaesthetist / resuscitator / emergency physician, 3.4 paediatrician, 3.5 gynaecologist, 3.6 consultant, 3.7 medical student.
	4. other health-care worker	4.1 therapist (physiotherapist, occupational therapist, audiologist, speech therapist), 4.2 technician (radiologist, cardiology technician, operating room technician, laboratory technician, etc), 4.3 other (dietician, dentist, social worker and any other health-related professional involved in patient care), 4.4 student.
Number:	number of observed health-care workers belonging to the same professional category (same code) as they enter the field of observation and you detect opportunities.	
Opp(ortunity):	defined by one indication at least	
Indication:	reason(s) that motivate(s) hand hygiene action; all indications that apply at one moment must be recorded	
	bef.pat: before touching a patient	aft.b.f: after body fluid exposure risk
	bef.asept: before clean/aseptic procedure	aft.pat: after touching a patient
		aft.p.surr: after touching patient surroundings
HH action:	response to the hand hygiene indication(s); it can be either a positive action by performing handrub or handwash, or a negative action by missing handrub or handwash	
	HR: hand hygiene action by handrubbing with an alcohol-based formula HW: hand hygiene action by handwashing with soap and water	Missed: no hand hygiene action performed

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Observation Form – Basic Compliance Calculation

	Facility:						Period:			Setting:					
	Prof.cat.			Prof.cat.			Prof.cat.			Prof.cat.			Total per session		
Session N°	**Opp (n)**	**HW (n)**	**HR (n)**	**Opp (n)**	**HW (n)**	**HR (n)**	**Opp (n)**	**HW (n)**	**HR (n)**	**Opp (n)**	**HW (n)**	**HR (n)**	**Opp (n)**	**HW (n)**	**HR (n)**
1															
2															
3															
4															
5															
6															
7															
8															
9															
10															
11															
12															
13															
14															
15															
16															
17															
18															
19															
20															
Total															
Calculation	Act (n) =			Act (n) =			Act (n) =			Act (n) =			Act (n) =		
	Opp (n) =			Opp (n) =			Opp (n) =			Opp (n) =			Opp (n) =		
Compliance															

Compliance (%) = Actions / Opportunities x 100

Instructions for use

1. Define the setting outlining the scope for analysis and report related data according to the chosen setting.
2. Check data in the observation form. Hand hygiene actions not related to an indication should not be taken into account and vice versa.
3. Report the session number and the related observation data in the same line. This attribution of session number validates the fact that data has been taken into count for compliance calculation.
4. Results per professional category and per session (vertical):
   4.1 Sum up recorded opportunities (opp) in the case report form per professional category: report the sum in the corresponding cell in the calculation form.
   4.2 Sum up the positive hand hygiene actions related to the total of opportunities above, making difference between handwash (HW) and handrub (HR): report the sum in the corresponding cell in the calculation form.
   4.3 Proceed in the same way for each session (data record form).
   4.4 Add up all sums per each professional category and put the calculation to calculate the compliance rate (given in percent)
5. The addition of results of each line permits to get the global compliance at the end of the last right column.

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Observation Form – Optional Calculation Form
(Indication-related compliance with hand hygiene)

	Facility:			Period:			Setting:								
	Before touching a patient			Before clean/ aseptic procedure			After body fluid exposure risk			After touching a patient			After touching patient surroundings		
Session N°	**Indic (n)**	**HW (n)**	**HR (n)**	**Indic (n)**	**HW (n)**	**HR (n)**	**Indic (n)**	**HW (n)**	**HR (n)**	**Indic (n)**	**HW (n)**	**HR (n)**	**Indic (n)**	**HW (n)**	**HR (n)**
1															
2															
3															
4															
5															
6															
7															
8															
9															
10															
11															
12															
13															
14															
15															
16															
17															
18															
19															
20															
Total															
Calculation	Act (n) =			Act (n) =			Act (n) =			Act (n) =			Act (n) =		
Ratio act / indic*	Indic1 (n) =			Indic2 (n) =			Indic3 (n) =			Indic4 (n) =			Indic5 (n) =		

Instructions for use

1. Define the setting outlining the scope for analysis and report related data according to the chosen setting.
2. Check data in the observation form. Hand hygiene actions not related to an indication should not be taken into account and vice versa.
3. If several indications occur within the same opportunity, each one should be considered separately as well as the related action.
4. Report the session number and the related observation data in the same line. This attribution of session number validates the fact that data has been taken into count for compliance calculation.
5. Results per indication (indic) and per session (vertical):
   4.1 Sum up indications per indication in the observation form: report the sum in the corresponding cell in the calculation form.
   4.2 Sum up positive hand hygiene actions related to the total of indications above, making the difference between handwash (HW) and handrub (HR): report the sum in the corresponding cell in the calculation form.
   4.3 Proceed in the same way for each session (observation form).
   4.4 Add up all sums per each indication and put the calculation to calculate the ratio (given in percent)

***Note:** This calculation is not exactly a compliance result, as the denominator of the calculation is an indication instead of an opportunity. Action is artificially overestimated according to each indication. However, the result gives an overall idea of health-care worker's behaviour towards each type of indication.

IDONEE MISURE DI PREVENZIONE E IDONEE MISURE DI GESTIONE DEL RISCHIO SANITARIO

▪ Idonee misure di prevenzione

- Misure sanitarie specifiche
- riguardano i processi assistenziali relativi al singolo paziente;
- Finalità di ridurre il rischio correlato ad uno specifico setting assistenziale
- Es. utilizzo del campo sterile nel posizionamento del catetere venoso-centrale

▪ Idonee misure di gestione

Distinzione tra:

- **Misure assistenziali generali:** intervengono nei processi sanitari, con finalità di riduzione del rischio; es. lavaggio delle mani, cambio delle lenzuola, etc.
- **Misure organizzative**: intervengono nei processi organizzativi; es. presenza di determinate funzioni, svolgimento di audit clinici, etc.

<u>Sia le misure di prevenzione che le misure di gestione devono essere non solo pianificate dalla struttura ma anche applicate e monitorate, al fine di verificarne l'effettiva e corretta attuazione</u>

VANTAGGI DEI BUNDLE PER MIGLIORARE L'ASSISTENZA

IMPLEMENTAZIONE DELLE MISURE PER LA PREVENZIONE DELLE INFEZIONI DEL SITO CHIRURGICO

Raccomandazioni

Quali interventi sono necessari per promuovere l'implementazione delle misure per la prevenzione delle infezioni del sito chirurgico?

- **Sorveglianza**. La sorveglianza delle ISC deve essere parte integrante di un sistema di prevenzione e controllo delle infezioni correlate all'assistenza (WHO 2016). Sorvegliare le infezioni del sito chirurgico (SHEA/IDSA 2014; NICE Quality standard 2013), su interventi ad alto volume e alto rischio. Identificare, raccogliere, archiviare i dati necessari per la sorveglianza, utilizzare definizioni aggiornate, fornire al personale un *feedback* continuo dei tassi di ISC, utilizzare dati automatizzati per aumentare l'efficienza.
- **Utilizzare la *checklist* dell'Organizzazione mondiale della sanità** per garantire la conformità con le migliori pratiche cliniche (SHEA/IDSA 2014).
- **Misurare e fornire *feedback*** a chirurghi e personale infermieristico sull'adesione a misure di processo (SHEA/IDSA 2014).
- **Eseguire una valutazione del rischio di infezione del sito chirurgico**, per specialità chirurgica, procedura e/o per chirurgo (SHEA/IDSA 2014).
- **Osservare le attività del personale di sala operatoria e la sanificazione ambientale** mediante ispezioni periodiche con osservazione diretta (SHEA/IDSA, 2014).
- **Utilizzo di fonti esistenti**. Se possibile, utilizzare i dati già disponibili nei flussi informativi correnti di Farmacia, Laboratorio, Economato, ecc. (SHEA/IDSA 2014).
- **Coinvolgimento degli operatori**. Organizzare una rete di operatori e coinvolgerli nelle strategie di prevenzione e controllo delle infezioni del sito chirurgico (SHEA/IDSA 2014).
- ***Bundle* da utilizzare per la formazione e verifica**. Considerare di definire un *bundle* per la prevenzione delle infezioni del sito chirurgico e utilizzarlo sia nella formazione del personale sia nella verifica dell'appropriatezza delle cure (SHEA/IDSA 2014).

***Bundle* da utilizzare per la formazione e la verifica**

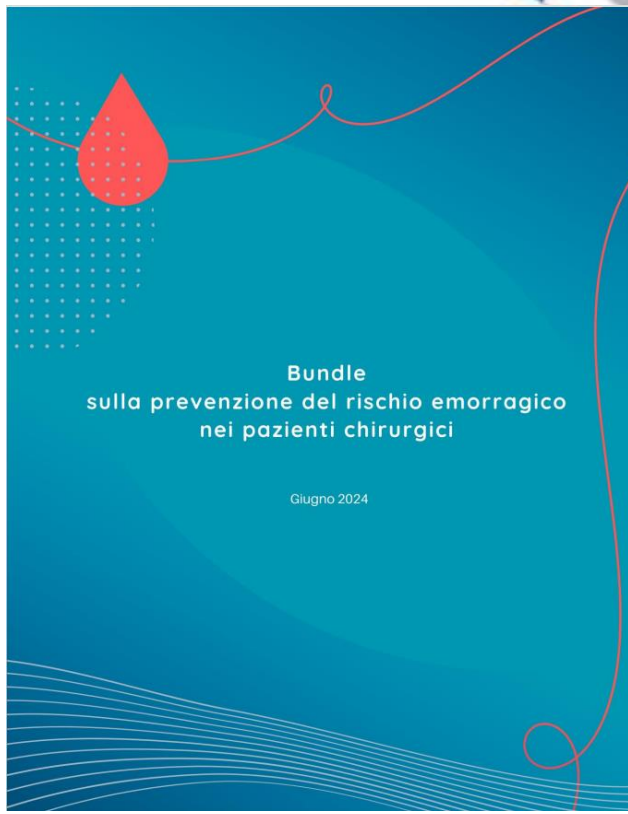
- Uno degli strumenti utilizzato negli ultimi anni come sistema per favorire l'adesione alle buone pratiche cliniche in diversi ambiti è il *bundle*. Con questa strategia si identifica un numero limitato di procedure basate sull'evidenza, generalmente da tre a sei, che devono essere applicate tutte insieme nell'assistenza del singolo paziente. Il *bundle* deve tenere conto anche delle caratteristiche delle strutture nelle quali viene applicato e può quindi variare da centro a centro. Probabilmente anche per questi motivi i risultati sinora ottenuti dall'applicazione della strategia del *bundle* nel controllo delle infezioni della ferita chirurgica sono variabili e ad oggi non esiste un consenso definitivo su quali debbano essere le componenti del *bundle*. Negli studi pubblicati finora le componenti più comunemente incluse sono rappresentate da:
  - normotermia intraoperatoria,
  - normoglicemia intraoperatoria,
  - corretta antibioticoprofilassi perioperatoria in termini di scelta della molecola, momento di infusione e durata,
  - corretta tricotomia.
- L'utilizzo del *bundle* ha sia una valenza educativa, rendendo più semplice e mirata la formazione dei professionisti, sia una valenza di verifica, permettendo una valutazione relativamente semplice dell'adesione alle procedure.
- Alcuni studi recenti dimostrano come la frazione di casi prevenibile utilizzando questa strategia sia sostanziale: in chirurgia colorettale una revisione di 13 studi condotti tra il 2011 e il 2014 ha evidenziato una riduzione della frequenza di infezioni del sito chirurgico da 15% nel gruppo sottoposto ad assistenza standard a 7% nel gruppo incluso in un trattamento *bundle* (Tanner *et al.*, 2015). In tutti gli studi considerati, l'attivazione di programmi mirati a modificare comportamenti assistenziali selezionati era accompagnata dalla puntuale rilevazione dell'adesione alle pratiche raccomandate e all'utilizzo di questi dati per promuovere il cambiamento.

L'utilizzo del Bundle ha sia una valenza educativa, rendendo più semplice e mirata la formazione dei professionisti, sia una valenza di verifica, permettendo una valutazione relativamente semplice dell'adesione alle procedure

INDIVIDUAZIONE DEI SET DI INTERVENTI PER LA SICUREZZA PROPOSTI COME IDONEE MISURE

1- Set di Interventi per la Sicurezza sulla prevenzione del rischio emorragico nei pazienti chirurgici (CNS)

2- Set di Interventi per la Sicurezza per la prevenzione delle infezioni del sito chirurgico (ISS, SIMPIOS,.....)



INDIVIDUAZIONE DEI SET DI INTERVENTI PER LA SICUREZZA PROPOSTI COME IDONEE MISURE

1- Set di interventi per la sicurezza sulla prevenzione del rischio emorragico nei pazienti chirurgici (CNS)

2- Set di interventi per la sicurezza per la prevenzione delle infezioni del sito chirurgico (ISS, SIMPIOS,.....)

1. **Evitare la tricotomia. Nel caso fosse indispensabile, utilizzare un rasoio elettrico.**
2. **Somministrare l'antibiotico prima dell'incisione per procedure chirurgiche ad alto rischio o quando viene impiantato materiale protesico e rispettare il timing ottimale**
3. **Utilizzare antisettici a base di alcol per la preparazione del sito chirurgico.**
4. **Risomministrare l'antibiotico per procedure prolungate e in pazienti con grave perdita di sangue.**
5. **Interrompere la profilassi antibiotica dopo l'intervento.**

SEZIONI PREVISTE PER I SET DI INTERVENTI PER LA SICUREZZA

1. ***Somministrazione questionario anamnestico per la determinazione del rischio emorragico***
2. ***Protocolli per il reversal della anticoagulazione e per la neutralizzazione dei farmaci antiaggreganti***
3. ***Protocolli di riduzione della perdita ematica intraoperatoria***
4. ***Utilizzo strumenti point of care***
5. ***Protocolli e tecniche di recupero intraoperatorio***

OSSERVATORIO NAZIONALE DELLE BUONE PRATICHE SULLA SICUREZZA NELLA SANITÀ

A tale scopo l'Osservatorio auspica il contributo delle società scientifiche e delle associazioni tecnico scientifiche attraverso la proposta di "indicazioni pratiche rivolte ad una categoria di operatori su una tematica specifica,", secondo il format dei bundle e in linea con il modello di evidenze scientifiche sviluppato dall'ISS, indicazioni che siano individuabili come idonee misure per la prevenzione e la gestione del rischio sanitario. L'Osservatorio si impegna altresì a definire alcune aree prioritarie per lo sviluppo dell'Insieme di interventi per la sicurezza a partire dall'analisi dei dati provenienti dai flussi informativi e dall'analisi dei documenti di indirizzo di livello internazionale per la sicurezza dei pazienti

BUONE PRATICHE E CONTENZIOSO = QUESTIONI APERTE

1. le **misure di prevenzione**, essendo di tipo sanitario specifico, potrebbero essere provate in relazione al singolo paziente a cui si riferiscono, al fine di fornire adeguata prova della loro applicazione al caso di specie?
2. le **misure di gestione del rischio sanitario e assistenziali generali** potrebbero essere provate considerando la loro esistenza, applicazione, implementazione e monitoraggio nella struttura di riferimento?

IN CONCLUSIONE..

- Sarebbe auspicabile che alle linee guida e alle raccomandazioni clinico assistenziali *ex* art. 5 l. n. 24/2017, si affianchi un *corpus* di **buone pratiche per la sicurezza** intese come **misure per la prevenzione e la gestione del rischio sanitario** che supporti i professionisti e le organizzazioni sanitarie nel migliorare la qualità e la sicurezza delle prestazioni;
- L'eventuale **individuazione** da parte dell'**Osservatorio**, con il supporto scientifico dell'ISS, di «**idonee misure**» per la prevenzione e la gestione del rischio sanitario, può favorirne non solo la produzione ma anche consentirne la diffusione, conoscenza, applicazione, monitoraggio, la loro valutazione come **quotazione del rischio** e, in ultima analisi, l'utilizzo come **elemento probatorio** nel contenzioso.

Grazie per l'ascolto

agenas. AGENZIA NAZIONALE PER I SERVIZI SANITARI REGIONALI