

Dott. Andrea Minarini

Risk Manager

Rappresentante ANMDO

Faculty LUISS

Faculty GIMBE

**29 NOVEMBRE** | Tavolo 2

🕒 9:00 - 13:00

**MONITORAGGIO E CONTROLLO DELLE INFEZIONI CORRELATE ALL'ASSISTENZA: ALLEANZA PER L'EFFETTIVA CONNESSIONE DEI PIANI DI ATTUAZIONE E SISTEMA DI SORVEGLIANZA**

In partnership con 

I Parte

Coordina **Angela Deni** **Giorgio Tulli** *Confindustria DM Comitato Scientifico Forum Risk Management*

Apertura

**Francesco Venneri** *Clinical Risk Manager Centro GRC Regionale, AUSL Toscana Centro*

Intervengono

**Andrea Menarini** *ANMDO*  
**Maria Luisa Moro** *Presidente SIMPIOS*  
**Maria Mongardi** *Presidente ANIPIO*  
**Pierangelo Clerici** *Presidente AMCLI Associazione Microbiologi Clinici Italiani Presidente FISMeLab Federazione Italiana Società Scientifiche di Medicina di laboratorio*  
**Sen. Ignazio Zullo\*** *Membro X Commissione permanente Affari Sociali, Sanità, Lavoro pubblico e privato, previdenza sociale Senato della Repubblica*  
**Stefano Lorusso\*** *Direzione generale della digitalizzazione, del sistema informativo sanitario e della statistica Ministero della Salute*  
**Fortunato Paolo D'Ancona** *Istituto Superiore Sanità*  
**Ottavio Alessandro Nicastro** *Direttore Sanitario AOU Policlinico di Modena, Coordinatore Sub Area Rischio Clinico-Commissione Salute, Conferenza delle Regioni e delle P.A*  
**Paolo Petralia** *Direttore Generale ASL 4 Chiavarese, Vicepresidente FIASO*  
**Amanda Zanchi** *Chair GdI Correlata all'assistenza Confindustria Dispositivi Medici*  
**Paolo Capelli** *Chair GdI Infezioni correlate all'assistenza*  
**Pierluigi Spada** *Policlinico IRCCS A. Gemelli, Divulgatore scientifico, Conduttore RAI*  
**Sabrina Nardi** *SalutEquità*

Armonizzazione dei percorsi formativi lauree magistrali, triennali e assistente infermiere  
**Alvisa Palese** *Conferenza dei corsi di laurea delle professioni sanitarie*

II Parte **La cybersecurity nell'uso dei dispositivi medici**

Coordina **Lorenzo Terranova** *Confindustria Dispositivi Medici*

Intervengono

**Paolo Mauriello** *Hospital Consulting*  
**Riccardo Coradeschi** *Fortinet*  
**Alessandro Picchi** *Direttore Area Tecnologie Informatiche Azienda USL Toscana Sud Est*  
**Gianluca Serati** *SBI Italia*

Ore 13:00 • Chiusura lavori



Mothers Against Medical Error,  
Columbia, SC, USA  
Haskell.helen@gmail.com  
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<http://dx.doi.org/10.1136/bmj.q2437>  
Published: 13 November 2024

## Surgical adverse events in the US

After all these years, why has patient safety not improved?

Helen Haskell, *president*

In late 1999, the US Institute of Medicine's report "To Err is Human: Building a Safer Health System" galvanized the nascent patient safety movement into action with its assertion that as many as 98 000 Americans died annually from medical error.<sup>1</sup> That alarming statistic was derived from the 1991 Harvard Medical Practice Study, a randomized chart review undertaken to create an evidence base for the controversy then raging around litigation against medical malpractice.<sup>2</sup> That study found that 3.7% of patients in a sample of hospital admissions in New York state had experienced serious adverse events, more than one fourth of which the researchers considered legally compensable. Overall, 48% of the events were associated with surgical procedures. A related study in Colorado and Utah a few years later showed similar percentages of surgical error, whereas a targeted follow-up study found that surgery accounted for two thirds of adverse events in hospitals in the same two states.<sup>3,4</sup>

In the linked study, Duclos and colleagues (doi:10.1136/bmj-2024-080480) set out to create an updated baseline for surgical adverse events in the US, broadly modeled on the original Harvard Medical Practice Study.<sup>5</sup> Data for Duclos and colleagues' study were derived from the 2023 SafeCare study, which used a "trigger" methodology to analyze a random sample of electronic inpatient records from 11 hospitals in Massachusetts.<sup>6</sup> In the subset of cases analyzed for Duclos and colleagues' study, the authors identified adverse events in 38% (n=383/1009) of surgical admissions. Nearly half were classified as major, and more than two thirds as preventable.

Since the Colorado-Utah study, research examining surgical outcomes across specialties has been sparse. Duclos and colleagues' study is therefore a valuable contribution; but its findings are not encouraging. To date, around a dozen large studies have been conducted on medical harm in the US and globally, and almost all used some version of the screening methodology employed by the Harvard Medical Practice Study.<sup>7-8</sup> Comparison between studies is complicated by customization and changes in the triggers used to flag events, but studies in the US have nevertheless produced remarkably consistent findings across the years. In 2010, studies of hospitals in Colorado and North Carolina found adverse event rates of 33% and 25%, respectively, with the North Carolina study showing no major improvement from 2002 to 2007.<sup>9-10</sup> Studies of Medicare patients by the US Health and Human Services Office of the Inspector General showed nearly unchanged rates of harm of 27% and 25% between 2008 and 2018, despite the 10 year difference.<sup>11,12</sup> Thus, over a period of some 17 years, medical harm may have continuously affected

as many as one in three or one in four patients in US hospitals. In all these studies, surgery accounted for around one fourth of adverse events.

Many reasons have been proposed for this failure to improve, among them a culture of disrespect, inadequate nurse staffing, ineffective implementation of proven strategies, and failure to take advantage of available technology that would allow real time detection and possibly prevention of adverse events.<sup>13-15</sup> All undoubtedly have played a part. The major omission in patient safety, however, is the patient. Although patient engagement is growing across other parts of healthcare, little progress has been made in including patients and families in the areas where they could contribute the most: co-creating their own history and unraveling the causes and effects of errors in their care. Information in the electronic medical records used to track adverse events is often incomplete, inaccurate, or recorded by overworked providers who may have little real knowledge of the patient's case.<sup>5</sup> Patients in the US can now view their medical records, a privilege not available in many countries, but they cannot comment on them, even when they spot obvious errors. When an adverse event occurs, patients and families are seldom interviewed, much less consulted, even if they are the sole witnesses. Confidential analyses of root causes and "disclosures" with confidentiality clauses may do more to hide problems about patient safety than to address them. Legal settlements silence entire swaths of people with non-disclosure agreements, and they prevent in-depth examination of the causes of harm.

Newly available tools such as large language models have the potential to transform patient safety by mining electronic records. But electronic records are only as good as the information they contain. If we are truly interested in advancing patient safety, patients and families need to be empowered to weigh in on the accuracy of the accounts of their own care and participate in finding solutions. Studies like the one by Duclos and colleagues are an important foundation for meaningful solutions, but those can only be found in tandem with patients and families.

Competing interests: The BMJ has judged that there are no disqualifying financial ties to commercial companies. The author declares the following other interests: None.

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1 Kohn LT, Corrigan JM, Donaldson MS, eds. *To err is human: building a safer health system*. National Academies Press, 2000.  
2 Lapeere JL, Brennan TA, Lencz N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med* 1991;324:84. doi:10.1056/NEJM199102073240605. pmid: 1824793

## Global, regional and national time trends in incidence of adverse effects of medical treatment, 1990–2019: an age-period-cohort analysis from the Global Burden of Disease 2019 study

Liangquan Lin

**ABSTRACT**  
Background: Current adverse effects of medical treatment (AEMT) incidence estimates rely on limited recent reviews and underrepresenting surveillance systems. This study evaluated global and national longitudinal patterns in AEMT incidence from 1990 to 2019 using the Global Burden of Disease (GBD) framework.

**Methods:** AEMT was defined as harm resulting from a procedure, treatment or other contact with the healthcare system. The overall crude incidence rate, age-standardized incidence rate and their changes over time were analysed to evaluate temporal trends. Data were stratified by sociodemographic index (SDI) quartiles, age groups and sex to address heterogeneity across and within nations. An age-period-cohort model framework was used to differentiate the contributions of age, period and cohort effects on AEMT incidence changes. The model estimated overall and age-specific annual percentage changes in incidence rates.

**Findings:** Although the global population increased 44.8% from 1990 to 2019, AEMT incidence rose faster by 50.3%. The net drift in the global incidence rate was 0.81% per year. The proportion of all cases accounted for by older adults and the incidence rate among older adults increased globally. The high SDI region had much higher and increasing incidence rates versus declining rates in lower SDI regions. The age effects showed that in the high SDI region, the incidence rate is higher among older adults. Globally, the period effect showed a rising incidence of risk after 2002. Lower SDI regions exhibited a significant increase in incidence risk after 2012. Overall, the cohort effect showed a continually increasing incidence risk across sequential birth cohorts from 1950 to 1995.

**Conclusion:** As the global population ageing intensifies alongside the increasing quantity of healthcare services provided, measures need to be taken to address the continuously rising burden of AEMT among the older population.

**INTRODUCTION**  
Adverse effects of medical treatment (AEMT) and patient safety have become pressing public health concerns worldwide. AEMT refers to any harm resulting

### WHAT IS ALREADY KNOWN ON THIS TOPIC

Traditional methods for estimating adverse events from medical treatment (AEMT) incidence rates have limitations, such as under-reporting and low sensitivity, with scarce information from low-income and developing countries. Directly comparing cross-sectional estimates of AEMT incidence rates between countries in early studies is prone to problems arising from heterogeneous data sources or inherent risks within each country's healthcare delivery system.

### WHAT THIS STUDY ADDS

This study uses a systematic, globally consistent method to accurately quantify AEMT incidence rates, addressing heterogeneity using sociodemographic index, age and sex, and using an age-period-cohort model framework to differentiate the contributions of age, period and cohort effects on AEMT incidence rate changes.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

This study identifies high-risk subgroups and time intervals among the SDI nations, providing information for prioritising resources and implementing targeted preventive strategies for AEMT, and emphasises the importance of enhancing optimising geriatric medical management to reduce iatrogenic harm.

- ▶ BMJ Quality & Safety (June 2024 )
- ▶ 18 milioni all'anno gli incidenti sanitari /eventi avversi (2019), nel 1990 11 milioni
- ▶ Aumento del 59% dal 1990 al 2019 ( più della crescita della popolazione pari al 45 %)
- ▶ Anziani più colpiti ( 65-69 anni )
- ▶ I danni sono più frequenti ove l'erogazione di assistenza sanitaria è maggiore
- ▶ Tasso di incidenza complessivo pari 823 su 100000 nel 2019
- ▶ Tra le persone anziane sono i farmaci la causa principale di questi danni a causa dell'età che influenza il metabolismo e la eliminazione dei farmaci , il fatto di assumere contemporaneamente più terapie, le patologie coesistenti e i cali delle funzioni cognitive e funzionali che comportano il rischio di errori di assunzione .

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EDITORIALS

**Surgical adverse events in the US**

After all these years, why has patient safety not improved?

Helen Haskell *president*

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SI  
Ge  
RIS | Società Italiana  
Gestori del  
Rischio In Sanità

**Kaoru Ishikawa**



Kaoru Ishikawa (1916-1989)

“analizza i fatti e parla con i dati”



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**AREZZO FIERE E CONGRESSI**

**19**

Le ICA e le AMR rappresentano l'evento avverso più frequente e la complicanza più grave dell'assistenza sanitaria e sono state dichiarate dall'Organizzazione Mondiale della Sanità un problema a livello globale.

## ICA e AMR

Sono un problema globale perché:

- Si presentano con **caratteristiche epidemiologiche specifiche per ogni singola struttura sanitaria e sono mutevoli nel tempo**
- Richiedono un **approccio multidisciplinare**
- Influiscono sull' **esito del processo di cura**
- Incidono sulla **qualità tecnica delle prestazioni e sulla qualità percepita dell'utente**
- Comportano **costi**

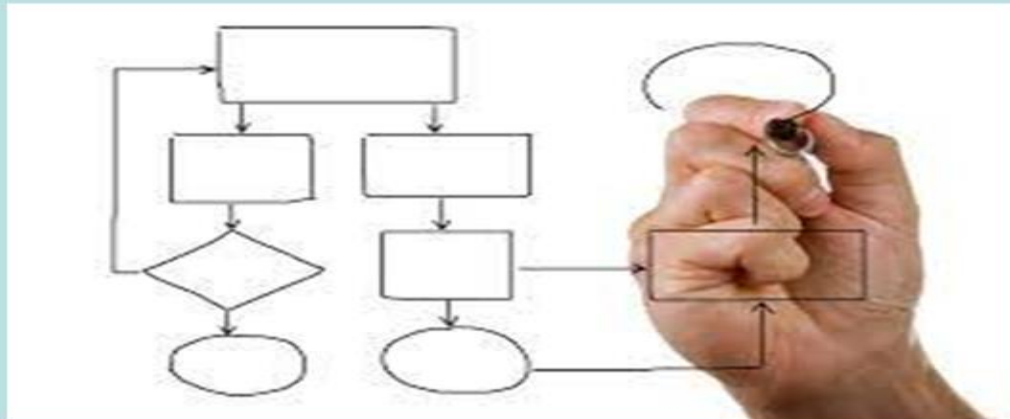
# Cultura della sicurezza e ICA : incidono pesantemente sulla organizzazione e sui comportamenti







## Ad esempio sulla formazione



- Dati recenti di letteratura dimostrano che gli operatori sanitari non molto abituati a gestire le malattie infettive hanno avuto maggiori probabilità di infezione da Sars-CoV-2.
- Quindi l'organizzazione corretta dei reparti, fornitura DPI e la formazione specifica hanno ruolo determinante nel ridurre il rischio di contagio .
- JAMA  
N.O.2021.15699/jama  
network open



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La percezione del rischio è il modo con cui gli individui percepiscono il pericolo. È un fenomeno molto complesso perchè intervengono non soltanto i dati obiettivi, ma anche aspetti soggettivi, sociali ed emotivi



# Analisi dei comportamenti



La percezione individuale del rischio:

- è influenzata da abitudini ed esperienze pregresse;
- si basa sull'esperienza personale o di altri;
- varia in rapporto all'accettabilità collettiva del rischio, che si modifica nel tempo, nei luoghi, nei gruppi di lavoro, nelle culture ed in rapporto ai valori personali e culturali, all'età, al sesso





Luiss Business School

"LA SANITÀ È UN AFFARE RISCHIOSO" (J. WILSON, 1998)

MA NON TUTTI LO CAPISCONO!

November 28, 2024

Causa	Numero morti in Italia, all'anno
Alimentazione scorretta	<b>Più di 100.000 (media annuale)</b> <small>Stima del 35% sui decessi totali per tumore - Fonte: Doll, Peto, 1981</small>
Tabacco	<b>80.000 (2000)</b> <small><a href="http://www.epicentro.iss.it">http://www.epicentro.iss.it</a></small>
Cause non mediche	<b>26.000 (2000)</b> <small><a href="http://www.epicentro.iss.it">http://www.epicentro.iss.it</a></small>
Alcol	<b>20.000 (media annuale)</b> <small><a href="http://www.epicentro.iss.it">http://www.epicentro.iss.it</a></small>
Infortuni domestici	<b>8.400 (media annuale)</b> <small><a href="http://www.ispesi.it">http://www.ispesi.it</a></small>
Influenza stagionale	<b>8.000 (media annuale)</b> <small><a href="http://www.trovanorme.salute.gov.it">http://www.trovanorme.salute.gov.it</a></small>
Incidenti stradali	<b>4.000 (2010)</b> <small><a href="http://www.aci.it">http://www.aci.it</a></small>
Suicidi	<b>3.000 (2009)</b> <small><a href="http://www.eures.it">http://www.eures.it</a></small>
Infortuni sul lavoro	<b>920 (2011) range: 900 + 1300</b> <small><a href="http://www.inail.it">http://www.inail.it</a></small>
AIDS	<b>120 (2011) **</b> <small><a href="http://www.salute.gov.it">http://www.salute.gov.it</a></small>

percezione individuale del rischio dipende da:

- la conoscenza dei pericoli, quindi la sensazione di in di coloro che hanno familiarità con una determinata
- l'immediatezza del danno
- la libertà nell'assunzione del rischio
- la concentrazione del danno nel tempo
- la dannosità dei pericoli presenti e la loro frequenza
- l'esposizione personale
- la valutazione soggettiva costi/benefici

È la percezione del rischio che fa la differenza : a fronte di 600 morti in un anno per criminalità la percezione è di 35 , mentre per 6000 morti per errori in sanità la percezione è 5





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### Cosa dice la letteratura

La letteratura che esplora la percezione del rischio infettivo degli operatori, in relazione al team work e ai diversi modelli organizzativo assistenziali, è estremamente esigua.



- *Il tema della misurazione e della informazione è uno dei più critici*

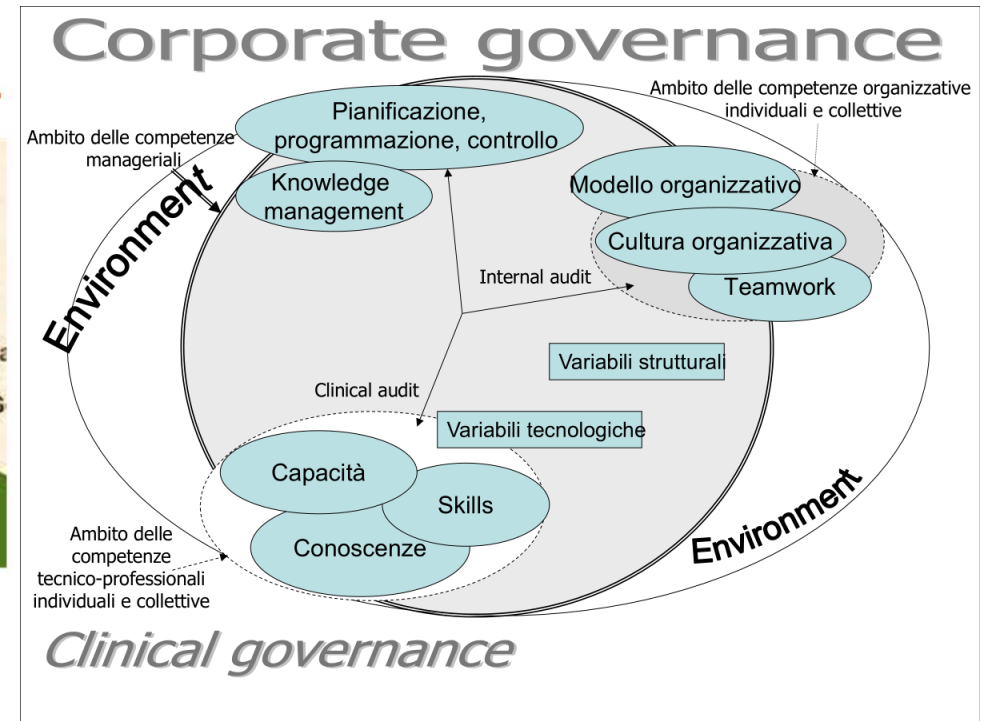
*Da un' iniziativa realizzata da Cittadinanzattiva , è risultato che nel 46% delle strutture sanitarie oggetto di monitoraggio, esistono difficoltà nel documentare con sistematicità i casi conclamati di insorgenza di infezioni correlate all'assistenza; nel 55% delle strutture mancano appositi registri per annotare eventi sentinella.*

*Amici Onlus in una sua surgery ha rilevato la carenza di informazioni sulle ICA: 1 paziente su 4 nessuna informazione .*



# GOVERNO CLINICO

- Il termine *Clinical Governance*, ovvero governo clinico è stato utilizzato per la prima volta nel 1983 dall'Organizzazione Mondiale della Sanità (OMS) e rappresenta lo strumento con il quale raggiungere una cultura d'eccellenza attraverso l'ausilio di diverse figure professionali. Tale concetto può essere riferito sia alla definizione, mantenimento e verifica della qualità clinica, sia ai meccanismi di responsabilizzazione, gestione e governo dei processi assistenziali. I sei pilastri su cui si poggia il governo clinico sono: l'efficacia clinica, lo sviluppo professionale continuo, la gestione del rischio clinico (risk management), l'organizzazione dipartimentale, i percorsi diagnostico-terapeutici e la qualità del servizio.



Dal governo clinico ad una nuova corporate governance  
integrata che consideri i fattori ESG&D :  
enviromental, social, governance and data stewardship





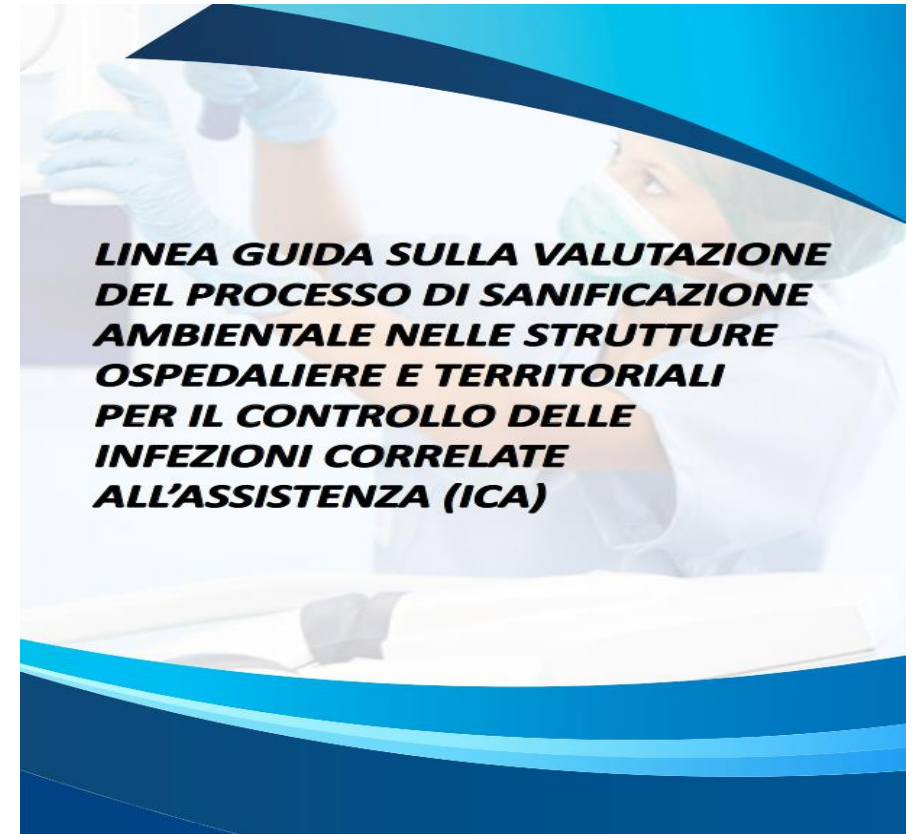
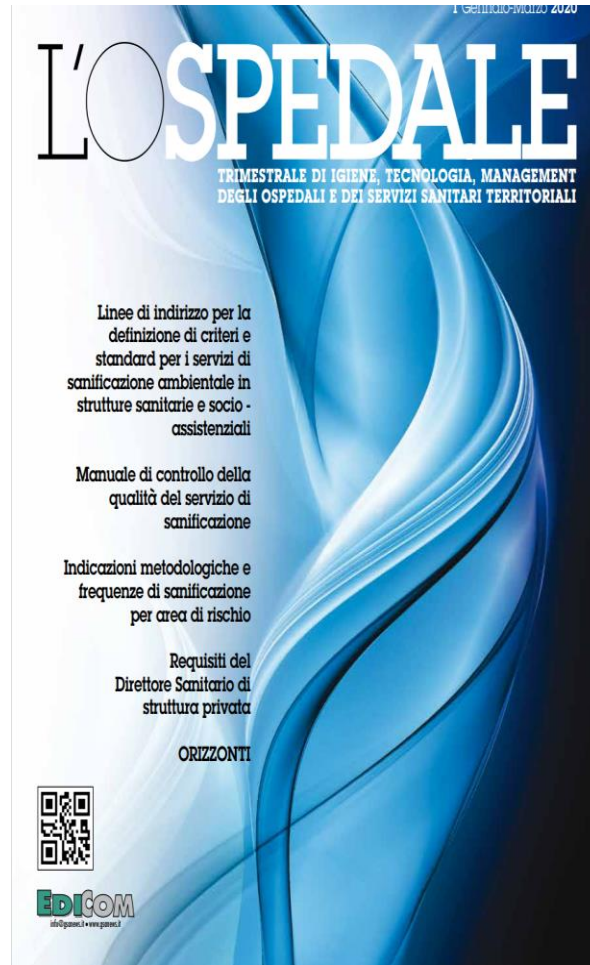
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## L'impegno di ANMDO





## Attività ANMDO

Revisione dei piani di gestione del rischio

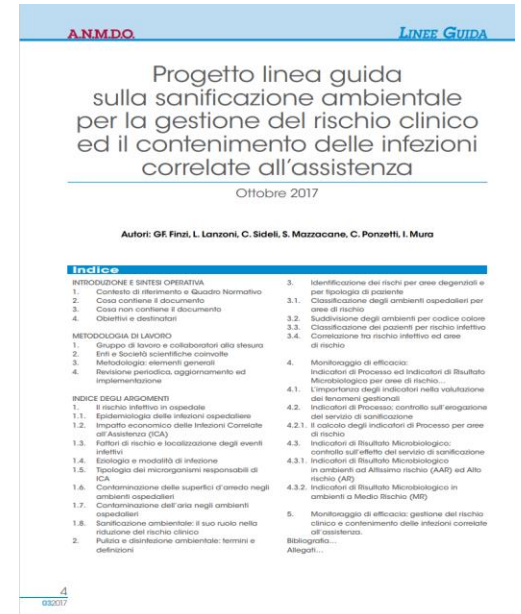
Costituzione di una task force multidisciplinare per la Stewardship e per l'infection control

Potenziamento delle misure di sicurezza in termini di utilizzo di DPI e di corretta igiene delle mani

Campagna di sensibilizzazione ed implemento delle procedure per la gestione degli accessi venosi centrali con l'introduzione di bundle

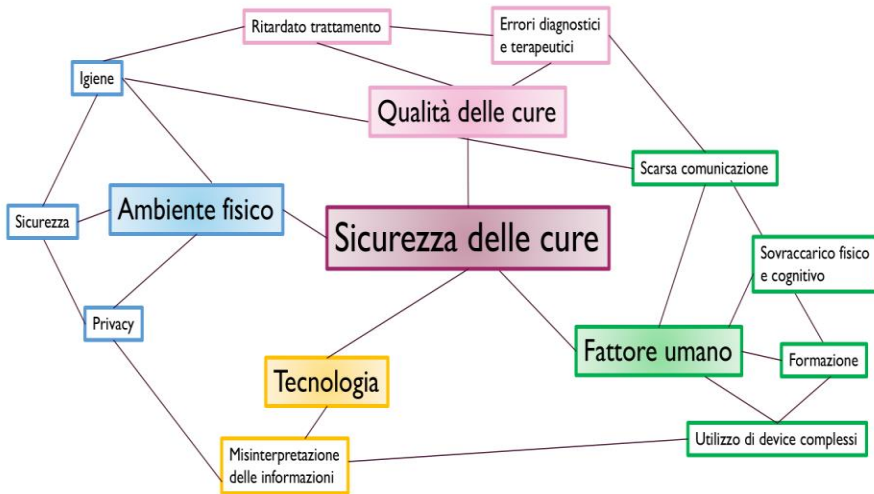
Incontri formativi per il personale

Estensione dello screening universale per la colonizzazione da MDR(multidrug resistant) all'ingresso a tutti i pazienti ricoverati in degenza medica.



FATTORI CHE INFLUENZANO LA SICUREZZA DELLE CURE

Phoenix 5.0 Ed. 2023



**Nuove proposte nella direzione della scienza della complessità**

Nuovo modello di lavoro , consistente nell'affrontare e governare con visione strategica i problemi complessi





- Programma di sorveglianza :  
Sistema di sorveglianza nazionale delle infezioni del sito chirurgico,  
Sistema nazionale di sorveglianza delle infezioni in terapia intensiva  
Studio di prevalenza delle infezioni correlate all' assistenza nelle strutture residenziali per anziani,  
Studio di prevalenza delle infezioni correlate all'assistenza negli ospedali per acuti.  
Sorveglianza del consumo di soluzione idroalcolica per l'igiene delle mani  
Sorveglianza per le infezioni da C. difficile e da MRSA.

criticità in merito alla  
standardizzazione dei metodi e degli strumenti  
per la raccolta e la gestione dei flussi informativi,  
alla copertura geografica, all'implementazione  
di questi strumenti su tutto il territorio nazionale  
in maniera omogenea e alla definizione di  
nuovi modelli o sistemi che siano coerenti con le  
problematiche più attuali.





### Proposte:

- Implementare protocolli (Gateway di Disinfezione) in punti chiave di transizione all'interno delle strutture sanitarie per minimizzare la diffusione delle infezioni, in particolare quelle acquisite in ospedale
- Percorsi di Sepsis: applicazione del metodo FRAM (Functional Resonance Analysis Method) per sviluppare linee guida più efficaci per la gestione della sepsi, riconoscendo che non solo gli sviluppatori di linee guida sono esperti, ma anche altri attori nel sistema sanitario
- Formazione ed informazione :fondamentale la formazione dei professionisti alla gestione del rischio ( vedi Raccom.del Cons.U.E.).
- Coinvolgimento attivo dei pazienti e delle famiglie e associazioni ( comunicazione e informazione integrata ).
- **Utilizzo di I.A e implementazione in contesti assistenziali :** (Scardoni A, Balzarini F, Signorelli C, Cabitza F, Odone A. *Artificial intelligence-based tools to control healthcare associated infections: A systematic review of the literature. J Infect Public Health. 2020;13(8):1061-1077. doi:10.1016/j.jiph.2020.06.006.* Shimabukuro DW, Barton CW, Feldman MD et al. *Effect of a machine learning-based severe sepsis prediction algorithm on patient survival and hospital length of stay: a randomised clinical trial. BMJ Open Res 2017;4:e000234. Doi:10.1136/bmjresp-2017-000234*)



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**19**

***GRAZIE***



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Associazione Nazionale Medici Direzioni Ospedaliere