



Ministero della Salute



Italian Presidency
of the Council
of the European Union
Italia2014.eu

UDINE 9 OTTOBRE 2014
GIORNATA REGIONALE DELLA SICUREZZA E
QUALITA' DELLE CURE

Patient Safety in Italia ed in EU

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The NEW ENGLAND
JOURNAL of MEDICINE

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SOUNDING BOARD

Balancing "No Blame" with Accountability in Patient Safety

Robert M. Wachter, M.D., and Peter J. Pronovost, M.D., Ph.D.

This year marks the 10th anniversary of the Institute of Medicine's report *To Err is Human*,¹ the document that launched the modern patient-safety movement. Although the movement has spawned myriad initiatives, its main theme, drawn from studies of other high-risk industries that have impressive safety records, boils down to this: Most errors are committed by good, hardworking people trying to do the right thing. Therefore, the traditional focus on identifying who is at fault is a distraction. It is far more productive to identify error-prone situations and settings and to implement systems that prevent caregivers from committing errors, catch errors before they cause harm, or mitigate harm from errors that do reach patients.^{2,3}

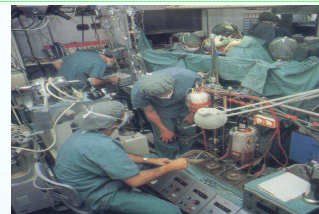
Most health care providers embraced the "no blame" model as a refreshing change from an errors landscape previously dominated by a mal-

Many health care organizations (including our own) have recognized that a unidimensional focus on creating a blame-free culture carries its own safety risks. But despite this recognition, finding the appropriate balance has been elusive, and few organizations have implemented meaningful systems of accountability, particularly for physicians. In this article, we describe some of the barriers to physician accountability, enumerate patient-safety practices that are ready for an accountability approach, and suggest penalties for the failure to adhere to such practices. We focus on situations in which the action (or inaction) of individual physicians poses a clear risk to patients, rather than on the broader issues of clinical competence or disruptive behavior; readers who are interested in the latter issues are referred to other sources.^{7,12,13}

....”un sistema in base al quale le organizzazioni sanitarie sono responsabili di migliorare continuamente la qualità dei propri servizi e garantire elevati standard assistenziali grazie alla creazione di un ambiente nel quale l’eccellenza dell’assistenza clinica può prosperare”.....

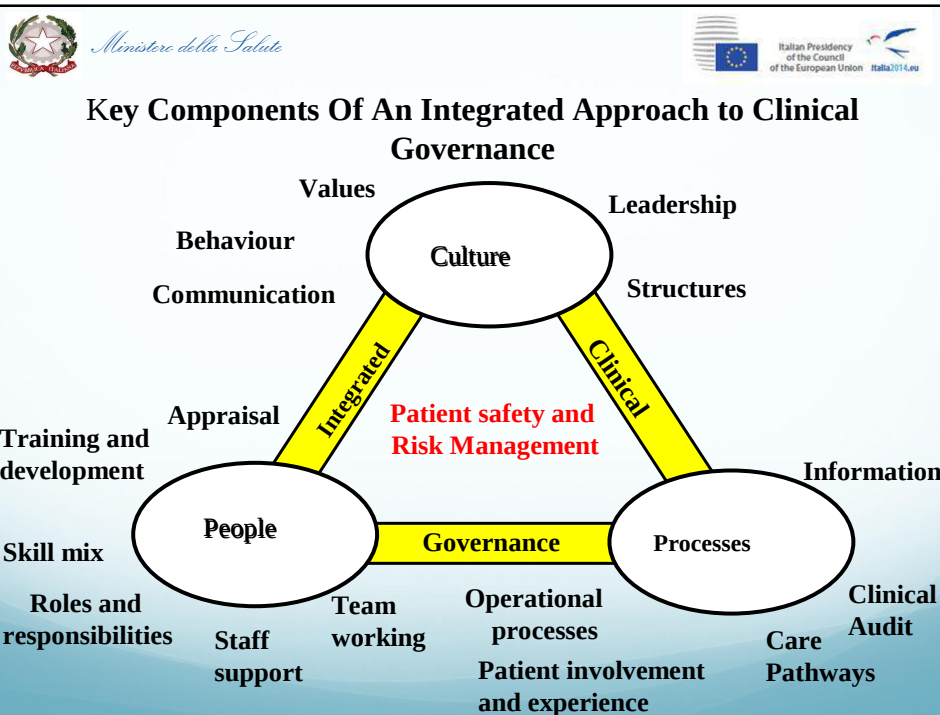


“rendersi conto per rendere conto”,



... nello spirito di responsabilizzazione che le professioni sanitarie assumono, verso gli assistiti e verso le istituzioni, circa le attività svolte, le prestazioni erogate ed i risultati ottenuti.

(Camera dei Deputati, Commissione Affari Sociali . 7 febbraio 1995:
Audizione del Ministro della Sanità, Prof. Elio Guzzanti)





EU Level

Council Recommendation 9 June 2009 on Patient Safety,
including the prevention and control of healthcare associated
infections

Council Recommendation 15 November 2001 on the prudent
use of antimicrobials agents in human medicines

Commission Action Plan against the rising threat from
antimicrobial resistance

Decision 1082/2013 on serious cross border health threats

Directive 24/2011 on patient mobility



Patient safety package



A patient safety package published on 19 June 2014 by the European Commission highlights how the Commission and EU countries are addressing the challenge of patient safety, progress made since 2009 and barriers to overcome to improve patient safety as foreseen in a [Council Recommendation 2009/C 151/01](#) (785 KB).

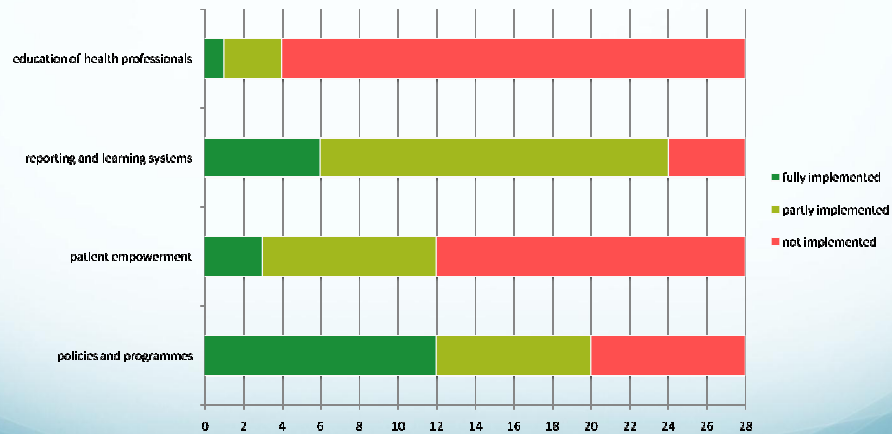
It consists of the following documents:

- The Commission's second [implementation report](#) (837 KB)
- [Infograph "Patient Safety in the EU: 2014"](#) (407 KB) - 2-sided [print version](#) (2 MB)
- [Public consultation](#) on patient safety and quality of care
- [Eurobarometer survey](#) testing citizens' perception of quality of care and patients' experience with healthcare.
- Key findings and recommendations on [Reporting and learning systems for patient safety incidents across Europe](#) (488 KB). Report of the Patient Safety and Quality of Care Working Group of the European Commission
- Key findings and recommendations on [Education and training in patient safety across Europe](#) (2 MB). Report of the Patient Safety and Quality of Care Working Group of the European Commission
- [Press release](#)

http://ec.europa.eu/health/patient_safety/policy/package_en.htm



Implementation by actions



Draft of Council conclusions on the "*Patient Safety and quality of care, including the prevention and control of Healthcare Associated Infections and contrast to the Antimicrobial Resistance*"
Dec 2014



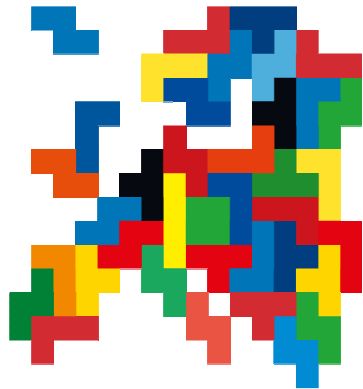
Establish and develop national policies and programs on patient safety, on prevention and control of healthcare associated infections and on antimicrobial resistance by:

- Patient safety a priority in the health policies and programs at national, regional and local levels
- Sustainable cooperation at EU level on PS
- Data, processes and tools, with the use of ICT
- Guidelines, Recommendations and good practices to support the appropriateness
- Inter-professional patient safety culture
- Education and training by innovative approaches
- Empowering and informing patients on their rights
- Research and innovations on patient safety, HAI and AMR
- Economic impact of adverse events
- AntiMicrobial Resistance: Surveillance of antimicrobial resistance;
Over-use of antibiotics



Directive on the application of patients' rights in cross- border healthcare

- The Directive 2011/24/EU on the application of patients' rights in cross-border healthcare promotes:
- **Transparency for patients**
Information about safety and quality standards and guidelines available for patients and healthcare providers
- **Information about healthcare providers**
Refusal of prior authorisation if doubts over quality and safety of a healthcare provider
- **Cooperation of Member States**
on standards and guidelines on quality and safety



The European Network
for
Patient Safety & Quality
JA PaSQ

Coordination meeting
Rome, 18 September 2014

Web site www.pasq.eu

PaSQ European Union Network
for Patient Safety and
Quality of Care



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International Organisations

WHO – World Alliance for patient safety

OECD - Indicators for Patient Safety

CoE - Recommendation of the Committee of Ministers to
member states on management of patient safety and
prevention of adverse events in health care

AHRQ - Making Health Care Safer II 2013

INFECTION PREVENTION AND CONTROL

- *Clean Care is Safer Care* - Promotion of best practices in hand hygiene
- Ongoing activities to respond to **Ebola** outbreak in West Africa
- Guidance on the **prevention of surgical site infection** in a global perspective
- Systematic reviews on **infection control interventions in developing countries**
- **Safe processing of medical devices** guidance document and education tools
- guidance document and tools for **prevention of BSI** based on the Matching Michigan project and other projects
- systematic reviews and develop tools for **infection control in Long-term Care Facilities**



ENSURE SAFE BLOOD TRANSFUSION PRACTICES

Vision:

- Self-sufficiency in blood and blood products for transfusion and universal access

Mission:

- Facilitate self-sufficiency, equitable access and appropriate use of safe and quality blood/blood products worldwide
- Ensure donor and patient safety, and contribution of BT to patients' health and survival





SAFETY CHECKLISTS

- **Surgical Safety Checklist**
- **Safe Childbirth Checklist:** A tool that assists health care workers in delivering essential maternal and perinatal care practices
 - BetterBirth study (2011-2017)
 - WHO Collaboration





AHRQ

10 pratiche "strongly encouraged"

- | | |
|---|--|
| 1. Checklist Preoperatoria e di anestesia | 6. Lista "Do Not Use" delle abbreviazioni pericolose |
| 2. Bundle per la prevenzione delle infezioni associate a catetere venoso centrale | 7. Interventi per ridurre le ulcere da pressione |
| 3. Interventi per ridurre l'uso di catetere urinario | 8. Barriere per prevenire le infezioni associate all'assistenza |
| 4. Bundle per la prevenzione della polmonite associata a ventilazione meccanica | 9. Uso di ecografia per il posizionamento del catetere centrale |
| 5. Igiene delle mani | 10. Interventi per migliorare la profilassi del tromboembolismo venoso |



AHRQ

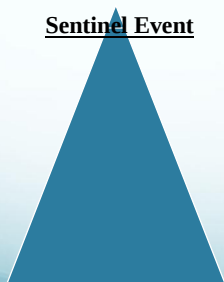
12 pratiche "encouraged"

- | | |
|--|--|
| 1. Interventi per ridurre le cadute | 7. Pratiche per ridurre l'esposizione a radiazioni da fluoroscopia e TAC |
| 2. Farmacista di dipartimento per ridurre gli eventi avversi da farmaci | 8. Misurare gli outcome chirurgici e uso di schede di valutazione |
| 3. Documentazione delle preferenze del paziente per il trattamento di sostegno alla vita | 9. Sistemi di risposta rapida |
| 4. Uso del consenso informato | 10. Utilizzo di metodi complementari per rilevare gli eventi avversi/errori medici |
| 5. Team training | 11. Prescrizione computerizzata |
| 6. Riconciliazione dei farmaci | 12. Uso della simulazione per migliorare la sicurezza dei pazienti |

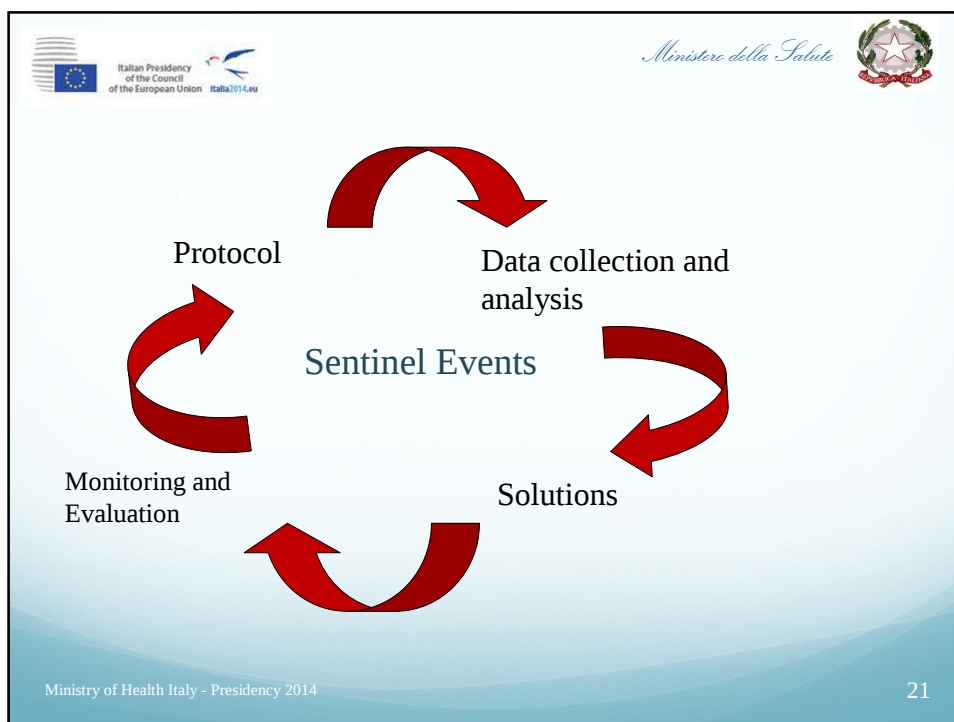
Sentinel Events

- Sentinel Event
Adverse Event
Near misses

Sentinel Event



TIPO EVENTO	N°	%
MORTE O GRAVE DANNO PER CADUTA DI PAZIENTE	471	24,56
SUICIDIO O TENTATO SUICIDIO DI PAZIENTE IN OSPEDALE	295	15,38
OGNI ALTRO EVENTO AVVERSO CHE CAUSA MORTE O GRAVE DANNO AL PAZIENTE	275	14,34
ATTI DI VIOLENZA A DANNO DI OPERATORE	165	8,6
STRUMENTO O ALTRO MATERIALE LASCIATO ALL'INTERNO DEL SITO CHIRURGICO CHE RICHIEDA UN SUCCESSIVO INTERVENTO O ULTERIORI PROCEDURE	159	8,29
MORTE O GRAVE DANNO IMPREVISTO CONSEGUENTE AD INTERVENTO CHIRURGICO	135	7,04
MORTE O DISABILITÀ PERMANENTE IN NEONATO SANO DI PESO >2500 GRAMMI NON CORRELATA A MALATTIA CONGENITA	82	4,28
MORTE, COMA O GRAVI ALTERAZIONI FUNZIONALI DERIVATI DA ERRORI IN TERAPIA FARMACOLOGICA	79	4,12
REAZIONE TRASFUSIONALE CONSEGUENTE AD INCOMPATIBILITÀ ABO	72	3,75
MORTE MATERNA O MALATTIA GRAVE CORRELATA AL TRAVAGLIO E/O PARTO	55	2,87
ERRATA PROCEDURA SU PAZIENTE CORRETTO	32	1,67
MORTE O GRAVE DANNO CONSEGUENTE AD INADEGUATA ATTRIBUZIONE DEL CODICE TRIAGE NELLA CENTRALE OPERATIVA 118 E/O ALL'INTERNO DEL PRONTO SOCCORSO	27	1,41
PROCEDURA CHIRURGICA IN PARTE DEL CORPO SBAGLIATA (LATO, ORGANO O PARTE)	26	1,36
PROCEDURA IN PAZIENTE SBAGLIATO	16	0,83
MORTE O GRAVE DANNO CONSEGUENTE AD UN Malfunzionamento DEL SISTEMA DI TRASPORTO (INTRAOSPEDALIERO, EXTRAOSPEDALIERO)	15	0,78
VIOLENZA SU PAZIENTE IN OSPEDALE	14	0,73
Totale	1918	100

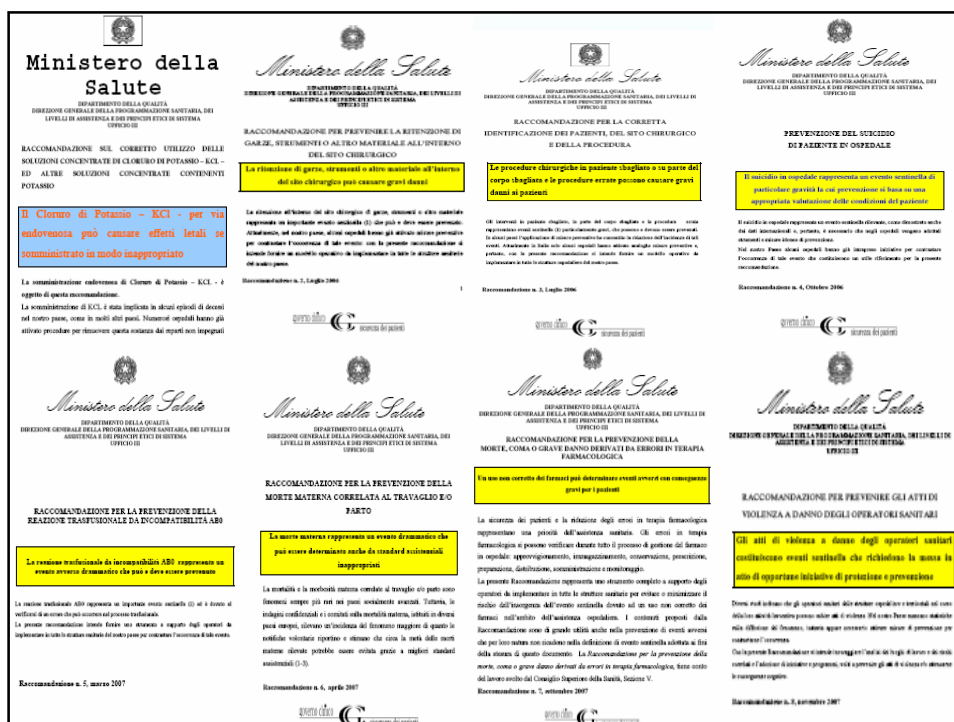


Logo of the European Union, Italian Presidency of the Council of the European Union, and Italia2014.eu.

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Osservatorio eventi sentinella SIMES

Il numero di piani di azione trasmessi dalle strutture sanitarie rispetto al totale delle segnalazioni degli eventi sentinella (1918) è pari a 66%





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Le Raccomandazioni per la prevenzione degli errori in terapia

- 1 Corretto utilizzo delle soluzioni concentrate di Cloruro di Potassio - KCL- ed altre soluzioni concentrate contenenti Potassio
- 7 Prevenzione della morte, coma o grave danno derivati da errori in terapia farmacologica
- 12 Prevenzione degli errori in terapia con farmaci “Look-alike/sound-alike”
- 14 Prevenzione degli errori in terapia con farmaci antineoplastici
- 17. Raccomandazione per la riconciliazione della terapia farmacologica - Ottobre 2014**

Linee-guida per la gestione della relazione tra strutture sanitarie e pazienti al verificarsi di un Evento Avverso, per una comunicazione aperta e trasparente

Safety Guides per il coinvolgimento degli Stakeholders

- Guide for providers of home care
- Guide for home care
- Guide for the safe use of medicines
- Guide for Citizens
- Guide for families
- Guide for volunteers
- Guide for Patients in dental care
- Guide for professionals
- Guide for healthcare facilities

Luxembourg Declaration on Patient Safety, 2005

inclusion of patient safety in the standard training of health professionals combined with integrated methods and procedures that are embedded in a culture of continuous learning and improvement, and welcomes the opportunity to address the issue of education in quality and safety at the EU level

EXPERT CONFERENCE

Krakow Statement

on Education in Quality Care and

Patient Safety

9 September 2011

ensuring better healthcare involves introducing and developing the different models of all health professionals' education and training, focused on teaching improvement science at the undergraduate, postgraduate and continuous education levels and that the development of the culture of quality and safety contributes to the provision of better healthcare

Council Recommendation 151/2009 on patient safety

embedding patient safety education and training for all health professionals, other healthcare workers and relevant management and administrative staff in the healthcare setting

GOVERNO CLINICO



AUDIT CLINICO



ENTRA NEL CORSO FAD

SICUREZZA DEI PAZIENTI E DEGLI OPERATORI



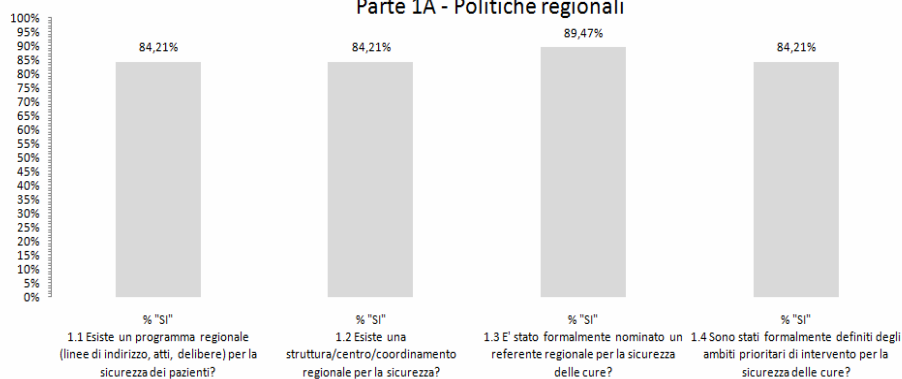
ENTRA NEL CORSO FAD



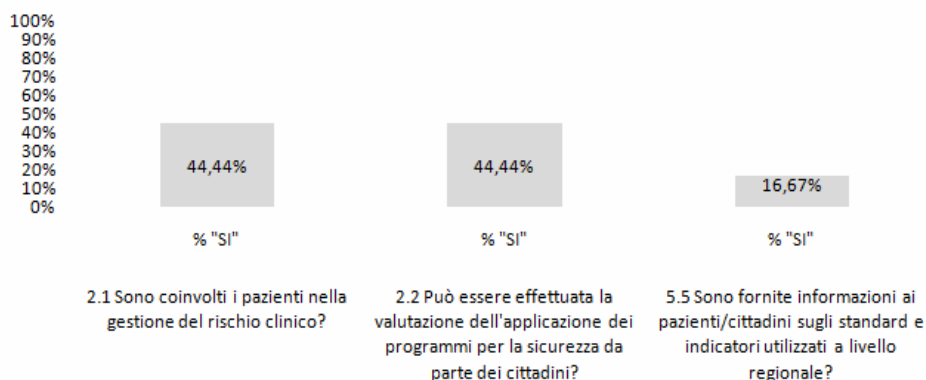
APPROPRIATEZZA

Rilevazione nazionale politiche regionali

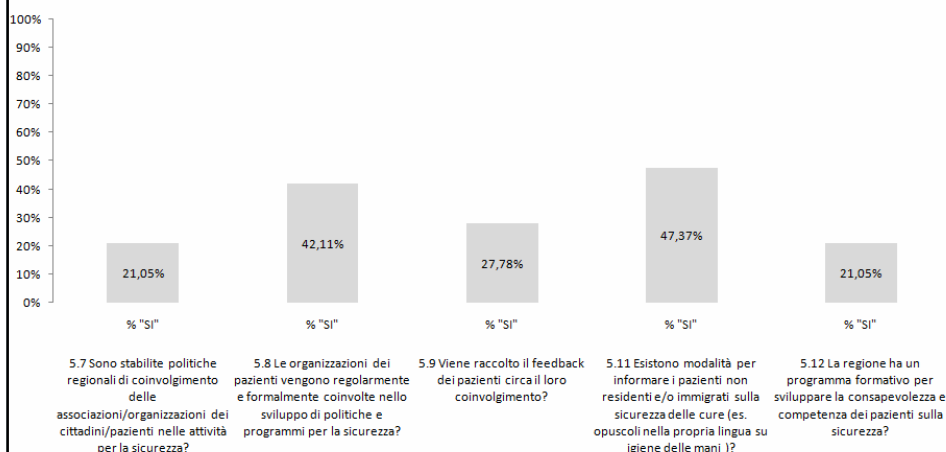
Parte 1A - Politiche regionali

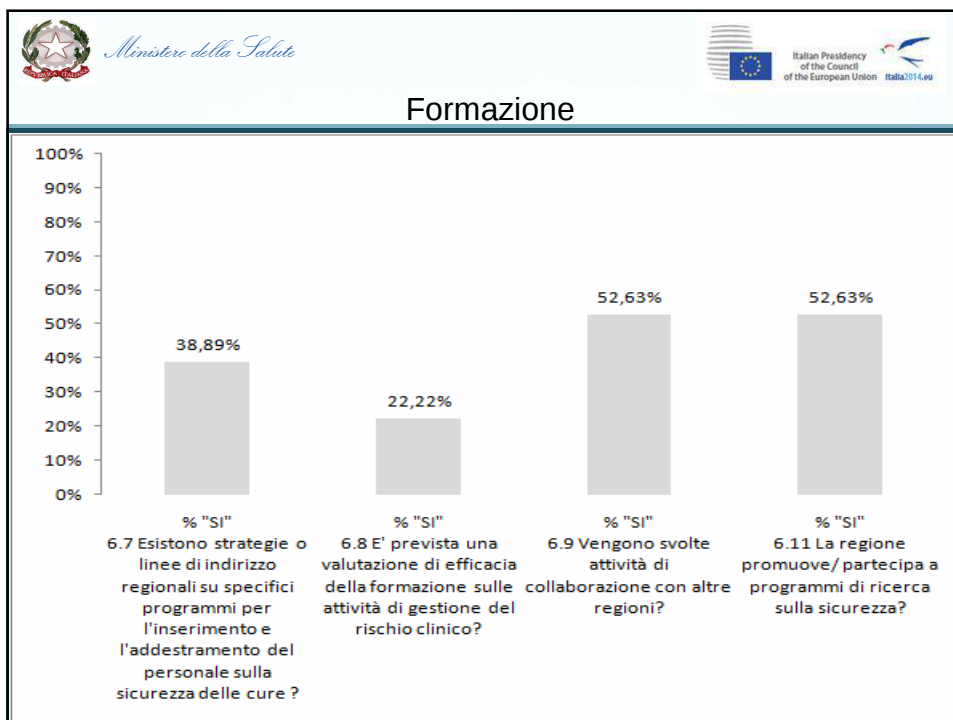
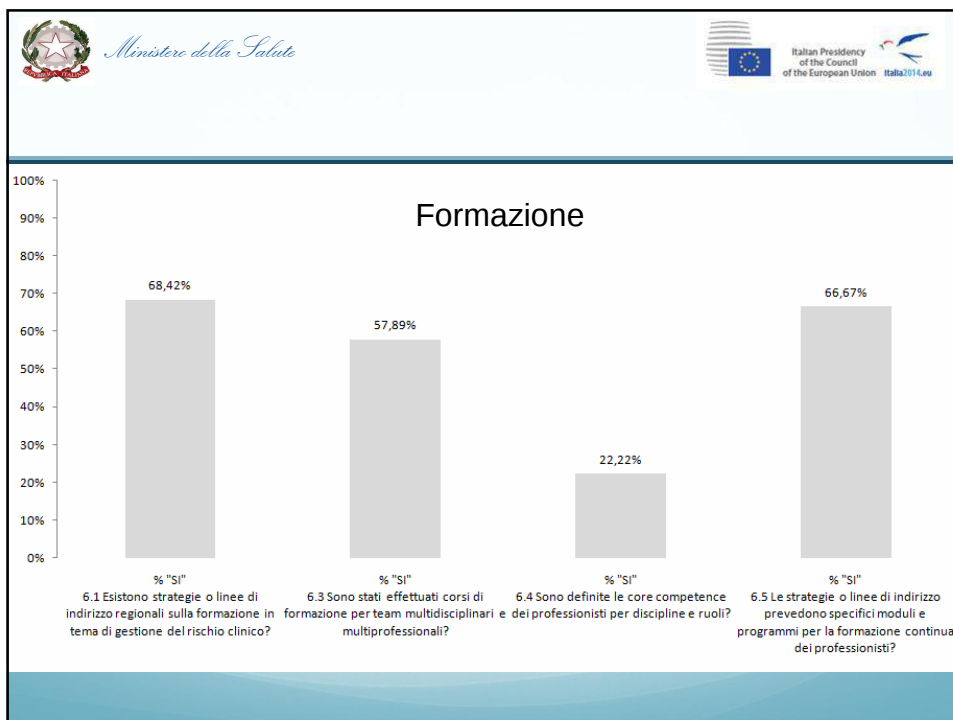


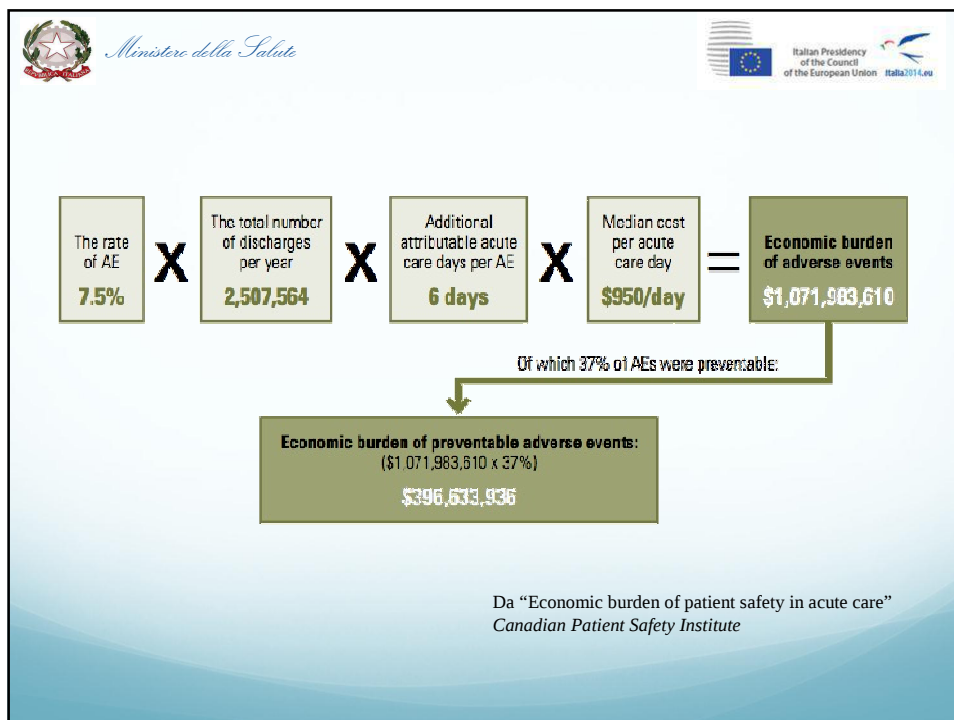
Coinvolgimento - 1



Coinvolgimento - 2







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BWH

Health Associated Infections:
Estimation of Costs and
Financial Impact on the US
Health Care System

ISQUA 2013

Eyal Zimlichman MD, MSc^{1,2}, Daniel Henderson MD¹,
MPH, Charles R. Denham MD¹, David W. Bates MD, MSc¹

¹Center for Patient Safety Research and Practice
Brigham and Women's Hospital and Harvard Medical School, Boston, MA

²Chief Quality Officer
Sheba Medical Center, Tel Hashomer, Israel



Results

National Cost Estimates

Total Attributable Financial Impacts of Health Care-Associated Infections in US Adult Inpatients at Acute Care Hospitals

Health Care-Associated Infection Type	Costs		
	Total	Lower Bound	Upper Bound
Surgical site infections	3 297 285 451	2 998 570 584	3 595 841 680
MRSA	990 539 052	93 785 080	1 935 883 296
Central line-associated blood- stream infections	1 851 384 347	1 249 464 195	2 636 608 279
MRSA	389 081 519	111 253 391	1 160 029 019
Catheter-associated urinary tract infections	27 884 193	18 765 813	37 002 574
Ventilator-associated pneumonia	3 094 270 016	2 796 898 212	3 408 445 101
<i>Clostridium difficile</i> infections	1 508 347 070	1 218 707 008	1 814 293 587
Total	9 779 171 077	8 282 405 811	11 492 191 220

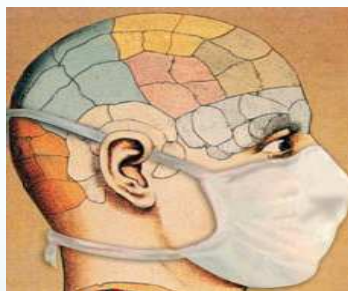


Cpt Chesley Sullenberger US Airways 1549



39

Technical skills



Non Technical skills



13/10/2014



Ringraziamenti

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Maurizio Cheli, Astronauta

Riccardo Tartaglia, Regione Toscana

Antonio Silvestri, Clinical Risk Manager, IRCCS LAZZARO SPALLANZANI

INVITO ALLA PARTECIPAZIONE

CONFERENZA DEL SEMESTRE DI PRESIDENZA
ITALIANA DEL CONSIGLIO UE

QUALITA' SICUREZZA E COSTO-EFFICACIA

ROMA 3-4 NOVEMBRE 2014

AUDITORIUM MINISTERO DELLA SALUTE