INSTITUTE OF MANAGEMENT

Scuola Superiore Sant'Anna

Conference on Quality, Safety and Cost-Effectiveness

MINISTERO DELLA SALUTE

Patient safety, economic perspective and evaluation techniques

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FONDAZIONE Arpa

Roma, 4 Novembre 2014

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Outline of the presentation

Patient safety

Economic perspective

Evaluation techniques

Recommendations

Outline of the presentation

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Patient safety

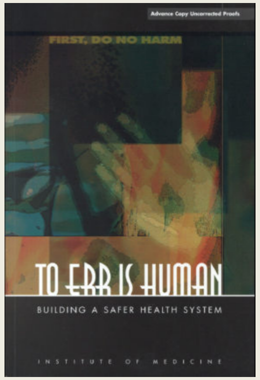
The dimension of the phenomenon

In USA from 44,000 to 98,000 preventable deaths annually due to medical error in hospitals

(IOM, 1999)

.....

equal to three Jumbo falling every two days....



"TO ERR IS HUMAN"

Building a Safer Health System
Committee on Quality of Health Care in America
Institute of Medicine, 1999

Patient safety

The dimension of the phenomenon

- HARVARD MEDICAL PRACTICE (Brennan & Leape, NEJM, 1991)
- THE QUALITY IN AUSTRALIAN HEALTH CARE STUDY, Wilson, Runciman: Med J Aust 1995
- ADVERSE EVENTS IN BRITISH HOSPITALS: PRELIMINARY RETROSPECTIVE RECORD REVIEW, Vincent, Neale: BMJ 2000
- INCIDENCE AND TYPES OF PREVENTABLE ADVERSE EVENTS IN ELDERLY PATIENTS, Thomas & Brennan, BMJ: 2000
- AN ALTERNATIVE STRATEGY FOR STUDYING ADVERSE EVENTS IN MEDICAL CARE Andrews, Stocking: Lancet 1997
- IATROGENIC COMPLICATIONS IN ADULT INTENSIVE CARE UNITS: A PROSPECTIVE TWO-CENTER STUDY, Giraud, Dhainaut: Crit Care Med, 1993
- A LOOK INTO THE NATURE AND CAUSES OF HUMAN ERRORS IN THE INTENSIVE CARE UNITS, Donchin, Gopher: Crit Care Med, 1995
- INCIDENCE OF ADVERSE DRUG REACTION IN HOSPITALISED PATIENTS: A META-ANALYSIS OF PROSPECTIVE STUDIES, Lazarou, Pomeranz: JAMA, 1998
- RISK FACTORS, Weingart BMJ, 2000

Patient safety

HARVARD MEDICAL PRACTICE (Brennan & Leape, NEJM, 1991)

Analyzed 30.121 hospitalizations in 51 acute care hospitals in the State of New York in 1984

- Adverse events with damage to the patient: 3,7% of hospitalizations
- 69% of damages due to errors (Leape, 1993)
- 13,6% had a fatal outcome
- 19% of adverse events was due to drugs
- 14% was due to wound infections
- 13% was due to technical complications

Patient safety

THE QUALITY IN AUSTRALIAN HEALTH CARE STUDY
Wilson, Runciman: Med J Aust 1995

- Analyzed 14.000 hospitalizations in 28 hospitals
- 16,6% of hospitalizations experiences an adverse event
- 51% of adverse events was considered preventable
- 13,7% of adverse events hesitated in permanent disability
- 4,9% of adverse events had a fatal outcome

Patient safety

ADVERSE EVENTS IN BRITISH HOSPITALS: PRELIMINARY RETROSPECTIVE RECORD REVIEW
Vincent, Neale: BMJ 2000

- Retrospective analysis of 1.014 cartelle in two acute care hospitals in London
- 10,8% of patients experienced an adverse event
- Approximately half of the adverse events was considered preventable
- One third of the adverse events hesitated in moderate to severe disability or had a fatal outcome

Patient safety

Risk factors, Weingart BMJ, 2000

- Age greater than 64
- Cardiothoracic surgery, vascular surgery, neurosurgery
- Severity of the underlying disease
- Intensive care unit stay
- Lenght of the hospitalization

Patient safety

The dimension of the phenomenon

USA (*Source: report IOM 1999*)

- 1 milion Americans every year suffer from damages due Medical treatments
- from 44,000 to 100,000 die

GREAT BRITAIN (*Source: report NHS 2000*)

- 28,000 people each year denouncing the NHS because of damages received from hospital care
- 1,500 die because of errors/bad hospital service

ITALIA (*Source: Rischio Sanità, 2001*)

- 320,000 people suffer from damages due to hospital care
- from14,000 to 50,000 die

Patient safety

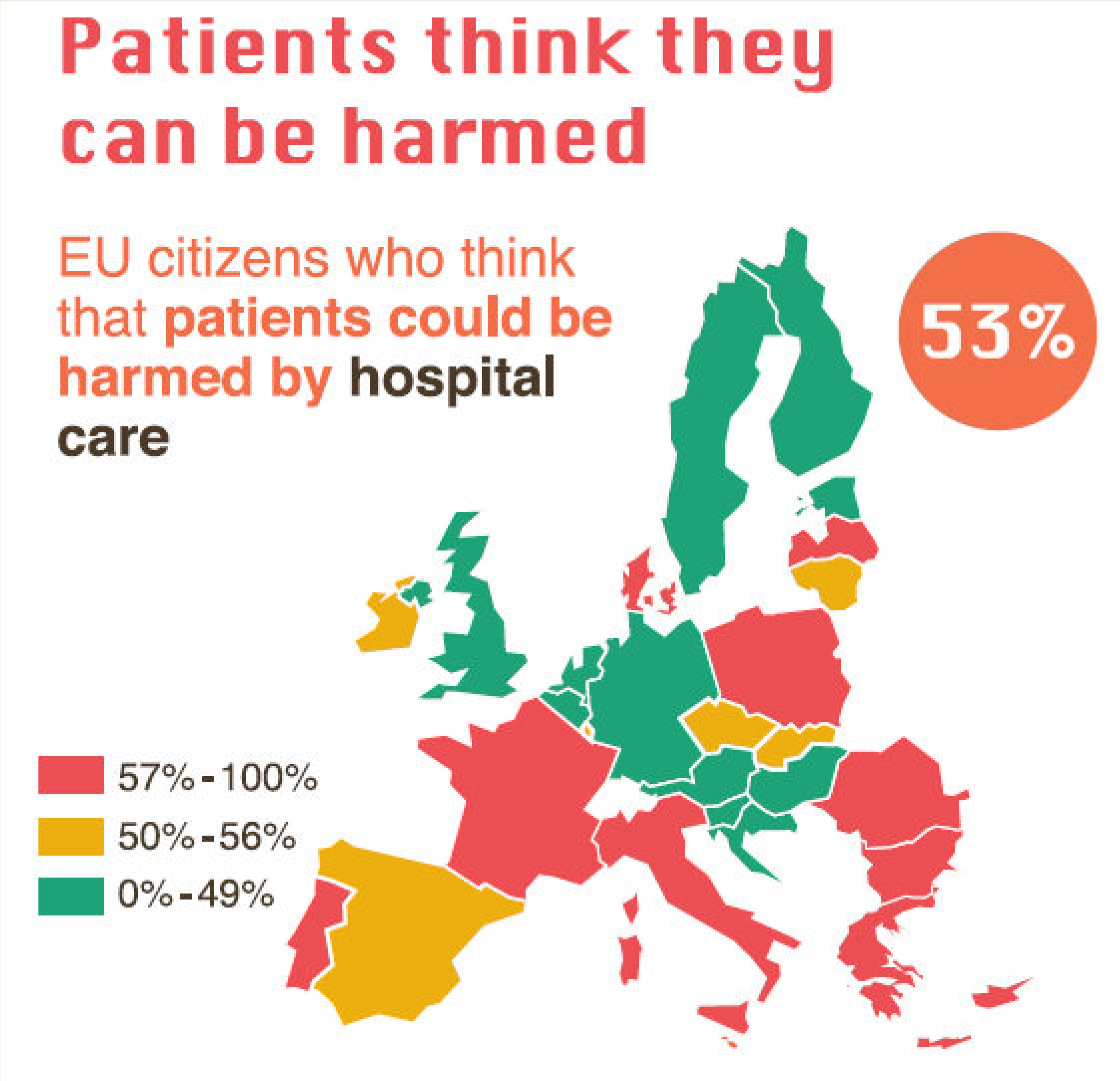
The dimension of the phenomenon

ITALY

Assuming an average of 30-35 thousand deaths per year:

- is equivalent to about 6% of all deaths in 2000 (557.584)
- equal to deaths from cancer of the lung, bronchus and trachea: 31.000
- equal to deaths from myocardial infarction: 35.515
- greater than deaths due to accidental and violent causes, including car accidents: 24.667

Patient safety



Eurobarometer, June 2014

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Economic implications

Annual financial losses due to health care-associated infections are also significant: they are estimated at approximately €7 billion in Europe, including direct costs only and reflecting 16 million extra days of hospital stay, and at about US$ 6.5 billion in the USA.
WHO, Health care-associated infections FACT SHEET

Healthcare-acquired infection (HAI) with methicillin resistant Staphylococcus aureus (MRSA) is a significant cause of mortality and morbidity in the United States accounting for up to $9.7 billion annually in additional health care costs, and €44.0 million annually in Europe.

Jinadatha C. et al., Evaluation of a pulsed-xenon ultraviolet room disinfection device for impact on contamination levels of methicillin-resistant Staphylococcus aureus, BMC Infectious Diseases 2014, 14:187.

In 2008, the costs related to medical errors in the United States amounted to $19.5 billion *(Andel C. Et al. The economics of health care quality and medical errors, J Health Care Finance, 2012; 39(1): 39-50)*.

Economic implications

The systematic review performed by Zimchman et al. evaluated cost associated with significant Health Care-Associated Infections (HAIs). The identified study were 26 and referred to the 5 major HAIs (surgical site infections (SSI), central line-association bloodstream infections (CLABSI), catheter-associated urinary tract infections (CAUTI), ventilator-associate pneumonia (VAP) and clostridium difficile infections (CDI). The review used PubMed for the period 1986-2013 and excluded the studies performed outside the United States.

Health Care-Associated Infection Type	Cost, 2012 $US	LOS (as Total, ICU), d
Surgical site infections	20 785 (18 902-22 667)[b]	11.2 (10.5-11.9)[b]
MRSA	42 300 (4005-82 670)[b]	23.0 (14.3-31.7)[b]
Central line-associated bloodstream infections	45 814 (30 919-65 245)[b,c]	10.4, 6.9 (6.9-15.2, 3.5-9.6)[b,c]
MRSA	58 614 (16 760-174 755)[c]	15.7 (7.9-36.5)[c]
Catheter-associated urinary tract infections	896 (603-1189)[b]	NR
Ventilator-associated pneumonia	40 144 (36 286-44 220)[b,c]	13.1, 8.4 (11.9-14.3, 7.8-9.0)[b,c]
Clostridium difficile infections	11 285 (9118-13 574)[b]	3.3 (2.7-3.8)[b]

Abbreviations: ICU, intensive care unit; LOS, length of hospital stay; MRSA, methicillin-resistant *Staphylococcus aureus*; NR, not reported.

[a] Data are reported as mean (95% CI) values.

[b] Estimates obtained from literature and 100 000-trial Monte Carlo simulations using triangular distribution.

[c] Estimates obtained from literature and 100 000-trial Monte Carlo simulations, using general distribution.

The authors realized Monte Carlo simulation techniques to estimate both cost and length of stay attributed to the 5 Major Health Care-Associated Infections for the US Adult Inpatient Population at Acute Care Hospitals[a]. (table).

Total annual costs for the 5 major infections amounted to $9.8 billion.

Zimlichman E. et al. Health Care Associated Infections. A meta-analysis of costs and Financial impact on the US health Care System, Jama Intern Med, 2013:173 (22): 2039-2046.

Economic implications

A Canadian study performed a literature research from the year 2000 to 2011 to **analyze the economic burden of patient safety in acute care.**

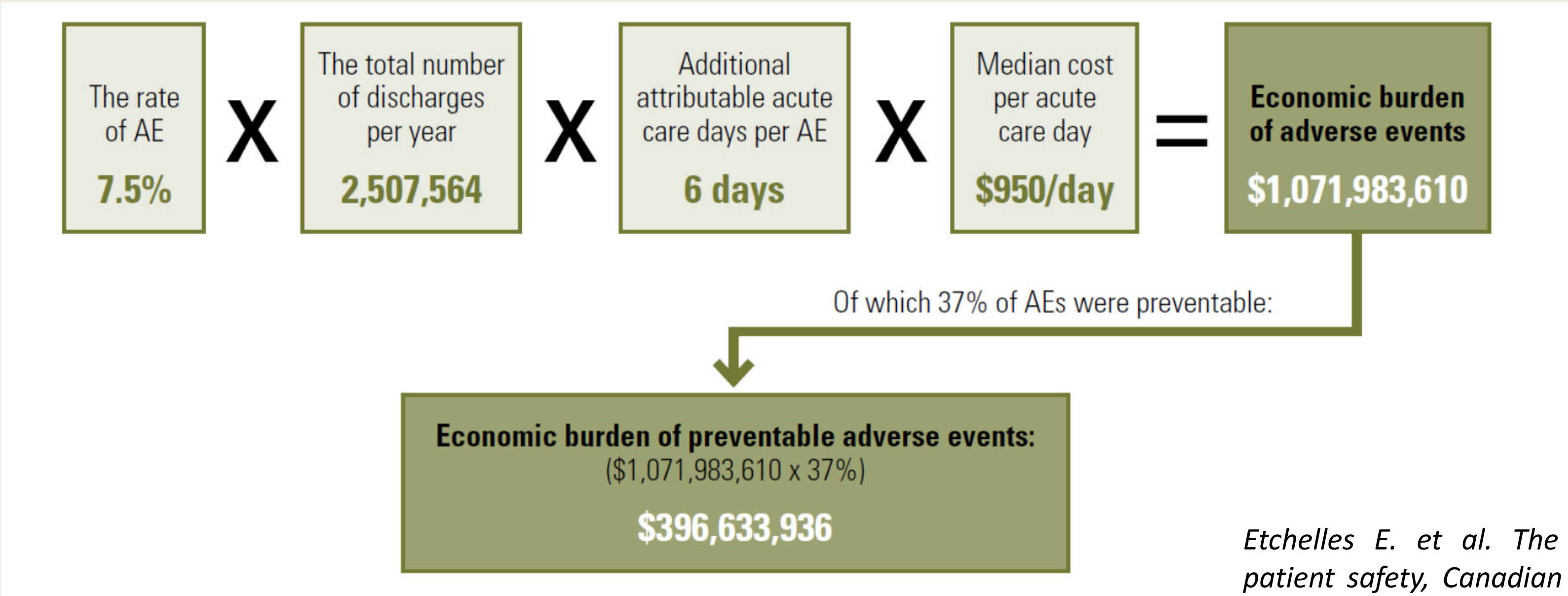
The identified studies were 158, of which 61 reported costing methodology. The majority of studies reported the economic burden of adverse events and nosocomial infections.

✓Costs of adverse events ranged from US$2,162 (CAN$4,028) to AUS$11,846 (CAN$12,648);

✓in general hospital populations, the cost per case of hospital-acquired infection ranged from US$2,027 (CAN$2,265) to US$12,197 (CAN$22,400);

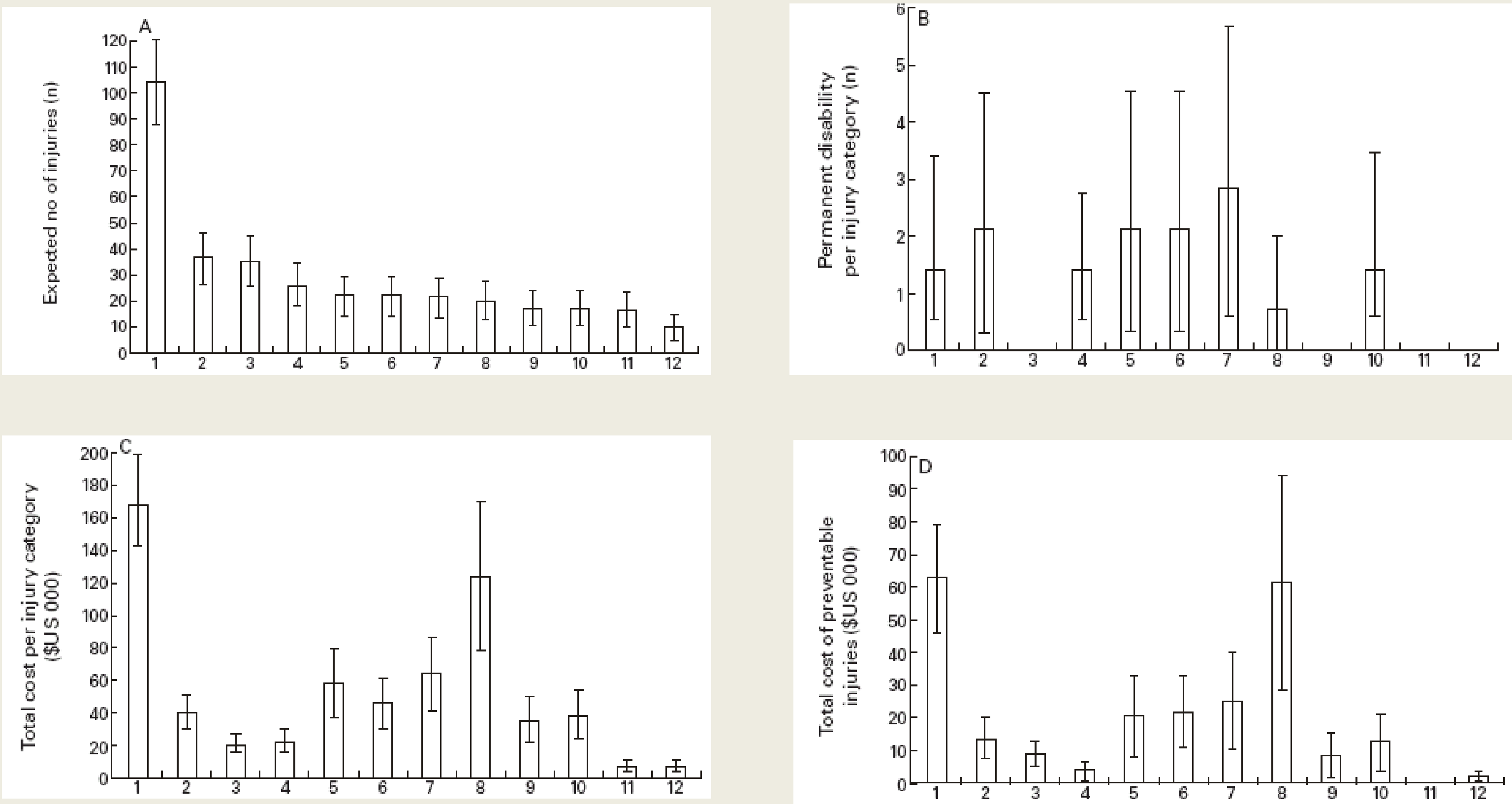
✓nosocomial bloodstream infection was associated with costs ranging from €1,814 (CAN$3,268) to €16,706 (CAN$29,950).

The economic burden of preventable adverse events in the Canadian acute care system was approximately $397 million in 2009-2010:



Etchelles E. et al. The economics of patient safety, Canadian Patient Safety Institute

Economic implications: an Australian study



Rigby & Litt, QHC, 2000

(A) Expected incidence, (B) permanent disability, (C) total average cost per category, and (D) total average cost of preventable injuries per category for every 10 000 hospital discharges.
1 = wound infections; 2 = pressure sores; 3 = urinary tract infections; 4 = inadequate manipulation of fractures; 5 = pulmonary embolism; 6 = unnecessary operations; 7 = falls admitted; 8 = warfarin related; 9 = bleeding due to non-steroidal anti-inflammatory drugs; 10 = deep vein thrombosis; 11 = postoperative nausea and vomiting; 12 = pneumothorax

Economic implications: an Australian study

There are damages that occur less frequently, but that determine permanent disability and/or high costs.

There are damages that involve high costs, but largely avoidable because the damages are largely preventable.

The average total cost to treat these 12 categories of damage is estimated at $ 636,000 per 10,000 hospital discharges.

The cost of avoidable damages is greater than $ 250,000, accounting for 2-3% of the annual budget for a typical Australian hospital of 120 beds.

Patient safety and quality of care initives are not free!

In a cost containment scenario, the risk is that you do not invest what you should

The *short-termism* prevails
and the investments in prevention are penalised

EVOLUTION OF TOTAL HEALTHCARE EXPENSE

Total healthcare expense (public+private), % of GDP											
	2000	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**
Italy	8,0	8,2	8,3	8,3	8,6	8,9	9,0	8,6	9,0	9,4	9,5
France	10,1	10,2	10,6	10,9	11,0	11,2	11,1	11,1	11,2	11,9	11,9
Germany	10,4	10,5	10,7	10,9	10,7	10,8	10,6	10,5	10,7	11,7	11,6
UK	7,0	7,2	7,6	7,8	8,0	8,2	8,5	8,4	8,9	9,8	9,6
EU-27	**8,1**	**8,3**	**8,5**	**8,8**	**8,8**	**9,0**	**9,0**	**8,9**	**9,2**	**9,9**	**9,9**
USA	13,7	14,3	15,1	15,7	15,8	15,8	15,9	16,2	16,6	17,7	17,6

Source: OECD 2012

How to structure the economic reasoning

1 - Costs of investing vs costs of not investing

2 - How to choose among alternative investment strategies

Cost of adverse events

Direct Costs, related to:

Repeat of the operation

Additional operations to reduce the morbidity (damage)

Longer stays in hospital

More and heavier assistance from families

Legal costs

Rise of insurance costs and uninsurability of hospitals (therefore: higher risks for citizens and professionals)

Indirect Costs, related to:

Image fall for the hospital and consequent economic losses for the local area

Late come back to work for patients (costs also for employers and social costs in general)

Loss of productivity for families (loss of working days)

Cost of adverse events

Latent costs, related to:

The health care organisation:

Wasting of resources

Duplication of activities

Bad quality of performances

The patient:

Intangible costs

Psychological costs

Opportunity costs

Activities not carried out

Defensive medicine

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Cost-Benefit Analysis (CBA)

CBA is a public sector decision-enabling and planning tool.

CBA aims at identifying whether a programme's or intervention's benefits exceed its costs, a positive net social benefit indicating that a programme its worthwhile (Drummond et al., 1997).

CBA allows the analyst to make a direct comparison of different options comparing their incremental costs with incremental consequences, all measured in monetary values by means of the Net Social Benefit (NSB).

Cost-Benefit Analysis (CBA)

The cost-benefit analysis uses the net social benefit (NSB) criterion for evaluation purposes, where NSB equals social benefits minus social costs.

Efficient social choices involve the selection of those projects for which NBS are highest.

The net social benefit criterion suggests that one should adopt only those programs and/or combinations of options having positive NBS

Cost-Benefit Analysis (CBA) to support patient safety and quality of care…an example

Volume 13 • Number 1 • 2010
VALUE IN HEALTH

Cost–Benefit Analysis of Preventing Nosocomial Bloodstream Infections among Hemodialysis Patients in Canada in 2004

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ABSTRACT

Objectives: Hemodialysis-associated bloodstream infection (BSI) is a significant public health problem because the number of hemodialysis patients in Canada had doubled from 1996 to 2005.Our study aimed to determine the costs of nosocomial BSIs in Canada and estimate the investment expenses for establishing infection control programs in general hospitals and conduct cost–benefit analysis.
Materials and Methods: The data from the Canadian Nosocomial Infection Surveillance Program was used to estimate the incidence rate of nosocomial BSI. We used Canadian Institute of Health Information data to estimate the extra costs of BSIs per stay across Canada in 2004. The cost of establishing and maintaining an infection control program in 1985 was estimated by the US Centers for Disease Control and Prevention and converted into 2004 Canadian costs. The possible 20% to 30% reduction of total nosocomial BSIs was hypothesized.

Results: A total of 2524 hemodialysis-associated BSIs were projected among 15,278 hemodialysis patients in Canada in 2004. The total annual costs to treat BSIs were estimated to be CDN$49.01 million. Total investment costs in prevention and human resources were CDN$8.15 million. The savings of avoidable medical costs after establishing infection control programs were CDN$14.52 million. The benefit/cost ratio was 1.0 to 1.8:1.
Conclusion: Our study provides evidence that the economic benefit from implementing infection control programs could be expected to be well in excess of additional cost postinfection if the reduction of BSI can be reduced by 20% to 30%. Infection control offered double benefits: saving money while simultaneously improving the quality of care.
Keywords: bloodstream infection, costs and benefits, health economics, infection control program.

Cost-Benefit Analysis (CBA) to support patient safety and quality of care…an example

Costs of the intervention

The cost of establishing and maintaining an infection control program in 2004 in a hospital in Canada was estimated to be CAD$133,633

Size of the phenomenon

The incidence rate of bloodstream infection (BSIs) was 1.4 cases/1000. Considering a total of 1,802,922 haemodialysis patients it was estimated a total of 2524 BSIs cases generating a total annual cost (for treatment) of about 49.01 million

Effects of the intervention

Reduction of BSIs cases in the range 10%-30%

When the control program could prevent 30% of nosocomial infection the ratio of benefits to costs is 1.80:1

Conclusions

Health-care practice has evolved during the last two decades. Our cost–benefit analysis demonstrated that there is a good benefit–cost ratio when the infection control program can prevent 20% to 30% of nosocomial BSIs cases.

Infection control offers dual benefits: it saves money while simultaneously improving the quality of care. Effective infection control programs generate monetary benefits by preventing nosocomial infections and increasing health care efficiency by reducing additional burden. From the standpoint of both the hospital and of the community, the benefits justify the costs. The economic future of infection control depends on its ability to continue to demonstrate that it is both effective and cost effective.

Cost-Effectiveness Analysis (CEA)

CEA is a comparative evaluation of costs and effects deriving from two or different strategies.

Contrarily to CBA it avoids impinging any monetary value judgment on the outcome, that is generally expressed in terms of clinically relevant measure.

CEA compares different options by means of the cost (C) effectiveness (E) ratio (C/E) and the Incremental Cost Effectiveness Ratio (ICER) that is the cost per incremental unit of effectiveness.

Cost-Effectiveness Analysis (CEA)

Given two strategies A and B and considering their associated costs (C_A and C_B) and effectiveness (E_A and E_B), ICER could be obtained as follows:

$$\textbf{ICER=} \frac{C_A - C_B}{E_A - E_B}$$

Options that are more costly and less effective than a given strategy results in a negative ICER and should not be considered. Similarly, options equally effective and more costly should not be considered.

Options more effective and more costly than a given strategy produce positive ICERs that need.. a *cost-opportunity* evaluation.

Cost-Effectiveness Analysis (CEA) to support patient safety and quality of care…an example

OPEN ACCESS Freely available online PLoS one

Quantifying Cost-Effectiveness of Controlling Nosocomial Spread of Antibiotic-Resistant Bacteria: The Case of MRSA

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Abstract

Background: The costs and benefits of controlling nosocomial spread of antibiotic-resistant bacteria are unknown.

Methods: We developed a mathematical algorithm to determine cost-effectiveness of infection control programs and explored the dynamical interactions between different epidemiological variables and cost-effectiveness. The algorithm includes occurrence of nosocomial infections, attributable mortality, costs and efficacy of infection control and how antibiotic-resistant bacteria affect total number of infections: do infections with antibiotic-resistant bacteria replace infections caused by susceptible bacteria (replacement scenario) or occur in addition to them (addition scenario). Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia was used for illustration using observational data on *S. aureus* bacteremia (SAB) in our hospital (n = 189 between 2001–2004, all being methicillin-susceptible *S. aureus* [MSSA]).

Results: In the replacement scenario, the costs per life year gained range from € 45,912 to € 6590 for attributable mortality rates ranging from 10% to 50%. Using € 20,000 per life year gained as a threshold, completely preventing MRSA would be cost-effective in the replacement scenario if attributable mortality of MRSA is ≥21%. In the addition scenario, infection control would be cost saving along the entire range of estimates for attributable mortality.

Conclusions: Cost-effectiveness of controlling antibiotic-resistant bacteria is highly sensitive to the interaction between infections caused by resistant and susceptible bacteria (addition or replacement) and attributable mortality. In our setting, controlling MRSA would be cost saving for the addition scenario but would not be cost-effective in the replacement scenario if attributable mortality would be <21%.

Cost-Effectiveness Analysis (CEA) to support patient safety and quality of care…an example

Costs of MRSA infection control

The cost of **Methicillin-resistant Staphylococcus aureus** (MRSA) **infection** control in 2004 was estimated to be €308,533 per year.

Costs for additional length of stay were €1,684 and €337 for ICU and non-ICU stay

Effects of the intervention

Reducing prevalence of MRSA and thus attributable mortality

Table 2. Costs, effects and break-even values for different attributable mortality rates in the replacement and addition scenario.

	Attributable mortality					
	0%	**10%**	**20%**	**30%**	**40%**	**50%**
Life years gained, discounted						
Replacement	0	7.0	15.7	26.8	41.7	62.3
Addition	227.9	252.3	282.6	320.9	371.3	440.3
Total incremental costs (€)						
Replacement	308,533	321,384	335,305	352,822	377,885	410,557
Addition	−1,092,781	−1,056,128	−1,011,708	−955,961	−884,808	−789,898
Cost per life year gained per year MRSA policy (€)						
Replacement	NA[b]	45,912	21,357	13,165	9062	6590
Addition	−4795	−4186	−3580	−2979	−2383	−1794
Break-even values costs infection control policy per year (€)[a]						
Replacement	NA[b]	127,783	287,257	491,900	764,120	1,144,144
Addition	5,959,726	6,411,444	6,971,136	7,682,879	8,618,626	9,904,560

[a]Assuming the Dutch threshold value for cost-effectiveness of € 20,000 per life-year gained.
[b]NA, not applicable.
doi:10.1371/journal.pone.0011562.t002

Considering the Dutch threshold value for cost-effectiveness of €20,000 per life year gained, there is strong evidence that the Dutch MRSA control policy is cost-effective.

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We believe that investing in quality of care and in patient safety is **convenient** from an economic perspective

but….

we need to **measure** it!

Necessary conditions

- Adoption of rigorous evaluation techniques
- Adoption of a wide perspective (social costs)
- Adoption of a longer time horizon
- Adoption of a better communication

The proper relation

Quality of care and patient safety

Efficiency and sustainability

“If we aren’t sure to be effective,
it is useless to worry about being efficient”

Arcibald Cochrane

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FONDAZIONE Arpa

Roma, 4 Novembre 2014

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