RCSI INSTITUTE OF LEADERSHIP

ISQua®

Tús Áite do Shábháilteacht Othar
Patient Safety First

Welcome to the ISQua Global Leader Lecture

"A Managerial or a Medical Approach for Assessment of Quality and Safety"

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Why measure quality improvement and for whom?

for a better rating
of health care organizations

OR

for a better life of patients?


No man can serve two masters


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LEADERSHIP

Physician, scientist,

chairman of public health agencies
Haute Autorité de santé (HAS)

A binary approach

individual interests, collective interests

A binary approach

individual interests, collective interests

- More efficacy (individual), more safety and sustainability (collective)
- More facilities for a patient, better distribution of available tools
- Patients'health, optimization of common resources

OVERVIEW

1. A binary approach
2. The search of underlying values
3. Insight and lessons

QUALITY OF health care products

health care organizations

SAFETY policy (guilty or no blame-no shame)

prescriptive strategy or autonomy

QUALITY ASSESSMENT

Quality assessment of
health care products

Quality assessment of
health care organizations

QUALITY ASSESSMENT

Quality assessment of health care products

Quality assessment of health care organizations

Quality assessment of health care products

After the market approval by EMA, FDA, or PMDA for European, American and Japanese populations,

health insurers assess the **cost effectiveness** allowing decisions for **price, reimbursement and volume of dissemination**

Quality assessment of health care products

Example of SOFOSBUVIR

NO REIMBURSEMENT

LEVEL OF EVIDENCE
(Randomized Trials)

SEVERE CASES

Quality assessment of health care products

A BINARY APPROACH

COST OF OPPORTUNITY

LOSS OF OPPORTUNITY

Quality assessment of health care products

SOCIAL VALUES

UTILITY =
COST OF OPPORTUNITY

EQUALITY =
LOSS OF OPPORTUNITY

Quality assessment of health care products

SOCIAL VALUES

UTILITY

ACCOUNTABILITY

EQUALITY

Quality assessment of health care products

INSIGHT & LESSONS

UTILITY

cost-qaly threshold: **REIMBURSEMENT**

ACCOUNTABILITY

willingness to pay : **PRICING**

EQUALITY

stratification:

VOLUME (or price x volume)

Quality assessment of health care products

INSIGHT & LESSONS

HARMONY

LIBERTY

PCORI (USA)

Patient Centered Outcomes Research Institute

ACA Law, Sec 1182 (e)

The Secretary **shall not utilize such an adjusted life year (or similar measure) as a threshold to determine coverage, reimbursement, or incentive programs** under title XVIII.

Quality assessment of health care products

SOCIAL VALUES

utility, accountability, equality, harmony, liberty…

UTILITY =
COST OF OPPORTUNITY =
COLLECTIVE INTEREST

EQUALITY =
LOSS OF OPPORTUNITY =
INDIVIDUAL INTEREST

QUALITY ASSESSMENT

Quality assessment of
health care products

**Quality assessment of
health care organizations**

Quality assessment of health care organizations

A BINARY APPROACH

Quality assessment of health care organizations

A BINARY APPROACH

MANAGERIAL:

Requirements effectively in place

Accreditation, process indicators, certification

MEDICAL:

Clinical Outcomes of patients

Mortality, complications, quality of life

NO CORRELATION
BETWEEN ASSESSMENT OF PROCESSES
AND CLINICAL OUTCOMES

Quality assessment of health care organizations

A BINARY APPROACH

A legal, administrative, insurance and regulatory perspective

OR

A better patient centered outcome strategy

For a protection against threats and complaints or for an improvement of clinical outcomes?

Quality assessment of health care organizations

VALUE OF HEALTH CARE

WHY and FOR WHOM
do we apply quality assessment

Quality assessment of health care organizations

VALUE OF HEALTH CARE

WHY and FOR WHOM
do we apply quality assessment

a better health

OR

a better stay in hospitals?

Quality assessment of health care organizations

VALUE OF HEALTH CARE

WHY and FOR WHOM

do we apply quality assessment

a perfect respect of processes and protocols

OR

efficacy, safety, access to care

?

Quality assessment of health care organizations

VALUE OF HEALTH CARE

*" In health care, stakeholders have a myriad of often conflicting goals… **The value is defined as the health outcomes achieved per dollar spent**. Cost reduction without regard to the outcomes achieved is dangerous and self defeating leading to false "saving"…"*

Michael E. Porter,
N Eng J Med
2010,363;26; 2477-2481

Quality assessment of health care organizations

VALUE OF HEALTH CARE

The goal and thus the value of health care are related to the clinical outcomes,

less mortality, less morbidity and a better quality of life.

Clinical outcome indicators

Mortality

Methodology available (Brian Jarman)

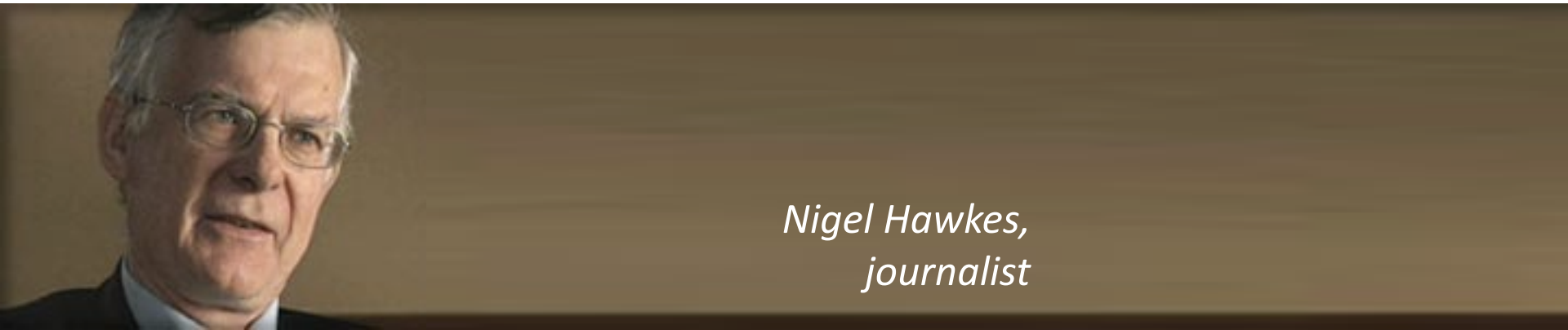
Gaiming (Mid Straffordshire NHS Trust)

Quality assessment of health care organizations

CLINICAL OUTCOMES : MEDICAL PRACTICE IMPROVEMENT OR ADMINISTRATIVE PURPOSES

"However the public inquiry into Mid Staffordshire NHS Foundation Trust, disclosed ingenious ways of modifying outcomes (in order to improve their rating) and concealing deaths.

For instance, changes in coding practice resulted in many deaths being excluded from the calculation of hospitals by classifying increasing numbers of patients as palliative care cases. …"



Nigel Hawkes, journalist

Quality assessment of health care organizations

REVERSE INDICATORS

- **HAS-BMJ symposium** « Clinical impact of quality improvements» *QSHC 2010, vol 19 spt 1*

- From clinical outcomes to processes
- Clinician involvement and enthusiasm

Quality assessment of health care organizations

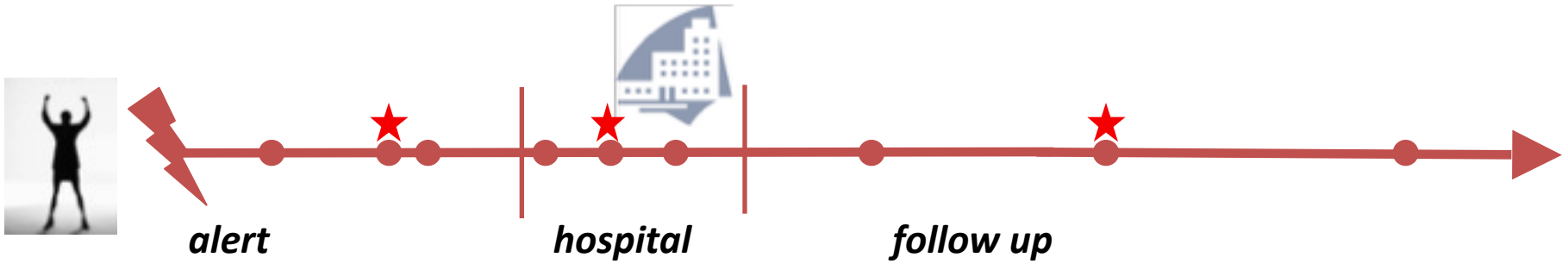
INSIGHTS AND LESSONS

if we admit that the value of health care
is the patient's better life

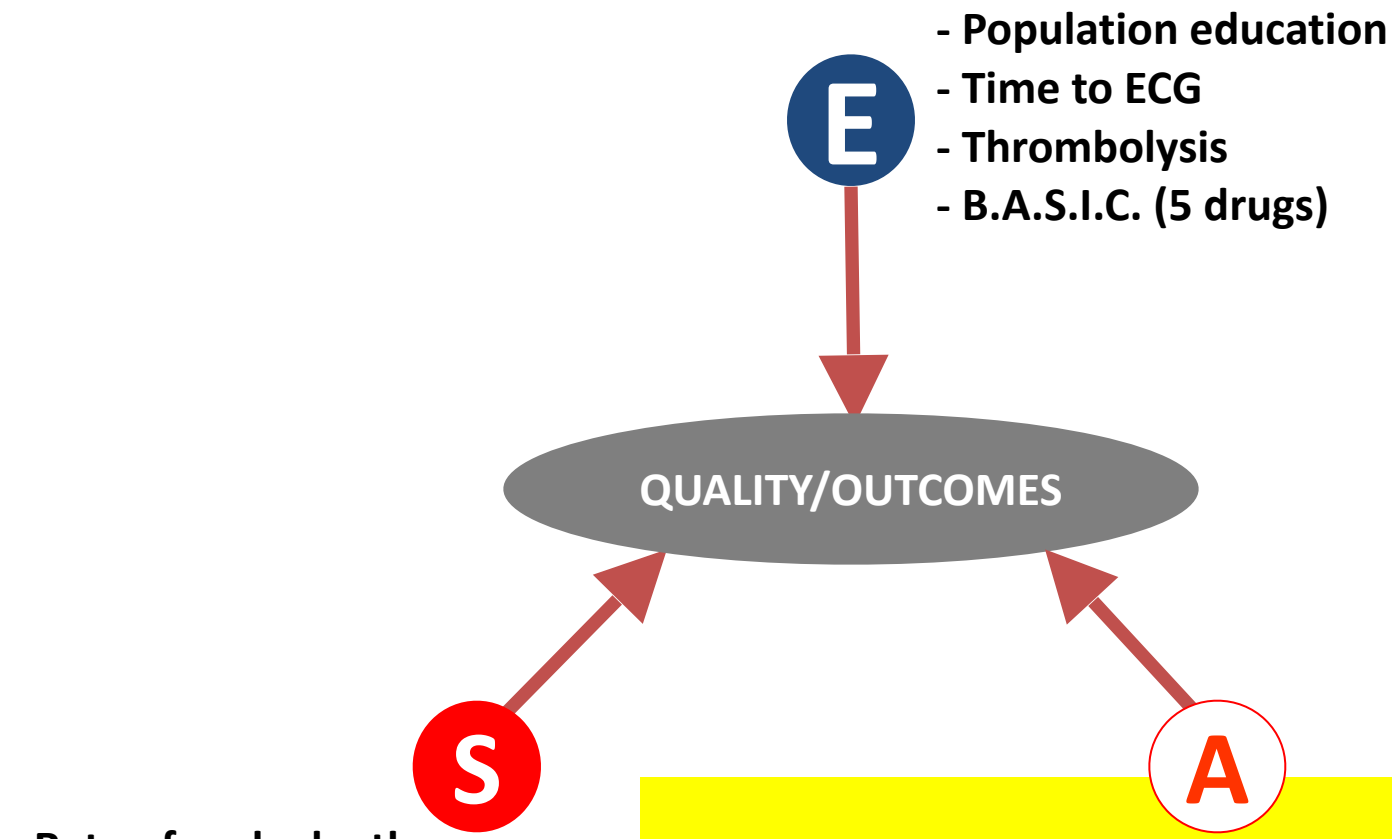
thus, we should assess clinical outcomes considering the full cycle care of patients

Full cycle care AMI and Stroke

- To construct the whole optimal pathway of the patient
- Time is “heart”, time is “brain”
- To integrate the Trio: **Efficacy, Safety, Access to care**



ESA Quality – AMI



Full cycle care: AMI

OPTIMAL PATHWAY

50% decrease of mortality

&

50% decrease of cost

a better life for the patient

and an economical advantage

What have we learnt from the past ?
Where should we move?

FROM	TO
• **Industrial approach:** processes and categories	• **Clinical outcomes:** QOL mortality, complications,
• **Managerial approach:** administrative indicators	• **Commitment of health professionals**
• **Segment of care**: structures, HCOs, GPs…	• **Full cycle care:** safety, efficacy, access to care

Quality assessment of health care organizations

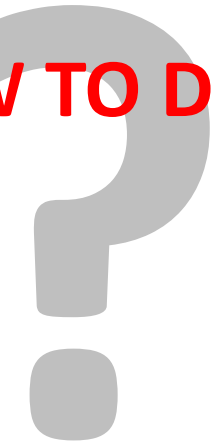
INSIGHTS AND LESSONS

Assessment of the optimal patients' pathway for each disease year after year

Unstability of health care in hospitals, due to multiple disruptive innovations

The question today is not
« do we have to move from accreditation and quality indicators of HCOs to outcomes indicators of the whole patient pathway? »
but

« HOW TO DO IT »



SAFETY ASSESSMENT

Quality and safety are consubstantial

safety is the first priority
of and for customers

Safety assessment
of health care activity

« While effort to improve patient safety have proliferated during the past decades, progress toward improvement has been frustratingly slow »

Quality Safety in Health care 2009, 18; 424-428

Lucian Leape, Donald Berwick, Carolyn Clancy et al

Safety assessment
of health care activity

Two French inquiries, ENEIS,
carried out at 5 years interval in 2004 and 2009
did not disclose any change in the rate
of severe adverse events in HCOs

QUESTION

HOW COULD WE INCREASE THE SAFETY IN HEALTH CARE

SAFETY ASSESSMENT

Safety assessment of health care activity :
no blame or sanction?

Prescriptive strategy or autonomy and
resilience engineering?

SAFETY ASSESSMENT

Safety assessment of health care activity : no blame or sanction?

Prescriptive strategy or autonomy and resilience engineering?

Safety assessment of health care activity

A binary behaviour:

guilty or not guilty?

Safety assessment of health care activity

A binary behaviour:

guilty or not guilty?

multiple causes inside the adaptative and evolutive complex system

Safety assessment of health care activity

A binary behaviour:

guilty or not guilty?

- To err, to wander is not to commit a fault
- The error is not human, the error is the result of multiple causes inside the adaptative and evolutive complex system

Safety assessment of health care activity

We should modify our initial spontaneous attitude

1. the last actor is not a guilty individual,

2. it is our duty to recognize and repair all the successive defective elements.

Safety assessment of health care activity

UNDERLYING VALUES

- “guilty and sanctioned” OR “no blame no shame” policies,
- “all about me” OR disclosure of all causes

a conflict between two values

individual interest
(transparency)

collective interest
(to repair the system)

Safety assessment of health care activity

INSIGHTS AND LESSONS

by law, privilege and confidentiality protections for patient safety work product

declaration to the police (Article 21)

one inquiry totally protected for the search of causes, the second totally opened to help the patient

information delivered immediately and

no fault compensation

Safety assessment of health care activity

INSIGHTS AND LESSONS

In France: program of accreditation of physicians

- accreditation of physicians “at risk” (surgeons, anesthetists, gynecologists) based on the **analysis of near misses**
- a financial incentive as part of the insurance premium
- a limited number of cases per year

leads to significant repair of the system

Safety assessment of health care activity

INSIGHTS AND LESSONS

- Reporting without a cause-analysis does not help safety
- The causes of the successive defects of an event will differ in each hospital
- What is the relevance of an exhaustive reporting (national data bank) of adverse events?

SAFETY ASSESSMENT

Safety assessment of health care activity : no blame or sanction?

Prescriptive strategy or autonomy and resilience engineering?

Prescriptive strategy or autonomy and resilience engineering

Two approaches originated by two tragedies

During the last World War, the US navy was in a great part destroyed in a short time.

➔ **Prescribed processes** allowed to obtain performing crews.

The shuttle Columbia exploded the 1st of February 2003 with 7 astronauts.

➔**Concept of resilience engineering**

Prescriptive strategy or autonomy and resilience engineering

"The definition of resilience can be the ability of a system or an organization to react and to recover from disturbances at any stage, with minimal effect on the dynamic stability"

Eric Hollnagel
Resilience engineering concepts and precepts
ASHGATE 2006 www. ashgate.com

RESILIENCE

Two instructive stories

During the take off from New York Kennedy Airport a flight was dangerously compromised. The captain, Chesley Sullenberger put the aircraft A320 in the Hudson Bay

The study of unexpected mortality after common surgery of 85000 patients in 186 hospitals during 3 years. The difference is due to anticipation and resilience.

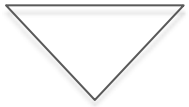
(*Ghaferi A.A. et al New Eng. J. Med 2009, 361, 1368-75*)

Binary values underlying prescriptive strategy and autonomy policies

Protocols and prescribed procedures constructed according to **previous accidents and events (like a rear view mirror)**

forward-looking adapting decisions according to variable circumstances

if **the error is not human**,
due to the complexity of the adaptative system,



the anticipation is human,
avoiding harms due to errors
arising during unexpected events

Prescriptive strategy or autonomy and resilience engineering

THE 2 POLICIES ARE NOT MUTUALLY EXCLUSIVE

Protocols are necessary but not sufficient

One needs to have perfect techniques to be talented

Prescriptive strategy or autonomy and resilience engineering

INSIGHTS AND LESSONS

to reduce the number of protocols to the minimum required

to be on alert, vigilant, attentive, strengthening the spirit of the team and team-work

in conclusion

we could caricature

the managerial, economical, regulatory approach, vying

- to avoid complaints and mishaps by perfect processes,
- to minimize the load by the cost of opportunity principle,
- to categorize the best and the worse through accreditation and industrial quality indicators,
- paying for performance
- looking for guilty people and sanctioning any error,
- refraining any autonomy, aiming to have a perfect system with fixed procedures,

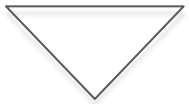
…and

- the patient centered clinical approach,
- looking for better clinical outcomes through efficacy, safety and access to care, managing for the optimal full cycle care, before, during and after hospitalization, comparing year after year the patient pathway for a disease,
- paying for participation in a full cycle care,
- applying the no-blame no-shame principle, to find causes and to repair the multiple defects,
- favoring autonomy, anticipation,

  resilience, adaptation

in fact

We need both approaches in order to have excellent and well organized HCOs, good links between the HCOs and their environment and to obtain the best outcomes for the patients.



The difficulty is to find a balance between the two approaches and not to be too “managerial” as we could have been in the past, nor too “medical” avoiding the risk of anarchy

Politicians, before making decisions,

wish to assess the national health system

criterions related to the health of the population

to the health expenses and

to the satisfaction of the population.

no correlation between health system assessment and the micro or meso

indicators of quality of health care

the satisfaction of the population is the major concern of politicians

satisfaction is mainly related to access to care

4 insights and lessons

1

Make a choice between

utility and equality

cost of opportunity and loss of opportunity

2

Move from
processes indicators
and accreditation of HCOs
to
full cycle care evaluation
and patient outcomes indicators.

To err is not human.

Errors are due to the adaptative and evolutive complex system.

It is preferable to apply a no blame no shame policy in order to find the multiple causes and to repair the system than to apply individual sanctions

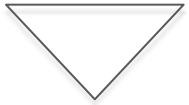
3

To anticipate is human

4

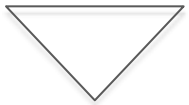
Resilience engineering is inherent to health care practice and vigilance and talents should be promoted.

satisfaction of the population about the health system is usually related to access to care and bundled care that is geographically, economically, and timely accessible,



a perfect example of medical and managerial combined effort

managerial **AND** medical approaches must be **complementary**
for assessment and improvement
of quality and safety in health care



they must pull themselves together,
hand in hand, in order to cope
successfully with the same goal…
a patient's better life.

THANK YOU