“Primum non nocere”

Patient Safety is not a luxury, nor a special programme

Prof. Dr. Jacques Scheres
EAHM,
Patients think they can be harmed

EU citizens who think that patients could be harmed by hospital care

53%

No change since 2009 (+3%)
Education and training of healthcare workers

Reporting incidents and learning systems

Patients...

...experiencing an adverse event...

27%

- 30% - 100%
- 25% - 29%
- 0% - 24%

...reporting it...

46%

- 50% - 100%
- 43% - 49%
- 0% - 42%

...to what result

- 37% - Nothing happened
- 20% - The doctor/nurse apologized
- 17% - An explanation for the error was provided by the healthcare facility
- 12% - Measures have been taken to prevent similar errors in the future by the healthcare facility
- 11% - The healthcare facility did not accept liability for the adverse event
- 6% - The person responsible was disciplined
- 6% - Financial compensation was given
- 6% - Legal proceedings are still underway
- 5% - Action was taken against the healthcare facility responsible
- 4% - Other (spontaneous)
- 3% - Don’t know
Further inspiring data

- Only 5% of incidents are adequately reported (to avoid blame/litigation)
- Medical error is the 3rd leading cause of death after cardiac and cancer deaths (US)
- IC serious complications: 75% related to infections, 40% of which are preventable
- Perspective: AMR will kill up to 10 Million people p.a. extra (by 2050)
Patient Safety, European Actors and policies

- EU Council / Commission / Parliament
- (DE, FR, IE, IT, NL), UK
- WHO (High 5s; WHA)
- IMPO
- Miscellaneous
Patient safety and healthcare associated infections

Report from the Commission to the Council

Maria Iglesia Gomez
Head of Unit Healthcare Systems
DG SANTE, European Commission
Suggested follow-up measures

1. A common definition of quality of care and support for common terminology, common indicators and research on patient safety;
2. EU collaboration on patient safety and quality of care;
3. Guidelines on how to provide information to patients on quality of care;
4. EU guideline on how to build patient safety and quality of care standards;
5. Reflection on the issue of redress as provided for in Directive 2011/24/EU);
6. Encouraging training for patients, families and informal carers;
7. Encouraging reporting as a tool to spread a patient safety culture.
• **Classify and measure patient safety**
  Co-financing of the Health Care Quality Indicators Project led by OECD
  Agreement with WHO on delivering EU patient safety taxonomy

• **Share knowledge and experience**
  EU expert group on patient safety and quality of care
  Co-financing of the EU network on patient safety and quality of care

• **Develop and promote research**
  Co-financing of projects within the Health Programme and research programme FP7
The European Network for Patient Safety & Quality

JA PaSQ

Update

PSQCEG
Brussels, 28 Sept. 2015
PaSQ Joint Action has 61 Partners, being all EU Member States plus Norway, and main stakeholders.
PaSQ networking approach

PaSQ = 61 partners: all MS and the main stakeholders
- Collective review and selection of good practices (SCPs & GOPs)
- Implementation of safe and transferable SCPs and GOPs
- Support based on exchange of experience and mutual learning
- Commitment of field workers and patients at all stages of the work through NCPs
- Development of IT tools to facilitate commitment and communication
- EU Convergence in the long term
Aims of Permanent PaSQ Network in Europe

- Share experiences to avoid duplication
- Efficient implementation of good practices
- Involve local, regional and national experts and stakeholders
- Common principles for quality improvements initiatives in the EU member states.
- Knowledge exchange and mutual learning via PaSQ web tools is credible alternative to European standardization.
- Permanent network for PS and Q in the EU will contribute to patient involvement and empowerment, implementation of GCP, reporting and learning
23 October 2015
EMA/762563/2014
Pharmacovigilance Risk Assessment Committee (PRAC)

Good practice guide on recording, coding, reporting and assessment of medication errors

Final guidance published (date of coming into effect) | 27 November 2015

Keywords | Medication errors, pharmacovigilance, good practice, ICSR reporting, intercepted error, potential error, adverse reaction, MedDRA coding, PSUR, RMP, patient safety;
Organised by the Policy Department A: Economy and Scientific Policy Committee on the Environment, Public Health and Food Safety (ENVI)

Workshop on
Safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance

Tuesday, 24 February 2015 - 13.00 - 15.00
European Parliament (Brussels), Altiero Spinelli (A5G-3)

The event is open to the public and will be web-streamed:
REPORT

on safer healthcare in Europe: improving patient outcomes and combating antimicrobial resistance (2014/2207(INI))

Committee on the Environment, Public Health and Safety

Rapporteur: Piemicona Pedicini
EP-Report on

Safer Healthcare in Europe: improving patient safety and fighting antimicrobial resistance ( "Pedicini Report"")

- 8-12% of patients in hospitals suffer adverse events
- around 4 Million HCAI, of which 20-30% preventable
- Worldwide 700,000 deaths by resistant infections
- Estimated extra costs by 2050: 100,000 million EUR.

= Unacceptable, unnecessary life and financial costs for society
EP-Report on

Safer Healthcare in Europe: improving patient safety and fighting antimicrobial resistance ("Pedicini Report")

- Ensure appointments of managers, doctors and non-medical staff free from political influence, but on merits and competences
- Economic austerity should in no way affect the proper functioning of the system and health institutions
- Monitor Adverse Effects / HCAI and ensure the use of the data
- Adequate training for all health professionals in these issues and verify the effects of training
- Independent institution to which all professionals and practitioners may report adverse events anonymously
- Collective redress mechanism for claims of damage by HCAI or medical error
- More appropriate use of ABs by campaigns and training
Clostridium difficile is spelled 371 different ways in NRLS reports.
Prof. Andrea Soricelli

Prof Soricelli highlighted the importance of a global approach towards patient safety, which involves procedural safety, physical safety, equipment safety, and healthcare staff safety. To implement such an approach, he strongly recommended the creation of

*a specific patient safety programme within each healthcare setting, and the appointment of a dedicated and accountable ‘patient safety manager’*

within the programme. The programme should clearly define: the quality objectives to be achieved; the mode and frequency of quality control checks to be performed; the relative level of accuracy of the instrumentation; the acceptance criteria of the test results; and the corrective measures to be undertaken in case of detection of abnormal situations.

- World’s most respected leaders discussed the future of patient safety, around the Patient Safety 2030 report

- Holistic, system-based approach

- Novel and innovative tools to safeguard care, including behavioural insights, digital health, and design

- Learning from other industries and health systems
4 Pillars of safety strategy

- A systems approach
- Culture counts
- Patients as true partners
- Bias towards action
Emerging Threats to Patients

- Increasingly complex cases
Emerging Threats to Patients

- Increasingly complex cases
- Increasingly complex care
- Budget constraints
- Antibiotic resistance
The first step toward reducing patient harm is to understand the magnitude of the issue. This can only be achieved with accurate reporting. In the UK, it is estimated that only 5% of incidents are adequately reported, largely as a result of attempting to avoid blame—that reporting an incident will lead to holding individual health-care workers solely responsible, and putting them at risk of litigation.

Using antimicrobial resistance as an example, Sally Davies, Chief Medical Officer for England, highlighted the increasing gap between knowledge and implementation of patient safety measures, saying “if only we put into practice what we know, millions of lives could be saved”. 
Recommendations PS 2030

- Leadership at all levels
- Education and training translating knowledge into practice
- Digital solutions, with rigorous evaluation
- Smartphones for measuring safety data
- Changing behaviour is fundamental
EXHIBIT 10: Four levels of leadership for patient safety
**Executive and Board Leadership**

1. Placing high organisational priority on quality and safety, and setting strategic goals which reflect this.
2. Removing blame and encouraging a culture which seeks to identify and prevent errors.
3. Supporting the use of measurement and the use of this information to realign strategic goals.
4. Reconfiguring internal structures and processes to increase board and executive oversight of quality and safety outcomes.

**Clinical Leadership**

1. Demonstrating personal qualities such as self-awareness and acting with integrity.
2. Working effectively with others, e.g. the ability to work in and lead teams and build and maintain relationships.
3. Efficiently managing people, resources and performance.
4. Improving services, particularly quality improvement.
5. Setting direction by critically evaluating the available evidence and evaluating impact of decisions and policies.

**Exhibit 11: Attributes of effective leadership for patient safety**
1. Placing high organisational priority on quality and safety, and setting strategic goals which reflect this.

2. Removing blame and encouraging a culture which seeks to identify and prevent errors.

3. Supporting the use of measurement and the use of this information to realign strategic goals.

4. Reconfiguring internal structures and processes to increase board and executive oversight of quality and safety outcomes.
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<tr>
<th>GLOBAL MOVEMENT</th>
<th>LONGER TERM</th>
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<td><strong>SHORT TERM</strong></td>
<td><strong>LONGER TERM</strong></td>
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<tr>
<td>• Launch a global declaration on patient safety setting clear shared goals</td>
<td>• Develop international standards and guidelines in areas of common concern</td>
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<td>• Enhance coordination, best practice sharing and mutual learning in the global patient safety community</td>
<td>• Expand the movement to include low- and middle-income countries</td>
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<td>• Define key questions that researchers should explore</td>
<td>• Develop an agreed set of validated, comparable patient safety indicators</td>
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<th>HEALTH SYSTEM LEADERS AND POLICYMAKERS</th>
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<td>• Review the effectiveness of current patient safety activities</td>
<td>• Work collaboratively with all healthcare actors, including industry, to implement the integrated patient safety strategy</td>
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<td>• Test novel solutions in areas like digital health, behavioural insights and design</td>
<td>• Ensure that new initiatives are constantly evaluated</td>
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<td>• Involve all healthcare actors in the development of an integrated, system-based patient safety strategy</td>
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<td><strong>SHORT TERM</strong></td>
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<td>• Develop a research agenda to address the priority questions of the global movement</td>
<td>• Address gaps in evidence, for example in cost-effectiveness of interventions</td>
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<td>• Strengthen international links between researchers</td>
<td>• Work in partnership with health systems and organisation to enhance impact of research</td>
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<tr>
<td>• Translate research findings into accessible policy recommendations</td>
<td>• Develop and validate novel patient safety interventions</td>
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1. Medication Accuracy at Transitions in Care;
2. Correct Procedure at the Correct Body Site;
3. Use of Concentrated Injectable Medicines;
4. Communication During Patient Care Handovers;
Status High 5s project  
(Leotsakos et al, 2014)

SOPs established for 3 of the 5 risk areas:
- surgery on the correct bodysite
- medication reconciliation
- concentrated injectable medicines

These SOPs are now being implemented and evaluated in multiple hospitals in 7 countries

“Only the beginning of an exercise in behaviour management, asking care givers to adapt behaviour and environment to standardize care process”
At UN, global leaders commit to act on antimicrobial resistance

Collective effort to address a challenge to health, food security, and development

21 September 2016, New York – World leaders today signaled an unprecedented level of attention to curb the spread of infections that are resistant to medicines that were previously effective.

Antimicrobial resistance (AMR) has been a growing threat for several years, but the threat was seen as less acute than that of other major threats. This phường is changing, and the world is now facing a growing problem of resistance to antibiotics and other critical medicines.

For the first time, Heads of States across multiple sectors, especially health, have been taken up by the UN level meeting was convened to address the issue of AMR.

5. To achieve this goal, the global action plan sets out five strategic objectives: (1) to improve awareness and understanding of antimicrobial resistance; (2) to strengthen knowledge through surveillance and research; (3) to reduce the incidence of infection; (4) to optimize the use of antimicrobial agents; and (5) to ensure sustainable investment in countering antimicrobial resistance. These objectives can be attained through the implementation of clearly identified actions by Member States, the Secretariat, and international and national partners across multiple sectors. The actions to optimize use of antimicrobial medicines and to renew investment in research and development of new products must be accompanied by actions to ensure affordable and equitable access by those who need them.
EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH

(EXPH)

Future EU Agenda on quality of health care with a special emphasis on patient safety
“Midsummary” for the hospital manager

• Patient Safety now on the agenda of the highest international health policy podia
• Gradual shift in attention: more towards infections
• Initial emphasis on standardizations and international regulations
• but increasingly on implementation and use of data for improvements; leadership, culture, attitude and behaviour.
• This calls for a strong role of local hospital managers
• Such role needs a work-out, development, training (f.i. IMPO model for Quality and Safety)
• (btw the same holds for patient leadership and participation)
• Inspired by Donabedian and EFQM management models, but more specific for healthcare organisations

• Differentiates between management and processes, but emphasises their interaction
4 Pillars of IMPO model

• **Inputs** are all that is brought externally and internally into the organisation

• **Management** is a specific process: **Processes** of the daily work performed by (medical) staff but management oversees those processes

• **Outcomes** should be patient-centred (containing all the effects of healthcare on patients and population) and should be of societal and macroeconomic relevance
Miscellaneous
New antibiotic Zavicefta approved in the European Union for patients with serious bacterial infections

AstraZeneca today announced that the European Commission (EC) has granted marketing authorisation for Zavicefta (ceftazidime-avibactam, previously known as CAZ AVI), a new combination antibiotic for the treatment of patients with serious Gram-negative bacterial infections requiring hospitalisation.

The approval includes intravenous use of Zavicefta for the treatment of adult patients suffering from complicated intra-abdominal infections (cIAI); Complicated urinary tract infections (cUTI), including pyelonephritis; hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP); and, the treatment of aerobic Gram-negative infections in adult patients who have limited treatment options.

Zavicefta has been developed in response to the urgent need for new antibiotics to treat serious infections that are becoming increasingly resistant, such as multi-drug resistant *P. aeruginosa*, carbapenem-resistant Gram-negative pathogens, and ESBL-producing *Enterobacteriaceae*. 
IRIDICA is the fastest, broad-based CE-marked molecular microbial identification system available – providing a level of insight that has never before been attained on a single microbial diagnostic platform.

- Detects and identifies 1,000 bacteria, fungi and viruses and 4 important antimicrobial resistance markers.
- Allows testing independent from culture and directly from patient sample with results in approximately 6 hours.
- Offers the most comprehensive array of bacteriology, virology and mycology testing among current diagnostic techniques.
IS-Pro Diagnostics

IS-pro: ultrafast clinical grade metagenomics

- From sample to analyzed results in six hours
- All analytic steps internally controlled
- Validated at clinical standards by clinicians
Eerste 'zwarte doos' in Nederlandse operatiekamer

Het AMC in Amsterdam installeert morgen als eerste Nederlandse ziekenhuis een volledig werkende 'zwarte doos' in een van zijn twintig operatiekamers. Net als in de luchtvaart worden tijdens operaties met de zwarte doos alle gegevens over de patiënt en de operatiekamer bijgehouden en g-analysed. Chirurgen willen zo de patiënt veiligheid verhogen.

Door: Maud Effting 7 juni 2016, 06:00
• Transparency and openness about errors and calamities, including the height of fines/redresses
• Registering and study of non-verbal communication behaviour between the doctor and patient in cabinet
• Staff safety
• Risk of Outsourcing
• Patient Safety in Personalized medicine/Pharmacogenomics
• Collaboration with partners
• Overdiagnosis (thyroid, prostate, ovarian ca, etc)
Is It Finally Time for a Personalized Medicine Approach for Fluorouracil-Based Therapies?

Steven M. Offer and Robert B. Diasio, Mayo Clinic, Rochester, MN

At present, implementation of pretreatment genotypic tests to individualize fluorouracil (5-FU)-based chemotherapy is limited despite a wealth of evidence demonstrating that individuals who carry certain variants of the dihydropyrimidine dehydrogenase (DPD) gene (DPYD) are at significantly greater risk of experiencing severe and potentially lethal adverse toxicity (grade \( \geq 3 \)) when receiving treatment with standard dosages of 5-FU. The DPYD *2A variant—also known as rs3918290, NM_000110.3:c.1905+1G>A, and DPYD:IVS14_1G>A—has been reproducibly shown to result in a catalytic inactive form of DPD using a variety of methods, including the study experienced grade \( \geq 3 \) adverse toxicity with this strategy. This rate is far lower than the historical mean of grade \( \geq 3 \) toxicity observed in individuals who carry the *2A variant (73%), according to a literature review conducted by the authors, and was similar to the rate of toxicity observed in noncarriers of *2A in the study by Deenen et al. (23%). This toxicity estimate is also consistent with values reported for *2A carriers in the NCCTG N0147 colon study—one of the largest studies to date—in which 88% of participants (22 of 25 participants) who carry *2A experienced grade 3/4 5-FU-related toxicity.9 The results presented by Deenen et al.
Thks
Patient Safety

* Healthcare systems must not be affected by austerity measures
* Patient-centred approach
* Multidisciplinary approach in medical treatments
* Managers of healthcare facilities to be chosen based on their merits, not on their political affiliations
Patient Safety

* Early warning alert systems on the prevalence and incidence of adverse events in Member States
* Ensure appropriate training of healthcare professionals and verify it
* Potential benefits of eHealth
Patient Safety

- Encourage blame-free and anonymous reporting of adverse events
- Check and enforce the ban on non-medical external staff when performing medical treatments
- Collective redress mechanisms for patients who have suffered an HAI or a medical error
Antibiotic use in human medicine

* Need for research for new antimicrobial drugs as well as for alternative methods aiming at fighting HAIs without using antibiotics