



ERICE CALL FOR CHANGE UTILISING PATIENT EXPERIENCES TO ENHANCE THE QUALITY AND SAFETY OF HEALTHCARE

Rethinking Causality, Complexity and Evidence for the Unique Patient!

François Houyez

virtual joint PCWP-HCPWP meeting, 24 June 2020

ERICE



A FOUNDATION FOR RESEARCHERS

The Ettore Majorana Foundation and Centre for Scientific Culture embraces 128 schools, covering all branches of Science. The Centre is situated in the old pre-mediaeval city of Erice in four restored monasteries

It hosts the International School of Pharmacology (ISP) "Giampaolo Velo"

ISP organises workshops on various topics, such as the safe use of drugs, drug innovation, medication errors, communication regarding drugs, patient safety...



THE ERICE DECLARATION

The Erice Declaration on Communicating Drug Safety Information was first published in September 1997.

It provides a vision of vigorous, open, ethical, patient-centred communications in drug safety that the world has yet to achieve.

Republished Drug Safety 2006; 29 (2): 1

objectives

The aim of the meeting was to discuss the challenge of causal complexity and individual variation in modern healthcare

Two patients take the same drug at the same dose. One has an adverse drug reaction, the other hasn't.

- Is it all explained by the “omics”? Can Big Data help?
- Or can the patients tell us something that helps understand why one has it, but not the other one?



THE GROUP CONCERNS

- The impact that new clinical decision-making tools, based on statistical correlations in large databases, could have on individual patient care if they replace other types of clinical investigation and knowledge
- It needs to be evaluated in light of the unique and complex reality of the individual receiving care





- How should clinical practice and research gather and utilise rich narratives of patients' individual experiences to improve general medical and therapeutic knowledge and patient safety?

Main question

The Approach to Patient Care

Evidence

Person-centred healthcare that is also evidence-based must take account of the multiple causal mechanisms and contextual factors that can affect the treatment of a single patient in their unique circumstances



not just normative

Such person-centred healthcare should consider more than just the normative data from controlled studies that are not likely to be generalizable to all individuals

Some challenges



Interventions that benefit or harm the community as a whole will not necessarily benefit or harm each member of that community

Public health versus individuals

How to ensure transparency of possible conflicts of interest (financial, religious, institutional, political, etc.) among clinicians and institutions that might affect their interpretation of causal evidence, their clinical decisions and their patients

Conflicts of different nature

How to ensure the humane and visionary purposes of traditional practice are not lost in an era of accelerating change

Human medicine and technological progress

Ensuring Best Outcomes of Patient Care

Tailored treatments

Patients should feel they get the treatment that is most accurately tailored to their individual needs

Challenges:

Restrictions of a healthcare system in which time constraints, bureaucracy and cost efficiency drive practice



Listening to patient

Causal considerations in patient safety, including drug safety and toxicity, must be focused on the particular individual by prioritising rich qualitative narratives of their context, history and experience

Narratives

What's
Your
Story



Often dismissed

as causally
irrelevant because
of their anecdotal
nature



And yet

Well-documented
spontaneous
adverse reaction
reports with
narratives are
valuable



We should

Collect, analyse
and use them
qualitatively in a
practical,
accessible system,
in an agreed
format that is
compatible with
high ethical
standards



Make more use

So that they can be
used as important
qualitative
evidence regarding
causation



Of them

For example: ADR
reports narratives
are not translated,
not transmitted to
EudraVigilance or
the MAH

A CASE

ACUTE KIDNEY FAILURE AND PHARMACOVIGILANCE



Routine blood exam

Acute kidney failure diagnosed

Patient treated with ibuprofen,
emtricitabine/tenofovir disoproxil fumarate,
diltiazem, perindopril/indapamide

All associated with some risk of kidney
dysfunction

Nephrologist consulted databases to see if any
synergistic effect

Medical advice: to stop ibuprofen

Otherwise risk of kidney dialysis in less than 10
years

When in fact the patient insisted he had been
exposed to high temperatures in recent days

And he rarely feels thirsty (hypodipsia)

So finally patient increased water intake

24h later: renal function went back to normal



THE IMPORTANCE OF LISTENING TO THE PATIENT

Patients to play an active role

Equal credibility

Patients should be invited to take an active role in their own healthcare, characterised by genuinely collaborative and egalitarian communication.



As other experts

They can be empowered by participating in transdisciplinary networks, with healthcare professionals working to push current thinking forward

AFTER ALL, WHAT IS THE MOST USEFUL FOR AN INVESTIGATION?

- The most important in a crime investigation?
 - Questioning all witnesses: 90% of the investigation
- The most important for a medical diagnosis?
 - Questioning the patient, physical exam: 90% of the medical reasoning
 - Exams are secondary



The process

participants

- Participants were selected by the organising committee on the basis of their broad interest and expertise in the discussed topics and representing their own views:
- scientific researchers, epidemiologists, clinicians, pharmacists, decision makers, drug manufacturers, communications specialists, patients and philosophers of science
- Rani Lill Anjum, Norway; Jean-Christophe Delumeau, Singapore; Ivor Ralph Edwards, Sweden; Birgitta Grundmark, Sweden; Kai Brynjar Hagen, Norway; François Houyez, France; Bruce Hugman, UK; Tobias Gustum Lindstad, Norway; Marie Lindquist, Sweden; Matthew Low, UK; Ugo Moretti, Italy; Eugenio Paci, Italy; Christine Price, UK; Elena Rocca, Norway; Lovisa Sandberg, Sweden; Ruth Savage, New Zealand; Penny Sawell, UK; Anders Sundström, Sweden

Find the Erice Call for Change

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Elena Rocca · Rani Lill Anjum

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Thank you for your attention.

François Houyez

Director of Treatment Information and Access

francois.houyez@eurordis.org