Evidence Live 2017 - Keynote Abstracts

Wednesday June 21st 11:00

Transparency of Trial Data, Improvements in Safety and Better Quality Research to Improve Healthcare

CHAIR Dr Kamal R. Mahtani

Transparency of clinical trial data and pharmacovigilance data from EMA

Fergal O'Regan
European Ombudsman

Lack of trust in medicine leads to sub-optimal medical outcomes. It also has serious cost implications for patients, health providers and pharmaceutical companies.

Transparency is vital for building such trust, especially transparency as regards the process by which the safety and efficacy of medicines is verified. The European Ombudsman has therefore placed great emphasis on encouraging EMA to strengthen its policies of making public information relating to its procedures for authorising medicines and monitoring their use.

The presentation will seek to give a "state of play" account as regards the transparency of EMA. It will cover the area of pre-authorisations, such as access to clinical study reports submitted by pharmaceutical companies with an application for marketing authorisation and the documentation generated by EMA when evaluating such applications. It will also cover post-authorisation evaluation procedures, such as access to EudraVigilance, the PSUR repository, and access to documents relating to "referral procedures" which aim to resolve concerns over the safety or benefit-risk balance of a medicine or a class of medicines already on the market.

One new area which has attracted the interest of the Ombudsman is the development of pre-submission guidance, and more particularly, the future use of "adaptive pathways". Transparency in these areas is vital to building public trust in EMA and the medicines it eventually approves.

The difficult issue of how to reconcile transparency with the need to protect the privacy of patients, especially in the context of "big data", will be examined in relation to the above issues.

Transparency also plays a key role in resolving any concerns that may exists as regards conflicts of interests at EMA or its committees, such as the CHMP and PRAC.

Finally, a very brief comment will be made on how Brexit may impact upon the proper functioning of all of the above.

Improving the evidence for improving healthcare

Professor Mary Dixon-Woods
University of Cambridge

Abstract: Although quality improvement (QI) is frequently advocated as a way of addressing the problems with healthcare, evidence of its effectiveness has remained very mixed. This lecture will identify some of the major challenges and offer suggestions on what needs to be done to get better at getting better. It will stress the need for strengthening of the scientific foundations of QI, for more rigorous evaluation, and for improved fidelity in the application of QI methods. It will also point to structural problems in the way QI is organised at present, including the tendency for pursuing it through time-limited, small-scale projects, led by professionals who may lack the expertise, power or resources to instigate the changes required. There is

insufficient attention to rigorous evaluation of improvement and to sharing the lessons of successes and failures. Too many QI interventions are seen as 'magic bullets' that will produce improvement in any situation, regardless of context. Too much improvement work is undertaken in isolation at a local level, failing to pool resources and develop collective solutions, and introducing new hazards in the process. Progress will depend on addressing these challenges.

Scandal of poor medical research

Professor Doug Altman
Centre for Statistics in Medicine, University of Oxford

Research has value only if the study methods have validity and the findings are published in a usable form. In 1994, in "The scandal of poor medical research", I concluded by arguing that we needed "less research, better research, research done for the right reasons." What progress has been made nearly a quarter of a century later?

My main concern in 1994 was poor methodology. Since then other deficiencies of research publications have become apparent. Notably, it is abundantly clear that questionable research conduct is exacerbated by poor reporting of research, making the methods unclear and non-replicable. CONSORT was published in 1996, and huge numbers of reporting guidelines have appeared since. But reviews of publications generally show painfully slow improvement. Also, misinterpretation of research findings, especially in relation to significance testing, remains rife. And reviews of methods show that bad methods remain common.

Research isn't just for the present. Researchers leave a legacy of scientific information for the future, so the consequences of bad research practice are very serious. But researchers, funders, and journals have largely failed to stem "questionable research practices". Bad research and bad publications remain much too common, and it is still a scandal.

Altman DG. The scandal of poor medical research. *BMJ* 1994;308:283-4.

Wednesday June 21st 17:00

Carrots, Sticks, or Stones? Audit and Accountability to Improve Research Quality

Dr Ben Goldacre
EBM Data Lab, Nuffield Department of Primary Care Health Sciences, University of Oxford

Audit and feedback are used extensively throughout clinical medicine to establish whether high standards are being achieved, as part of the "quality improvement cycle". When shared openly the results of audit can help drive up standards, by identifying sites or individuals that might benefit from additional support, and outstanding performance that others can learn from.

These opportunities have been relatively neglected when addressing problems in research, such as trials transparency and reporting quality. Work on research integrity typically reports summary figures for the overall prevalence of a problem, without identifying the individual research centres, funders, studies or researchers that are found to have breached guidelines or ethical obligations. This deprives the system of important information needed to improve quality and performance, and of contextual knowledge needed to interpret published research.

This talk will explore the opportunities and challenges around using open audit and feedback in the field of research integrity, with examples taken from the COMPare Trials projects, the TrialsTrackers, audits of transparency policies, and other audits outside of medicine. It will discuss how this approach may improve both data quality and impact; but also how, as with all open performance data, open audit can be unpopular, or met with anxiety.

Thursday June 22nd 09:30

Better data, reduced waste in research, and public engagement to transform patient care

CHAIR Tessa Richards

Going beyond the patient to add value in research

Simon Denegri
NIHR National Director for Patients and the Public and Chair, INVOLVE

Health researchers are involving patients, carers and the public - 'the public' - more and more in the design and delivery of their work. A growing number of research funders are also expecting researchers to demonstrate how they are involving the public. They are recognising that the insights gained through public involvement can lead to better research - more relevant, efficient and with greater reach - and better evidence upon which to base future health care practice. This presentation will look at examples of public involvement in research from a number of countries and the impact this has had on research. It will also consider the deeper partnerships being formed between the public, researchers and health professionals in research and how this might influence the wider health care system.

How to improve patient care through publishing research that truly adds value

Dr Trish Groves
Director of academic outreach, BMJ and Editor-in-chief BMJ Open

Given estimates that 85% health research is wasted - asking the wrong questions, using poor designs, getting only partly reported - there's an urgent need to increase value in health research and make it truly able to improve patient care.
Responsible innovation focused on the needs and preferences of patients and wider society depends on changes at every stage of research: priority setting, grant-giving, ethics approval, regulation, reporting and publication, educations, and shared decision making. In this short talk Trish will focus particularly on the reporting of research.

Care Opinion: people helping health/care get better

James Munro

Care Opinion is a non-profit platform for public feedback about health and care services across the UK. We want people to be able to share their experiences of care in ways which are safe, simple, and lead to learning and change. We aim to provide a service which makes it easy for people to share honest feedback without fear, and for everyone to be able to see how and where services are listening and changing in response. In a sense, this is crowd-sourcing patient-centred improvements in care.
Currently about 1850,000 stories are available through the Care Opinion site, of which 75% have received a response from staff. About 7,000 staff and students from 600 organisations use the platform to hear what people are saying about local services, and the stories have been read about 89 million times in all.
I am CEO at Care Opinion and my background is in public health medicine and health services research. In 1994 I learned about evidence-based medicine from David Sacket at McMaster University and now, to my own surprise, I find myself promoting experience-based health care via an online service.
Working at Care Opinion has caused me to reappraise my own assumptions about healthcare, to reflect on what matters most to people, and think about the different kinds of evidence we need to ensure that health services are safe, effective and life-enhancing for those who use them and those who work in them.

Thursday June 22nd 16:00

Evidence Policy and impacting on Global Health

CHAIR Fiona Godlee

Transforming the humanitarian-health interface

Professor Mukesh Kapila CBE
University of Manchester

About a billion people around the world are struggling every day at the frontlines of armed conflicts and so-called natural disasters, not all of which make the headlines. For them, the margin between life and death can be very thin and their access to healthcare can make a vital difference.

In reality, access to such care is an unfairly-skewed lottery of chance and circumstance. It does not have to be that way because even amidst the direst humanitarian crises, we have the knowhow and means to bring healthcare essentials, anywhere and everywhere. Conflicts and disasters will continue to happen but, if you have not been killed by the initial trauma or shock, it should be fully possible to maintain adequate health and well-being among affected people. Keeping people as strong and resilient as possible amidst the depths of misfortune and adversity is an essential investment for finding sustainable solutions to underlying causes, and ultimate crisis recovery.

"Crises" are created in the minds of people and that is where they must be tackled. Thus, the real crisis we face is that of the paucity of vision and ambition in the face of inevitable catastrophes in the world we inhabit. Indeed, we will have more of them in the future as many adverse planetary and people factors collide.

In that mind-set, what does an improved policy for humanitarian work look like? What is the evidence-based package of health essentials that should be part of humanitarian crisis response? What will it take to put this into practice so that, in the words of the United Nations Agenda 2030, "no one is left behind"?

Improved policy for a positive impact on global health

Dr Marie Lindquist
Uppsala monitoring Centre

Marie Lindquist will discuss the concept of health and the role of science and scientific evidence in guiding and defining health policy. She will challenge the notion that health policy in itself will have a real impact on global health. The substance of her argument will be presented on the day, when an abstract and script will be made available.