EvidenceLive 2015

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I attended the second day of this conference in Oxford. The venue was the Examination Schools, University of Oxford and hosted by CEBM Centre for Evidence-Based Medicine and the BMJ.

Since reading the article by Trisha Greenhalgh – *Evidence based medicine: a movement in crisis?* I thought it would be a good idea to attend to see exactly what is going on as part of my job involves disseminating information on EBM. Here are summaries from 5 of the 8 sessions I attended.

Real v rubbish EBM: what is the state of evidence-based medicine, and is it broken? – Trisha Greenhalgh – Professor of Primary Care
This was the first session of the day and the best! Trisha explained that a big issue in EBM today is the lack of individualism – more concern with evidence findings from clinical trials which can lead to a less than optimal diagnosis of the patient, as how a patient in a clinical trial responds to a drug will be different from how a patient in a doctor's surgery will to the same drug.

To expand on this idea further, Trisha gave the example of a serious bicycle accident she had causing multiple fractures and some additional injuries. An evidence-based protocol existed on each separate injury but the combination of all added up to a unique case which was out of the scope of EBM recommendations. She concluded that 'evidence is never self-interpreting and that real EBM for one patient may very well turn out to be rubbish EBM for another'.

From this talk two additional remarks from the audience during questions stand out:
'Doctors are not taught how to deal with uncertainty' and 'We're training the young minds to have boxed-in thinking'.

Right of the public to access clinical trials data: a search for legitimacy and trust – Fergal O'Regan – Head of Unit at the European Ombudsman

Mr O'Regan outlined his role in managing a team of lawyers who work on behalf of the European Ombudsman, Ms Emily O'Reilly, who reports to the European Medicines Agency. He is a lawyer himself. Three case studies illustrated how he supported members of the public gain access to information not released.

Case 3: In 2012 a researcher sought access to the clinical trial CSR – Clinical Study Report for the drug Humira. The pharmaceutical company AbbVie, who manufactures this drug, took the researcher to court aiming to block access to this report. The European Ombudsman intervened in support of the researcher claiming the reasons for withholding this report weren't justified. The court case was dropped after an agreement

whereby a redacted report would be released. However, what was taken out included sample size and dosage calculations, protocol changes, testing methods, histology tests and secondary endpoints. This information was crucial in understanding how the drug worked and after further negotiations this information was released. Issues like IPD – Individual Patient Data, weren't compromised here, even indirectly, or commercially confidential interests.

It is important to note that the ombudsman's decisions aren't legally binding, but are subject to the approval of the European Medicines Agency. They rule that CSRs are made available following deletion of any information that might compromise personal data protection or be considered commercially confidential. An example of commercial confidentiality is where a pharmaceutical company has designed a new diagnostic testing process that is more efficient than the standard method, thereby gaining a commercial advantage as the standard is shown to be inferior, without other firms knowing the new technical details.

Progress and Barriers on Clinical Trials Transparency – Ben Goldacre – Clinical Research Fellow

The focus of this talk was how to get all trials reported. Ben Goldacre is co-founder of the **AllTrials** campaign started 2 years ago. The problem in medicine is that sometimes the results of clinical trials are routinely and legally withheld from the medical community. A landmark announcement from WHO released at 13.00 on 14/4/15, 2 hours after Mr Goldacre's talk, calls for the disclosure of results from clinical trials regardless of the result within 12 months of completion, and this includes all older trials.

Dr Kieny said in this WHO release “Failure to publicly disclose trial results engenders misinformation, leading to skewed priorities for both R&D and public health interventions”

It also stated that “in a study that analysed reporting from large clinical trials (more than 500 participants) registered on ClinicalTrials.gov and completed in 2009, 23% had no results reported.”

There are legal issues on full disclosure of clinical trial data. EU legislation provides ample guidance on IPD, however there is no agreed or binding definition of commercially confidential information.

A new key way to help ensure clinical trial transparency is to use audit which has only rarely been used in relation to clinical trial information. Using a clinical trials register you could monitor who was compliant in reporting all the necessary information and who wasn’t, then seek to gather any missing information. Asking pharmaceutical companies for this information would thus be a more compelling argument for disclosure as it was evidence of lacking information that couldn’t be disputed.

Goldacre B. (2015) How to get all trials reported: Audit, better data and individual accountability. PLoS Med 12 (4) 1-5

Workshop – Critical Appraisal of Systematic Reviews – David Nunan
This gave me a useful insight into how critical appraisal is taught in the medical community by doctors for doctors. We were given 10 minutes to read the article and the rest of the 90 minute session to answer the

checklist questions. We got bogged down on some minor points and the session was extended by 30 minutes to complete the questions. The group agreed on this. The emphasis was on how to quickly assess the paper and interpret the statistics efficiently. This is easier said than done, as we struggled a bit, but got there in the end. That librarians at Imperial College campuses, where I work, are now facilitating critical appraisal sessions for NHS staff can only be a good thing.

EBM in crisis (Real v Rubbish Part 2)

This was the last session before closing remarks. There were various speakers and again Trisha Greenhalgh's section caught my attention here with this slide:-

The six biases against the patient – (forthcoming paper)

- Lack of patient input to research – patient/academic barrier
- Low status of narrative in the hierarchy of evidence – a personally significant emphasis is important.
- Shared decision-making – is this reflexive approach appropriate?
- Power imbalances that silence the patient's voice – acknowledging that illness weakens the patient's ability to discuss issues with the doctor allowing paternalism to take over.
- Over-emphasis on the consultation – unnecessary community mindfulness: a shared perspective on illness – the patient going on a bit.
- 'Hidden denominator' of those who do not seek (or cannot access) care – how to solve this problem

And finally, in this session there was mentioned the “over-diagnosis of the worried well” as a related issue that needs addressing – see **The 2014 Preventing Overdiagnosis Conference**
http://www.preventingoverdiagnosis.net/?page_id=846

In summary, this was a very good conference as I learnt a lot about the current state of EBM and how it is practiced, but also, importantly, that the medical community recognise the problems and are addressing them.

A lot of this conference is now available on Youtube - https://www.youtube.com/watch?v=ofgycxnioTM&list=PLPdZt8YjI_fCdMQiFysZUAgGlFz2g2t-T