



## A report on the European Conference on Scientific Publishing in Biomedicine and Medicine (ECSP2)

by Kari Skinningsrud

The second ECSP congress took place at the National Hospital (Rikshospitalet) in Oslo on 4-6 September this year with 145 participants. The main aim of the conference was to broaden researchers' understanding and knowledge of the rapid changes in the scientific communication and publishing environment and its direct impact on the research community. Two major themes were addressed; the first was about Open Access (OA) publishing and the second about measures of research quality. The conference gathered the most authoritative opinions on these issues and shed light on many interesting facets of STM (Science, Technology and Medicine) publishing.

The chairman of the European University Associations' (EUA) steering group on OA, Dr Noorda, emphasised the importance of widening the user perspective from just the academic community to the general public, health professionals and business innovators. In March 2008, the EUA adopted a policy on public access to reviewed academic publications, which is just one of many examples of a global move towards OA. Alma Swan from Key Perspectives Ltd talked about what hinders and helps OA and how we can get there. Getting researchers to add their papers to a repository is one way of achieving OA, but increased awareness about such possibilities is clearly needed as only 40% of life science researchers are familiar with OA. Policy awareness does not seem to change behaviour, but mandates do and increased visibility via Google leads to more citations and greater impact. The embargo factor is a hindrance, 24 months is not good but 6 months is bearable. Most publishers agree to make metadata available for the final manuscript, and then researchers can go onto Google and make contact with the author if they want more information.

Robert Kiley from Wellcome Trust started by pointing out that the message is very clear for Wellcome-funded researchers—free accessibility in UK PubMed Central within 6 months of publication. The Trust supports OA to improve quality of research by developing repository-based services to meet the needs in the UK research community, improving the research process through improved integration of literature and underlying data and maximising access to research outputs. Wellcome meets all publishing costs if there is an OA author-pay option, but publish-

ers must give something in return, for example deposit the final manuscript in a repository. Now most publishers have agreed to Wellcome's specification, regardless of their publishing models. The top 30 Trust-funded institutions get block grants from Wellcome to cover the OA publication costs. If block grants are not available, the Trust supplements individual research grants. Robert Kiley finished off his talk with UK PubMed Central (UKPMC), which has been available for the research community for 2 years. More funding has been approved to be able to expose the contents of UKPMC to text mining solutions and add additional content such as clinical trials, guidelines etc.

Stephen Pinfield from the University of Nottingham gave his speech on how institutions can help authors move on to OA and cover the costs. UK research councils, Wellcome Trust, the European Research Council, NIH and the Australian Research Council have OA mandates. The database SHERPA Juliet lists funders and their OA policies. SHERPA Romeo lists publisher copyright and self-archiving policies. All institutions should set up a repository and in fact, most have these days. The costs for OA should be covered by the institution rather than by the library. According to Pinfield, OA costs can be taken from project budgets and overheads to form an institutional funding stream for OA. For example, if publication occurs after a grant is closed then that is when the institutional funding stream kicks in.

Kaitlin Thane from Science Commons gave a talk on how Science Commons works with publishers, academics and institutions in order to make content and scientific data available. She spoke about Creative Commons licences (CC) as an answer to copyright challenges in the digital world. She said authors should be given control; they are the publishers of scientific data. The goal is to create legal zones of certainty for scientific data on a 'research web'. The first publishers to have adopted the research web idea are BioMed Central, PLoS and Hindawi. Academics need policies to help them retain rights to self-archive their work. Institutions who are looking to implement OA policies need OA policy guides and white papers. Håkan Carlsson from Göteborg University in Sweden said that about 20% of all published research is or will soon be OA. Those who pay the research are increasingly demanding that it is made OA.

Barbara Kalumenos from the International Association of Scientific, Technical and Medical Publishers (IASTM) spoke about the PEER (Publishing & Ecology of European Research) project which aims to get evidence about the

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effect of embargos of varying lengths to the various stakeholders. The project started 1 September this year. Graham Lees, editor and owner of *The Scientific World Journal* (TSWJ), gave a talk on ‘The Future of Journal Publishing’. When starting a journal, who should pay - readers or authors? Graham thinks both, because not all authors can pay for OA.

Anthony van Raan, Director of the Centre for Science and Technology Studies at Leiden University, gave a fact-packed presentation about his work on measuring citation patterns and impact (based on articles, individual scientists and research groups and institutions). The tools that Anthony’s group have developed over the past two decades are extremely powerful. Until recently, the base data he and his colleagues have used came from Thomson Reuters (the ISI databases) but they now also include data from Elsevier’s Scopus service. Anthony’s conclusions were that bibliometric analysis is a very useful, informative and penetrating methodology for assessing research effort, but that it should never be used in isolation, only in conjunction with other assessment regimens, particularly peer review.

***Authors agree that too much emphasis is given to impact measures based on citations... commentators recommend a more balanced approach to assessing research “quality”.***

Mary Van Allen, Manager of the Research Services Group at Thomson Reuters (aka ISI) talked about ‘Beyond Impact Factors’. A new website called Researcher ID allows researchers to create an authority file of their own papers and get a real-time display of their citations, h-index (quantifies both the actual scientific productivity and the apparent scientific impact of a scientist) and so forth. The big idea here is to provide a collaboration network diagram, which can be displayed by geographic region or down to individual institution. Clearly, Web of Science is working hard on developing new metrics from its databases. A question as to whether Web of Science intends to give citations from different journals a different ‘importance’ was answered in the negative, partly because weighting is a subjective issue and partly because there is no consistent approach—many papers published in *Nature* and *Science* are never cited (apart from self-citation).

Richard Gedye (Chair of COUNTER and the UKSG Working Group on Usage Factors and Research Director in the journals division at Oxford University Press) spoke about measuring usage of articles – or rather, of journals, as that is the base point used by COUNTER. He described the research programme that has been carried out by the UKSG on usage, including qualitative surveying of librarians and authors and large-scale online surveying of the same constituencies. The more metrics that can be brought into play the better. Richard reported that both UKSG’s

survey and the previous one by the CIBER Group showed that 70% of authors are enthusiastic about a usage-based measure for assessing research journals. Richard also reported that plans are underway for a study to outline the metrics currently being assessed, whether any of them are suitable and how publishers can establish a consistency over how they report usage. There was some discussion over the significance of download numbers.

Then we heard from Howard Browman, Principal Research Scientist at the Institute of Marine Research, Storebo in Norway, speaking on the use and misuse of bibliometric indices in evaluating scholarly performance. Howard gave an overview of existing metrics, of 21 ‘problems’ with the Journal Impact Factor, and emphasised that ALL bibliometric indices have such limitations. Only people with a thorough understanding of these limitations should apply the metric indices in practice (i.e. assessment of an individual for promotion or tenure); it should never be done by uninformed panels of assessors. Howard showed data that confirm that the Pareto Principle holds for any individual scientist’s citations (i.e. a minority of articles get the majority of the scientist’s citations) and this also holds when whole journals are studied. He also showed that almost 50% of articles in the Web of Science database have never been cited at all. Journals with high impact factors have a high degree of editorial pre-screening (editors screen before manuscripts are sent out for review) and a relatively low acceptance rate. Howard’s questions:

***One speaker questioned whether journals and articles will continue to retain their significance and brand importance.***

are we saying that 80% of articles published are of low quality? Are 80% of journals of little significance? Or is there something there that is not captured by citations? We are accustomed to focusing on the ‘quality’ (i.e. highly-cited) end of the published corpus, but what about the rest?

Authors, according to the CIBER study, tend to agree that too much emphasis is given to impact measures based on citations, and other commentators too are recommending a more balanced approach to assessing research ‘quality’.

The final speaker was Ed Pentz, Executive Director of CrossRef, the scholarly publishers’ facilitator of the reference-linking system (currently with 550 publishers and 15000 journals. CrossRef now has 35 million items including journal articles, books, book chapters and so forth. He explained that the Digital Object Identifier (DOI) was developed to create a unique and less vulnerable identifier to articles than URL (web links often do not work after a while). The DOI is unique, while the URL it refers to may be updated if for example a journal changes its address. DOI is much used now, currently with more than 20 million clicks on DOI links per month.

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Ed Penz questioned whether journals and articles will continue to retain the significance and brand importance that they presently enjoy. The rise of informal 'Web 2.0' tools for communication and the linking to new kinds of content are changing the paradigm. So are new kinds of 'publication', such as databases (e.g. protein sequence databanks) that are already assigning DOIs to items and wikis as a platform for (almost-formal) publishing. The latter are not yet assigning DOIs, but the indications are that they are moving in this direction. Blogs are citing DOIs, even if they are not assigning any, and we are now seeing aggrega-

tions of blogs (e.g. Science Blogs), and scientists looking to such developments to give recognition to their work outside of the traditional mechanism of citing journal articles.

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The above text has been prepared with reference to the following websites:  
<http://ecsp2.blogspot.com/>  
<http://konferanser.blogspot.com/2008/09/ecsp2-dag-2.html> (Norwegian)

## Basic Results Reporting at ClinicalTrials.gov and 'Prior Publication'

We have received questions concerning the posting of results at ClinicalTrials.gov (<http://clinicaltrials.gov>) in compliance with US Federal law and 'prior publication' decisions by journal editors.

As you may know, US Public Law 110-85, Title VIII, mandates the submission of 'basic results' data for certain clinical trials of drugs, biologics, and devices, effective September 27, 2008. The law applies to trials that are not Phase 1 or small device feasibility studies, and that have at least one site in the US or, if conducted completely outside the US, involve interventions manufactured in the US and regulated by the FDA, regardless of who sponsors, finances, or conducts the trial. Certain other trials may also be covered by the law. In general, these summary results data must be submitted within 12 months of the completion of data collection for the primary outcome measure. The law also requires submission of results for pre-specified secondary outcome measures registered at ClinicalTrials.gov. Delays in submitting results may be granted for certain reasons, but not generally for journal submission. There could be significant penalties for failure to comply with this law.

These 'basic results' include summary data tables of baseline characteristics, participant flow, outcomes, and adverse events. With the exception of several brief free-text fields for providing descriptions of the data, no narrative information is included (e.g., there is no discussion or conclusion section). There will be no patient level data.

The June 2007 ICMJE Update on Trial Registration [1] states that "the ICMJE will not consider results posted in the same primary clinical trials register in which the initial registration resides as previous publication if the results are presented in the form of a brief, structured (<500 words) abstract or table (p. 2)." The ICMJE recently reaffirmed this position at its 2008 annual meeting in Philadelphia.

Further, a January *BMJ* editorial [2] urges other journals to consider publication of results reported under the law to ClinicalTrials.gov for the following reasons:

'Firstly, disclosure will be a legal requirement, so there is nothing editors can do about it if they still want to publish important trials of drugs and devices. Moreover, journals will continue to add value by publishing useful and readable trial reports that clinicians, the media, and patients can interpret and use. And, most importantly, the results disclosed for the FDA will not have been externally peer reviewed and will be preliminary. Peer review not only provides a stamp of quality assurance, it often leads to reanalysis of results (p.170).'

In July 2008, a *PLoS Medicine* editorial endorsed "timely and accessible reporting at all stages of clinical drug and device development." [3] In particular, the following statement has been added to its Author Guidelines:

'PLoS supports the public disclosure of all clinical trial results, as mandated for example by the FDA Amendments Act, 2007. Prior disclosure of results on a public website such as [clinicaltrials.gov](http://clinicaltrials.gov) will not affect the decision to peer review or acceptance of papers in PLoS journals.[4]'

More information on the 'basic results' database can be found at <http://prsinfo.clinicaltrials.gov/fdaaa.html>.

Please also feel free to contact me if you have any questions about this new feature of ClinicalTrials.gov.

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