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ISDB General Assembly: More Reports

Bias in reports of drug studies: why are independent drug bulletins important?

Presentation by Lisa Bero, Professor, Department of Clinical Pharmacy, School of Pharmacy and Institute for Health Policy Studies, School of Medicine, University of California, San Francisco (Report by Andrea Tarr)

There are many potential sources of bias in drug trials. They include the way the research question is framed, the design of the study, the conduct of the study, and the publication (or not) of the full results. Financial conflicts of interest can be the root cause of bias in pharmaceutical research as a result of the research being used as a marketing tool by pharmaceutical companies. Selective publication of trial results can limit the access that clinicians, researchers and the public have to clinical trial data, even for approved drugs. Furthermore, when there is selective publication of drug trial results, systematic reviews and meta-analyses that are based only on published data may consequently over- (or under-) estimate the efficacy of drugs.

Dr Bero described the extent of reporting bias in relation to drugs (new chemical entities) that were approved by the US Food and Drug Administration (FDA) in 2001 and 2002. Drug trial data reported in FDA reviews were compared with the published reports of trials for the same drugs. The researchers found that 78% (128/164) of the efficacy trials contained in FDA reviews of 33 drugs had been published in the medical literature.[1] A multivariate model showed that trials with favourable primary outcomes were more likely to be published (OR=4.7, 95% confidence interval [CI] 1.33 to 17.1, p = 0.018). There were 43 outcomes described in the FDA reviews that did not favour the drug. Of these, 20 (47%) were not included in the published papers.

In a follow-up study, the researchers found that when unpublished trial outcome data identified in FDA reviews was added to published meta-analyses of the drugs (n = 42), the results of the meta-analyses changed.[2] The direction of change in the efficacy estimates varied by drug and outcome.

The results of this research support the case for making unpublished trial outcome data more easily available and for including it in meta-analyses. Drug bulletins have an important role to play in exposing bias through critical appraisal of the data and by seeking and exposing data from unpublished studies. It is probably safer to always assume that publication bias exists and use judgement to downgrade the overall body of evidence.

1. Rising K, Bacchetti P, Bero L. Reporting bias in drug trials submitted to the Food and Drug Administration: review of publication and presentation. PLoS Med 2008; 5(11), e217. doi:10.1371/journal.pmed.0050217.
2. Hart B, Lundh A, Bero L. Effect of reporting bias on meta-analyses of drug trials: reanalysis of meta-analyses. BMJ 2011; 344: d7202. doi: 10.1136/bmj.d7202.

Make the content of your bulletin fit for health professionals' continuing education programs and e-learning: why and how?

Workshop run by Florence Vandevelde, Prescrire, France (Report by Andrea Tarr)

Prescrire, which was founded in 1981, began its continuing education program in 1988 with the Prescrire monthly readers' test. This was found to be effective in helping readers to remember important information in the bulletin's articles. In 2006, taking advantage of new legislation and mandatory continuing medical education in France, Prescrire launched two other education programs:

- Thematics, consisting of around 100 pages of a thematic compilation based on articles in Prescrire, together with a 100-question readers' test.
- An education program for pharmacy teams, in the form of a 1-page fact sheet, summarising Prescrire's reviews. Work on this stopped in 2010, and an education program for nurses began in 2011, also based on a 1-page fact sheet.

Apart from these programs, which centre around readers' tests, Prescrire also developed 'Preventing the preventable' in 2006 – an online program aimed at achieving improvements in quality of care and patient safety by analysing errors or circumstances that may have led to errors ('near misses'). Through the program, subscribers share their experiences and work out solutions, without judgement and in confidence.

Contents

New sections in the bulletin

Another activity that a bulletin can implement is to develop new sections, as Prescrire did in 2007, with a critical appraisal section designed to help students prepare for an important test.

From experience, the Prescrire team proposes seven critical success factors for continuing professional development programs and e-learning:

1. *Know yourself. Use the SWOT (strengths, weaknesses, opportunities, threats) analysis to:*
   - Identify your real added value for health professionals' continuing education.
   - Anticipate difficulties in the area where you still need to build expertise, for example informatics.
2. *Be focused on patients*
   - Identify health professionals' needs for better patient care.
   - Foster collaboration among caregivers, for example through a multidisciplinary editorial team.
3. *Make health professionals aware of their education needs using marketing techniques*
4. *Implement a rigorous editorial process*
   - Use the same text structure, e.g. introduction describing the questions to be addressed; headings and subheadings to structure the different parts of the text; a final subheading summarising what to do 'in practice'.
   - Distinguish between facts and opinions, e.g. present opinions in a box called 'Editorial team's opinion'.
5. *Assess participants' work so as to give them feedback*
   - Corrections of the tests by the educational team.
   - Review of the participants' reports by the educational team.
   - Make sure answers can be printed.
6. *Devote adequate human resource to enable support for, and interaction with, participants*
7. *Make sure that participants' commitment is sufficiently acknowledged/publicised*

Summary

Producing continuing education programs can lead to educational enhancement of the bulletin's content and represents a diversification of activities that can generate income. Continuing education activities can increase readers' loyalty to the publication and can be used to target specific groups of readers (e.g. nurses, students).

E-learning, which can be done at home, can fit well with health professionals' needs, but the need for interactivity and support of participants should not be underestimated. It is crucial to plan and conduct your projects step-by-step (i.e. alpha- and beta-testing, then pilot the program, then launch the real program).

A favourable context is key for the launch of a new product. If continuing education is not mandatory in your country, create a favourable context!

ISDB at Work: Reports from its Working Groups

Conflict of Interest

John Dowden, Coordinator

At the ISDB General Assembly in March 2012, David Menkes presented the results of the survey of member bulletins about conflict of interest. After the presentation a small group met to consider the results.

The group included Kenny Van Deventer, Gisela Schott, Giampaolo Velo and John Dowden. Since March we have had email discussions about the forms bulletins could use to help manage conflicts of interest.

In Vancouver, it was proposed that bulletins use the forms developed by the International Committee of Medical Journal Editors. These forms cover conflict of interest involving editors, editorial staff, authors and reviewers. We found that some of these forms were not suitable for drug bulletins as they had been designed for medical journals publishing clinical trials. It also became clear that different drug bulletins have different needs. As reported in the ISDB survey, some bulletins already have good policies.

The group has now prepared simplified forms. These will be discussed at a future meeting of the ISDB Committee to decide which parts are suitable for all bulletins and which parts can be adopted to meet the particular needs of individual bulletins.

Clinical Trials in Developing Countries

Nuria Homedes, Coordinator

The Network of Clinical Trials and Ethics is largely a Latin American Group that involves many researchers, but is open to everybody. The list of members is at http://www.saludyfarmacos.org/relem/lista-de-miembros/. The work of this Group is supported and encouraged by ISDB so we keep ISDB informed of its activities.

In June 2012, Antonio Ugalde, Bruno Schlemper Junior and Nuria Homedes attended a meeting arranged by the Centre for Research on Multinational Corporations (SOMO) and Wemos (a Dutch organisation that works to influence international policy in such a way that the right to health is respected, protected and promoted). The aim of the meeting was to explore whether the recommendation for participants in clinical trials to have access to treatment after the conclusion of the trial could be implemented and even enforced.

The Spanish version of the publication Clinical Trials and Ethics should be available in November 2012. An English version of Clinical Trials and Ethics is being prepared which has been updated and improved and we expect to have it ready by the end of October 2012. We do not have a publishing contract for this English version but have received very positive feedback from the publisher, Springer.

Antonio Ugalde and Nuria Homedes are also writing an article outlining problems with codes used by the pharmaceutical industry in www.clinicaltrials.gov. This article describes irregularities we found when helping an Argentinian researcher with the evaluation of a clinical trial that he considered unethical and is being implemented in 100 sites, both in high and low income countries. This article is in the final stages of development so we will report when it is available.

We have ideas for a couple more research projects, so hopefully we will have more to report in the next few months.

Educational Information for Health Workers and Consumers

Natalia Cebotarenco, Coordinator

The Educational Information for Health Workers and Consumers Working Group (EIWG) was established in March 2012 during the Vancouver ISDB General Assembly. Currently this group comprises:

- Coordinator: Natalia Cebotarenco, Moldova
- Assistant coordinators: Dulce Calvo, Cuba and David Menkes, New Zealand
- Members: Sulagna Dutta, India; Vijaya Musini, Canada; Benoit Marchand, Nicaragua; Clotaire Nanga, Burkina Faso; Zahed Masud, Bangladesh; Isidro Sia, Philippines; Jose Julian Lopez, Colombia; Viktorija Erdeljic, Croatia; Kumud Kafle and Vabha Rajbhandari, Nepal; Christophe Kopp, France; Mathias Hammerer, Austria; Carlos Fonseca, Costa Rica; Nuria Homedes, USA.

The role of the group

The main function of the group is to share information and educational materials that might be useful for ISDB members in educational programs at the country level as well at the international level.

Fast access to expertise

One of the most important features of the EIWG is that it allows members to get a rapid response from other members on difficult therapeutic questions. For example, a question was circulated about the use of sildenafil in the treatment of pulmonary arterial hypertension in newborn children. Within a very short period of time helpful and useful responses with evidence-based reviews were received from Vijaya Musini (Canada), Carlos Fonseca (Costa Rica) and Christophe Kopp (France).

Shared information

Several useful papers have already been shared within the EIWG, including:

- Scott I, Greenberg P, Poole P, Campbell D. Cautionary tales in the interpretation of systematic reviews of therapy trials. Intern Med J 2006 Sep;36(9):587-99.
- Schechter MT, Leblanc FE, Lawrence VA. Critical appraisal of published research. In: Troidl H, Spitzer WO, McPeek B, Mulder DS, McKneally MF, Wechsler AS, et al., editors. Principles and practice of research: strategy for surgical investigators. 2nd ed. New York: Springer-Verlag; 1991. p. 81-7.
- Lowe MP, Hayhow BD. Beyond critical appraisal. Aust Prescr 2006;29(5):122-4.
- Critical Appraisal Skills Programme: making sense of evidence about clinical effectiveness. UK: Public Health Resource Unit; 2006.
- Bassler D, Briel M, Montori VM, Lane M, Glasziou P, Zhou Q, et al. Stopping randomized trials early for benefit and estimation of treatment effects: systematic review and meta-regression analysis. JAMA 2010;303(12):1180-7.
- Fowkes FG, Fulton PM. Critical appraisal of published research: introductory guidelines. BMJ 1991;302(6785):1136-40.
- Feise RJ. Do multiple outcome measures require p-value adjustment? BMC Med Res Methodol 2002;2:8.

The following articles on new terminology used in scientific publications have also been circulated:

- Stichele RV. The 'wise list'- a comprehensive model for drug and therapeutics committees to achieve adherence to recommendations for essential drugs among prescribers? Basic Clin Pharmacol Toxicol 2011;108(4):221-3.
- Cornu P, Steurbaut S, Leysen T, De Baere E, Ligneel C, Mets T, et al. Effect of medication reconciliation at hospital admission on medication discrepancies during hospitalization and at discharge for geriatric patients. Ann Pharmacother 2012;46(4):484-94.

Also shared was a list of presentations used in workshops at Oxford University's Centre for Evidence Based Medicine (http://www.cebm.net/index.aspx?o=1083).

Can you help?

The EIWG is hoping to start some new activities soon on patient/consumer education, medical errors and self-medication. To help us in this work we are seeking new members who are prepared to contribute their time, knowledge and experience. If you are interested in joining the EIWG please contact Natalia Cebotarenco epn_nis@yahoo.com.

Some members of the Educational Information for Health Workers and Consumers Group pictured at the General Assembly in March 2012

Advocacy

Teresa Alves and Florence Vandevelde

Since the General Assembly in Vancouver in March 2012, there have been several teleconferences of the ISDB advocacy group. As most of the group are from Europe, the focus has mainly been on European issues. The activities have notably included analysing the European Commission's legislative proposals and proposing improvements, and meeting Members of the European Parliament. Our position papers and accompanying press releases were prepared on behalf of ISDB by the ISDB advocacy group and the ISDB Executive Committee. The ISDB President gave final approval.

Pharmacovigilance legislation

ISDB has responded to two consultations about the new pharmacovigilance legislation.

ISDB and allies say no to a fee-for-service system for pharmacovigilance activities

The new legislation enables the European Medicines Agency (EMA) to charge fees for its pharmacovigilance activities (previously, it was specified that pharmacovigilance activities were to be publicly funded in order to guarantee EMA's independence in this sensitive field). The main points of a joint response by ISDB, Medicines in Europe Forum and HAI Europe, to the public consultation were:

- Industry fees undermine the independence of regulatory agencies: this structure could have perverse effects, as regulatory agencies would become dependent on

funding from the very industry that they are supposed to be regulating.
- Institutionalising biased decision-making: the new legislation foresees a stronger role for the pharmaceutical industry in collecting and analysing adverse drug reactions data, 'letting the fox guard the hen house'.
- There are alternatives to a fee-for-service system: pharmaceutical companies can be required to pay a percentage of their sales (global turnover) or promotional budgets; or a tax (i.e. a very small amount of money for each box of medicine) could be charged to everyone in a medicine's distribution chain (marketing authorisation holders, prescribers, wholesalers and pharmacists).

The link to our response and the accompanying press release is at http://english.prescrire.org/en/79/207/46302/2173/1884/SubReportDetails.aspx.

Informing the public about medicines' adverse reactions profile: EMA's implementation plan is insufficient

ISDB underlined that the EMA's draft paper about product information submitted for consultation did not reflect the spirit of the new pharmacovigilance legislation, which is to prevent drug-induced harm by making the summary of product characteristics (SPC) and package leaflet more informative. Our proposals for improvements were that product information should:

- easily identify products subject to additional monitoring or whether a medicine's marketing authorisation has been granted under special conditions or exceptional circumstances (i.e. use of a well-known symbol [such as the downward pointing black triangle] on the outer packaging)
- identify recent clinically relevant changes to the product information, in particular those made for safety reasons
- enable patients to understand the harm–benefit balance
- encourage health professionals and patients to report any suspected adverse drug reactions.

Our response is at http://www.isdbweb.org/documents/uploads/campagne/16%20August%20Answer.pdf.

Revision of the European clinical trials regulation

On 17 July 2012, a new proposal to change the regulations governing clinical trials in Europe was made public. Our key concerns before the release of this proposal were:

- Increased transparency: compulsory registration in an open registry of all clinical studies submitted during and after a marketing application.
- Public access to all clinical trials data (in a user-friendly, searchable and downloadable format).
- Safeguarding ethics in clinical trials: enforcing European regulations that foresee the implementation of the Helsinki declaration in all trials used in an application for marketing including trials conducted outside Europe.

Unfortunately, the proposed new regulation does not address these concerns, but rather deregulates the system to allow an increase in the number of clinical trials conducted in Europe. The link to the proposed new regulation is at http://ec.europa.eu/health/files/clinicaltrials/2012_07/proposal/2012_07_proposal_en.pdf.

Prescrire is going to prepare a first analysis of this document, which will be circulated for review and endorsement among ISDB members. Please send any comments to Teresa at talves@prescrire.org.

A focus on the 'Access-to-data' issue

The EMA is holding a workshop on access to clinical trial data and transparency in London this month. Teresa will be attending this meeting and will report in the next newsletter.

In October 2012, HAI Europe also held a seminar on access to clinical data. Teresa was a respondent in one of the panels and presented the ISDB perspective on why we need access to information from the agencies to enable us to do our work as drug bulletins. (Thanks a lot to the friends who answered Teresa's survey on ISDB members' documentation needs!)

'Transparency' of pricing

Released in March 2012, the new European Commission's proposal on transparency in the regulation of the price of medicines and their inclusion in public health insurance systems, endangers countries' health systems and their health technology assessment procedures.

The European Commission claims to obtain '*faster access to medicines for patients*' by revising the 'Directive on the transparency of prices', but in reality the proposal does not meet patients' interests.

The main problems are:

- The proposal is solely driven by pharmaceutical competitiveness, to the detriment of public health. Shortening review deadlines for reimbursement applications and for price-setting practices is likely to weaken the quality of the assessment and undermine decision-making.
- The European Commission is going well beyond its remit and is interfering with Members States' health systems organisation. The approach is unbalanced: Member States are asked to provide detailed substantiation of evidence to companies about decisions on delisting, price decreases or price freezes, whereas pharmaceutical companies have the right to ask for price increases at any time.

Members of the Medicines in Europe Forum (MiEF) are following the new proposal closely. The joint policy briefing is available at http://english.prescrire.org/Docu/DOCSEUROPE/En_TransparencyReimbursmtPrices_Analysis2012.pdf.

Medical devices

On 26 September 2012, the European Commission published a proposal for a new regulation on medical devices, see p. 8 of this Newsletter. This is an important issue for ISDB to address and follow up. The link to the proposed regulation is: http://ec.europa.eu/health/files/clinicaltrials/2012_07/proposal/2012_07_proposal_en.pdf. Prescrire is going to prepare a first analysis of the proposal. Please send any comments about it to Florence at fvandevelde@prescrire.org.

If you are based outside Europe, you can join the group to raise issues that are important to you! Please contact talves@prescrire.org.

Upcoming events of interest

22 November 2012:
European Medicines Agency's workshop on Access to clinical trial data and transparency - 12.30–17.00, London, UK

31 January 2013:
Prescrire's Golden Pill, on Access to Data, Paris, France (in French) (ISDB friends are welcome if they wish to attend; invitation available on request to fvandevelde@prescrire.org)

Conversations with some ISDB members

Héctor Buschiazzo, Folia Doc

Why was your bulletin started?

At the beginning of 1998, the Pharmacology Division of the Medical Federation of the Province of Buenos Aires (FEMEBA) entered into an agreement regionally (with schools of medicine, dentistry, chemistry and pharmacy of the National University of La Plata) and nationally (with Argentine Group for Rational Use of Medicines) to collaborate on activities to improve the rational use of medicines.

Staff members of Folia Doc, from left to right, Héctor Buschiazzo, Guillermo Cobián, Perla M.de Buschiazzo, Martín Cañás

Because health professionals are frequently exposed to biased information it was decided that one of the key strategies would be to prepare independent, reliable and up-to-date information about quality use of medicines for health professionals and to distribute it on a regular basis. It was agreed that the bulletin should concentrate on the most important drug and therapeutic issues in the treatment of prevalent diseases and on medicines whose use is controversial.

How long has your bulletin been going, and how often do you publish?

The first issue of Folia Doc was published in March 1998. Until 2003 it was posted free-of-charge to each physician in the province of Buenos Aires (19,000). In 2003 FEMEBA changed its distribution strategy and Folia Doc was only available electronically on the Federation's website. Since 2008 Folia Doc has been published in both electronic and print format—the print run is 10,000 copies.

Initially the bulletin was published 4 times a year, but since the Argentine economic crisis of 2001–2002 it has only been published 3 times a year; however supplementary issues are sometimes published.

What staff and resources do you have to produce the bulletin?

Three physicians regularly contribute to the development of each edition. FEMEBA Foundation is the organisation responsible for publication of the bulletin and provides the funding.

Who receives the bulletin?

The bulletin is mainly written for physicians so it is distributed through local medical associations in each city of the Province of Buenos Aires. The electronic version of the bulletin is available on the internet (http://www.femeba.org.ar/index.php?op=4&sop=66&ssop=326) and is freely accessible to anyone.

Do you liaise with other like-minded organisations in your area?

All our staff are members of the Drug Utilization Research Group of Latin America, Health Action International, and the Argentinean Group for the Rational Use of Medicines. We also have a strong links to the Pan American Health Organization/World Health Organization.

What kind of materials do you cover in your bulletin?

The usual content covers recommended therapies, relevant news and information about medicines including efficacy, safety, adverse reactions, interactions, and local medicines prices.

Sources of information for the material published in the bulletin include academic journals, independent bulletins, databases, adverse medicines reaction bulletins, warnings issued by regulatory agencies and 'Dear doctor letters'. The data are analysed according to the principles of evidence-based medicine, with an emphasis on results obtained from clinical trials. The information is edited and formatted to allow for wide dissemination and easy reading.

What are your main problems and challenges for the future?

Our main problem for the bulletin is the funding. We need more sources of funds that do not compromise our independence so we can employ more staff and subscribe to an increased number of relevant newsletters and journals.

Philip Sax, Pharma Israel Drug Bulletin

Why was your bulletin started?

I started the bulletin because there were no sources of independent drug information in Israel. Physicians told me they were confused with conflicting claims made by various manufacturers of ACE inhibitors.

How long has your bulletin been going, how often do you publish it and who receives it?

The bulletin was started in 1994 and is now published 6 times a year. It is still the only source of independent drug information in Israel. Which doctors we send it to depends on the subject of each issue of the bulletin. The bulletin is distributed electronically.

What resources do you have to produce the bulletin?

My wife, Dvora, and my daughter, Sharon, help me to produce the bulletin. Sharon is a pharmacist with experience of clinical trials in the medical device industry.

Philip Sax with staff/family members of Pharma Israel Drug Bulletin

Do you liaise with other like-minded organisations in your area?

There are no similar organisations in our area.

What kind of issues do you cover in your bulletin?

Our usual focus is on assessing new drugs but sometimes we review a therapeutic group. In light of my research interest, I also use the bulletin as a forum to disseminate my analysis of issues in drug policy and economics.

What is your main challenge for the future?

To keep the bulletin going.

Editor Training

Sue Phillips, Chief Executive Officer, Therapeutic Guidelines Limited

In 2007 Therapeutic Guidelines Limited (TGL) established a visiting editor program to provide editorial training for healthcare professionals from developing countries who are actively involved in the development of drug bulletins or treatment guidelines. The training covers all aspects of TGL's activities but is tailored to take into account each candidate's experience and specific needs. The training takes place over 2 to 4 weeks, depending on how long the candidate can stay away from their country. Time permitting, visits to other relevant organisations (eg Australian Prescriber) are also arranged.

To date, three of the candidates have been involved with ISDB bulletins: Dr Siddhartha Gupta (Bodhi, India), Dr Dulce Calvo (Boletin de Informacion Terapeutica, Cuba), and this year's candidate Ms Cristina Edono (RDU Update, Philippines). For these candidates ISDB generously supported the program by providing the funding for travel to Australia.

This year's trainee, Cristina Edono from the National Drug Information Center in Manila, provided the following report at the end of her training:

"The training consisted of two weeks of sessions on science writing and editing, Word editing, using the internet for research, analysing the literature, style guides, electronic publishing and understanding copyright/permissions. Every session was worthwhile. TGL staff imparted a lot of information that will be of much help to my work in the Philippines.

Susan Daskalakis (editor) provided MS Word training. She is a MS Word genius and she showed me a lot of magic moves in MS Word.

Melanie Jeyasingham (editor) gave a lot of important points in analysing literature. Jane Watson-Brown (health information officer) explained about copyright, which was useful because we are having discussions about intellectual property rights in the Philippines. Luciana Ignatiadis (evaluation officer) allowed me to observe how evaluation is done and I can see that without feedback we will not be able to know if we are doing the right thing.

I met John Dowden from Australian Prescriber in Canberra and got useful suggestions from him. All the Australian Prescriber people were very nice and I had a wonderful time with them.

Above: Cristina Edono (centre) with Therapeutic Guidelines editors Carol Norquay (on left) and Jenny Johnstone (on right)

Below: Cristina Edono with Therapeutic Guidelines editor Susan Daskalakis

They shared many things worth considering when I get back to Manila. I also shared time with Graeme Vernon (Drug Information Service, Austin Hospital, Melbourne). He understands the situation in the Philippines and suggested some open access websites, available to everyone.

I attended two Psychotropic Expert Group meetings and was able to see how they finalise the information that they include in the guidelines. With this I was able to see that Therapeutic Guidelines is not drug-centred, but more disease-centred, which is why they have a positive impact on medical practitioners and students.

I always think that Filipino people are the most hospitable people in the world but that was until I met the TGL people. They made my stay in Australia comfortable and easy. All the members of the organisation are very helpful and accommodating. They perform their respective jobs well and they are always excellent in what they do.

The program is very helpful for the developing countries that do not have fully developed guidelines and policies to assist healthcare providers in delivering good quality health management. The training provides the editors with skills and knowledge to produce better bulletins and guidelines for safe drug use. I am grateful to TGL and ISDB for sponsoring this kind of training."

All the candidates to date have been equally appreciative of the training they have received. The success of the program is largely due to the staff members at TGL who are exceptionally generous with the time and effort they contribute. Special thanks go to Carol Norquay and Jenny Johnstone who have been largely responsible for most of the liaison with the candidates and the administration for the program.

Evidence Alley

David Menkes, Academic Psychiatrist, University of Auckland (Member, Healthy Skepticism)

Psychiatry conferences in New Zealand and overseas have long been sponsored by the pharmaceutical industry. While we recognize the vital role that drug treatment plays in psychiatry, an increasing number of us within the profession have been concerned about our dependence on commercially sponsored education, for several reasons. Chief among these is the concern that psychiatric practice is harmed by commercial sponsorship, notably by the biased information provided by companies with vested interests. The public image of psychiatry also suffers when our patients and others see evidence of what appears to be a cosy relationship with industry.

With these concerns in mind, we developed an alternative set of exhibits called 'Evidence Alley' at the NZ national psychiatry conferences in Rotorua (2009) and again in Wellington (2012). The 'Alley' showcases the availability of evidence-based materials to support clinical decision making, and is designed to provide an alternative to commercial exhibits and their promotion of particular products. This year the conference

theme of Integrated Care across service and diagnostic boundaries was particularly apt in its focus on the translation of evidence into practice.

ISDB was represented at both meetings, particularly Wellington 2012 where eleven 'live' exhibits included the Cochrane Collaboration and three full members of ISDB: Prescriber Update (NZ), Therapeutic Guidelines (Australia) and Therapeutics Letter (Canada).

Feedback was overwhelmingly positive from Alley participants, conference delegates, and students. Commercial sponsors were mixed in their reaction; while some were good natured about the 'competition', others complained about the fact that Evidence Alley exhibitors paid only marginal costs to participate, in contrast to the steep sponsorship fees required of drug companies. One drug rep also complained about the segregation of Evidence Alley from the commercial exhibits and asked, "if they're Evidence Alley, what does that make us, Bullshit Boulevard?". A good question.

Evidence Alley participants (with the Evidence Alley logo) in Wellington, New Zealand, in September 2012

We intend Evidence Alley to become a regular feature of Australasian psychiatry meetings, and to help eliminate commercial sponsorship of our education. We welcome input.

New Cochrane Satellite Group


Cochrane Satellite Group, Navarre, Spain

Juan Erviti

The Boletín de Información Terapéutica de Navarra (Bit Navarra) was established in 1993 (www.bit.navarra.es) and the English version, Drug & Therapeutics Bulletin of Navarre (DTB Navarre), was commenced in January 2007 (www.dtb.navarra.es). The English version made it easier for our group to participate in various international networks and as a result an important collaboration has now eventuated.

The Cochrane Hypertension Group, which is attached to Therapeutics Initiative (www.ti.ubc.ca) at the University of British Columbia (Vancouver, Canada), offered the people at DTB Navarre the opportunity to establish a Cochrane satellite group in Navarre to undertake systematic reviews of clinical trials to answer relevant clinical questions.

In October 2011 three members of the Vancouver Cochrane group – namely James Wright, Ciprian Jauca and Douglas Salzwedel – came to Spain to attend the Cochrane Annual Colloquium in Madrid. While they were in Spain they conducted a workshop to help the Navarre Cochrane satellite group get started.

This year the Navarre Cochrane group has defined the protocols for two systematic reviews: 'Monotherapy versus combination therapy used as first-line therapy for primary hypertension' and 'Blood pressure targets for the treatment of patients with hypertension and cardiovascular disease'. The Cochrane Collaboration has now approved both these protocols so work on these reviews will commence shortly. It is expected that these two reviews will be published in approximately 12 months' time.

Medical Devices - The Untold Risks

Jörg Schaaber

Current situation in the European Union

Several medical device scandals over recent years (faulty cardiac defibrillators, hip replacement breakages, leaking breast implants) have highlighted the serious failings of the European system to evaluate and monitor high-risk medical devices.

Medical device approval requirements in Europe focus heavily on technical aspects rather than safety. An assessment of the harm–benefit balance is not required for market approval and devices can be marketed without any approval by health authorities. This lack of regulation is based on the belief that post-marketing surveillance provides sufficient control. Recent scandals clearly illustrate that this is not the case especially as the current post-marketing surveillance system is almost incapable of collecting data on adverse effects of medical devices.

The European Commission has plans to introduce a new legislative framework for medical devices in September 2012. But despite the numerous scandals surrounding medical devices, there are no substantial changes to the system to evaluate medical devices in the proposal, only a provision for more rigorous vigilance once a device is on the market.

Given the serious safety problems which have emerged in Europe in recent years, ISDB together with Medicines in Europe Forum (MiEF) and the social insurance platforms AIM and ESIP urged the European Commission to revise European medical device legislation, specifically to:

- make high-risk medical devices subject to approval by health authorities
- improve monitoring of adverse reactions occurring due to medical devices (materiovigilance), and
- strengthen the rights of patients who have been harmed by faulty medical devices.

ISDB and its allies believe that a more rigorous approach is needed to protect patients from faulty and dangerous medicinal products and they met with the European Commission on 30 May 2012 to outline their concerns and ask for more stringent regulation.

Requirement for approval at European level

The current European system needs to be replaced by a central and independent approval procedure. A specific scientific committee should be created within the European Medicines Agency (i.e. called 'Committee for High-Risk Medicinal Devices for Human Use' [CHMD]) and should be responsible for the scientific assessments of high-risk medical devices and implantable devices on the basis of comparative clinical trials (demonstration of efficacy, safety, quality and therapeutic advance compared to the already available therapeutic options).

The results of clinical trials should be stored in a publicly accessible central database. The database should include officially approved information: a summary of the product characteristics and a patient leaflet for distribution with the product. Such officially approved information would provide professionals and users comprehensive information about the product and its use.

For high-risk medical devices already in use, a procedure for approval – in which efficacy and an acceptable adverse reaction profile are to be clinically demonstrated – should be put in place in the interim.

Post-marketing surveillance and transparency

A strengthened materiovigilance system for high-risk medical devices needs to be established which should address the following issues:

- **Traceability:** Each high-risk medical device and implant should receive a unique identifier code to allow clear identification of the product. This unique identifier should also include information about the origin of the product, where it was produced, etc. (This issue is now being considered by the Commission.)
- **Mandatory surveillance registries** should be established and data made available to the general public.
- **Long-term post-marketing studies:** The results, even if negative, must be made public within 12 months of completion of the study.
- **An improved reporting system for adverse events,** which should include industry, healthcare professionals, hospitals and patients.
- **Sharing results of reported incidents and speeding up corrective actions:** Vigilance data have to be made publicly available.

Rights of patients harmed need to be strengthened

Because damage caused by faulty medical products can easily amount to several million Euros this can lead to insolvency of the manufacturer and a lack of patient compensation. Therefore it is recommended that EU legislation should require mandatory liability insurance as a pre-condition for market access. Also, the principle of compensation for damages to patients and third-party payers should be recognised, and the burden of proof should be reversed. In the case of damage involving a medical device, the manufacturer should have to prove that the device was not responsible. Patients harmed by defective products should have the right to join a class action.

Global perspective

Globally, medical devices seem to be much less regulated than pharmaceuticals. According to our ISDB friends from Public Citizen, the US system is far from perfect but it imposes stricter control than the European Union.

We would like to ask ISDB members outside the EU to let us know how medical devices are regulated in their country? Please send the information to fvandevelde@prescrire.org with a copy to president@isdbweb.org.