Strategic MedComms Forum 2011

Trust and transparency – myth and reality

A report of the main points discussed by David Williams, 3C Strategy Limited and Ryan Woodrow, Woodrow Medical Communications Limited

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www.medcommsforum.com

NetworkPharma

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David Williams pursued a career in the pharmaceutical industry for 12 years before joining the medical communications sector in 1989 to deliver educational and training multimedia programmes to clinicians, nurses and other health professionals on behalf of the UK Department of Health and Central Office of Information. Subsequently, David worked with a broad range of agencies primarily in business development roles. With a focus on publication planning and brand development, he developed a number of early intervention strategic solutions to support the commercialisation process within the international pharmaceutical sector.

David then progressed to collaborate with medical and clinical associations, societies, colleges and accreditation authorities in Europe, America and Asia to develop and deliver fair, balanced, unbiased and independent accredited events and on-line programmes in support of medical continuing professional development. David is now owner and managing director of 3C Strategy Limited, an independent communications and CME consultancy: is a member of the European CME Forum and a founding participant in the Good CME Practice Group.

Since becoming a consultant to the industry, David has been engaged in reviewing the medical communications sector across the whole of Europe. He is currently developing models for the assessment of effectiveness of medical education as part of medical Continuing Professional Development, and its impact on day-to-day medical practice.

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Strategic MedComms Forum 2011: Trust and transparency – myth and reality

14th September 2011, Wellcome Collection Conference Centre, London

Chairman and Inquisitor: Phil Hammond (GP, writer and broadcaster)

Session 1: Innovation, transparency and excellence from early phase onwards. Partners or foes?

Session Lead: Leo Francis (President, Publicis Medical Education Group) together with Karen Winterhalter (Managing Director, Onyx Health), Graham Cox (Principal, IDEA Pharma), Mat Phillips (Director, Neovoca and Founder of ENGAGE) and Dennis Joseph (Area Head Clinical Operations, Pfizer)

Session 2: Sharing data. Opening the Pandora's box?

Session Lead: Adam Jacobs (Director, Dianthus Medical) together with Tatjana Poplazarova (Director of Scientific and Public Disclosure, GlaxoSmithKline Biologicals), Iain Hrynaszkiewicz (Journal Publisher, BioMed Central), Doug Altman (Co-founder EQUATOR and Co-editor of *Trials*) and Lorna Fay (Senior Director, Publications Management, Pfizer, Inc.)

Session 3: Good Practice Guidelines. A triumph of hope over experience?

Session Lead: Charlie Buckwell (Chief Executive, Complete Medical Group Worldwide) together with John Gonzalez (Director of Publications Policy, AstraZeneca and MPIP steering committee member), Eugene Pozniak (European CME Forum and Good CME Practice Group), Iain Hrynaszkiewicz (Journal Publisher, BioMed Central) and Elizabeth Wager (Publications Consultant and co-author GPP1 guidelines)

Session 4: Does transparency lead to trust? Or just loss of control?

Session Lead: Richard Evans (Managing Director, Darwin Healthcare) plus Paul Woods (Director, Paul Woods Compliance), Chris Rains (Head of Global Publications, Shire Specialty Pharmaceuticals) and Ben Goldacre (Writer, broadcaster and medical doctor)

Session 5: So, after all that, what next?

Led by Charlie Buckwell together with Leo Francis, Adam Jacobs and Richard Evans

Introduction

Following the successes of the inaugural MedComms Forum in 2010, the aim of the 2011 meeting was to build upon some of the important discussions that took place at the first event, while also tackling some of the key issues that have occurred in the medical communications field in the past 12 months.

Major issues that are particularly impacting on the pharma and medical communications industry at the current time are those of transparency, trust and reputation. We are at an important crossroads where the majority of stakeholders agree that we should aim towards increased openness in an effort to increase trust amongst clinicians, the media and the public. However, it is proving somewhat difficult to find practical solutions. The Association of the British Pharmaceutical Industry (ABPI) are looking at this issue on behalf of UK pharma companies, but medical communications companies and some of the deliverables that we produce (e.g. publications) are not specifically covered by the ABPI's remit.

Medical Communication professionals need a voice, and need to consider practical solutions. Without it, poor practices and bad press will continue. An example of recent negative media press was the article on "Ghost-Writing" in the *Guardian* (**http://www.guardian.co.uk/science/2011/may/20/drug-companies-ghost-writing-journalism**). Examples of negative press aimed at clinicians are also available; for example, the dedicated resource to Ghost-Writing on PLoS Medicine (**http://blogs.plos.org/speakingofmedicine/category/ghostwriting/**). With these types of issues in mind, the main purpose of this meeting was to bring together a relevant audience to openly discuss the problems we face and to start to generate solutions.

Tweeting in and out of the event was encouraged, wide-ranging and far-reaching with people unable to attend joining in the discussion on the day. Links to the Tweets and other outputs can be found at **www.MedCommsForum.com**. It is hoped that the conversation will continue within the community, within individual organisations, at special interest events and in LinkedIn discussion groups, such as the MedComms Forum group at **http://www.linkedin.com/groups?gid=1865105**

The event

Over one hundred specialists gathered in the lecture theatre of the Wellcome Collection. They included representatives of the medical communication industry, publishers, pharma companies, and other organisations involved in medical publications.

Under the expert guidance of Phil Hammond, who acted both as moderator and inquisitor, five sessions were held at the meeting to debate and discuss the following main points:

1. The need for greater transparency of information on early phase compounds and how this could increase innovation and trust.
2. The benefits of greater sharing of more product-related data than is already in the public domain.
3. The usefulness of Good Practice Guidelines, and how their utility can be enhanced.
4. Whether transparency leads to trust, and if so, how the industry can become more transparent.
5. How we can make the consensus from the meeting a reality; what are the next steps?

As well as being a respected commentator on health issues in the UK, Phil Hammond is a qualified doctor. By way of an introduction, Hammond started with an analogy. He mentioned that the determinants of health are partly social and not just to do with which drugs we take. Likewise, meetings such as the MedComms Forum that have networking elements (i.e. debate and discussion) are important, as they can improve corporate health and image.

Hammond then asked the audience how many people think the pharma industry could be more open and transparent, and how many people think that pharma companies could be completely open and transparent or in other words publish absolutely everything? This was to be an important theme throughout the course of the day. Overall, fewer supported the latter option although the majority were in favour of both.

Hammond went on to discuss what he does in an average week. He is a practicing GP one day per week, writes for *Private Eye* each week, does a little bit of lecturing and dabbles in medical politics, but spends much of the rest of his time doing investigative journalism mainly supporting NHS whistle-blowers. At that point he commented that both the pharma industry and the NHS have not been particular champions of helping those who expose poor conduct and wish to improve transparency.

Hammond mentioned that greater transparency is definitely needed in the pharma industry. He therefore felt that it was a good start to discussions that the majority of meeting participants were in favour of greater openness.

Session 1: Innovation, transparency and excellence from early phase onwards. Partners or foes?

Leo Francis (Publicis Medical Education Group) discussed the changing environment facing the pharma industry. He mentioned that pharma used to be highly introspective, and not at all patient focused. Pharma was seen as closed, selective and controlling, and the medical communications community has played a part in creating and perpetuating that perception. While this is a thing of the past, what would happen if we became open, transparent and supportive?

> *Is the lack of transparency actually inhibiting innovation?*

Many industries go about their development in a much more collaborative, open and transparent way. A good example is in the software industry where a group of developers globally would work together, no-one owning but everyone being a stakeholder. Can we apply these themes to our business? Can innovation and transparency sit side-by side in the pharma industry? Could we go further and ask is the lack of transparency actually inhibiting innovation?

Francis suggested that if we were to apply these themes, this would require a whole new way of working. Above all we would need clarity and transparency of motives and motivation. Why do we do what we do? Are the motives of the pharma company really being shared with the patient organisation? We also need to acknowledge the consistent dilemmas that exist – the reality of the environment we are in: shareholder value versus affordability; intellectual property (IP) protection versus collaboration; open communication versus media 'spin'; needs of the individual versus needs of populations; private (industry) is bad versus public is good. Healthcare is different. The industry significantly improves peoples' lives but it has to be acknowledged that the industry generates profits based on this premise.

Opening it up to the floor, Hammond asked the audience to consider how transparency of early data might help or compromise a pharma company.

The first audience response raised concern about sharing information too early in the development process. Pharma are extremely cognisant of the implications of releasing potentially sensitive data into the public domain too early. It is therefore not just about the data itself, but also about the language used to communicate data, and the timings.

Karen Winterhalter (Onyx Health) made the point that it is not just about data sharing but also about corporate communications. It is the business-to-business role that is being played out as partners are sought to get drugs to market. We tend to focus on the publication plan but in fact there is much more of a business/corporate role to be played. Many small companies are looking to make partnership deals with big pharma and have the answers to a lot of the challenges, and yet they cannot get near the people that they need to talk to because the industry is incredibly closed. So the challenge is for everyone to be more open, not just in what we do but in who we talk to.

In response, Mat Phillips (Neovoca) suggested that there are pharma companies taking the lead in encouraging collaborations. However, pharma has concerns about telling everyone about everything because this would not only confuse, but could also lead to greater bureaucracy and 'clog-up' the system. In this regard, the media in particular may well publish stories about drugs that are in very early phase development, which may never get to market. At what point does it become important to share information about products, when do they become newsworthy, and who does this information become important to?

Along similar lines, Dennis Joseph (Pfizer) asked everyone to bear in mind the huge attrition rate in the drug development process. For every 10,000 or so compounds, only one gets through to the marketplace. Therefore, the industry has to be selective about information sharing. The question of when does information become relevant is critical. In his opinion, as the molecule enters Phase II is about the right time to more openly share information publicly. At this stage, the compound is close to proof of efficacy, and is therefore something that patients and physicians can relate to.

One audience member commented that sometimes it may be investors who want the company to release data to show that it has a rich pipeline, but as many drugs may not make it to market, the danger from the patient perspective is that you are creating false hope and, ultimately, many false dawns could discourage people from accessing data. There is therefore a potential struggle regarding how transparent we can be – do we flood the

market/confuse the patient, or give people the power to push for innovation. In response to this, Francis felt that patient engagement is key, even before identifying the need for a new drug and engaging in clinical development. However, this will require a change in mind-set.

It was mentioned that some of the issues relating to early phase products could potentially be solved by good marketing considerations, i.e. understanding customers' needs and designing products and releasing information in response to that. However, in the public's mind, marketing has become a dirty word associated with spin, sales, and so on. The panel was asked what they thought about the idea that good marketing can support good medicine.

Graham Cox (IDEA Pharma) focused in on the medicine part of the question. He mentioned that drugs are seldom bad, but like some children, are sometimes the result of bad parenting. In this regard, Cox was referring to badly designed trials, the development of 'me too' products, and the frequent observation that pharma companies make small adjustments in the formulation of drugs to combat generics. These types of cases lead to marketing spin, which is not ever a healthy situation.

In response, it was stated that within pharma there are potentially two needs for marketers. First, there is the promotional side, which is mostly what the medical profession sees as marketing. However, there is also a potential need for marketers at early developmental stages, and pharma is the only profession that does not allow its marketers in at early phases. The debate should really be about when to involve good marketers, who will try to get the best of the molecule to those people that will benefit most from it. The key is to distinguish between marketing and promotion, as they are not always the same thing.

Some audience members agreed that pharma should involve marketers earlier, and involve patients in their planning. However, others were unhappy at the thought of marketing becoming involved earlier in drug development. One participant commented that if doctors really practised evidence-based medicine then marketing would not be needed at all and would not work. However, doctors allow their emotions to be led by marketers, and that is why marketing companies exist within pharma. Another participant commented that he would be concerned about involving marketers at an early stage with a molecule pre-Phase II that might ultimately not work. Francis responded by saying that problems will always arise if we continue to separate drug development from patient need. Marketing should be all about satisfying that customer (patient) need.

The take-away message is that the industry needs to develop a listening ear

The discussions were then taken to the topic of how pharma should communicate earlier? Cox's response was that this already happens to some degree. The Investigators' Brochure is probably the single most effective communication tool that comes out at Phase I/II. Through this document, experts are getting the scientific story that marketing has absolutely no say in, so you have already positioned your drug without involving marketers, and some might say without the benefit of a broad understanding of the market.

Also in relation to the question of how to communicate at earlier stages, Joseph stated that there is definitely a lot of room for improvement, but that the industry does already engage at this level. Scientific advisory boards were cited as a good example of where experts are shown information and asked to comment about indications and insights. However, it was recognised that assumptions are made that the thought leaders are representative of the wider physician population.

Phillips mentioned that there is not just a need to communicate with clinicians and that it is critical also to consider how to involve patient advocacy groups at earlier stages. Winterhalter agreed that this was important. She provided an example of where a patient advocacy group had been consulted for a particular drug at an early stage of development, and the feedback received was influential in making the pharma company consider an alternative route. As a result of its collaborations with patient advocacy groups, and because of its willingness to change course, the pharma company in question gained respect and kudos. The take-away message is that the industry needs to develop a listening ear.

On a different note, Philips asked whether the global pharma industry has a responsibility beyond just launching products. If it does, then it is not targeting its efforts correctly in terms of unmet need nor is it conducting its R&D in more than a few countries. Essentially, pharma currently serves a western population because that is where the financial benefit is and this can make onlookers uncomfortable. However, collaborating to benefit poor communities is where the industry would have more impact on world health. Charlie Buckwell (Complete Medical Group Worldwide) believes that pharma is changing its focus on emerging markets. The question was then asked whether that focus is on generating data/recruiting patients more cheaply in those markets or whether it is on

products to actually treat those populations? It was generally thought by participants that the answer is both, but it is agreed that broader collaboration is still required.

The final question in this session from Ryan Woodrow (Woodrow Medical Communications) was related to early publication, and whether publication from as early as Phase I might be useful to allow researchers and investigators to learn from the experience of others? Woodrow quoted research from a survey, soon to be presented at ISMPP Europe, that had recently been conducted by himself and colleagues illustrating that over 40% of medical publication professionals felt that it should be mandatory for pharma to publish findings earlier than Phase II. In response, Joseph commented that Pfizer is not only looking at its own R&D, but is setting up all sorts of collaborations where it is now sharing information with universities and other pharma companies to improve discovery and innovation. Publication is one aspect, but there are other ways of learning from the experience of others.

Session 2: Sharing data. Opening the Pandora's box?

Adam Jacobs (Dianthus Medical) chaired the second session of the Forum and quoted Rudyard Kipling's 'Six Honest Serving-Men' poem providing him with six questions about sharing data – What? Why? When? How? Where? and Who?

What data should we (and do we) share?

In one way data are shared when research is published, but this debate is potentially talking about going further than that, not just the statistics but the raw data that other people can analyse.

Why share data?

What are the benefits to us/everybody else? The temptation is for us to agree for other people to share their data and not for us to share our own, so the true benefits to all need to explained and understood.

When do we share data?

Jacobs thought that the same time as results are published would be reasonable but other opinions may differ.

How do we share data?

Do precautions need to be taken to protect patient privacy? If we have patient details such as age, the hospital they have been treated at and the fact they have potentially quite a rare disease, how anonymous are the data? Are patients therefore happy for raw data to be accessible? Nobody is asking for their consent currently so this could pose a real issue.

Where can we share data?

We publish in journals and journals have websites. Can we deposit data there or should there be specialised data repositories?

Who owns the data?

There are IP implications to sharing data.

After discussing these questions, Hammond passed over to the expert panel to begin addressing some of the issues raised. Iain Hrynaszkiewicz (BioMed Central) chose to address the 'where' question and, as a publisher, mentioned that his organisation was quite happy to accept data sets subject to peer review and patient privacy. The important point is that it can be found and linked to publications and other relevant data sets. They must be permanently available and discoverable in the same way as journal articles are.

Hammond asked, given that most people in the room said it was a good idea, why so few companies are sharing data? One answer came from the audience who said that pharma companies do share data with their business partners all the time. Hrynaszkiewicz said that sometimes raw/additional data do get published, but it depends on the area. In clinical research it is uncommon, but in genomics and bioinformatics it is not uncommon to include data files. It is a field-specific issue and the mechanisms are there, but perhaps not the motivations.

Lorna Fay (Pfizer) added to the discussions stating that it is not standard practice for data sets to be shared unless IP rights are protected up-front through agreements/contracts. People can and do ask for data sets and these requests are looked at on a case-by-case basis. Agreements can then be drawn up. An example given was where a Pfizer investigator recently wanted to merge Pfizer data with his research data for analysis.

To probe further as to why more data are not being more publicly shared, Hammond offered three possible answers – it is not happening because it is a problem in terms of processes and regulations; it is not happening

because pharma sees no advantage in doing it; it is not happening because pharma are worried that ideas can be copied. The unanimous response from the panel was 'all of the above'. Fay said that many working groups are now addressing these questions, but Doug Altman (EQUATOR) said that some groups have been discussing this for 10–15 years and have yet to provide firm solutions. It was mentioned that many still think in terms of journal publication, but data can be made available in other public places (e.g. clinicaltrials.gov).

Overall, the panel felt that as long as there are no incentives to pharma for sharing data and while no-one else is doing it, it will never become part of the culture. There is a clear societal benefit because we know there is selective reporting and publishing the raw data set allows much richer analysis by other people. There are also clear benefits to researchers/meta-analysts. However, the incentives to pharma need to be made clearer.

Richard Evans (Darwin) asked who will analyse the data when we find a home for it. The average GP will obviously not have time. They have six minutes with a patient if they are lucky, so would not have time to analyse the data and work out the implications of the analysis. Jacobs answered that one group of people who are going to analyse it are respectable meta-analysts such as the Cochrane group. That is a good thing and that will help evidence-based medicine and is to be encouraged. At the other end of the scale there will be mischief makers who will conduct data-dredging exercises to support conspiracy theories. Tatjana Poplazarova (GSK Biologicals) shared her concern about this in relation to vaccines (where there are public examples of misrepresentation of data). However, she said that fear should not drive our decisions and if the data are there and there are mechanisms for storage and re-analysis that are scientifically validated, this could actually support the proper uptake of vaccines.

In practical terms, Altman pointed out that there is no requirement or expectation that these data will be re-analysed. A lot of published data will never be re-analysed but it is a great help to transparency because you trust the results more if you know they are there to be re-analysed. Furthermore, it acts as a deterrent to selective reporting. Jacobs went on to say that industry and academia need to be comfortable with losing a certain level of control as you do when you publish data, and this could be the biggest challenge of all.

Hammond wanted to know if there are implications for resources. Data sets are already in a format suitable for the FDA so the mechanics of uploading, for instance onto a pharma website, should be relatively straightforward. Poplazarova brought forward both ethical and logistical issues in response. Just checking informed consent and protection of confidentiality, for example, is a high resource exercise, as is ensuring that the data are up-to-date following review. It was also mentioned that patient consent forms do not regularly include a paragraph on potential publication of raw/patient level raw data, meaning that data could not be shared in these cases without going back for permission. Jacobs suggested that in future anyone involved in drawing up these types of forms should endeavour to have this type of statement added to make sharing of raw/patient-level data easier.

Patient confidentiality is a real issue relating to making raw data available

It was proposed that a solution to this entire data sharing issue could emerge from journals. If high-ranking/respected journals say they will not publish studies unless the data is deposited in a public place, this could be the catalyst that changes the culture.

Fay thought that increased publication of data has the potential to enhance trust and it will happen eventually. However, Hammond commented that it remains to be seen as to whether it is the pharma companies who will initiate this themselves, which would be a fantastic PR coup and would certainly go some way to restoring some of the trust that has been lost, or whether it going to be forced upon them either by journals or the regulators.

A question was posed about how the data will be found once it is published. Search engines will be useful to some degree, but if a site has an access page, then search engines will not find it the data. One solution could be for data to be posted in a specific location, such as clinicaltrials.gov. Jacobs believes that publication on this site would be a perfectly adequate solution.

Jacobs summed up the session. He mentioned that it is interesting to look at the barriers to publication of raw data and the feeling is that it is mostly due to inertia: "No-one else is doing it so why should we?". Once the processes are in place, the resource implications should not be that great, but putting those processes in place in the first place is a big job. Jacobs stated that it is encouraging that nobody really brought up IP and the fact that it could hurt competitive advantage if raw data are available. This has often been quoted as a reason in the past. Finally, Jacobs said that patient confidentiality is a real issue relating to making raw data available and this needs to be addressed as soon as possible when drafting future patient consent forms.

Session 3: Good Practice Guidelines. A triumph of hope over experience?

Charlie Buckwell chaired this session, which examined the barriers to the adoption of guidelines in practice, looked at the role guidelines can play in helping address transparency and trust, and questioned whether the existing guidelines go far enough. The premise to the session was that if we have well-designed, well validated, credible and comprehensively implemented guidelines that are understood by the medical publications/ communications community then that should facilitate the whole transparency, trust, accountability, reputation debate.

Buckwell mentioned, however, that we also need to consider what others think of our industry and showed some clear examples of how others perceive and criticise what we do. In particular, the ghost-writing debate was highlighted, and it was shown that the industry is often represented by poor journalism. Media stakeholders and critics need to be considered when drafting and implementing guidelines.

Buckwell highlighted that there is no shortage of guidelines for pharma. He then charted the causes of a gap between guidelines and practice, but quoted evidence showing a narrowing gap and the importance of guideline familiarity and of companies instituting their own publication policies. Maximising the chances of success includes some common sense factors, especially ensuring stakeholder ownership. As an example, it was mentioned that Publication Policy Statements are rare on pharma company and medical communications company websites. However, having these displayed would highlight the ethical approaches taken by those companies in generating publications, and would also make very clear statements in terms of what practices the companies would not get involved in.

Hammond immediately posed a question to the audience – with all these guidelines available, how many people think that pharma is so well regulated that significant 'bad' marketing is or is not going on in the industry? A show of hands demonstrated that the majority of the audience thought bad marketing still occurs and consequently Hammond made the point that while some critics may have been over sensationalising our practices, there is still a story to be had for journalists. Despite all of the guidelines being in place, some marketing is being pushed beyond the boundaries either because people are not reading the guidelines or because the guidelines do not have any teeth.

Examples of good guidelines that have made a significant difference include those associated with Good Publication Practice (GPP). Liz Wager (Sideview), the first author of these guidelines, highlighted that 10 years ago she asked the industry if they would endeavour to publish clinical trials of marketed products. It was explained how this would be a great bit of PR and how it would lift the level of trust that the general public had in pharma. She naively thought that they would jump at the opportunity, but the response she received was rather different. It was perceived as dangerous for many of the reasons that have been mentioned in the previous sessions. However, 10 years on, pharma have accepted that they do need to publish clinical trials of marketed products and are even talking about full data sharing. The implication is that we have come a long way, guided and informed in some part by GPP.

Wager also picked up on Hammond's point about bad marketing and re-phrased it to encompass bad publication practice where there has been a huge growth in awareness of what you should and should not be doing, resulting in an overall decrease in 'dodgy' publication practice. Hammond wanted to know what happens if bad publication practice is encountered today and Wager responded by saying that pharma audit and monitor themselves much more and that journals are a lot more clued up so the deterrent is the likely embarrassment for a company if it is exposed for having involved a ghost-writer or paid an author and not declared/acknowledged the support. The reputational risk is generally enough to stop the practice.

John Gonzalez (AstraZeneca) commented on the perceived lack of teeth in guidelines, but drew the audience's attention to the fact that many pharma companies now have a Corporate Integrity Agreement (CIA) in place that is issued by the US government. Most will have publication clauses and companies do need to abide by those clauses. Companies are audited on compliance with the CIA and the consequences of not complying are very serious. The ultimate sanction is that a company's licence to operate in the US can be withdrawn. Buckwell made the point that this feeds through to agencies as well. Agencies are bound by clients' CIAs so this is another way of ensuring compliance. Francis agreed, adding that compliance officers make clients jump through hoops and that in itself is an incentive.

Jacobs commented that journals could do more to assist compliance. Their generalised format for checking compliance is quite passive and does not challenge the industry to question its own practices. Whilst journals do not have the resources to police this, the situation could be improved if journals asked more direct questions of authors. However, Jacobs felt that there is not much of an appetite amongst the journal community to do this.

Francis stated that the medical communications community are complicit in bad practice if we don't challenge our clients when we see poor practice. We have a responsibility to change behaviour. A comment from the floor asked for a dose of realism. Small agencies are unlikely to challenge big pharma in the way that is being described. The notion that an agency of 10 or 15 people based in the UK is going to challenge a big pharma company, at the risk of them unleashing their legal team on the case, is flawed. Hammond agreed and revisited his role as supporter of whistle-blowers. In the NHS and elsewhere, whistle-blowing is a pejorative term with connotations of snitch or tell-tale, whereas it should be rebranded as a duty to speak up. He also highlighted that people who do whistle blow (in the NHS and pharma) encounter extraordinary stresses on their personal and professional life. The way he makes this work in the NHS is by uniting patients, carers, families, nurses and MPs so that they feel comfortable raising concerns. There has to be some safe way to raise concerns.

Buckwell concurred and also agreed with Francis by saying that many agencies live with guidelines on a daily basis and are often more familiar with them than their clients in industry. Therefore, there is an innate responsibility to guide the client through the maze of guidelines. If there is a perceived problem, the panel recommended that agencies go within their clients to their own compliance departments rather than blow the whistle externally.

Gonzalez, on behalf of AstraZeneca, participates with a couple of other large companies in a forum called the Medical Publishing Insights and Practices (MPIP) initiative. In that forum they discuss issues surrounding the publication of industry sponsored clinical research. What journals tend to say is that the larger pharma companies usually have their policies and practices in place and they adhere to them. Although we have been of late pre-occupied with ghost-writing, one of the main issues that also worries journal editors is fraud and/or plagiarism and this generally does not involve the industry. If an article goes through the peer review process and appears on the pages of their journal, but then appears to be fraudulent, there is a whole process of retraction to manage as well as the impact on reputation that such a publication could bring. The issue of ghost-writing is important, but there are other issues for journals to consider.

Wager, who is Chair of the Committee of Publication Ethics (COPE), mentioned that she too has found that journal editors are much more worried about data fabrication, plagiarism etc., and generally such instances do not come from industry-funded studies. She quoted a study by Karen Woolley that examined retractions (for having done something bad) and corrections (honest errors), and analysed these in relation to industry-funded studies and those that involved a named medical writer. The research found that if you had industry funding and you had a named medical writer, the chance of having the study retracted, i.e. for fraud, was vanishingly small and much smaller than with academic articles.

Buckwell moved on to note that there is sometimes an overly conservative interpretation of guidelines because of ambiguities in the system and because of a fear of what might happen. An example of this relates to the publication of 'off-label' studies. The unseemly rush to suppress the publication of studies that are not on-label needs to addressed because it is unethical not to publish the data from these studies. If new studies are seen as off-label promotion, clients need to be reminded and reassured that they have a responsibility and an obligation to publish. Hammond commented on this saying that if the culture is one of anxiety and fear, it does not encourage transparency.

The other argument that has been embedded is promotional versus educational, but Buckwell think this is irrelevant. Instead, consideration should be given to – is it informed, is it accurate, is it credible, is it well-founded, is it likely to support evidence based decision making? If it does those things and you know who it is coming from, then is it important whether it is promotional or educational? Buckwell quoted an example of a pharma company's legal counsel removing all of their company product information from a medical education symposium. The data that was to be presented in the symposium had been published and was on an approved product. The end result was that the only topic the symposium did not cover was their company data. This overly conservative approach prevents the sharing of balanced evidence and will, Buckwell believes, push the industry towards more promotional activities.

Eugene Pozniak (European CME Forum) commented from a CME perspective saying that in the CME space anything that is controlled by a drug company, however much the company says it is educational and not promotional, it is *de facto* promotion. The rules are such that it is deterring experts from getting involved with industry. If they are asked to declare their interests prior to being invited to be on a guidelines committee or to work with government and declare an association with industry, they are automatically excluded. The unintended consequence is that it pushes the industry towards a more promotional focus because they are not allowed to do anything else. If the industry becomes disconnected from the scientific exchange, it is going to be very damaging to the development of new treatments and to patient care.

Coming back to the need for individuals to take responsibility for highlighting bad practice, Hammond observed that the most depressing thing he had heard during the meeting is that not one of the audience had blown the whistle despite admitting to seeing bad practice taking place – albeit in the past. He felt that steps need to be put into place to aid whistle-blowing and that this is the quickest way to root out bad practice. In defence of the

industry, it was suggested that the ABPI monitors and acts regularly on bad practice and each company wants to do the right thing for patients. Therefore, if people do see an issue, then they can go to the ABPI and report that there is something bad going on. However, some audience members questioned whether the ABPI really has sufficient power to act against malpractice, and it is also questionable whether the ABPI have a remit regarding publications.

> *Agencies should take a lead in advising or counselling clients in terms of how they need to operate*

A final comment from the floor was that we should not forget the integrity of the doctors in all of this. There is a need for clinicians to also familiarise themselves with, and adhere to, guidelines if they are working alongside the pharma industry. They are also important stakeholders who can be responsible for aiding poor practices. An example given is that authors sometimes are reluctant for medical writers to be acknowledged on their articles. Additionally, clinicians (particularly in emerging countries) sometimes want payment for authorship, which is deemed unacceptable by some guidelines.

In summary, Buckwell wanted to reinforce that agencies should take a lead in advising or counselling clients in terms of how they need to operate. Pharma companies take compliance very seriously, and clients will generally align with guidelines if they are brought to their attention. He also highlighted that agencies should turn away work from clients who will not adhere to guidelines and good practice.

Session 4: Does transparency lead to trust? Or just loss of control?

Richard Evans introduced this session with a story about everyday folk! The famous (infamous) saga of Ryan Giggs versus the media from the beginning of 2011 illustrates how lack of openness and transparency can dramatically backfire, leading to a total breakdown of trust. In the same way, in our industry, a lack of transparency in the past has led to a breakdown of trust. However, Evans stated that there are increasing controls imposed on the pharma industry. We are highly regulated in areas such as drug development, manufacturing, pricing and communication (codes of conduct). The industry has made great strides in policing itself and in interacting with its stakeholders. Therefore, with these guidelines and controls in place, we should now be judged on current actions not past misdemeanours.

Hammond asked Ben Goldacre (Writer, broadcaster and medical doctor) to comment on this topic. The issue that Goldacre was most concerned by is that pharma hide data from trials (i.e. do not publish the results), because the trials do not quite provide the answers that the company wanted. Goldacre went on to quote from personal experience when he prescribed a drug (reboxetine) in good faith and based on published supporting data only to discover at a later date that 76% of the data was withheld (finally released October 2010) and that this showed that the drug was at best ineffective and at worst may have actually caused more harm than good. This was a reflection of what was deemed by some to be acceptable behaviour (i.e. unflattering data being withheld and good data being published). Goldacre commented that this was unearthed by some persistent academics and what is startling is that it is nobody's particular job to monitor this. The biggest flaw in the information architecture of academia and medicine as a whole is that we do not have clear systems for spotting unpublished trials, and subsequently following up.

An audience member flagged that all data should be published on clinicaltrials.gov and that pharma companied have a duty to publish there within a specific timeframe. In response, for an upcoming paper, Goldacre stated that he has tracked a significant number of trials that are supposed to have posted results to clinicaltrials.gov and to see if the FDA Amendment Act 2007 has changed the frequency with which people do post results within one year. He felt that the Act has had a marginal effect and based on his so far unpublished research, the number of people posting results on time is still only around 1 in 5. If there is no-one/no organisation monitoring this poor compliance, then the regulations are entirely irrelevant. In this regard, he stated that although the consequence of not posting is $10,000 per day per trial (which Goldacre feels is an inconsequential amount), no fines have ever been imposed. He also mentioned the clinical trials registry in Europe that was set up for the purposes of transparency and yet this is held in complete secrecy. Goldacre cannot understand why the pharma industry is not fighting to get that to be made publicly available.

In answer to a question from Hammond about what type of data should be published, Goldacre stated that there are some things that are unarguable. All results must be published in full for all trials that are conducted in people and whilst many agree with this assertion it is unfortunately the norm that a large proportion of data is withheld from researchers, doctors and patients. Goldacre describes this as unforgiveable and probably the single biggest ethical problem facing medicine today.

Chris Rains (Shire Pharmaceuticals) mentioned that there is a clear disconnect occurring when all the companies represented at the forum, including Shire, have policies in place to ensure that data are disclosed and/or published, yet Goldacre states that 76% of reboxetine data were not published. Several people in the audience suggested that this is because the reboxetine story is old news and things have moved on since then, but Goldacre said he was told ten years ago that this problem had been solved and yet similar examples have happened since. Goldacre's own personal view is that full transparency has not yet been attained. Meetings such as this talk about how (slow) progress is being made towards it, but until the industry becomes more open, then the correct position for doctors, patients, and commissioners of healthcare is to not trust the industry. His opinion is that it is important for public health that doctors, patients and healthcare commissioners do not trust the industry and are advised not to trust the industry in an environment where 76% of the data on the efficacy of reboxetine can be withheld with impunity.

A member of the pharma industry in the audience advised Goldacre to check his data because there is an acknowledged backlog on clinicaltrials.gov and it is a constant worry to people that the information provided does not appear; and this could explain why the fines have never been imposed. This audience member felt that the fault does not generally lie with the pharma company because, when it comes to clinical trials posting, companies do take the posting of this data very seriously. Goldacre responded by saying that the bottleneck is in not getting data through to researchers, doctors and patients, and that his research on clinicaltrials.gov clearly highlights a concern. The issue that Goldacre would like to see being answered by the pharma industry is "how can we make sure that we hose data out of our organisations as quickly as possible to get into the hands of doctors and patients and commissioners who need it".

Hammond felt that one of the most powerful outcomes from the meeting could be a decision to audit changes in the regulations to see if they actually result in a change in practice. Hammond asked if anyone in the audience had ever done this either for themselves or on behalf of a client and no-one had.

With regard to selective reporting, Hrynaszkiewicz framed the scale of the problem by quoting a paper published in *Trials* journal that showed there was selective reporting in forty different medical indications and fifty different medical interventions, so it is really big issue. A question from the floor asked what proportion of these statistics came from academia and what proportion from industry. Goldacre acknowledged that this is a problem in academia too, but he believes a majority of all clinical trials are funded by the pharma industry and that makes the industry the biggest player in town so the industry sets the tone of the culture. These quite marginal figures for poor trial results in academia are almost inconsequential. Pharma is the clinical trials industry.

Goldacre then stated a concern that pharma and others sometimes misuse the regulations in the UK for their benefit. He mentioned that GSK was allowed to withhold data on Seroxat's use in children because there was no licence for its use in children. This was a loophole in the regulations that enabled selective reporting and he would rather people try to get data out to doctors and patients whether it is good or bad rather than hide behind loopholes.

In addition to pharma, Goldacre emphasised the role of clinicians in tackling selective reporting of data. In his opinion, there is a failure of leadership to tackle publication bias in the medical and academic professional bodies. He mentioned that none of the Royal Colleges, General Medical Council, Royal Pharmaceutical Society or other professional physician bodies in the UK have it in their code of conduct that publication bias is research fraud.

As a possible solution, Hammond suggested organising a multidisciplinary group to promote good practice. Goldacre thought this was a good idea and the reason that collective action is required is because people generally do not want to be the only ones 'doing the right thing'. There are individuals who can take a lead (e.g. the current GSK CEO who insists on all trial data being made available) but one person cannot be depended upon to instigate global change. It requires a multidisciplinary industry-wide group.

On a different issue relating to transparency, a question from the audience took the debate away from selective reporting and instead onto the topic of value-based pricing. In 2013, the UK government is going to introduce a new pricing system that will include new criteria for determining the value of a drug. An element of this will be focused on innovation. The pricing system will not only examine how effective the drug is, but also whether the drug provides a new breakthrough in terms of its mode of action. The panel were asked about the impact of this in relation to the day's discussions, and on how future trials will be conducted and reported. Rains picked up this question and was familiar with the move towards value-based pricing in a number of countries. He is not sure that it will change the overall framework for pharmaceutical research and development. It may lead to additional

health economic and outcomes research studies and endpoints. There is already a shift towards patient-reported outcomes versus surrogate end points, but Rains is not convinced that it is going to make a major change in the overall drug development process.

In summary, Goldacre expressed a view that pharma has it within its power to effect cultural and regulatory change. In his opinion, by doing this, pharma would be addressing the single most important problem affecting medicine today.

> *Pharma has it within its power to effect cultural and regulatory change*

Session 5: So, after all that, what next?

Led by Charlie Buckwell, the Session Leads for each of the sessions reconvened on stage to consider 'what next?'. Buckwell introduced this final session by asking what would we as a community want to do in response to some of the issues that have been raised today?

- Do we have the will as a community to say that we stand up for something and take a view to effect change either by ourselves or with other stakeholders?
- What form should auditing take in terms of assessing what is happening behind the cases we have heard about?
- Should there be a systematic review of the literature on industry practice as it compares to guidelines?
- How could we improve the monitoring, tracking and sanctions associated with non-compliance with guidelines?
- What could we do as a group to hold each other (and other stakeholders in the mix) to account?

An audience member started the discussion from the floor by endorsing calls to 'hose out all trial data', although emphasised that the data are released does perhaps need to be provided with some context (rather than just raw, patient-level data). A template is needed. As a next step, the audience member suggested that a multidisciplinary action group is formed to discuss this further. There appeared to be a consensus in favour of this view.

Jacobs pointed out, however, that there are two aspects to this. While we should be doing everything to publish current/future data, there are a lot of historical data that have not been published. Is there a consensus to go back and publish everything retrospectively? A note of clarification explained that 'publish' in this context could mean simply placing data on clinicaltrials.gov and not necessarily publishing in peer review journals. Gonzalez believes that publishing historical data is fraught with logistical issues, and perhaps the focus of the discussion should be on the current/future situation. This is in the belief that most companies are publishing most data now. However, Woodrow did raise the fact that in a survey conducted amongst publication professionals in the last few months, it has been noted that around 30% of people said that they know of negative trial data that have not been published in the last three years, so the problem has not gone away completely. Hammond declared that the excuse that some of these issues are historical is not one that will wash.

Wager offered a suggestion that perhaps one of the first steps would be to get pharma companies to publish their publication policies. She consults on many of them and has to sign a confidentiality agreement before she does. In her view, these policies should be discussed with investigators and should be visible on the company websites. Jacobs added that he has encountered the same problem. One of his clients has the perfect policy in terms of content, but it is filed under confidential.

As a concluding remark, Buckwell urged for the momentum generated at the meeting not to fade and for a discussion to take place on how to tackle practically the issues that were discussed. His opinion was that in our meeting in 2012, we should be talking about practical results and how things have been moved along. Hammond agreed. He mentioned that medicine has its own deep-seated problems, but the vast majority of doctors and nurses, just like the vast majority of people who work in the pharma industry, want to do good. Hammond said that he and Goldacre would be delighted to join a multidisciplinary group, and that they would bring a critical eye to any proposed activities. Ultimately, our aim should be to conduct ourselves in a way that benefits patients.

More information about future developments and links to the outputs of this meeting can be found at www.MedCommsForum.com

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