**INVOLVE Conference 2012**

**Transcription of Opening Session: Welcome to the Conference and Keynote speech**

**Stuart Eglin**

I’m really excited about these two days, also slightly in awe. I have been saying to various people this morning that if this goes really well, there’s a large group of people who are responsible for the two days. If it goes really badly it’s probably down to me but that’s, I guess, the nature of things. I’ve got ten minutes in which I need to convey a few things to you. There’s the normal stuff that you’ll have heard before about things like there is no planned fire alarm / fire test. So if the fire alarms do go off we’ll need to leave the building following the green signs and gather outside. And then the other important thing is about mobile phones. If you could either switch them off or turn them to silent that would be very helpful.

But there are some other things that I need to tell you which I hope will be helpful and useful as well. But I did want, just quickly, to reflect on INVOLVE Conferences. I’ve had a link with INVOLVE for quite a number of years. And, the first Conference I went to was back in 2000. I think it was at Kensington Town Hall. A long time ago. It was quite different in that there weren’t anywhere near as many people as there are here. Over the two days here we’ve got 495 people attending, which I think is an incredible achievement for public involvement in research that we’ve got such a high level of interest. That first conference though that I went to, and I think it was the second INVOLVE Conference, had some key features to it. I’d been to conferences before but I’d never been to one quite like that. And I think the reason why was because of the level of enthusiasm, the level of friendliness, and I was, way back then, quite used to going to conferences and feeling slightly phased by them and not really feeling like I knew anybody. It was an environment where everybody was very friendly, very keen to come up and shake hands and say hello and that just felt so different to me. That was something I wasn’t used to. I hope we can reflect that today. And I’ve seen already over lunch, of course, that level of buzz and friendliness, which is fantastic to see. There were lots of ideas around then. Now I guess there’s probably ten times as many ideas that are reflected in the programme. But above all there was a buzz and a sense of a community building. And I think today I’m seeing that huge sense of a community just in the first hour or so that we’ve been here.

So I won’t talk about INVOLVE in detail. I’m sure Simon’s going to do that. There’s an opportunity for you to find out more at the INVOLVE stand, which is near the entrance where you came in. Those who’ve been to conferences before this INVOLVE Conference will be familiar with the format. We’ve got more posters than ever (we’ve got over 70 posters), a significant number of sessions and of course nobody can get to everything. I was reflecting on this and thinking I guess there’s two ways to do it. You can either be like a bumble bee, buzzing around and trying to get to as many things as you can in the two days and exhausting yourself over the two days. Or you can be, kind of butterfly-like and just, sort of, flit around in and out of things, take a break. There’s a quiet room upstairs above the reception area where you can go and have a rest if you want to. It’s up to you. There’s no requirement to keep going for the full two days if you don’t have to. So take it at the pace that’s right for you. I think, and hope you’ll agree with me, that the conference pack is phenomenally detailed. There’s a lot of information in there and that will give you a flavour of the things that you’re not able to attend. And by all means feel free to contact people if there’s something there that you think is interesting, that was going on whilst something else was going on that you were attending.

Things that are different this year: since the last Conference, we’ve been doing what we can to embrace social media, I guess like everybody. So, you’ll see up there our Twitter hashtag: #INVOLVE2012. So if any of you tweet, please feel free to tweet about the Conference over the two days. And in tweeting if you can use that hashtag, people from INVOLVE will make sure they retweet you. If that sounded like a foreign language, there are other ways you can do things like that. There are things like the Soapbox and in your pack there’ll be a card like this. I think there’s a couple of cards for you. If you’ve a burning issue or something that you want to stand

up and speak about, please use this and put it in the box by the entrance and then they’ll be an opportunity for you at the Soapbox tomorrow to stand up and have your say on an issue. If you’ve got burning issues, things you want to raise, there’s a postcard as well for you to do that with. So, I’ve mentioned the Soapbox, I’ve mentioned burning issues… There’s a ground rules sheet. I’d ask you please to take a look at that. There are a lot of people here over the two days. There’s some very busy workshops. So the workshops will work best if we all adhere to the ground rules. They’re pretty common sense things like making sure that you respect other people and that you give people a chance to speak and we don’t interrupt each other and things like that. But there’s some very important things in there like making sure that you have the microphone when you speak so that everybody can hear you and things like that. But I just ask you to look at that. I think I’m almost done now.

The only other thing to mention is that one of our members, Tara Mistry, mentioned that today is and tomorrow is the Festival of Diwali. So for the poster session this afternoon there will be Indian sweets available for that. And then tomorrow is World Diabetes Day so there are glucose checks available! [LAUGHTER] I did say to Simon: “Will I be politically incorrect if I link those two?” And he said: “Well, see how the audience reacts to it.” So, I got my reaction Simon.

Right, I think I’m done. All that remains for me to do is to say have a fantastic two days. Sorry, I have missed one thing out. You’ll already have noticed that there’s a cunning code in that some people have purple straps and some have orange. The purple straps are people from INVOLVE, members of INVOLVE and people who have been involved in organising the two days. So, if you’ve got any problem, anything you need any help with, search somebody out with a purple strap and we’ll see if we can help you with it. Or go to the main desk at the front. So, have a good two days. Enjoy it. And now I’m going to hand over to Simon Denegri, who’s the Chair of INVOLVE itself. Thank you.

[ROUND OF APPLAUSE]

**Simon Denegri**

Good afternoon ladies and gentleman. And can I just join Stuart in welcoming you here today and for the next two days. I’m so thrilled to see so many people here. And I think it’s a sign of the interest in INVOLVE and in public involvement and the very important subjects that we need to discuss in the forthcoming sessions and debates.

Can I thank Stuart and the Conference Group and also the staff for getting us here today. I think a lot of the rest is really down to us as delegates. I think we’re going to hear a lot more from me in the next few days and I’m giving the end note tomorrow. So, I’m not going to prolong what is already a quite tight, if not tightening, timetable. But I did want to say that from my experience of INVOLVE Conferences, these are very much occasions for dialogue and discussion and debate, for sharing learning and experiencing the experience. And also for thinking through some of the challenges ahead. And I’m sure you would all agree with me that we are faced with quite an uncertain environment with many fluctuations and changes, both in terms of health and social care and also research. So for that reason, I’m sure my predecessors as Chair have said this, but I really do think this is going to be one of the most important INVOLVE Conferences that we’ve ever had.

So, who better to get us started than our keynote speaker this afternoon, Sir Iain Chalmers. And let me tell you a little bit about Sir Iain. So, Sir Iain practised medicine in the UK and Palestine before becoming a health services researcher. In 1992 he became Founding Director of the UK Cochrane Centre, which convened the meeting at which the International Cochrane Collaboration was inaugurated. Since 2003 he has coordinated the James Lind Initiative, which I’m sure many of you have heard of, promoting better research to inform better health care, particularly through greater public involvement in research. He coordinates the development of Testing Treatments Interactive and edits the James Lind Library. He is a fantastic patient advocate and someone who I’ve drawn a great deal of confidence in, in terms of asking some challenging questions out there of our colleagues. And I’m delighted that you could be with us today, Sir Iain. I know this is, I think, the third time you’ve been at the INVOLVE Conference, the last time in 2008, and we look very much forward to what you have to say. Thank you.

[ROUND OF APPLAUSE]

**Sir Iain Chalmers**

Good afternoon everybody. And thank you very much indeed Simon, not just for the introduction but also for the invitation to give this talk. And indeed to the staff of the INVOLVE Support Unit for their help in the lead up to this meeting. As you see, I’m going to be talking about waste in research and what I think should be a much bigger public role in reducing waste. I’m going to be talking about some skeletons in academic medicine’s cupboards and there are really quite a lot. And I think it’s very important that people become aware of what these are. I’m not going to cover them all.

In this paper published in 2009, Paul Glasziou and I identified four main sources of waste. And we reckoned that 85 per cent of the total investment in research was being wasted every year. A massive proportion. I’m going to pick off just two examples for your consideration. The first one won’t be strange, I suspect, to many of you. That researchers often look at questions, address questions, which are of really low priority to the users of research. They don’t look at outcomes that patients and carers consider important. And clinicians, and I emphasise clinicians as well as patients, are not involved in setting research agendas. I’m not talking about PPI. I am talking about involving the users of research results, whether they be professionals or patients or carers, in this work. I’m going to give two very long established examples of the mismatches that exist. These are well known, they were shown over a decade ago. But this is a particularly striking one. It shows that the research areas which patients, and actually professionals as well, want to see researched for osteoarthritis of the knee, involve almost everything except for the things that researchers are actually researching. They research drugs. Patients and clinicians want to see better research on knee replacement, on physical therapies, education and advice. Similarly, when patients became involved in advising rheumatoid arthritis researchers, the researchers found out that pain was not their overwhelming problem. It was fatigue. And that really hadn’t come over the horizon at all for the researchers. Now it has because the rheumatologists have been better than most in trying to find out how to serve the interest of research, users more effectively than they have done.

I believe this is an extremely important initiative: the Core Outcome Measures in Effectiveness Trials, the Comet Initiative, which has been led from Liverpool. And it’s a very good sign that this issue about trying to find out what patients want to see measured in research is being taken more seriously. Another example is Healthtalkonline. And within Healthtalkonline, DIPEx it used to be called, some of you will be familiar with it, I hope in fact quite a lot of you will be familiar with it. It relates to specific health problems but it also has information on what it’s like to be involved in, or indeed to refuse participation in clinical trials, both for adults, parents and children themselves. And in fact, Louise Locock has asked me to draw your attention to a new survey, a new study that is being done by Healthtalkonline, and would like you to consider participating and contributing to that survey. There you see her details, they’re elsewhere in the Conference venue for you to note down, if you’d like to.

How can patients and the public help to reduce waste in research? Well, over two decades ago I wrote a letter which was published in the Lancet calling for a patient-led, good controlled trials guide, a bit like a good food guide. And what I suggested was that consumer patient commentaries on trials that were ongoing could cover, for example, the importance of the questions being addressed, whether previous research had been properly evaluated and that the ongoing study designed in the light of that information was ethically robust, that the primary outcomes chosen were ones that actually mattered to patients, the importance of communicating the results of research done to those who had participated, and in that way, hopefully, to reorientate the clinical research agenda to serve the interests of patients better. Now there has been progress but over the last 20 years not nearly as fast as I would have wished.

Back in 2002, INVOLVE commissioned a survey to find out what patients wanted to know about clinical trials. They wanted information about ongoing clinical trials, the information designed for use by potential participants. And way back in 2008 I actually used the opportunity which I’ve been given today, on an earlier

occasion but asking what should be available to these patients? Well, I said the UK Clinical Trials Gateway should aim to provide access to a lay summary of the research, the patient information sheet, core items which had been agreed by WHO, the protocol with links to the systematic reviews of existing evidence showing why the trial was needed, and the trial website if one exists. Unfortunately, reliable, user-friendly information about specific ongoing clinical trials is still not generally available. And at a conference where the byline is putting people first in research, I think that’s an insult to patients. It’s not as if there aren’t the resources available to enable this to be done. And as I say, I think it’s a disgrace that more than a decade after the

findings of the INVOLVE survey, we still haven’t got generally available, reliable, user-friendly information about specific ongoing clinical trials.

I work in a programme called the James Lind Initiative. And this is probably the last major public occasion when it’s going to be possible to review what we’ve been up to in this Initiative over the past decade. So I’m going to review what we’ve done for your information and suggestions. It arose, this programme, from a booklet that was published by the MRC following a working group report called Clinical trials for tomorrow. It stated in the booklet that the MRC is committed to involving patients and consumers in all aspects of clinical trials that it funds. And it was in future going to help promote that engagement by setting up a communications and discussion forum on randomised controlled trials, which would involve patients, practitioners, researchers and others. Now, in 2006 in fact, the emphasis of funding for controlled trials moved from the MRC to NIHR, the National Institute for Health Research.

So, although the MRC was involved in this programme of work in the early days, it hasn’t been for a number of years. The idea was that this initiative would promote acknowledgement of uncertainties about the effects of treatments and research to address them. In other words, not to promote clinical trials directly. This was a roundabout way of getting to say, if there are uncertainties about the effects of treatment, what is the proper response from professionals and patients and the public? Often they will come to the conclusion that, in fact, there is no need for more research because in fact existing research actually resolves the uncertainties but people don’t know about it. But often it will lead people to think, we actually need some more evidence. So this article was published at the end of 2003 to sort of introduce this initiative, where I emphasised again that trials are frequently designed and conducted in ways that yield little information relevant to patients, health professionals and policy makers. And it’s usually impossible to assess the significance of individual controlled trials because the reports seldom indicate what difference the new results make in an updated systematic review of all the other relevant evidence on that question.

So, there are three elements to the James Lind Initiative and I’m going to take you through them, one by one. First it is involved in identifying and publishing uncertainties about the effects of treatments in a database, which we call the UK Database of Uncertainties about the Effects of Treatments (DUETs). So here we are, this is the receptacle we created for making uncertainties explicit. These are the two people who set it up - Hazim was the designer, the software designer, Mark Fenton was the editor and still is largely responsible for it. The sources of these uncertainties were patients’, carers’ and clinicians’ unanswered questions, research recommendations in reports of systematic reviews and clinical guidelines, and ongoing research, both systematic reviews-type research and new primary studies. Now that has been incorporated within NHS Evidence, which is part of NICE’s

group of sources of evidence for everybody. And it’s very nice. As far as I know it’s the only bibliographic database in the world that specifically guides you to uncertainties about the effects of treatments, as opposed to things that aren’t actually divided between uncertainties and more certain things.

The second element of the James Lind Initiative was taking these uncertainties and working out with clinicians and patients and carers what the priority uncertainties were, the ones that most needed further research, whether in the form of systematic reviews or new primary research. And this was established in 2004. Nick Partridge and John Scadding - Nick from INVOLVE, John Scadding from The Royal Society of Medicine - and I were the people that launched this rather crazy idea to see if it would work. For those of you who don’t know, James Lind was a 18th century Scottish naval surgeon, confused by the varying views about how you should treat scurvy, which was killing people. So, he actually did a controlled trial to find out

which of six alternative treatments was better. So, these are the things that the James Lind Alliance was concerned to address. We wanted to shift the focus of the therapeutic research agenda, and to do this by promoting priority setting partnerships involving patients and clinicians to identify and promote their shared priorities for therapeutic research. In other words, something that they could all sign up to because the research funding agencies would be far more interested in questions which had been endorsed as important by both patients and clinicians. Here are the wonderful people who made it happen. I don’t think Sally Crowe’s here but otherwise all of them are in the audience. And please go and see the stand that exists, I saw it in the dining room, it’s at the end of the poster boards. And you’ll get lots more information than I’m going to be able to give you just now. And talking of the poster boards, there are some fantastic posters out there. I used the time between my arrival here and now to look at some of them. And I want to thank particularly those people who produced an A4 sheet, which reproduced what was on their poster. That’s incredibly useful because it means that I’ve gone away with a stack of those that did have that available.

So, there are some principles which have underpinned the way that these, wonderful facilitators have done their work. You’ll see them listed there. I’m not going to go through them one by one but basically the idea is to be inclusive, not to exclude anyone, with a possible exception of researchers actually. I mean, it’s actually very important that this is driven by jobbing clinicians and patients. It has to be supportive of what will almost certainly be a range of capacities and skills and it has to be transparent and democratic. Here are the priority setting partnerships that have been completed and those that are currently ongoing. As you see they cover a very wide range of health problems. And I don’t think anyone could have predicted quite how much of a success they have been. And this reflects, I would say above all, the facilitation skills of the people whose pictures you saw just now. But also the people who come to these priority setting partnerships also come with a recognition that this is an opportunity. And that actually requires generous spiritedness to be able to make the thing work.

So what we’ve got here is a situation where DUETs harvests raw uncertainties, let’s call them that. From those, after you’ve taken out the ones that in fact are not uncertainties, people just didn’t know that they were certainties, you’ve got some which basically are making the same point but using different words. So, from that population of uncertainties, indicative uncertainties are derived. And then those go into a prioritisation process. The first bit of it is by email, by surveys. And then there’s a face-to-face meeting at the end of the day, where each of the priority setting partnerships tries to come up with ten highest priority uncertainties. And down on the right of the slide, you’ll see the gradual whittling down. This is for all of the ones that have been completed already by the way, those totals. It gives you some idea of the refinement process that happens during this procedure. And then those uncertainties are pushed to the funding agencies with the backing that they have had support from these combined shared efforts of clinicians and patients.

Now what’s interesting, and this is work which Sally Crowe has done particularly, is to see the themes that tend to come across, whether one’s looking at incontinence or type 1 diabetes or schizophrenia, any of these things, there are certain themes that come across in the priorities. People participating in these partnerships are interested in long term effects of interventions, whether wanted or unwanted. They’re interested in the assessment of safety and adverse effects of treatments. They’re interested in knowing what complementary and non-prescribed treatments have to offer. They’re concerned, particularly if they’ve presented with advanced disease, they’re interested in ways of trying to raise awareness of the possibilities that something might be done. I remember particularly I went to a priority setting partnership of people who are troubled by balance disorders. And they just wished that general practitioners were more receptive and knowledgeable about how to deal with presentation with that. And then they’re interested in the effectiveness and

safety of self care. It’s very interesting. There’s not a great deal of research. And indeed if you look at these themes, I think you’ll probably agree that they’re not the themes that really dominate in the research chosen by researchers.

If you want to find out more about the James Lind Alliance, you can find it on their website and you can find a fantastic guidebook, which has been presented describing the experience that has developed from people involved in these priority setting partnerships. That too now is being mainstreamed. It’s being mainstreamed in the NIHR Evaluation, Trials and Studies Coordinating Centre in Southampton. And the people who are taking responsibility for assuming the future of the James Lind Alliance are Tom Kenny, Pamela Young and Sarah Fryett. This again is a very heartening bit of evidence that these methods and their development have been taken seriously by the National Institute for Health Research.

Right, I’m now going to move to the second of the two areas of waste, which is that over 50 per cent of studies are never published in full. And those that do get published are an unrepresentative sample of those that have been done. Here’s the actual data for you in a paper published in 2009. And what you’ll see is, contrary to widespread belief that this is something which only the pharmaceutical industry is guilty of, it’s not. It’s across the board. It’s academia, and indeed in this town there was a very, very important trial completed about ten years ago, which still hasn’t been published which was MRC funded. So this is a problem across the board. It happens to trials wherever they’re done, however big or small they are, whatever phase they are and whoever funds them. And as you’ll see from this statement,

the ones that report positive or statistically significant results are more likely to be published and outcomes that are statistically significant have higher odds of being fully reported. It also happens in animal research. And, after all, people keep on saying that animal research is very important for developing better treatments in people. And here’s an example of an analysis which shows publication bias in reports of animal studies, leading to a distorted picture, which may lead people to go into human trials which aren’t in fact justified.

I want to bring this home to you by quoting again what an Italian researcher, who’s also a patient, said in a personal view to the BMJ. And we quoted him at the beginning of our article about waste in research. It’s Alessandro Liberati. He said this: “Research results should be easily accessible to people who need to make decisions about their own health. Why was I forced to make my decision knowing that information was somewhere but not available? Was the delay because the results were less exciting than expected? Or because in the evolving field of myeloma research [he had myeloma] there are now new exciting hypotheses or drugs to look at. How far can we tolerate the butterfly behaviour of researchers, moving onto the next flower well before the previous one has been fully exploited?” Alessandro died on the 1st of January this year, still waiting for the results of the trials which he knew had been completed years before. That’s the human face of publication bias and under publication. And because research results have not been made public, patients have suffered and died unnecessarily and resources for health care and health research have been wasted.

I could give you lots of examples. I’m going to give you this one because it will be familiar to some of you. PAREXEL is a private medical research company based at Northwick Park. And a few years ago, one of the things that hit the news really quite massively was the experience of six healthy research volunteers, who were given a drug, a new drug, and had what’s called a cytokine storm. Basically they all needed intensive care at Northwick Park. And as you’ll see, they had really nasty side effects. Some of them lost fingers and toes, for most of them probably. All of them, their immunological competence is probably being affected for a lifetime. Now what’s sad about this is that there were unpublished data, in fact only a single case, using a similar drug which had had similar effects. And the Professor who was responsible for this study felt that because the drug was not going to become a commercial success, there was no point in submitting it for reporting and so it wasn’t. Had it been, then perhaps that would have reduced the risk of what did happen to those young men.

The trouble is that this is not an uncommon problem. I’ve already indicated that it’s actually very common. And what are the responsibilities of people who hope that a drug is going to be helpful but then abandon their interest in it when the results are disappointing? Those results ought to be made available if only to stop people going up other blind alleys, but certainly to show proper respect to the patients who participated in those studies. Why is medical academia content to acquiesce in this biased underreporting of research? Well, Edwin Gale in a commentary in the BMJ published not long ago, last year, said: “Academic and non-academic medicine are pervaded by conflicts of interest, and too many people benefit from the situation for this to be openly acknowledged. What is needed is a change of culture in which serving two masters becomes as socially unacceptable as smoking a cigarette.”

Some of you may have heard that Ben Goldacre, the author of Bad Science, has recently published a new book called Bad Pharma. And there are all sorts of reactions to it, trying to say that what he has written about is actually a thing of the past. It’s not the case. It is not a thing of the past. But although his byline is how drug companies mislead doctors and harm patients, my contribution to the back cover, together with Dara O Briain, is to actually blame my profession. It’s my profession that has allowed this to happen. The industry could not do what it tries to do without the complicity of my profession, and my profession should be held to account for allowing it to happen.

The BMJ, of all the major general medical journals, has probably been best about exposing the scandal that we’re acquiescing in, most recently about Tamiflu. Why won’t Roche, that make the drug, let us have all of the data on which it was let loose on the public? I’ll leave you to guess. But what I do know is that, worldwide, billions of pounds have been invested in stockpiling this drug. And the evidence, such as it is, suggests that it probably doesn’t have any advantages over paracetamol. Now, the Board of Directors of Roche contains just one medically qualified person - that’s him, John Bell, Sir John Bell. An open letter was published to John Bell, who’s the Regius Professor of Medicine in my home town, at Oxford University, from the editor of the BMJ, asking, as a member of the Board of Roche, what he is doing to get Roche to behave in a publically accountable way. That prompted me to submit, and it’s now published on the BMJ’s website, a letter that I’d written to John Bell in 2006 when he was President of the Academy of Medical Sciences. I asked in that letter, what is the Academy’s position on biased underreporting of research? That was in October 2006. I hadn’t had an answer by June 2007. He said: “I think I may have mislaid your letter. Can you send me another copy?” This is the compliment slip that I wrote to go with the second copy but I still haven’t heard.

What should be done? Well, and this is what I’m trying to do now, the public needs to be made aware of how the resources they provide for research are being wasted. Make no mistake, the public picks up the tab for this type of misbehaviour, either through paying for drugs or through its taxes. And its taxes can contribute either directly from funding, for example the Medical Research Council, or indirectly by the fact that charities are tax exempt. So all of us left to produce the income from taxation have to pay a bit more because organisations like the Wellcome Trust, for example, are charities. And it needs to hold the research community to account and be critically involved in research from agenda setting to dissemination of results. And looking through those posters this morning, it’s very clear that things are happening, are moving in the right direction. But I think people need to far more robust in the way that they challenge the research community.

So the third and last element of the James Lind Initiative, which will actually go on for three more years at least, is to try and produce resources which will help equip members of the public with the wherewithal to be confidently critical of scientific medical research misconduct, which is widespread as I’ve tried to show you. I edit two websites relating to this. One’s called the James Lind Library, you’ve heard who James Lind is. The essays about helping people understand tests of treatments are in seven different languages, up there. The other effort is through this book which was first published in 2006. The authors are Imogen Evans who was a Lancet editor, Hazel Thornton who’s a patient representative, myself in the first edition, joined by Paul Glasziou, a general practitioner, in the second edition which was published last year. In that book we try to promote research. But we also say that it is very important that people are selective in terms of the research that they choose to encourage. I’m going to suggest that you write your suggestions on those postcards that Stuart made reference to earlier in his introduction, in response to the things that I’ve said already, and pin them up on the Burning Issues noticeboard at the Conference. And I hope that my colleague, Patricia Atkinson, will make a note of the suggestions that you have for how this scandal can be addressed more forcibly than it has been. Among the suggestions we have at the end of this book, in the action

plan that we propose, is certainly a call on people to promote research which addresses inadequately answered questions about the effects of treatment, which you regard as important. But only if it meets scientific and ethical principles. And that implies agreeing to participate in a clinical trial on condition that the study protocol has been registered and made publically available, that the protocol refers to systematic reviews of existing evidence showing that the trial is justified, and that you receive a written assurance that the full study results will be published and sent to all participants who indicate that they wish to receive them.

This is a new website called Testing Treatments interactive. And it uses as a starting place the text of the second edition of the book but adds video material, games and other things to help people understand some of the ammunition they need to equip themselves with, to engage in this debate. It too will be in a number of different languages. It’s already in Arabic but there are about 12 different languages lined up to produce not just the translations of the book into those languages but also sibling websites in those languages so that they can use examples that are in Arabic already.

I’ll end with this picture. This little girl is reaching out for the first imprint of Ben Goldacre’s book Bad Science. And on the front cover is written: “Bad Science introduces the basic scientific principles to help everyone become a more effective bullshit detector.” [LAUGHTER] Those words were mine. I’m her Grandfather. Thank you very much.

[ROUND OF APPLAUSE]

**Simon Denegri**

Thank you very much, Sir Iain. I think that was really provocative and thoughtful and I think it’s really going to stir some debate up over the next few days. Sir Iain, are you willing to take some questions? Great. So we are running a little bit over but we started late. So I’m going to allow about ten minutes for questions. I’ve got someone over here. And I think we have roving mics.

**Member of the audience**

Thank you very much for that. I found it a wonderful keynote and it touched on so many different levels. My interest is paediatric oncology and it’s a burning question ...

**Sir Iain Chalmers**

You’re a star. I’d say that, this is not flattery, the paediatric oncologists have built evaluative research into their practice for the last four decades. And that’s one of the reasons that compared with when I was a medical student, leukaemia in children was a death sentence, it now isn’t. And it’s because of the self discipline that that lady’s speciality has applied to their work.

**Member of the audience**

I should clarify my background was in epidemiology and then I was a parent of a child with leukaemia. So it’s kind of two hats. I’m just curious that in peer reviewed journals, do you think that you would get published if you’re not finding significant findings? Will it still get published? And the other question is just in the way that trials are working, certainly with children, phase one, where because of this long drawn out procedure with regulations and so on, if this drug doesn’t work then they can put the next one in the new trial design and how they would feed that one back?

**Sir Iain Chalmers**

Two things. First of all, luckily there’s evidence to answer your first question, strong evidence. The problem of non publication is not rejection at the journal level. It’s non submission. There’s overwhelming evidence to show that that’s the problem. It’s researchers and sponsors not submitting for publication. People have looked for evidence of selection bias at the peer review stage but they can’t find formal evidence that that’s a major problem. So that’s the first thing. The second thing, which I should have written down but you’re going to remind me what it was.

**Member of the audience**

Sorry. Just the new way that they’re trying to trial ...

**Sir Iain Chalmers**

Oh yes, it’s the phase one studies. Okay. Now I was at a meeting about three years ago and some data were shown, showing the high failure rate of phase two trials, and showing that the failure rate was actually increasing over time. So I asked the question, in fact two separate people from industry presented the same data,

whether that might reflect the fact that phase one trials weren’t getting published. And they both agreed that that was part of the problem. Later in the afternoon someone from Quintiles, which is a contract research organisation, without referring to that conversation, said: “One of the things that really frustrates us as a company is we’re asked to design and run a trial for a company and we know it’s going up a blind alley because we’ve been up that blind alley with another company but we can’t tell them.” So there is built-in inefficiency into the research process, the discovery process, because people are not publishing things that have been disappointing. And as you saw earlier this can have devastating effects sometimes, as it did for those lads at Northwick Park. I hope that answers your two questions.

**Simon Denegri**

I’ve got a question right at the back there.

**Member of audience**

Obviously I share your concern about the underreporting, as someone with lived experience of using services. And I really would like to know a bit more about the drugs I’ve been offered and the drugs my colleagues are offered. I just think, the issue it seems to me, obviously isn’t that the study fails, that people regard it as failure, they regard it as underperformance but yet knowledge is power and information can have a cash value. And it just seems to me that the only way that you can tackle this, if they’re not going to listen to the ethical argument, is actually make it profitable to report your failures, or not even call them failures, but reporting the result of studies that don’t do well actually has a cash value because it saves you time in doing something else. So if you had some kind of way of reporting that in a website or some other way that was actually profitable, perhaps not as profitable as releasing the drug but made an income anyway, then maybe more people would do it.

**Sir Iain Chalmers**

Yes and in fact GlaxoSmithKline has recently announced that it is going to make all of the results of its studies, phase one onwards, available publicly. So there are some drug companies who are taking the lead but they’re doing it on, I think, a moral basis. And it would be sad to me if the public who are the victims of this behaviour felt that the only way to conceptualise solutions to it were through profit. It maybe that a carrot should be used in addition to sticks. But I think the public ought to be angry about what is happening. And they ought to be demanding better standards from the research community. And it’s my profession that should be challenged. As I say, industry, the people who have to satisfy their shareholders, that’s their raison d’être. In some senses you can understand them, getting away with whatever they can get away with, within the law. But my profession should not be able to be allowed to acquiesce in that. So yes, by all means, try and see whether that approach might work. I suppose that Glaxo have decided that there’s not sufficient market threat in doing what they’re doing to allow them to go forward with the initiative that they’ve taken. But time will tell. But in the meantime people should be angry. They’re not getting value for their investment and some of them are actually suffering as a consequence.

**Simon Denegri**

Sir Iain, I’m going to take one last question. I’m sorry because we really are running quite a lot over now. Just this lady down at the front row.

**Member of audience (Sylvia Bailey)**

Thank you very much for your presentation. My name is Sylvia Bailey and I am from the West Midlands doing patient and public participation with University of Birmingham CLAHRC Theme 1. I wonder, as sort of a lay person if the solution to this isn’t as simple as we, as tax payers, are having our money wasted. We’re also having briefed or selected outcomes of the research. Isn’t it as simple as our money, laying down the rules of the protocol to say, all results should be published? That is the criteria for having our money.

**Sir Iain Chalmers**

I agree with you wholeheartedly. I would love to hear the public, I don’t know who the public is but do you know what I mean? It’s not just people like me, who’ve come to know the details of this evidence through being a researcher. It needs more than people who are in the know because they’re inside the research community. It needs the public to make a big noise about it. Now a group of us, including an MP, Sarah Wollaston from Totnes, went to see the Minister in the Lords last week about this issue. And we were very encouraged to feel that he was prepared to listen. And more than that, that he identified with our concerns about the problems that we had brought to his attention. But it is the public that must make it clear that they are unwilling to tolerate this, not oddballs like me, who have happened to have studied this phenomenon. The data are there for you and people like you to go to your local newspaper and saying how many studies done in my city years ago have still not been published? And what’s the excuse that the researchers are giving for that?

It won’t be taken seriously until the public as a whole take it seriously.

**Simon Denegri**

Thank you. Now, I’m very sorry, I am going to close it there just because we are over time. I think the number of hands that went up just shows you, Sir Iain, what a fantastic talk you’ve done. And it’s been, I think, so provocative and helpful for us to hear your views on this. I know the discussions are going to go on, so I just want to make two or three very quick announcements. The first is Sir Iain mentioned Ben Goldacre’s book, Bad Pharma, and there is a competition running on the INVOLVE stand to win one of four copies of that. All you have to do is put a slip of paper with your name in a bowl, I think it is or business card. the second thing is to say that there is a blog on the INVOLVE website and we have written about Bad Pharma on Friday. So you might want to check that out if you’ve got a moment. And I will also be returning to the theme in my keynote tomorrow afternoon.

And the very last thing before you go off to your next session is to say that if you’re an associate member, we’re having a gathering above reception during the poster session, which is the session after this. So please enjoy the next hour or so. I will leave it up to the Chairs whether they want to cut it off at where the timetable start of the poster session is, or if they want to prolong it a bit to make up the time. But see you later. Thank you very much indeed.

[ROUND OF APPLAUSE]