IDEAL Policy Workshop

Monday 19th October 2020

Virtual Conference held on Zoom

Executive Summary

IDEAL is a new paradigm for the scientific evaluation of complex therapies. It sets out a staged description of the life cycle of devices and procedures and provides an itegrated evaluaotin pathway for them, specifying recommendaitons for study design and reporting at each stage. It has attracted attention from regulatory, HTA and coverage organisaitons as a potentially useful way of looking at the evidence for new devices and procedures. This workshop was held to explore the potential usefulness of IDEAL to UK government organisations which deal with the scientific evaluation of safety and effectiveness of medical treatment. The meeting was supported by funding from UKRI, Research England and the University of Oxford's QR fund. Representatives attended from the four government organisations with a major role in evaluation in this area (MHRA, NICE, NHS England Clinical Commissioning and NIHR) and from the medical device industry.

Five working groups were formed, based on these 5 major stakeholders. Groups were facilitated by members of the IDEAL Collaboration and met online several times before the plenary conference. The four organisation-based groups were each asked to produce a consensus report on the feasibility and desirability of integrating IDEAL into their organisations' infrastructure for evaluation or (in the case of NIHR) creation of clinical evidence. The industry group were asked to critique the work of the four organisations in their current state, and consider whether their fitness for purpose could be enhanced by integration of IDEAL.

Proposals from the IDEAL Collaboration suggested several ways of integrating IDEAL into infrastructure, with the potential for benefit roughly correlating with the cost of implementing them in terms of finance, human resources and organisational change required. These were:

- **Level 1:** Adopting the language of IDEAL to identify and describe innovations, evaluations and likely evidence gaps
- **Level 2:** Recommending IDEAL as a useful framework for designing research (providing tools)
- **Level 3:** Requiring evidence which addresses key IDEAL Stage questions
- **Level 4:** Linking staged approval to staged evidence production, using IDEAL to guide process

The industry group indicated that using IDEAL as a common language shared by NICE, MHRA and Commissioners to describe treatments and their stage of evolution, and the study types used to evaluate them would be welcome They recognised that IDEAL could help identify research needs at different stages in the device life cycle. It would help industry if all three government bodies whose approval they would need approved and accepted

IDEAL format studies, so that evidence could be “produced once and used often”. They emphasised also that evidence requirements need to be tailored to the risk profile of the device.

The four working groups based on organisations all saw the arguments for integrating IDEAL into their systems and agreed there was a potential benefit to varying degrees. The MHRA were constrained by their ongoing development of an entirely new UK-specific approval system for devices, which prevented them from commenting in a range of areas but engaged positively in discussion about the potential benefits of more standardised set of guidelines for studies to support approval applications. The NHS Commissioning group was very positive about the potential for IDEAL to be integrated into their work and suggested further contacts to explore this. NICE were interested in the possibility of using IDEAL as a common language, but were more cautious about other measures, arguing that their current systems appeared to be functioning well and had received widespread approval. The NIHR group considered that IDEAL had great potential and set out a series of practical steps which could help ensure it is used more in research. These included encouraging funding and scientific boards within the NIHR programmes to use IDEAL language when discussing studies of complex interventions and promoting the use of IDEAL pilot studies leading on to RCTs. The meetings closed with an agreement that IDEAL would follow up with each stakeholder group to explore whether there were specific opportunities for change which they wished to discuss further.

Objective and Procedure of the workshop:

The objective of the workshop was to discuss the desirability and feasibility of integrating the IDEAL framework and recommendations into the policy of UK government organisations who deal with production of clinical evidence for complex treatments. The two questions posed to each organisation and to Industry were:

1. Does IDEAL meet a need or offer an opportunity for your organisation/sector?
2. Could it be incorporated into current structures without major reorganisation?

Each sub-group prepared a summary report which was circulated before the plenary meeting and presented together with a summary of conclusions and remaining challenges. Facilitated debate followed each presentation, and a plenary discussion including suggestions for further actions closed the meeting.

Introductory Scene Setting:

Peter McCulloch, Chair of the IDEAL Collaboration reminded participants of the key features of IDEAL and suggested ways in which IDEAL might be introduced into the UK clinical evaluation infrastructure policy “The innovation within IDEAL is the idea that there is a significant gap for complex interventions such as therapeutic devices between the first in human demonstration and the randomized trial, where there is no standard template to prepare for the randomized trial.”

“The different organisations involved have different priorities. The MHRA deal with device regulation so their focus must be on safety and performance, NICE deal with assessments of effectiveness and value, whilst the Commissioners within NHS England need to make

decisions based on cost-effectiveness and relative value. NIHR funds and thereby creates research, and its main focus in this is comparative effectiveness."

In this setting, IDEAL could contribute by:

- Providing a common language for organisations dealing with complex therapies
- Plugging current gaps, especially in early "safety" studies and post-market surveillance
- Promote "joined up" evaluation with agreement on evidence which would serve the purposes of more than one organisation
- Provide higher quality evidence overall, with less risk of safety mishaps – a response to Cumberlege
- By reducing uncertainty, decreasing time and costs of evaluation whilst raising quality, making the UK more competitive versus the US and EU.

The levels at which IDEAL might be introduced (see above) were briefly discussed in terms of their potential advantages and current challenges.

It was also noted that the experience gained from integrating IDEAL into systems could and should be used to facilitate refinement of the IDEAL Framework itself.

Case study of IDEAL implementation in a real-world setting:

Janet Martin, Director of the MEDICI Centre, Western University, Ontario, Canada

Janet has led the development of a centre for Health Technology Assessment and coverage decision making in Western Ontario. She described the phenomenon of "stealth research" ie, innovation without evaluation. She outlined the 'Know 4 Go' framework she developed in Ontario for surgery, anaesthesia and critical care to prioritize innovation, decision making and implementation. A major development of this system was integration of IDEAL into its steps and processes.

"So now, when we start to innovate with a new procedure or device, we identify which IDEAL stage of innovation we're working on allowing us to decide how we're going to progress evaluation through our centre alone, or with other centres. We now have a much more clear and efficient progress through the stages of innovation as a result, which has increased our efficiency and clarified our decision making."

Discussion Q&A

How do you define "new", since much technology change is incremental? – This is a continuous process – using a system of trade-off colour coded tables (each IDEAL stage has a colour)

Is this only a local initiative? Discussions are ongoing about expanding it nationally

How did IDEAL add value when it was added to Know 4 Go, which was already in place? JM: IDEAL greatly reduced confusion by moking it easy for researchers to place innovation at a defined stage. IDEAL also provides a culture and shared language, as well as tools to conduct evaluation.

Industry representative working group.

Hani Marcus, Academic Consultant Neurosurgeon, Queen Square Institute of Neurology.

The group included representatives from spinouts and start-ups as well as the largest device companies. The key points which emerged from discussions were:

A regulatory system is needed that demonstrates that devices are safe and effective, but also identifies and facilitates dissemination of devices that meet those criteria for more rapid patient benefit.

Brexit provides the UK with a chance to develop a robust national regulatory system for devices which avoids the weaknesses of the EU and US systems.

A critique of the current system identified two significant problems: First, there is a varying degree of clarity between official bodies (regulators, NICE, Commissioners) about their evidence expectations. Second, some bodies (particularly NICE) were seen as taking a narrow and restrictive view of what evidence is worth considering.

Hani outlined three requirements for an improved evaluation system:

1. **Open:** The evaluation system needs to be open and transparent around the principles on which decisions are made. Having illustrative case studies and case examples available would be helpful.
2. **Efficient:** Evidence should be produced once and used many times. This requires co-ordination and collaboration between bodies, so that evidence produced for the early stages can be re-used appropriately in subsequent stages.
3. **Progressive:** The levels of evidence and elements required for devices for a first in human study should be very different from those required for devices which in widespread use. Integration of IDEAL was seen as potentially very helpful in delineating what evidence is appropriate at different stages in the life cycle.

There was consensus that integration of IDEAL could be helpful in defining the evidence needs at each stage in the life cycle, and that it would be very helpful if IDEAL studies were accepted by all parties including NICE Technology Appraisal. The group considered that in Stage 4 of IDEAL, more clarity is needed on the use of real-world data.

There was agreement that the level of evidence required at each IDEAL stage should be related to the class (risk level) of the device: Janet Martin's system provided a useful exemplar of clear rules which achieved nuanced balancing between the desirability of primary outcome and predicted risk.

Cost effectiveness needs to be incorporated into evaluation, and definitions of effectiveness need clarity. These are especially important for surgical robotics. Work is being done in this area by NESTcc. https://nestcc.org/

Reports from the 4 governmental organisation sub-groups.

1. ***MHRA. Presenter Peter McCulloch*** –
   The MHRA maintain awareness of what new medical devices are being used, and supervise the licensing process, but do not themselves issue CE marks or conduct evaluation: These are functions of the Notified Bodies, a feature of the EU system, which the MHRA will continue to allow as a route to licensing until 2023. The MHRA provide

innovators and manufacturers with advice on the acceptability of their evidence development proposals. Brexit may provide opportunities to create a new system free of some of the negative features of the EU system. It was noted that the MHRA's situation at the time of the Workshop, when they were rapidly trying to develop a new independent regulatory system in strict confidence meant they were not able to express a view on considerable areas of the discussion around policy.

Areas of agreement:

- Greater clarity about what the MHRA expects methodologically would be welcome.
- Better integration with NICE and the commissioning processes will be welcome, particularly the development of a common language (see earlier comments).
- The Total Product Lifecycle Concept (TPLC) and the idea of staged approval linking evaluation to licensing were considered potentially valuable but challenging.
- More specific guidance on long term surveillance was universally agreed to be necessary.

Areas of disagreement/uncertainty:

- There was a lack of consensus around the use of equivalence to support licensing, ie, devices being licensed because they are like other devices. This remains a major loophole in the US system, but some contributors supported its limited retention.
- There was some scepticism about whether IDEAL or any other template could deal effectively with the heterogeneity of therapeutic devices. This led to the suggestion of a pilot study – attempt to use IDEAL in a random sample and test how well it performs.
- Some felt that it was unclear how an IDEAL based graduated market approval system would work
- There was no clear agreement on what principles should apply to effective post market surveillance systems.

A range of options were discussed for the MHRA in terms of integrating IDEAL:

Adopting the IDEAL framework as a useful language (see above)

Using the questions posed by each stage of the IDEAL framework to guide innovators with suggestions and other non-risky way of using IDEAL;

Recommending specific IDEAL study designs

Adopting the TPLC-based graduated approval approach – the most radical option, but worth considering given the unusual opportunity for change that Brexit has caused.

Discussion

Not only will the MHRA system be completely reformed but the new MDR regulations come into force in the EU level soon, to address deficiencies and problems with the notified body system – this was considered very much needed.

The MHRA made clear that their enthusiasm for "equivalence" is low, but they consider that building up a broad picture of the evidence around a device is necessary. Depending on what the device is, the evidence requirements will vary in depth and rigour.

Can all relevant evidence for devices be channelled into a conventional research framework? This is the key question. Two corollaries are: 1. Who will pay for the evaluation? Will it make medical device research even more expensive? 2. The role of research ethics committees and governance may need to be revisited. This is currently minimal in the pre-RCT space, and formal informed consent, for example, is frequently not done in the patients being treated with a new device. There are therefore major underlying questions about restructuring research governance to develop better evidence.

The UK is only a small market globally, and most device developers will wish to have approval from the US and EU in any case: this may constrain UK freedom of action in making radical changes which diverge from the major players.

Developers need guidance on what evidence to provide – this is not yet transparent. https://www.nihr.ac.uk/partners-and-industry/industry/access-to-expertise/medtech.htm NIHR MICs offer some help. Guidance could potentially point to IDEAL papers and tools.

2. NICE/HTA subgroup – Presenter Bruce Campbell

NICE has a broad remit to assess evidence and provide guidance, and its processes are complex. Bruce outlined the structures involved with evaluating device evidence – the Interventional Procedures Panel (IPP) and Technology Appraisal (TA).
The different panels tend to relate to different IDEAL Stages, but there is no neat mapping.

Areas of agreement.

- IDEAL is a useful form of evaluation, and could:
    - Allow a clear guide on appropriate evidence for both developers for companies and for 'payers'
    - Provide a shared language, for NICE, the MHRA and Commissioners.
- Internal NICE research demonstrates a strong correlation between IDEAL stages and NICE interventional procedures recommendations (Stage 2a correlating well with "research only").
- NICE processes are very well established and therefore there is a challenge with the idea of getting IDEAL incorporated into them – change is difficult when things are apparently working well.

How might NICE adopt or use IDEAL? -

- Adopting **IDEAL language** appears feasible, ideally, acting jointly with payers and MHRA to use IDEAL and its stages to describe devices and studies. It could be integrated into NICE Scientific Advice, which advises companies about the kind of evidence they should be producing.
- IDEAL could be used as a guide to IPP decisions and recommendations, aligning IDEAL stages with the 3 categories "research only" "with special condition" and "generally"
- It could be used as a threshold for entry to the Technology Appraisals Programme. This programme is highly selective, and could require the availability of a specific level of IDEAL evidence (usually IDEAL 2b) for consideration of a technology. This would be a strong driver to production of the evidence.

NICE representatives suggested that the first suggestion was much easier to consider than the others. It was suggested that practical experience is needed to identify the *added value* of IDEAL in addition to standard methodology.

What are the potential advantages for NICE from adopting IDEAL?

- *Improved efficiency and interactivity of evaluation processes.* Promoting the generation of better, more appropriate evidence and making evidence expectations for developers and companies clearer not just for NICE, but for the MHRA, payers and AAC, using the **shared language** that IDEAL offers, and allowing the use of the same studies and evidence for several purposes.
- *Improved clarity on expectations for SMEs.* It was suggested that SMEs producing devices may have limited resources and expertise for evaluation, and that a clear guide such as IDEAL could help them prepare evidence more effectively.
- *Simpler identification of products to be considered for accelerated access.* The AAC pointed out that the AHSNs, with which it works, have a range of different frameworks to identify candidate devices for rapid access, and standardisation using IDEAL might improve performance.
- *Barriers and challenges* –
    - **Flexibility**, in decision making was emphasised as extremely important by NICE representatives – expert panels need to be able to diverge from frameworks when necessary.
    - **Understanding the language of IDEAL** may require some training and information – many people in the relevant systems are unfamiliar with it and this would need to be overcome before piloting actual use.

Discussion

A criticism of the procedures used by NICE was that they only consider peer reviewed publications. BC commented that some NICE panels also review other sources.

PMcC suggested NICE need an incentive to change. Their current entrenched processes are difficult for SMEs to navigate and insistence on RCT evidence overlooks utility of RWD and value of pre-RCT studies.

BC also commented that “Getting the NICE processes changed is a Herculean leap that is probably not attainable. On the other hand, the idea of getting IDEAL language and principles used more in terms of scientific advice, in terms of Medical Innovation Briefings, and in terms of research methods recommendations from IPAC could be very helpful”

It was pointed out that many SMEs do not have the money, expertise or infrastructure to conduct the necessary research and changing the terminology wouldn’t change that. Many SMEs need guidance on what they need to do. PMcC that the IDEAL Advisory service could help them to design early stage pilot studies.

HealthTechConnect https://www.healthtechconnect.org.uk/ already tries to help device developers with checklists but most don’t go that route due to lack of infrastructure, as most device companies are very small-scale It is also important to think about how companies engage with investors, and here the framework and the language used are very important.

3. Commissioning group – presented by Robert Wilson

Robert summarised the role of commissioners and the basic problem they wrestle with: The demands on healthcare are essentially infinite, and will always exceed the resources available, so difficult choices must be made. Being a commissioner is about having to choose, and inevitably, that means disappointing some people, whether that's patients, clinicians, providers or politicians. To minimise controversy Commissioners need to have a robust and transparent process for making prioritization decisions, which should be **based on evidence**.

Robert contrasted the volume of evidence usually submitted for a medicine with that for devices, which is usually hugely less. He pointed to the contrasting story around scandals due to harms from devices, which have been much commoner in the last 2 decades than in pharma - eg, breast implants, mesh, hip replacements etc The big pharmaceutical companies have huge resources, and can afford huge budgets for evaluation, which most device companies cannot. But we do expect high quality evidence for interventions other than medicines.

Where or how could we use IDEAL? –

Using IDEAL routinely as a system for assessing evidence and research would promote better research and better collection of data to start because i**f people knew that's the model, we were going to use, they would collect the information, which would allow us to evaluate it**. In **evaluative commissioning** we stimulate or fund a research element as part of what we pay for routine treatment. We will pay for a limited number of these procedures in a select number of centres and on condition that evidence is collected that will allow a decision to be made on whether that treatment should be routinely funded. That sort of process would be perfect for using IDEAL to generate evidence through commissioning. In NHS England we already use IDEAL in the individual funding request process, IFR. Our process specifically name checks IDEAL as our assessment of the level of evidence that's submitted.

IDEAL could be used at the beginning of our process, allowing us to look at the quality and suitability of evidence, and determine whether it is worth looking at more detail. Assessing IDEAL stage as part of the evidence review could be very useful. There's also a stage right at the end, after we fund things, where requiring IDEAL Stage 4 surveillance could contribute to a robust process for evaluating new treatments and innovations. Once we are routinely funding an intervention, we should be collecting data, and monitoring whether it's delivering what we were expecting and is it still safe and effective.

We are very supportive of IDEAL. It's an idea whose time has come and you're pushing against an open door – it delivers a lot of what we are looking for, for commissioners and we feel we should just to get on and use it.

Discussion

A clinician who uses both drugs and devices commented on evaluation differences between drugs and devices:

A lot of drug trials now are looking at very small effect sizes, which is why they need to be so large. Many devices, conversely, have got pretty large effect sizes compared to a placebo, So smaller trials are it's perfectly reasonable to expect smaller trials to have adequate

power. Equivalence has value if it means accepting that something is similar enough to another thing that you can extract some useful information based on the counterpart.

RW - I think there is merit in trying to see how IDEAL would fit into the existing framework. It's not about starting from scratch. I think you could quite easily see where the various IDEAL steps might fit into the framework for making specialised commissioning decisions, particularly where there isn't a NICE assessment for us to use.

Comment ; It's important to distinguish the difference between the evidence we require around efficacy, which may well come from relatively small numbers and the evidence around safety, where extremely uncommon events are still important. We need to have a dual process, and I think we do need to re-consider the whole concept of how we can get evidence around safety.

Comment from Jane Blazeby: 'New Hospital Procedures Committees' are a significant problem in evaluating new devices. These can approve applications from clinicians who want to try something. Our recent work shows huge and frightening discrepancies about what Trusts approve and the use of evidence in doing so. This urgently needs to be rationalised. It should be noted that the Royal College of Surgeons of England already recommend IDEAL as a process for collecting evidence to monitor the introduction of new devices and procedures into an institution.

Comment (P McC) What we really need to improve safety is strong incentives for people to collect data comprehensively over the long term. At present these don't exist.

4. **NIHR group – presented by Jane Blazeby**

Jane summarised the discussion with the NIHR members. "At the moment, the timing is absolutely right for us to get more evidence using IDEAL because there's been such a shift in surgical research over the past 10 years. There are many more surgical RCTs funded, largely because of the Royal College of Surgeons initiative. It's a logical next step to consider how to get NIHR funding for using IDEAL to create evidence which will facilitate and complement the RCTs.

Jane considered the five different stages of the IDEAL framework, and where each one fit in terms of which funding body within NIHR could support it. IDEAL Stage One and 2a could be funded by MRC, Innovate UK, i4i, and possibly RFPB. Stage 2b could be supported by EME and randomized trials (IDEAL assessment stage 3) by HTA. It was more difficult to determine where NIHR might fund IDEAL stage 4 studies. Programme grants, however (PGfAR) provito ded a great opportunity work across several IDEAL stages in the life-cycle of an innovation.

But what has happened to date?- Few studies with an IDEAL format or label have been funded by NIHR over the last 5 to 10 years, These include FUTURE-GB (image guided surgery for brain tumours, EME) and a randomized trial with a nested IDEAL 2b study in it - the ROMEO study.

However despite wide international awareness of IDEAL, increasing number of papers being written using IDEAL methods and the updated Lancet papers in Annals of Surgery and BMJ, there remains a paucity of funded studies in the UK using clearly labelled IDEAL methods.

So what can we do about it?

1. Consider **how IDEAL fits within wider research methodology** – there is a soon-to-be published 3rd version of the MRC framework for evaluating and developing complex healthcare interventions. We need to define the added value of IDEAL.
2. S**urgeons and clinical trials units could label all surgical phase three RCTs as IDEAL stage three studies**. BC has said how much language matters: we need to get better language and more publicity around IDEAL.
3. **The IDEAL group needs to work to develop more practical, usable protocols, and study proposals for designing and deliver IDEAL studies**. We should develop a set of "off the shelf" exemplars for writing grant applications, designing trials, and planning early phase studies.
4. We should **demonstrate the added value of IDEAL methods, with some methodological research** that would help its uptake. Two studies that are under way may help – one on the contribution IDEAL could make ot reducing research waste, the other on the impact of "2b like" cohort studies on the quality and success of later RCTs.
5. The group discussed how to **influence funding boards**. One suggestion was to persuade funding boards to ask the key IDEAL questions routinely when considering a proposal. IDEAL 2b **pilot phases for RCTS** could be a way to promote the wider use of IDEAL methods.
6. **Working with patients and public partners to lobby on the need for funding to capture long term safety data (IDEAL Stage 4) for** procedures and devices. If no funding mechanism currently exists for this type of evaluation nationally, we could work with patients and the public to lobby for investment.

Discussion

*Comment: H*ow do you persuade NIHR funders to move away from a system that seems reasonably effective?

Response: We've been talking about how NICE And NHS England could talk start talking IDEAL language - If those two bodies started classifying things using IDEAL and saying, 'we want to see an IDEAL 2b study on this', NIHR will follow. The NIHR exists to inform the UK health sector, so if the major customers are demanding such studies, NIHR will move, because it's there to support people who want evidence. And if the evidence users say they want evidence in a format NIHR will attempt to provide it."

JB reply: I agree with you, why change anything if it's working and I think the phase three RCTs in surgery are working well in the UK. The thing that's not working are the early phase studies. There is a complete lack of MRC, i-4-i, RFPB, EME, grant applications that aim to study surgery in those early phases. And one key reason for this is because surgeons can currently just innovate without evaluating properly. There's no pressure to evaluate if they can easily get approval from their new hospital procedures committee to "do the next 10 patients using this device". If we could prevent that from happening, and encourage grant applications, then it might shift."

Surgeon comment – We agree! We would like to see funding calls for early stage evaluation.

Comment: Isn't it different if it's a device which has CE mark vs a procedure that has no prior research?

JB response: The problem there is that the CE marked device may be modified, or used in a different patient group, or in an environment where the team are unfamiliar with the equipment or ancillary devices are needed to make it work. Unfortunately, when clinicians find something doesn't work in their hands, they usually don't report the results, so somebody else is likely to make the same mistake in another centre. IDEAL, with its insistence on transparency, could prevent this and provide clarity about what makes something new.

Comment PMcC – I agree the NIHR is great for RCTs but the gap that remains for early stage studies is due to both surgeons not having to evaluate formally and the lack of funding opportunities for which they could apply.

Comment Dabbling surgeons do not respect their responsibilities when using beyond the licenced use of manufacturer.

Funder comment – We would welcome early stage applications but surgeons go to RCTs preferentially

Plenary summation – Peter McCulloch

Thank you everyone for making today such a success. I would like to ask the representatives from each body represented to report back to your organizations formally, and to put to them any propositions that you have heard today which you think might have value for them. And of course, we'd also like more feedback. JB has made some comments about how IDEAL could do more to explain itself, and we take all such comments very seriously. The more we can understand about how we're viewed, and how our message may be failing to reach our audience, the more helpful we can be to you. So could I start the final discussion by asking people to reflect on what they'll take back to their organizations?

MHRA – we are going on a journey over next year or two. We'd like to continue the conversation across the organizations represented here. We need a dialogue about how the different pieces can fit together so that innovators in the early stages are presented with a very clear comprehensible trajectory through regulation, HTA and commissioning, all sung the same language and tools.

NICE - There are some real benefits from looking at the language and the incremental approach - but it may require a change in terminology and processes on all sides. It may be that IDEAL needs to adapt a little bit, not just the evidence users. The framework has remained the same for the last 11 years, and the world has moved on: For example, an understanding of real world evidence is absolutely key, but this is not dealt with in Stage 4 of IDEAL. So IDEAL has some work to do as well. We would all sign up to a common language around the evidence which worked to make things safer for patients.

*PMcC:*I would absolutely agree with that. We're working hard on our position with real world evidence because, ten years' ago it was not a thing, and we need a response to it, which I hope we will soon have.

NHS England – Will follow up with PMcC on specialist commissioning.

Industry comment: A comment on why industry doesn't get involved more, around registries. We are committed to the concept of real world evidence registries, but its costly and difficult to implement. Even within the NHS, I cannot get four hospitals to agree to the consenting process for my registry and all the EU countries have a different governance

processes, so the hurdles are impressive. I started with a staff of four people, I now have ten just trying to set the registries up. It will need combined input from NICE, NHS England and all the other bodies to develop functional registries that we really can utilise effectively.

NIHR – AC will take forward to various panels./ i-4-i new Innovation Service

JB highlighted the gap for non-randomised, early phase studies that don't fit into EME and are difficult for i-4-i to handle. This leaves them with no clear funding stream, but perhaps more importantly, weak Trust governance on new procedures removes the incentive to seek funding to do proper research.

Close of Meeting

Further Action

The IDEAL Collaboration undertook to produce this report and share it with all participants, and to distribute summaries and extracts on the IDEAL website, Twitter account and other means of public dissemination. Great efforts have been made to ensure confidentiality, but we would seek the help of the organisations who attended in ensuring accuracy. If you have any concerns about the accuracy of any statements in the report, please get in touch via the website or e-mail the co-ordinator at allison.hirst@nds.ox.ac.uk within a month of receiving your copy.

Participants were asked to formally report on the meeting to their organisations, and to let us have feedback on any responses or reactions. IDEAL will also contact individuals with detailed knowledge of their organisation's higher management and policy functions to explore whether opportunities to take the conversation about integrating IDEAL further.