Responses to CSO strategy

Whilst I am delighted to see the headline figures for R&D approval being so short, these data always miss one of the longest/slowest parts of the process- getting individual department sign-off. This is time consuming (and usually wastes investigator and research nurse/data manager time rather than R&D staff time), and in many cases is relatively pointless since it is rare for a hospital department to refuse to support a study. This volume of work is largely hidden in the current process as it is not done by, and so not recorded by, R&D departments. If we can move to a position whereby if the work required of a department is essentially the same as what would be done off protocol (eg drug dispensing, imaging, blood tests) and the workload generated by the study makes up, for example, < 1% or even < 0.1% of a department's workload, it might be better to have an agreement whereby sign-off is done at a higher level in the hospital management rather than by every individual department.

Question 1: Should CSO and the Health Boards set any eligibility criteria for nodal R&D Directors? Should appointment of a nodal R&D Director be for a specific term, and if so what term would be appropriate?

I believe that if CSO sets out the key roles and deliverables for R&D directors, then their appointment should remain primarily with the health boards. CSO should be invited to assist in the shortlisting and attending the interview, so it will have influence. What perhaps also needs to be considered is whether for some of the smaller boards, joint R&D directorships could be created to span two boards to avoid overduplicaiton of effort. Posts should perhaps be for 5 years in the first instance, and once renewable by interview?

Question 2: CSO proposes to approve the functions of staff in R&D Offices; should CSO seek to standardise local R&D functions across Scotland, or is it preferable to allow local flexibility?

Local flexibility is important: but one imagines there is still significant duplication of effort. Perhaps part of the review of how boards are doing in research should involve review of their R&D processes and looking for learning that can be shared between boards. I would not propose standardisation for the sake of it, but rather working towards harmonisation where appropriate – they may well be good reasons for local differences, particularly with regard to other institutions eg. HEIs.

Question 3: Are there other NRS functions that might usefully be transferred from the Health Boards or CSO to the new NRS-GMS? Are there functions not currently being undertaken that the NRS-GMS might carry out?

Whilst I recognise that the boards are the legal bodies that have to oversee research delivery, for multi-centre studies the risks and responsibilities are the same/similar. So to my mind the more work that can be done once for all Scottish sites and NOT replicated at board level, the more we should be able to speed up trial opening and reduce costs/time spent. Some examples might be review of contracts, standardised trial prescriptions. Build on the success and acceptability of NRS and see if for studies that are close to standard of care and recruiting modest numbers of patients we can get to the point where one board and/or NRS can open a study on behalf of Scotland, and not repeat the work across 14 boards.

Question 4: To what extent should the joint planning of the deployment of infrastructure resources be formalised? Should there be a formal record of such discussions?

Yes. It is essential that CSO investment to support research does just that, and in the places where the research is done. Again, there needs to be local variation, and the investment of the CSO support has to be in tune with NHS needs and structures, so ideally this would be a three-way discussion: board level R&D, local research active department and the national leads to reflect national priorities. The principle is easy to state…the devil will be in how this is done without being overbureaucratic or oppressive.

Question 5: Taken together, will these steps to both free up and promote the availability of NRS resources address current concerns over lack of time and support? If not, are there other steps CSO should take?

The clinician time needs to be linked to the rest of the infrastructure and delivery. There may need to be local initiatives and solutions: but in any hard-pressed service (either due to excess clinical activity and/or vacant posts) it will always be hard to ensure service doesn't swallow job-planned research time. Thus there may be occasions when the clinician time is re-invested in other staff to facilitate the delivery of the service AND the research. I am not sure there are specific additional steps – but we need an environment where there is transparency about the resource, and about the decisions made to deploy the resources.

Question 6: Are there any further changes that should be made to improve the efficient delivery of patients to studies through the NRS Networks and Specialty Groups?

We absolutely need to minimise barriers to cross-boundary referral of patients. Many studies cannot open in every scottish board: and if NHSS is serious about clinical research, then patients should be able to travel to undertake research and there needs to be a simple, and retrospective, approach to any cross-charging, plus the NRS approval process needs to ensure that follow-data can be obtained across board boundaries without a separate complex Caldicott approval being required. This way clinicians can refer directly for inclusion in a trial and not await local health board approval processes. One might want to place ceilings on the numbers

for those studies that recruit very large numbers, but in principle this would make delivery more efficient.

Question 7: To what extent do delays continue to occur as a consequence of differing NHS and university requirements? To what extent is closer integration of NRS and university functions possible and desirable?

In my experience this is not a real issue, but then most studies I do are not sponsored by my (Scottish) University but elsewhere. However there may well be further room for improvement.

Question 8: Would a trial register be of benefit to patients seeking trials? Would it be an effective way to partner patients with researchers.

I don't see a need for a Scottish register – and there are already a number of registers of trials in existence. However what we do need is a system to allow patients to see what trials might be available. This will need to be a web interface (so accessible by a patient OR health professional) and with some certain information about the patient and medical conditions, access the UK trials register (eg via UKCRN) and ALSO inform the patient where the nearest sites are. This way most patients will seek Scottish sites, but it would also allow the Scottish public to access trials run elsewhere in the UK, and vice versa.

Question 9: Would using electronic NHS patient records to alert GPs to research studies for which their patients may be eligible be a service the NHS should offer? If so, would a process where NHS records are only accessed by identified NHS staff working in secure facilities, and only passing potential participant names to their GPs or hospital consultants for consideration, be a suitable way to proceed?

This is only of use if the GP is interested in research….and I would have expected most who are to already be thinking like this. So I am not in favour of this approach as it could deluge the GPs with information. What would be better (see question 8) would be a GP or patient-initiated automatic way of uploading relevant information to see if there are suitable studies for a particular patient. In other words – it is not that the NHS alerts the GP to the existence of a study, but rather the other way around, the request is initiated by a GP or a patient.

Question 10: What proportion of CSO funding should be available for deployment in new research initiatives relevant to the NHS? In what areas should CSO seek to disinvest to free up resources?

Question 11: Is the focus of the CSO response mode grant schemes adequately defined and understood by the research community? Should there be a narrower focus to complement and avoid overlap with other funding streams Scottish researchers have access to? What is a realistic upper level for CSO grants to allow worthwhile projects to progress?

Whilst we are part of the UK overall funding structure for clinical research, I would suggest that CSO grants should remain small and essentially pump-priming, with a view to being able to develop pilot/phase II data to support an application to a wider Uk funding stream, as that is

likely to ensure higher quality research is funded. The only exception would be if, and only if, a project would not be of any relevance to a UK funding stream. It is hard to think of such an example – but perhaps the CSO could announce that up to 500k or even more could be available for an exceptional study that can only be done in Scotland – playing to some of our unique strengths. The committee however should be minded that this sort of sized grant would normally expect to be competitive on a UK basis (eg MRC, HTA, UK wide charity), and applicants would have to explain why the exceptional application was NOT suitable for a UK funding stream.

As for new initiatives – it is always good to have some money available for novel, left-field multi-disciplinary collaborations, so I would be supportive of them, again asking why they are best done in Scotland.

Question 12 – What should determine the creation and continued funding of a CSO unit? Should any new unit have a plan for CSO funding to be time limited?

I would take a similar approach as above – why does this need to be funded in Scotland? An option would be to expect all such units to be co-funded by someone else, to ensure that they are internationally competitive. 3 current units are MRC co-funded – and the ECMCs are co-funded with CRUK. This way the CSO becomes a leverage process, only investing if there is evidence of international quality in terms of being able to leverage additional external monies. All funding should be subjected to quinquennial international peer review so in my view ALL unit funding is time limited.

Question 13: Are there other key areas of partnership CSO should be seeking to build?

Hard to answer as I don't know how successful the current ones are. Certainly from the perspective of doing partnerships with commercial companies I don't see any benefit on the ground – they still run the same awkward inefficient processes and we don't see anything to suggest a genuine partnership in terms of how studies are designed, set up, run or monitored. How genuine are these partnerships?

What about others small countries – these might be more productive?

Question 14: Would the creation of a CSO International Advisory Board be a positive step in raising Scotland's research profile and supporting our ambition? What should be the make-up of such a Board?

Potentially. This should be about pointing out scotland's particular strengths and seeing how they can leverage inward research investment in a genuine partnership. The make up should mix academic and commercial, but might well need subgroups for certain top areas of research- diabetes, cardiovascular, oncology etc.: the risk is that a few internationally known people sit round a table and don't really come up with anything we don't already know….so membership would have to be carefully chosen.

Question 15: Are there other areas where CSO funded research could better support the Health Directorates Quality agenda?

Hard to answer as I don't really understand what SISCC is about. Perhaps CSO needs to establish a dialogue with the medical directors and ADMDs across the NHS to ask them what key clinical questions remain unanswered?

Question 16: Is the Primary Care Research Career Award scheme suitably focused to attract suitable high quality applicants? If not, what would a revised focus be?

I suspect there is a deeper issue here- how does NHSScotland embed clinical research in to GP-land? What about funding academic GP training posts…with protected time for research which could be clinical, epedimiological, clinical trial based etc.? then those who graduate from such schemes could be open to apply for more senior primary care research positions?

Question 17 : Are the current CSO personal award schemes targeted to meet our future needs? If not, should CSO conduct a wider review of its capacity building schemes?

Personally I think the challenge facing the NHS is around models of care delivery with constrained budgets. We tend to think of medical research as clinical, and leave the business of running the NHS to politicians, civil servants and managers. Has the CSO ever funded clinicians to do things like MBAs with a research training, in order to train a future generation of clinical high level, strategic health service delivery?

Question 18: not on your list. How does the CSO effectively integrate a bioinformatics research agenda with routine NHS board eHealth departments? This to me is a real issue – the eHealth departments with whom I have worked seem to have NO clinical informatics agenda – it is all

about reporting metrics of performance and providing point of care electronic access to information. I would argue that with things like the FARR institute, we need to "drag" eHealth departments into an informatics age where a significant part of their focus is about collating and analysing health service data in order to better predict events, demand, and manage capacity in a way that is more effective. I would, given Scotland's excellent NHS data, propose CSO focussed resources on this area as a potential invest to save concept – better data on our health care models could well lead to changes that makes us more efficient and effective in the future delivery of care!

One of the challenges is delivery to target. Who sets the target, and was it realistic? Companies often require the same recruitment target for all sites as it makes contracts easier, clinicians are poor at estimating recruitment figures as they rarely have the right data from which to make accurate predictions, and if there is no mechanism to gatekeep which studies are opened, then there is a risk that individual consultants open the study they like and suddenly there are competing studies in sites and unrealistic, and thus undeliverable recruitment targets. We need to work towards a mature understanding of clinical research being a corporate not an individualistic approach – and therefore we need to ensure the ability to understand what has gone wrong when sites don't deliver and be able to work with R&D departmetns to reduce such issues in the future.