CSO Research Strategy 2014 – Lothian response

NHS Lothian and the University of Edinburgh College of Medicine and Veterinary Medicine welcome the CSO research strategy document for 2014. In the main we found the document useful, highly supportive of clinical research and pragmatic.

Chapter 1 – Efficient R&D Support for Research

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

Response:

It would be reasonable to set eligibility criteria for nodal R&D Directors. We consider that the post holder should be an active clinical researcher, have strategic vision, have strong links to a Higher Education Institution (HEI) and possess clinical and academic skills.

A reasonable term of appointment would be five years, and there may be merits in this being renewable for 2 or 3 terms.

Q2: 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?

Response:

There are potential benefits to both standardisation and maintaining local flexibility. This depends on the diverse functions that R&D deliver. It may also not be cost-effective or efficient to standardise and specify certain functions as they may not play to local needs or resources. Local flexibility is the preferred option for some aspects of study oversight and implementation because models of healthcare delivery differ from centre to centre. On the other hand, national standardisation (and connectivity) can help with some R&D functions. For example, the current need for staff to maintain two separate IT systems, neither of which currently accept data from IRAS nor provide access for researchers to maintain their own records, is manpower intensive and, if addressed, could be more cost effective and efficient.

We welcome the proposal (in 1.9 and sequential paragraphs) of having an NRS General Manager who would work at a level above those of the Health Boards and would be able to achieve coordination even in situations where there might be a “political” difficulty or other conflicts.

Q3: 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?

Response:

The management of NRS investments is an important section and we were pleased to see, amongst other things, the requirement that Boards take adequate steps to promote

availability of resources to support research. Likewise the establishment and approval of infrastructure investment and the development in networks is important and we are pleased to see this given priority.

We believe it will be important to reassess the newly formed NRS-GMS after 2-3 years before deciding whether further functions should be centralised from the Health Boards or CSO.

Q4: To what extent should the joint planning of the deployment of infrastructure resources be formalised? Should there be a formal record of such discussions?

Response:

In respect to the above it would make sense to both record discussions and jointly plan the deployment of infrastructure in a more formal way.

We look forward to engaging with the newly restructured Networks. It will be important to maintain a degree of flexibility and local discretion to allow rapid and efficient response to new opportunities. A modest discretionary fund would be seen as highly valuable to relieve road blocks to research or assist with important rapidly emerging strategic areas for development.

Q5: 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?

Response:

We agree that this is important. It is most welcome. The importance of adequately funding researchers time is crucial to NRS/CSO resource being used to deliver clinical research effectively.

Q6: 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?

Response:

The commonest and most frequent request from researchers to aid patient recruitment and trial delivery is the provision of research nurses. We foresee that the best way to improve patient recruitment is through the provision of additional research nurses who are trained in clinical research conduct and the specialty within which patients are to be recruited. There is some current capacity for this but it needs to be strengthened and expanded. This will assist in keeping in step with NIHR approaches to recruitment that often creates disparities and challenges when participating in multicentre UK-wide clinical trials.

We welcome the aspiration to spread and share good practice referred to in paragraph 1.22 and elsewhere. This is challenging but should be possible and this links well with the aspiration to combine the Scottish Research Ethics Service and the NRS R&D offices to create a single entity.

Q7: 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?

Response:

There are already very valuable and highly effective models where Universities and Health Boards/NHS R&D offices are aligned or jointly providing a single one-stop shop for researchers. This form of best practice should be encouraged across Scotland.

We are unaware of any delays that are a consequence of differing working patterns or requirements in Lothian. Close integration occurs between NHS Lothian and the University of Edinburgh. This is welcomed by both partners and we continue to work together closely.

Chapter 2 – Partnership with Scottish Patients & the Public

Q8: Would a trial register be of benefit to patients seeking trials? Would it be an effective way to partner patients with researchers? Is there a danger that expectations of taking part could be unfairly raised?

Response:

Our experience in Health Board and other committees is that involvement of patient or lay representatives is highly valuable and should be the norm.

Based on experience in NHS Lothian, the use of patient public registries has proven to be rather inefficient. Often the database has poor information, few patients have the condition being investigated and some patients are looking for large sums of money for participating or have unusual expectations of what trial participation means for them. Clinical researchers can also have unrealistic expectations of what such registries are able to provide. For example, one researcher used a publicly available register of patients interested in research. The majority of the patients did not meet the study entry criteria and a large amount of time was spent searching the database and inviting many patients for screening. This resulted in recruitment of only one patient who lived 60 miles away from the research centre. This researcher no longer wishes to use such registries. Whilst an attractive concept, the practical implementation, logistical constraints and utility of a public trial register poses many challenges.

Q9: 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 welcomed and, to a degree, already happens. All studies where the Principal Investigator wishes to recruit patients from primary care are currently offered to GPs in Lothian and Borders on a monthly basis. If GPs agree, their records are searched and the appropriate patients contacted. Currently this is done within the practice but we look forward

to the infrastructure being available for centralised searches under safe haven conditions. We will investigate whether this will be feasible using SPIRE data although current experience suggests this may not be detailed enough for many studies. However local centralised access to the full record will become available over the next 2 years.

Chapter 3 – Targeted Deployment of Resources (and Infrastructure)

Q10: 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?

Response:

The level of funding has been unchanged for many years. Current investment in clinical research in NHS Scotland is running at approximately a half of that in England. We would welcome increased investment in clinical research and appropriate incentivisation of clinical research activity.

The clear accountability of CSO funding for clinical research has become progressively clearer over the last 5 years. However, some funding remains to be clearly separated: specifically NRS Researcher Support. Protected researcher time is a key central principle to be able to ensure clinicians have the time to commit to clinical research activities. It also means that they are accountable for this research activity and this will incentivise clinical research delivery.

Q11: Is the focus of the CSO response mode grant scheme 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?

Response:

Current CSO grant schemes (and indeed other grant schemes offered in Scotland or from other UK sources) effectively provide a broad and highly flexible portfolio. Narrowing focus would in the long run reduce the effectiveness of research and particularly the opportunity to support both surfacing talent and developing ideas. These not infrequently emerge in unexpected settings, areas and specialities. The response mode grant scheme is adequately defined and understood. It does complement current NIHR programmes.

The current funding limits on CSO funded research projects are problematic and limit the type of research performed. This is particularly an issue for early phase clinical trials that are often expensive. A realistic upper level for CSO grants would be at least £500,000 with full economic costing.

Q12: 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?

Response:

Some CSO units seem to be historically funded and have themes that are out of step with current research priorities. This does need to be revisited.

Going forward, CSO units should be subject to quinquennial review, perhaps be fully or part funded for one or two cycles, and work towards a self-funding model. Inevitably, units tend to play to local strengths rather than a national service. It would seem appropriate that as a unit becomes successful, core infrastructure should come from the host NHS Health Board (through CSO allocations) and, where appropriate, contributions from partner Higher Education Institutions.

The identification of specific areas in which added value could be gained for Scotland by bringing together a unit might be an important rolling agenda item for the advisory committee referred to in 4.11.

Chapter 4 – Working in Collaboration

Q13: Are there other key areas of partnership CSO should be seeking to build?

Response:

The key partnerships are clearly set out. We would welcome greater links with the NIHR and perhaps greater narrowing of the NIHR funding streams in that there are disparities which run the risk of causing a Scottish brain drain – particular at more senior clinician level with respect to fellowships to support translation/trials based career development.

Additionally it was perhaps a little surprising not to see direct reference to MRC, Wellcome Trust or the major pan-UK research charities in this section.

Q14: 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?

Response:

Where there are clear strategic uncertainties, this may have benefits. However, the Scottish clinical research community is very mature and has many international interactions on a number of levels (nationally, regionally and within academia and industry). It would be important to define what an International Advisory Board would specifically be asked to consider, and where there are uncertainties that need to be addressed. The latter often arises out of a lack of understanding or information of the current national and international research landscape. This would require background research to be performed where gaps and concerns lie, and will need adequate resourcing for this to be achieved. This could be channelled through Health Sciences Scotland.

Q15: Are there other areas where CSO funded research could better support the Health Directorates Quality Agenda?

Response:

Health services research is an area that is clearly relevant to the Health Directorates Quality Agenda. There are several existing investments in this area. However, it is a less mature area of research and needs careful development. Currently, there is a lack of expertise and this will require major investment (financial and academic personnel) and considerable effort to deliver. This will also require major engagement with Higher Education Institutions: an area of research that is not a major strength in institutions across Scotland. However, strategic investment in this area may be welcomed by Higher Education Institutions given the increasing importance of impact within the Research Excellence Framework. Again, this is something that could be progressed through Health Sciences Scotland and a strategic initiative.

Chapter 5 – Investing in The Future

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

Response:

We have found that some GPs who are interested in research find time to do this somewhat later in their careers than hospital doctors. They prefer to get established in a practice before pursuing clinical research part-time. However, this often involves a substantial drop in salary. The previous CSO fellowships, particularly pre-doctoral, do not provide sufficient support for some GPs to transfer some of their sessions to research. This disincentivises suitable candidates for the career-scientist type of posts that are well remunerated. Doctors who have pursued an initial academic career in general practice are often at a stage when they have young families and significant financial commitments. A partnership with a much higher salary is often preferred to that offered under the Primary Care Research Career award. Despite this, some committed GPs have undertaken it.

For these and other reasons, this scheme is not performing well at present. Enhancing research capacity in General Practice is a priority (particular with the development of Greenaway and new models for delivering community care, the development of telemedicine, and the opportunity to address Scotland's remote and rural issues) and this means that this area cannot be neglected. We would suggest a careful review and relaunch of this scheme with a detailed discussion involving stakeholders and how resource might be best deployed to give value. Note, for example, that the NES-funded lectureships in General Practice cannot be flexibly employed for talent when it surfaces because of prescriptive stipulations over the year of training in which they can be awarded. This is an example of how effective research could be disadvantaged by an inadequately developed programme.

With respect to paragraph 5.7, we consider it essential that CSO continue its strong and vocal support of the SFCF scheme. Scotland is extraordinarily successful in exploiting the enhanced numbers of clinical PhDs that have come through investment by the Wellcome Trust, MRC and others. Whilst there is an argument for enhancing the capacity of

intermediate fellowships, there is a real danger that without a senior exit point for our brightest and best, they will leave Scotland. This is a matter of the utmost importance.

Q17: 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?

Response:

We agree that CSO should conduct a wider review of its capacity building schemes.