CONSULTATION ON PROPOSED CHANGES TO
THE SUPPORT STRUCTURES FOR NHS
RESEARCH IN SCOTLAND

Responses should be sent to Charles.weller@scotland.gsi.gov.uk
by 23 August 2013
Introduction

The 2020 Vision for Health and Care in Scotland is that everyone is able to live longer and healthier lives at home or in a homely setting. NHS research will play an important part in realising that aim, ranging from developing new medicines to trialling new devices and interventions to support remote delivery of services.

Great progress has been made in recent years to improve the way research is conducted in the NHS. Through the creation of NHS Research Scotland (NRS) we have seen the adoption of common contracts and costings, the removal of time wasting and unnecessary duplication of governance checks and improved engagement with industry. In terms of infrastructure, we have seen over 180 new posts created across the NHS to better support the delivery of studies.

But our systems are not perfect and in particular there is room for further improvement in the delivery of studies to time and target.

The announcement of a reorganisation of the English National Institute for Health Research Clinical Research Network (NIHR CRN) to better support efficient study delivery provides a timely opportunity to similarly review the position in Scotland. By April 2014 the NIHR will replace its existing 7 Topic Specific Networks and 23 Specialty Groups with a new structure, which, at the top level, will see the creation of 12 NIHR CRN Theme Director posts. The details of the new organisational structure, including the proposed Themes, are attached as Annex A with further information available at:

http://www.crncc.nihr.ac.uk/evolving_the_network/nihr_crn_structure

Ministers have agreed that it is sensible for Scotland to adopt the new NIHR Themes to ensure continued cross border engagement and collaboration on clinical studies. Moreover this forthcoming reorganisation of Scottish NHS research structures provides us with the opportunity to link more closely the CSO research funds won through research in particular clinical disciplines and those undertaking that activity, and to ensure there is an effective dialogue between the R&D Offices responsible for deploying the significant CSO infrastructure investment and the researchers who use those services. This consultation document therefore builds on the substantial achievements by the Health Boards and in particular the NHS R&D Directors in ensuring research funds are freed up and available to support clinical studies. Further changes over the next few years will see all CSO resources allocated to the NHS to support research fully disembedded from the clinical budgets. The document seeks views on how the new Themes and the underpinning Scottish research support structures should be further developed to both support and improve delivery of studies to time and target.

The aim is to have revised structures in place by April 2014. This is an ambitious timescale but one we believe to be achievable with the support of the research community. The publication of this consultation document is the first step in a process of on-going dialogue to ensure Scotland remains a leader in attracting, and delivering, clinical research.
This consultation paper invites comment on three dimensions of the current arrangements – Structures, Funding and Leadership & Delivery. It then seeks views on one possible model for implementing the new research Themes in Scotland.

**Structures**

**Networks**
The current 7 Topic Specific Research Networks followed the model of the pre-existing cancer network that was seen as an efficient way of co-ordinating research resources. The 7 Networks in Cancer, Children, Dementia, Diabetes, Mental Health, Primary Care and Stroke provide research leadership across Scotland and manage delivery of studies that they adopt.

In Scotland, each Network is represented across the 4 NRS Nodes (NRS North East, East, South East and West) with resource allocation and activity coordinated through a Network management structure - hosted by that Network’s lead Health Board - which includes a Network Director and Management team.

It has been a matter of some discussion that not all major clinical disciplines are covered by Topic Networks (e.g. there is no cardiovascular network). A further complication is that the Networks do not manage all the research within their disease area, only those that they adopt into their portfolio. As a consequence there can be a large number of studies within a Network disease area that may not have optimal support and coordination nor national oversight of its delivery. Furthermore there is potential confusion between NHS R&D commercial staff seeking to manage and oversee recruitment to studies within the Network portfolio. This is particularly the case outwith a Network’s host Board.

**Specialty Groups**
Specialty Groups were created to manage the delivery of studies in the clinical areas outwith the Topic Networks. They have no role in developing studies and are intended to have a focus on delivery. To date our attempts to replicate similar Specialty Group arrangements in Scotland have not been successful because Leads have operated in isolation from the 4 local delivery systems associated with the NRS. Moreover, CSO has not had the funds to embed a Specialty Group Lead in each NRS Node. Specialty Group Leads work largely independently from the new NRS infrastructure investments and have limited access to wider support. In commercial studies, Specialty Group leads and R&D commercial staff appear to operate independently in all NRS nodes.

In effect we currently have three categories of study management oversight: Network managed, Specialty Group managed and those outwith the Network portfolio (and therefore unmanaged). A more appropriate structure would address this.

**Question:** Does the current structure wherein each Network is aligned with a lead Board with national responsibilities deliver optimised national access to studies and effective study delivery?
Question: Are the respective responsibilities of Networks (within their portfolio) and R&D staff (outwith the Network portfolio) in overseeing delivery of multi-site studies within the same clinical area clear or sensible?

Question: Does the current position of Specialty Groups within the wider NRS structure allow Specialty Group leads to manage their whole portfolio efficiently? What are the key structural issues?

Question: Is it equitable or efficient to have some clinical areas managed as Networks and others as Specialty Groups?

Funding

Since the creation of the Topic Networks and Specialty Groups there have been major developments in Scottish Infrastructure aimed at delivering greater effectiveness to the NHS R&D functions and improving opportunities for patient participation in research. These have focussed upon NRS nodal working which has seen, for example, significant efficiencies associated with R&D permissions as well as the creation of 4 NRS biorepositories to enable coordinated collection and supply of tissue. This progress has been underpinned since 2009/10 by reinvestment of £10m per annum of NHS funding into additional NRS Infrastructure designed to support clinical studies.

Concurrently Network funding has remained largely static. This is seen to be a barrier to increasing activity beyond that delivered through greater efficiencies. As a consequence, and as mentioned earlier in this document, there are a large number of studies within the Networks’ disease areas that are not being managed by them.

Researcher Time

CSO allocates £12.7m NRS Researcher Support per year to NHS Boards to pay for the time of research active NHS employees. These funds traditionally have been embedded in the wider clinical budgets and as a consequence are frequently unavailable to buy out researcher time. This is now being addressed with the plan over the next few financial years to make all such funds available for research purposes. This funding is activity based, in that it is proportionate to the research under taken by the Board. Moreover, £3.2m of this budget is awarded as a “patient premium” in recognition of the Scottish Government’s aim of maximising patient participation in clinical studies. This funding element is proportionate to the number patients recruited.

Question: What are the main barriers to Networks supporting all the studies within their portfolio area?

Question: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?
Question: Should the proposed Themes have more direct access to the time earned by research active NHS employees through the NRS Researcher Support budget? Would linking the level of Theme research activity to such funding act as an incentive to undertake studies and recruit patients? How could this be implemented in practice given the job planning process?

**Supporting Infrastructure**

Currently both specialist and non-specialist staff who support clinical studies are funded through the Networks. When the Networks were originally created, the original aim was for specialist staff (largely nurses) to be embedded in the Networks with separate funding being provided to the Health Boards to employ non-specialist staff. This flexible way of working has been only partially successful.

The Specialty Groups have no dedicated medical staff to support study delivery. The aforementioned NRS Infrastructure investments are available to support studies within their disease area. However, the separation of the management of the Specialty Groups from the management of the NRS Infrastructure has meant that there is at best limited local collaboration and little, if any, national oversight. In CSO’s view this is a major structural deficiency that should be addressed under any new arrangements.

Question: Do the current Network and Specialty Group funding arrangements allow the best use to be made of the supporting infrastructure?

Question: Would linking more directly the resources awarded through the work of various clinical groupings and their management structures improve study delivery?

**Leadership and Delivery**

One of the key issues being addressed in England through the NIHR reorganisation is the role of the Networks. Networks fulfil a dual purpose at present – developing a portfolio of studies within their disease area and the delivery of those studies to time and target. In contrast, the Specialty Groups focus solely on delivery of studies.

While Scotland attracts a disproportionately high level of health research funding, our success in recruiting patients to studies is proportionately lower than in England. CSO believes the structural and funding issues highlighted earlier in this document are the key problems associated with this. Nonetheless, managing delivery of studies across Scotland from a single Specialty Group or Network site presents its own problems, the most obvious of which is the separation of responsibility and accountability. In particular, Specialty Group Leads are charged to deliver studies but have no access to or responsibilities for the resources required to meet that aim.

CSO also believes that it is desirable to retain a portfolio development function for key areas. Having this in place for the 7 Networks and not the Specialty Groups is inequitable, yet it would not be a good use of scarce NHS research resource to create that development role for all 22 Specialty Groups. In any event there are many other fora in which academic researchers come together to plan research
studies collaboratively; this is a shared agenda and not one for the NHS alone. CSO appointing and funding 12 National Theme Leads for the purpose of portfolio development seems an appropriate investment from the NHS for a country of our size.

Delivery of studies in terms of recruitment would be the job of a new group of individuals – Local Theme Leads. These would be employed through the 4 NRS nodes and work within that structure to oversee study delivery in their disease areas

Question: Compared to present systems, would transferring responsibility for delivery of recruitment to all studies be better managed through locally appointed Theme Leads employed through the NRS Nodes?

Question: What attributes and qualifications are required by Local Theme Leads to successfully undertake this delivery focussed role?

Question: How best would Local Theme Leads cover multiple disease areas (e.g. there would be a single Lead for stroke and cardiovascular disease and a single Lead for diabetes and renal disease)

Question: Would it be desirable for Scotland to put in place through the appointment of 12 National Theme Leads a national portfolio oversight and development role for each of the new Themes similar to that currently undertaken within the Networks?

Possible Model for the Future

• We appoint 12 “operational Theme Leads” in each of the 4 NRS Nodes where the activity levels support such appointments
• Their focus will be solely the delivery of studies to time and target
• They will be appointed through local competition
• They will be supported by shared administrative teams in each NRS Node

• “Operational Theme Leads” will have a proportion of their time paid for by NRS
• Each NRS Node will be allocated on an activity basis a budget to cover all Theme areas
• Allocation and utilisation of resources will be transparent and prioritised against need and coordinated through NHS R&D Directors
• CSO will advise on:
  – (i) Researcher Support and
  – (ii) SSCs attracted by each local theme activity
• to allow the calculation of:
  – (i) researcher time to be allocated to each theme and
  – (ii) infrastructure support earned and required
• We appoint 12 “strategic Theme Leads” for Scotland
• Their focus will be strategic oversight and development of their clinical research theme including attracting studies to Scotland
• They will be appointed through national competition
• CSO will buy out a proportion of their time for national leadership activities
• Together they will form a senior “faculty” with which CSO will engage regularly
• Furthermore a national Biorepository Lead, and national Data Safe Haven Lead and the 4 R&D Directors will also be part of the “faculty”
Annex A – NIHR new organisational structure including proposed Themes

http://www.crncc.nihr.ac.uk/evolving_the_network/nihr_crn_structure