CSO Research Strategy 2014-SPCRN Response

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?

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?

Standardising local R&D functions across Scotland and streamlining governance with a greater emphasis on supporting research rather than approving it are all positive developments.

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?

Since practice nurses have little time to undertake research in addition to patient care and the network has no dedicated nurse resource, SPCRN is directed by CSO to utilise Clinical Research Facility research nurse support for studies conducted in primary care settings. In reality, access to research nurse time for primary care studies is variable across Scotland and there is reluctance in some areas to commit resources to primary care projects. Joint planning of deployment of infrastructure resources which involves networks and are formally minuted would help to make access to research nurse support more equitable.

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?

Although a number of Boards have taken steps to allocate NRS Researcher Support funding to clinical departments in line with research activity in the last few years, this has largely applied to secondary care consultants and not primary care clinicians acting as PIs. This is a barrier to GPs and other independent contractors participating in research; ensuring that these funds were used to reward primary care professionals acting as PIs would help grow primary care research capacity including the ability to support speciality network activity.

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?

For SPCRN, additional funding from CSO to roll out the RSI scheme currently being piloted in NHS Tayside and Fife together with greater access to CRF outreach research nurses who could deliver studies in primary care would allow more efficient delivery of patients to studies. RSI is important to increase research capacity in general practice by facilitating the development of skills and knowledge, which in turn facilitates practices gaining greater experience and expertise in the doing of research, which is required if they are to act as local PIs on future studies. Experienced research nurse resource is also required to enable practices to practically deliver clinical studies locally, although in the longer run some practices/practice nurses may take over this (and the provision of an experienced research

nurse resource for clinicians to draw on does reflect the specialist/hospital model that already exists).

Section 2.5: CSO will require the newly restructured NRS Research Networks to show evidence of involvement with the public in their work, and to embed patient and public involvement in their management processes.

Meaningful public engagement requires proper funding, and unlike some of the other networks, SPCRN has no allocated resource for doing this (the budget having been set 8 years ago, and fully committed to staff costs). The network has funded PPI developmental activities using underspends in the past but this is not sustainable. We would welcome the opportunity to increase and better embed our patient and public (PPI) involvement, but this does have resource implications.

Question 8: 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?

We think this is of likely benefit, but it is unclear how this would be different from what SHARE is doing, and a more generic research register has greater value than one that only focuses on trials. Such registers are hard to implement for the reasons identified (because most patients with a condition will not be eligible for any particular study, and many patients will be ineligible for every study since age or comorbidity restrictions are routine). SHARE is successfully consenting patients for contact and has started linking the register to routine data to inform sampling, but now needs investment to link it to routine data to develop and optimise recruitment methods. In the medium term, that link is likely to be to primary care data via SPIRE, but linkage to other data now and recruitment to studies using it would be very helpful to inform the way that the future SHARE-SPIRE link and a Clinical Trial Register will work. Also if the decision is made to have both a clinical trials register and SHARE, then rather than 'patients not "eligible for their preferred study will be given the opportunity to register for SHARE", it would be better if all patients contacting the clinical trial register were given an opportunity to register for SHARE (the two should be tightly linked, not alternatives).

Section 2.13: We believe offering patients participation in clinical studies should be a key aim of the NHS as an integrated part of patient care. Assisting GPs and hospital consultants in identifying patients who might be invited to participate in a research study relevant to their condition is therefore a service we believe worthy of consideration.

Leaving GPs and consultants as the gatekeepers is probably a sensible first step towards contacting patients directly. Helping GPs identify eligible patients is a service that SPCRN already provides.

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?

Whilst this may be appropriate from a research governance perspective, is unlikely to be very effective without support for clinicians to do something with the information. A lot will depend on the specificity with which patients are identified, and whether the expectation is that clinicians just send information on to the patient, or do some initial screening (at a minimum presumably clinicians will be expected to screen out patients likely to be unsuitable, but better judgement of eligibility would likely require manual record review for hard to code elements).

This is concerning from SPCRN's perspective as it is clearly specified that NHS staff will access NHS patient records and the majority of network staff aren't employed by the NHS. This suggests that identifying patients will be undertaken by a programming team working within a secure environment rather than this being a network activity, so has substantial implications for SPCRN role and skills required.

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?

The PCRCA was designed to allow doctors with a PhD or MD working as NHS GPs to have dedicated research time. The problem is that few NHS GPs have a higher degree, because GP clinical speciality training is only 3 years long and there was no mechanism historically for GPs to do a PhD or MD during it. When this scheme was launched by CSO in 2003, there was a very narrow field of suitable qualified applicants due to the strict criteria which CSO insisted on (GPs or other primary care professionals with a PhD or MD) and most of these individuals were funded in the first couple of years (Stewart Mercer, Ron Neville, Pat Hoddinott, Phil Wilson, Brian McKinstry, Chris Burton etc.).

The PCRCA scheme therefore worked in terms of helping eligible GPs make the shift to successful academic careers, but rapidly recruited almost all potentially eligible GPs, because of the long-term lack of investment in GP academic training. This has been partially redressed in the last 5 years, with the establishment of a GP SCREDS scheme and NES funding for post-CCT one year academic fellowships. This partly redresses the longstanding difficulties in GPs gaining academic experience during a very short and hospital/service dominated speciality training and has led to growing success in obtaining nationally competitive PhD fellowship funding (although it is worth noting that there are still only 4 GP SCREDS Lecturers at any one time despite GPs being almost half the medical workforce). There will therefore be a group of GPs with formal doctoral research training emerging in the coming years, with a risk of the existing investment being wasted without access postdoctoral fellowship support for the best candidates. Given that GPs remain excluded from much current support, including the NRS Research Fellowships whose eligibility criteria for medical applicants assume direct NHS employment and a consultant contract, this will require a review of the PCRCA scheme’s eligibility.