CSO RESEARCH STRATEGY - Response to Consultation from the CSO core-funded Units

The CSO's six core funded Units welcome this opportunity to respond to the consultation on the CSO's future research strategy. We are responding as a group rather than individually, as many of the key issues facing the Units are common to all six. In what follows we answer those questions most relevant to us, as University-based centres of excellence in translational health research. To begin with, we should like make the following general observations

First, throughout the document little reference is made to health services or population health research. These are areas of research strength in Scotland, due in substantial part to the role of CSO-core funding in sustaining research capacity in these areas.

There was a noticeable lack of reference to key policy ambitions of the Scottish Government, such as the priority areas highlighted in the Route Map to the 2020 Vision for Health and Social Care, or to and the implications such priorities have for research in Scotland. For example, no mention is made in the substance of the document of how the move to integrate health and social care is to be reflected in research strategy. This risks driving a damaging wedge between the CSO's strategy and that of the Scottish Government's Health and Social Care Directorates.

Third, the focus of the document, and implicitly of the CSO's overall strategy, is inconsistent. Although the preface refers to health research, the focus elsewhere is on 'clinical' or 'medical' research. One of the questions posed is whether CSO funding is adequately defined, well understood and appropriately targeted. Avoiding confusion about the CSO's mission is crucial to all three.

We return to some of these issues in our responses to specific questions.

Chapter 1 – **Efficient R&D Support for Research**

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 time, 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?

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?

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?

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?

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 Speciality Groups?

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?

Units' response We welcome the measures set out to improve the efficiency of the R&D Support process, but would add the following observations.

High standards of research governance are essential, but governance processes must be efficient as well as rigorous so that potentially beneficial research is not stifled. One area of inefficiency in the current process is the duplication of the peer review undertaken by research funders that occurs when ethics committees make decisions on the basis of methodological rather than ethical considerations. Research methods are developing more quickly than the experience and ability of some committee members, opening up a training gap that needs to be closed by improved guidance. The problem is confounded by inconsistent decisions. We are finding that particular approaches to recruitment may be approved for one study and not for another, or allowed by one committee and turned down by another. Again, improved guidance should help – for example, a taxonomy of permissible approaches that researchers can assume will be approved, unless a specific reason is given by the committee for making an exception.

A second issue is that of excess treatment costs for non-clinical interventions, such as obesity interventions delivered in the community by non-NHS staff, and other social care and public health interventions. Such interventions are a rapidly developing area of both research and policy interest, and the announcement that Public Health England would pick up treatment costs for non-NHS trials adds urgency. Clarity from the CSO on its position in relation to these costs would help many researchers in Scotland, within and beyond the CSO units. A related issue is support for recruitment to non-clinical studies, along the lines of the support available for clinical research via the NRS Networks and Specialty Groups. Such support is available in England via the CLAHRCs, and its absence here places researchers based in Scottish institutions at a disadvantage.

Chapter 2 – **Partnership with Scottish Patients and Public**

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?

Units' response: Such a register may well be useful, especially if it is open to the whole spectrum of research that the CSO funds, including studies other than clinical trials. Patient expectations should be manageable, given that they would be volunteers, and their rights and obligations could be clearly defined at the point of joining. The main problem may be too little interest rather than too much, without a significant effort to promote the register. As the document notes, it would also be critically important to define clearly how the new register would interact with the ongoing SHARE initiative.

Question 9: Would using electronic NHS patient records to alert GPs to research studies for which their patients may be eligible 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?

Units' response: We are less convinced by this proposal. It would build some of the existing bottlenecks into a new system, and it is not clear from the consultation document what would happen after the names were passed to the GP or hospital consultant. We are aware of trials of point of care randomisation for comparisons of standard treatments (see e.g. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4062282/; http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3934788/), but all such approaches need to include safeguards so that patients do not feel coerced or obliged to take part in research because the opportunity is presented to them by their doctor. Data security is not the only issue, and there may be advantages to having researchers rather than clinicians make the approach. Research to determine patients' preferences may be a useful starting point for developing such a system.

Chapter 3 – **Targeted Deployment of Resources and Infrastructure**

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?

Units' response: The greater proportion of CSO funding is tied up in NHS infrastructure investments, rather than direct funding for research activity. In seeking to free up resources for new initiatives, the CSO should review this balance, rather than only identifying resources for new initiatives within existing budget 'pots'.

Setting a fixed proportion aside for new initiatives would be a mistake, as it relies on the untested assumption that new activities will be more productive than existing ones. In principle, the allocation of resources should be guided by the (expected) return rather than setting a fixed proportion. In practical terms it may be necessary to identify a budget amount but the comparative returns to this investment should be monitored. Similarly, disinvestment should be based on relative returns rather than across the board cuts. It follows that new initiatives should be launched only after a thorough appraisal of the expected value of, and strategic need for, the new activity, and a comparison with the return on existing activity. Alongside the consideration of new initiatives, CSO should therefore explicitly consider which current funding streams are performing well in terms of research quality, productivity, importance and impact. Systems and initiatives that are working well need and deserve continued support. Any new research strategy should seek to protect, and where a case can be made, expand funding for existing strengths as well as considering novel initiatives.

A more general point is that value should be assessed in terms of improving health and reducing health inequalities (another of the Scottish Government's overarching priorities), rather than in the narrower sense of 'relevance to the NHS'. The Preface to the consultation document refers to 'improving the health of the people of Scotland', and goes on to say that the CSO is part of an even wider ambition. We support that wider ambition, but much of the document takes a much narrower focus with clinical research misleadingly presented as synonymous with health research as a whole, and research infrastructure equated with NHS infrastructure.

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?

Units' response: The focus of the CSO's response mode grant schemes is appropriate to their size, and defines a useful niche for the CSO in relation to the larger NIHR, MRC and medical research charity funding streams. The best markers of whether this focus is understood by the research community are the flow of applications, and the kinds of grants awarded by the Health Services and Population Research Panel in recent years. Our perception is that both would indicate that the message has been reasonably well received and understood by Scotland's health services and public health researchers, but it deserves greater prominence on the CSO's website. It would also be worth emphasising that CSO grants may cover research of specifically Scottish interest, and therefore unlikely to attract NIHR support.

The only other funding stream which specifically focuses on early phase work such as development, pilot and feasibility studies is the MRC's PHIND scheme, which is smaller than the CSO funding streams, has a lower grant ceiling, and is unable to fund full pilot studies. This means that the CSO project grant has an important strategic role. Diverting resources away from this kind of work would severely reduce the opportunities available to researchers based in Scotland to do the preparatory work that will enable them to submit high quality proposals for larger scale intervention studies. Widening this focus to include 'phase IV' or implementation research is worth considering, to capitalise on the emphasis in the Research Excellence Framework on impact and knowledge mobilisation, as this is another area where funding opportunities, especially for Scotland-specific service delivery and organisation issues, are relatively scarce.

A narrower focus would entail setting priorities in some way, such as identifying particular topics. This would be a mistake, given that the value of research depends on its specific contribution to the evidence base rather than the topic it addresses.

Raising the upper limit of CSO grants will tend to increase overlap with other, larger funding steams, as well as reducing the number of awards. We would not recommend raising the limit substantially unless the overall size of the budget for response-mode grants were increased. While a modest increase to take account of inflation since the limit was set is worth considering, the fact that two thirds of applications are under the limit suggests that it does not rule out worthwhile proposals. If ResearchFish data allow an analysis of the productivity of grants within the broad cost bands used in the consultation document, the findings would provide a useful basis from which to review the current ceiling.

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?

Units' response: Both new and existing Units should address a strategic need, as well as delivering excellent research and sustaining Scotland's capacity and expertise in key areas of the health sciences. The key criteria for investing in the creation of a new unit should be an identified need for research which is not being undertaken in existing funding streams, a need to build critical mass in a key area, and fit with other CSO investments, including other units.

Consideration of whether existing units remain strategically important is explicitly incorporated within the CSO processes for reviewing Units at five year intervals. Having this separate, prior stage of strategic review is valuable because it prevents the possibility of strategic need being confused with quality of the science, or scientific excellence being used as a proxy for relevance to decision-making in health policy and practice. Once a continued strategic need has been established, other criteria that should be taken into account in deciding whether to maintain support for an existing unit are scientific productivity and capacity to leverage additional funding (either core or grant funding). We regard the existing mechanisms for five yearly reviews, coupled with the annual meetings that most Units have with CSO and other key stakeholders, as adequately robust, as evidenced by the closure of two Units in recent years, but also flexible enough to allow reshaping, as in the case of SPHSU in 1998, and NMAHPRU more recently. Scientific productivity and leverage are now measurable via ResearchFish, so that benchmarks can be established and comparison drawn with other funding modes, providing the opportunity to make the process still more rigorous.

Time-limiting the funding for new (or existing) Units would be a mistake because, again, it assumes that (1) some alternative use of the funds will automatically be better than continued support for a Unit at a fixed point in the future, or (2) some alternative funder will step in at that point. Neither is necessarily the case, and (2) is highly unlikely. The CSO, unlike many other funders, has generally avoided the common pitfall of switching funds between short-term investments in infrastructure that can only yield benefits over much longer periods, and this should continue.

An issue specifically in relation to public health research is that the major new NIHR infrastructure spending, notably the £20 million invested in the English School of Public Health Research from 2013-18, has not been matched in Scotland. The five UK Clinical Research Collaboration Centres of Excellence in Public Health Research plus the SCPHRP, all of whose funding was renewed in 2013, can be cited as a positive example of CSO infrastructural funding for this field (CSO's contribution is one twelfth of the total funding for all six), but the future for these centres after their current funding ends in 2018 is very unclear. The CSO, in concert with its UK funding partners, needs to begin work now on planning the type and level of public health research infrastructure it should provide from 2018 onwards.

Chapter 4 – **Working in Collaboration**

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

Units' response: The partnerships mentioned in the consultation document reflect the restricted focus we identified in answering Q10. If the CSO is going to address the health and social care agenda that dominates policy thinking in SG, it needs to consider building links with special health boards, such as Health Scotland, HCIS and NES, as well as the regional NHS boards, and with Community Planning Partnerships, third sector and other non-health organisations whose activities may impact on population health and wellbeing, not just with the NHS, the industries which supply it, and the medical charities.

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?

Units' response: Scotland's research profile will depend primarily on the volume and quality of research it produces, and the extent to which arrangements for hosting studies, linking data, etc., are efficient and accessible. The CSO has made great strides in these areas. An International Advisory Board will not do much to further raise Scotland's profile, but may have value in providing access to new ideas from elsewhere about strategic innovations in research. Its make-up should not be exclusively academic but should also include representation from Government and industry. As with the SHIP Board, it might be most effective to have an independent chair.

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

Units' response: The Quality Strategy covers Health and Social Care, rather than just Health. Much of the focus of the Quality Strategy and 2020 Vision is on health and social care integration. Social care is mentioned only once in the consultation document, but is looming larger as the population ages and more care is delivered outside hospitals. It is not clear from the document whether the CSO wishes to embrace this wider agenda or focus more narrowly on the clinical end of the health research spectrum.

One area whose fit with the scope of CSO's health services and population health research funding is worth clarifying is work on the boundary between health services research and 'educational' research, i.e. research on the impact on health care quality and safety of educational and training interventions for health and social care professionals (including undergraduate, postgraduate and 'in service'). Solutions to the issues highlighted in the Francis Report include educational interventions, and such interventions could reasonably be counted within the scope of health services research. Explicitly flagging up to the research community that CSO funding for health services research includes work of this kind could be valuable, and would encourage studies that could lead on to NIHR Health Services and Delivery Research applications.

Chapter 5 – **Investing in the Future**

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?

Units' response: In the light of our comments elsewhere about widening the focus from clinical and medical research, we suggest that the remit of the scheme be similarly enlarged to address the integration of health and social care and the increasing role of local authorities in public health.

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?

Units' response: We welcome the suggestion that the CSO should review its capacity building schemes. This would be consistent with the emphasis in Ch 3 on regular review of all the major CSO funding streams. One issue for the review is whether the current balance between clinical and non-clinical schemes is appropriate. The HSPHR fellowship schemes are extremely valuable, but there is no 'senior' non-clinical equivalent to the Scottish Senior Clinical Fellowship scheme. While we accept that not all of the funding streams available in England can be mirrored in Scotland, the lack of support for clinically qualified researchers who wish to pursue research careers outside the NHS (e.g. in public health) is a significant gap.

Consideration might also given to prioritisation of key areas for capacity building, along the lines of the MRC Strategic Skills Fellowships in Population Health, Health Economics, and Methodology. A specific gap in the range of personal awards available in Scotland is scholarships for students wishing to study for an MSc in Health Economics, akin to the NIHR MSc studentship in Health Economics (awarded to Universities).

A third issue is the retention of trained researchers. In a number of domains, the research environment, and in particular the shortage of clinical academic positions, is such that many able, motivated, and experienced researchers leave research, and the investment in training and developing expertise is lost. As a result, there is a pool of ex-researchers across Scotland who could be "re-engaged" in research to the benefit of the academic community and the NHS. Evidence from recent schemes for nurses and allied health professionals has demonstrated that these individuals can be located and re-engaged in a highly productive manner. Consideration of an expansion of current schemes to support "re-engagement" should therefore be considered.