The Glasgow Biomedicine response to the CSO Research Strategy Consultation (2014)

General comments

Overall this is a laudable document, and if the goals and visions described within this outline strategy come to fruition, we have much to be optimistic about.

However, the key to maintaining Scotland's standing in clinical research is the strength of the partnership between the NHS and Scotland's universities. In Greater Glasgow & Clyde, for example, this partnership and its shared strategic vision has enabled over £60M of investment in state of the art facilities at the South Glasgow University Hospital campus. These facilities include:

- a £25M purpose-built Learning & Teaching facility for medical training;
- a £5M dedicated floor for the new Stratified Medicine Scotland Innovation Centre and incubator units for SMEs;
- a new £5M Clinical Research Facility for stratified medicine clinical trials in adults, adolescents and children;
- a £16M investment in a world class Imaging Centre of Excellence with an additional £7M of charitable investment for a 7T MRI.

Working together, NHS GG&C and the University of Glasgow have created facilities that will be unrivalled within the UK and have the potential to revolutionise health care globally whilst catalysing local and national economic development.

We believe that, in its current form, the strategy does not place sufficient emphasis on the value of these crucial partnerships, which will be essential in the delivery and implementation of CSO's goals.

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

We agree that the eligibility criteria and job descriptions for nodal R&D Directors should be set by organisations with a significant interest in the progression of national and local research priorities. However, the document currently underrepresents the value of the crucial partnership between the NHS and Scotland's universities.

Notwithstanding the strength of the partnership between the University of Glasgow and NHS GG&C (as illustrated in our general comments above), the universities with medical schools lead / collaborate in the majority of research ongoing within the NHS (over 70% of the active clinical research in NHS GG&C is undertaken in partnership with University of Glasgow), and so the criteria for such pivotal appointments should be driven by local requirements and set by the Health Board and lead university partner with input from CSO. In many cases, the R&D Director is likely to be a clinical academic the imperative is to appoint the best person for the job.

A fixed term for nodal R&D Directors is appropriate and a 5-year duration would allow performance to be effectively assessed.

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?

Greater harmonisation of approach across R&D offices is essential to provide greater clarity for service users and to allow benchmarking between regions. However, requirements will differ due to scale and complexity of the research portfolio and the partnership arrangements between the NHS and the university partners. Therefore, local flexibility within defined parameters is our preferred model.

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 undertaken that the NRS-GMS might carry out?

The NRS-GMS is a positive development provided that it reduces administrative burden and releases funding for research. However, it is essential that NRS is overtly impartial and the transfer must have robust governance arrangements and clear procedures for engaging with Health Boards and university partners to ensure this impartiality can be maintained.

Centralising local NHS R&D functions to NRS-GMS, is less attractive because it would dissociate and distance an important part of the support service from university and NHS researchers. It is essential that researchers have access to a comprehensive service within a single R&D office. In addition transferring staff from the NHS to secondments within NRS-GMS will need to be carefully managed as without backfill, the support provided locally will be diminished.

NRS-GMS should become the entity which actively promotes NRS clinical research activity through the media and maintenance/development of the NRS website.

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?

We agree that there should be a transparent and formalised record of the deployment of NRS infrastructure funding. However, it is clinical academics that catalyse the research culture within the NHS and, through the attraction of external funding, provide sustainable opportunities for NHS colleagues to partner in research: the universities must therefore be a part of this process. Local plans for deployment of NRS infrastructure must be developed through collaboration with university partners to meet CSO objectives.

We agree with the proposal in **para. 1.14,** but believe that the review would be most effective if it involves input from the Health Boards *and* the university partners.

We are very concerned by the intention stated in **para. 1.15**. The existing mechanisms employed to measure activity are too simplistic and take little account of complexity of studies, difficulty in recruitment, data quality etc. Ultimately, this will change behaviours and drive focus away from innovative, early stage research with potential to generate a step change in treatment towards studies with easy recruitment and high throughput. Scotland's international reputation is based on our pre-eminence in Phase I and Phase IIa and IIb studies and this work should be encouraged by the metrics employed: rewarding easy recruitment will damage Scotland's competitive edge in the longer term. We urge CSO to consider carefully the consequences of changes to funding and to ensure any changes are made following further consultation, which should include representation from the university partners as well as NHS stakeholders. Priorities for use of infrastructure should take into account both local and national priorities, particularly where there has been substantial investment in internationally recognised centres of excellence.

The University of Glasgow believes that CSO should consider allowing Health Boards and their university partners to agree local strategic priorities against which success can be measured and rewarded alongside any activity metrics.

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?

Freeing up research time for NHS clinicians is a very important step to increase research capacity within the NHS. The NRS Fellowship scheme has been successful, although additional funding focussed on clinicians at different career stages would also be effective as outlined in our response to Question 17. NHS GG&C will work with CSO to agree how to use the overall Researcher Support budget to best effect. Redirecting this money within boards will be challenging, particularly to ensure that it does not impact adversely on clinical care.

Lack of research capacity within the NHS is compounded by the current distribution of NES academic trainee posts which means that far fewer post-holders are able to train within the largest, most research active Health Board in Scotland – this disadvantages the trainees as well as NHS GG&C and the University of Glasgow.

Notwithstanding the above, the University of Glasgow believes that the current 9+1 NHS consultant contracts do not attract the very best clinicians to Scotland nor provide the foundation for enthusiastic engagement with research.

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?

Open competition is essential when it comes to recruiting Speciality Leads and Network Champions. As is providing them with protected time to really commit to the role and provide the necessary oversight at a national level. It is essential that the selection committees include expertise from elsewhere in the UK and internationally to ensure the appointees are internationally recognised clinician scientists who can focus on excellence.

As currently configured, the Speciality Group disease areas are unduly rigid and often overlap (e.g. diabetes and cardiovascular; diabetes and renal; renal and rheumatology; etc). Appropriate mechanisms must be implemented to reward / support the groups to collaborate rather than to work in isolation or in competition.

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?

The proposal to integrate the Scottish Research Ethics Service within the NHS R&D Offices (**para. 1.23-1.24**) is sensible. However, it is essential that Scotland's REC remains independent in its decision making and continues to align with the rest of the UK to avoid unintentional barriers for multicentre clinical research that will span the UK.

The requirements for undertaking research within the NHS are set at a national level and provide a clear framework of responsibilities and standards. Within the parameters of this framework, local NHS and university partnerships have developed long standing arrangements for how university clinical research is reviewed and managed by NHS R&D. We agree wholeheartedly that close partnership, including joint offices, should be commended, but we caution against standardising these arrangements at a national level which will create unnecessary upheaval with very little gain in efficiency. Greater gains may be possible by

reviewing the significant administrative burden that the current regulatory and governance framework places on clinical research.

Health Science Scotland will only make a useful forum for strategic discussion and for the resolution of issues if it is reviewed and strengthened considerably from its current state (**para. 1.26**).

Furthermore, true integration of university and NHS priorities and requirements will only happen if the universities are an integral part of CSO strategy and decision making process through formally recognised channels.

Question 8: Would a trial register be of benefit to patients? 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 are not convinced by the need for another register of this type. Indeed, the additional burden of dealing with hopeful patients who do not ultimately meet the entry criteria is likely to outweigh the small numbers of additional recruits that might be gained.

The register is likely to also have a reasonable administrative cost in its set-up and maintenance. CSO may wish to consider diverting these funds to enable the Speciality Networks to increase their active dissemination of opportunities, which is likely to be much more effective and can targeted via existing disease databases.

Further to this, investment in Patient Groups to work with researchers from initial study design through to recruitment would enable targeting of the opportunities to participate in research and facilitate the achievement of the objective outlined in **para. 2.5**. CSO may also wish to consider the views of patients and the public on the benefits of a trials register. Some charities such as CRUK have already done this and may be able to provide valuable insights.

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 the NHS records are only accessed by identified NHS staff working in secure facilities, and only passing potential participants names to their GPs or hospital consultants be a suitable way to proceed?

Provided the system complies with the legal and ethical requirements governing the processing of patient information, the use of electronic prompts for GPs and hospital consultants to enable the identification of patients for studies is an excellent idea.

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?

This question is difficult to answer with the limited information provided in the document. CSO must retain its focus on research that is likely to affect clinical practice. Current levels of regional infrastructure funding must not be degraded to provide money for short term initiatives or project based work.

New research initiatives such as the strategic investments being made in stratified medicine and informatics are most effective when CSO has the capacity to invest alongside the relevant industry partners. This model of working will become increasingly important as the cost of cutting edge research increases.

CSO may also wish to reflect on how the existing pool of funding is allocated. Currently, funding can be wasted on studies that are not and never will be clinically relevant either because they are too basic in nature or because the sample size is too small to be statistically robust.

Question 11: Is the focus of the CSO responsive 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?
In response to the questions:

i) CSO responsive mode grant schemes are not well defined: greater clarity would be appreciated.
ii) With a limited funding pot, it would be reasonable to consider shifting funding to Scottish research where no obvious alternative funding is available, for example, linking it to important but neglected health areas. However, CSO should also consider retaining the valuable breadth of scope of the funding by using joint funding / partnership arrangements to make the pot go further.
iii) The upper limit of CSO grants should increase to at least £300,000. Exceptions to this rule must be possible to accommodate research that is increasingly expensive due to, for example, the use of advanced imaging or 'omics. Partnership arrangements (as proposed under (ii)) would enable CSO to fund above its limit enabling Scotland to take the lead in more UK and International clinical research projects rather than being reliant on coordination from elsewhere.

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?
The process for determining the creation of a new CSO unit needs to be transparent and must involve input from NHS and university partners. To justify setting up a new unit, there needs to be a clear demonstration of need, expertise, ability to draw together cross-cutting themes, and possibly the absence of defined funding schemes from elsewhere.

All CSO units must be evaluated rigorously and regularly (every 5 years) to determine their continued excellence, value for money and productivity. Time limited funding is less attractive for new units as it will reduce the ability to attract the best researchers and limit the scope for developing excellence.

Point of accuracy: The title of the 4th CSO Unit listed in ***para. 3.17*** *is incorrect. This should be MRC / CSO Social and Public Health Sciences Unit, University of Glasgow.*

Question 13: Are there other key areas of partnership CSO should be seeking to build?
The proposed partnerships look sensible and this approach is to be encouraged. These must be true partnership arrangements involving academic input and the development of joint approaches to research and its funding: token gestures do not work.

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?
The creation of an International Advisory Board to provide expert advice on strategic research issues and to inform the allocation of funding across research priority areas and initiatives is essential for Scotland's standing globally. CSO should remember that Scotland is home to some of the world's foremost clinical researchers who are affiliated with some of the UK's top research intensive universities: it is important that these individuals are able to inform future

CSO strategies. The constitution and make-up of the Board should be such that its focus is on strategic direction and it is not subordinated by a need to ensure equitable regional distribution of funding.

Question 15: Are there other areas where CSO funded research could better support the Health Directorates Quality agenda?
We have no comments.

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?
CSO should consider reviewing its long-standing initiatives in the way proposed for the CSO units. CSO funding should be committed to fostering excellence in research whilst supporting the development and retention of the very best early career researchers in Scotland: investing in a scheme that has proven unsuccessful in recent years may not be appropriate.

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?
The remit of the current SSCF is admirable and the presence of excellent, SSCF-supported, professors within the University of Glasgow is clear evidence that it is effective. The scheme should be a priority for greater investment.

We urge CSO to put further thought into the NRS Career Research Fellowships. These fellowships are required due to the fact that standard NHS consultant contracts are very service focussed so that participation in research is a low priority. Whilst many NHS consultants would appreciate and benefit from greater involvement in research, the career paths for fellowship holders are not clear and it would be advantageous to understand how best to support them in the longer term. Losing their expertise as they return to traditional NHS contracts is a concern that must be addressed.

Additional investment in schemes which provide early support for promising young clinicians who have demonstrated a capacity to lead clinical studies as they emerge from clinical training would be beneficial. This would minimise the risk of losing highly promising researchers to conventional NHS consultant posts.

Scotland must also maintain its competitive edge within the UK. NIHR Clinical Lecturers in England, for example are 50:50 clinical: research whereas the equivalent in Scotland is 80:20.

Further comments:

Para. 5.15. Given the aim to publish a separate informatics strategy in 2014, it is disappointing that this consultation did not include the opportunity to comment. Informatics is increasingly important for Scotland, UK and internationally and Scotland is home to many internationally recognised academic and industry experts in this area. The strategy should be developed with wide consultation including University, Industry and NHS partners to ensure it is fit for purpose. Furthermore, the use of patient data for research is an emotive subject and the public and patient groups should also be consulted.

Para. 5.17. The funding for the NHS Stratified Medicine Applied Research Programme is a very positive initiative. It will be important that it is developed with the international leaders in the stratified medicine field who are associated with the SFC funded Stratified Medicine Scotland Innovation Centre.