

**Consultation on proposed changes to the support
structures for NHS research in Scotland**

Collated Responses

September 2013

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1. Alzheimer Scotland

Introduction

Alzheimer Scotland is Scotland's leading dementia voluntary organisation. We work to improve the lives of everyone affected by dementia through our campaigning work nationally and locally and through the provision of specialist and personalised services. We also offer information and support through our 24 hour freephone Dementia Helpline, our website (www.alzscot.org) and our wide range of publications.

We welcome the opportunity to contribute to the consultation on proposed changes to support structures for NHS research in Scotland. Alzheimer Scotland supports dementia research at the Universities of Edinburgh, Stirling and the West of Scotland. We have also recently established a Scottish Dementia Research Consortium.

Response to consultation questions

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?

The current structure serves dementia research very well. However, it should be noted there is very limited academic old age psychiatry, the main clinical specialty involved with dementia care in Scotland.

The Scottish Dementia Clinical Research Network (SDCRN) has taken a lead in clinical research and this reaches almost all Health Boards' in Scotland. The impact of the Network on clinical research publications and recruitment into studies has been considerable within a very short period. An example of this is Dr Tom Russ, SDCRN Clinical Research Fellow. This Fellowship was funded by Alzheimer Scotland. Dr Russ has had several high profile dementia-related papers published in peer reviewed journals.

Restructuring along the four nodes of the main academic health boards would be extremely deleterious to a national approach. Two of the academic centres of dementia research, Stirling and the University of the West of Scotland, are outwith these health boards.

Alzheimer Scotland believes the only appropriate structure is a national approach with a lead board.

In summary, the current structure has proved to be extremely effective and there is therefore no sound reason to change it.

Are the respective responsibilities of Networks (within their portfolio) and R&D staff (out with the Network portfolio) in overseeing delivery of multi-site studies within the same clinical area clear or sensible?

Engaging people with dementia in research is not a generic skill.

Dementia research requires specialist researchers. Clinical Research Officers have been recruited by the SDCRN. These Clinical Research Officers have received specialised training and have clear responsibilities to engage people with dementia in research.

Research and development staff outwith the SDCRN would not have such training. These staff would not have any specific responsibilities in this area – this would be detrimental to dementia research.

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?

We are unable to comment on this since dementia has a dedicated research network in Scotland.

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

Yes.

The Scottish Government set priorities for health research. If this were not the case, research funding might merely reflect the agendas of commercial companies. These are unlikely to be the same as those in the public interest.

It is therefore entirely equitable to structure research support to reflect Government priorities. Dementia is a national health priority. The Scottish Government's Second National Dementia Strategy commits to a Dementia Clinical Research Network.

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

As far as Alzheimer Scotland is aware, the SDCRN supports nearly all dementia related clinical research in Scotland. Dementia related research has increased considerably since the inception of the SDCRN.

There will be dementia research where researchers do not require the support of the SDCRN. And researchers should be free to decide this. It would be restrictive to insist on researchers having studies adopted by networks and this should not be a target.

Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

We are unable to comment on this since dementia has a dedicated research network in Scotland.

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?

This would be bureaucratically complicated. The current situation of allocating resources directly to Networks is effective and efficient.

The major issue is clarification on how research time funded by eligible funders is protected within job plans, given this may vary over relatively short periods. The current SDCRN arrangement, where networks can fund sessions for research active networks over a longer period, works well and should be promoted.

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

As far as the SDCRN is concerned, we believe it is. We cannot comment on arrangements for Specialty Groups.

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

We are unclear how this pertains to the SDCRN since the current management structures appear to be delivering studies very well as far as the wider dementia community in Scotland is aware.

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?

No. As set out above, the current structure works extremely well for clinical dementia research in Scotland. Moving to a four hub structure is likely to have a major deleterious effect on dementia research and Alzheimer Scotland is very seriously concerned about this proposal.

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

This is not an issue given that a Local Theme Lead role is not appropriate (see previous responses).

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)?

This is not an issue given that a Local Theme Lead role is not appropriate (see previous response). Moreover, dementia research is currently well served by a specific network and this works more effectively, we believe, than the English equivalent DENDroN which has a dual focus of dementia and neurodegenerative diseases that can lead to tensions in terms of research focus and prioritisation of resource allocation.

The SDCRN should remain dementia focused and continue to build on the specialist skills of its staff rather than be diverted to other, non-dementia research areas.

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?

This is not an issue given that changing the current structure is not appropriate (see previous responses).

2. Arthritis Research UK

Many thanks for asking Arthritis Research UK to respond to the proposed changes to support structures for NHS research in Scotland. As a national charity working across the UK we recognise the importance of the clinical research network support to enable the funders such as us to support clinical research across all the nations within the UK. It therefore makes sense that Scotland adopts the same thematic structure as the rest of the country. It is a real challenge to ensure that resources are linked to success, particularly when such a system is retrospective, but there is no doubt that NHS employees that can be freed up as part of their job plan to support research is a strong plus.

However there has to be an issue of measuring delivery and this balance between allocating resources pre hoc and post hoc is always a difficult one. It is difficult for us to comment on some of the locality issues but in general we are supportive of the plans you outline.

3. Association of Medical Research Charities (AMRC)

The Association of Medical Research Charities is the membership organisation of the leading medical and health charities funding research in the UK and overseas. Our vision is charities delivering high-quality research to improve health and wellbeing for all. Securing the best environment for medical research in the UK is key to achieving this.

Our members invested over £1.2 billion into UK medical research in 2012. Medical research charities have consistently spent more than £1bn on research over the past five years. Much of this investment supports research in the NHS, either directly or as part of university-funded studies. Scotland offers a high-quality research environment which attracts investment, evidenced by the fact that with approximately 8% of the UK population, Scotland consistently attracts 13% of UK medical research charity investment (*AMRC figure from AMRC grants database*). We welcome steps to maintain and improve this research environment.

We have confined our remarks to those areas most likely to raise issues for medical research charities.

As research funders investing in projects throughout the UK and overseas, our members value simplicity and consistency to enable them to navigate regulatory and infrastructure processes and identify and address problems quickly. This ensures the maximum proportion of each charity pound can be invested in the research project and the least is needed to cover administration costs. These proposals appear focused on achieving this, however it will be important to review the impacts as they are implemented to ensure the new structures are easily navigable by funders and compatible with processes in England to facilitate cross-border collaborations and multi-site trials.

The proposed concentration of research into a single set of themes corresponding to those operating in England is a welcome move if it ensures that all disease areas are properly covered and provides clarity in the strategic oversight of each clinical research theme. With this in mind we welcome the creation of operational, strategic and local theme leads which creates leadership with both national oversight and local expertise. However it is important to ensure that the delivery focus of the themes is aligned across the four NRS nodes to ensure delivery throughout Scotland. This is needed so patients can take part in appropriate research wherever they live, which will be an important factor in maximising patient participation in studies.

Steps also need to be taken to ensure strategic, operational and local theme leads have a strong dialogue with each other, and R&D staff and researchers, to foster greater collaboration, develop joined-up working and allow barriers to be quickly addressed.

The proposals if properly implemented should ensure a more consistent means of resource allocation across themes and regions which is welcome. It is not for those outside the system to comment on the precise financial flows but it is clear that where research budgets are embedded in other budget lines, they can easily be imputed to other costs, meaning they are then not available to support the research budgets for which they were intended. Clarity over who pays for research costs is important to ensure perceived financial disincentives do not impact on research projects. The AcORD principles which are supported by NHS Scotland² provide such clarity. It is also important to ensure there is clear responsibility for covering any excess treatment costs for NHS patients taking part in research.

² http://www.cso.scot.nhs.uk/SuppScience/Attributing_Costs.htm [accessed 22 August 2013]

It is important that the detailed design of these proposals facilitates the standardisation of data outputs across the network. This will be valuable to assess the impact of these changes and identify improvements. This will also allow the research support structures to demonstrate their value to future investors.

We welcome the ambition laid out in these proposals. As our members fund across the UK, steps to harmonise NHS research support structures across England and Scotland and ensure patients can take part in appropriate research wherever they live are welcome. It is important the impact of these changes is assessed throughout implementation to quickly identify and address any unforeseen negative impacts. We would be happy to arrange a meeting of research managers to scrutinise the impact of your proposals in more detail should this be helpful.

4. Brain Tumour Research (BRT)

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?

No it does not; there are some studies which are headed up by specialty groups which are outside the responsibility of Networks. This could lead to duplicated studies and the wasting of valuable funding. We suggest a cancer research register should be instated. This would ensure transparency in funding and prevent any duplication of work.

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?

No it is not, as it is not efficient to have a number of groups commissioning studies as we have previously mentioned it might lead to duplication of studies. This could be prevented by instating a register of research.

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?

There are a number of structural issues; there is limited local collaboration and national oversight between the two. Specialty groups also have no medical staff to oversee the works that they are doing, this may mean that work is taken on that is not suitable or effective but is not noticed because it is commissioned by a bureaucrat. Any restructure must bring in the specialty groups or have some sort of oversight in order to better collaborate, ensure effective delivery and prevent duplication of research. It is usually more efficient to have money concentrated in a few centres of research rather than dispersed very widely.

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

Despite the structural problems previously raised, it might be equitable to have some degree of independence as otherwise some detailed and niche research which would have been taken up by Specialty groups might not be taken up by Networks. But there should be some oversight to make sure this work is effective.

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

The main barrier for Brain Cancer Research is the lack of funding it receives. Approved Cancer studies were only 1.7% of all the applications to the CSO and brain cancer research was only 1% of all NCRI funding. Any reorganisation would need to set aside more funds for brain cancer research in order to make up for the severe lack of previous underfunding.

Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

Specialty groups would be able to access more funding if they were brought within the Network NRS node structure. However guarantees must be made that niche research will not suffer if brought into the Network system.

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?

Yes they should. It sounds like more of the budget is being freed up irrespective of any reforms. This will act as an incentive for more research. However NHS Scotland must ensure that niche studies will not be discriminated against, as by their nature smaller studies will attract fewer patients. However these studies can lead to important breakthroughs, and therefore they must be encouraged.

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

Currently specialty groups do not have medical staff to support delivery or supervise studies. We believe that there should be some requirement of medical staff, this may mean that work is taken on that is not suitable or effective but is not noticed because it is commissioned by a bureaucrat with little knowledge of medical procedures. We therefore believe that the planned closer relations with the CSO are welcome ones.

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

With more management there is the danger that the direction of research becomes disjointed and negatively affects research. If the proposed changes were implemented there should be clear job descriptions and power structures in order to avoid this and allow researchers to get on with the task of researching.

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?

It would be more effective than currently, where recruitment is managed through a number of different bodies. However one must question whether local Theme Leads would be able to commission and employ researchers for sufficient niche studies, and whether this problem would occur in every trust. Any reforms must address this issue.

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

They must have a suitable knowledge of medical research, they must be aware of smaller studies in their area of expertise, they must be able to keep track of all the studies going on in their area and nationally (a research register which we spoke of earlier would help this).

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)

This does not affect brain tumour research. Cancer would have its own local theme lead.

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?

If we are adding another level of bureaucracy we must ensure that it will work with the other levels effectively. The National Theme Leads must have medical experience, especially in some of the niche areas in their Theme to ensure that they will not be ignored. We welcome the fact that this would bring about a closer relationship with the CSO, which would hopefully lead to more funding for brain tumour research.

5. British Heart Foundation (BHF)

The British Heart Foundation (BHF) is the largest single funder of cardiovascular research in the United Kingdom, with a portfolio that includes clinical trials and clinical studies covering the broad remit of cardiovascular medicine. We spent over £5 million on research in Scotland in 2012-13. The BHF is the leading funder of clinical studies on the National Institute for Health Research's Cardiovascular Portfolio and as of December 2012 was funding over 100 of the 220 clinical studies recorded as 'open'.

The BHF thus has a strong vested interest in the Clinical Research Networks across the UK and how they operate and welcomes this opportunity to respond briefly to the Chief Scientist Office's consultation.

We are pleased to see that the proposed plans in Scotland mirror those in England in terms of a small number of Clinical Themes, including one devoted to Cardiovascular disease and Stroke, and we strongly support this change. In the context of a legacy of inconsistent infrastructure support for cardiovascular clinical research under the current system of geographically distinct Comprehensive Local Research Networks, and consequent delays in the progress of BHF-funded cardiovascular studies, these developments are welcome, and should directly address these barriers to research and help to ensure a consistent and streamlined approach to the support of clinical studies across the United Kingdom.

We also strongly support the continued promotion of incentives to conduct research in the NHS in Scotland via modifications of the NHS Research Scotland Researcher Support scheme (such as more direct access for the Themes to time earned by research active NHS employees) that will encourage and facilitate participation in clinical research.

6. Cancer Research UK (CRUK)

Cancer Research UK is broadly supportive of the proposals laid out in this Consultation. Research networks play a vital role in supporting research studies and are a key factor in the UK's position as a world leader in medical research. We agree that the adoption of the new NIHR themes in Scotland will promote cross border engagement and collaboration, which will be conducive to a better UK research environment. In our response to the NIHR Clinical Research Network consultation on clinical themes in February 2013, we emphasised the need to consider the impact on devolved nations of these changes and so we especially welcome this move to facilitate UK-wide studies.

We understand the move away from Topic Specific Research Networks towards themes and we welcome the continuation of cancer as a theme. However, elements of the current system do work well, in particular the support of cancer research nurses in clinical trial recruitment. We would ask, therefore, that existing expertise and areas of good practice are acknowledged and that steps are taken to ensure that this expertise is not lost during the transition.

We have some concerns about reduced resource level for cancer patients on clinical trials (which is already less than that available in England) following the reorganisation. We would like to see the level of per patient resource aligned with the level provided by the NCRN.

The fundamental aim of this system should be to enable and support research within Scotland (and, more widely, within the UK) and, as such, we believe that any new system should be pragmatically and flexibly designed in order to facilitate the work of researchers. We would ask that this main aim be borne in mind throughout the implementation of the proposed changes. In this context, we welcome the commitment in the consultation document to ongoing dialogue with the research community.

It is important to note that the Academic and Clinical Central Office for Research and Development (ACCORD) will further change the landscape for support and delivery of clinical research in Scotland. As a new initiative, it is too early to fully assess the impact of ACCORD, but it is an important element of the background against which these reforms are taking place and, as such, we believe it should be taken into account during implementation and evaluation of these changes.

We would also support the inclusion of a national Biorepository Lead and national data Safe Haven Lead within the "faculty" as we recognise the importance of biobanking and access to patient data for researchers.

As with any newly established system, we would ask that these changes are subject to rigorous evaluation and review. Opinions should be sought from those working within the system and there should be sufficient flexibility to adapt to any significant criticisms or problems which emerge once the system is established.

7. Dr David Hughes

Consultant Paediatric Nephrologist, Royal Hospital for Sick Children, NHS Greater Glasgow and Clyde

The single most important research development in my professional career, that has allowed me to actively contribute to paediatric clinic research, has been the development of the ScotCRN and its counterpart in England - the MCRN. Paediatrics has suffered in the past from poor research support because of its relatively small size and the particular challenges of recruiting children to clinical research studies. The coordinated links established across paediatric centres in Scotland have been very successful in promoting and implementing research. Support from trained paediatric staff has been crucial to this successful research. I know for certain that I would not have been able to participate in key research in my area if the ScotCRN support had not been available to me.

This paediatric research centre coordination benefits from the parallel development of paediatric national managed clinical networks that have been successful in supporting paediatric specialty medical care across Scotland. As the former lead clinician for the national paediatric renal and urology network (SPRUN) I have direct experience of the positive effect of the ScotCRN structures in drawing in other paediatric clinical units in DGHs to speciality clinical research. I have been able to encourage clinical colleagues to engage in research simply because of the ScotCRN support available.

As a speciality, paediatric nephrology across the UK has been recognised, along with paediatric rheumatology, as being one of the most successful in developing a paediatric research portfolio. It is crucial that any changes to the Scottish research structures recognises the particular needs in paediatric practice and in paediatric specialties that need to work across Scotland and the UK in developing the research network portfolio.

I am anxious that the proposed review does not adequately recognise the particular needs in supporting paediatric research. I would be hugely disappointed if the review sees paediatric research return to its 'poor relation' status in a research agenda shaped to meet the needs of the much larger adult research program and that the success of the ScotCRN is not built on.

8. **Dr Mark Petrie**

Consultant Cardiologist, Golden Jubilee National Hospital

It is acknowledged that a major gap in the research networks to date has been the absence of cardiac disease.

The new proposal to group all cardiac and cardiovascular research under "cardiovascular disease" is likely to have a detrimental effect on many areas of cardiac research. This is for 2 reasons:

1) There are some powerful players with a major interest in hypertension that may result in "cardiac" research being neglected.

2) There are identifiable enthusiasts in particular subgroups of cardiac disease that could easily link up around Scotland if enabled. Heart failure and acute coronary syndromes are 2 good examples. These should be treated separately. Scotland should have all regions linked up funnelling every patient with these conditions into clinical trials. Most studies in these areas are well funded. The benefits to NHS Scotland, researchers and patients are obvious.

If these areas are clumped together there will be many lost opportunities.

9. Dr Steve Cunningham

*Consultant and Honorary Reader in Paediatric Respiratory Medicine
Royal Hospital for Sick Children, Edinburgh*

I answer as a PI for pharmaceutical and non-pharmaceutical clinical trials. A CSO 'local champion' for the ScotCRN Board. A member of the MHRA Expert Advisory Groups for Paediatrics (PMEAG) and Cardiac, Diabetes, Renal, Respiratory, Allergy (CDRRA EAG).

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?

My experience is of a PI in medicines and non-medicines studies in children. For non-medicines studies the ScotCRN network has helped support a level of communication that has been very helpful in delivering multicentre national studies to time and budget. The infrastructure of experienced paediatric research nurses in each node was critical in the delivery of our HTA funded Bronchiolitis of Infancy Discharge Study (www.hta.ac.uk/2390) to time and target. For studies of medicines in children, pharma companies approach us both independently through our R&D departments and through ScotCRN. The direct approaches by pharma companies tend to be where we have a relationship with them (particularly as we are now known for our ability to deliver complex, low number, high impact, phase II protocols in young children). It is correct to say that this is not co-ordinated nationally, but is adopted within the portfolio of ScotCRN. Importantly however, the industry approaches via ScotCRN are gathering momentum; having established a strong portfolio of phase II and III studies, we are now approached about drug development opportunities pre PIP, and have continuing conversations with these biotech companies via ScotCRN. So yes, current arrangements provide advantages for both national identity and access, and also via specialist expert nursing teams 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?

The CSO is correct in identifying that there could and should be improved communication, information sharing and workflow between nodal R&D departments and networks. Scotland does not present itself as a 'unit' for investigation of pharmaceutical products (in paediatrics). A non-competitive understanding between nodal R&D departments that the collective Scottish output would be greater than the sum of its parts is work in progress. From my perspective, ScotCRN is providing some improved non-competitive understanding across nodes.

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?

As a ScotCRN network member, I am unable to comment on the efficiency of the adult Specialty groups. In paediatrics we have all adult specialties represented (Care of the Elderly being replaced by neonatology). With small numbers of specialists representing each of these specialty groups, work progresses to encourage paediatric specialty group involvement in Scottish research projects, particularly in relation to pharmaceutical trials. In some paediatric specialty groups cross nodal workflow already occurs, but not sufficiently for Scotland to be considered a

'unit' of application for effective delivery of phase I, II or III pharma trials in children across all specialty areas.

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

It is not equitable. But with limited resources it could be argued to be efficient. Momentum is key to the delivery of research projects to time and budget. Momentum requires all critical points in the chain to work effectively and efficiently - this requires funding and an element of flexibility.

Pharma momentum is being driven by Paediatric Investigation Plans: these are acknowledged to be slow burning in how many PIPs are coming through to clinical studies, but the reward scheme is providing increasing dividends - the notification to the MHRA of planned studies for the next 2-3 years in children shows significant acceleration. I believe that such studies will not be attracted to Scotland without (1) good paediatric infrastructure in CRFs - ScotCRN has enabled this in 3 of the 4 nodes (2) R&D departments working efficiently and effectively (as described in your text - some gains already made), (3) Effective PIs in each node for each paediatric specialty group.

Non-pharma momentum is being driven by the swing of funding to clinically based trials (from basic science 10 years ago).

The current research infrastructure, with core funded research staff developing and performing studies, will be vital to maintaining clinical PI involvement, but importantly too, to encourage greater involvement of PI naïve NHS consultants to engage in studies. ScotCRN enables and facilitates this model of working. A move away from this efficiency of working for clinicians would reduce or reverse the momentum for paediatric research in Scotland.

I accept that this will seem inequitable to some. CSO would need to be clear whether it could support all specialty groups to achieve an adequate level of momentum, or by distribution of support to all specialty groups would not enable any to adequately achieve and reduce the ability of the current networks to sustain their momentum.

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

I would consider there are five barriers

- (1) Relevance. In paediatrics there are many specialty groups. The networks need to appear relevant to all studies within the portfolio areas. The development of 'local champions' (similar to the proposed local leads) is helping to improve relevance of the network for all research. Work in progress.
- (2) Oversight. A single stream for clinical research in each node, reporting centrally, would enable a greater appreciation of all studies in each portfolio area and with it open opportunities to researchers and to networks at the same time. This requires a better workflow between R&D departments and networks so that information from all portfolio studies are shared and do not need to be 'adopted'.
- (3) Flexible skilled research nurse time. Our paediatric research nurses are highly skilled and this skill is gained over many years. The system needs to enable a core group of skilled nurses to be retained independent of short-term fluctuation in studies. The ScotCRN research nurse network is vital for that highly skilled and informed research nurse structure within paediatrics in Scotland.
- (4) Research interested and enabled PIs. The Scottish Government focus on 1 SPA consultant contracts for newly appointed consultants has been a disaster for encouraging younger research savvy consultants to work flexibly to enable pharma trials in their specialty area. Pharma studies in particular have few drivers for young consultants as the research usually does not lead to principal authorship on papers, carries less weight for University acknowledgement than researcher lead hypothesis driven research (which is where research savvy consultants come from and are comfortable with), and the Scottish Governments language and actions with regard to Consultant

awards provide no financial incentive to work outside job planned activities (note the recent reversal of this approach by the NI assembly due to the negative effect on the calibre of consultant appointments).

- (5) The patient premium. The patient premium drives high number studies with quick throughput but not necessarily of a high quality that will place Scotland in a position to be of relevance in acquiring world-wide quality studies. Studies that are low number, high input, high relevance and impact, score badly in this system and are poorly represented.

Question: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

I am not a member of a Specialty group area and therefore cannot comment.

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?

Yes. But careful consideration would need to be given as to how this would be considered success or otherwise.

With the ebb and flow of clinical trials, consultants will need to be provided with some time-based security of tenure. It should be made clear what studies would be included in the 'incentive to undertake studies and recruit patients'. It should also be made clear the objectives for recruitment over the timescale of the agreement (?3 years - possibly 5 years if first 3 years good) - high numbers or high impact? It would be important that the Theme leads both nationally and locally were able to guide decision making for these approving and removing these posts at a local level, and this be embedded in future management structures. In practice, many new consultants are on 10PA contracts and could take on additional duties as EPA. This would be straight forward. Consultants on 12PA contracts may be reluctant to replace EPA, unless there were a clearly understood time based security of tenure and specific guidance as to what would be considered appropriate activity to retain or lose the research EPA at subsequent review.

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

The current funding arrangement enables paediatrics to attract and retain high quality senior paediatric research nurse in most nodes. Without this platform it would be difficult to entice prospective PIs to engage in the current complex world of clinical trials, particularly for CTIMPs. Network management helps to provide a pan Scotland approach to projects - key for providing research opportunities to all in Scotland.

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

Yes - but the structure of this funding stream would need careful consideration. Paediatric capacity and momentum are built over time, and encompass intensive study of small numbers of patients, but with high impact for disease. A multidimensional assessment for funding would be complex but necessary to reflect the required outcomes for patients, academia and industry within Scotland.

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?

In many ways this reflects the current position for ScotCRN 'local champions', who look for issues relating to study recruitment and work to resolve them at a local

level. We still need to work within a Scotland wide framework and management structure to facilitate good communication and effective study support. Localism will embed localism and in this small population country I firmly believe that all children should have access to good quality research studies regardless of where they live.

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

As a ScotCRN CSO local champion, I am in many ways fulfilling this role in SE Scotland for paediatrics and so probably reflect my own attributes here, but would consider they would need

- (1) Research experience to MD level at least
- (2) Experience of working with pharmaceutical company sponsored trials
- (3) A clinician embedded in the current clinical service in that area; to understand the strengths of departments and individuals and how to enhance them.
- (4) Encouraging and enabling personality
- (5) The obvious GCP etc etc.
- (6) As 'desirable', membership of grant body review board or medicines regulatory board - to enable rapid sifting of study protocols to gauge quality and feasibility.

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)

I work with this for paediatrics. Along with senior CRF staff, I make myself aware of who currently is research active and those areas where requests are made for PIs, but with none currently available to support studies. Local meetings with clinical teams provide an open discussion on the benefits of working with the CRF and ScotCRN, and the support that can be provided. Experience in research and scientific review is vital to enable a rapid appreciation of study protocols with a few pertinent questions from specialists in the area.

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?

Yes.

Possible Model for the Future

Overall this would work were there management infrastructure for the strategic theme leads that enabled them to develop the theme and also provide oversight (I assume this would be similar to current Network managers).

10. Dr Steve Turner

*Senior Clinical Lecturer in Child Health and Honorary Consultant Paediatrician,
University of Aberdeen*



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23 August 2013

Mr Charles Weller
Chief Scientist Office
Scottish Government Health Directorates
St Andrew's House
Regent Road
Edinburgh
EH1 3DG

Dear Mr Weller

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

Thank you for the opportunity to comment on these proposed changes. I am a senior clinical lecturer in child health at University of Aberdeen and honorary consultant paediatrician at NHS Grampian. Change is usually good and it makes good sense to consider the organisation and remit of the present research networks north of the border given the changes in England. I have been in post for ten years and the introduction of the children's research network has revolutionised research in children in Scotland by, for example, allowing researchers to "buy" fractions of research nurse time for studies. The PAGES study (<http://www.asthma-pages.com/> funded by CSO) and BiDS study (<http://www.scotcrn.org/bids/> funded by NIHR/HTA) are perfect examples of how the network has enabled recruitment for multicentre studies in children. Additionally, the network has provided research governance support/advice for researchers and facilitated research/recruitment in centres outside of Glasgow, Edinburgh, Dundee and Aberdeen. As a direct result of the endeavours of the network, many more children living in Scotland are now engaged in research activity. We have a healthy track record for being able to recruit children. Clearly I am anxious that the major advances in child health research which have been enabled by the children's network are safeguarded during and after the proposed changes.

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?

Yes, in the case of the children's network.

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?

Yes, in the case of the children's network.

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?

The key structural issues are getting access to patients and access to GCP-trained and experienced research nurses (who are often employed on a sessional basis)

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

There are no specialty groups within paediatric specialties in Scotland of which I am aware but given that there are 16 clinical academic paediatricians in Scotland and a similar number of academic NHS staff, there are unlikely to be sufficient numbers in paediatric subspecialties to have such groups. The variety of paediatric specialties means that a single clinical paediatric specialty group would be very large and potentially inefficient and quite possibly unworkable. The present network is a more efficient model for Scotland's children.

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

The lack of research trained senior clinicians and trainees is probably the main barrier. Nursing staffing shortfalls appear to be quickly remedied by seconding staff from NHS and there are staff coming forward to such posts when advertised. Accommodation for research activity in primary and secondary care seems ample.

Question: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

Financial leverage is used by the children's network

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?

This is an excellent proposal but my experience with the NRS career research fellow's initiative is that awardees find it hard to pass on their clinical sessions and take up research activity. The profile of research within the NHS still needs to be elevated and using funding as incentive is a good way to make the NHS management sit up and listen. One way to ensure that research becomes part of routine NHS practice is to have newly appointed consultants (obviously with the relevant training at ST/SCRED level) with NRS sessions, I think we also need to identify champions (eg NHS consultant with HTA grants) in each centre to show that it can be done. The old model of academic or clinical/NHS consultant is outdated and every department should have a sessional commitment to research.

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

Always hard to compare the present arrangement with a theoretical alternative but I can't see how the present arrangement could be made considerably more cost efficient (1 administrator, pharmacist, data manager and research nurse in 4 centres)

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

Not easily applicable to child health due to the wide variety in subspecialties. Children are not small adults

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?

Again, hard to compare the observed against an expected/ideal but the present arrangement is very effective. On a practical note, I suspect that it will prove a challenge to identify a paediatric theme lead in each node.

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)?

I have serious concerns that a theme lead who was, for example, a stroke physician would be appropriate for children. Whilst I appreciate that there are generic research skills across all themes, having a lead for children's research who has no paediatric expertise is contrary to the ethos of the government's "A Scotland for Children" and "Better Health, Better Care".

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?

I would support a national vision for child health research (and for the other themes). To me it does not matter who puts this forward as long as there is a two-way dialogue between researchers and network/theme leader and that the vision is realistic but still ambitious.

Reading the proposed new model, the main difference seems to be that the proposed theme leads are likely to be clinicians who will be leading strategy and development whereas the present network has had a greater focus on the practicalities of delivering research. The logical progression would be for the children's network to remain in situ and a theme leader providing strategy and development which are then delivered by a structure very similar to the children's network. There can be no point in having strategy and development plans without the capacity to deliver.

Kind regards

Yours sincerely



Dr Steve Turner
Clinical Senior Lecturer

11. Managed Service Network for Children & Young People with Cancer in Scotland

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

RESPONSE FROM MANAGED SERVICE NETWORK FOR CHILDREN & YOUNG PEOPLE WITH CANCER IN SCOTLAND

The Managed Service Network (MSN) for Children and Young people with Cancer was established in 2011 and published its first Cancer Plan in 2012. One of its main aims is that every child and young adult (CYA) with cancer in Scotland is enrolled into and treated on a clinical trial, where a clinical trial for their particular cancer is open. Treatment on a clinical trial is regarded as the gold standard of care and paediatric trial recruitment has led all other cancers in this area. The current excellent survival rates for many cancers in children is due to serial improvements over time, which have been achieved through comparing different treatment strategies within large national and international trials and recruiting sufficient numbers of patients to power the randomised questions. The 150 new cases of cancer in the 0-15 year age group and 150 new cases in the 16-24 year age group, presenting each year in Scotland, represent a spectrum of cancers with insufficient patients with any specific cancer to run independent trials. Children treated within Scotland are therefore entered into trials which may be United Kingdom, European or internationally based. Increasingly, advances in prognostic markers are driving the development of trials for small subgroups of specific cancers, which can only accrue sufficient patients within an international setting. Whatever the recruitment population, it is likely that these trials will be part of the National Cancer Research Institute (NCRI) portfolio and be approved and overseen by the NCRI Children's Cancer and Leukaemia (CCL) Study Group.

The regulatory requirements of the European Directive on Clinical Trials has made the opening and running of clinical trials extremely onerous and as a result the number of open clinical trials available to children has fallen and this is reflected in trial recruitment ; 80% for leukaemia and 25-30 % for solid tumours in children. The rate of recruitment of teenagers and young adults has always been poor compared to children; perhaps one of the reasons that survival is inferior in this age group.

Although overall survival rates are in the region of 80% for all cancer types combined there is considerable variation between specific cancer types and across the age range from 0-24years. National and international comparisons are confounded by small numbers and diverse pathology across any tumour type, which explains many apparent differences in outcomes. However, we have little room for complacency.

Phase I and II trials, involving new therapeutic agents, are organised under the auspices of the European Innovative Therapeutics Consortium for Children (ITCC). There are nine ITCC accredited centres in the United Kingdom, one of which is Glasgow. All children in Scotland have access to new agents available within phase I and II trials, although not all of these trials will be open in Scotland.

Up until 2011, children with cancer in Scotland were treated on clinical trials run by the United Kingdom Children's Cancer Study Group (UKCCSG), later called the Children's Cancer and Leukaemia Group (CCLG) or the Medical Research Council (MRC). Part of the core funding of the UKCCSG/CCLG came from Cancer Research UK and based on patient numbers, this part funded data managers at the UKCCSG /CCLG Centres. After 2010/11,

academic trials were transferred to the National Cancer Research Institute Children with Cancer and Leukaemia (CCL) Group portfolio and in England a CCL NCRN was established to support data management, trial coordination and research nursing at the centres. The NCRN is not part of the devolved nation's structure and when the NCRN assumed support for clinical trials in children with cancer in England, Scotland, in line with the other devolved nations, found itself with no funding for trial support.

There is a perception, frequently articulated, that trial activity and support for childhood cancer is well organised and supported in Scotland. This is a false perception. CYA with cancer in Scotland are treated on both academic and commercial trials. These historically achieved good accrual rates because of dedicated data management and research nursing within each treatment centre. This model has been replicated by the NCRN, but neither the Regional Cancer Networks nor the Medicines for Children Network have replicated this level of dedicated support in Scotland. Currently data management and research nursing is funded by a mixture of NHS and endowment monies.

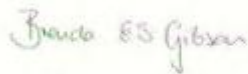
We are familiar with the reorganisation of the English National Institute for Health Research Clinical Research Network (NIHR CRN), and welcome the opportunity to respond to the consultation document on proposed changes to the support structures for NHS Research in Scotland which recommends adoption of the new NIHR structure. Furthermore, we welcome the opportunity to give our opinion on how research activity in CYA cancer should be organised and funded. The MSN has representation on the UK and Ireland Children's Cancer and Leukaemia Clinical Research Forum which the NIHR Cancer Research Network for Children's Cancer and Leukaemia established to maintain dialogue and inclusiveness, and we were therefore party to the discussion as these changes were introduced in England. It is difficult to comment in detail on the issues raised by the Scottish consultation document because we have little experience of the current structure, sitting virtually outwith it. However, we can support the following:

- There should be equity and uniformity between topic networks and specialty groups.
- Research funding should be separated from NHS support costs. Activity based funding may seem appropriate, but linking funding proportionately to patient recruitment disadvantages low volume, but complex and resource intensive studies. Childhood cancer will always be disadvantaged by a system which is solely dependent on the number of patients recruited even if recruitment is 100%. Because of the regulation around trial conduct in children, these are resource heavy and will only achieve acceptable recruitment if monies are ring fenced.
- A structure of 12 themes, each with a variable number of diseases, seems a reasonable structure. The issue for CYA with cancer is which theme would best serve its needs. Our collective view is that alignment with the Cancer Theme would be optimal for the following reasons:
 - Cancer services for children and young people in Scotland would be aligned in the same way as children and young people are aligned in England. This consultation document makes the point that it considers it sensible for Scotland to adopt the new NIHR themes to ensure continued cross border engagement and collaboration on clinical studies.

- CCL is rare, representing around 0.5% of all new cancers. It is well established that progress in treatment is crucially dependent on full integration of research into the treatment service, with high rates of participation. The clinical community in England considered all options within the restructured NIHR Clinical Research Network when it was at the stage of consultation, and felt that the Cancer Theme represented the only appropriate place for CCL to be placed.
- Adult, Teenagers and Young Adults (TYA) and Children's Cancers are all managed with a common approach, which is within a single service network structure, and should all be governed by national strategy and common local approaches. This provides the appropriate culture for a seamless approach to study delivery and development.
- Studies should be based on biology rather than age. Investigators are being encouraged to remove lower age limits for studies except where there is scientific justification. There are an increasing number of studies where there is overlap with patients that fall within the TYA population, such as Acute Lymphoblastic Leukaemia, and also with older adult patients, such as Osteosarcoma. TYA patients with cancer are managed by clinicians who treat children as well as clinicians who treat adult patients. The collaboration between these two groups of clinicians is essential to deliver not only optimal care but successful clinical research studies.
- In terms of the infrastructure to deliver research studies, the model of delivery for CCL relies upon the cooperation between Treatment Centres and their associated Paediatric Oncology Shared Care Units. One of the next stages is to ensure this can be delivered across all age cancer research studies.
- The conduct of experimental therapeutic Phase I/II studies within CCL is a highly specialised area within cancer. It requires a combination of specialist clinical skills and a clinical trial infrastructure to meet the demands of pharmaceutical companies. At present the early phase research is limited to 9 accredited Innovative Therapies in Childhood Cancer Centres in the UK that are all part of the Paediatric Network of Experimental Cancer Medicine Centres. Delivery of these clinical trials within a cancer theme provides the necessary expertise relating to complexity and potential toxicity of novel anti-cancer treatments.
- Radiotherapy treatment makes up an important part of the management of certain childhood cancers. This is overseen by Clinical Oncologists who predominantly manage adult disease but have a specialist interest in treating children. Radiotherapy treatment does not have a role in any routine non-cancer care of children. Radiotherapy represents only one of a number of highly specialised therapies relevant to cancer. Others include autologous stem cell rescue, use of tumour vaccines and cytotoxic pharmacy, and in each case collaboration between adult and paediatric infrastructure is essential to deliver not only care but clinical trials in these areas.

The single most important factor for the successful operation of clinical trials in CYA with cancer is funding for dedicated research and administrative support within children and young people cancer units. This will have to be ring fenced and recognise that

payment by recruited numbers will always disadvantage this age group. Within the structure of 12 themes, CYA cancer would best align with the Regional Cancer Networks. However, it is our strongly held view that an independent CYA cancer theme or specialty group with ring fenced resources would best serve children and young adults by allowing streamlining of processes, and that a single approach to rare tumours presenting in a diverse geographical area would optimise trial recruitment.



PROFESSOR BRENDA E S GIBSON

National Clinical Director

Managed Service Network for Children & Young People with Cancer (MSN CYPC)

12. Medical Research Council (MRC)

The Medical Research Council (MRC) is one of the main agencies through which the UK government supports medical research. We support research across the entire spectrum of medical sciences throughout the UK, in universities, medical schools and hospitals, independent research organisations, and in our own research units and institutes. We work closely with the UK health departments and NHS, and other research funders in delivering our mission to improve human health by funding world class medical research.

The MRC welcomes the opportunity to respond to this consultation on proposed changes to the support for NHS research in Scotland. The NHS Research Service (NRS) in Scotland has provided a very effective mechanism for delivery of research in the NHS. It is clearly recognised across the UK as a successful approach and MRC supports it being used as a firm framework for beneficial change.

The MRC has responsibility for funding across the UK and, as such, welcomes the proposed harmonisation with NIHR on national CRN themes. Many clinical studies that MRC funds or sponsors are conducted in both Scotland and England and an aligned approach to research in the NHS is strongly supported in order to support and further develop cross-border initiatives. The aim to increase patient recruitment in Scotland is, of course, strongly endorsed.

The proposed model allowing more proportionate and equitable support across the range of clinical research themes seems well reasoned and the MRC supports this, provided that Scottish researchers are also broadly in favour.

The MRC would also welcome CSO fully disembedding its funds from clinical budgets, allowing more transparency as to the use of allocated research funds and ensuring optimal value for CSO in delivering its core aims.

13. Medicines for Children Research Network

Professor Michael W Beresford & Dr William van't Hoff, Joint Interim Directors & Dr Vanessa Poustie, Assistant Director, Medicines for Children Research Network

We appreciate this opportunity to respond to the above consultation and would wish to offer the following comments from the perspective of the NIHR Medicines for Children Research Network (MCRN) for England. As you may be aware, the MCRN and the Scottish Children's Research Network (ScotCRN) have collaborated closely since both networks were established, and communicate regularly at both an operational and strategic level to ensure synergistic systems and processes to enable the effective delivery of paediatric research undertaken across the UK.

We welcome the proposal that revisions to the configuration of the research infrastructure in Scotland should mirror those currently underway within the English NIHR Clinical Research Network (CRN) as this approach will ensure that the new structure is as simple and streamlined as possible, particularly to clinical investigators, the pharmaceutical industry, and children and families. We note that the intention is to implement the revised structure by April 2014, and would reflect that whilst this is date matches the implementation of the revised NIHR CRN, it will be challenging to achieve this ambitious timeline.

One of the major changes within the reconfiguration of the NIHR CRN is the bringing together all of children's research within one theme, a departure from the arrangement to date which includes paediatric medicines research supported by a topic-specific network, and non-medicines paediatric research as a specialty group. We see this change as a very positive one which will bring great benefits paediatric research, and which mirrors an arrangement that has been in place for several years within Scotland – there is much that we can learn from ScotCRN as we take the NIHR CRN Children's theme forward.

We note the suggestion that within Scotland, network infrastructure becomes more evenly located across all of the existing nodes, rather than each area being aligned to a lead Board, and whilst we cannot comment on which approach is best for Scotland, we would reflect that the existing arrangement within ScotCRN works extremely efficiently. We are very much aware that ScotCRN have worked hard to ensure excellent engagement of paediatricians and paediatric research nurses from across all four nodes in the leadership and operation of the network, so would suggest that the existing arrangement within ScotCRN is working well. In addition, we know from our own experience that strong linkages with Children's Clinical Research Facilities has a significant positive impact on delivery of paediatric research, and agree with our colleagues within ScotCRN that ensuring this relationship is maintained is key. It is important that any changes to the overarching infrastructure doesn't compromise the considerable success achieved by ScotCRN to date.

The national oversight of research delivery has proved essential in ensuring the success of the paediatric portfolio in England, and we know that this is also the case in Scotland. A large proportion of paediatric research is in rare conditions (which makes up 70% of the MCRN portfolio) and is multicentre or multinational. National oversight of such a portfolio allows effective performance management, and the sharing of best practice and lessons learned, and is the most efficient way of managing these studies. The continued need for national oversight has been recognised within the agreed new structure of NIHR CRN within England where Children's research will be a theme within its own right, with national operational management in addition to clinical leadership. We would recommend that for the effective delivery of paediatric research in Scotland to continue, then appropriate national management structures need to be in place to complement local arrangements.

We hope that our comments are helpful and that you take these in consideration when shaping the future research infrastructure within Scotland. We are concerned that some elements of your proposed model may risk compromising the considerable progress made and success to date which has been achieved by ScotCRN, and could lead to a situation where by paediatric research once again becomes lost within the adult specialties, which would be very damaging indeed.

14. National Waiting Times Centre Board

Dr Catherine Sinclair, Research and Development Manager, National Waiting Times Centre Board

First thing to note is that this Board is a tertiary referral centre which specialises in interventional cardiology, cardiothoracic surgery and hosts the national Advanced Heart Failure, Pulmonary Vascular Disease and Adult Congenital Heart services. We have all of the usual support services – critical care, anaesthetics, nutrition, physiotherapy etc and have a very high through put hip and knee arthroplasty service. We currently host about 80 studies – mainly actively recruiting but some in follow up – most of which would be termed complex – device, CTIMP or surgical interventions. About 30 of these are commercially sponsored/funded with the rest split between eligible and NEF funding. The current network/speciality group structure does not appear to be within these topic areas so there has been minimal interaction with them.

Second thing is that we have been developing performance management bits and pieces which is essentially monitoring recruitment to target. Where there is a problem, the Research Support Manager (appointed but not yet started) will intervene and assess resource requirements. Previously this has been done through existing resources (me) but the RSM will take on this role in the next few weeks.

GJNH is in the fortunate position of CSO funding not being embedded so we can intervene (mostly extra nurse hours) quite quickly.

So, that is the position here and my thinking on the possible configuration of the Networks is as follows:

1. Their role in performance management should be carefully looked at. This is currently carried out by me for all studies and additionally by NIHR Portfolio people for eligible studies for which we are the lead site. Adding an additional level of performance management would (in my opinion) be a step too far for some researchers and may be counterproductive.
2. If the Networks were funded in some way and could provide resources, it would be something additional that we could call on if there was a study that needed resources we couldn't provide.
3. I support the third option in the document where theme leads have strategic oversight. I like the idea of open competition for the lead posts and hope that there will be a number of applications from DG Boards.

15. NCRI Consumer Hub

Peter JG Rainey, Chair, NCRI Consumer Hub

I've read the document circulated and the only comment I would make is that there is no mention of any role for Patient and Public Involvement or any reference to the potential contribution of PPI to the research effort. Given that CSO is an NCRI partner, this is very disappointing. Once again, I am left feeling that we are behind our colleagues in the South when it comes to integrating PPI activity into the model.

Largely due to the experience in cancer research, it is now widely acknowledged that patients, carers and members of the public have a positive role to play as “research partners”; helping to set research priorities, providing input to study design, recruitment strategy and dissemination – in fact every step of the research cycle. They are also well equipped to assist with issues of strategy and governance. This capability really ought to form part of the “supporting infrastructure” referred to in the document.

PPI should be an integral part of any new research organisation in Scotland. There should be clear funding for the identification, recruitment and development of people who can potentially contribute time and skills to the process of making sure research delivers better outcomes for patients.

16. NHS Ayrshire & Arran

Dr Alison Graham, Medical Director, NHS Ayrshire & Arran

Structure

Question 1 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.

Response The success of this model is not uniform. The model may have delivered more if there had been sufficient resources within each of the networks to either adequately staff or fund access to studies and delivery across all Board areas. Networks have adopted different models of addressing these issues and perhaps models of best practice could inform future developments. However despite these concerns NHS Ayrshire & Arran has worked hard to develop excellent working relationships with the existing networks that have allowed the portfolio of studies to increase and to engage with local clinicians. It is hoped that this success can continue and develop further.

Question 2 Are the respective responsibilities of Networks (within their portfolio) and R&D staff (out with the Network Portfolio) in overseeing delivery of multi-site studies within the same clinical areas clear or sensible?

Response There is a potential risk of duplication or omission if network staff and R&D are not in regular effective communication. Any reorganisation must ensure that artificial barriers to effective cross-agency working are not introduced in areas where effective relationships are already established.

Question 3 Does the current position of Speciality Groups within the wider NRS structure allow Specialty Group leads to manage their whole portfolio efficiently? What are the key structural issues?

Response

Engagement between the parties across the wider NRS structures may lead to some inefficiencies. Some further central direction may be helpful such as utilising national meetings to facilitate engagement opportunities.

Question 4

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

Response It is not equitable that some clinical areas have inequalities in the management structure of the research portfolio.

Funding

Question 1

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

Response The scale of the portfolio varies between portfolio areas and criteria for inclusion of studies may contribute to the barriers.

Question 2

Do Speciality Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

Response

Unlikely that there is sufficient financial leverage, however time is also a limiting factor for engagement with colleagues outwith own Board areas.

Question 3

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?

Response

Researchers do not state money as the issue for not participating in research. More often it is time and researchers regularly refer to job plan issues and time management with clinical service pressures as limiting factors. The role of research nurses in supporting researchers had proved invaluable as an incentive for local researchers in NHS Ayrshire & Arran,

Supporting Infrastructure

Question 1

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

Response It is unclear that funding arrangements are the main limiting step in the utilisation of the supporting infrastructure.

Question 2

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

Response

The criteria for linking could act as an unintended disincentive. Disease profiles require different study types and these evolve as diseases become better understood. In addition there needs to be a clear understanding that study delivery does not finish on the last intervention procedure for the last recruit. Shifting resources such as reallocation of staff to actively recruiting studies could seriously compromise studies which have follow-up for 10-20 years and may negatively impact on the quality of the full dataset that could be achieved in a study.

Leadership and Delivery

Question 1

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?

Response

It is unclear what added operational management advantage "operational theme leads" will add to the process of monitoring recruitment that is already occurring on a monthly basis between trial sites and centres and the network and R&D monitoring of trial activity at a local level. The scope of the role needs to be clarified.

Question 2

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

Response

Difficult to answer as the role needs to be clarified but given the emphasis of recruitment they would need to be highly experienced senior research nurses with excellent communication, negotiation and diplomacy skills.

Question 3

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)?

Response

They would need extensive training to develop the skills and knowledge for multiple disease areas. Without sufficient /effective training these roles run the risk of individuals being professionally vulnerable and compromised when dealing with experts in the disease area and promoting themselves as recruitment champions /troubleshooters.

Question 4

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?

Response

Any portfolio oversight and development role would require robust performance measures, regular monitoring of objective delivery. Given the different needs of different disease areas these objectives may not be standard across the 12 National Themes.

17. NHS Dumfries & Galloway

Dr Gwen Baxter, Research & Development Support Unit, NHS Dumfries & Galloway

P2 Structures

Q 1 of 4

We find that the structure of the cancer networks is best for this HB

Q2 of 4

This works well for us

Q3 of 4

No

Q4 of 4

No

P3 Funding - Researcher time

Q1 of 3

The main barrier would be network staff without a local presence by this we mean the network would have staff employed to work in this HB who would not be burdened with travel time.

Q2 of 3

We do not know

Q3 of 3

At DGH level the potential to offer research directed SPA sessions given an increasingly standard 9+1 contracts might well need back fill. Also consider teaching fellow model

As for time earned – yes

As for acting as an incentive - yes

Funding - Supporting infrastructure

Q1 of 2

Yes for cancer network

Q2 of 2

Needs attention to level and type of local support

P3 Leadership and development

Q1 of 4

We would use the term “Theme or composite Theme leads” – 12 may be too many for each node to staff individually – thereafter our response is yes

Q2 of 4

Management or clinical lead (an ideal candidate would have both attributes) and would need broadly based research experience

Q 3 of 4

We would agree with this accepting that there would be a need to combine /consider clinical staff with a broad remit e.g. acute general specialism, clinical pharmacology experience

Q 4 of 4

Yes

Comments on the model

12 may need to be combined at operational level

18. **NHS Fife**

Dr Alex Baldacchino NHS Fife Research and Development Director.

Thank you for the opportunity to comment on the proposed changes to the support structures for NHS Research in Scotland. I agree in principle that one urgently needs to review the current arrangements provided by the thematic groups and networks but reading through the document I was not sure on some macro issues:

- (1) It is not clear if this change will create a parallel system to that already in place through the R&D departments or will be in view of changing the current system into pathology related mini R&D departments
- (2) I do not think I understand the rationale of having 12 operational theme leads x4= 48 (Scotland wide) and then another 12 'strategic' leads mentioned. Do you mean that there will be 60 individuals involved in this process. Why not look at how the current R&D infrastructure can participate in how one can provide the leadership/strategy and then rationalise the operational leads.
- (3) The performance matrix of the expectations to these changes are unclear.
- (4) Is this an attempt to Anglicise a system and so does one intend to copy the NIHR model?

19. NHS Forth Valley

Allyson Bailey, Research and Development Officer , NHS Forth Valley

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?

Definitely not. There has been no incentive and generally little inclination to take or support studies outside the lead Boards.

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?

I have never found them so. Outside the lead Boards there has been considerable confusion around who is supposed to do what.

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?

I have little or no experience dealing with speciality groups or their leads.

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

I feel that if an area has active research then it should be managed the same as other areas, allowing for variations in scale. From the point of view of logistics and use of resources, this would probably mean combining the management of some smaller areas.

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

Presumably a combination of funding and staffing. There has also been a lack of knowledge among some investigators about the Networks, and some restrictions by the networks as to which projects they will accept

Question: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

I have no information about this, but I suspect not

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?

As I understand it, each Theme will be funded at several levels to help facilitate and increase research in those areas. There will be a local director deciding where resources should go. At Board level we would hope to get the following from the Theme leads: information on new studies, support for our clinicians in applying to take part and in some cases staff or financial support to help with capacity, and ongoing support in terms of things like supplying recruitment figures. Presumably all of this is what the Theme will be funded to do. Researcher Support is intended to pay for the time our staff spend on research locally, so unless some part of that is undertaken by the Theme I am not sure why they would have direct access.

If pretty much all clinical areas are covered by a Theme then there is not much reason to link Theme research to funding, unless the Themes are quite restrictive in the projects they adopt. In that case, the link would tend to disadvantage new, small scale research that is important because it is the starting point for investigators who will later go on to larger fully funded work.

Question: Do the current Network and Specialty Group funding arrangements allow the best use to be made of the supporting infrastructure?
As so little has reached our Board I can't really say

Question: Would linking more directly the resources awarded through the work of various clinical groupings and their management structures improve study delivery?
Does this mean linking the resources awarded to the management?
Not sure, but wherever possible the resources need to be weighted toward actually delivering the research in the Boards/Trusts rather than toward maintaining the Theme infrastructure

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?
Using Theme leads makes sense, as presumably they will have an understanding of the clinical issues, patient population etc. I'm not so sure about tying them to the Nodes (though they could be physically based there)—the remit should be for the whole of that theme across Scotland

Question: What attributes and qualifications are required by Local Theme Leads to successfully undertake this delivery focussed role?
As above, they need to have the clinical knowledge that most R&D staff lack plus an understanding of NHS organisation in order to help with issues such as clinic capacity etc

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)
Clearly it would be best to link condition areas that have a natural link, like stroke and cardiovascular. Where the areas are relatively small and need to be lumped together without an obvious link, the Theme lead will need very good links with clinicians in each area

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? What would the alternative be?
It probably makes more sense for the local leads to concentrate on delivery, feeding up to a smaller number of national leads (or just 1) who can look at the whole picture, liaise with leads in the rest of the UK and deal with any oversight issues. Better delivery will lead to better development almost on its own.

20. **NHS Grampian**

Joanne Rodger PhD, Senior R&D Manager, NHS Grampian

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?

The current structure seems to work better for some networks than others – it may be worth exploring where there have been successes what was it that worked and why. At present there does not always seem to be a fair and equitable process for access to studies across the whole of NRS.

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?

This currently leads to confusion as to who is ultimately responsible as both R&D and the networks have the same objectives eg for patient recruitment. It is not a good use of resource / time to have two separate groups overseeing the same functions ie duplication of effort. If the networks had a reporting structure through R&D who had overall responsibility for objectives in their board/node then this would seem to be a more efficient process.

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?

This probably could work better with a different structure. At present it is difficult for Specialty Group leads to intervene when a study is struggling to recruit outwith their own area. There may be local issues that are best dealt with at Board level rather than at a national level. However, it is useful if one site is not recruiting to have the national picture to help determine if it is a local issue or if there is a study-wide issue eg an issue with the protocol.

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

Definitely not, currently this is an unfair system where if you happen to work in an area with a network you have access to more resource than if in a Specialty Group. Support should be available to all if carrying out successful research programmes.

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

This depends on the definition of 'supporting' studies. Studies often require different levels of support from significant input research nurse time to update training of experienced research staff. The structures in place need to be able to respond to these varying levels of support required. Some researchers would find practical support on working through the approvals required and the set set-up of site files extremely helpful – although this type of support is also often available via sponsors and R&D there is a variable picture across NRS of amount of support available.

Question: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

No, although the solution is often not financial but lack of time eg consultant time. As Specialty Group Leads have a national role but funding is for support locally it is difficult to help in some situations eg a Specialty Group Lead in Glasgow would not fund research nurses to support recruitment in Lothian – this would have to be negotiated with Lothian.

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?

The issue is often not financial but time. The best researchers tend to do it for interest and for patient benefit rather than financial incentives. However, to have the time spent on research identified job plans would be good. This of course brings issues when research objectives are not delivered and how this would be judged prior to re-allocating research sessions from one researcher to another. In areas with limited consultants there may be staff keen to partake in research (with funding available) however, there may not be anyone else available to pick up a clinical session making the negotiations very difficult as the tensions between clinical work and research are stretched.

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

No, this needs to be more flexible as the numbers of studies (and intensity) in different areas fluctuate over time and we need to be able to be responsive to these changes and needs.

Question: Would linking more directly the resources awarded through the work of various clinical groupings and their management structures improve study delivery? Possibly. It would probably be of benefit in areas where research needs to be seen as integral to patient care eg oncology. If clinical management could more clearly see the benefits to research and subsequently encourage participation in research then it is a win win for research, clinical and the staff involved.

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?

Some of the network managers have managed this very well as a national role and without the requirement to be clinical. However, for others it has not been so successful. Again communication / interaction and problem solving is important to help manage delivery. Having local staff to be responsible for recruitment is probably a good thing as long as there are solutions available and there is still a national link to understand if the issue is only local rather than a study-wide problem.

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

Good communication skills and enthusiasm will be key in these roles as well a track record in successful delivery of research. A solution driven attitude is also important.

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)

This is a very difficult ask and will work better in some areas than others. For the Theme Leaders not to be conflicted will be difficult but perhaps with strong links / support to R&D, who can be independent, any issues can be resolved quickly.

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?

It is useful to have a national overview and it helps to share areas of best practice.

21. NHS Greater Glasgow and Clyde

Professor Chris Packard, R&D Director, NHS Greater Glasgow & Clyde

General remarks

We welcome the opportunity to comment on the document and to provide detailed responses to the specific questions. This is an important but challenging restructuring of the way clinical research is undertaken in the NHS across the UK. There are strengths and significant deficiencies in the current system of networks and specialty groups. The original cancer network continues to operate well and is considered a success. The effectiveness of the networks/ specialty groups in other disease areas is variable and some important topics such as cardiovascular disease do not receive the support needed. Thus, change is welcome and a more uniform approach across specialties will be fair and workable, and with time to become established should increase overall productivity.

With respect to the planned reconfiguration within NIHR (as in the diagram) there appears to be a high degree of complexity, overlap, and possible duplication of responsibility. It is not easy to see how this will work well or efficiently. What is put in place in Scotland should, while inter-linking with the NIHR solution, be simpler, cost effective, goal-driven, and easy to understand and navigate. It may well be worth piloting new structures to ensure they are effective before they become embedded. This could be undertaken in the more cohesive groupings first e.g. cancer or diabetes/ endocrine.

Further general concerns are the potential for increased bureaucracy if the Theme leads act as an additional management layer with data gathering and reporting requirements. Also, importantly, while the thrust of the change is to increase delivery of projects with regard to recruitment, this is a crude goal and overlaid on any new framework for research support must be the strategic objectives of excellence and the promotion of cutting-edge research that will enhance Scotland's reputation around the world; a single advanced gene therapy / stem cell trial outweighs any number of low level questionnaire studies in terms of impact and relevance.

Detailed responses to the questions posed in the consultation document are given below:-

Structures

Question 1: 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?

Networks vary in their national coverage and effectiveness. Evidence indicates that the network is most active and productive in the lead/ host Board (building on the enthusiasm of the network lead and management team) and that commitment is diluted as the geographical range increases.

Question 2: 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?

From a R&D perspective, there is ambiguity over who is responsible for key aspects of a study where a network is involved. This arises from the patchy interaction between network management teams and R&D offices. There is also a confusing lexicon of eligibility and

adoption that can lead to misunderstanding on occasion as to which organisation should provide what resources for multi-site studies. The relationship between networks and the local CRF is varied. Where it works well, collaborative working enables more studies to be conducted. In other cases, the CRF is only approached when there are staffing issues in the network (maternity; sickness). When networks maintain a distance in order to retain complete autonomy, they are likely to miss out on research opportunities that the NRS infrastructure offers. This is not sensible strategically.

Question 3: 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?

The ability of Specialty Group leads to manage a portfolio of studies can be hampered by lack of access to resources. The role of those leads in Scotland who are not UK national leads has not been entirely clear and many are unsure as to how to proceed to increase delivery of successfully completed projects. With a small number of exceptions, Specialty Group leads have provided a variable degree of leadership and in comparison with network directors have not been as accountable or productive.

The key structural issues are the nature of Specialty leads, their understanding of the role and responsibilities of the post, access to resources and lack of clear goals and deliverables. Without a clear understanding of their local or national role by other clinicians, their ability to influence is limited.

Question 4: Is it equitable or efficient to have some clinical areas managed as Networks and others as Specialty Groups?

Taking a long term view, there is no logical reason why some topics became networks and others the bailiwick of Specialty groups. Cardiovascular disease is a case in point where the major disease area in the country was not a network and hence did not receive the resources needed to operate at peak efficiency.

Ideally resources would flow to areas of research strength – or even areas specifically targeted to increase research strength. The split of funding between networks and the CRF (remaining specialties) would be better to be determined locally.

Funding

Question 5: What are the main barriers to Networks supporting all the studies within their portfolio area?

This is a multi-faceted issue. There is the perceived problem of access to sufficient resources beyond those that the network controls. Also, the buy-in from possible researchers across the country in boards that are not the network lead may be patchy. The exception here is cancer where the regional networks are integrated into clinical systems and there is effective national coverage. Networks also have to prioritise the studies they support, and this may be a reflection of personal interests of lead figures or the availability of specialist expertise. For networks to be all-encompassing, goals and objectives would need to be revisited and revised.

Network funding created additional layers of management, administrative and education support that arguably could be better spent on more nurses and data managers.

Question 6: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

Specialty leads have little in the way of leverage, in part through a lack of direct input into the local and national planning process. They have limited say in how resources (especially nurses) are allocated to studies and R&D/ CRF senior staff must weigh competing demands from different specialties.

Question 7: 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?

Linking funding to activity can be a means of increasing accountability and act as an incentive to perform. However, the more direct the link, the more practical and fair has to be the means of implementing it. It is difficult to see how a scheme that allowed a Theme lead to distribute research sessions to individual consultants would work. Job plans are decided on an annual basis by clinical directors, general managers and consultant staff. They tend to be relatively stable. Researcher Support will be provided by R&D to allow research sessions to feature in the job plans of the most research active consultants and this distribution will be decided each year or over a longer interval.

For Theme leads to be able to give a research session for a particular study as an incentive to participation there would need to be a pool of available (i.e. unallocated) sessions, the willingness of the consultant to give up a clinical session (or take an additional session) and the agreement of the clinical director and general manager. This all involves considerable negotiation as evidenced by implementation of the NRS Career Research Fellowship scheme. As a management approach to increase effectiveness of study delivery, it is unlikely to be agile enough to help specific projects that are in recruitment difficulties. The Theme lead may be able to be involved in the annual/ biannual strategic allocation of research sessions but again clinical directors may have different views on job plans and priorities.

Theme activity could be more easily linked to research nurse support.

Question 8: Do the current Network and Specialty Group funding arrangements allow the best use to be made of the supporting infrastructure?

Networks have access to nurses and other resources that are part of the NRS generic infrastructure, and there are examples of this working well and other examples where it has not. Specialty Groups are less functional and those researchers within specialties e.g cardiovascular disease have applied directly to CRFs for support and received it.

In practice the research infrastructure is still being developed and those networks/specialties that fully engage in the process of creating a fit for purpose infrastructure will get most out of it.

Question 9: Would linking more directly the resources awarded through the work of various clinical groupings and their management structures improve study delivery?

It depends entirely on what is impairing study delivery. The range of reasons as to why studies do not recruit to target on time is as wide as the studies themselves. Often, the target is set too high on the basis of partial or flawed information, or because a certain number needs to be promised to secure the work. More realistic project feasibilities will deliver an improved performance (measured as % of target recruited); these are achieved through an informatics-driven approach to target setting. Many trials currently seek small numbers per site and the patients are difficult to find; further resources will not help in this instance but again better intelligence and use of electronic health records will make a difference.

There are instances where the short-term application of additional resources will help. The nature of the support required varies substantially; sometimes it is a nurse to conduct visits, or a radiologist to read scans, or a cardiologist to monitor patients as they receive an infusion. No single formula will generate the flexibility needed and the pool of deployable resources needs to be large enough and able to be moved between specialties.

Question 10: 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?

There is a benefit in having a uniformity of approach rather than the current disparate management of topic specific networks – specialty groups – generic CRF support. Further, national networks do not appear to work equally well at all sites. A more harmonised, distributed model focussed on the 4 NRS nodes would provide more even coverage and arguably better management overall. Not all Themes will be equally active at all nodes and so there will need to be a matching of resources to activity with a provision to grow areas of strategic importance on a local or national basis.

Question 11: What attributes and qualifications are required by Local Theme Leads to successfully undertake this delivery focussed role?

The proposed model is dependant entirely on the quality and commitment of the Theme leads. In order to direct and influence behaviours they must be at a reasonable level of seniority – consultants or equivalent - and be willing to commit time and effort to further the work of others. The job requires considerable amounts of tact and diplomacy, negotiating skills and ingenuity. Consideration has to be given to the length of tenure and if clinically active consultants are appointed backfill for their current duties. It will be important that Theme leads are/have been research active and hence have direct knowledge of and are sympathetic to the difficulties that investigators face in delivering trials on time and target.

In the Beatson, delivery of trials is overseen by a committee comprising key clinicians, R&D, pathology, imaging etc. This committee looks at feasibility and clinician performance/ size of current portfolio. Such a committee can support a Theme lead.

Question 12: 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)

This should not be a huge issue in some areas such renal disease/ diabetes/ cardiology since the problems faced in recruiting to chronic disease trials will be common across specialties, and in many instances there are cross-cutting interests, for example coronary disease is a usual endpoint in many diabetic studies. Where the width of coverage is likely to be a problem is a Theme where the included topics are not naturally cognate e.g. 'haematology and childbirth', 'dermatology and musculoskeletal'. If a proposed solution is piloted it may be that what works for certain Theme areas is not a tenable solution for the more disparate specialty mixes, and other solutions will be required.

Question 13: 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?

It is important that development within the specialties is undertaken at a national level and matched to what is happening in other countries. There is a clear need to have Scotland represented in UK wide fora where studies are being conceived and designed. With the dissolution of the UK wide aspect to UKCRN networks and specialty groups and the development of the NIHR framework, Scottish researchers must continue to have a voice in the decision making process. We endorse the proposal to appoint Theme leads through open competition.

22. NHS Highland

Frances Hines, Research and Development Manager, NHS Highland

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?

No. It may work for the larger Health Boards, but is inconsistent in applications all the HBs in Scotland. One of the issues at the current time for Scotland appears to be that the NRSPCC office in Aberdeen are not automatically informed of all studies (commercial and academic) which are supported by the research networks, so there remains a discontinuity relating to sources of studies for R&D offices in NHS Boards. It would seem sensible regarding access for NRSPCC to be the collating point for all studies, whether network badged or not – it is not the job of the networks to process governance from feasibility onwards after all. This would relieve the burden of such processes from network staff allowing them to focus on implementation of studies more effectively. The current situation, where Boards are drip fed studies from some networks who make initial decisions about which Boards to include should be stopped. The decision should be taken by CI / sponsor or NRSPCC.

Study delivery whilst being monitored by networks at a national level, should be the responsibility of the network representative at the local level, and the Board R&D Office combined. Local governance and monitoring systems and personnel should always be the first port of call for sponsors and networks if recruitment targets are not being met.

The running of the networks in terms of quality, access and management is inconsistent. Some are well run e.g. SPCRN, and SCRN but others are poorly managed or have limited resources / development, and frankly are lagging behind the ambitions and focus of the Board R&D offices / strategies. They can be a rate limiting factor in determining the amount of studies taken up by Boards / Nodes. In NHS Highland, we have real support from SPCRN and SCRN, a tiny amount of support from the Scottish Dementia RN and even less from the Scottish Diabetes Research Network, and nothing from any other network. Despite this, we are one of the most active diabetes research HBs, have five stroke studies including CTIMPs, and have studies in many other clinical areas that are not supported by networks. So while the networks are supportive in some areas, they are not the main focus of the study obtaining and implementing process in NHS Highland R&D.

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?

Currently, it appears that there is some confusion about responsibility for the obtaining and implementing of multi-centre research studies. As previously stated, where the networks provide real support on the ground then it is much easier to work out what the different responsibilities are, but at national level there is a lack of clarity and not all the networks appear to act in an integrated and cooperative manner with the NRSPCC office or the Nodes.

On the ground support staff are vital for networks if they are to provide real support for research activity, however, they DO need to be fully integrated into the R&D department of each Board. Currently, it appears that in some Boards the research network local coordinator may not sit within NHS R&D or interact with them on a daily basis, which is inefficient. In addition, it is considered vital that the local

representative is fully integrated into the clinical research team i.e. clinical research nurses / data managers and others, as again greater efficiency can be achieved by having a very closely aligned approach with clear definitions and allocations of responsibilities and activities (this can be slightly different for each study – on a case by case basis).

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?

Speciality Groups appear to be so remote from the R&D process with no contact or interaction at NHS R&D level, that it is difficult to see how they can be called efficient. This aspect of the system needs to be completely restructured and a local representative / contact needs to be integrated into the R&D system in the same way that the better networks operate. That is, if the speciality groups really have something to offer that is different from the networks. We are aware that the specialty groups exist but have little or no real contact with them.

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

Obviously this is not equitable as that was the intention when these were set up, but mostly in relation to funding rather than management structure. It is an inefficient construct to have speciality groups and networks. Themes are more efficient, will cover more clinical areas and will enable a higher level of integration and support as long as this occurs with the NHS R&D office.

2. Funding

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

Again, this comes back to working 'better' with NHS R&D and the support provided through R&D funding for clinical and other staff to support studies generally. Capacity can be more efficiently used if it is doubled or tripled up with other research activities, i.e. network staff working locally would sit well within or integrated into the working processes of the NHS R&D offices.

Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

This seems unlikely. As the specialty groups are so poorly explained in terms of working directly with R&D offices in HBs, it is not clear whether they have access to any funding or resources to encourage the participation of local HB PIs. In NHS Highland, the R&D Office is the central point for stimulating and encouraging clinical specialists to become involved in research. New studies are obtained through NRSPCC feasibilities, through some of the networks or through regular reviews of UKCRN Portfolio and other database and direct contact with CIs to elicit confirmation about interest in new sites. We are aware of a very small number of studies that may have proceeded from specialty groups but because there is such limited exposure to their work, it is difficult to get an understanding of how effective they are.

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?

How would this be different from the engagement activities of the R&D Office as detailed above? Researcher support is already directly provided to actual and

potential PIs at local level to encourage participation in research studies. It is useful to be able to link activity to funding in this way. Any Board employee receiving funding for research activity needs to have this routed through the NHS R&D office. If the suggestion is that Research Support funding is removed from Boards and given to Themes, there might be a risk of some Boards having a reduction in local activity if Theme leads are not equitable in allowing access to all studies for all HBs. How would this work? Surely it is more efficient for R&D offices to identify the specifics of resource requirement of PIs locally rather than an at distance individual making those judgements – especially if the PI requires local support in terms of research nurses etc.

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

Since the current funding arrangements lack much clarity it is difficult to tell. However, from the R&D perspective the current approach is efficient, and we would suggest that infrastructure coordinated and focused through NHS R&D offices with integration of network activity / themes will always be more efficient.

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

What clinical groupings are being suggested here? Speciality Groups? Themes? Other? Seems unlikely. NHS R&D Offices should retain responsibility for managing funding that is attracted for R&D purposes. If there is other resourcing or funding going into clinical groups / areas then if it is for R&D activities then it should be coming through R&D? In terms of study delivery, if an R&D Office is not achieving target recruitment and making best use of local resources, then it is up to the R&D office to put that right. It is difficult to see how an at distance body / group would improve that (other than to put pressure on the PI – and it is often not the PI who is causing the problem).

3. Leadership and Delivery

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?

NHS R&D is essentially responsible for obtaining recruitment targets for all studies, but works with networks to achieve this. Some networks are much more interactive than others, so it is not consistent. If R&D has ultimate responsibility then whether it is networks or theme leads or other model as long as integration is complete and efficient then that is all that matters. If theme leads were appointed what extra would they bring to the table? Again, they could try pressurising PIs but frankly it is not often the PI who runs screens, identifies patients, and carries out the great proportion of research activity – it is the research team often paid for or supported by the R&D Office i.e. the research nurses, pharmacy, radiographer, data managers and so on. In the case of NHS Highland, how would an individual in NHS Grampian for example make a difference to recruitment in NHS Highland?

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

Whoever supports research activity in nodes / Boards / locally, a person acting for a specific clinical theme (especially covering a range of clinical specialisms) will need to have substantial research experience, a thorough understanding of different types of research (from Phase I CTIMPs onwards and all other likely activity in between, devices, including commercial and academic studies, primary care and secondary

care and so on), an understanding of the complexities of budgets and funding, an understanding of the NRSPCC system and Node working and an ability to fully integrate with the R&D system without adding more complexity for researchers. We would not expect this role to actively engage with clinical staff supporting research i.e. research nurses / pharmacists etc locally as this activity is fully managed through NHS R&D.

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)

It is unlikely that a local theme lead will truly have a full understanding and substantial research experience in all of the clinical areas covered by a theme. Inevitably, it might be that one clinical specialism lost some of the focus of that theme lead which would be a substantial weakness if the HB had specific clinical concerns and issues that were high on its priority list because of local populations. Local network supported individuals tying the focus of the HB and the node into the work of the R&D office would be much more equitably and independently managed.

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?

National steer through theme leads would be sensible, whilst allowing for nodal and local prioritisation where it did not conflict with the national focus. For example, if there was a disease prevalence in one node or HB then it should be possible to reflect this in local prioritisation. But a national lead could give credibility to Scottish health / medical issues as long as they were accessible to clinicians from across the whole of Scotland.

Views on proposed model

There has to be a change without a doubt. However, it would be inefficient to add layers into the system to replace existing layers as the issues that cause current problems would be replaced with similar problems. The R&D Offices need to be seen as the focus for more effective integration. While the networks are generally useful, they need to be quality controlled more effectively and to follow standardised processes in line with the R&D offices. Funding support can either come through networks for local individuals or through the R&D offices to support network individuals – this should not be insurmountable. National leads are a very good idea, but an extra layer of local / nodal leads unless they are advisory / focus related would seem unnecessary – especially if they were supposed to actively engage with local staff to support recruitment. Themes are a better approach than networks and specialty groups, but in the end that would seem to be semantics – it is not the name of the groups but their function and integration that is important.

23. **NHS Lothian**

Fiona McArdle, Deputy R&D Director, Research & Development Office

Structures

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?

Not consistently. This is variable and we should learn from where it works well and not so well.

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?

No. This needs to be more joined up to avoid duplication, and help consistency of data collection etc.

R&D staff do not know which studies are being supported by networks or specialty groups. It is not clear who should monitor recruitment and contact the PI if there seems to be an issue. Specialty groups do not have any resource to offer if there is a problem. The responsibility of the CI for recruitment is unclear within the current structures – absolutely nothing will overcome poor protocol design (academic and commercial).

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?

No. It needs a rethink. A reorganisation to place more emphasis on the Speciality group co-ordinator's role (time perhaps needs to be increased) and empower them to do more proactive management of studies. The Speciality Group Leads should have a more advisory role.

The meaning of 'manage' needs to be defined in this context. What is the responsibility of the CI/ PI here – do they contract with the specialty group leads?

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

Not equitable clearly. The delivery and development roles need to be more clearly defined and objectives set.

I would suggest that you nominate 30 key opinion leaders from the 30 speciality groups identified. Within these 30 leaders, I would suggest that some Theme Leads could be identified so that they have a dual role.

Funding

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

Capacity and engagement.

Quality – some studies may be good science, but the procedures are badly designed and they are never going to recruit well. Should networks take these studies on to help or avoid them to stop their recruitment figures looking bad?

Question: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

No. This needs to be joined up with local R&D funding.

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?

Possibly but challenging. There are many dimensions and issues here. Incentives are necessary. This may be very challenging to implement.

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

There are many examples where this does occur. The main problem is capacity and volume of activity.

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

Potentially. There is a need for incentivisation but whether the above delivers this is unclear.

Leadership and Delivery

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?

It would be better managed by dedicated Speciality Group managers rather than Theme leads.

It also pre-supposes that all studies fit neatly into themes but currently many studies are adopted by more than one network. This is confusing, particularly to researchers.

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

Not sure they exist. The Theme Leads should have an advisory role to the co-ordinators and managers. They are best placed to comment on strategy and direction as well as provide leadership for their Speciality Group area.

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)

With difficulty. This is particularly the case for some of the multiple disease areas incorporated into one Theme. This does not seem sensible.

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?

No. I think this is best served at the Speciality Group Lead level. Perhaps some select Theme Leads in areas of particular strength and importance for Scotland could be replicated but perhaps not all 12.

24. NHS National Services Scotland

Response to consultation on proposed changes to the support structures for NHS research in Scotland

The consultation paper sets out proposals to restructure NHS Scotland research infrastructure so that the current structure and resources are more efficient and transparent and are configured to align with NHS England and support UK wide research initiatives.

The paper is mainly focused on restructuring the clinical studies and trials infrastructure in the territorial Boards. The 4 Regional Hub Bio-repositories do have some impact on research and development in NSS and discussions are underway with CSO around NSS's alignment with the Lothian Hub.

We would like to draw attention to Recommendation 3 of the House of Lords Science and Technology Committee Report on Regenerative Medicine: which recommends that National Institute for Health Research (NIHR) establish a regenerative medicine stream of its clinical research network which spans the UK and builds on existing developed infrastructures like NHS Research Scotland (see below).

*“Consequently, we recommend that the NIHR establish a regenerative medicine stream of its clinical research network. Such a move would support researchers in addressing the specific needs of regenerative medicine clinical trial design, help overcome difficulties in identifying patients and ensure that doctors interested in such trials could be easily identified. The network could also facilitate dialogue with regulators on future regulatory needs and issues encountered with regulation. The regenerative medicine stream of the network should employ a hub and spoke model for allogeneic treatments, whereby it has one or two co-ordinating centres and regional operations. Given the need for clinical trials of a certain size, this network should span across the UK and build on existing developed infrastructures like NHS Research Scotland (paragraph 89). (**Recommendation 3**)”*

Ref: House of Lords Science and Technology Committee 1st Report of Session 2013–14
Report on Regenerative Medicine. July 2013
<http://www.publications.parliament.uk/pa/ld201314/ldselect/ldsctech/23/23.pdf>

25. NHS Tayside (2 responses)

(1) Sarah Auld, NRS Research Manager, NHS Tayside

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?

From my initial view of recruitment across Scotland it seems that there are still a number of smaller and more rural Boards which do not have the same level of recruitment or access to studies that the bigger boards do. From this I would deduce that access to studies is not optimised. I also think it is difficult for one central person to manage a portfolio of studies over such a big area, with multiple sites. I would imagine there is currently the potential for the host node to get more attention than the other nodes.

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?

This question appears to contradict the previous statement in the consultation, “we currently have three categories of study management oversight: Network managed, Specialty Group managed and those outwith the Network portfolio (and therefore unmanaged)”. As there is no real infrastructure to support the speciality group (SG) studies I would not define them as having study management oversight. There is potential here for overlap between the R&D departments and the networks. There does not seem to be a focus on monitoring performance of non-portfolio studies. There is also the potential for overlap between the networks, SG’s and the commercial teams. In my previous role there was clearer definition for portfolio studies as the R&D departments were not responsible for the delivery of studies, this was solely down to the networks (topic or comprehensive). The staff responsible for delivery of commercial studies were those based within the networks, rather than R&D. I believe that there is a lack of clarity and perhaps it comes from the lack of a comprehensive network, to provide management and infrastructure support to deliver and monitor the performance of the SG studies.

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?

I believe that the speciality groups do not have the resources (funding or staff time) to manage their portfolio of projects. In some cases the SGs have as big or a bigger portfolio of studies than the topics (e.g. cardiovascular) but the funding and resources to support this portfolio are not proportionate. To allow for closer management of their portfolio I believe it would be sensible to have local speciality or theme leads in each node.

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

As above. It is unfair for one group to have less access to resources to support the delivery of research than another. Resource allocation should be dependant on activity, but all specialities should have some access to resources. Perhaps an element of pump-priming is necessary for the areas with less studies, to generate more activity. If we move to one structure for all “Themes” I would imagine that the central performance monitoring and reporting would be more straightforward.

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

Limited resources, e.g. time to manage all the studies, staff to actively support the studies (limited research nurses etc), limited support cost funding, concerns about the quality of the studies.

Networks will not want to support studies where the study targets (e.g. recruitment) are unachievable as this will affect their metrics.

Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

If income from research (minus staff costs etc) is held centrally rather than fed down to the research active department there is no leverage.

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?

Yes I believe it would act as an incentive to link funding to research activity. It is important to have equity across the themes and to consider the complexity of a study (CTIMP/non-CTIMP, long follow up etc) as well as recruitment when attributing funding based on research activity. The allocation of funding from each node to the 12 themes would need to be transparent and evidence based. There would need to be a level of core funding paid initially (to allow for staff employment), then top up funding based on activity. There still needs to be central management of staff time, for those funded specifically for research. I also feel that by moving to a theme structure this should provide more stability and diversity for research staff. E.g if there is a lull in diabetes studies, the DSNs could support renal studies instead/as well. Have you considered the implications for retraining/ upskilling staff members to work in additional clinical specialities?

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

I am not clear how easy it is for speciality group studies to access additional supporting infrastructure e.g. nurse resource. I would hope that the changes to the themes would make the distribution of resources fairer.

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

There has to be a performance management and staff/resource management system within the SG's as well as the Networks. This should be in place for all themes under the new arrangement.

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?

Yes I think it will be easier to monitor performance and influence delivery at a local level rather than a national level, as those influencing will have greater understanding of the local situation. It is important that the local R&D directorate have input into who is selected for these roles.

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

There needs to be consideration for the existing structure and staff. It appears that the local operational theme lead roles are still clinical (consultant level or possibly senior nurse). I think this is necessary in order to be able to influence other researchers and clinical investigators. This means that the existing national leads will be able to apply for the strategic and operational positions. Some areas will need to identify a number of new leads.

There is too little detail at present regarding the management structure of the themes. Who will be responsible for the management of the administrative staff, Research Nurses, Clinical Studies officers etc? Is it the theme leads, a CTC/CTU or someone else? Where does the current R&D structure fit in? Will the new themes sit within the R&D directorate?

I do not feel that the majority of clinicians will have the expertise to manage this operational role in isolation. What about the role of the current network managers or similar? I think the current balance in the networks of clinical and managerial leadership experience has been very successful and should continue into the new themes. What is the rationale for not following the NIHR lead of including research delivery managers? The network managers are the current staff who will be most familiar with focussing on study delivery (reviewing performance metrics etc) and will also have the staff management expertise. There are a number of local and national options for what level of management you have (e.g. one "research delivery manager (RDM)" per node, one RDM per division per node, one RDM per theme per node etc), but I believe that some level of local management is necessary. This would create a role for the current research managers, and provide a management structure for the current network and administrative staff. You should also consider where the management of commercial studies fits under the new theme structure. An organisational chart similar to what NIHR have produced would be very helpful.

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)

By utilising expertise from current network staff in the new themes. By encouraging staff to diversify and cross specialities (particularly relevant to Research officers, research nurses etc). As before, consider retraining etc.

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?

Yes this role is especially important to ensure that there are studies coming through. We need to have a continuous flow of studies recruiting, to allow for job security for Theme staff.

A number of additional questions:

How will the delivery of each of the local themes be managed or monitored- by the R&D directorate in each node, or centrally by the CSO, by the national strategic theme leads or by the "faculty"?

Can someone be national strategic lead and also a local operational lead?

What FTE will operational/strategic theme leads have to dedicate to their role?

Have Scotland confirmed that they are adopting the same 12 themes in the same make up as the NIHR? Have we done modelling to show there is a fair spread in activity in Scotland across the 12 themes (as this may be different from England)?

(2) Professor Jill Belch, NHS Tayside R&D Director

Sarah makes quite a few of the same points I have made, in particular PIs do not have the Operational skills for this strategy, and we need some local managers to manage this process.

I have also made the point that clarity is essential over the role of the R&D office, and in particular the R&D Directors. The local PIs will need to be joined into a cohesive band and managed. This needs further discussion.

As you also know I am very supportive of this as it will allow a more equitable share of resources across all specialities. The devil is in the detail of implementation as all Institutions involved with the employment of current Network staff will have concerns regarding redundancy.

26. **NRS Industry manager**

Dr Steven G Burke, NHS Scotland Industry Liaison Manager

In general, it is vital that our customers (Pharma, MedTech) realise the benefit of support available within the NHS. Currently, the benefits associated with Network adoptions are unclear and support not equitable across Scotland. Therefore a joined-up, coordinated and consistent approach to the delivery of commercial studies across Scotland would further enhance our commercial offering and provide a unique selling point.

- ***Question 1: 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?***
 - In some cases the value that commercial companies receive from the Networks is clear and the support in setting-up, facilitating and delivering commercial studies is apparent (Dementia Network), and this provides a clear added-value selling point for 'adoption'. However, on the whole it is not clear what the benefit of network adoption brings to commercial studies in Scotland. Support can range from nursing to admin but how this is spread across, and within, nodes equitably is not clear. As a consequence it is not easy for NRS to sell 'network adoption' to commercial companies and there is no clear added-value that accompanies adoption. So, currently what do adoptions provide other than another round of approvals to access inconsistent levels of support at some sites? Again it is my experience that the Networks tend to focus on 'home' Boards rather than looking at support for studies across Scotland as a whole.
 - In addition, there does not appear to be any accountability for the networks to deliver and any revised structure should place an emphasis on detailed, accurate assessment of feasibility, planning and performance related funding with a management mechanism is essential. A national focus is also vital to ensure that the research capability of the country as a whole is developed giving research access to all patients regardless of geography.
- ***Question 2: Are the respective responsibilities of Networks (within their portfolio) and R&D staff (out with the Network portfolio) in overseeing delivery of multi-site studies within the same clinical area clear or sensible?***
 - The disparate approach to oversight of delivery often results in confusion, duplication of effort and is, at present, ineffective. R&D play a clear role in managing contractual obligations associated with commercial studies and tracking of delivery and resolution of infrastructure issues is a key role. However, the role of the Networks in overseeing delivery of multi-centre studies across Scotland is unclear and there does not appear to be any strategy in place to rescue studies that may be failing. Moreover, there do not appear to be clear lines of communication between R&D offices and the networks making effective management much more complicated.
- ***Question 3: 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?***
 - Currently the role of the specialty groups is unclear in terms of facilitating and delivering commercial studies. This may be due to the lack of access for Group leads to support infrastructure. In addition, management structure and responsibilities of the Speciality Groups are not well defined.

- ***Question 4: Is it equitable or efficient to have some clinical areas managed as Networks and others as Specialty Groups?***
 - No, a standard and equitable access to resource, planning and management of studies is required across the country ensuring we can attract Sponsors to open more sites in Scotland with managed delivery.
- ***Question 5: What are the main barriers to Networks supporting all the studies within their portfolio area?***
 - Network resource and access to external (outside of network) infrastructure can be a barrier to Networks supporting all studies within their area. In addition, there is a danger that network resources and support may be channelled to areas where the network leads have a particular interest, either geographically or academically.
- ***Question 6: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?***
 - Currently group leads have little or no control over research infrastructure. The poorly defined roles and responsibilities of the Specialty Groups mean that the groups compete for resource at the same level as all other investigators.
- ***Question 7: 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?***
 - Time access for investigators on commercial studies is key to increasing commercial activity and delivery across NRS. Therefore, it is essential that funds support areas of activity. In addition, while linking funding to activity ensures incentive to deliver on individual studies; there is also a responsibility to ensure resource is allocated in an equitable and transparent manner based on the merits of each individual study rather than geographical or academic interests of the Group leads. Allocation of researcher support may be a decision best made in conjunction with the R&D offices to ensure it meets demand and aligns with the research strategy of the Board. It would be difficult for the therapy group leads to negotiate and implement changes to sessions locally.
 - A danger of linking activity to funding comes from areas that are not currently active looking to increase activity and not having the funding platform to build from. So there should be a mechanism to foster research in new areas, perhaps encouraging a pay-back system where funds provided to buy out time to support commercial research can be recovered from the commercial income allowing a link with activity and also the capacity for the therapy group support to grow organically.
- ***Question 8: Do the current Network and Specialty Group funding arrangements allow the best use to be made of the supporting infrastructure?***
 - Currently Networks exist as separate to NRS and the infrastructure and have access and control over their own dedicated resources (nurses, administrators). Consequently, there is no cohesive approach to supporting studies across the country or even within each Health Board.

- ***Question 9: Would linking more directly the resources awarded through the work of various clinical groupings and their management structures improve study delivery?***
 - Moves to empower the new Therapy groups to plan manage and ensure delivery through peer support with a direct reporting responsibility to the R&D office may provide a useful and productive model. With this in mind, branding the therapy leads as NRS Delivery may help promote their role. Potential investigators should be able to have a co-ordinated interaction with R&D and Therapy leads when opening a new study allowing the formation of clear recruitment plans and defined mechanisms for identifying patients and solutions when recruitment does not go to plan.
- ***Question 10: 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?***
 - There will be a direct benefit in ensuring a consistent approach to study management across Scotland. Although there should always be national focus, some of the groups will be stronger in certain areas and these stronger areas should help support and encourage activity at other centres. Consistent, peer-led, solution based study management will ensure that studies are delivered to target. However, there must be clear lines of responsibility and the Theme Leads should report to other groups, such as R&D, who oversee the management of studies. Locally, a unified approach and regular trial/delivery steering committees could have a direct impact on study delivery.
- ***Question 11: What attributes and qualifications are required by Local Theme Leads to successfully undertake this delivery focussed role?***
 - Senior staff should be engaged as Theme leads, consultant level would be ideal. These Theme leads should preferably be NHS employees with a focus on NHS delivery across all responsible areas to ensure that access to resource is equitable. The leads should be research active/focused and have a good understanding of the commercial research arena and awareness of the aims of NHS Research Scotland. Theme leads should be team players keen to help Scotland deliver world class service to Pharma and ensure our patients benefit from new treatment options.
- ***Question 12: 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)***
 - This may be easy where there are defined groups that have some common cross over; however, some of the proposed themes do have quite differing therapy areas and this may be harder to manage without specialist input.
- ***Question 13: 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?***
 - It will be vital to this new approach that there is strategic oversight and the offering develops consistently across the country and indeed across the themes. There is a real opportunity to build something that will be a unique selling point for Scotland and further enhance our reputation as a place to deliver research.

On the whole the proposal looks like it will help move us forward; however, there must be clear lines of responsibility and accountability to ensure the groups meet the aim of ensuring delivery. Close and well defined working relationships with R&D will

be essential to ensure that studies are supported effectively and equitably across the portfolio.

27. Parkinson's UK

Parkinson's UK welcomes the opportunity to respond to this consultation. We're the largest charity funder of Parkinson's research in the UK. Major advances have come from research we've supported, and these have helped to improve treatment and care for people living with Parkinson's, both within the UK and worldwide.

So far, we've invested more than £60million in groundbreaking Parkinson's research. We currently support around 90 Parkinson's research projects totalling over £20million across the UK, and have some £5million committed to research based in Scottish Universities. We want to make sure that people's donations bring the greatest benefits to people affected by Parkinson's.

We would like to respond to a number of points raised in the discussion document.

Bringing Neurological Conditions into the Scottish Dementia Clinical Research Network

One of the main proposals in the new structure would broaden the work of Scottish Dementia Clinical Research Network to incorporate research into neurological conditions. Parkinson's UK believes that there are benefits to adopting similar structures to those in England, especially in terms of fostering and sustaining cross-border research collaborations.

Parkinson's UK strongly welcomes the proposed broadening of SDCRN's remit, as long as the new network is able to support neurological work in addition to its existing dementia workstreams. We believe that it will be challenging to achieve this broader remit without additional resource to support the expansion, and we are concerned that the consultation does not mention any increase in staffing or budget to support this new area of work.

We believe that research on neurological conditions is not currently receiving optimal coordination and support. Some researchers who undertake their research outside the current networks have commented that they find some of the bureaucracy associated with research cumbersome, and would particularly welcome a structure that minimised the bureaucratic burden. This is particularly the case for those who also carry a heavy clinical commitment, and whose research work presents low risk to participants.

Dementia is an important symptom of Parkinson's, with a major impact on quality of life for individuals and carers. One in three people living with Parkinson's have some form of dementia and up to 80% of people with Parkinson's may develop dementia during the course of their condition. Despite this, Parkinson's dementia remains an under-researched area. To date, the SDCRN has been involved with only one specific study on Parkinson's. This may reflect the fact that clinicians specialising in movement disorders work in different departments (and NHS structures) than those who specialise in Alzheimer's and other types of dementia.

In addition to encouraging researchers to consider cognitive symptoms as an important area for research, we hope that the expanded network will provide a

strategic focus for clinical research into neurological conditions. Neurological conditions such as Parkinson's are a major cause of disability. They account for one in five unplanned hospital admissions, and one in eight appointments in primary care, so research into these conditions has real potential to reduce NHS costs as well as improving lives for many people.

We are delighted that Parkinson's researchers and clinicians are at the vanguard of the ongoing development of neurological conditions research, such as the MRC Scottish Centre for Regenerative Medicine, the MRC Protein Phosphorylation Unit in Dundee, and the Anne Rowling Regenerative Neurology Clinic. We are excited by the potential synergies of bringing together researchers working on different conditions, where findings in one disease area may be relevant to others. We would hope that the new structure would encourage researchers to consider undertaking research work in neurological conditions.

Biorepository Lead

Parkinson's UK would welcome the appointment of a national Biorepository Lead to facilitate more coordinated working with tissue banks both within and outside Scotland. We believe that the cross border element of this work is essential - the Parkinson's UK Brain Bank at Imperial College in London is a member of the MRC UK Brain Bank Network, and the charity is also very involved in the Network which fosters collaboration between the UK's tissue banks.

The Parkinson's UK Brain Bank is the UK's largest brain bank dedicated to Parkinson's. It currently supports more than 100 research projects, and has more than 6,000 registered potential donors, including many who are based in Scotland. The high numbers of registered donors reflects considerable work by the charity to raise awareness of the importance of this area of research, and to recruit people with Parkinson's as well as our supporters without the condition to consider brain donation. The Brain Bank supplies brain tissue to researchers around the world, and we would be delighted to see more researchers in Scotland making use of this resource.

We would like to see the Biorepository Lead doing some work to engage with NHS colleagues to facilitate tissue donation where possible. We are aware that it can be very difficult for bereaved families in Scotland to fulfill their relative's wish to donate brain tissue, due to a lack of clarity about the legal and policy issues by some NHS employees. We would hope that having someone in a leading role within the NHS would make it possible to disseminate information and policy so that people's wish to donate can be respected, and to maximise the opportunities to obtain these valuable samples.

Separating Research and Clinical Budgets

Parkinson's UK strongly supports the decision to separate the research budget from clinical budgets, and hope that this will enable more research to be funded. We would also hope that, while recognising the importance of commercially funded trials, the new structure will also support more pragmatic clinical work that is not income-generating.

About Parkinson's

About 10,000 people in Scotland have Parkinson's.

Parkinson's is a progressive, fluctuating neurological disorder, which affects all aspects of daily living including talking, walking, swallowing and writing. People with Parkinson's often find it hard to move freely. There are also other issues such as tiredness, pain, depression, dementia, compulsive behaviours and continence problems which can have a huge impact. The severity of symptoms can fluctuate, both from day to day and with rapid changes in functionality during the course of the day, including sudden 'freezing'. There is no cure.

The average age of onset of Parkinson's is between 50-60 years of age, and incidence increases with age. One in twenty people with Parkinson's is diagnosed before the age of 40.

28. Professor Helen Colhoun

Prof Helen Colhoun, University of Dundee

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?

I agree it would be sensible to have a single entity responsible for overseeing the recruitment and ongoing fieldwork of approved studies and providing core centralised support – however there also needs to be versatility and a concerted effort to reduce bureaucracy. One way to do this would be for R&D staff to have clearly demarcated core functions that are generic across studies (costing contracting governance checks etc) whilst maintaining more clinically designated functions too (specialty specific recruitment and burse management) to some extent this already happens but could be more formalised.

In certain disease areas having nursing staff who are specialised in a given disease area can be an enormous boon to recruitment and of course embeddedness in the local clinical delivery team is even better. – this shouldn't be over looked. So the key issue is how to maintain this whilst a more “ generic “approach is being adopted. There should be explicit consideration with each study over its complexity and whether the design warrants any nursing specialisation or not and then a mechanisms for assigning specialised teams as needed.

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?

The key issue is how to ensure transparency over which studies get prioritised for recruitment. There needs to be a better oversight mechanism for ensuring that studies of importance to NHS policy are given as much priority as commercially funded studies and that an appropriate balance is achieved across specialties. One way to do this would be to consider the health policy impact of a given study. Another important structural / financial issue is how to ensure that funding from commercial studies is used efficiently to maintain and improve recruitment.

Question: Is it equitable or efficient to have some clinical areas managed as Networks and others as Specialty Groups? No its not.

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

Available nurse time both due to lack of secure bridge funding for nursing staff but also often lack of availability of nursing staff even where funds exist. Also competition for the same group of patients between different studies – this requires a policy on how to handle competing studies after an initial one has started.

Question: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

I don't think participation in research per se as distinct from being a local PI, is motivated by financial concerns generally – if you mean preparedness to become a local PI in trials then yes its important to ensure that enough of the funding received from commercial studies is made available as discretionary local spend to support further research related activities travel to meetings etc.

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? There should certainly be a transparent link between prior activity and future investment and there should be some part of the budget that is at the discretion of the theme.

Question: Do the current Network and Specialty Group funding arrangements allow the best use to be made of the supporting infrastructure? In my local experience no – but the more complex you make the structure the more remote the link between the investment and the desired outputs. So I think the key objective should be to maintain some degree of financial autonomy and flexibility whilst providing some aspects of the infrastructure in a more centralised way. I also think that consideration needs to be given to improvements in information systems and information flow as a means of making better use of infrastructure.

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

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?

See response 1 above only if the theme leads had some considerable budgetary discretion and control over nursing resource.

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

Experience of study fieldwork, good local reputation, good management skills, commitment to transparency and flexibility, a commitment to fairness and a personal interest in research.

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). I think the core function of theme leads isn't to think up research ideas or obtain the primary funding from studies – rather its day to day fieldwork management – so I can't see why that can't cut across a few disease areas.

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?

I agree that the intention to have champions for research would be useful. I would see these roles as being people who are essentially very research active themselves, have some reputation already with the pharmaceutical sector and who are prepared to act as champions or ambassadors for bringing in clinical research studies into Scotland. It might be best to avoid these people being called leads – as otherwise others in that disease area may start to worry that this will lead to a imbalanced allocation of funds or an appropriation of activities. These theme champions should have a small budget for promoting research in Scotland and Scottish participation in multicentre studies. They must be sufficiently well regarded across Scotland in their field. I actually think that although the local theme leaders can cover several disease areas that these national champions shouldn't be at theme level but at disease level – so for example outside of diabetic kidney disease – the renal specialty would probably want to have its own champion, and that person would in any case be more on top of renal specific trials programmes etc. So in short there is probably scope for more champions than thematic areas since primarily they would only need a travel budget?

On a final point (not a question specified in the consultation document)- some of the other core funding egg to support database development for research in different disease areas has proven invaluable in increasing Scotland's profile - I believe this should be maintained and indeed enhanced in the future and that greater sharing of expertise between disease areas on such

database development activity, but initially within thematic area, would be a good way to help to gel the different disease areas within themes together.

29. Professor S F Ahmed

(Confidential Response)

30. Prostate Cancer UK



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21st August 2013

To whom it may concern,

Consultation Paper: Proposed Changes to the Support Structures for NHS Research in Scotland

Prostate Cancer UK welcomes the opportunity to respond to CSO's consultation on the Proposed Changes to the Support Structures for NHS Research in Scotland. We have not answered all of the consultation questions; we feel we may not be best placed to answer some of these and we also did not consider that the required response is specific to our particular disease area, hence our responses are not necessarily directly relevant to prostate cancer research in Scotland, rather disease research on a more generic level.

Prostate Cancer UK is the UK's leading charity for men with prostate cancer and prostate problems. We support men and provide information, find answers through funding research and lead change to raise awareness and improve care. The charity is committed to ensuring the voice of people affected by prostate cancer is at the heart of all we do.

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?

The current structure is not fully inclusive to capture all studies, the 4 NRS Nodes would need to have both Networks and all Specialty Groups represented in each Node to ensure successful, coordinated delivery in all disease areas.

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?

This system allows studies to fall through the gaps where delivery is not being overseen and coordinated by either a Network or a Specialty group. This is a burden on R&D staff to try and

ensure they oversee multi-site studies when they are based in one site, and is not likely to be achievable.

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?

Key structural issues are that they work in isolation from the 4 NRS Nodes and the associated investments, thus have less funding and support. Also, there is not a Specialty Group Lead represented in each NRC Node, so geographical coordination is limited or simply not possible. These issues do not allow them to manage their portfolio efficiently.

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

This does not seem to be a sensible system. The same model should be adopted across all disease areas, the current system is wasting money and causing inefficiencies in study delivery. Networks have access to more investment and support and thus can deliver more effectively, as well as being represented across all 4 NRS Nodes. Specialty Groups do not have these advantages, thus certain diseases in certain areas are not catered for in terms of study recruitment and delivery. This is not efficient or equitable.

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

If there is crossover between disease areas this may create a barrier, and one or both Networks do not see this as within their remit. Equally this may happen if a project was spanning both a disease area covered by the Network, as well as one covered by Specialty groups or not covered by either. The Network would struggle to support, for example, a project on stroke and cardiovascular disease as not both of these areas are managed by Networks, highlighting the problem of this barrier.

Question: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

Specialty Group Leads do not receive the same amount of investment and support as the Networks. Service Support Costs cannot be claimed by Specialty Groups, thus they do not have financial leverage to encourage participation in research.

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

The Networks are not all-encompassing for all disease types and have given rise to the Specialty Groups which work independently from the NRS Nodes and are not formally embedded as part of the structure. This leaves some Specialty groups not existing within all NRS Nodes, thus leaving studies with no national coordination and management. The best use of supporting infrastructure would be if the Networks and Specialty Groups were amalgamated as one group and represented across all NRS Nodes, all with equal rights to access Service Support Costs.

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

Coordination and oversight at a national level would improve study delivery, to ensure that studies are truly representative of the population and including all the data and expertise necessary to deliver the goals. Access to tissue and clinical data should also be linked and coordinated at a national level to maximise the benefits from this resource.

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?

Yes, we believe this would be better, using Local Leads to manage study recruitment within a structure that is overseen nationally. Local responsibility for recruitment will be much more effective than at a national level.

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

Project management skills are required to coordinate and deliver at the local level. Also, someone with experience in data management and biorepository management would be of significant benefits to ensure careful and optimum use of tissues and clinical data collected through studies.

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)

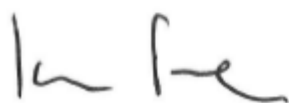
A single Lead would seem to be the most logical approach, but there would also need to be a role in place to keep an oversight at a national level, assist coordination of the studies nationally and play a role in development. Where there is crossover between disease types there would need to be agreement and commitment from both leads from the disease area to coordinate and support activities for this research.

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?

It would be desirable and would make much more sense to have national portfolio oversight of all disease areas, rather than the current system which results in exclusions and omissions in national oversight of all disease area studies. These roles should have strategic oversight of research activity in Scotland and work in coordination with the local, operational leads.

Thank you for considering this response from Prostate Cancer UK. Please do not hesitate to contact me with any questions.

Yours faithfully



Dr Iain Frame
Director of Research
Prostate Cancer UK

31. **Scottish Cancer Research Network (SCRN)**

Response from the Scottish Cancer Research Network

1. *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?*

Regional network responsibility to deliver to a National agenda of topic-specific performance objectives has been a key part of the success of the cancer research network. This, in combination with close alignment with the cancer research networks in other three nations in the UK, has given a strong sense of vision and identity. SCRN Clinical Leadership within each Cancer Service Network gives credibility to the Service interface and an expert steer to the local research workforce. Having an elected Chair provided valuable leadership and single route for reporting and correspondence.

2. *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?*

- Network personnel's experience and expertise in the cancer specialty gives clinical credibility within the Service. This affords intelligent portfolio management and contextual reporting.
- Study-specific delegated responsibilities to research staff are clear.
- Roles of R&D staff and Network staff in approval process are also clear.
- Reporting to the same performance measures is a duplication of effort. More sensitive, disease-area specific reports should be provided by topics/specialities.

Feasibility management can also be duplicated. The required expertise and close interface with the clinical service means this responsibility sits well with the Networks but must continue to be closely linked with the local Industry coordinators in R&D & NRS team.

3. *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?*

Unable to comment on Specialty Group portfolio delivery

4. *Is it equitable or efficient to have some clinical areas managed as Networks and others as Specialty Groups?*

A proportionately high level of research activity has influenced the development of and requirement for research networks and this investment must continue to be supported

5. *What are the main barriers to Networks supporting all the studies within their portfolio area?*

- Competing studies
- Lack of interest in the study question
- Local service capacity/delivery issues
- Lack of resource

- Consultant shortage in Scotland (largely due to less favourable conditions of employment compared to England)
 - Lack of clinician time and research interest
 - Inability to provide standard of care treatments that are not funded in Scotland
6. *Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?*

Unable to comment on Specialty Group finances

7. *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?*

In general, linking the level of theme research activity to NRS Researcher Support funding would act as an incentive towards initiating new studies and increasing recruitment.

For developing new researchers, the investment needs to be upfront rather than dependent on delivery, as per the current NRS fellowships.

Activity-based reward to allow allocation of research sessions in job plans will act as an incentive for researchers. There should be local freedom about how this is applied to the department/teams/individuals.

8. *Do the current Network and Specialty Group funding arrangements allow the best use to be made of the supporting infrastructure?*

SCRN funding is managed regionally and so can respond to local resource gaps, within the constraints of the budget. The funding is spent on research personnel with minimum contribution to non-salary costs (training, travel). Decisions regarding employment of network management staff are made at a regional level, based upon the size of those networks. Based upon the recruitment per capita to date across the network, these appointments can be concluded to have had a cost-effective impact.

There are local systems in place for workforce planning. The requirement to spend salary within the financial year means the ability to respond promptly to vacancies is paramount. Greater flexibility across years would significantly improve the current funding model and allow opportunity to offer longer term contracts which would make for a more competitive recruitment pool for research specialty careers.

There would be benefit from a more joined-up research workforce review and planning, specifically for posts where specialty experience is non-essential, or for cross-cutting posts (for instance within radiology, pathology, pharmacy). There should be defined budget to allow these departments to support research and respond with extra resource as activity increases.

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

We would very much welcome activity-linked resourcing. What will be crucial, however is

taking into account the level of resource required to conduct each research activity. If the metric is simply numbers of patients recruited then there is a clear disconnect. Some studies involve taking one blood sample from each patient; others involve preliminary molecular screening, months of complex often novel intervention (e.g. delivery of intraperitoneal chemotherapy) and then prolonged follow-up of the same individual. There may be as much as a thousand-fold difference in the cost per patient of delivering these two studies.

In addition with increased move towards individualisation of care in cancer research, the trial portfolio is moving in a direction of smaller study populations, increasingly complex trial design and more resource intensive studies. The resource required to deliver the contracted long term follow up (required for the majority of studies with curative intent) is significant. Earlier diagnosis and increased survival mean this resource requirement will only continue to grow.

10. *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?*

The present system for Cancer is such that local delivery is actively managed and overseen by regional leads and managers, with reporting responsibilities to the Cancer Service Networks. Becoming embedded in the NHS Cancer Service has been key to the success of cancer clinical research delivery. Any major change will threaten this. NRS Node boundaries are different and would alter the current staff management, patient referral pathways and reporting arrangements. In the case of cancer the current regional boundaries follow those of the existing clinical networks so change to this would result in a decrease in efficiency due to inability to follow the usual patient pathway for the patients within those clinical networks.

11. *What attributes and qualifications are required by Local Theme Leads to successfully undertake this delivery focussed role?*

- Experienced Trialist & Investigator
- Senior Clinician
- Leadership
- Team working
- Performance management/project delivery experience

12. *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)*

For Cancer this is already the position as it overarches multiple specialities and specialists within oncology and clinical haematology. In addition, the multidisciplinary team (surgeon, oncologist, radiologist, pathologist) approach to cancer patient care means relationships between specialties are already well-forged.

13. *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?*

The experience with cancer, particularly at the UK level, suggests that giving a theme lead the role for both development of, and delivery on the portfolio works, as can be seen in the significant rises both in the number of cancer trials, and the recruitment to that expanded portfolio. Co-ordination across Scotland will allow some clinical questions to be answered

just within Scotland – others will still need collaboration with the rest of the UK and beyond, but being able to co-ordinate this across Scotland will enhance our delivery and allow Scotland to go back to punching above its weight. The Theme leads will have to understand and work with the clinical community whose support is essential for research delivery.

14. *Possible future model*

- There needs to be Patient and Public Involvement which should include representation at both National Executive Board and Local Delivery Level. The Consumer Research Panel for the SCRN should offer representation. There should be clear funding for the identification, recruitment and development of people who can potentially contribute time and skills to the process of making sure research delivers better outcomes for patients.
- UK-wide networking has been fundamental in the success of the SCRN. The Theme structure must link with counterparts in the rest of the UK to share expertise and experience.
- For cancer, funding is currently allocated across Scotland per population – this has the advantage of securing staff resources. For some specialties inactive areas/teams can waste valuable resources. On the other hand, recruitment-based funding risks workforce stability and penalises portfolios heavy in complex, resource-intensive, stratified treatment trials. The example of the hybrid approach as has happened in England, where the topic networks have core population-based funding, supplemented by CLRN budgets based on research activity provided both stability and rewarding the research active, minimising the risk of staff being in post but doing little research in research inactive teams/disciplines.
- The NIHR have agreed stable core funding for Cancer in recognition of the NCRN track record of delivery, and study type: treatment duration/long-term follow-up study requirements. This is required in Scotland to minimise research governance risk and to maintain current high workload.
- The NIHR include Childhood Cancer and Leukaemia in the Cancer Theme. This should also be the case in Scotland in order to provide the teenage and young adult trial portfolio with equitable access to resource and to allow smooth clinical research pathways between paediatric and adult cancer care.
- Currently the Network Clinical Lead holds budget responsibility and workforce planning. In England this responsibility will remain with a Clinical Director independent of RM&G. Prospectively resource management will sit with the R&D Directors while portfolio delivery and performance management will remain the responsibility of the Operational Theme Lead.
- Will the Clinical Theme budget allocation be at National Executive Level or NRS Node level? How will equity be ensured in Nodes where Themes have local academic and clinical strength? A hybrid funding model (core and activity-based) would help reduce risk of inequitable access while reward success.
- The National Executive Board should be supported by a Chief Operating Officer who will be responsible for reporting research delivery to defined measures, workforce

composition and performance, and national budget. The COO will also have responsibility to interface with counterparts in the rest of the UK.

- The Operational Theme Lead should have responsibility for portfolio composition to address gaps, to support local areas of expertise.
- The Operational Theme Lead needs to have a professional (clinical expert) line of responsibility to the Theme workforce.
- The consultation paper makes no reference to how the clinical themes will be managed. The NIHR will have at least one research delivery manager for each division. The new structure must include Research Delivery Managers. If responsibility for performance to time and target sits with the NRS Nodes, there needs to be investment in divisional research delivery management at each node.
- Risk to currently active studies must be kept to a minimum by ensuring stability to grass-root personnel.

32. Scottish Children's Research Network (ScotCRN)

Question 1: 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?

The present ScotCRN structure with its national coordination and responsibilities is delivering optimised national access to studies and effective study delivery. ScotCRN has consistently exceeded recruitment targets as set by the CSO and despite only contributing 8% of the Child population to the UK contributed more than 15% of all child recruits to trials and clinical studies in the last reporting year (2012-2013).

ScotCRN is led by practising paediatric clinicians from all four NRS nodes and its lead board meets in the respective Children's CRFs in the four main Children's Hospitals on rotation. All ScotCRN core funded research paediatric nurses submit monthly recruitment figures for their respective node and meet on a 6-8 weekly basis to discuss recruitment to each trial and to resolve network and research issues. The network manager also meets with the senior managers in all four NRS nodes on a regular basis and commercial managers in each node are made aware of all contact with clinicians in their respective nodes. Commercial managers take responsibility for Confidentiality Agreements (CDAs) for their respective boards and network support is provided in the set up and delivery of trials with recovery of funds for any required additional paediatric research nurse support required for trial delivery. The availability of core funded experienced paediatric trained research nurses has proved invaluable in assessing feasibility for locally based clinicians, for training and mentoring of locally appointed research nurses on fixed term contracts and for providing back up and cover for illness and annual leave. Core funded ScotCRN staff also support the recently established Young Person's Group (YPG) which provides valuable public engagement and which is increasingly being accessed for advice on the feasibility of research protocols for commercial and investigator led research studies and trials. Access to the YPG has also proved invaluable in identifying the key concerns of young people in the secondary use of NHS data including electronic patient records and biological samples in pursuit of important research questions and safety issues.

The current infrastructure which includes a manager, pharmacist and data/ web manager who have national responsibilities and a network of paediatric clinicians covering the paediatric subspecialties means that sites are identified and potential local PI's approached close to where

the required patient population is clinically managed. The MCRN (England) and its successor have a dedicated industry team who work with Pharma to bring commercial trials to the UK, and ScotCRN benefits from this valuable infrastructure as all feasibility enquiries received by the MCRN are sent directly to ScotCRN. In addition some requests are received from NRS-Permissions and directly from Pharma. Good communication is now established across Scotland through existing NRS structures and paediatric clinical speciality service groups which ensures a rapid response to such enquiries. If user views are required access to the ScotCRN YPG can also be arranged.

ScotCRN in partnership with the other 3 equivalent UK children's networks is increasingly being asked by industry and CI's to comment at an early stage on the feasibility of proposed trials and research projects. Such communication is encouraged by the Paediatric Committee of The European Medicines Agency which is concerned about the subsequent non feasibility of some protocols submitted as part of Paediatric Investigation Plans (PIPs). The latter appears to be in part due to a lack of early discussion with clinicians practising in the European context of member state provision of health care for children.

In our experience study delivery is most effective in nodes where the Children's CRF and Network nurses are embedded within the paediatric and child health clinical service. Where lead research nurses are line managed (for clinical aspects of their role) by the senior management of the respective children's hospital there is a clear understanding of the role of the Network nurse. In Aberdeen, Dundee, Ayrshire and Arran and Lothian the Network lead research nurse is considered as the local Specialist nurse for clinical research and attends all local Specialist nurse meetings. Consultant Medical Staff, as well as other interested researchers in Paediatrics and Child Health, together with R&D staff and Academic Science Centres recognise the Specialist nurse as the local operational manager of the network. The lead nurse has autonomy to manage delivery of the local portfolio and a team of research nurses. This includes allocating, nurses to trials, managing nursing resources to provide sickness and leave cover and responding to urgent requests for support from Specialist Nurses in the delivery of clinical trials. Local paediatric consultants are aware of their Network lead nurse and approaches are made directly to them regarding network support for feasibility, set up, and/or sessional support for the delivery. The lead nurses regularly communicate with the Network manager and both feasibility responses and support in multi-site trials are coordinated across all sites. The research nurses operate alongside clinical specialist nurses

in clinics and on wards to provide the research expertise as required. A different model is implemented in the west NRS node where all research nurses are line managed solely within NHS R&D resulting in some reduction of their visibility and that of the Network within the respective children's hospital. Within West node the paediatric research nurses are all appointed at the same grade with no designated clearly identified team leader within the paediatric CRF. The ScotCRN nurse attends ScotCRN nurse meetings but has no autonomy to implement SOP's or strategies locally. As can be seen from the ScotCRN 2012-2013 annual report despite having the highest number of trials open and the highest proportion of the Scottish child population this node had experienced a decrease in the number of children recruited to adopted clinical studies.

Thus, clear line management within teams of research nurses, all reporting trial delivery against target to the Network Manager is proving to be the most effective model within ScotCRN. Any problems in recruitment are identified at their onset and strategies put in place to return to monthly target. If low recruitment is due to problems out with that of the local team, the network manager or pharmacist can identify whether these problems are also occurring in the other UK and all work together to resolve issues.

The ScotCRN pharmacist liaises with paediatric and clinical trials pharmacists across all nodes via the Scottish Neonatal and Paediatric Pharmacy (SNAPP) Group and is also a member of the national pharmacy Clinical Trials Special Interest Group (CTSIG). Links are maintained with MCRN pharmacists and the ScotCRN pharmacist is a member of the MCRN pharmacist group that reviews commercial trial protocols submitted for adoption, to identify any IMP management or set-up issues.

Unlike the adult specialty networks all paediatric sub-specialties, with the current exception of cancer are supported by ScotCRN. This requires networking to identify the strengths and needs of PI's in each paediatric specialty within each node. Having a national manager who works with the established paediatric managed clinical network leads in Scotland, with the equivalents across the UK and who can represent Scotland at the UK and European level has proved invaluable. SCotCRN is one of 18 category 1 (the highest level of competence) networks recognised by the EMA and only one of 3 with an established YPG.

In rare conditions and in trials with a small number of eligible patients, (which currently form the majority of industry led trials, it is essential that close collaboration between the four NRS nodes is maintained. It is fortuitous that in Scotland such children are managed nationally within managed clinical networks and that ScotCRN has established excellent working relationships with these networks in the

development, feasibility assessment and delivery of industry sponsored clinical trials and investigator led studies.

Question 2: 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?

ScotCRN extended its remit in 2010 to all eligible clinical research in children. This has been very successful and the MCRN (England) and its successor have now also adopted non-medicines clinical research studies. For multi-site studies, which form the majority, management within a national network has the same advantages as outlined above for industry sponsored clinical trials.

Question 3: 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?

The Specialty Group relevant to ScotCRN is the non-medicines specialty Group. As stated above our remit covers both medicines and non-medicines trials. All paediatric specialties apart from cancer are supported within the ScotCRN. There are no key structural issues for ScotCRN, apart from the lack of visibility of the West Node amongst local practising clinicians consequent to current positioning and line management of research nursing staff within NRS.

Question 4: Is it equitable or efficient to have some clinical areas managed as Networks and others as Specialty Groups?

ScotCRN covers all specialties within paediatrics, with clinical representation from all NRS nodes on the Management Board of ScotCRN. The clinical specialty groups (and Managed Clinical Networks) are accessed to provide specialist advice when feasibility enquiries are made. This enables a rapid consultation on feasibility in the Scottish context with access to the YPG if required (see earlier comments in response to question 1). This is of particular relevance when a PIP has been approved by the EMA Paediatric Committee. The PIP may have been approved before the phase II adult data has been obtained and in that time there may have been significant changes to clinical practice or the availability of alternative drugs for the same indication. Hence the increasing realisation by industry and the regulator of the importance of early consultation with clinical research

networks such as ScotCRN with access to the relevant clinical expert opinion (see also response to question 1).

Question 5: What are the main barriers to Networks supporting all the studies within their portfolio area?

There are no barriers to Networks supporting all studies within their portfolio if they have the nursing capacity to do so and if research nurses are visible to and accepted within their respective clinical service. The latter issue is in our view central to the establishment of good relationships and successful study adoption and recruitment at local level (see further comments on research nurse management in response to question 1). Nursing capacity can be built using flexible strategies if these are supported by R&D and Hospital management. There have been difficulties recruiting staff to fixed term contracts in Boards where there is uncertainty of redeployment back to the NHS. Part time secondment opportunities would be attractive to nurses that want to maintain clinical skills whilst working for defined periods in research. Such movement between the clinical service and research also has benefits in contributing to the establishment of a research culture in the NHS.

Question 6: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

Financial leverage is not used by ScotCRN. In our experience clinicians are encouraged to participate in research by providing experienced assistance in completing feasibility questionnaires, Site Specific enquiries by CROs and industry sponsors in the completion of IRAS applications and in the provision of experienced research nurses able to support and mentor clinical research staff on term appointments. Clinicians see advantages in participating in trials in order to provide access for their patients to novel therapies and indications while contributing to the clinical therapeutic evidence base. In ScotCRN's experience the main perceived barriers are their own and clinical specialist nurse time and knowledge. If this can be resolved with practical help and support through the research governance process, pharmacy support and experienced research nurse support clinicians are generally willing to participate in clinical trials and applied clinical research as evidenced by the greater than expected contribution of Scottish centres, on a population basis, to UK wide paediatric clinical research.

Question 7: 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?

ScotCRN would welcome more direct access to the NRS researcher support budget as this would recognise individual clinicians' contributions to the promotion and delivery of clinical trials and applied clinical research within the NHS. As the majority of clinical trials in paediatrics and child health and an ever increasing number of applied clinical research studies require collaboration and coordination across sites we feel that this needs to be reflected in management of such support. This would require input from both network and respective NRS nodes in the allocation of such support in and in the informing of job plans and contributions to annual appraisals. Allocation of a dedicated specialist/research nurse to a research active team with a portfolio of trials would be one cost effective way of supporting clinical consultants with time constraints. Many clinical drug trials are integral in the clinical treatment of the patients and increased specialist/research nurse that can support clinics could free up consultant time rather than trying to identify additional consultants to cover clinics.

Question 8: Do the current Network and Specialty Group funding arrangements allow the best use to be made of the supporting infrastructure?

The current arrangements need to be standardised across all boards. In Lothian, Dundee and Aberdeen remuneration from non commercial or commercial trials is used to build capacity with the respective paediatric CRF. In Glasgow this is absorbed in to the adult CRF. As a result less nursing support is available in Glasgow compared to the other three nodes. This has caused difficulties in staffing and the consequences are evident in recruitment per node as reported in our Annual Report. ScotCRN has appointed 2 paediatricians in each of the four nodes with minimal or no financial recognition for their role as local representatives and members of the ScotCRN board. We would welcome formal contractual recognition of this commitment and would be willing to assist the respective nodes in monitoring the time commitment to applied clinical research and its promotion at their respective sites.

Question 9: Would linking more directly the resources awarded through the work of various clinical groupings and their management structures improve study delivery?

Yes, see response above and previous comments and observations about the line management and recognition of research nurses within the clinical service community.

Capacity building is essential in order to ensure a pool of experienced research staff that can mentor and support naïve researchers and for the allocation of paediatric trained research nurses as required to trials.

Leadership and Delivery

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 areas 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.

We do not recognise the division between the ScotCRN research network and the paediatric specialty groups as outlined above. All enquiries about trials and applied research are relayed to the relevant leads and/ or recognised clinical experts with the offer of network support. National Theme leads (NHS consultants on a sessional basis) would require to undertake many of the functions of the current full time National Network managers; interfacing with other UK Networks for Commercial and non commercial feasibilities, liaison with other UK Network managers to identify collaboration to benefit from the larger network infrastructure, PPI, discussing feasibility of studies in rare conditions with Managed Clinical Networks and working with CRO's and Pharma to identify potential PI's and sites across all boards in Scotland. It would be a more beneficial allocation of resources to appoint an additional five Network Managers to cover all Themes.

Question 10: 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?

Responsibility for delivery of recruitment can in our experience be managed successfully by lead nurses in each node, supported by national leads. Lead nurses that manage the portfolio locally can, if additional support is required, allocate nursing time appropriately. However studies that are not recruiting to target are in our experience in the main due to patients not meeting the inclusion criteria, to local PI's

moving to other locations, or to problems with the supply of IMP or the Electronic reporting forms. If there are problems with a study at more than one site, national strategies may need to be identified e.g. patients being approached via a different route such a primary care rather than secondary care, an approach that we have successfully applied. A network pharmacist that can resolve issues with supply or delivery of IMP is also invaluable.

Question 11: What attributes and qualifications are required by Local Theme Leads to successfully undertake this delivery focussed role?

Local theme leads need to have a clear understanding of the regulatory and governance issues involved in managing clinical trials – from set up to the delivery. They require access to a pool of specialist research nurses so that a portfolio of trials can be managed through periods of staff annual leave and sickness. Local leads require the support of a national lead to ensure that they have the appropriate derogations and autonomy to implement strategies where necessary. Required attributes include excellent communication skills, in depth understanding of GCP, experience in managing concurrent trials, experience in managing small teams and a good relationship with clinical colleagues.

Question 12: 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)

In paediatrics all subspecialties apart from cancer are covered. This requires establishing good communication with specialist teams in each of the four main children's hospitals and regular contact with the relevant Managed Clinical Networks.

In rare conditions and trials with a small number of eligible patients it is essential that there is cooperation between the nodes to map the clinical trials on to clinical service and shared care arrangements. Children are managed nationally with formal or informal managed clinical Networks. Several sites across Scotland may have to be opened in order for children to participate in a trial if their care is managed across Boards.

Question 13: 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?

Yes a national role is essential if we want to work with the UK networks, Europe and industry in an effective and joined up manner. In recent conversations with one of the CROs with whom we have a relationship we were informed that they found that Networks in general and ScotCRN in particular gave them a more balanced response to feasibilities with a clear oversight of potential PI's and sites across Scotland. IN this context it would be essential to retain structures and ways of working collaboratively that avoid unnecessary and unhelpful competition.

Possible Model for the Future

This is similar to our structure of a national clinical lead (Strategic Theme Lead) with three Champions (Operational Theme leads) at the other nodes (All sessional posts). There is no full time Network Manager, pharmacist or Data Manager posts in the structure proposed and which for ScotCRN would seriously impede our ability to continue to meet the high level of participation currently being achieved, the maintenance of our public engagement through our YPG, the support and mentoring for clinical colleagues and our contributions at national UK and European level.

33. Scottish Dementia Clinical Research Network (SDCRN) (2 responses)

(1) Peter Connelly, Consultant Old Age Psychiatrist, NHS Tayside, Co-Director, Scottish Dementia Clinical Research Network

Some initial comments while the document is being considered in more detail by our wider group.

My overall impression of the document is that it is strange to see a solution proposed which has an air of finality about it, i.e. following the English model, when there are so many unanswered questions within the document. There are also some issues for dementia research in Scotland which may not be shared by the other clinical areas covered by Network arrangements currently. Perhaps it might be easiest to cover what I perceive as working well and what I perceive as problematic and get your opinion on whether or not the proposed new structure would address them or complicate matters unnecessarily.

In the Dementia Network we have staff in each of the mainland Health Boards, not only the Health Boards of the 4 nodes. Their training, development and many HR roles are co-ordinated by our highly able Network Manager, ensuring that there is a consistency of approach, that there is someone to maintain an overview of recruitment to the Research Interest Register and an awareness of overall capacity of potential sites to take on the projects which pass through our hands. Because of the absence of an academic department of Old Age Psychiatry in Scotland we also have a role in developing research interest and in even the basics of protocol development, some of which is beginning to show fruit.

As noted in the new Scottish Dementia Strategy, we are also about the launch the Scottish Dementia Research Consortium, which brings together researchers from basic science, genetics, imaging, social and clinical fields. The Dementia Network has had a key role in the development of the Consortium and will continue to have a key role in co-ordinating the development of a dementia research programme with the added potential of a clearer focus on translational studies, which at the moment are pretty thin on the ground in Scotland.

The Network is increasingly seen as a source of research advice, particularly for feasibility pilots and phase 2 studies of one type or another and this has allowed collaborations to develop with, for instance, the University of the West of Scotland, Glasgow Caledonian University and Stirling University, none of which have a strong clinical focus.

My initial thoughts are that a structure which dismembers the Network will compromise the gains I have outlined above.

The problems I see may well be related to my relative inexperience in the research field, but are genuine nonetheless.

The separate arrangements for funding University led research and clinician led research clearly interfere with the ability to plan, cost and undertake projects. Differences in HR policies between the institutions only complicate this. I can use my own position as an example – some of my salary is paid indirectly by the University of Dundee who, not unreasonably, have an expectation that I will highlight my role within the University when publishing anything or presenting at a Conference, but when I try to apply for a grant I cannot be regarded as a University employee. I had feedback from one grant application to CSO that because I had a contract with the NHS and with the CSO in part, then I should really be seen as a free resource, though there is an obvious limitation to that argument.

All of the projects in which the Network is involved are channelled through local R&D. I would not fault the level of help we get when we ask, but it is far from clear what level of support to which we might be entitled, eg. research statistics, etc. nor does the disbursement process appear transparent. For instance, when we submitted our last Report to the CSO we were unable to account for all of the time our staff spent on commercial studies, contrary to the agreements we have. Partly

this results from 4 different Accountants having been involved in the research sites, and this very arrangement is what is being proposed in the discussion paper.

At the moment the funding of Network staff involved in projects is unclear. Typically we might be approached by a researcher who has or is applying for a grant, which includes costs for research staff. If the funder is “eligible” then there is an expectation that Network staff will be supplied free of charge, raising the obvious question of what happens to the funds allocated to the research workers in that study which do not accrue to the Network.

The issue of embedding research funds within clinical budgets is important because none of the job plans of my colleagues has any time directly associated with research built in to it. Thus, there is no leverage to encourage participation of colleagues, other than to offer financial incentive – which cannot be done because (a) “their salary is being paid already” and (b) no money accrues to the Network from supporting studies.

Once again I do not see anything in the paper which would address these points.

(2) Scottish Dementia Clinical Research Network

Response by the Scottish Dementia Clinical Research Network

In formulating this response I have taken into account discussions with staff from the Scottish Dementia Clinical Research Network (SDCRN) plus further discussions with Charles Weller and Alan McNair. In addition, Emma Law, our Network Manager, has fed in comments from a meeting of the Network Managers with CSO. My response is thus on behalf of the SDCRN and not simply my personal comments.

Proposals for change

I have commented previously on the proposals for change, including the unusual situation where a document is apparently proposing a solution whilst leaving a multitude of questions unanswered. In addition, I have commented on the absence of any description of the role of R&D and the potential modifications which could be made in these departments to enhance the generation and delivery of research. Furthermore, there appears to be a lack of full transparency about how research funds can be utilised and a lack of co-ordination between parties interested in developing and delivering research and those interested primarily in developing and delivering services. Consequently, both job planning and opportunities for staff development seem to have restrictions which make it very difficult to organise and deliver research taking place episodically rather than at a continuous level. Many of these issues require solutions if the revised structure is to work better.

Within the consultation document the key question appears to be the first one asked. [Q1. 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?]

The question is phrased as though the lead Board for each Network has national responsibilities, whereas it is the Networks themselves which have this role and are hosted by the Boards. I have already alluded to the advantages of having a national oversight of research activity and the ability to allocate the projects at that level [Q2],

which we think would disappear if responsibilities were dispersed to local R&D departments. This I have previously referred to as “dismembering” the Network.

The current proposal involves the National Theme Lead continuing to have a national oversight and working at a strategic level within a Faculty of Theme Leads, R&D Leaders and CSO. The National Lead would also have an ambassadorial role liaising with colleagues in the other nations within the UK and, potentially, internationally. This would be a good role which would raise the profile of dementia research, but I do not think it is feasible to have the focus solely on research delivery. Since SDCRN was created it has developed as a “brand” which focusses researchers on the potential to develop clinical research studies. This would be compromised by a move to a 4-node focus, and may also be lost if the Theme includes topics other than dementia. Therefore it would make sense, in the field of dementia, to empower the Leader with a remit to champion the development of research within the NHS. They would thus need time for negotiating with key University and NHS Board level Directors. In addition, they may need to provide a stimulus for the nurturing of staff interested in research at local levels. I do not see how this could be done in a 1 – 2 session post, which is a similar commitment to the current Network role.

The proposal is to enhance the existing role of Network Manager and also cement the role as truly national, as was described for the Theme Lead. The SDCRN Network Manager already has a national remit and responsibility for liaising with R&D, HR and managerial staff in each of the Health Board areas. The proposal is to have the Delivery Director role as one which involves more direct negotiation with R&D Directors and other key staff in the NHS and in Universities to increase the awareness of the need to develop sufficient staff to allow clinical research in dementia to be developed and then successfully delivered. We would see this as a positive development, though there would need to be considerably more clarity about responsibility for developing research within the NHS and about how the infrastructure of R&D is utilised. There also needs to be much more clarity and perceived parity about how research funds are utilised to support researchers from an NHS or University background who are developing or undertaking clinical studies.

At a more local level the proposal is for R&D departments to directly manage research staff. In SDCRN most staff are on secondment from a mainstream post and / or work part-time for the Network. Line management arrangements are with the Service responsible for the majority of their contract, which is usually within the nursing or AHP hierarchy. HR issues are handled by the NHS Board in which SDCRN staff work. At present our Network Manager liaises with the Board HR and appropriate managerial staff, which allows a consistency of standards across Scotland, and benchmarking of these standards for the purposes of contributing to appraisal, personal development planning and KSF for each individual. R&D departments are likely to have a less global outlook, leading to the possibility of differential standards being put in place across Scotland.

The current arrangements allow our Network Manager to contribute more directly to staff training and development through the creation of a cohesive forum of which each of our staff is a member. This allows the development of a high level of interpersonal and peer support reflected in the strongly positive feedback on the

level of professionalism, respect and quality of working relationships within SDCRN. The local focus of R&D nodes would make this cohesiveness difficult to replicate.

The role of our current local Clinical Leads is not clear in the new structure. It may be that they will have a local responsibility for the delivery of research, but they will require to have some responsibility for the development of research locally as well. In each case their line management will continue to be through their appropriate (primarily medical) managerial structure and it is difficult to see how having a direct responsibility to R&D departments would work in practice.

So far therefore the suggested proposals tend to mirror or enhance some of the key leadership roles currently in place in SDCRN but at the cost of more diffuse management, reduced cohesion and variability of standards being introduced for research staff on the ground. The managerial structures of the vast majority of research staff will remain within their core nursing or AHP systems, which cannot be directly controlled by managers sitting within different Health Board areas from that in which the staff member works. More thought is required on how a well worked Network structure, such as in SDCRN, could work more cohesively with R&D infrastructure whilst maintaining sufficient identity to ensure the necessary single minded approach to improving the development and delivery of research in dementia across Scotland.

There has always been an issue that the position of dementia within the research community is rather different to that of other topics. Although there is a strong base of basic science research, imaging research, genetic research, social research and so on, the number of research projects generated from the field of Old Age Psychiatry has been historically low.

There is no academic department of Old Age Psychiatry in Scotland and neither of the recently appointed Professors, in Stirling or the West of Scotland, has an active clinical role in the field of Old Age Psychiatry. There has been historically more interest from colleagues in Medicine for the Elderly, but no University has formed a hub to drive pan-Scotland development of dementia research such as we are attempting to do from within the Network

The picture is very different in the other UK nations where strong academic units provide the stimulus for research projects, and differs also from England where there are numerous clinical academics in the field of Old Age Psychiatry.

The consequence is that, in Scotland, there is a need not only to deliver research but also to generate it. Both the Prime Minister's Challenge and the Scottish Dementia Strategy emphasise the need for more dementia research and, in Scotland, if a University is not taking the lead in developing a pan-Scotland research initiative this task will fall to the NHS. The SDCRN is comprised almost entirely of NHS staff and thus fills a gap not seen in other areas.

There is a clear case for improving the co-operation between Networks and current specialty groups, both for the development and delivery of research studies. In our view this is best achieved by retaining a national overview of the special interests and capacity of potential researchers and the research infrastructure. A simple

amalgamation of Network and specialty groups is likely to lead to problems of capacity for the current Network Managers and future Delivery Directors. As with any system which requires cross fertilization the presence of distinct or even rigid boundaries can have an adverse impact. It is perhaps unfortunate that the structure illustrated in Annex A appears to have discrete boundaries and the diffusion into four nodes also carries this risk.

[Q5: What are the main barriers to Networks supporting all the studies within their portfolio area?]

Of the barriers to Networks supporting studies within their portfolio, the main one is possibly that although researchers will contact R&D when drawing up a grant application, Networks are not necessarily notified. By contrast, studies notified in development to SDCRN are always passed to the local R&D department. The second barrier is the relatively low percentage of grant applications which are funded. This makes it difficult for us to allocate staff in support of a grant as there would be clear capacity issues if all current applications were funded at or around the same time. Being approached and asked to supply staff once a grant has been awarded also creates difficulties, particularly if the grant has been awarded by an eligible funder.

[Q7: 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?] [Q9: Would linking more directly the resources awarded through the work of various clinical groupings and their management structures improve study delivery?]

A further barrier to the development and delivery of research is the lack of transparency about the current distribution of research monies within the NHS. This often leads to potential new researchers being told that “they are being paid already” and, as research time may not have been included in their job plan, they are then put off from developing a career which includes a contribution to research. Simply removing some money from a medical budget would have adverse impacts on service delivery, leading to difficulty in meeting various Government targets and is, therefore, likely to be resisted by Board Chief Executives and Directors. Attempting to remove money from an individual consultant or group of consultants is likely to lead to extensive and extended job plan appeals and would be very counter-productive when trying to motivate people to become involved in research. Awarding additional and time limited payment is feasible, but very dependent upon the capacity and willingness of staff to undertake research roles. A transparent system of incentives is required.

[Q 10-13: 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?]

The final four questions are again set out in such a way in that the answer to the first determines the answers to the others. We would argue that having a national overview of recruitment and capacity, coupled with delegated local responsibility for

recruitment is a better system than charging local Theme Leads with this task. There is already an issue about the relationship of study recruitment to the location of the host Board of individual Networks and this is likely to be worsened by a 4-node, potentially competitive structure.

We fully accept that there is a need to modernise research infrastructure, but in our opinion the model of the SDCRN represents a good one on which to base this modernisation, though enhancing responsibilities at national level for key personnel would be most welcome.

34. Scottish Diabetes Research Network (SDRN) (2 responses)

(1) Professor Rory J. McCrimmon, Professor of Experimental Diabetes and Metabolism and Honorary Consultant, Lead Clinician Scottish Diabetes Research Network

Professor Donald Pearson, Consultant Diabetologist, Aberdeen Royal Infirmary

Dr Robert Lindsay, Reader in Diabetes And Endocrinology, University of Glasgow

Thank you for taking the time recently to come up to Dundee to discuss this consultation document and to listen to the views of the Scottish Diabetes Research Network (SDRN) concerning the future developments of NHS research in Scotland. We look forward to working with the CSO as it seeks to develop an outstanding support system for academic and clinical research across all of Scotland.

In responding to the consultation document, it should be noted that our views are those of an established clinical research network. The SDRN was commissioned in 2006 by the CSO and is represented across the 4 NRS nodes with resource allocation and activity co-ordinated through its lead health board (Dundee). Its primary focus is to improve the quality and quantity of diabetes research throughout Scotland across both commercial and academic fields. In this respect, we would contend that the SDRN has been remarkably successful and in some respects should be considered a template for how to achieve successful clinical research in Scotland. The SDRN has achieved international recognition for the quality of its work and this has brought significant sums in terms of commercial and grant income to Scotland. A prime example of the benefit to Scotland in creation of the SDRN is the recently funded REMOVAL trial in type 1 diabetes (PI Petrie). REMOVAL (now 75% recruited) is proof of concept of what can be achieved when government invests in a network structure. It is one of the first academically led clinical trials in diabetes in Scotland of an investigational medicinal product with multiple overseas sites and a UK institution as sponsor. The SDRN was instrumental in helping negotiate the many complex hurdles to multi-national, multi-centre clinical research that made this trial possible and it is a great success for Scotland.

Despite the economic downturn, which has had a significant impact on research funding both commercial and academic, the SDRN has seen a year-on-year increase in patient recruitment to trials. In 2012 SDRN-registered sties conducted more patients visits than ever before (7718 visits in 2012 vs. 5594 in 2011), and diabetes research activity was continuing to increase in all the smaller health boards consistent with the strategic aim of the CSO to develop clinical research throughout Scotland. In addition, the SDRN has recently started a novel initiative in Primary Care, making clinical research available to patients in the community. Our first clinical trials are already recruiting in these test practices in Tayside and Fife, and this represents an exciting way forward. In our major commercial trials we currently target recruitment at 50-100% more than our allocated patient number increasing our trial revenue from commercial bodies. In addition, through our National Diabetes Research Register we are able to recruit very quickly (usually within a few weeks) to commercial trials in a way that has become the envy of other trial centres in the UK. Recently we recruited the first patient in a major, multi-centre, international trial (GET-GOAL), an event that was announced at an international clinical conference (American Diabetes Association meeting in Chicago, June 2013) and is the type of success that attracts major pharmaceutical research to Scotland.

At the same time the SDRN, through the SDRN Epidemiology group has enabled outstanding epidemiological research of direct relevance to the health care of people in Scotland as well as attracting major grant funding to Scotland. The SDRN epidemiology group has now published 17 high impact publications, and presented at numerous national

and international meetings at each of which the SDRN gains valuable international recognition. Examples of recent successes include:

- Type 1 Diabetes Bioresource (Diabetes UK, CSO)
- SCOTS (NHIR-HTA)
- REMOVAL (Juvenile Diabetes Research Foundation)
- UNITED/MODY (Wellcome Trust)
- DIRECT (European Union Innovative Medicines Initiative: **Euro 27M**)
- SUMMIT (European Union Innovative Medicines Initiative: **Euro 48M**)

These large clinical trials provide employment for a variety of research and support staff and put Scotland on the research map as a major contributor to diabetes worldwide.

Within this overall context, we feel it is very important that the CSO should view the SDRN as a model for how successful research networks may be developed. There are certain elements of the SDRN that have enabled it to exceed its goals.

1. A National Diabetes Research Register - recording permission to contact patients about clinical trials, and that is linked directly to SCI-dc that contains secure clinical and biochemical data pertaining to that individual. This is the bedrock of both our commercial and academic research success, and its value cannot be overstated. The register also ensures that our screen failure rate is extremely low and this makes the network very appealing to pharmaceutical companies. We firmly believe its more widespread implementation across disease themes would accelerate research in Scotland. The recently funded SHARE initiative could provide this type of information to other research themes, but there needs to be clarity in the processes through which individual themes access this database ensuring no obstacles to clinical research. In addition, it is essential to be able to link the register with chemical or phenotypic biomarkers of disease – this stratified approach accelerates clinical and academic research. Such a model if implemented would transform disease registers across Scotland.
2. A network manager has proven essential to the successful running of the SDRN. While we agree that there is the potential for overlap between NHS R&D commercial staff and the network management structure and that clarity between roles of each of these two groups would be beneficial, it remains our opinion that the network manager is best placed to; oversee the trial portfolio within each theme(s), to encourage all investigators to use the network, to provide an identifiable contact for the pharmaceutical industry/ academics, and to provide oversight to ensure completion of clinical trials as well as resource allocation throughout Scotland. R&D is better able to provide the infrastructure and support necessary to bring a trial to fruition (i.e. from costing and ethics to local allocation of resources). The important distinction here is that while R&D provide the critical infrastructure and support needed to run a clinical trial across the breadth of research themes within a given node, the network manager provides an identifiable focus for that particular theme (e.g. diabetes) across Scotland and internationally, improving communication between commercial companies, academics and health boards. In widening the portfolio of the network manager through devolving of some of their activities to local R&D the CSO will need to ensure that this identity is not lost.
3. A major factor in our success has been the central funding of a body of research nurses that are able to provide support for commercial and academic trials in each node and in smaller health boards. Study delivery is most effective where nursing staff are assigned to networks, are specialists in their field, and supported by

excellent clinical staff. The SDRN nurses also provide flexibility and innovation. We recognise that there is a perhaps an efficiency saving in bringing CSO funded clinical research nurses within the umbrella of local R&D departments, allowing for more generic nurse support. This would remove line-management roles for the Network managers and provide more security for the nursing staff. This must however be balanced against the loss of speciality expertise (e.g. in insulin adjustment), and it is not clear how nurse support for the smaller health boards or for trials in primary care would be maintained.

4. Finally, a cohesive executive body with representatives from each node, from the smaller health boards and from the patient body ensure clarity of process, fair allocation of resources and infrastructure support across Scotland. Lead clinicians also provide, through national and international leadership roles, an important role in attracting clinical research to Scotland. Critical to the success of the SDRN executive and leadership was funding from the CSO to provide the time and incentive for clinicians to engage in clinical research. Withdrawal of direct funding NHS will seriously reduce the incentive to NHS physicians increasingly hampered by job plans to contribute to commercial research within their health board. There is very little reward on a personal or career level for this type of research and it succeeds primarily because of the good will of each specialist group. The CSO needs to consider how best to maintain the incentive for clinicians to take part in clinical research and we believe that a clear identity to the network, funded time to engage in clinical trials and the ability to develop independent research skills is critical to this.

We are grateful to the CSO for seeking our views in this critical area. Developing and sustaining a world-class clinical research infrastructure in Scotland is in all our interests and critical to the health of the nation. The SDRN has worked hard to establish an international identity. It is important to remember that most multinational commercial companies still work within disease themes as do most academics and so establishing our “brand” as the SDRN has been instrumental in our success and in bringing in clinical trials to Scotland. Dilution of the SDRN brand through merging with a number of themes is likely to have a negative impact on this.

*(2) Shona Brearley Scottish Diabetes Research Network Manager (Primary Care)
University of Dundee*

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?

In the case of SDRN , the current structure does optimise study delivery. More than 75% of diabetes studies currently being conducted are supported by SDRN (the other 25 % we know about but haven't got research nurse capacity to support completely – we do support these studies in other ways by helping with recruitment, SOPs, GCP training). The current SDRN structure has allowed studies like the Type 1 bioresource to maximise recruitment across Scotland and allow patients equitable access to participate in research.

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?

We have a good working relationship with R&D offices and manage almost all the diabetes studies (all the commercial studies are managed by us)

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?

N/A

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

I think this is dependant on the potential level of research activity and the research interests of physicians working within the specialty – not all clinicians are interested in research.

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

Lack of nursing resource is our greatest barrier – we have lots of studies and patients but specialist diabetes research nurses are the limiting factor.

Question: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

N/A

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?

This assumes that the PI recruits the patients , which is simply not true. Recruitment to trials is critically dependant on the research nurse, not the Pi.

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

Yes

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

Yes, we could supply more research nurses and increase activity significantly with more money.

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?

No, it would be more difficult to maximise efficient use of the resource as it would be broken down with no national oversight and some Health boards would miss out on opportunities to participate in research

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

These local Theme leads would be better placed as managers , rather than clinicians , as they need to understand patient population, capacity issues at sites , interest within the disease area . National managers have this information at their fingertips but local theme leads will not be expert.

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)?

I think this would be difficult as the academics are interested in their own particular area of research so may prioritise their particular area . Managers building up a portfolio of studies are better placed to avoid bias and give all areas more opportunities.

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?

I think this is simply adding another management layer, money would be better spent employing more research nurses to deliver on studies .

35. **Scottish Enterprise**

This document is a response coordinated by Scottish Enterprise to the consultation on proposed changes to the support structure for NHS research in Scotland.

Feedback on the style of consultation document

General feedback is that this document is hard for people not intimately familiar with the current NRS system to understand the current support structures or the proposed changes. A glossary of terms would be helpful and schematic diagrams would be beneficial to include.

General comments:

1. Restructuring and aligning the Scottish NHS research support structures with the newly introduced ones in England and Wales is supported. This will make it easier for the Scottish NHS to be part of multi-center trials, a necessary prerequisite for staying competitive in the UK-context.
2. A structure around themes/disease areas is believed to encourage greater collaboration in these key areas and enable the NHS to maximise and develop skills in these areas (clinicians, nurses...)
3. Some parts of the newly proposed Scottish NHS research support structure appear overly management-heavy (for example, 48 local theme leads are proposed). In times of scarce resources, it is considered that this may lead to a shift of resources into management away from hands-on research.
4. One of the reasons for the restructuring at the NHS in England and Wales was to make research and the NHS more accessible to companies and potential investors. Given the Statement of Intent, this ought also to be an objective in Scotland - it is not clear how the proposed structure would achieve this. It would be helpful, for example, to clarify who in this structure would liaise with industry.
5. The capabilities of Scotland in delivering commercial trials are an important part of the proposition to attract international business in the Translational Medicine space to Scotland. However, there is no mention of how these NRS structure changes will affect the availability of time (both for clinical staff such as Clinical Investigators, clinical research nurses and for administrative staff) for supporting commercial clinical trials
6. A new group of individuals referred to as 'National Theme leads', has been proposed as responsible for recruitment of patients to studies. From the document, it was unclear how this might impact on the existing system, especially for commercial studies.

Response to selected questions

1. Does the current structure, wherein each Network is aligned with a lead Board with national responsibilities, deliver optimized national access to studies and effective study delivery?

Central coordination of activity around each network to increase efficiency and enable clear communication with external parties would be beneficial

2. 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 and sensible?

No.

3. Does the current position of Specialty Groups within the wider NRS structure allow Specialty Group Leads to manage their portfolio efficiently? What are key structural issues?

No. Such groups have limited access to wider support and NRS infrastructure investment.

4. Is it equitable or efficient to have clinical areas managed as Networks and others as Specialty Groups?

No. See above.

5. What are the main barriers to Networks supporting all the studies within their portfolio area?

Lack of adequate resourcing can be a significant barrier.

6. Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

Unable to comment

7. Should the proposed Themes have more direct access to the time earned by research active NHS employees through the NRS research 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?

Yes. Linking the level of Theme research activity to funding should incentivize involvement in patient recruitment. As research activities are not clearly defined in the document, it is hoped the proposed changes will favour incentivisation of practical hands-on work.

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

No. From what the document states, there appears to be a lack of transparency regarding for instance the use of CSO funding.

9. Would linking more directly the resources awarded through the work of various clinical groupings and their management structure improve study delivery?

Yes (especially if “work” is defined to be high-impact). This would afford increased clarity about funding provided and increased accountability.

10. Compared to present systems, would transferring responsibility for delivery of recruitment to all studies be better managed through locally appointed team leads employed through the NRS nodes

Yes. This would ensure more balanced resources and support for the ensemble of studies.

11. What attributes and qualifications are required by local Theme Leads to successfully undertake this delivery focused role?

Project management training and clinical trial management training or expertise (on time and on target delivery is essential to build the credibility of the system)

12. How best would local Theme Leads cover multiple disease areas (There would be a single lead for stroke and cardiovascular diseases and a single Lead for Diabetes and Renal Disease)

They might have to rely on the support of selected specialist staff.

13. 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.

Yes. This would ensure national coordination and a central resource to recruit studies and oversee the workload of the system at a national level.

36. Scottish Mental Health Research Network (SMHRN)

Prof Stephen Lawrie, Director, SMHRN

Dr James McKirdy, Manager, SMHRN

We welcome the opportunity to provide feedback on the review of the position of the research networks in Scotland and look forward to being able to continue facilitating effective and straightforward cross border engagement whilst simultaneously improving efficiency and delivering top tier performance.

We think it is important to recognise the achievements of the networks thus far. Since its inception, the SMHRN has increased both the amount of mental health research studies adopted per year, and the number of participants recruited. Our support for protocol development activities has resulted in a number of successful grant applications and this development role is arguably particularly important for those involved in supporting mental health research. Our current alignment with NHS Lothian as lead board has, to date, proven to be highly successful and we have endeavoured to develop strong working relationships with the other NHS boards.

We acknowledge that some mental health research is not managed within the SMHRN portfolio but we have made major inroads to increase awareness and engage with much more of the mental health research community. We do not feel that there are any barriers to the SMHRN supporting all of the studies within our remit if we had the resources to do so, supported by the NHS and CSO.

Our commercial portfolio has grown extensively and continues to flourish. We currently lead the UK in recruitment to two Pharma studies (Roche Impact of Illness and Abbvie cognition enhancement). This is probably the single greatest research area that has expanded as a direct result of the SMHRN and would be at risk if resources for the SMHRN were reduced or divided in any reorganisation. We employ a number of highly skilled research assistants (mainly psychology RAs) who carry out many of the study procedures necessary for recruitment and ongoing assessments. We are also fortunate to be accommodated within the University of Edinburgh Division of Psychiatry where we have ready access to the requisite clinical facilities, clinicians and a potentially eligible clinical population. This work would be immeasurably more difficult to conduct elsewhere. It is important to recognise that psychiatry patients are mainly seen in separate hospitals by separately trained staff to those in the rest of medicine (including neurology and geriatrics).

We can see that there could be economies and advantages by combining extant networks and to have some of the clinical areas currently managed as speciality groups come under the aegis of an expanded topic network and we would be certainly willing to consider such collaborative enterprises. However, care would have to be taken to ensure that support could be delivered to disparate studies in disparate sites and done by differently trained staff in any new infrastructure. The implications of a consolidated network encompassing dementia, neurology and psychiatry – or indeed one combining mental health with any of the extant networks or topics - on the ability to access the necessary range of clinical expertise, staff capability and participant interaction could be profound. We therefore suspect that any such combination might best be served by having Co-Directors and Co-Managers for any such disparate subject areas.

Another issue to consider is that of remuneration or others types of reward for those participating in the activity of the networks. The SMHRN currently compensates the Directors for the time they invest in research development and in supporting the activities of the adopted studies. Our Management Group also receives some remuneration. We are

concerned that any division or loss of resource through reorganisation might adversely impact upon our ability to call upon these important individuals. On the other hand, some reorganisation and renewal would perhaps provide a good opportunity to identify more 'research champions' for mental health and to promote the importance of medical research in the activities of the NHS on a wider basis.

Overall, therefore, we are committed to and enthusiastic about making improvements to the way that we work and the way that support is provided through NHS Research Scotland but we do have concerns that reorganisation might reduce our ability to do so. We hope that there will be clear communication about any proposed adjustments and the opportunity to consider the potential impact that these would have on the SMHRN and related bodies. Ideally any reorganisation should be planned with plenty of advance notice so that we can ensure that we can continue to provide support to our current commercial and non-commercial portfolio but also be able to accurately plan what we could support in the future.

37. Scottish Paediatric and Adolescent Rheumatology Network

Joyce E Davidson

Consultant Paediatric Rheumatologist,

Scottish Paediatric and Adolescent Rheumatology Network

As an NHS clinician who has been involved in research throughout my career, I have greatly valued the support provided from the Scot CRN in recent years. Their network of experienced research nurses working within paediatrics has been able to facilitate the involvement of busy clinical teams in paediatric studies. In my own specialty, paediatric rheumatology, all studies are multicentre either on a UK-wide or international level. Being able to link to the MCRN through the ScotCRN greatly facilitates discussion about, and involvement in, studies on a Scotland-wide level.

As a current user of CRF support in Glasgow, Edinburgh and Aberdeen I have concerns that a change in the structure to a regionally based support system may have a potentially detrimental effect on paediatric research in Scotland. My personal experience of different centres has been that where the paediatric research support is embedded within paediatrics rather than within an adult CRF it works better, both in terms of being able to support paediatricians in delivering research and also in raising the profile of paediatric research within the hospital.

My experience of the CRF in Edinburgh has been particularly positive, and the model that works there is I think an excellent example of how the ScotCRN structure has been able to support delivery of research.

In Glasgow where the CRF is managed as part of the adult CRF I have also had excellent support from the research staff but do have concerns that it feels as if it neither belongs fully within paediatrics nor within the adult CFR. The staff are relatively isolated from the main paediatric structures and therefore less accessible to clinical staff both in terms of offering support but also raising awareness of research within the hospital. It also makes prioritising development of the paediatric side within the CRF more difficult: I am aware that studies in which I have been involved have come with financial support in Glasgow and am concerned that I have not been able to see that translated directly into an increase in resource for paediatric research.

We have made huge strides in the UK in recent years in terms of being able to develop structures to ensure that research in children is prioritised and seen as essential to everyday clinical practice. History has repeatedly demonstrated that unless paediatrics has a separate identity it will always find it difficult to hold its own in a system where there are large adult studies competing for priority. Within paediatric rheumatology, the development of the MCRN/ARUK Clinical Studies Group, mirrored by support in Scotland from ScotCRN, has resulted in significant strides being made in terms of the number of studies that are being supported on a UK-wide basis.

As a specialty, we deliver clinical care as a national Scotland-wide managed clinical network with specialist clinics in every district general hospital. One of our stated aims as a specialty within the UK is to be able to offer all children the opportunity to be involved in clinical research as appropriate. A research structure that operates

nationally and mirrors our clinical service is hugely valuable in helping us move towards that goal. Fragmentation of the support that we receive, with lack of the unified approach supported by the ScotCRN can only be detrimental to this goal.

38. **Scottish Primary Care Research Network (SPCRN)**

SPCRN Background

The Scottish Primary care Research Network was established in 2002 as a framework to co-ordinate national research activity in primary care. The overall aim of SPCRN is to increase the amount of research relevant to patient care undertaken in a primary care setting.

SPCRN facilitates the timely, appropriate and effective recruitment and follow-up of patients in primary care settings and covers the entire range of clinical research areas.

Examples of SPCRN successes

- SPCRN works with a wide range of primary care health professionals and promotes high quality research in areas for which primary care has particular responsibility. These include disease prevention, health promotion, screening and early diagnosis, as well as the management of long-term conditions, such as arthritis and heart disease.
- SPCRN has worked with more than half of the GP practices in Scotland from 2007-13 (613/1000 practices have taken part in SPCRN adopted studies)
- SPCRN has increased the number of patients recruited to studies by 229% from 2 698 in 2011-12 to 6188 in 2012-13
- SPCRN has successfully administered the primary care Service support cost budget on behalf of CSO since 2008 and has set up a streamlined and efficient system for reimbursement of primary care professionals participating in research
- SPCRN has developed a close working relationship with PCRN and collaborate on a number of studies -in 2012-13, 24 (40%) of the studies in the SPCRN portfolio were recruiting in Scotland and other parts of the UK.
- SPCRN has excellent relationships with the other topic specific networks in Scotland and collaborated with SDRN, SRN, ScotCRN and SDCRN on 10 studies in 2012-13. SPCRN and the Scottish SDRN are running a joint initiative to increase capacity for diabetes research in primary care. The initiative will concentrate on running commercial studies in the initial phase hosted in selected practices in NHS Fife, Lothian and Tayside with a rollout programme for all Health Boards if successful.

Examples of studies supported by SPCRN leading to publication:

a) **Study title:** Bell's Palsy: early Acyclovir and/ or Prednisolone in Scotland. A multicentre factorial trial of the early administration of steroids and / or antivirals for Bell's Palsy. Funded by the HTA

Sullivan FM, Swan IRC, Donnan PT, Morrison JMM, Smith BM, McKinstry B, Davenport RJ, Vale LD, Clarkson JE, Hammersley V, Hayavi S, Daly FD. Early Treatment with Prednisolone or Acyclovir and Recovery in Bell's palsy. N Engl J Med 2007; 357:1598-607.

b) **Study title:** WIME: Developing and evaluating interventions to reduce inappropriate prescribing of antibiotics in primary care: comparison of paper-based and web-based modelling experiments. Funded by the Chief Scientist Office.

Treweek S, Barnett K, MacLennan G, Bonetti D, Eccles MP, Francis JJ, Jones C, Pitts NB, Ricketts IW, Weal M, Sullivan F. E-mail invitations to general practitioners were as effective as postal invitations and were more efficient. Journal of Clinical Epidemiology 2012. doi:10.1016/j.jclinepi.2011;11.010

c) **Study title:** HITS: Sharing Responsibility: The public health impact of a nurse-led telemetric home blood pressure monitoring service. Funded by BUPA

McKinstry B, Hanley J, Wild S, Pagliari C, Paterson M, Lewis S, Sheikh A, Krishan A, Stoddart A, Padfield P. Telemonitoring-based service redesign for the management of difficult-to-control hypertension (HITS): a multi-centre randomised controlled trial. *BMJ* 2013;346:f3030

SPCRN response to consultation document proposals:

1. Structures

Since primary care deals with all disease areas, and performs a role in research on multiple morbidity, a structure which separates activity into the proposed themes appears less effective. Although we work with colleagues in dermatology, musculoskeletal, health services research, dental and public health we also work with topics situated in other themes.

The consultation document states that the *'Topic specific Research Networks do not manage all of the research within their disease area, only those that they adopt onto their portfolio'*. This is an incorrect statement for SPCRN as the only studies that SPCRN don't adopt are those that fall outwith the CSO's definition of 'eligibly funded'. SPCRN offer support for other studies where possible although there is already an issue of having to prioritise support because of limited network capacity and resource. Discussion within SPCRN attempts to ensure that poorer quality studies are not supported at the expense of higher quality studies.

Ultimately, recruitment to individual studies has to remain the responsibility of the PI rather than research support staff. The PI and his/her team are the people best placed to motivate participants because of their knowledge of the topic and the study design. The more research support structures there are, the greater the difficulties in co-ordinating effort and ensuring adequate communication. This is compounded by the tendency to overload people with unnecessary detail whilst forgetting to summarise and highlight important messages.

Lack of infrastructure in the form of access to research nurses who can support studies which are recruiting patients and delivering interventions in a primary care setting is a particular issue for SPCRN. For the majority of studies supported by SPCRN (64% in 2012-13) the participating practices acted as Patient Identification Centres (PICs) i.e. responsible for the identification of potential participants who are subsequently invited to take part in research through a different site which takes on responsibility for seeking consent and undertaking research procedures. Although the patients recruited to these studies are usually referred on to secondary care for consent and study procedures, they provide the opportunity for patients to participate in research.

Scotland would benefit from more infrastructure support directly to GP practices in a similar way to the English GP incentivisation scheme or Research Site Initiative (RSI) www.crncc.nihr.ac.uk/about_us/pcrn/eoe/resources/RSI.htm as, under current systems, they act as gatekeepers to patients. Alternatively there is a need to rethink whether it is still appropriate for GPs to have this exclusive role. A national initiative to allow remote access to GP data and processes to enable contact with patients directly rather than through their GP would greatly facilitate recruitment as both stages are bottlenecks in the process. SPCRN have taken the lead in developing SHARE for this purpose.

a) 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?

We can really only comment upon the situation for SPCRN whose lead board is Tayside. It is useful for the network to be provided with support by a board, including for governance and reporting purposes. It makes sense to have everyone in a research theme working together at a regional and national level for the benefit of the individual studies. Any “portfolio” should include all studies that have been deemed to be worth supporting – there is a need for clearer criteria on how to prioritise support when there are capacity and resource issues. There would be benefits to doing this on a national level, in order to minimise competition and maximise collaboration between NRS areas. Such an approach would ensure efficient use of resources, for example, so studies can be matched to areas best placed to deliver at a specific time. Study delivery, whilst being monitored by networks at a national level, should be the responsibility of the network representative at the local level, and the Board R&D Office combined.

b) 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?

SPCRN is a cross cutting network which adopts all eligibly funded research which requires recruitment of patients from primary care. SPCRN's main role is generally identification and invitation of patients on behalf of the study team and for studies where GP practices are acting as PICs, SPCRN works with secondary care teams and CRF nurses to ensure study delivery. The respective responsibilities of Network and R&D staff should be clear but in practice this has not always been the case-this has been a particular problem in the West node of NRS with the creation of a primary care initiative by NHS Greater Glasgow and Clyde R&D department. The most important thing going forward is that both networks and R&D staff have a duty to collaborate to maximise the likelihood of the success of any given study.

c) 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?

From the SPCRN perspective, the current position of the network within the wider NRS structure has allowed it to manage its portfolio efficiently, although a competitive approach rather than collaborative one within the West NRS structures has impaired efficiency. This highlights the need to promote collaboration rather than competition when the national goal, to maximise research capacity and effectiveness is a shared one.

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

Topic specific networks were created in areas of high priority in Scotland (stroke, cancer, diabetes, mental health and dementia), and over-arching networks were established to support research across a variety of disciplines (the Children's Research Network and the Primary Care Research Network). Specialty Groups were set up to manage the delivery of studies in the clinical areas outwith the topic Networks with the intention of being as equitable as possible with limited funds available. Themes seem to be a more equitable way of ensuring that most major clinical areas are open to the possibility of studies being carried out to answer important questions and can access support if necessary. It is of paramount importance that the same opportunities exist for grant funding too.

SPCRN already promotes high quality research in areas for which primary care has particular responsibility. These include disease prevention, health promotion, screening and early diagnosis, as well as the management of long-term conditions, such as chronic pain,

mental health, diabetes and heart disease. SPCRN already works closely with researchers in areas such as dentistry and age and ageing which would form part of the new theme which primary care would be part of. Health services research is also a key feature of primary care research. There needs to be acknowledgement of the growing importance of cross cutting/multitheme research which will be of growing importance in view of changing population demographics. Overemphasis on disease specific research would not meet the needs outlined in the 2020 Vision for Health and Care in Scotland.

2. Funding

a) What are the main barriers to Networks supporting all the studies within their portfolio area?

This is not currently perceived to be an issue for primary care research as already outlined above (see 1. Structures). However, if SPCRN were to undertake more studies where patients are consented and interventions delivered in a primary care setting rather than identifying patients then referred into studies running in secondary care, a Research Site Initiative (RSI) would need to be rolled out in Scotland. RSI schemes in England have been very successful in incentivising GP practices to support studies by providing funding that can be used to employ research nurses. Barriers can also be related to capacity issues. Capacity is limited if there is insufficient investment to protect research time or to make processes efficient and remove any bottlenecks. Consideration needs to be given to a fair way of prioritising projects when capacity is limited (related to importance of the study to clinical practice etc., rather than who the CI is)

b) Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

SPCRN do not rely on financial leverage to facilitate participation of colleagues in research. Whilst the majority of primary care professionals identify advantages for their patients taking part in research, including access to novel therapies and contributing to the research evidence base, they are independent contractors who do not have time for research unless sessions are funded for this purpose. In our experience, the factors that encourage primary care professionals to engage in research are: a research question that is interesting and relevant to their patients, support from SPCRN or experienced research nurses to ensure that their time commitment is minimal and sufficient remuneration by way of either service support cost payments or per patient fees for pharma studies.

c) 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?

Direct access to funding for the time earned by research active primary care professionals through the NRS Researcher Support budget is a particular issue for primary care. Historically this funding has been received by the NHS Boards as part of the Support for Science allocation but in some NHS Boards has not then been paid to the primary care staff who had earned the funding, either directly or indirectly. Direct linkage of activity to funding would act as an incentive, and should allow job planning to employ research specific staff in centres of high activity by giving a source of bridge funding between grants.

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

There is currently no link between research activity and investment in infrastructure which could be implemented in the form of an RSI scheme (see 2. a). Investment in such schemes by NIHR has allowed GP practices in England to become more experienced in conducting research and take on more studies, thereby increasing primary care research activity, quality and capacity.

In general, as long as there is a clear allocation of responsibilities for different tasks to prevent duplication of effort, devolving the budget allows local flexibility. There should be greater equity of funding between different clinical areas. A central repository of approvals and study documents, accessible by everyone would save lots of duplication. Other ways of minimising bureaucracy so that it is proportional to risk should be explored-one possibility would be allowing greater access to SREDA, the NHS R&D database where much of this information is already stored.

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

Responsibility of delivery of recruitment is currently successfully managed by SPCRN research coordinators based in each node, supported by national leads. The reasons that problems are experienced with studies not recruiting to target are usually due to patients not meeting the inclusion criteria, often due to inadequate feasibility work by the research team prior to study commencement. This is a particular issue for studies which were designed to recruit patients from secondary care settings which then fail to recruit and request assistance from SPCRN to identify patients via GP practice databases.

Putting research infrastructure funding into clinical groupings increases the risk of the resources being used for clinical purposes. However, there are definite advantages to research being part of the core business of the team by linking delivery to resources and primary care research would benefit from encouraging this.

3. Leadership and Delivery

It is essential that a national management role with oversight of the clinical research portfolio and responsibility for performance is retained for the 12 research themes which are to replace networks and specialty groups. This would continue to ensure an easily identifiable point of contact for multicentre studies both for academic researchers, commercial sponsors and NIHR CRN colleagues in other parts of the UK. National oversight would also ensure lessons learned and effective practices could be shared, opportunities for collaboration could be more easily identified and allow monitoring to facilitate early identification of problems or deficiencies. We would suggest that a national management approach would promote ongoing and effective quality improvement activities.

a) 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?

We consider that many studies require national as well as regional co-ordination - in 2012-13 there were 32 national and 28 local studies on the SPCRN portfolio. Appointing Theme Leads locally may just be adding another layer of bureaucracy. Responsibility for recruitment should remain with the CI/PI to keep the study grounded, and they should be able to select from a range of support services to suit the study. Perhaps the money would be better used to support local PIs for each specialty.

We are unsure of the argument for having all of the staff in the new structures employed through NRS Nodes? SPCRN currently has staff employed in the NHS

(Lothian and Highland) and Academic Primary Care Departments (Tayside, Grampian and Greater Glasgow and Clyde) and this hasn't proved to be a barrier to good communication and relationships between SPCRN and researchers and NHS R&D colleagues in all areas. In fact the opposite has been true, current structures have promoted collaborative working and information sharing to mutual benefit. There will be TUPE implications for some staff.

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

It is likely that additional funding for time spent as a theme lead will be required as those most likely to be effective in this role are likely to be heavily committed and will need backfill sessions to compensate their teams. A detailed knowledge of the research areas covered by the theme, excellent communication skills, experience of line-management and performance management, proactive and reactive budget management, workforce planning and development and a track record of effective collaborative working would be needed in order to deliver this role.

Local Theme Leads would not be required if you had research enthusiastic Speciality Leads instead, who could act as local PI, plus a range of support services to facilitate delivery. This would then minimise conflict of interest between disease areas.

c) 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)

Local Speciality Leads would be preferable.

d) 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?

National coordination and leadership for each Theme is essential, with structures in place so that decisions made at a national level can be acted upon locally. Primary care should remain a network. National Theme Leads would be a better investment than local ones, to encourage greater collaboration between areas. Regionalisation of Themes with no national leadership and management would inevitably lead to lack of focus and consistency and prioritisation of local NHS R&D priorities as has already been experienced to the detriment of primary care research in NHS Greater Glasgow and Clyde.

Views on proposed model

This is similar to the existing SPCRN structure of a national clinical lead (Strategic Theme Lead) with five research coordinators (Operational Theme leads) in each of the SPCRN nodes. We strongly feel that the omission of a full time national Operational Theme Lead Manager (equivalent to the Research Delivery Directors in the NIHR structure) would render the proposed structure unworkable. National management of each theme is essential to ensure one point of contact for multicentre studies both academically-led and industry sponsored, sharing of best practice, progressing our public engagement agenda and ensuring continued engagement at a national, UK and European level. Portfolio development and management would be better done at a national level, with delivery of studies being delegated to local areas in discussion with the Speciality Leads.

Key Points:

- We strongly request that a national structure for co-ordinating primary care research be retained

- A full time national Operational Lead for each Theme is essential to ensure one point of contact for multicentre studies, sharing of best practice, progressing our public engagement agenda and ensuring continued engagement at a national, UK and European level
- We consider that many studies require national as well as regional co-ordination
- Lack of infrastructure in the form of access to research nurses who can support studies which are recruiting patients and delivering interventions in a primary care setting is a particular issue for SPCRn
- It is likely that additional funding for time spent as a theme lead will be required as those most likely to be effective in this role are likely to be heavily committed and will need backfill sessions to compensate their teams

This document incorporates comments from:

Prof Frank Sullivan, SPCRn Clinical Lead

Dr Alison Hinds, SPCRn Manager

SPCRn Research Coordinators (Dr Ellen Drost, Marie Pitkethly, Amanda Cardy, Rebecca Skillen)

Prof Christine Bond

Prof Frances Mair

Prof Bruce Guthrie

Prof David Weller

Prof Stewart Mercer

Prof Philip Wilson

Dr Janet Hanley

Frances Hines

39. Scottish Specialty Group Lead for Cardiovascular Disease

Allan D Struthers , Professor of Cardiovascular Medicine, University of Dundee

You talk about 12 Themes but the Annex seems to only have 6. I could not find what the 12 themes were going to be.

Also you talk about “national theme leads” and “local theme leads”(so far so good, I was understanding at this point) but then at the end, the terminology changes to “operational theme leads” and “strategic theme leads”. By the end I was thoroughly confused as to why we have four terminologies for two posts, I think..

Also it is true that current specialty leads have no ability to divert funds to failing studies as NHS R and D managers control this. However in your new system, this sounds no better as you say that theme leads will have to coordinate resources through NHS R and D Directors, which sounds like the status quo and no improvement

40. Scottish Specialty Group Lead for Clinical Genetics

Dr Jonathan Berg, Senior Lecturer and Honorary Consultant in Clinical Genetics, NHS Tayside

Specialty Groups and Networks - amalgamating specialty groups

I think that here, I agree. The difference between Topic networks and specialty group creates an inequity. They should fulfil the same function. Therefore, the creation of new groupings makes a lot of sense, covering all specialties in an equal fashion.

The catch is that the groupings are essentially administrative and the overlap between specialties in each is limited. So, for example, in my own, I am not sure that a haematologist could represent the interests of genetics or obstetrics effectively. Similarly, a geneticist would struggle to help develop research in many areas of obstetrics. People from one specialty would wonder why the guy from genetics was telling them what to do.

If the job of "NRS operational theme lead (OTL)" was mainly administrative - in terms of monitoring recruitment only and allocating resources, then it might be more tenable, but would only work if the person was given enough assets to do the job - I think I would describe these as (a) knowledge (b) teeth and (c) administrative support.

I suspect the Scottish contribution to the networks/specialty groups has been limited because of inadequate admin support and a lack of consequence to a number of researchers for failing to comply with recruitment.

(1) So, I conclude here that direct responsibility for allocation of the resources by operational theme leads in each NRS node should improve their ability to ensure compliance with recruitment targets. Time allocation for this role should NOT be minimal. Admin support needs to be significant and highly qualified, not nominal and poorly qualified. You need an effective communicator with a thick skin. Probably not a world leading researcher with their own agenda and no time.

(2) It would make sense to have a mini-committee of the 4 NRS node operational theme leads to provide an element of mutual support and allow effective national decision making - supporting the one strategic representative to the national faculty.

Representing multiple specialties in one theme

This is problematic in many ways - not many people in one specialty command the respect of all those in other specialties - and most would lack the knowledge to represent a sub-theme at faculty level that was not their own.

(3) It would make sense for each NRS node operational theme lead to have local representatives from the other specialties - this would not require much time cost (perhaps) but requires additional admin support - so each node has a Theme operational committee supporting their operational theme lead

(4) A slightly clunky, but inevitable solution might be to ensure that the Theme lead in each node represented a different aspect of their theme - e.g. genetics in dundee, paediatrics in edinburgh, haematology in aberdeen - making sure the specialties are covered and providing advice/support on specific issues.

Representation in UK

It is possible that UK specialty groups will continue to exist in some form - separating, for example genetics and paediatrics, in which case it may be essential to ensure that appropriate specialty representation can continue - idea (4) above would keep this covered

Senior Faculty

On the whole, I think this is a good idea, although I have some concerns.

A strategic theme lead from one specialty might struggle to have a developmental role for another - I think that points (2) and (4) defend against this a bit - as the Strategic lead has the support of specialists from other clinical areas. It is essential that these "sub-networks" are properly supported. The money to make this happen cannot just disappear into the system.

The ideal person-type for this role is harder to envisage. It could be a very time-intensive role, and requires someone with really good links, and who can command respect nationally and across specialties. It is actually very different to the requirement for an operational lead, and would require a specialised support infrastructure.

Other comments

I note that pathology doesn't come into this at all - I think that it is a specialty that should be represented, as it provides key infrastructure in a number of areas

Last Question

Is there a space for extra consideration for rare diseases ? I know that I keep flagging this - but it has a number of difficult to solve problems with commercial and national studies that may require unique solutions - would it be a comparatively easy way of supporting the area, and answering a number of points in the rare diseases plan, by giving this area more specific representation on the faculty ? It is fairly cross-cutting with examples of rare disease in almost all specialties.

41. Scottish Specialty Group Lead for Dermatology

Professor Jonathan Rees FMedSci Grant Chair of Dermatology, University of Edinburgh

Dermatology in England has done remarkably well from the system there. How long this will continue I do not know. Obviously in Scotland the resource has not been available, although for funded studies with clear lines of non-NHS support such as my dermofit project, we in Scotland have punched above our weight.

Scotland has worked remarkably well in other cross-Scotland initiatives such as Photonet and the Scottish Melanoma Group, although the latter is not doing well I fear. This is in large part because they were clinically driven, and integrated with the other organisations. There was community buy-in, and the activities were run 'bottom up' rather than managed from above.

I think if the speciality link between 'those who might enter patients in a discipline' and those 'directing' things is broken, participation and buy-in might be a problem.

Any system of performance management and funding has to take note of the realities of an increasing inability to meet clinical service demand, and a failure to deliver on agreed levels of teaching to undergraduates. These are real issues in Lothian dermatology. These facts inevitably colour my views. One of the reasons many do not enter patients into studies is that the resource (especially time) is not there —or local management do not admit it is there.

42. Scottish Specialty Group Lead for ENT

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25th July 2013

KMACK/ss

Dr Charles Weller
NRS Networks Manager
CSO
St Andrews House
Regent Road
EDINBURGH
EH1 3DG

Dear Dr Weller

Consultation on proposed changes to support structures for the NHS research in Scotland

Thank you for your email of 14.7.13. I am Mr Kenneth MacKenzie, Consultant ENT Surgeon at Glasgow Royal Infirmary and am responsible for specialty representation for Otolaryngology Head and Neck Surgery (ENT) for Scotland.

In ENT we are a relatively small surgical specialty, around approximately 70 full time consultants in Scotland, with three very clear areas of subspecialisation namely, otology and audiology, rhinology, and head and neck surgery. With this further super specialisation within our specialty my opinion is that the effective way to optimise access to studies nationally is through the specialty group representation and subsequent direct contact with potential researchers within the clinical set up. As a consequence I believe that this is the most efficient way to manage the portfolio.

From a practical stand point we have no financial leverage to encourage and facilitate participation of colleagues in ENT research. The most effective way for this to be achieved would be to identify potential key workers, based on current enthusiasm and previous performance and fund part of their current job plan/contract with specific aims and objectives for a fixed tenure of that research inclusive contract.

Such a grouping would effectively be responsible for the generation of sub specialty research activity within Scotland and optimising participation in the portfolio activity in addition to creation of new studies. I would suggest that it is unlikely that a theme based approach would be best for ENT as a specialty in Scotland.

Yours sincerely

Kenneth MacKenzie FRCS (Ed)
Consultant ENT Surgeon

43. Scottish Specialty Group Lead for Hepatology

Professor Peter Hayes, University of Edinburgh

Seems complex and thorough. One consideration is whilst 12 theme leads to cover delivery of studies on time seems great, these people might well not be the same folk who have 'lead' specialties in your current system. There might well be a potential conflict here between the theme leads and the specialty 'research activists' . Also in my area of hepatology if the theme lead was a gastroenterologist he/she might know relatively little about Hepatology and certainly wouldn't be Hepatology research active. Horseshoes for courses I suppose but it would be nice to have the specialty research active leads to continue to have a voice somewhere through CSO

44. Scottish Specialty Group Lead for Infectious Diseases & Microbiology

Professor David Goldberg, University of Glasgow

I am fully supportive of the Theme Lead proposal. This will be good for infectious disease as I have found this territory particularly challenging because i) I am not a clinical infectious diseases consultant and ii) there is no academic dept of clin infect diseases in Scotland. Over the years I have had only a handful of enquiries! The Theme Leads would have to demonstrate their ability to cover the theme areas but I do not think there will be a problem in getting appropriate personnel as the more formal approach of competitive appointment, coupled with a contract outlining what is expected for whatever remuneration, will do the job!!

45. Scottish Specialty Group Lead for Injuries & Accidents

Dr James Dear, University of Edinburgh

My group would like to see theme leads with real resources that can allow research to be performed outside of the established centres. Our feeling is this involves real access to research nurse time based on research activity. My own feeling is the themes should be based on skills rather than organs. So we have experience of recruiting patients in emergency settings. I would like us to be with other studies than could benefit from our experience.

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?

JD - no I don't believe it does. My group would favour more regional delivery.

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?

JD - my experience is that it is difficult to engage with ED departments outwith the established research active centres. This would be improved by more regional delivery.

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

No!

Question: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

JD. No. The major block to increased portfolio trial uptake in Emergency Depts is lack of embedded resource. For example I run the MAPP portfolio trial. I have been inundated with requests to open as a site from English centres and have opened 9. Only Aberdeen has opened in Scotland. Asking why to colleagues, it is lack of embedded research nurses in EDs. To be clear, many of the sites in England are small DGHs that still have highly developed research nurse networks.

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?

JD. We agree that money should follow activity.

The main concern with the new structure is that smaller specialty groups such as I&E will get lost in groups with unnatural other disciplines. My suggestion is to form the

groups by skill mix. For instance the great skill of my specialty group is recruiting in Emergency settings with complex consent processes etc. I would like to see groups that reflect the skill set of the specialities .

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?

JD: yes

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

JD: strong track record of running successful portfolio trials

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)

JD: again, I think the key is that the local themes reflect skill sets needed for trial success rather than bits of the body. For instance an emergency diabetes study might fit well with emergencies theme rather than diabetes.

46. **Scottish Specialty Group Lead for Metabolic & Endocrine**

Graham Leese, Consultant and Professor in Diabetes and Endocrinology, Ninewells Hospital and Medical School

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?

This seems to work well in the majority of cases. It makes the locus of control/responsibility clear and allows the network to become a real entity and not just a virtual entity.

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?

With good organisation and if R&D departments respond to requests for information and communicate well, this can be effective. If an R&D department were to take on this role there may develop conflicts of interest to a greater degree than with a Network co-ordinating this.

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?

Specialty group leaders need support to do this effectively, which has been provided by R&D departments.

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

No. If there is a difference, the split should be done on size of portfolio. The smaller portfolios would be reasonably managed as a specialty group.

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

Lack of open communication. Communication barriers are slowly being broken down, but localities, can be reluctant to share key information with a Network located in another area. In Diabetes a lack of research nurse time – especially nurses with disease expertise eg insulin management.

Question: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

Is there any financial leverage?! Even in Networks it is difficult to move funding around from areas with lower recruitment to support areas with greater recruitment.

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?

It is increasingly difficult to undertake research as an NHS employee. NHS demands have increased, as has research governance, and as a result it is difficult to get research momentum. The Networks should not be placing demands on NHS researchers. Those who are successful should be “rewarded” by useful support, such as paid sessions or

Personal assistant support – which is widely valued by University Academics as a way to work more efficiently.

The other issue is salary security. NHS clinicians will be reluctant to risk research funding time and time again if they are always at risk of losing their funding if they have a fallow period. Once agreed, research support funding should be for 3 years minimum (or not all), and probably 5 years (or more) for more established researchers, depending on previous track record. Again University academics usually seek long-term security once they have “proved themselves” for 5 years. No such research financial security exists for NHS researchers. These comments apply to Consultants on 11-12 sessions. For consultants on 10 sessions, the current financial risk lies with the NHS Board, for individuals where the funding is not continued.

In summary, for those who have a sufficient track record, an offer of funding for 3 years should be made, extending to 5 years on renewal. This could be for any number of sessions. Although this makes the system less responsive on a year by year analysis, it creates more security and therefore is more likely to be attractive for keen and able researchers.

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

They are fairly efficient.

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?

The Networks have had local leads up until now, but the SG have not. The National Network leads should be managing the local leads to enhance recruitment.

- a) Local leads should be given more responsibility for this role
- b) The National leads have little power to influence local leads, and they need more. Local leads should be appointed for a 3-year term and be expected to reapply for their post after this time (like happens in NES). It may also be useful for National leads to have some discretionary funding which can be allocated on an annual basis
- c) With the new 12 Themes this may become easier. If each theme (like each Network before it) has a local lead, they could be given responsibility to help with the other specialties in their theme – at least top facilitate and liaise. This option has not been available so far to National SG leads, but it would be very useful

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

They need a track record in recruiting to research, and hopefully publishing. They need to be collaborative, persuasive and have good communication.

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)

They will need to rely on the co-operation of local champions in the disease areas that they are not expert in, and to create a local Theme group.

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?

Yes. This would work if properly managed by the National Theme Lead.

With the model proposed, it would be possible (and desirable for some areas) for the National Lead to be the same person as the Local lead. That would help improve efficiency for some, and allow a greater flexibility of approach depending on the local areas needs.

In the NIHR model, it is not clear what the Research Delivery Directors will do and what their role is. There is not much discussion of this in the document and it potentially undermines the Themes. It looks as though the long-term plan may be to merge the "Themes" into the "Delivery" areas.

47. Scottish Specialty Group Lead for Nervous System Disorder

Malcolm Macleod, Professor of Neurology and Translational Neuroscience, University of Edinburgh

Firstly, I should say that the grouping of specialties makes no sense. No-one has been able to convince me that the grouping fell this way for anything other than administrative reasons relating to the NHS in England. That's a bad starting point. As the NHSs in England and Scotland become increasingly diverse, the rationale for this approach diminishes. I'm surprised that the Scottish government are pursuing this line, which does not seem to be in our (Scottish) national interest.

In terms of delivery of stroke research, the system in SE Scotland has worked well. Of course, Edinburgh would do pretty well anyway given the University activity here, but though supporting research nurses in Fife and Forth Valley (and over the years we have focussed resources where they do most good, disinvesting from NHS Borders because of poor returns) we have extended the opportunity to participate in research to patients in these areas, and I am clear in my own mind that this would not otherwise have been the case. We're talking about hundreds of patients recruited, and in fact in 2007 or 2008 Forth Valley was the second highest recruiter (after Glasgow) to stroke portfolio studies in Scotland. Further, we have been able to use a small amount of resource to support an acute stroke rota in Edinburgh which sustains the thrombolysis service and which is permissive for recruitment to acute stroke trials, one of our identified areas of weakness but an area where there is great potential (Salman and haemorrhage, myself and hypothermia, Pippa Tyrell's IL1-RA study).

The CSO should be in no doubt about the following –

1. Grouping stroke with cardiovascular makes no sense, because these patients present to different clinical teams, at different times, often in different hospitals (eg different rehab units) and – generally (but perhaps not in my centre ;-)) the relative status of cardiologists and stroke doctors will make us, once again, the poor relation. This would be a major step backwards. Having a day or 2 a week of a cardiology research nurse when s/he is not busy on a cardiology study is neither use nor ornament.
2. It takes time to build research activity. As well as training the individuals involved, and the start up time required for individual studies, there is the time taken to build a reputation for efficient and timely recruitment and for good data quality. The idea that funding might stop in April next year, and then we'll start trying to get resources through the new system, would be an unmitigated disaster. CSO has to understand the need for continuity, either by underwriting current posts through a different funding scheme during a transitional period or delaying the implementation of the new system so that, on the ground, I can have continuity of research nurse function (allowing, of course, that there may be changes in how this function is delivered).
3. I appreciate that there is a lack of equity in the provision of research resources, and as I say above I see both sides of this. But building research recruitment in for instance NSD will take time, and there is no doubt in my mind that recruitment in stroke will fall precipitously if resources are withdrawn. There is also the question of morale – if people come to believe that there is to be disinvestment in stroke research, it will be much more difficult to motivate people to perform, to innovate, to develop.

I have no strong views of what the “superstructure” might look like at a national level – the critical thing is clinicians on the ground (doctors and nurses) delivering the research. However, I do think we

need to avoid redundancy, and having 12 folks in each of 4 nodes seems to me to be a bit much (say 1 PA each takes you to £500k, or one lead per 100,000 population ...) – I'd rather trade one national lead for stroke for 4 regional stroke/cardiology leads.

For Nervous Systems Disorders, we have an emerging model in Forth Valley which I think will work well; Suvankar Pal has an NRS Fellowship, and is building a research portfolio. As he generates income through grants and some commercial research activity we are in the process of finding a generic Neurology research nurse. They will be mentored by, sit beside and provide cross cover for our stroke research nurse. He will, I'm sure, recruit well to a number of studies –in his field he's already competing with Lothian. If the funding for the stroke nurse was to be substantially reduced then clearly the most sensible thing would be for a joint neurology/ stroke specialist nursing role rather than involving cardiology. A small amount of funding to each neurology unit (university or DGH) in the form of 2 or 3 PAs of consultant time and a band 6 research nurse would go a long way.

I think this illustrates a need to build in flexibility in implementation. Where stroke sits more closely with Neurology there should be the opportunity to create joint posts, even if the funding flows from different parts of the superstructure. Perhaps the trick would be to have the oversight of recruitment to target etc invested in the Cardiovascular national lead, but resources delivered at board level through research leads in each speciality negotiating with local R&D, with the starting point for discussion being the status quo.

Finally, if I might be parochial. The 4 nodes are centred around the 4 university hospitals, and researchers in other boards have traditionally struggled to be adequately resourced. Since funding has often followed recruitment, this has been self sustaining. Where resources have been invested in peripheral boards (as SSRN have done, in Fife and Forth Valley and Lanarkshire), recruitment has followed. If the resources are taken back into the 4 nodes, the proportion that will flow to the peripheral boards is in my view highly likely to fall below a level at which any meaningful research activity is feasible. Not only will this deprive people living in those board areas of the opportunity to participate in research (and I think there are almost as many people in SE Scotland who live outside Lothian as who live in it), by creating boards where there are few opportunities for research activity these will become unattractive to potential high calibre recruits.

At present it is possible to be appointed as an NHS Consultant in a peripheral board and, within 7 years, be a Professor of Neurology. This was my career path, largely made possible by resources made available through SSRN. CSO should be very careful not to dismantle a system which at times works very well (as it has done for stroke) without very good reason. Rather, they should seek to evolve, taking the best from what we have and using that experience and those models to bring about improvement where this is required.

48. Scottish Specialty Group Lead for Ophthalmology

Dr Roshini Sanders, Consultant Ophthalmologist, NHS Fife

It is an excellent document and I have nil to add.

49. Scottish Specialty Group Lead for Paediatrics

Professor Jürgen Schwarze, Edward Clark Chair of Child Life and Health, University of Edinburgh

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?

I fully support the ScotCRN response to this question.

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?

I think both networks and local R&D staff have clear, distinct and necessary roles in delivering studies. Networks are essential in the acquisition/development of studies, the assessment of their feasibility, and in facilitating multi-site studies, which are of major importance in children's clinical research. In addition, networks provide training and guidance to local PIs which also clearly improves study delivery and they help determine the support needed for a study locally. Local R&D staff have to assess/ help adapt studies and their funding according to local NHS needs. Currently, local R&D staff allocate resources beyond the core network resource (e.g. network research nurses). In NHS Lothian this is a collaborative process involving the ScotCRN research nurse lead.

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?

In my experience it is still difficult for a SG lead to manage the portfolio, since the documentation of paediatric non-medicines studies on the NIHR portfolio web site is often incomplete or incorrect. Often paediatric non-medicines studies are not listed under that heading. The decision of ScotCRN to support both medicines and non-medicines studies, which both can be adopted by the network (and listed) has made an overview much easier.

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

I fully support the ScotCRN response to this question.

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

I fully support the ScotCRN response to this question.

Question: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

SG lead / networks /themes should have more influence on the local allocation of NRS resources in their clinical research area. To develop and deliver clinical studies, in particular investigator led studies, the PI will usually need allocated and protected time. SG leads/networks/theme leads should have knowledge of local R&D budgets in their clinical area across Scotland and should have real influence on the allocation of research PAs to consultants, in order to encourage and facilitate study development and delivery.

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?

Please see above. NRS funding to health boards could come with the stipulation that theme leads are given access to budget details including funds received, funds spent on research nursing support, and on consultant PAs. They could then see if funds are being spent as intended. If there is insufficient spending to support consultants as PIs they could help identify relevant colleagues who would undertake clinical research if given the time to do so. The theme leads would suggest research time allocation to these colleagues to clinical directors/R&D directors. This would need to be underpinned with the threat of a reduction in funding to the health board if these suggestions are ignored over a certain period of time (e.g 2 years). If a health board genuinely cannot backfill research time for a consultant who wants to develop clinical studies it may be an alternative to allocate research time to a specialist nurse who is working with this consultant.

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

I fully support the ScotCRN response to this question.

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

I fully support the ScotCRN response to this question.

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?

I fully support the ScotCRN response to this question.

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

I fully support the ScotCRN response to this question.

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)

I fully support the ScotCRN response to this question.

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?

I fully support the ScotCRN response to this question.

50. Scottish Specialty Group Lead for Reproductive Health & Childbirth

Professor Jane E Norman University of Edinburgh, and Professor Siladitya Bhattacharya, University of Aberdeen

We have read the consultation document with interest, and we largely support the proposals in described at the end of the document as the “Future Model”. We believe that ensuring researcher and infrastructure support for is key to optimizing recruitment (study delivery) in each specific theme, and we agree that Scotland’s performance has been poorer than England’s in this area. We believe that the proposals presented in the document will go a long way to addressing this issue.

Although a somewhat separate issue, we agree that researcher led portfolio development (specifically attracting grant funding) in Scotland has traditionally been excellent. The proposals presented will strengthen this further and facilitate wider portfolio development (particularly attraction of commercial studies) to Scotland.

The document poses a number of specific questions which we have reprinted in blue and which we have responded to below each question.

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?

Our own specialty of Reproductive Health and Childbirth is not aligned to one of the current seven networks. Perhaps because of this, recruitment to studies in our discipline in Scotland has been less than would be expected based on population. For example, OPPTIMUM, ISRCTN14568373, www.opptimum.org.uk recruited in 62 sites in the UK, over the period 2008 - 2012, of which only 4 were in Scotland. This is despite the Chief Investigator (JEN) being based in Edinburgh. The total number of women recruited to OPPTIMUM was 1230, of which 59 (less than 5%) were recruited in Scotland, of which only 18 were recruited outside the lead centre of Edinburgh. The funding structure in England led to us being actively contacted by sites in England who were keen to participate and had funding to recruit. In contrast in Scotland funding had to be negotiated with local R & D leads, although those in Lothian and Aberdeen were supportive. We have had similar experiences with other Scottish led studies (eg. EMPOWaR 51279843). This does not reflect lack of research “knowhow” in Scotland, given excellent recruitment when recruitment funds are embedded in the study grant (eg STOPPIT)([1](#)). In contrast we believe that the problem is lack of CLRN leadership and awareness among NHS clinicians/managers/ of the benefits (including financial) of recruiting to national trials

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?

They may be clear for those specialty areas included in a Network, but they are not clear for specialties (such as Reproductive Health and Childbirth) which are not covered by a Network.

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?

Although specialty groups can act as a champion of research in their specialty, and we have done this with some success (eg with the HTA funded EMPIRE study, led from London - <http://blizard.qmul.ac.uk/research-generation/254-empire.html> - and which will start recruiting in Edinburgh and Glasgow shortly), Specialty Groups are significantly hampered by lack of resource, and lack of an efficient structure (in contrast to English CLRN) as well as the challenge of Scotland's geography. There is little scope for regular meetings of research active clinicians, recruiting nurses/midwives and the specialty group lead. Again, projects have to be negotiated on an individual study basis with R & D directors which is inefficient and does not encourage a nexus of activity in a specific specialty area.

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

No

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

This question is not relevant to Reproductive Health and Childbirth as we are not part of a network.

Question: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

No – as mentioned above the lack of financial leverage and the inability for Specialty Group Leads to provide funding for recruitment is a major barrier in preventing participation of colleagues in research. Financial support is needed firstly for meetings and travel to maintain a vibrant and efficient research environment which is supportive of expanding the recruitment base. Additionally, funds are needed to support recruitment with a clear pathway for communicating with those who are able to release these funds. At the moment this is an ad-hoc exercise which does not work well in practice.

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?

We believe that use of the NRS Researcher support budget (at least for medical staff) has worked reasonably well in Scotland, allowing research active NHS employed clinicians to develop and lead their own research. Linking of Theme research activity to NRS Researcher support funding would certainly incentivise recruitment, but unless linked to wider infrastructure funding (eg research nurses and midwives) may not address the major barrier to recruitment.

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

No, there is no direct link between recruitment and funding, with no supporting infrastructure to support recruitment in some specialties and we believe this is the major reason for Scotland's poor recruitment compared to England. Lack of centralized leadership means that funding decisions are often local and patchy

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

Yes, definitely. This would allow a nexus of infrastructure staff in a particular specialty, who could recruit to a portfolio of studies. We have also noted and strongly agree with the problem outlined in the document that "Specialty Group Leads are charged to deliver studies but have no access to or responsibilities for the resources required to meet that aim" – this is

a major current problem that linking resources to clinical groupings and management structures would address.

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?

Yes. Local theme leads are best placed to ensure delivery of recruitment - they are familiar with local resources (both in terms of clinicians and potential research participants), will have local knowledge of what is likely to “work” or not work and can develop an infrastructure to support a portfolio of studies. An important caveat is that Theme Leads can only ensure recruitment if they have a budget - presumably in negotiation with the local NRS nodes and R & D offices.

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

Local Theme Leads should be enthusiastic about research, should be familiar with research methodology including clinical governance issues (GCP certification should be mandatory) and should be acknowledged as clinical experts in their areas. They should have good interpersonal skills and a track record in leadership in other scenarios.

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).

Theme Leads will need ongoing communication with clinicians in other disease areas within their theme. This could be organized through an email distribution list, regular (? quarterly) meetings and/or a web-portal, and would require minimal if any specific additional funding.

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?

Yes. This would help co-ordinate delivery of research, and ensure that Theme specific good practice is shared amongst the Local Theme leads. Additionally, the National Lead could have a role in Portfolio development, which could include facilitating and supporting researcher led study development, engagement with Chief Investigators of projects on the UK research portfolio, and engagement with pharma to attract commercial research investment in Scotland.

In summary, we support the proposals outlined in the document. We strongly believe that linking activity to output is the strategy most likely to be effective in increasing research – although this is possible in the current set up, local clinicians have to negotiate infrastructure support for each specific project they wish to participate in. Such a procedure is inefficient and contributes to Scotland’s suboptimal performance in research recruitment.

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51. **Scottish Stroke Research Network (SSRN)**

Overview

This document summarises responses of members of the Scottish Stroke Research Network to the CSO consultation exercise on proposed changes to support structures for NHS research in Scotland. It provided the collated view of this group 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. For clarity the structure of this document has been aligned with the consultation paper.

General comments

Scope and implementation of the proposed reconfiguration

Several respondents commented that the topic networks were set up to address specific challenges (for example recruitment to large clinical trials) in specific areas identified as important but historically under-served, such as Stroke. As such those areas which were generally well resourced, such as Cardiovascular Medicine, were not felt to be in need of a Network structure. The Networks did not “manage all the research within their disease area, only those that they adopt into their portfolio” because there was a need to focus on specific priorities such as recruitment to late phase clinical trials. Concern was expressed that the broad and ambitious scope of this proposal may lead to a situation where the reconfigured organisation tries to do a little of everything without making much impact.

There is a clear need for some continuity, either by underwriting current posts through a different funding scheme during a transitional period or delaying the implementation of the new system so that, on the ground, we can maintain existing activity and honour our research commitments allowing, of course, that there may be changes in how this function is delivered. There are risks that recruitment in stroke will fall precipitously if resources are withdrawn, and that morale will be adversely affected. If the general perception arises that there is to be disinvestment in stroke research, it will be much more difficult to motivate people to perform, to innovate, and to develop.

Composition

Another theme which emerged clearly from the responses received was the composition of the proposed group. The decision to place Stroke with Cardiovascular Medicine seems to be based more upon administrative expediency than clinical practicality. Our patients present to different clinical teams, at different times, often in different hospitals (e.g. different rehab units) and there was concern that relative numbers of cardiologists and stroke doctors will make stroke, once again, the poor relation. The SSRN was formed to resolve this problem, and this change would be regressive in that regard. More generally there was disappointment expressed at other complex and somewhat unwieldy “themes” however the significant risk inherent in the adoption of a very different organisational structure from that to be implemented in England and Wales was acknowledged.

Structure

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?

Whilst the strengths of the current structure were acknowledged, as evidenced by the enhanced national recruitment to clinical studies since its inception, there was also acknowledgement of the importance of adaptive change in response to the NIHR reorganisation.

More broadly, whilst not specifically requested by the consultation, comment on the management structure that will sit under both national and nodal clinical leadership & R&D Directorship was received. It may be that this is to be decided to suit the needs of the Nodes (which vary in size and areas of academic and clinical expertise). The NIHR model has a Chief Operating Officer per geographical network and has a Research Delivery Manager per Division: both roles will have a nationally agreed job descriptions.

Under the proposed arrangement the responsibility for portfolio delivery (to time and target) will remain with the Clinical Lead, but the workforce (& budget) will be managed by the Director of the Research Node. This is a different model to England where the R&D Management and Governance is an advisory capacity. A view was expressed that there needs to be a professional reporting line from the theme workforce to the Clinical Lead.

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?

There was consensus among respondents that this is not the case. Two different sources of funding lead to different management structures which do not necessarily see eye to eye. Having a network lead and their administrative office, at a centre far away from the research active centres has not been an effective or efficient use of resources. It has created potential for disproportionate allocation of resource without sufficient clarity or management oversight.

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?

Engagement between specialty group leads and the Scottish medical schools needs to be improved. The poor quality of this interface is a key structural issue which would be relatively easy to remedy. A second area of concern relates to the day-to-day oversight of activity at a local level which is not readily achieved given the current configuration.

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

There was general consensus among respondents that this is not the case, and that two separate management structures introduce unnecessary complexity.

Funding

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

The main barriers so far to specialty groups nationally and to networks locally are communication. Respondents pointed out the inherent complexity of a model involving multiple layers of staff. The 12 national specialty group leads will require clear links to local specialty champions who have knowledge of the budget, and budget allocation that follows activity (after a reasonably equitable start). Most of the budget should be spent on identifiable core generic staff who deliver the research. The use of nurse 'pools' where responsibility and accountability are ill-defined would be highly detrimental.

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?

The complete separation of CSO resource allocated to support research from clinical budgets is welcomed, as will be further information on how this will be achieved.

It is too early to judge whether the NRS researcher scheme has been successful, however the general concept was supported by respondents. Quantification of research time and recruitment and linking this to funding is important. However, the funding needs to be transparent and needs to be seen to deliver real gains and measurable outcomes. The reductionist focus on numbers of patients recruited as an index of achievement (and hence incentive) was not felt to be the best metric to use.

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

There was a general view that funding to support studies could be better managed. More flexible arrangements for staff working could be implemented. With the greater availability of part-time medical staff and staff on flexible contracts, the potential benefit of more innovation in disposition of staff was suggested. This could be facilitated by greater involvement of clinical researchers in the decision-making structures.

There would be potential benefit from resource-sharing where possible across the clinical themes, subject to the caveats regarding "nurse pools" above. Access to a

more flexible research workforce may allow a broader range of studies to be undertaken.

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

Respondents indicated that this would be the case.

Leadership & Delivery

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?

This arrangement would overcome the current issues with local oversight of a national trial portfolio. The concern would be whether the retention of a new tier of local theme leads would diminish the financial resource available to support the conduct of clinical trials. The effectiveness of these individuals would also be determined by the degree of budgetary control afforded to them.

Some concern was expressed over the practicality of maintaining 12 theme leads per node in Scotland. This could represent a “top heavy” approach with too many generals and too few soldiers. 12 leads for Scotland were suggested as a more efficient model. It was recognised that Stroke may not be directly represented because the Stroke and Cardiovascular theme may well be lead by someone with little knowledge of stroke. It may be that the existing strong links between stroke researchers in Scotland, previously nurtured by the SSRN, will create an informal stroke research group across Scotland which can feed into the new system to ensure that adequate resources are available to support the ongoing Stroke research activity

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

Local theme leads need to be research active and have an experience of clinical research. The leads will need to have protected time. It is not essential for them to be from the NHS and it is likely that a high proportion will be university employed staff. Irrespective, they will need protected time and associated PAs.

Question: How best would Local Theme Leads (LTLs) 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)

This was identified by respondents as a crucial area. There was widespread concern that activity in the “smaller” disciplines such as stroke would struggle to achieve the same priority as larger ones and would suffer as a result. A further challenge lies at the interface between primary and secondary care research which was identified as problematic. One potential solution would be the creation by LTLs of local working groups. They will need a deputy who is from a different background within the same

theme. LTLs will need to have a fixed tenure with transparent appointment processes. To be effective LTLs should play an influential role within the local R&D management structure.

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?

It was felt that this arrangement would strengthen the structure and provide oversight if implemented carefully. The role of this group would need to be carefully defined to retain a focus on supporting research in Scotland.

52. SDRN Epidemiology Group

Dr Robert Lindsay, Reader in Diabetes & Endocrinology, University of Glasgow

I am writing as Chair of the SDRN epidemiology group in response to your consultation document.

I appreciate that the consultation document deals with the larger issue of support for research in the NHS in Scotland but clearly restructuring of the networks could threaten the work that the SDRN epidemiology group has developed. In brief we believe that we have been very successful in achieving what was asked of us. We have 17 high impact publications (v.i.) and importantly the efforts of the epidemiology group have not only drawn attention to SDRN more generally but also formed the sampling frame or the opportunity for longer term follow up in a number of large studies as listed:

- Type 1 Diabetes Bioresource (Wellcome Trust)
- SCOTS (NHIR-HTA)
- REMOVAL (Juvenile Diabetes Research Foundation)
- UNITED/MODY (Wellcome Trust)
- DIRECT (European Union Innovative Medicines Initiative)
- SUMMIT (European Union Innovative Medicines Initiative)

By any measure the relatively limited investment made by CSO has been very successful and in that I acknowledge particularly the work of Professor Helen Colhoun in Dundee and Sarah Wild in Edinburgh. We have always thought that development of the links between trials and routine NHS data promotes a key competitive advantage in attracting such trials to Scotland and wish to continue and strengthen this in the future.

Again I appreciate that the document is written with a much more general purpose but it would be helpful to clarify what CSO intention might be for the future of the epidemiology limb of SDRN, not least so that we can clarify the situation to staff employed by SDRN and the researchers with whom we collaborate,

53. UK Specialty Group Lead for Age & Aging

Professor Marion McMurdo, University of Dundee

Structures

A key selling point for the transition to Themes in England was to create, for the first time, a (more) level playing field between the Topics and the Specialty Groups (SGs). The Topics have had the lion's share of resource for decades, and have accordingly assembled large portfolios. To remove the existing inequities, resource will have to be disembedded from the Topics and made available across Themes. This will be deeply unpopular with the Topics, for obvious reasons. If there is a genuine intention to create equitable research delivery across Scotland, it is critical that the basis for resource allocation is *not* portfolio size. Topics have built large portfolios *because* they have had the advantage of significant resource for many years. Most SGs could have done similarly given the sustained level of investment that the Topics have enjoyed. The key for resource allocation should be quality of delivery, comprising proportion of studies reporting, proportion of studies which close time to target etc. These metrics are already routinely collected.

Funding

A criticism of the Topics has been that they struggle with the age-related issues of multimorbidity and frailty. These are growth areas of research. The drawback with continuing to allocate funding based on past performance is the structures that are created might not reflect future trends in research, including the needs of industry. A potential strength of the new Themes would be flexibility. However shifting resource within Themes will be inevitably be contentious.

SG Leads are severely constrained in their ability to influence "time to target delivery" in Scotland. What they can do is to check that sample size, start date and end dates are correct, whether the study is open to new sites, identify obvious barriers etc, all of which is important and necessary. However Leads have no access to tangible resource for example research nurse time, which is most often what transforms recruitment. They have no financial leverage or influence over research support staff resource. Remedying this disconnect would be very helpful.

I am 100% certain that linking resources awarded to study delivery would be a great advance. Care needs to be taken about link being exclusively to "number of participants recruited". Quality must also be factored-in. See my earlier comment on metrics. Otherwise a Node with a 3,000 participant questionnaire study will command the majority of this premium, which would not be sensible.

But the resources must not just be linked to the Nodes, each Node must incentivise its researchers (as happens in England) by guaranteeing that a proportion of the "patient premium" directly reaches the research teams involved.

Leadership and delivery

I propose that portfolio metrics become part of the Performance Management assessment of Medical Directors in NHS Boards, as is the case south of the border. This would ensure genuine commitment and interest from senior NHS staff in the research success of its own region.

I am delighted that portfolio development is a key role in Scotland for Themes. This is what excites the research community, and encouraging more national-level collaborations will increase Scotland's competitiveness, and will also allow big questions on how to improve the health of the country to be formulated and answered. Bringing national researchers together and then not letting them generate new research, as is the plan in England, is bizarre.

Academic medicine and clinical research is very well developed in certain SGs – cardiovascular for example. Indeed a number of these specialty-specific infrastructures were in place long before SGs came into being. However research activity is less well established in SG areas which are equally important to the health of Scotland.

Having 12 “operational Theme Leads” in each of 4 nodes has some advantages, but would require a large number of individuals, the very situation our friends in England are trying to exit from. A consideration of current and potential activity level would need to be taken into account. The challenge will be the desire to have a one size fits all approach, when in fact the quantity of research going on across SGs is very wide. These individuals will require access to advice from the components of the Theme. For some Themes cross group knowledge is plausible (e.g. stroke and cardiovascular), for others (e.g. Age and Ageing, Oral and Dental, Health Services Research and Public Health) this will be impossible. Indeed the term “theme” is a considerable misnomer for what are predominantly convenience conglomerations of unrelated groups and Topics.

The proposal for “strategic Theme Leads with a role in development is an exciting one, which would for the first time in Scotland promote strategic thinking and planning.

54. **UK Specialty Group Lead for Critical Care**

Professor Tim Walsh, SG Lead for Critical Care, Edinburgh Royal Infirmary and Edinburgh University

Question: Does the current structure where in each Network is aligned with a lead Board with national responsibilities deliver optimised national access to studies and effective study delivery?

It seems logical to me that in a country the size of Scotland for a single lead board to be the main administrative organisation for each network

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?

There is a “disconnect” between the specialty groups and “network” structures that is a contributory factor in the perceived poor success of this structure in Scotland. In the successful English CLRNs (based on my critical care experience), the local specialty groups worked with the CLRN to agree the resource and management structure for “mini-networks” that worked within the context of the national effort in that area. This meant they had actual resource to manage locally, and were able to pro-actively look for studies and research activity, and effectively do workforce and capacity planning. In Scotland the SGs were not set up as networks nationally, and local “mini-networks” only really exist where there was particular local support or activity (often in my experience in critical care based around an individual(s) providing local leadership).

I see it as more sensible going forward for all research specialties/areas, to work more on a network model proactively with local Boards/R&D depts. to plan and manage portfolio activity proactively. This again demands leadership either from a clinician or a senior research manager/nurse. Some of the most effective “stories” I have heard in England were led by Nurse specialists/managers.

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?

No. As above they need access to staff through R&Ds to really manage activity and plan a strategy over several years looking forward. This could link to the moneys from R&D being released into clinical directorates, especially if each directorate could identify an individual with lead responsibility for organising and leading portfolio research (for example with a PA or half PA in job plan). This would seem a good use of part of the released R&D funding if done well.

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

No. I think the future should be a network model for all, although some could be networks within boards that are active in certain areas; ie not all boards may have “mini-networks” for all research areas. Equally, I think some SGs could well merge in terms of how they run a portfolio of research based on similar areas of the hospital, similar research challenges (eg emergency care; consent processes etc). The current arrangement seems associated with big differences in access to infrastructure for meetings and management between SGs (that have v little) and funded topic networks (that seem well resourced)

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

I cannot speak for the established networks. The important issue regarding the SGs, which were put in place to support the comprehensive CRN in England (the biggest network of research activity), is that they have NOT been set up as networks in Scotland. In England they have worked well when CLRN DID set up mini-networks for either individual SG researchers or groups of them that naturally overlapped. In Scotland we have in general, as far as I see, left individual studies to be supported instead of putting in place the more efficient methods of employing generic staff with the right skills to deliver a multi-study portfolio in a particular theme or clinical area. My own experience having been well supported by R&D with “generic” research staff is that when well managed the efficiency of screening for multiple studies simultaneously for multiple PIs/studies works very well. It also enables holiday cover etc to ensure gaps in screening do not occur. The barriers are still the actual resource available in person time (especially research nurses/coordinators in my experience), but by working on multiple studies within a mini-network/group restrictions are decreased. This approach also enables co-enrolment and agreed priorities for potentially “competing” studies to be agreed and managed well by a single group. The use of generic clinical research facility nurses has some merits, but does not encourage the development of specialist knowledge and skills or a close relationship with clinical staff in the relevant areas, which can be challenging on both sides. A model that uses CRF line managed staff, but dedicated to work with certain clinical groups (often on the wards/clinic rather than within the CRF) has worked well for us.

Question: Do Specialty Group Leads have sufficient financial leverage to encourage and facilitate participation of colleagues in their disease area in research?

Not currently I suspect in most areas. A more direct connection between SG leads at local level and the R&D depts. in agreeing support needed etc would help. I think this direct planning of budgetary use (especially now that funds are being dis-entangled) would be a major step forward and could certainly occur when themes map onto to clinical directorates in terms of NHS management.

There is a major problem with engaging colleagues at a time when there is a reduction of SPA time and an effective loss/reduction in the incentive provided through discretionary points/merit awards (a real threat to retention of highest quality people in Scotland). A solution would be for SG leads or network leads at local level to be able to directly influence job planning in terms of arguing for

protected time for those research active consultants/clinicians. It is also VITAL that our new consultants are given the opportunity early on to participate and lead research. Current job – planning does not allow for this, and a system where a lead could offer a new consultant time to take on a local study(s) would be a step forward, even on a yearly basis through job planning.

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?

Yes to all in my view. This would need more pro-active management of resource between R&D, clinical directors/managers, and research leads within organisations linked to an existing or proposed research portfolio. This would be more transparent, accountable, and most likely more productive and efficient. The relatively small size and number of organisations in Scotland should mean this might be done without being too administration-heavy (although I accept this would have challenges)

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

In my opinion it is probably still not a level playing field for all. I suspect that pro-active planning within R&D boards/depts. would help but there needs a greater connect between researchers leading a portfolio and the R&D managers/leads. There is definitely room for improvement, but care needs to be taken not to create an administration heavy system (as occurred in England).

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

Yes. I think transparency and activity based funding is both incentive and reward, and enables resource to flow where effort and success goes. However, this only works if the recognition of differing levels of complexity of study is adequate. I know the inflation factor for study management/hosting reflects this to some extent, but the current fixed researcher premium of £100 does not really do justice to different levels of complexity at recruitment and “coalface” study management level

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?

I think this could work well as long as the themes were manageable and meaningful. I am not convinced that the proposed themes are the “right” ones for Scotland. We want groupings that reflect the clinical areas, screening and consent challenges, and clinicians requiring engagement. I suspect something between the SGs and themes in terms of numbers of areas/groupings is actually

ideal for delivery. This could be decided at NRS node level according to local strengths and priorities, although ideally we need matching grouping for multi-centre studies. This will only work if leads have time and to influence the funding to support an agreed portfolio of research over a rolling 2-3 year period.

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

Time, leadership skills, credibility among clinical colleagues, research experience. Does not have to be a medic but would need to have senior status to be a leader rather than manager if from non-medical background. Ability to bridge R&D and clinical organisations.

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)

There has to be some grouping of current SGs and networks, but I believe the current proposed themes are too big to work. The driver in England has been, in major part, to save money. The plan to apparently retain the SGs as well illustrates the strong feedback received that delivery only works when the leadership is for a relevant clinical/disease area and is manageable in size. I think a discussion in Scotland could provide a system that maps to the English system without necessarily mirroring it. The proposed English Theme leads will, to my mind, have an almost impossible role in delivery as they will be too distant for the various component clinical/disease groupings

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?

Yes but only if:

☐ We review what the themes should be

☐ How these individuals are connecting with the NRS hub leads

☐ How these national and local NRS leads in specified disease/clinical areas are allowed to plan their portfolio (2-3 year “business plans”) and then work with R&D depts. to secure researcher support and other support for the whole portfolio (research nurse etc)

55. University of Glasgow.

Response from the College of Medical Veterinary and Life Sciences, University of Glasgow

- **Overview**

- This document summarises responses of staff of the College of Medical Veterinary and Life Sciences at the University of Glasgow to the CSO consultation exercise on proposed changes to support structures for NHS research in Scotland. It provided the collated view of this group 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. For clarity the structure of this document has been aligned with the consultation paper.

- **General comments**

- *Engagement of Scottish Universities*

- It is highly likely that the 4 Scottish clinical medical schools will provide a high proportion of the 12 strategic theme leads. The interface between the NHS and Scottish Universities will be crucial in the success of the proposed changes, however, the consultation document does not define how existing successful partnerships such as the Health Science Scotland will contribute to the reconfiguration. The operational component of the new entity's management is clearly described but the nature of strategic oversight is less apparent and will require further development in partnership with all stakeholders.

- *Scope of the proposed reconfiguration*

- Several respondents commented that the topic networks were set up to address specific challenges (for example recruitment to large clinical trials) in specific areas identified as important but historically under-served. As such those areas which were generally well resourced were not felt to be in need of a Network structure. The Networks did not "manage all the research within their disease area, only those that they adopt into their portfolio" because there was a need to focus on specific priorities such as recruitment to late phase clinical trials. Concern was expressed that the broad and ambitious scope of this proposal may overstretch what resources are available.

- *Composition*

- Another theme which emerged clearly from the responses received was the composition of the proposed groups. Some disappointment was expressed at some of the complex and somewhat unwieldy "themes", however, the significant risk inherent in the adoption of a very different organisational structure from that to be implemented in England and Wales was acknowledged and for multi-centre studies it is critical that the administrative parts of the network interface seamlessly with England. This harmonisation should encompass the broader infrastructure supporting trials, including CTUs, laboratory and pharmaceutical support.

- **Structure**

- *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?*

- Whilst the strengths of the current structure were acknowledged, as evidenced by the enhanced national recruitment to clinical studies since its inception, there was also acknowledgement of the importance of adaptive change in response to the NIHR reorganisation.

- More broadly, whilst not specifically requested by the consultation, comment on the management structure that will sit under both national and nodal clinical leadership & R&D Directorship was received. It may be that this is to be decided to suit the needs of the Nodes (which vary in size and areas of academic and clinical expertise). The NIHR model has a Chief Operating Officer per geographical network and has a Research Delivery Manager per Division: both roles will have a nationally agreed job descriptions.
- Under the proposed arrangement the responsibility for portfolio delivery (to time and target) will remain with the Clinical Lead, but the workforce (& budget) will be managed by the Director of the Research Node. This is a different model to England where the R&D Management and Governance is an advisory capacity. A view was expressed that there needs to be a professional reporting line from the theme workforce to the Clinical Lead.
- *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?*
- There was consensus among respondents that this is not the case. Two different sources of funding lead to different management structures which do not necessarily see eye to eye. Having a network lead and their administrative office, at a centre far away from the research active centres has not been an effective or efficient use of resources. It has created potential for disproportionate allocation of resource without sufficient management oversight.
- *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?*
- Engagement between specialty group leads and the Scottish medical schools needs to be improved. The poor quality of this interface is a key structural issue which would be relatively easy to remedy. A second area of concern relates to the day-to-day oversight of activity at a local level which is not readily achieved given the current configuration.
- *Question: Is it equitable or efficient to have some clinical areas managed as Networks and others as Specialty Groups?*
- There was general consensus among respondents that this is not the case, and that two separate management structures introduce unnecessary complexity.
- **Funding**
- *Question: What are the main barriers to Networks supporting all the studies within their portfolio area?*
- While the sense in the decision for Scotland to adopt the new NIHR Themes to ensure continued cross-border engagement and collaboration is noted, significant differences in the role of the medical universities in the distribution of financial resource is identified as a potential barrier to that goal. Full engagement of Scotland's four clinical medical schools throughout the reorganisation process will be essential for the full potential of the exercise to be realised. The complete separation of CSO resource allocated to support research from clinical budgets is welcomed, as will be further information on how this will be achieved. There emerged a firm view that the current provision of support for the 4 NRS biorepositories is inadequate at present, and that this creates a significant barrier to the full exploitation of those significant resources by the Networks and other research groups. It was felt that remediation of this issue would yield benefit across the Scottish Biomedical community.
- There are more parochial barriers. In some clinical areas there is a perceived lack of local leadership as management structure has been unclear. Without clear leadership which has the local interests of the network at heart, supporting studies

locally can be challenging. There is also perception of opacity in funding streams for research support and with that it is unclear as to how funding is available to appoint staff. With this opacity, the incentives have been unclear and opportunities to optimise recruitment have not been realised. The difficulties in appointing staff are linked to opaque funding streams and lines of communication between researchers and management. There needs to be greater involvement of staff involved in clinical research in the management structure.

- *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?*
- It is too early to judge whether the NRS researcher scheme has been successful, however the general concept was supported by respondents.
- Quantification of research time and recruitment and linking this to funding is important. However, the funding needs to be transparent and needs to be seen to deliver real gains and measurable outcomes. The reductionist focus on numbers of patients recruited as an index of achievement (and hence incentive) was not felt to be the best metric to use. Whilst the importance of phase 3 clinical trials is acknowledged, a key component of the future success for Scottish clinical research lies in Phase I and Phase IIa clinical trials as well as a new stratified or personalised clinical trials. These are complex multi-visit interventions where the head-count is not a sufficient metric.
- *Question: Do the current Network and Specialty Group funding arrangements allow the best use to be made of the supporting infrastructure?*
- There was a general view that funding to support studies could be better managed. More flexible arrangements for staff working could be implemented. With the greater availability of part-time medical staff and staff on flexible contracts, the potential benefit of more innovation in disposition of staff was suggested. This could be facilitated by greater involvement of clinical researchers in the decision-making structures.
- There would be potential benefit from resource-sharing where possible across the clinical themes. Access to a more flexible research workforce may allow a broader range of studies to be undertaken.
- *Question: Would linking more directly the resources awarded through the work of various clinical groupings and their management structures improve study delivery?*
- Respondents indicated that this would be the case.
- **Leadership & Delivery**
- *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?*
- This arrangement would overcome the current issues with local oversight of a national trial portfolio. The concern would be whether the retention of a new tier of local theme leads would diminish the financial resource available to support the conduct of clinical trials. The effectiveness of these individuals would also be determined by the degree of budgetary control afforded to them.
- *Question: What attributes and qualifications are required by Local Theme Leads to successfully undertake this delivery-focussed role?*
- Local theme leads need to be research active and have an experience of clinical research. The leads will need to have protected time. It is not essential for them to be from the NHS and it is likely that a high proportion will be university employed staff. Irrespective, they will need protected time and associated PAs.

- *Question: How best would Local Theme Leads (LTLs) 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)*
- This was identified by respondents as a crucial area. There was widespread concern that activity in the “smaller” disciplines would struggle to achieve the same priority as larger ones and would suffer as a result. A further challenge lies at the interface between primary and secondary care research which was identified as problematic. A view emerged that LTLs will need to develop local working groups. They will need a deputy who is from a different background within the same theme. LTLs will need to have a fixed tenure with transparent appointment processes. To be effective LTLs should play an influential role within the local R&D management structure. With regard to taxonomy, it was suggested that rather than calling these nodes, a term such as ‘Regional Biomedical Research Centres’ could be used. These RBRCs should have a clear and transparent management structure. The Oxford Biomedical Research Centre was proposed as an exemplar. (<http://oxfordbrc.nihr.ac.uk/about-us-intro/>)
- *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?*
- It was felt that this arrangement would strengthen the structure and provide operational oversight if implemented carefully. The role of this group would need to be carefully defined to retain a focus on supporting research in Scotland. Furthermore, we would like to see a more senior strategic advisory board, perhaps best the renewed and updated CSO/HSS Advisory Board. This very strategic body should bring together Chief Executives of four academic Boards and Vice Principals/Heads of College from the four universities with medical schools.

56. (Confidential Response)