Appendix 1

Sheffield Hospitals NHS Foundation Trust

Research and Development

External Review 2013

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1 BACKGROUND

1.1 Sheffield

Sheffield Teaching Hospitals NHS Foundation Trust (STH) is a large University Teaching Hospital Trust that has partnerships with University of Sheffield (UoS) and Sheffield Hallam University (SHU). Both higher education institutions employ staff who are active investigators in the NHS. UoS jointly supports research in the NHS most notably in the Clinical Research Facility (CRF) and School of Health And Related Research (ScHARR). The Trust hosts the South Yorkshire Comprehensive Local Research Network (CLRN) and the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) for South Yorkshire.

In 2007, Professor William Rosenberg and Ms Christine McGrath undertook an external review of Sheffield and made a number of observations and suggestions. In general, these suggestions have been taken on board and implemented. Since this review, STH and UoS have been awarded several NIHR Infrastructure grants: 2 Biomedical Research Units (BRUs), Experimental Medicine CRF and CLARHC for South Yorkshire. The BRUs have not however been renewed because of a lack of perceived breadth of the portfolio within these Units.

In the last review, it was notable that:

“Research Leaders in Sheffield have expressed the view that clinical research is not currently attaining the level of performance expected in terms of research funding or research output. There is a clear ambition to enhance Sheffield’s standing in the field of clinical research over the coming decade.”

This view and aspiration remains 6 years later.

2 REVIEW METHOD

2.1 Briefing

The reviewers were briefed by Professor Simon Heller prior to their visit.

2.2 Materials

A substantial dossier of information was provided by the Clinical Research Office prior to the visit. This contained information regarding the background to the STH and UoS, and their research strategy. It also provided comprehensive information regarding STH and UoS research delivery and support including research centres and infrastructure. Finally some information was provided on the industry portfolio and external collaborations. There was not complete information regarding research outputs (publications, grant awards, PhD studentships) in all areas but this was perhaps beyond the scope and timeframe of the review.

2.3 Interviews

Interviews were conducted over two days with representatives of the STH and UoS. All interviews were treated as confidential and observations have not been directly attributed. The reviewers conducted interviews with senior members of STH including the CEO (Sir Andrew Cash) and Chairman (Tony Pedder) of STH. It was unfortunate that we did not meet with either the UoS Pro Vice Chancellor or his Deputy. A series of interviews were also made with clinicians, academics, allied health professionals, STH and UoS support services (Clinical Research Office (CRO), information technology (IT), laboratories, pharmacy, radiology, innovation services) and infrastructure leads (CLRN, CRF and ScHARR).

3. OBSERVATIONS

The reviewers were made to feel extremely welcome by all staff, especially at the Clinical Research Office. We would like to thank them for their support and responsiveness, as well as their hospitality.

We were impressed by the enthusiasm of all members of staff who shared the common goal of improving research activity and quality in Sheffield. The openness and candour was welcome and greatly assisted with the review.

3.1 Vision

There was clear commitment from the top of STH that clinical research is a key goal for the Trust. The vision is to improve the delivery and development of clinical research and that this needs to be achieved in partnerships with higher education institutions, principally UoS.

There was evidence that this vision is starting to filter down and accepted by all. However, this remains work in progress.

3.2 Ambition

There is a clear ambition to improve and develop clinical research further. However, there was evidence that many felt they could not compete on an international footing and that the loss of the Biomedical Research Units (BRUs) had impacted on confidence. This has led to two major detrimental effects: a reluctance to take risks, and under selling the strengths of Sheffield. This has had a number of consequences including underbidding for resource in some of subsequent infrastructure bids, and being too conservative in the aspirations for the institutions.

Better promotion, self-belief and ambition needs to be proactively encouraged and shared by all. There is evidence of growing enthusiasm that needs to be captured and encouraged by a more dynamic research culture.

3.3 Strategy

There is an excellent opportunity to capitalise on the emerging and established clinical academic base in Sheffield. There were many examples of truly excellent world leading investigators whose research has had, and is having, an impact. To progress this further needs a number of approaches.

3.3.1 Strategic Aim

There was a view that STH and UoS should rebid for at least one BRU and that a Biomedical Research Centre (BRC) is not achievable. These should be carefully considered. There is evidence of breadth across many specialist areas and it is unclear whether creation of a cohesive group of different interests could be presented for either BRU or BRC status. At present, it appeared to the reviewers that the

neuroscience academic directorate was the strongest and most likely to be a competitive BRU candidate. It is perhaps unfortunate therefore that the Department of Health have discouraged an application in this area because of perceived overprovision.

There should be consideration for investing strategically in other areas rather than focus on trying to rectify the loss of the BRUs. STH have been successful in other areas of the NIHR infrastructure. Arguably more resource, research activity and capacity could be generated by playing to these strengths, such as applied and HTA-funded research through ScHARR.

3.3.2 Academic Directorates

The development of academic directorates has heightened the profile of the value of clinical research to STH. This label has in itself been important. These directorates are beginning to see the benefit in terms of research being seen as part of their core NHS business as well as the provision of clinical research co-ordinators who were critical in the realisation and facilitation of the research activities. There were examples of excellent co-ordination and commitment from NHS service and finance managers with clear integration of clinical research activities into the normal running of the department. However, this was not universal and the flagship of neurosciences is an excellent model that other directorates need to follow.

Within the non-academic directorates, there were many bright enthusiastic researchers. There is a danger of disenfranchising these individuals given their directorates had been judged not to be sufficiently academic and that they had limited access to resources such as co-ordinators. Some non-academic directorates (not an ideal term) had evidence of large volumes of research. The selection and designation of academic directorates is unclear. This designation and approach may therefore need to be reviewed to maximise potential opportunities.

The academic directorates are a great starting point but consideration should be given to alternative models where clinical research can be supported across all disciplines. Perhaps at a group level (multiple directorates with a mix of complementary or shared research activities and capacity) rather than at a single directorate level.

3.3.3 Building Clinical Academic Capacity

There is clear evidence of an inadequate number of clinical academics in Sheffield. Attempts at external recruitment have been variably successful. Although many felt that this was a “Sheffield” effect, this is common to many (if not all) higher education institutions and the recruitment of up-and-coming or established academic clinicians is always challenging but is a key priority. Such recruitments will obviously need to be strategic and in line with the strengths and aspirations of STH and UoS. They also need to be realistic in terms of the package needed to recruit leading individuals. Strong early investment will often pay major subsequent dividends. There was evidence of a reluctance to entice key individuals with substantial packages. This should be reconsidered especially if an appointment will be strategically critical.

The approach to nurture clinical academic clinicians from within Sheffield is also appropriate but will require strong and appropriate mentorship to enable the attainment of the critical mass seen in neurosciences. A model of supporting the

brightest young clinicians showing early promise in research by integrating them into the strengths of Sheffield would work well. In this regard, young potential academics from multiple and potentially diverse specialties and directorates could interact with ScHARR, CRTU and RDS to develop research trials and be mentored by this leading expertise within Sheffield. A competitive internal scheme to award 4-5 PAs of time to a select 6 individuals would be one such approach.

In the last review of 2007, a recommendation to have dedicated clinical research PAs was made. However, this has still not been realised. Whilst these are "in the system", there is no accountability or direct attribution. This needs to be rectified as a priority if an impact on research activity and quality is to be realised.

3.3.4 Clinical Research Finance and Income

To foster a culture of increasing research activity requires transparent attribution of research income to those conducting and developing the research activity. This incentivises researchers and demonstrates one dimension of the value of clinical research to the directorates. This incentivisation is critical.

At present, the transparency of financial income and allocation is patchy. Some directorates have successfully implemented this approach that has helped to support, value and develop clinical research. These practices need to be more wide spread.

A key strategic priority is to achieve financial transparency of research activities at all levels: clinic research staff, support departments, and service departments.

3.4 Infrastructure

3.4.1 Clinical Research Office

Since the last external review (2007), the clinical research office (CRO) was established with better integration of UoS and STH. However, this office has yet to realise its full potential and this is disappointing. The appointment of Dr Peter Sneddon is welcome but many of the issues are operational rather than strategic and this is where the focus needs to be.

The CRO structure is too top heavy. There are too many senior graded members of staff for the structure and positions of responsibility. Whilst there was evidence of excellent practice, many users remained extremely frustrated by their interactions with the office. A service was not being provided and proactive assistance was not always forthcoming such that process became more important than getting the research started. Closer collaboration and interaction between the CRO and the support departments and research infrastructure is needed as many processes and checks were being duplicated and staff were not empowered to provide appropriate sign offs. Some of these obstacles could be overcome by better information technology solutions to increase efficiency as well as making financial costings and attribution more transparent. The implementation of a Research Management System in May will hopefully assist with some of these issues.

Engagement with industry is critical. Commercial clinical research is a priority and approval times and engagement are currently poor. Improved liaison, refined

processes (including contracting) and more rapid responses are need if Sheffield is to remain competitive and increase its activity.

3.4.2 Clinical Research Facility

The Clinical Research Facility (CRF) successfully gained funding from the NIHR Experimental Medicine CRF call. The activity of the CRF continues to grow and is now involved in one half of all research activity that is taking part in STH. The majority of investigators found the CRF to be very professional and provide an excellent service. Occasional investigators commented on some capacity/access issues but this was the exception rather than the rule.

As with the CRO, the CRF structure was rather top heavy. There were a number of senior graded staff and the balance of bands 7 and 8 nurses and managers could be examined in relation to their roles and responsibilities. In contrast, we were impressed with the approach of using band 3 clinical research data co-ordinators and the band 5 nurse training posts (something we will take back to Edinburgh!). There was also scope for the band 2 clinical support workers to assist in study set up to take away some of the basic duties from the nursing staff. The Lead Nurse for Research and Development is a valuable role and is taking encouraging steps to better align research nurse structures and to performance manage research nurse activity across STH. This is important given the quantum of research nurses employed within STH.

3.4.3 School of Health And Related Research

The School of Health and Related Research (ScHARR) is clearly a great strength for Sheffield. It has a major national and international reputation. This unit is closely aligned with the key priorities of STH and is therefore an ideal partner in research and development.

ScHARR has helped develop many clinical academics and seems an ideal environment to nurture future academic talent within Sheffield. This will be critical going forward to develop and increase clinical academic capacity in the STH. This may require addition investment in ScHARR if activity increases substantially.

3.4.4 Clinical Research Trials Unit and Research Design Service

Both units were enthusiastic about supporting researchers in clinical trial design and grant applications. There remains capacity to help investigators further and is a resource that should be more widely used with better earlier engagement in the evolution and development of novel research. These services need to be exploited better to increase capacity and also attract major grant awards. This is currently a missed opportunity.

3.4.5 Collaboration for Leadership in Applied Health Research and Care (CLAHRC) for South Yorkshire

This was seen as a key development and a successful NIHR infrastructure. With major funding and hosting in STH, this appears to be a major priority that needs the continued support of STH as it enters into its renewal phase. The major achievements and outcomes of this infrastructure were not readily apparent to the reviewers and perhaps require better promotion.

3.4.6 South Yorkshire Comprehensive Local Research Network

This is a thriving CLRN that appears to be delivering its targets well. Continued and strong engagement with the CLRN will be important for clinical research delivery going forward.

3.4.7 Imaging Infrastructure

The provision of clinical imaging appears to be a major gap in both academic activity and clinical research capacity. This is limiting the breadth of activities that Sheffield can engage in and narrows the dimensions upon which it can compete.

3.5 Priority Areas

3.5.1 Key Strengths

The reviewers felt that there were many major strengths in STH. The enthusiasm and desire to do more clinical research (delivery and development) was clearly articulated by everyone we met. We would highlight:

- Neurosciences and SITraN
- Respiratory Medicine
- Diabetes and Endocrinology
- Bone Metabolism
- School for Health And Related Research
- NIHR Experimental Medicine Clinical Research Facilities
- Devices and Engineering
- INSIGNEO

3.5.2 Areas for Review

Cancer and cardiovascular disease are often key components of clinical research activity and funding in most centres since they are major funding priority areas. Cardiovascular disease is currently vulnerable because there is not a critical mass of investigators. Stronger leadership and investment is needed if it is to regain and realise its potential.

Cancer is an area that needs some consideration. Although a CRUK “centre of excellence”, much of its activity is directed to research delivery. The trial portfolio is large but dominated by hosted trials led by commerce or other higher education institutions. Consideration for succession planning for Professor Coleman and appointment of a senior academic with an interest in developing their own portfolio of research should be considered.

Respiratory, Bone Metabolism and Diabetes/Endocrinology are clear areas of international expertise and promise. However, they have not yet achieved critical mass or breadth and rely on one or two leading academic clinicians some of whom are nearing retirement. These are key areas that could either grow or implode. A strategic review of these areas with a view to future prioritisation and sustainability is needed.

The interactions between the MRC Centres in Musculoskeletal Aging and Developmental and Biomedical Genetics with STH were less clear. Given that these

Centres have MRC status, consideration for better exploitation of clinical research opportunities should be explored.

4. RECOMMENDATIONS

4.1 Strategy

Consideration should be given to the formation of a small short-life working group composed of 4-6 senior UoS and STH staff who will decide and implement a strategic development plan for both UoS and STH. This will need to consider:

- disease areas for prioritisation
- target for infrastructure award (if appropriate) and consider other opportunities (such as HTA-funded research allied to strengths)
- capacity building for academic clinicians: to include external recruitment and internal competitive fellowships for young research active and newly appointed consultants. This should include external recruitment of 2-3 key individuals with substantial packages, and internal competitive research fellowships potentially with an external advisory board/committee.
- cultural change to value and encourage ambition, self belief and clinical research activity
- better co-localisation and streamlining of activities to improve service, delivery and opportunities: CRO, CRF, ScHARR
- address deficiencies in infrastructure such as imaging

The reviewers were uncertain that the strategy of trying to re-establish a BRU was appropriate and STH and UoS may be better focused on winning major grant income from HTA or other funding streams that were more in line with Sheffield's strengths including ScHARR. This strategy would also be more closely aligned with the increasing emphasis on clinical impact. If a BRU were to be reconsidered, then reviewers felt that Neuroscience, Respiratory Medicine and Diabetes/Endocrinology had the strongest potential to be developed into a competitive bid but further external recruitment will be needed for some of these potential areas.

4.2 Incentivisation

Consideration should be given to providing clearer and more transparent incentives for clinical research conduct if STH are to improve involvement of NHS colleagues. This will need to include:

- unambiguous attribution of research costs, finance and income to directorates
- protection and valuing the attribution of PAs for clinical research conduct
- improving research infrastructure

4.3 Infrastructure

Some infrastructures are working well but there is a clear need for improvement in other areas. As a priority the Clinical Research Office needs to be reviewed and optimisation of processes essential. Many internal and external users are dissatisfied with the service they receive. This key priority is recognised and the appointment of Dr Peter Sneddon will be critical to sort out the operation problems that the office is experiencing.

Better integration of the various research infrastructures is needed. This has started to happen but there is further scope to work more closely and avoid duplication and streamline processes. Continued and better engagement between UoS and STH is essential and co-localisation of some of the infrastructures would greatly assist here.

5. CONCLUSIONS

Sheffield is entering a critical period of its development. STH and UoS have world leading academics and clear excellence in clinical research. It has some very successful elements of research infrastructure. However, if it is to realise its full potential and become more competitive, it needs strong and clear strategic leadership. Selective and targeted modest investments combined with better collegiate and efficient working practices have the potential to transform its clinical research output. Re-engagement of clinical academics with strong NHS support will be critical to achieve the Trust's goals. There remain major opportunities that can be realised by an enthusiastic and ambitious strategy and workforce. The next 5 years will be an exciting time for STH and UoS.