Summary of responses to the 'Strengthening Clinical Research' Call for Evidence

The responses to the call for evidence are summarised as follows:

Funding medical research

- Many respondents identified problems associated with lack of funding for research infrastructure and insufficient support for the overhead costs of conducting research.
- With regard to funding projects and people, the inability of the MRC to continue to respond to new opportunities was perceived as a particular problem by some, with a succession of funding crises undermining research efforts.
- Broadly it was observed that there was lack of long-term funding for translational research, follow-ups to clinical studies and insufficient core funding to provide research nurses, data managers etc. There was also inadequate funding for both experimental medicine and for development activities such as clinical trials- where venture capital provision was characterised as conservative.
- New incentives for industry to fund basic medical research would be seen as helpful.
- There was a call for the research community to do more to show donors, government, patients and the general public that research has been "useful" and, therefore, merits funding. Increasing the funding of basic research at the expense of clinical research may have had the opposite effect, if the general public do not appreciate the value of basic research; lack of public engagement can lead to a research drive that reflects the interests of academia rather than the health needs of the public or health practitioner.
- It was suggested that there should be better separation between grant-giving bodies and university management structures in order to protect scientists from political forces within their departments and institutions.

Research evaluation and Research prioritisation:

Processes

• The Research Assessment Exercise was considered insufficient to recognise that clinical research has a different set of challenges to basic research. There are general difficulties in comparing quality and outcome of clinical and basic research using the same criteria. For example, it was observed that in clinical research it can be unethical to have matched controls and it can be difficult to identify and recruit useful comparison groups. There are also implications for career development: for example, clinicians who obtain a PhD are encouraged by the current system to perform high impact (in terms of citations) basic research.

- Some respondents perceived excessive emphasis favouring the "Golden triangle" research centres and a dominance of the evaluation and prioritisation review procedures by the established institutions.
- This problem was compounded by inadequate involvement of international assessors: the remedy was seen to lie partly in the establishment of working panels e.g.: learned Societies, international experts, funding bodies, in defined research areas to develop national plans.
- Developing coherent strategy would be augmented if the research charities, and other research funders, did more to coordinate the pursuit of their priorities.
- Basic research is disproportionately represented in successful applications for funding.

Specific areas

- Funding is also disproportionately high for "fashionable" areas. An inappropriately low level of funding was claimed for: neuroscience, musculoskeletal research, liver disease, dental caries; the problems of underfunding are compounded when the corresponding national charity is small.
- The importance of primary care research was confirmed by many respondents, for example with regard to the contribution to epidemiology. Problems of patient recruitment, retention and outcome ascertainment were noted, together with the current lack of infrastructure and networking opportunities among researchers and access to training, to enable multi-disciplinary teams to be established. A remedy was suggested in the introduction of the academic equivalent of Clinical Research Centres.
- Behavioural science problems were also raised with regard to funding programmes of research encompassing the development and evaluation of complex interventions. For example, in attempting to change determinants of behaviours affecting health there is a large workload involved between the steps of initial model testing and operationalising behaviour change techniques. The solution may be to develop multi-disciplinary groups linked to Clinical Trial Units with sufficient availability and coordination of risk capital-Research Council funding to support all phases from proof-of-principle through to clinical application. It was proposed that behavioural science should now be recognised as a core discipline in the UK as it is in the US vital for the successful implementation of medical science.

Research infrastructure and governance, particularly with regard to interdisciplinary and translational research

• Many respondents identified a threat from the restructuring of health authorities and Primary Care Trusts (PCTs), who may not regard research as a core activity (and this threat is exacerbated by worries about clinical and research governance). Generally, NHS managers are characterised as not seeing research as a high priority. Denominator-based studies – dependent on GP registers of patients – may be threatened by new ways of delivering primary care. The proffered solutions depend on investment to promote research management and training and to link initiatives to improve data capture and involve other relevant disciplines.

- There was considerable support for the principle of basic and clinical researchers working together.
- While welcomed in principle, there was concern that NHS Research Governance may create a process that acts to stifle clinical research. There was also concern at the impact of poorly-considered European legislation, in particular the Clinical Trials Directive.
- The lack of support and infrastructure for clinical trials and large-community-• based studies was frequently raised. Some of the specific weaknesses identified were statistical methodologies, imaging, data handling, tissue banks, resources for sharing Good Management Practice and advice on governance and ethics. Particular problems in the initiation and conduct of multi-centre trials were noted. In principle, the UK is considered to be in a good position to conduct translational research because of the close relationship between teaching hospital and medical school but such research does not receive sufficient support from Research Councils or from the medical research charities and there is rarely a long-term strategy. Translational research suffers from the competing demands on clinician time and in consequence of a funding gap between basic research and hospital-based programmes. Research should be accorded a higher priority and departments develop the critical mass to allow them to support the roles of health care delivery, teaching and research.
- Interdisciplinary research particularly between the clinical disciplines is important in developing the knowledge base of health and social care but is again, some feel, insufficiently encouraged. The Research Assessment Exercise has been a disincentive.
- The lack of coordination between clinical centres and lack of network between clinician, academic and policy-maker in public health has resulted in strategic gaps but also in duplication of research and inefficient use of resources.
- In order to address these weaknesses, there is urgent need for both leadership and training in clinical and health services research and in support for specialities (for example, health economics, statistics). There is, again, an opportunity to develop Clinical Trial Units to provide infrastructure for translational research and to aid recruitment and patient monitoring.

Research procedures

- Many respondents raised expressed concern at the threat to research from confidentiality, data protection, record linkage issues and the consequent difficulties in obtaining consent and recruitment to trials. There is scepticism that the Data Protection Act, as currently enforced, is compatible with the needs of public health. Even when research was permitted, the delay in set-up times for trials because of local and MREC ethics committee systems had become problematic.
- One particular example noted was the diminishing value of databases, for example cancer registries, if there is incomplete or skewed collection of samples because of consent problems. Access, use and banking of tissue was an area agreed as demanding immediate attention from policy-makers so that banks of tissue, properly organised and with due care taken with regard to consent and ethical issues, were available as an essential research resource.

More effort is also needed in constructing and managing databanks of patient information as a research resource.

- It was noted that the movement towards more explicit usually more specific

 forms of consent for medical treatment and for use of tissues might be driven more by the need to defend against litigation rather than a desire for an ethically better way.
- A disparity in codes of conduct was identified some medical researchers (clinicians) are professionally accountable whereas others (academics) are not professionalised in the same way.
- Most of the problems were worse for paediatric research regarding ethical approval, consent, record linkage, data protection, tissue access and use, recruitment and follow-up. There were also specific problems in obtaining consent for mental health research.
- On animal research, there was alarm that animal activists had dominated the public debate and there was a plea for the Academy together with research funders to speak with one voice and no hesitation in support of well-regulated research.

Career development

- Many general concerns were raised about lack of career structure and inadequate remuneration in both basic and clinical research (from PhD student through to professor). Increasing regulatory and administrative requirements further encroach on the time available for research.
- Introduction of the specialist training grade has increased the pressure against spending time on research. Patient-orientated research is not perceived as a valued career choice perpetuating the problem, as there is then a lack of mentors. Introduction of the Clinician Scientist scheme has been helpful but there is a continuing deficiency in support for other clinicians who wish to pursue careers in research but not necessarily in academic posts. It was suggested that the major research funders should address the specific issue of a standardised scientific contract (analogous to maintenance of parity with NHS contractual arrangements previously).
- There was support for expanding intercalated BSc and MB/PhD programmes (together with assessing the career pathways of those from these programmes).
- The particular problem of younger researchers, with little or no track record, attracting funding was identified. There was also frequent concern expressed at the MRC abandonment of single investigator grants, impairing career development of younger scientists it was suggested instead that cooperative programmes should be built by assembling single investigators.
- Some also worried about the lack of support for the senior scientists who are not in a regular university faculty position to confirm the earlier point, there is a need to create a research faculty career track
- Research Institutes might also be strengthened by promoting mobility encouraging secondment for those who reside primarily in teaching positions into core research facilities. Many confirmed that research is an essential component of effective teaching and expressed dismay at the outcome of the Research Assessment Exercise, emphasising that teaching will be damaged if research is withdrawn from an institution.

• It was accepted that incentives for scientists to return to the UK from the US might help recruitment but such support needed to be sustained and monitored for long-term impact.

As clinical and non-clinical career development issues are covered by other Academy of Medical Sciences initiatives, they were not discussed specifically in this Report although the issues are considered generally, for example, in the context of improving research infrastructure and productivity.

Regional issues

- London clinical research undoubtedly requires an organised clinical service but London (and the other conurbations to a varying extent) suffers from significant problems associated with staff turnover, population turnover, pressure on beds etc.
- Northern Ireland while Higher Education policy and funding is a devolved matter, there is a tendency to take the lead from policies developed in England but highly selective research support policy is not appropriate in developing a research culture across the health and social services. Specific contractual arrangements for clinical academics also create problems.