



**The Association for
Clinical Biochemistry**

Dr Ian D Watson PhD FRCpath
Chair
Association for Clinical Biochemistry
Dept Clinical Biochemistry
University Hospital Aintree
Lower Lane
LIVERPOOL
L9 7AL

17th July 2006

The Association for Clinical Biochemistry (ACB) welcomes the proposals for improved delivery of research funding as it relates to Health Care. While recognising the strengths of the proposals we would offer some suggestions that could ensure more effective delivery.

One important function of research within health care is to respond to local research needs and service priorities. Within the UK, different needs and priorities exist in distinctive geographical locations including the devolved administrations in Scotland, Wales and Northern Ireland e.g the high prevalence of CHD in Scotland. In order to ensure that local research and economic priorities can be addressed, we propose that some research funding should be restricted for use in specified geographical areas. Indeed we would contend that due to the differences across healthcare in England, a similar case can be made for the new Regional Health Authorities, who will each have a population similar in size to Scotland, having a similar arrangement. The allocation of all funding should be subject to the same high standards of review.

We welcome recognition that research is an integral part of health delivery and that while some topic areas are currently identified, there will be the opportunity for researchers to address areas that reflect their strengths and important needs yet to be defined.

One particular area that is unexplored, but is of increasing cost and relevance to Health Care is the assessment of diagnostic tests. There are an increasing number of previously unidentified markers being associated with disease processes for the purposes of diagnosis, monitoring and prognosis due to use of new and developing technologies: including chromatographic detection systems such as tandem mass spectrometry, proteomics, metabonomics.

The Association for Clinical Biochemistry wishes to highlight the need for a well-coordinated, multidisciplinary, approach to establish a framework for evaluating the use of emerging techniques in the diagnosis, classification and monitoring of disease. Classically, diseases were identified by their clinical or phenotypic manifestation. Due to the ease with which biological specimens can be obtained safely and non-invasively and advances in analytical techniques, a dilemma has been created whereby individuals are being identified as having, or at risk of developing a condition, when they are clinically asymptomatic and do not exhibit any features of the condition. Two of many examples of this are highlighted by the measurement of B-type natriuretic peptide (BNP), and associated molecular forms of the peptide, and cardiac Troponin (cTn).

BNP measurements have the potential of redefining heart failure, widening the scope of the condition to include many who at present would not be included within it and altering treatment strategies. cTn measurements were adopted before internationally recognised standards were agreed, leading to major difficulties with the emergence of a new condition “acute coronary syndrome” replacing myocardial infarction but encompassing far more people within its ambit.

Inadequate assessment of such “simple non-invasive bloods tests” have major implications for the design and delivery of healthcare provision, pharmaceutical interventions as well as major implications for the insurance industry. This issue will become increasingly important with advances in DNA / RNA microanalyses, proteomics and metabolomics. As there is currently no mechanism for evaluating new diagnostic tests with respect to clinical utility and cost effectiveness the Association would advocate that diagnostic procedures should undergo a detailed assessment, prior to their introduction, that is as rigorous as that required prior to the introduction of a new form of pharmacological intervention. The Association would hope that any changes to the funding of research in the UK would recognise the current problems and facilitate such developments.

The diagnostic companies play a crucial role particularly as it relates to the translation of original research into products that can be adopted for clinical use. The need is analogous to pharmaceutical research in which collaboration is essential, with trials delivered to defined standards to ensure a clinically and economically robust outcome based on good research methods. Rigour in validation of diagnostic tests as fit-for-purpose is essential.

We trust you find these observations of value and would be pleased to develop these further with you in the future

Yours sincerely,

Ian D. Watson PhD, FRCPATH
Chair, Association for Clinical Biochemistry