

Government response to "The work of the Medical Research Council" report by the House of Commons Science and Technology Select Committee (HC 132) / presented to Parliament by the Secretary of State for Trade and Industry.

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“The work of the Medical Research Council”
Report by the House of Commons Science and
Technology Select Committee (HC 132)**

Department of Trade and Industry

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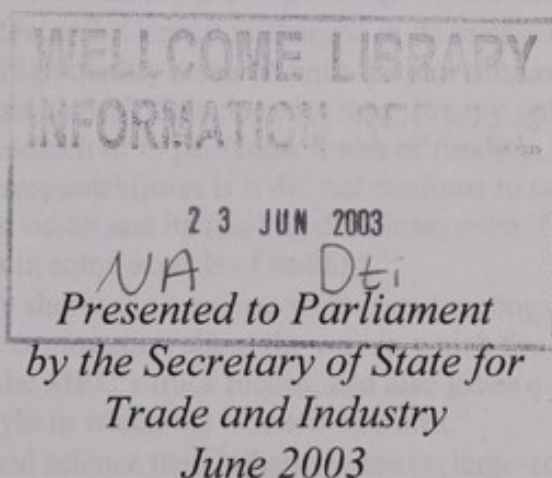


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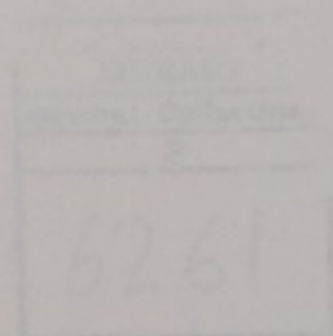
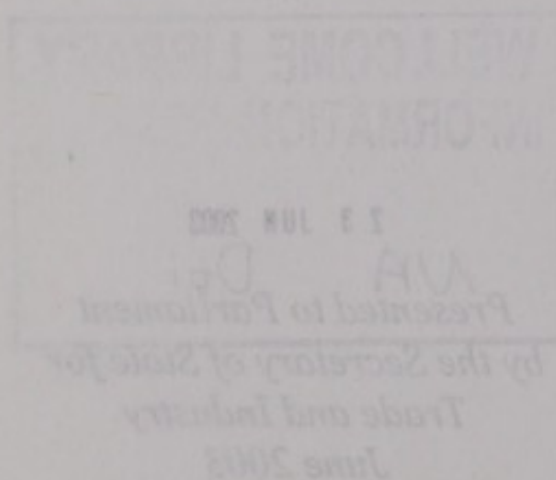
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Department of Trade and Industry



Introduction

1. As indicated in the response to the report on the work of PPARC, <http://www.publications.parliament.uk/pa/cm200203/cmselect/cmsctech/507/507.pdf>, the Government welcomes the interest of the committee in the work of the Research Councils and is happy to offer any assistance as may be required.

2. The Government strongly endorses the committee's view that the MRC has a distinguished history and can claim much credit for the high status of UK biomedical research. This is a substantial achievement. The Government's view is that, given MRC's long-term vision and scientific strategy there is every reason to expect a similar record in the future. As the primary public sector body with a national responsibility for medical research and training, the MRC has a responsibility to plan for the longer term. In this it works closely with the Department of Health and the NHS as well as with the OST/DTI and other stakeholders.

3. Since the publication of the committee's report we have received a number of letters from leading academics supporting the work of the MRC, which include the following comments:

- Cooperative group grants "one aspect in favour of the scheme has been its role as a spur to greater collaboration, assisting individual groups to work across disciplines, I would regard this as increasingly necessary as we attempt to take an integrated approach to understanding human health and disease, giving individual researchers access to a larger range of facilities."
- "The Medical Research Council is charged in its mission with 'encouraging and supporting high quality research with the aim of maintaining and improving human health'. This does not map directly onto providing support for university research or to particular forms of funding, and the MRC would be failing in its responsibilities if it did not continue to take the long term view, both in its vision and its funding decisions, even if this creates short term difficulties in some aspects of funding."
- "This University shares the concern, widespread amongst informed members of the academic community, about the way in which the report misrepresents the facts about the MRC's track record, and also gives a distorted view about the ethos and style in which the Council operates."
- "More biomedical science than hitherto relies on large-scale research", "The select committee appears to ignore the outstanding success of some of the MRC's long-standing major endeavours for example the remarkable success of the Laboratory for Molecular Biology".
- "The Select Committee should have applauded the MRC's appreciation of the way in which science evolves"
- "I strongly believe that, although the report raised a number of important issues, it reflected an incomplete picture of MRC activity and vision. I was also concerned that the Committee appeared to be heavily influenced by the view of a relatively small number of scientists in specific research areas."
- "the MRC has to prioritise and, naturally some individuals will disagree with the priorities that are set.", "The MRC also has an excellent track record in getting it right".
- "The report effectively ignores the approximately 50% of MRC resource which funds its intramural Institutes and Units. Their success in meeting national research needs, stimulating exploitation, and in competing at the highest international level, is a matter of record"

- "The MRC has successfully put into place some of the large scale projects that will be necessary if we are to remain competitive in post-genomic research over the next ten years."
- "I feel strongly that this report has seriously misrepresented the MRC's position with regard to science funding in the United Kingdom."
- "We would be seriously concerned if this report were to lead to any lessening of the support that the Council receives from Government and Parliament."
- "It is unfortunate that a more balanced input from the wider research community could not have been considered by the Committee before its conclusions were reached."

4. The MRC's Annual Review, Annual Report and other documents bear testimony to the outputs in recent years in delivering the mission. The Annual Review in particular is a compelling account of how MRC-funded basic science, and research at the level of patients/volunteers and populations, continues to lead to a whole range of health interventions.

5. The timescale for turning outputs from the science base into health care products is complex and lengthy. However, the MRC's record in commercial exploitation is also outstanding. This has been achieved through investment in an in-house technology transfer capability now operating as an MRC company – MRC Technology. MRC start-ups continue to flourish. These, and the setting up of the UK Medical Ventures Fund/MVM Ltd, with substantial initial venture capital raised externally from the private sector, on the strength of MRC's scientific reputation, are models of best practice as recognised in the National Audit Office Report on 'Delivering the Commercialisation of Public Sector Science' in 2002.

6. Another area of best practice is research management in which MRC has made excellent progress in working with consumers. MRC continues to review particular areas of research relevant to health policy, often at the request of stakeholders such as the Department of Health. Since its establishment following public advertisement in March 2000 members of the MRC Consumer Liaison Group (CLG) have participated as full members of research reviews of complex fields such as Chronic Fatigue Syndrome. CLG members have provided a conduit for bringing consumer perspectives to the table which would not otherwise be achievable.

7. The Government accepts that judgements made in funding and delivering research which will ultimately benefit human health, require fine judgement on the part of the MRC Council and its other advisory bodies. Such judgements rightly attract questions and criticism, and the Government welcomes informed debate on these.

List of Recommendations and Government's Response

Recommendation 1 Research Councils should be able to use their funds flexibly but we would not support the use of this flexibility to starve current research projects of funds (paragraph 6).

Response The Government recognizes that Research Councils should be able to use funds flexibly and continues to work with them towards this end. OST is currently discussing a revised framework for the transfer of budgets from one year to the next ("End-Year Flexibility"), and as a first step, the Council may carry forward up to 10% of its annual resource budget from one year to the next, compared with the previous 5 %. A short-term planned under-spend for a particular year may in some circumstances be the best way of smoothing the flow of research funds available for new awards overall.

Recommendation 2. We understand that Research Councils UK is undertaking a programme to streamline the administration of the Research Councils. We recommend that as part of this process a standard and extensive set of performance indicators is drawn up which will be applied to all Research Councils (paragraph 8).

Response The Government welcomes these comments. As their Departmental sponsor, the Science & Engineering Base Group in OST is working with the Research Councils to develop the existing performance management framework in line with the recent guidance from the Treasury and Cabinet Office on the governance of non departmental public bodies. The key aspects of this work comprise the cascading of objectives and targets alongside funding, down through the various levels, as initially set out in the new Science Budget Allocations 2003-04 to 2005-06; business planning by the Councils to deliver these required outcomes; and the monitoring, evaluation and reporting of subsequent performance. OST is working to establish this new framework, the associated processes and practices, and the related suite of key indicators in time for the SR2004, working closely with the Councils during the intervening period of development and migration. The management statement and financial memorandum with each Council will be revised accordingly, and this new framework will apply to all the Councils, as the Committee recommends.

Additionally, OST will be working with the Chairs and members of the Councils to help them develop and improve their core performance management role and practice.

Clarification note MRC Annual Reports do provide performance data in areas – such as public engagement – mentioned by the Committee. The targets set under the Government's 'Service First' policy, which the Committee highlighted, are not MRC's only performance targets.

Recommendation 3. If the research community is under the misapprehension that small project grants are not available when in fact they are the MRC is doing a poor job of communicating with its community. We recommend that the MRC gives a higher priority to keeping its research community better informed of its policies (paragraph 13).

Response The Government accepts that the MRC needs to do more to keep the research community informed of its research support policies. Communication with the research community operates at a number of levels – for example:

- Clinics/open meetings/workshops for universities for discussion/explanation of MRC research schemes and policies (12 such events were requested by and held at universities last year – MRC plans to offer similar events in the coming year for universities who have not been included thus far)
- Use since 2002 of E mail lists of all grant-holders, MRC Advisory Board (MAB) members (500+) and university grants administrators to alert the community to new highlight notices/calls for proposals and other new developments and/or to launch rapid consultations
- New quarterly newsletter – electronic and print-based
- Annual regional MAB meetings to consult/update on policy developments
- Short ‘open session’ introduced in 2002 at MRC Research Board meetings to discuss any broader policy issues members wish to raise
- Revamped website presentation, in response to suggestions from the scientific community, giving detailed information about grant schemes and award rates over the previous 4 years

MRC aims to intensify and target these communications further in future. The MRC’s annual Operational Plan will be published on its website for the first time this financial year, this will provide general details of the MRCs scientific plans.

Clarification Note Table 7 in the report is inaccurate and misleading. The reference quoted gives 378 Strategic Grants not 368. In addition the number of grants awarded are said to have fallen from 1500 in 1996-97 to 250 in 2000-01. In fact the first figure is *awards in existence on a particular date* and was taken from an old Annual Report; the second is *actual awards made in a single year*. The figure for awards in existence on 1 April 2001 is 1057, which is 4 times the figure in the report.

It is assumed that the Committee’s recommendation actually relates to small *programme* and not *project* grants.

Recommendation 4 We welcome the fact that the budget for its Career Establishment Grants is ring-fenced but recommend that the MRC reconsiders the amount of money available and the size of individual grant in order to support a greater number of young researchers (paragraph 14).

Response The Government takes seriously the need to provide appropriate training opportunities for young scientists and to provide adequate access to research funding for newly established principal investigators. In MRC provision of the latter is available partly in its own units and institutes (where scientists are employed by MRC at various career stages) and also, as the Committee noted, through the Career Establishment Grant (CEG) scheme (104 awarded up to 2001/02). The Government will encourage MRC to continue to review its niche in provision of research support for newly established principal investigators, alongside that of other funders. The MRC has taken the view that it may not be in the long-term interest of these researchers to limit their funding further in order to be able to fund more of them.

In FY2003-04 to 2005-06 the allocation of funds to enhance the transferable skills for postdoctoral researchers (across all research councils) will increase to £7.5 million by 2005-6. In addition 1000 new academic fellowships across all research councils areas will be created over the next 5 years. The additional funds for this have not yet been allocated but will be announced as part of the review of the dual support system in due course.

Clarification Note Funding is also provided for a range of fellowship schemes – much of the expansion in funding (from £27m to £42m) referred to by the Committee in paragraph 14 is for such schemes, which also provide career paths for newly trained researchers.

Recommendation 5 The balance of response mode and managed mode funding is a sensitive issue for researchers and the MRC should communicate its research support strategies openly and without ambiguity (paragraph 15).

Response As discussed under recommendation 3 The Government accepts that the MRC needs to do more to keep the research community informed of its research support policies. The MRC will be encouraged to do this.

We agree that the balance between response mode and managed mode (which we understand in this instance to mean large projects such as Biobank and the Mary Lyon Centre) is an important issue and one that the MRC keeps under review.

Clarification Note National facilities, such as Biobank and the Mary Lyon Centre, may appear to be top-down (therefore “managed mode”): initiatives however they have been prompted by demand from the research community who play a major role as members of advisory boards and committees in developing MRC’s research strategy in general and detailed plans for these facilities in particular. Likewise strategic grants, for example to fund clinical trials, are essentially investigator-led and so could be classed as response mode.

Recommendation 6. It is regrettable that any artificial alliances encouraged by Cooperative Group Grants are only likely to be identified after they are funded. We were under the impression that rigorous peer review would be able to pick out such marriages of convenience before the money is allocated. (Paragraph 17).

And

Recommendation 7 Having embarked on a programme of collaborative research on the basis that this would provide sustained funding, many researchers are now having the rug pulled out from beneath their feet (paragraph 18).

And

Recommendation 8 The Cooperative Group Grant scheme has provoked understandable resentment and frustration among the medical research community. The MRC should take an objective look at the system and be honest enough to admit the scheme's failing and make the necessary changes (paragraph 20).

Response The Government notes the Committee's comments on the co-operative grant scheme. MRC will take these into account in its independent review of the Co-operative Group Grants scheme.

The aim of the Co-operative Group Grant scheme is to foster collaboration between researchers and to add value to individual research projects. Typically, a core grant provides funding for shared infrastructure. Holders of core grants are expected to have a minimum of 3 peer-reviewed grants (component grants).

The Government recognises that "artificial alliances" are a potential risk of the scheme. However we believe that these would be picked up when applications for Co-operative Group Grants are first peer reviewed. However this is a novel approach to research funding, and the retrospective review of the scheme (discussed below) should provide robust evidence of the added value, or otherwise, of these alliances.

As with other grants schemes, the MRC's expectation is that there will be some turnover within the Co-operative Group Grants scheme to allow for new entrants. There will therefore always be some groupings that cannot be sustained in the longer-term.

MRC set up a Monitoring and Evaluation Steering Group chaired by the Chairman of Council in 1998 as soon as the new funding schemes (including the co-operative grant scheme, see below) were introduced. Membership and terms of reference for the Group were announced at that stage and comments invited on an ongoing basis on any aspect of MRC research support policies. The group's work plan has also been published and updated on the website at regular intervals.

There was extensive consultation during 2000, via the web-site and at road shows, on the criteria for reviewing the success and added-value of individual Co-operative Group Grants.

Evaluation of the Co-operative Group Grants scheme as a whole was always planned for 2003 by which time the earliest grants will have been in existence for 5 years, and some may be seeking renewal. The Committee has been developing a specification for evaluation of the scheme for some time – with

an initial discussion in December 2001 and approval of more detailed plans in November 2002. The final plan, discussed at the most recent meeting of the Committee in April 2003, is for a scoping study whereby committee members will conduct some initial evaluations (mainly by teleconferencing but also possibly some site visits). A specification for issues to be addressed in the scoping study will be finalised and published in the next few weeks. This scoping study will inform development of a full specification for an evaluation of the scheme, involving external consultants. Results of these studies will be considered by the Council at the end of the year.

Recommendation 9. The Research Councils are embarking upon a process of harmonising their administration, including their grant-awarding strategies. This process should recognise that different areas of research have contrasting requirements but this is a valuable opportunity for the MRC to reconsider its research support strategy (paragraph 21).

Response The Government agrees.

Recommendation 10 The MRC has mismanaged its fund in such a way as to create unwarranted fluctuations in its awards of new grants with consequent adverse impacts on their research community. It appears to have gambled on increases in income that were not, and were unlikely to be, forthcoming (paragraph 25).

Response The Government and MRC regret the fluctuations in award rates in recent years, but decisions in July 2000 were made on the best information available to MRC Council at the time on the scale of the SR2000 settlement and its impact on the MRC portfolio. The sharp increases in funding and the limited ability (5%) that the MRC had at this time to carry forward funds presented particular challenges.

The Government has been concerned that MRC needed to improve the processes underpinning its Council's ability to make judgements of the financial implications of funding plans and proposals and to plan its forward expenditure in detail. We have worked with them to achieve that. However we do not feel that this is properly described as financial mismanagement and so cannot agree with the committee's assertion that the MRC has mismanaged its funds. Subject to this one area of operation we are satisfied that the MRC has properly controlled its expenditure: its accounts have been audited by the NAO.

Once the actual implications of the SR2000 settlement became clear, the MRC took a number of steps to mitigate the effects of the reduced headroom for new awards after the 99/00 session, including deciding to draw on its Private Funds and Commercial Fund in the 01/02 financial year.

In March the MRC published its best estimates for funding during the SR2002 period, and the assumptions and financial modelling on which these are based. An important aim of this is to achieve a responsible balance between provision of funds for the maintenance of long-term teams and facilities and for new awards. Another is that MRC is committed to 'smoothing' as far as possible the funding of new awards from session to session, a policy which will be

facilitated by the increased carry-forward flexibility mentioned earlier'. MRC will continue to keep the scientific community abreast of the funding position in this way.

Clarification Notes Paragraph 25 of the Report says that the MRC drew £1.7m from its private fund and £7.5m from its commercial fund in 1999-2000 which suggests that they supplemented their income in that year from other sources. This suggests possible mismanagement through the MRC aggravating the fluctuations in funding as 1999-2000 was the year when the highest level of new awards were made. However the statement is based on a misunderstanding. The £1.7m from private funds was money that had been donated over a number of years for a specific purpose (namely a new building for the Dunn Nutrition Unit) and so had to be drawn in the year when the money on the new building was spent. The £7.5m commercial fund money was the income that the MRC received in 1999-2000 from commercial exploitation; this money was not used in that year to make any research awards. In fact, the MRC did draw on both private fund and commercial fund money in 2001-02 to alleviate the position in a difficult year.

Recommendation 11. Research funders all risk unpopularity among those researchers whose applications are not successful, and it is in the nature of the business that not all applications are successful, but the recent success rate for the MRC's grant applications has fallen to levels that are unacceptable (paragraph 26).

Response The Government notes the Committee's comments and will encourage the MRC to consider in discussion with the research community, the scope for introducing different or additional approaches to demand management. Discussion could include, for example, extended use of outline proposals.

Clarification Note The Table in the Report shows a success rate for Co-operative Group (COG) Grants in 2001/02 of 11% (it was actually 10%). This is lower than MRC would wish, but is 10% of all applications (Group and Component Grants). The success rate for highly regarded (alpha-A) COG applications was 60%.

Recommendation 12 & 13 (Duplicate) The anger of the research community at the MRC's funding problems is not only understandable but entirely justified. (Paragraph 27).

Response There are more high quality research opportunities than there are funds to sponsor research. The MRC therefore has a very difficult task in balancing its portfolio to support the needs of long term research projects as well as taking advantage of shorter term research opportunities. This requires difficult decisions to be made and disappointment in some sections of the community is inevitable

Recommendation 14 The MRC has failed to make realistic predictions about future income nor has it achieved a sensible balance of long-term and short-term research funding. It should remedy this situation in the future. (Paragraph 28).

Response As already indicated (see recommendation 10) judgements were made in July 2000 on the best information available at the time. As indicated in the MRC Strategic Plan and more recently in the Vision, the MRC Council sees MRC's current niche as being in long-term research, especially given the extensive short-term funding available from other UK funders. It follows that assumptions have to be made about funding beyond the relatively short-term horizon of a spending review. The position will continue to be kept under review and the OST and the MRC accept that such research policies need to be clearly communicated. MRC has many stakeholders however and there may not be universal agreement across the full range of MRC stakeholders on what the optimal balance of long term/short term funding should be.

Recommendation 15 The MRC has not been entirely frank with the Committee or the media about the shortage of funds available for grants in 2002. It is vital that public bodies are open. (paragraph 29).

Response The Government agrees that it is vital for public bodies to be open and transparent in dealings with Committees and the public and we encourage increased openness in these activities. The Government encourage all the Research Councils to be entirely open and honest with the select committee review process.

MRC staff are required to answer all external queries honestly using the best information available to them at the time. On the rare occasions when the MRC has had to provide individuals or organisations with supplementary data, or update information this has been intended to support or clarify earlier remarks rather than obscure facts.

As indicated under recommendation 10 the MRC published its best estimates for funding during the SR2002 period, and the assumptions and financial modelling on which these are based in March.

Recommendation 16 It is extremely regrettable that the policy decisions of the MRC should impact on other funders. We hope the establishment of Research Councils UK will prevent this situation in the future. We also recommend that other medical research funders are consulted before any further change to the MRC's funding strategy (paragraph 30).

Response The Government is not aware that the MRC's policy decisions have had a negative impact on other funders. We reiterate our support for co-ordination and active dialogue between funders. We have already facilitated this through RCUK and the first Research Base Funders' Forum will be convened in summer this year. This will provide an arena where funders can consider the collective impact of their strategies on the sustainability, health and outputs of the research system and where the Committee's concerns, detailed above, can be addressed.

Recommendation 17 The MRC is justifiably keen to support the next generation of medical scientists. But it must not do this at the expense of current research. We believe that the MRC's current financial problems should have been borne more equally across all its budgets (paragraph 32.)

Response The Government agrees that whilst it is important to support the next generation of medical scientists a balance has to be struck with support for current research. In fact, the MRC training budget has borne its share of the most recent cuts made to generate headroom for new grant awards (a 15% cut in 2001 which is still in place). Studentships are awarded to universities on a triennial basis and cannot be reneged upon.

Recommendation 18 The MRC has on three occasions corrected information submitted to us relating to its expenditure on new awards. This does not give us confidence in the rigour with which it publishes financial data nor the seriousness with which its views our scrutiny of its work (paragraph 33).

Response The Government agrees that it is essential that information provided to the committee and to all other external sources be correct. As indicated in the last Annual Report, MRC has been carrying out a detailed review of its management information systems to enable it to meet this requirement even more effectively. This process nears completion and the MRC Council will be discussing the strategy and the resource implications of this in July.

MRC staff provided the Committee with data using the best information available to them at the time. When the MRC submitted supplementary data it was intended to support or clarify earlier submissions.

Recommendation 19 While ring-fencing of the MRC's budget for some projects is useful (see paragraph 14), in general we believe that it should have set a notional proportion of its budget for different schemes but allow itself flexibility to respond to unexpected demands (paragraph 34).

Response The Government notes these comments. In February 2003 the MRC Council discussed setting notional budgets for other research support schemes. As with the present MRC system these budgets would need to preserve sufficient flexibility to meet unexpected demands. The need to ensure comparable quality standards across all schemes and budgets is also vital and well recognised by MRC. The Council intends to discuss these issues further later in the year. Progress will be reported in summary of Council meetings which will be placed on the MRC's website in the usual way.

Recommendation 20 We appreciate the difficulties in anticipating the effect of the new employment regulations and the increased salaries for postdoctoral researchers but it is important that the MRC makes the best estimate it can. A business would expect to calculate, as best it can, the impact of new regulations or changes in legislation on its income and expenditure. The MRC should be run in a business-like fashion (paragraph 35).

Response The Government acknowledge the need to run the MRC in a business-like fashion. This is achieved by the MRC producing its strategic plan, operating plan and annual report and accounts. From 2003-4 all this information will be published on the MRC's website

As researchers become more expensive either due to their individual increased experience or to general rises in levels of wages this will result in a rise in the cost of grants. From a business perspective if the overall income does not rise equally, this may mean the number of grants awarded being reduced.

Recommendation 21 We appreciate that not all contract researchers will have either the inclination or the experience to apply for MRC grants. What is important is that this option is available to them and that those with a good idea for a research proposal are free to pursue it. We commend the MRC for this policy (paragraph 36).

Response The Government notes these comments

Recommendation 22 We recognise the importance of the Research Professorship scheme for attracting and retaining top flight researchers in the UK and the value of creating secure research-only academic posts so that individuals can play to their strengths rather than being distracted by teaching obligations. The MRC's decision to focus on shortage areas seems a sensible one (paragraph 37).

Response The Government welcomes the committee's endorsement of the MRC Research Professorship scheme. We would also like to acknowledge the role of the MRC's International Appointments initiative which has played a key role in enriching UK science by attracting senior UK returners and other key senior figures from overseas. The Government attaches considerable importance to this strategy.

Recommendation 23 It is important that the MRC takes a dynamic approach to the funding support for its own research institutions, which it enables it to exploit new areas of research and avoids ossification (paragraph 39).

AND

Recommendation 24 There is no point in spending money on infrastructure by setting up MRC Centres but then denying them the funds to conduct any research (paragraph 40).

Response The Government supports the MRC's long-standing policy and practice to take a dynamic approach to funding to prevent ossification in its research institutions. These institutions are fully funded (ie both infrastructure and research are funded) by MRC once the quality of the science has been

assessed, on setting up and at subsequent quinquennial review, in competition with that from universities.. Where a decision is taken to close a site, either for strategic reasons (ie when a Director steps down) and/or where the science is no longer competitive, funds released are used to support research elsewhere.

Clarification Note Units are reviewed every 5 years. For the purposes of forward financial planning the MRC assumes a continuing commitment at existing levels of support. The "new awards" of £42m in 2000-01 and £10m in 2001-02 referred to in paragraph 40 of the Report are to cover expansion in unit research programmes beyond the existing baseline (the figures are for funding over a 5 year period). No significance can be attached to the figures in any particular year because the sums awarded will fluctuate markedly from year to year according to the programme of reviews i.e. the number and size of Units and institutes under consideration. For instance, the MRC's Laboratory of Molecular Biology was included in the 2000-01 programme whereas none of the MRC's largest establishments were reviewed during 2001-02.

Recommendation 25 The MRC has failed to provide a coherent and consistent assessment of the funding of the Mary Lyon Centre. It should be more open about its finances if it is to avoid arousing suspicion that its financial management is not all it should be (paragraph 41).

AND

Recommendation 26 Out of date information on the MRC's website undermines confidence in the accuracy of information it places there. It does not reflect well on the priority given by the MRC to communicating with its community. It is disappointing that the Mary Lyon Centre will be opened later than originally planned and regrettable that the MRC seems to wish to obscure this fact (paragraph 42).

Response The Government is supportive of the Mary Lyon Centre. It is an excellent initiative which will provide the mouse models of inherited disease which researchers require if the UK is to maximise the implications of genomics for health care.

As indicated in recommendation 15 the Government agrees that clarity and openness is essential. It is true that Council revisited the costing for the Mary Lyon Centre, however the MRC did not obscure the details, both Council's original decision and the approval of additional costs were reported on the MRC website.

The internet is a very important source of information and therefore websites should be reviewed and updated regularly. The MRC endeavours to keep its website up to date but as with all large organisations there may be a slight lag time.

Clarification Note The two figures that the Select Committee report are consistent with each other but have been drawn by the Committee from different documents and refer to different costs. The figure of £21m is the total level of funding that was approved by Council in 2000/01 which includes salaries, recurrent expenditure, building, and other capital costs. The figure was derived by the Select Committee from figures provided by MRC for awards made in 2000/01. The second figure of £11.3m is the estimated *capital* expenditure for the first three years of the project, which the Select Committee obtained from the Council's Operating Plan of July 2002.

Recommendation 27 The MRC should find a healthy balance between its spending on blue skies research and that directed by the nation's immediate health care needs. We are reassured that the processes are in place to achieve that balance but concerned by the MRC's temptation to place a greater emphasis on short-term health care needs (paragraph 43).

Response The Government agrees that a balance is needed between blue skies research and health needs. This is the heart of the MRC mission, which is to promote research aimed at maintaining and improving human health. It is also reflected in the terms of the MRC's Concordat with the UK Health Departments – a relationship which is reviewed annually at least and which has often been cited as a model for partnership working between government departments and research councils.

Medical research is a continuum requiring approaches at the level of cells, individual patients and volunteers, and populations. Individual research proposals can be, and are, assessed using a range of criteria including relevance to health and health burden. The precise weighting given to the latter will vary as science develops – hence the need for the first-rate peer reviewers, able to exercise these judgements, on whom the MRC depends. As the primary national publicly-funded organisation for medical research, MRC would be rightly criticised if it was not mindful of and responsive to 'health care needs'. However, responsiveness to health care needs does not imply that funding is diverted to less high-quality projects designed to solve short-term problems. In practice MRC can and does bring a variety of strategic approaches to areas of 'health need'. Examples include:

- Setting up of a new MRC Unit (typically this is the response in areas of research where there is clear health need, under-investment in research in the UK, a need to provide critical mass to attract researchers into a new field, and need to optimise basic/clinical research interfaces(eg setting up of the MRC Prion Unit)
- A rapid review of the research evidence base (eg MMR/Autism; Chronic Fatigue Syndrome)
- A call for research proposals (eg antibiotic resistance)

Recommendation 28 We are pleased to learn that Professor Radda is so positive about the development of the National Cancer Research Institute. We shall be monitoring its progress closely as it develops (paragraph 46).

Response The Government welcomes the Committee comments and interest

Recommendation 29 The Stem Cell Bank is a world-leading venture which we wholeheartedly support but the management and transparency of this publicly funded initiative must be beyond reproach. (Paragraph 51).

Response Like the Committee, the Government wholeheartedly supports the setting up of the stem cell bank. The oversight committee was appointed by the MRC's Council (which is an independent group representing major stakeholder interests) following discussions with key stakeholders including consumer groups, charities and the Department of Health.

Recommendation 30 We appreciate the difficulties in projecting the long-term running costs of Biobank at this stage but we are reassured to see that the issue is being actively considered now (paragraph 54).

AND

Recommendation 31 The Biobank is an exciting project and we commend the MRC's efforts to ensure that the UK is taking the lead in harvesting the fruits of the human genome. We are concerned, however, that funds were allocated to the project before the scientific questions over its value and methodology were fully addressed. (Paragraph 57).

Response The Government endorses the Committee's commendation of the MRC in ensuring that the UK continues to take a lead in harvesting the fruits of the human genome research. Unanimity is rare among the scientific community for a major project. One of the reasons that the project has taken so long to bring to fruition (the first joint meeting held by MRC and Wellcome Trust for scientists wishing to assist in development of the concept was in 1998) is that the funders have engaged scientists and other stakeholders on an inclusive basis from every stage. Now that the 'hub' and 'spokes' responsible for collection and analysis of samples and data have been selected, work will continue on finalisation of a business plan and protocol and these will be widely disseminated.

Recommendation 32 It is not clear to us that Biobank was peer-reviewed and funded on the same basis as any other grant proposal. Our impression is that a scientific case for Biobank has been put together by the funders to support a politically driven project. (Paragraph 58).

AND

Recommendation 33 We recommend that the MRC publish the comments of Biobank's peer reviewers anonymously to build confidence that the project is fully justified and supported by the scientific community (paragraph 59).

Response The idea of the Biobank was first raised by scientists and the project was peer reviewed. However it would not have been appropriate to review the project like 'any other grant proposal'. It is designed as a national resource for future research projects which cannot yet be specified in detail (though there will of course be peer review of these). The joint peer review procedure used by the funders (DH, Wellcome Trust and MRC) involved predominantly international experts as it was agreed that this was the best way of ensuring objectivity and independence and avoiding conflicts of interest.

The Government accepts the integrity of the peer review operated by the funders in relation to the UK Biobank project. Reviewers comments cannot be published as they were sought in confidence by funders in the normal way. Peer reviewers' comments are currently exempt from the Freedom of Information Act disclosure requirements which take effect in 2005. Any changes to current practice on peer review would need to be discussed, agreed and implemented consistently by all the research councils and other stakeholders.

In response to initial ideas from the scientific community, MRC bid for funds for its share of Biobank under SR2000. These were allocated by Government for this specific initiative, as is normal under the SR process. No funding has been released by the funders prior to peer review.

Recommendation 34 We believe that fully informed consent is an essential requirement for participation in Biobank. The MRC may have good enough grounds for not adopting the Human Genetics Commission's guidelines on consent for Biobank but it should state clearly what its position is and, if it disagrees with them, explain why (paragraph 60).

Response The Government agrees that fully informed consent is paramount. Planning for BioBank has always been on the basis that fully informed consent is an essential requirement. The discussions on consent in the HGC report *Inside Information* are not guidelines but rather general points to consider. These are consistent with the principles for consent which the funders are developing for BioBank, and with the guidelines developed by an expert MRC Working Group on DNA collections, which was published following wide consultation in 2000. In practice therefore, the HGC's points will indeed be followed.

Recommendation 35 We fear that the project's long-term viability could be threatened if Biobank's funders fail to adopt a more open approach and engage not only the projects' participants and stakeholders but the wider public (paragraph 63).

AND

Recommendation 36 It is our impression that the MRC's consultation for Biobank has been a bolt-on activity to secure widespread support for the project rather than a genuine attempt to build a consensus on the project's aims and methods. In a project of such sensitivity and importance consultation must be at the heart of the process not at the periphery (paragraph 65).

Response The Government recognises that consultation forms a vital part of the development of a project such as this. MRC and the other funders are committed to continued wide consultation as the project develops. The UK BioBank project is predicated on the willingness of volunteers to participate – broad public acceptance of the aims of the project is therefore an essential part of its implementation.

Consultation with a wide range of stakeholders, including the public, has been a fully integrated part of project planning over the last 3 years and this is one of the reasons that the project has taken so long to bring to fruition. Initiatives include:

- Informal consultation workshops with health professionals (GPs, nurses etc) across the country in 2001 and in 2003
- Independent qualitative and quantitative research by (different) consultants in 2000 and in 2002, reports of which have been published. The 2002 study was followed up, partly at the suggestion of some focus group participants) early in 2003 with further work with those social groups that had been under-represented.
- An ethics consultation workshop in 2002, involving ethicists and special interest groups. The report has been published and has informed development of the current draft ethics and

governance framework on which there will be further consultation in 2003

- Workshops for the wider research community wishing to contribute to development of the project (in 2001 and 2002)
- Presence at science festivals eg BA, Cheltenham
- Meetings with HGC including a public forum in 2002
- A parliamentary briefing event in 2003

Most of these consultations have indicated broad support for the Biobank concept. Comments on the ethics and governance structure and on the scientific protocol are being taken into account in developing the project further.

The Biobank's communication and consultation strategy over the next few months will focus in a number of different areas. External consultants have been commissioned by the funders to explore attitudes to the proposed ethics and governance framework for the project. In parallel, the funders will start to develop, with the newly appointed CEO for Biobank, a longer-term communications and consultation strategy for the project. This will include communications and consultation work to be done locally by the spokes with potential volunteers and health professionals, to underpin final development and piloting of the research protocol (a copy of the current draft has been available on the Biobank website since the summer of 2002). The CEO plans to appoint a Communications Director for the project later this year. Funders are also in the process of setting up a Public Panel. This is a group of approximately 50 people who have participated in previous consultation work commissioned by the funders and who have expressed an interest in some continued involvement.

Recommendation 37 The MRC appears to be taking a sensible attitude to industrial involvement in Biobank. It must be made clear that all results will be in the public domain but we recognise that if new therapies are to arise from Biobank industry's involvement is inevitable and necessary (paragraph 66).

Response The Government welcomes this recommendation

Recommendation 38 We agree with the Human Genetics Commission that Biobank's participants should be represented on the independent oversight body or on participants' panels at each regional centre. It is vital that participants play an active role in the management of the project (paragraph 69).

Response The Government and the MRC agree that volunteer participation in oversight of the project would be helpful nationally and/or locally.

Details of the members of the oversight group will be made public. This will mean that although the identity of volunteers and all data and samples would be confidential volunteers who are on the oversight group may be identifiable as volunteers. This would need to be adequately explained and consent obtained.

Recommendation 39 The Human Genetics Commission has recommended that the government fund research into encryption techniques to ensure data security. We support this view (paragraph 71).

Response Work is already underway within the NHS' national IT programme leading to the determination and establishment of reliable and robust standards that will ensure the confidentiality and security needs of NHS patient data are satisfied. These new arrangements will include appropriate means to anonymise, pseudonymise and encrypt patient data according to identified and agreed needs and that are suitable for patient data stored in databases or that is communicated electronically between information partners. The standards for achieving this security and confidentiality will be piloted and validated within arrangements for the NHS' national IT programme and will be available to the MRC for adoption as required.

DH is working closely with government security authorities including 'The Central Sponsor for Information Assurance' to ensure appropriateness of NHS methods and to achieve alignment with government advice where appropriate.

Recommendation 40 It is important that participants in Biobank are aware of the risk that police could obtain access to their data and samples before giving consent and before their samples are taken. The funders should monitor to what extent this issue acts as a disincentive to participation. (Paragraph 72).

Response The Government agrees that participants are made aware of this issue. The position of the funders has been that police could not search the database but that they could not refuse specific access in the unlikely event of a court order. When the issue of police access was explored during consultation, people seemed accepting of this approach.

Recommendation 41 (Conclusion) The MRC has a distinguished history and can claim credit for the high status of UK biomedical research. We commend it for valuable work it undertakes to maintain that reputation. Nevertheless, there is significant disquiet about the policies and performance of the MRC form individual researchers and organisations. We realise that we were unlikely to receive submissions from people with no grievances but we have concluded that those who have submitted evidence have legitimate concerns. We have found evidence of poor financial management and poor planning, with too many funds committed over long periods leading to large numbers of top quality grants proposals being turned down. The MRC has introduced misguided strategies for its research support that have discriminated against young researchers and some disciplines. It has been guilty of inconsistent and inadequate communications which have hampered our ability to access the MRC's performance and mislead its research community. Combined, these have harmed the reputation of the organisation and caused great resentment among and inconvenience to the research community it is meant to be supporting. (Paragraph 74).

Response The Government welcomes the Committee's attempt, in this conclusion to balance the MRC's continuing track record against the complaints the Committee have received.

The MRC has an excellent track record and as is shown in its annual reports the MRC meets its mission as set out in their Royal Charter.

While we agree that some areas of financial management and planning could be improved, we believe that as a whole the MRC is able to plan and control its expenditure, their audited accounts have been approved by the NAO.

The government does not agree that the MRC's research strategies are misguided. The MRC's long term strategies are developed by the MRC Council, which has representatives from the scientific and medical communities, in consultation with a range of organisations including the MRC research boards and Government Departments

The Government has acknowledged throughout this response the need to pay greater attention to communication with the research community, and to evaluation of research policy and strategy.





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