A GENERAL RESPONSE BY THE COMMON SERVICES AGENCY OF THE SCOTTISH HEALTH SERVICE TO THE INSPECTION OF SNBTS REGIONAL TRANSFUSION CENTRES BY OFFICERS OF THE MEDICINES DIVISION (DHSS)

MARCH 1982

November 1982

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(CSA/82/6)

GENERAL COMMENTS

The Agency would wish to record that the SNBTS Directors welcomed the courteous, constructive and co-operative approach of the Medicines Division's Inspectors. The visits provided a unique and welcomed occasion for them to review with their staff the overall function and performance of their respective Centres.

All Directors were nevertheless conscious of the fact that the time allotted to the inspections by the Medicines Division was wholly inadequate and compared most unfavourably to the time given to the first inspection of PFC. Nonetheless, the Directors, and indeed the Inspectors, did their best to counter this problem and it is accepted that substantial improvements in practices can, and should, emerge.

There can be no doubt that there is a need for colleagues within the Medicines Division to define with considerable precision what areas (functions) within a Regional Transfusion Centre they intend to cover(inspect) with regard to those deliberations destined to provide a Centre with a Manufacturer's Licence. The inspections suggested to the Directors that this basic preliminary work has not been done and, as a consequence, it was felt that the Inspectors were, on occasions, feeling their way. Evidence for this conclusion is illustrated by a certain lack of format in the Reports and, as a consequence, they make difficult reading. Moreover, there appears to be a lack of understanding or a refusal to accept the consequences, that a substantial part of the clinical practice of blood transfusion in the UK resides, not only in the Regional Centres, but in the hundreds of District General Hospitals which house Peripheral Blood Banks.

None of the problems referred to above are insoluble or overwhelmingly formidable, but the Agency would submit that it would be in the interests of all concerned if these policy decisions were made before any further inspections of the SNBTS Regional Transfusion Centres. The SNBTS would be pleased to offer every assistance in this exercise.

Finally, the respective Departments of Health need to consider the status of a Manufacturer's Licence for Regional Transfusion Centres, both now and in the future. The Agency is aware, and must express some concern, that the Regional Transfusion Centres in England and Wales were never issued with Manufacturer's Licences, as of right, yet this was deemed important for the Scottish Transfusion Centres. This may reflect, in part, differences in the law between Scotland and the rest of the UK. However, if so, then

the fact is that these Licences expired in June 1981 and no policy decisions were conveyed to the Regional Transfusion Directors with regard to the status of their Centres' work, despite the fact that this expiry took place in the full knowledge that formal inspections of the Scottish Transfusion Centres, with appropriate Reports, would not materialise for at least 12 months thereafter. The Agency, as the Licence Holder, requires formal advice on this matter, particularly with regard to the issue of temporary Manufacturer's Licences as the issue of full licences will require further visits from the Inspectors which, according to the Reports, will take many weeks.

The Agency would not wish to be overcritical, but there was at least one feature in the Reports which indicates that the Inspectors strayed far beyond their remit. The system by which the SNBTS calculates the distribution of blood products issued from PFC to Regional Centres has nothing to do with GMP (item 68 in Edinburgh Centre Report). The Inspectors, in the Agency's view, should not incorporate advice on such matters in their Reports. This does not imply that criticisms on this topic are not welcome; the forum was wrong.

Whilst not wishing to distract from the exceptional energy and professional skill put into the inspections by the Inspectors in a very short period of time, the Agency cannot escape the conclusion that the areas covered were incomplete and inconsistent between Regional Centres (see Appendix I). This factor no doubt contributed to the variable quality of the Reports. This could give rise to some delay in achieving optimal and matching responses between Regional Centres. This was unfortunate, for it is important to emphasise that, unlike the position in England and Wales, the Agency is the single Employing Authority with responsibility for all the Scottish Transfusion Centres. The Agency would not wish to see any one Centre lagging behind in its moves towards satisfactory GMP on the grounds that an essential part of its function had not been inspected. This, however, begs the question of what the definition is with regard to essential functions.

Conclusions

Notwithstanding these comments, the Agency takes the view that there is sufficient detailed information in the Reports which justifies a positive and constructive general response. A more detailed response will follow as soon as possible.

RESPONSE

The Agency wishes to preface the General Response to the March 1982 Reports by conveying to the Medicines Division the fact that in its long range planning strategy, which began in 1979, many of the problems delineated by the Inspectorate had been foreseen.

The general responses can be summarised best by consideration of the following areas:

BUILDING PROGRAMMES

(a) General Remarks

(i) The Agency has already approved in principle substantial building programmes for the Aberdeen, Dundee and Inverness Centres (see below).

(ii) The Reports did not convey clear guidelines with regard to the standards required for blood processing areas, although the Agency has recognised that most existing facilities are well below its standards. The Agency, however, would wish to put on record that the proposals implicit in the deliberations between the SNBTS and a previous Inspector (in 1977) are unacceptable. Specifically, the Agency rejects the need for rooms with Class I environments for pooling plasma destined for fractionation. This conclusion is based upon previous experience within the SNBTS which has been scientifically validated, and on the unacceptably high cost of such proposals. Moreover, it rejects the concept of the need to sanitize the external surface of blood bags after centrifugation. This latter feature, developed by the previous Inspector in 1977, appeared in one of the March 1982 Reports (item 46, Glasgow). The Agency takes the view that it should not be implemented until there is sufficient scientific and cost-effective evidence to justify it. As additional support for this conclusion it would draw the Medicines Division's attention to the fact that the introduction of a sanitizing system in one Regional Centre in England and Wales has proved to be extremely costly, both with regard to capital and revenue expenditure. Moreover despite considerable effort they have failed to demonstrate it improves the quality of the pooled plasma with regard to microbial contamination (published comment of senior staff member from Centre involved at Biotest Symposium, Edinburgh, 1981).

In an effort to clarify the position with regard to an overall

concept for a blood processing area, a proposal with relevant notes can be found in Appendix II. This proposal, the Agency believes, is an acceptable compromise and, coupled with appropriate staff training and supervision, is entirely adequate.

(iii) It is accepted that the storage facilities in most Centres are one of our major problems, both with regard to quantity and quality. This will be remedied.

(iv) It is accepted that consideration must be given to preventing unauthorised persons entering laboratory areas. This problem will be solved in a variety of ways.

(b) Regional Programmes

Aberdeen

(a) Refurbishment of Existing Building

The Inspectors' criticisms of the refurbishment plans have been examined in detail and the Agency is confident that an acceptable outcome will be possible in the light of its commitment to proceed, as soon as possible, to the building of a new Centre, as recommended by the Inspectorate. Work is now proceeding to establish final costs etc. with a view to commencing the refurbishment programme as soon as is practicable.

(b) New Centre

The Director and Director Designate have been instructed to commence the preparation of a brief for a New Centre, forthwith. At this time it is not possible for the Agency to confirm that this new Centre will be commissioned in 5 years. However, it is the intention of the Agency to use its best efforts to see this is achieved.

Dundee

The criticism, with regard to the new accommodation required at the Centre, is accepted. Discussions are currently in hand between the Agency and the Tayside Health Board with regard to obtaining extra accommodation in the Ninewells Hospital complex. It is hoped that existing vacant accommodation in the Ninewells complex will be released for use and appropriately fitted out. The Agency has noted the Inspectors' desire to see this new accommodation commissioned by June 1984 and will use its best efforts to meet this deadline.

Edinburgh

The Agency is in a position to draw to the Medicines Division's attention the fact that the new accommodation in Phase I of the new Royal Infirmary and at Livingstone House is now commissioned. Thus, there

has been a substantial improvement since the inspection in March 1982. In addition the Regional Director and his staff are currently working with architects and engineers on a major upgrading programme of the Blood Bank/Crossmatching Areas (Report reference p.5) in the existing (old) building. This upgrading is regarded as a high priority.

The Agency would wish to challenge the Inspector's recommendation that the Livingstone House operation must be re-incorporated into Phase I of the new Royal Infirmary no later than June 1985. Whilst recognising that the present arrangement leaves much to be desired, the problems are primarily related to the management of the Regional Centre as a whole. Moreover, it is necessary to emphasise that there are significant problems with regard to the current planning of Phase I of the new Royal Infirmary and that access to this residual accommodation is not the direct responsibility of the Agency. The Director is of the opinion that the highest priority is the upgrading of the Blood Bank Area and that his senior staff (after commissioning Phase I and Livingstone House and, in the near future, the Blood Bank Area) require a period of stability in order to consolidate the management of the Centre. Nevertheless, the Agency intends to review the future of the Livingstone House operation as soon as possible after the planning of the new Blood Bank Area is completed. In the meantime, continued efforts will be made to validate the effectiveness of GMP at the Livingstone House operation.

Glasgow

The Agency is now in a position to advise the Medicines Division that the Plasma Freeze Drying Plant will close on the 31st December, 1982 and that the refurbishment of the Preparation Area is now underway (reference, item 40 of Report).

The Director and his staff have been advised to submit to the National Medical Director, as soon as possible, the plans for proposals which will meet the criticisms (which are accepted) particularly with regard to the Processing and Storage Areas. These agreed plans will be processed by the Agency's architects and engineers and there is every reason to believe that all these planning activities will be completed by June 1983 (the date recommended by the Inspector).

Inverness

The Agency has approved in principle a substantial upgrading of the Inverness Centre. Final design details are being reviewed in the light of the general comments made above with regard to the standards required for blood processing areas. It is anticipated that the Agency's architects

and engineers will begin work on this project in December, 1983. In the meantime, minor works are already in hand, including those which will improve the Crossmatching Laboratory. However, in the light of the commitment described above and the long and excellent record of blood product safety within this Centre, the Agency does not accept the need to move precipitously (by December 1983) with regard to the installation of a small aseptic facility.

Conclusions

Some minor works are already underway which will cover some of the criticisms contained in the Reports. However, the main burden of the criticisms will not be resolved until more detailed plans have been finalised. All such plans are in an active state of preparation. The Agency has recognised that these plans may not be finalised until the next financial year (1983/84) but, nonetheless, has earmarked a bid for its 1983/84 capital programme of £461,000 in an effort to secure a start to some or all of the Regional Centre building programmes in 1983/84.

EQUIPMENT PROGRAMME

As a result of its long-term planning programme for the SNBTS, the Agency has been able to undertake the following actions with regard to the purchase of equipment which relates directly to the criticisms of the Inspectorate:-

1. Authorisation has been given for the purchase of certain items of equipment in 1982/83 (Appendix III).
2. A bid has been made for the purchase of general equipment in 1983/84 Revenue Estimates, and some items will be specifically related to the Reports.
3. A bid has been made (£435,000 capital and £89,750 revenue) for the purchase of advanced blood grouping machines in 1983/84 for the Edinburgh and Glasgow Centres.
4. A bid has been made for the purchase of computers, at an estimated expenditure in 1983/84 of £356,000 (capital) and £38,744 (revenue), for the Edinburgh, Dundee, Aberdeen and Inverness Centres.

Conclusions

The Agency has taken this aspect of its Response as far as possible at the present time. Further requirements are anticipated when the Regional Directors have completed their detailed studies.

STAFFING CONSEQUENCES

The Agency recognises that the implementation of changed procedures

which enhance GMP may have consequences on staffing levels in some of the Centres. Many of these consequences have yet to be fully delineated and approved, but certain staffing establishments have already been approved or noted within the Agency's routine forward planning arrangements which have a direct bearing on its response to the criticisms of Medicines Division. Appendix IV contains a list of relevant (Medicines Inspectorate Report) staffing positions which are already under consideration in the bids for new revenue expenditure in 1983/84.

Conclusion

The staffing consequences of the Agency's response to the Report are still under review. Some elements, however, have already been instituted.

DOCUMENTATION

Every reasonable effort is being made by the Agency to facilitate the formidable task of generating and maintaining satisfactory documentation in the Regional Centres. To this end it is hoped to instal word processors thereby relieving secretarial staff of some of the considerable burden of this exercise. The Agency would wish to draw to the Medicines Division's attention that the SNBTS Directors have established a national Working Party under the Chairmanship of Dr R J Perry (Head of Quality Assurance at PFC) on which all Regional Centres are represented, to provide a facility for inter-Centre cross-fertilisation and aid.

The Agency would wish to record its view that the deadline for full and adequate documentation set by the Medicines Division of March 1983 is unrealistic and would wish to point out that at PFC, despite considerable efforts, the task is not yet fully completed some 3 years after the first inspection. Of no less importance is the fact that until such times as the Medicines Division defines its policy with regard to the areas in the Regional Centres it wishes to inspect, then the difficulties are compounded. Even when this policy emerges there will be a requirement for advice on priorities.

Conclusion

Steady progress is being made in this area. It is the view of the Agency that the deadline set by the Inspectorate is unattainable.

QUALITY ASSURANCE

The Agency would wish to emphasise in the strongest possible terms that this area within transfusion practice is the most difficult one to

respond to adequately. The problems are multifactorial and complex and relate to the paucity of pharmacopoeial data in relation to blood and blood products, and thus the consequent limitations with regard to agreed specifications and quality control parameters, both with respect to environmental conditions and actual products. These problems are recognised internationally and indeed are the subject of study at the present time by the Council of Europe's Committee of Experts on Blood Transfusion and Immuno-haematology.

The Agency would wish to see these matters resolved and, to this end, it notes that the SNBTS has established a Working Party (under the Chairmanship of the National Medical Director) to consider the specifications of fresh frozen plasma destined for fractionation and how these may be validated. Furthermore, the SNBTS has formally requested the NBTS that steps be taken to establish a joint (UK) Working Party to make recommendations with regard to specifications and quality control of blood and blood products, taking into account the work of the Council of Europe's Expert Committee. Until these deliberations are completed the Agency takes the view that major expenditure on the creation of elaborate quality assurance programmes cannot be justified. Nevertheless, as an interim, the National Medical Director has agreed to consider, after consultation with the Regional Directors, the development of a limited programme of quality assurance that will not involve a substantial commitment to increasing staffing establishments.

Conclusions

Every reasonable effort is being made by the SNBTS to introduce a realistic approach to the problem of quality assurance in blood transfusion practice. The Agency does not feel at the present time that there is sufficient data upon which to base major expenditure in this area. Accordingly, it envisages its programme to be a limited one until such times as appropriate studies and discussions have taken place.

AREAS RECEIVING ATTENTION AT THE FIRST INSPECTION OF SNBTS REGIONAL CENTRES (1982)

	ABERDEEN	DUNDEE	EDINBURGH	GLASGOW	INVERNESS
Donor Sessions	Partial	Partial	Yes	No	No
Reagent Production/ Serological Practices	Not mentioned	Not mentioned	No	No	No
S O Ps	Yes	Yes	Yes	Yes	Yes
Storage	Yes	Yes	Yes	Yes	Partial (only Cold Stores)
Blood Processing Areas	Yes	Yes	Yes	Yes	Yes
Q C Hepatitis/Syphilis Testing	Yes	Yes	Yes	Yes	No
Serology	Yes	Yes	Yes	Yes	No
Q A Blood Products	Yes	Yes	Not mentioned	Yes	Yes
Environmental				Yes	Yes
Formal Staff Training	Yes	Yes	Yes	Yes	Not mentioned
Receipt of Blood and components	Yes	Yes	No	Not mentioned	No
P P M	Not mentioned	Yes	No	Not mentioned	Yes
Issue Blood Products	Not mentioned	Not mentioned	Yes	Not mentioned	Yes
FURTHER TIME (WEEKS) JUDGED BY INSPECTORS TO "COMPLETE" INSPECTIONS	2	1	2	2	1