

Dr McIntyre

cc Dr Scott

INFORMAL VISIT TO BLOOD TRANSFUSION SERVICE FACILITIES AT ABERDEEN AND EDINBURGH -
DR MOIR AND DR FLETCHER (DHSS)

Aberdeen

As a result of informal enquiries it was felt advisable to visit both of the above centres. At Aberdeen we found that the patient reception areas and facilities for blood donation were excellent, as were the laboratory facilities for all analytical tests and quality control work. Much of the laboratory side dealing with analytical tests is not strongly related to BTS functions but provides facilities for the Grampian Region. The space available for record keeping is woefully inadequate as all the detailed records (and staff lockers and some small items of laboratory equipment) require to be kept in the main corridor of the second floor of the Transfusion Centre which is concerned with laboratory facilities and blood processing. The area available for blood processing is woefully inadequate in terms of space as it amounts to one small L-shaped room without a clean air supply. They have a tiny section of another room (approximately 4' x 6') equipped with a large laminar flow cabinet however because the laminar flow system is of the open type the fans required to provide the air supply to both the room and the cabinet make the noise level of working in the room almost unbearable and I gather that in practice this facility is seldom used. While the cleanliness and organisation of this unit indicated a very high order of appropriate "housekeeping" it is quite clear that this Centre's service role is seriously impeded by lack of space. It would appear that there would be a need to have proper facilities for all the records and an expansion of upgrading of a number of areas concerned with production facilities.

I hope that Dr Fletcher will give me an informal note of his views on these problems within the next week or so.

Edinburgh

Much of our time during the Edinburgh (and indeed part of the Aberdeen visit) dealt with the problems of pigtail bags and a defence of the open system (see below). During the visit it was clear that the way in which the Centre is sited in a number of parts of relatively old buildings which have been upgraded is far from satisfactory notwithstanding the fact that those concerned have obviously done their utmost with regard to the major structural alterations given the difficulties of their starting situation. While the technological procedures for processing blood are of a very high order and have brought into play a number of extremely innovative, useful procedures there were numerous examples of minor and unnecessary contraventions of good manufacturing practice (simple irritating things that would undoubtedly cause a member of the Medicines Inspectorate considerable irritation - labels stuck inside laminar flow cabinets, use of note books inside laminar flow cabinets, transfer of blood products through open systems without wearing gloves etc.). There did not seem to be a great point in making an issue of these minor details at this stage as the Blood Transfusion Service in Edinburgh is destined to move into new facilities in phase 1 and 2 of the Royal Infirmary therefore both Dr Fletcher and myself concentrated our attentions on persuading Dr Cash that it would be timely for him to have a look at a number of recently constructed centres in the south which have been able to provide entirely satisfactory environments for the processing of blood products (Liverpool and Birmingham were chosen in view of the fact Dr Cash appears to be on relatively good terms with their Directors).

Blood Bags

There has been considerable concern over the use of Travenol pigtail bags since the Director of the Leeds Transfusion Centre reported that a small leak in the pigtail of 2 bags had produced a leak-back of water (from wet balancing) into the blood bag. Travenol were approached on this matter and have confirmed that such an event may indeed occur in 1 - 2% of their bags. They have come forward with a number of possible solutions only 2 of which looked to be satisfactory possibilities. Unfortunately the adaptation which was theoretically most useful would have required a retooling of the instruments concerned with manufacturing which could not have been done without the approval of the USA parent company and which would have been unlikely to have been able to be brought to market within less than 18 months. A simpler form of double capping of the pigtail is to be tried to see if this will decrease the likelihood of an air leak in the pigtail. It is quite clear that if the leakage rate of Travenol pigtail bags cannot be reduced to something like 1 in 1000 this bag is likely to be withdrawn from the market (this may occur as a result of the firm's own wish to stop manufacturing the bags rather than through any action taken by the Licensing Authority). It should be noted however that part of the hazard caused by the leaking of the pigtail bags is due to the fact that in a number of English centres (Leeds included) there is the practice of wrapping the pigtail round the bag so that the cap comes to lie underneath the bag during centrifugation and there is also the practice (strongly disapproved of by the Licensing Authority) of "wet balancing". From what is known of our Scottish Transfusion Centres the practice of wet balancing does not appear to be used also where pigtail bags are in use the pigtail is doubled up and held at the top of the bag by an elastic band. In discussions in Aberdeen it appeared that Dr Lewis was certainly concerned to note the position with Travenol bags and could easily be persuaded to change to the double packing system if the situation with Travenol was not resolved however it was noted that about half the pigtail bags used were produced by Tuta and so far it has not been shown that this pigtail bag is subject to the same defects as the Travenol one. The problems of pigtail bags were discussed with Dr Cash at Edinburgh in some considerable detail. All the pigtail bags used in the Edinburgh Centre are of Tuta type. He appreciated the potential seriousness of the defect found in the Travenol bag and it seems likely that he will be prepared to undertake assessment of whether the same type of fault can occur with the Tuta bag, which does appear to have a doubt seal of sorts on its pigtail.

As can be seen from the copy of Dr Cash's letter to Dr Fletcher he is prepared to put us a spirited defence of the open system using pigtail bags and certainly it would appear that he has extensive bacteriological data as a result of fairly intensive monitoring of the various blood fractions the Edinburgh Centre produces. However while the monitoring appeared to be first class it will be appreciated from comments above that the inbuilt quality control did appear to leave quite a lot to be desired and monitoring is no substitute for quality control aspects of quality assurance.

GRO-C

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