

PENROSE INQUIRY – C1 – GUIDANCE DOCUMENTS – NOTE BY EM**Collection, Processing and Manufacture****NBTS, “Memorandum on the Selection, Medical Examination and Care of Blood Donors”**

1. The Memorandum was prepared by the National Blood Transfusion Service for England and Wales. Versions were produced in 1977 (SNB.002.5348), 1983 (SGF.001.0377; enclosed with letter dated 12.9.83 by Dr Entwistle to Dr Brookes, SGF.001.0375), 1985 (DHF.001.8931) and 1987 (SNB.006.6410). As the name suggests, the Memorandum covered the selection, medical examination and care of blood donors. The SNBTS Directors commented on the draft 1977 Memorandum (SGH.002.5862). They also commented, via Dr Brookes’ membership of Dr Entwistle’s Working Party, on the 1983 Memorandum.
2. The Memorandum was superseded in 1990 by the “Guidelines for the Blood Transfusion Services in the United Kingdom” (see below).

SNBTS guidance on the selection of blood donors

3. Each Scottish region had its own guidance on the selection of donors in the 1970s and much of the 1980s. The regional guidance took account of the NBTS Memorandum on the Selection etc of Donors but did not necessarily follow it in every respect.
4. In 1985 Dr Gillon led an attempt to produce collective SNBTS guidance on the selection of donors (see SNB.003.9864 and SNB.003.9905). Such guidance, also referred to as “A-Z Guidance for the Selection of Donors”, was issued in November 1988 (PEN.016.0479), re-issued in August 1990 (SNB.006.6484) and revised in early 1991 (SNB.011.7435).

“Standards for the Collection and Processing of Blood and Blood Components and the Manufacture of Associated Sterile Fluids” (the “Red Guide”)

5. These Standards were compiled by the DHSS (presumably by the Medicines Division) in consultation with the RTDs of England, Wales and Scotland, the Directors of BPL and PFC and the SHHD. The only version the Inquiry is

aware of are the 1979 Standards (PEN.002.0249). The SNBTS Directors commented on the draft Standards (SGH.002.5862, SNB.002.5156, SGH.002.5801 and SNB.002.5424). The Standards were also referred to as the “Red Guide” or “Red Book” (see SNB.002.0133 and SGH.001.3012 at .3013).

“Guidelines for the Blood Transfusion Services in the United Kingdom”

6. These Guidelines (also known as the “Red Book”) were prepared jointly by the UKBTS and the NIBSC and published by the Department of Health. The guidelines were started in 1987, on the initiative of Drs Cash, Wagstaff and Schild. The first edition, while entitled “Guidelines for the Blood Transfusion Services in the United Kingdom 1989”, was published in 1990 (the Inquiry has a hard copy).
7. The first edition of the Guidelines comprised 3 volumes, namely (1) “Guidelines for blood components prepared at regional transfusion centres” (which included guidance on the selection of donors), (2) “Guidelines for the preparation of plasma fractions” and (3) “Guidelines for reagents for blood group serology and HLA typing”.
8. The current edition of the Guidelines is the 7th edition, published in 2005. The Guidelines aim to define guidelines for all materials produced by the United Kingdom Blood Transfusion Services for both therapeutic and diagnostic use. The guidelines reflect an expert view of current best practice, provide specifications of products and describe technical details of processes. Donor Selection Guidelines (drafted by the Joint Professional Advisory Committee for the UK Transfusion Services on Care and Selection of Donors) are now contained in an appendix to the Guidelines.

“Guide to Good Pharmaceutical Practice” (the “Orange Guide”)

9. This Guide was published by the DHSS, the SHHD and other government departments and was compiled by the DHSS (presumably by the Medicines Division) in consultation with other interested bodies. The first edition of the guide appeared in 1971. It had no statutory force and described “measures for control of quality during manufacture and assembly, with particular reference to those aspects that are associated with safety”. The second edition of the Guide was published in 1977 (DHF.001.2933). The third edition of the Guide

was published in July 1983 (see DHF.001.4990). The Guide was also referred to as the “Orange Guide” (see SNB.002.0133). The current edition is “Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007”, published by the Medicines and Healthcare products Regulatory Agency (MHRA). The document is still referred to as the “Orange Guide”, by virtue of it having an orange cover.

Clinical Use

“Notes on Transfusion”

10. The Notes on Transfusion, which gave guidance on the clinical use of blood, were published by the DHSS in 1973 (DHF.001.2039) and revised in 1984 (DHF.003.0394). The introductory paragraph of the 1973 Notes stated that they had:

“been prepared by the Committee of Regional Transfusion Directors of the Department of Health and Social Security and Welsh Office. The booklet is intended primarily for use by medical staff of hospitals and its purpose is to describe briefly some of the principles of the practice of transfusion and to suggest procedures ... the booklet should not supersede already established local practice”.

11. The 1984 version of the Notes contained a number of factual and printing errors (SNB.008.6081). There were also reservations among the SNBTS Directors about the content of the Notes. The SNBTS Directors considered that the Notes should not be issued to the NHS in Scotland. Dr McClelland was asked to prepare a new booklet. In the meantime, Drs McClelland and Urbaniak were to circulate to the other Directors a copy of the guidance given to house officers in their respective regions (see SNB.003.8411 at .8415; SGH.001.0445 at .0448; and PEN.010.0037 at .0042 and .0043).
12. The “Notes on Transfusion” were superseded in 1989 by the “Handbook of Transfusion Medicine” (see below).

“Handbook of Transfusion Medicine”

13. In 1984 Dr McClelland set up a group of experts to start work on what became the United Kingdom Blood Services’ “Handbook of Transfusion Medicine”. The first edition, edited by Dr McClelland, was published in 1989 (SGH.008.3503). The Handbook provided guidance on the clinical use of

blood. The most recent version of the Handbook, the 4th edition, was published in 2007 and was, again, edited by Dr McClelland. It provides that:

“The purpose of [the] handbook is to help the many staff involved in providing and using blood products to make sure that the right blood product is given to the right patient at the right time”.