

SUPPLEMENTARY NOTE B

1. Introduction

This note aims to provide a non-technical outline of the Inquiry's approach to selecting cases for clinical review as part of a wider investigation of the adequacy of care received by children within the terms of reference. It also seeks to respond to comments received by the Inquiry concerning the sampling approach and derivation of the sample numbers, as set out in July 1999¹.

The note outlines the Inquiry's approach to selecting cases for review; clarifies how sample cases have been derived; identifies the steps taken by the Inquiry to validate the sample; and sets the clinical review exercise in the context of wider evidence on adequacy of care.

2. The Inquiry's Approach to Selecting Cases for Clinical Review

The Inquiry's approach to selecting cases for expert clinical review is based on a set of key guiding principles which can be summarised as follows:

- selected cases must be representative of all children falling within the Inquiry's terms of reference, as identified by the United Bristol Healthcare NHS Trust [UBHT] through a formal discovery process;
- selected cases must reflect those concerns that led to the Inquiry;
- cases must be selected in a way that is fair, transparent, rigorous, statistically valid, and feasible.

On the basis of these guiding principles and expert statistical advice, the Inquiry decided to select a stratified random sample of 80 cases, weighted preferentially towards children who

- were under one year at time of their first procedure;
- received higher risk open heart procedures;
- died within 30 days of their last procedure.

For comparative purposes, and to allow adequate investigation of morbidity as well as mortality, it was decided to select equal numbers of children who had died (40) and children who were alive (40).

The sampling approach and method have been devised to reflect the concerns that led to the Inquiry, and to ensure a balanced view of the care of all children falling within the terms of reference of the Inquiry. Statistical advice to the Inquiry confirms that all these aims are met by the achieved sample of 80 cases.

¹ An initial description of the case selection process was set out in the document *The Inquiry's Approach to the Assessment of the Adequacy of Paediatric Cardiac Surgical Services*, published in August 1999.