

**BRI INQUIRY PAPER ON INFORMED CONSENT: CONCEPT,
GUIDELINES AND
PRACTICE WITH REFERENCE TO CHILDREN UNDERGOING
COMPLEX HEART SURGERY**

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EXECUTIVE SUMMARY

The purpose of this paper is to use the academic, research and professional literature on informed consent with particular regard to children undergoing complex heart surgery to clarify expectations of what should happen in this area and to identify factors which may influence the process of giving and obtaining consent in such a context. The paper excludes discussion of aspects of consent which are not obviously relevant in this case, such as refusal to consent, consent for research, and consent for other specific groups (eg incompetent adults) or particular types of treatment (eg sterilisation, treatment for mental illness).

The paper draws heavily on the work of Dr Priscilla Alderson, who has undertaken extensive empirical qualitative research on the care of children in hospitals (including a study specifically on young patients undergoing complex heart surgery) and has written extensively on the issue of informed consent in this setting. In addition, reference is made to other relevant books and guidelines and peer review/research papers identified via Medline searches.

Section 1 outlines the concept of informed consent, its purpose and criteria and summarises the legal position on informed consent (in general and in regard to children) during the period 1984-95.

Para 1.1 begins by outlining the ethical basis of consent. Guidelines on informed consent in relation to medical **research** as defined in the *Nuremberg Code* and the *Declaration of Helsinki* are then outlined, and the nature of the information required to ensure informed consent to **treatment** is discussed, along with suggested criteria for assessing the competence of patients (both adults and children) to give consent. The importance of consent being voluntary, as well as is informed, is briefly explored and potential benefits to the patient of the requirement for informed consent are considered.

Para 1.2 describes the sources, scope and content of guidelines on informed consent applicable during the period 1984-95, with particular reference to requirements for consent in relation to children under the age of 16. Apart from broad ethical guidelines agreed by medical associations and some basic guidance from the Department of Health, the main guidance on consent is given by case law, evolved in response to particular disputes.

Various aspects of consent on which guidance exists are then discussed. These include: the circumstances in which consent is required in verbal or written form; the question of who can give consent and how children and parents should be involved in decisions about treatment; the amount of information required to be given to patients and the criteria for determining whether this is appropriate; and the extent to which consent applies to specific treatment decisions.

Para 1.3 considers the information available to show how well the process of obtaining informed consent is actually carried out in practice. Attention is drawn to a number of areas in which potential problems have been identified. These include readability of consent forms, potential difficulties for particular patient groups such as those with low literacy skills and learning disabilities; concerns about the knowledge base of staff involved in obtaining consent; problems of unsystematic and inconsistent approaches to obtaining consent; concerns about the inadequacy of healthcare professionals' communication skills; and about the extent to which staff recognise the need for consent to be obtained.

Section 2 explores the potential information needs of children and their parents in relation to informed consent, and draws attention to aspects of the care of children undergoing complex heart surgery which may complicate the process of giving and obtaining such information in this context. It also identifies factors which affect the amount, content and quality of discussion between patients, parents and hospital staff and the value to patients of the information they receive

Para 2.1 suggests that patients need information which is timely, accurate, reliable, relevant, understandable and sufficient to meet their needs and wishes. In the context of complex paediatric heart surgery, the availability and provision of such information may be particularly difficult. First, because the nature of the problems and their treatment (typically highly technical, dangerous, uncertain, non-standard and multi-faceted) increases the difficulty of estimating and balancing the various risks involved. Second, because the fragmentation of care over time and place, and the involvement of many different people in a range of different settings make it difficult for both staff and families to ensure that all relevant information needs are addressed. Third, because the involvement of parents and families in making decisions with or on behalf of their children raises issues of how information is shared and exchanged amongst everyone concerned.

Para 2.2 considers how the quality, amount and content of discussion with patients and parents preceding consent are influenced by patients' and families' capacity to ask for information and by the extent of information offered to them by staff. Factors affecting the former include: physical presence and involvement with the child's care; feeling able and empowered to ask; knowing what and whom to ask; and being in a fit state to ask. Factors affecting the latter include: extent of staff knowledge about the patient's problems and treatment; the status, responsibilities and professional perspective of different staff; attitudes to the importance of patient involvement and perceptions of their capacity to understand; awareness of patients' needs and concerns; availability of time and appropriate skills; and extent of co-ordination and team-working between staff.

Finally, attention is drawn to the importance for patients of understanding and being able to remember information they are given and of feeling able to trust in the competence and commitment of those that provide it. The paper concludes with a summary of the main points raised.

1. THE CONCEPT OF INFORMED CONSENT

This section:

- * outlines the concept and purpose of informed consent, discusses the criteria that must be met to justify the claim that informed consent has been given or obtained and considers how patients may benefit from informed consent
- * summarises the legal position on informed consent during the period 1984-1995, with particular reference to the giving of consent in relation to children
- * identifies some of the ways in which the process of obtaining informed consent may, in practice, be inadequate

1.1 The concept of informed consent

1.1.1 *The ethical basis of consent*

- i. Consent in the context of medical care is not a legal, but an ethical doctrine. It flows from the Kantian imperative of respect for each persons as a person in his own right. One of its crucial consequences is that we should respect each person's autonomy, their power to make their own decisions and to act on them. Consent is one aspect of respect for autonomy. In the context of medical ethics it means that a doctor may not touch or treat a person without their consent, always assuming that the persons is competent to make an autonomous decision.

Kennedy¹ points out that consent is also an ethical doctrine about power, in that it seeks to transfer some power to the patient in areas affecting their self-determination, "so as to create the optimal relationship between doctor and patient, which is the same as that between any professional and his client - namely, a partnership of shared endeavour in pursuit of the client's interests. Good medical ethics strives for a relationships which is neither one of "medical paternalism" nor "patient sovereignty", but one of "shared decision-making".

1.1.2 *Informed consent in relation to medical research*

- i. Informed consent is most clearly defined in guidelines on consent to medical research, not to treatment. The *Nuremberg Code*² requires that "there should be made known" to each research subject:
 - * the nature, duration and purpose of the intervention
 - * the method and means by which it is to be conducted
 - * all inconveniences and hazards reasonably to be expected
 - * the effects on the subject's health and person which may possibly come
 - * the liberty to withdraw if the subject has reached the physical or mental state where continuation of the experiment seems to them to be impossible

The *Declaration of Helsinki*³ adds that potential subjects should be informed of:

- * anticipated benefits
- * their liberty to refuse to take part

1.1.3 *Informed consent in relation to treatment*

i. The definition and application of clear guidelines on informed consent has been a much slower process in relation to medical treatment. Ley⁴ suggests that minimum criteria for informed consent to treatment should include information about:

- * the benefits and risks of the proposed treatment and their probabilities of occurrence
- * the benefits and risk of alternative available treatments and their probabilities of occurrence
- * the probabilities of the various outcomes if the patient decides to have no treatment at all

1.1.4 *The role of voluntariness*

i. Alderson⁷ stresses that as well as being informed, consent should also be voluntary. She suggests that voluntariness includes "a sense of moving forwards towards a chosen direction, like a sailor following a chosen course though partly driven by such forces as the wind and tides. Similarly, the patient follows a chosen course in two senses: the final goal and the means towards it. The goal may be good health after hazardous treatment, or it may be to endure illness with as little discomfort as possible for the brief life remaining. Although affected by many pressures, patients may be said to have voluntarily consented if the final goal and the main means towards it are what they most want or least fear." Voluntariness can be inhibited by several influences which may alter the chosen direction against the patient's will. These include:

- * the unavoidable effects of the illness or treatment, such as unwanted major surgery if the patient is to gain the goal of good health
- * the effects of social pressure consequent on medical advances which mean that patients now hope to survive in circumstances where previously this would not have been the case. Families may feel compelled (by their own or other people's expectations) to risk treatment when they are not convinced that the benefits exceed the harm.
- * the way health care is provided. Surgery is surrounded by many routines which patients find uncomfortable and sometimes unnecessary. They consent to the operation, but not to all the routines.
- * the impact of medical information and influence, such as pressure to consent, deceit by misinformation or omission, over-emphasis of hoped-for benefit or under-emphasis of risk, other forms of coercion such as refusal of treatment unless a patient agrees to certain conditions. These pressures may be deliberate

or unintended.

1.1.5 Pre-requisites for the giving of informed consent

- i. A number of pre-requisites have been identified as necessary to enable a patient to give their informed consent.⁵ These include:
 - * the capacity to reason and make judgements
 - * the ability to make the decision voluntarily and without coercion
 - * a clear understanding of the benefits or risks of treatment, as well as the alternatives and the implications of non-treatment
- ii. In relation to children, it has been suggested⁶ that assessment of a child's competence to consent should be based on evidence that they have:
 - * The ability to understand language and the concepts relevant to the decision. This requires "sufficient life experience" to appreciate what it might be like to be in a particular state or condition.
 - * The ability to engage in reasoning, which includes drawing inferences and comparisons as well as weighing and considering the probability of different outcomes.
 - * A set of values which will enable evaluation of various benefits and risks.
- iii. Clearly, for both adults and children, the ability to meet these criteria will vary according to both the quality and complexity of the information and choices presented to them, and the circumstances in which they are asked to give consent. Clearly, also, the assessment of individual competence in these respects is not straightforward.

1.1.6 The benefits of informed consent

- i. Alderson⁷ identifies a number of ways in which the requirement for informed consent may be beneficial to the patient:
 - * it can satisfy the patient's wish to be informed
 - * it can help patients accept and understand their treatment. Alderson cites a number of research studies which show that: information aids therapeutic adjustment to illness and treatment; informed patients are less anxious during treatment and recover more easily afterwards; and patients who understand the meaning and purpose of their treatment are more likely to co-operate
 - * it can help defend against unwanted interventions. The process of obtaining informed consent enables patients or their parents to decide when they believe medical explanations to be inadequate or unconvincing and when they wish to refuse proposed treatment

- * it respects the patient's right to self-determination

1.2 Guidelines in relation to informed consent

- i. General information with regard to the requirements for informed consent for health professionals and patients is contained in a number of guidance documents produced by the Department of Health.^{8,9,10} These documents include model consent forms and information about the rights of patients to give and refuse consent and to receive information about treatment options. They do not go into detail about the process of obtaining consent i.e. how it should be done or who should be involved. Some advice on such issues is contained within guidance on ethical practice provided by professional associations such as the GMC¹¹, BMA¹² and UKCC¹³. Beyond this, the main guidance on consent is given by the law, mainly case law, evolved in response to particular disputes. The law is not clear or comprehensive, and is complicated by vague words such as "reasonable".

1.2.1 *Circumstances in which consent is required*

- i. The *Patient's Charter*¹⁴ states that everyone has the right to be given a clear explanation of any treatment proposed, including the risks attached to alternatives, before deciding whether to consent to treatment.
- ii. Consent does not relate only to major decisions - it is required prior to any procedure or treatment. Consent is frequently given verbally or implied (e.g. by rolling up a sleeve for an injection), but written consent is required for any investigation or treatment carrying a substantial risk or substantial side effect. Department of Health guidance⁹ specifies that written consent should always be obtained for general anaesthesia, surgery and certain forms of drug therapy. However, the existence of written consent is not, in itself, evidence that informed consent has been given. The most important element of a consent procedure is the duty to ensure that patients understand the nature and purpose of the proposed treatment.

1.2.2 *Who can give consent?*

- i. In English law, adult patients are responsible for consent to their own treatment and, even if they are too ill to consent, nobody else can do this for them. Proxy consent can only be given on behalf of children under the age of consent. Sixteen is the age above which patients can automatically give consent. Below this age, the law does not say that children cannot give consent. The issue is seen as one of competence, which relates to "the child's maturity and understanding and the nature of the consent which is requested." Doctors are now in law expected to request children's consent when, in their view, the child has "a sufficient understanding and intelligence to enable him or her to understand fully what is proposed" and "sufficient discretion to enable him or her to

make a wise choice in his or her own interests".¹⁵ Parental consent should be obtained "where a child does not have sufficient understanding and is under 16".⁹ But even where children do not have sufficient understanding to make a valid decision, the presumption is that they should be consulted and account should be taken of their feelings and their wishes.^{16,17}

1.2.3 *Amount of information required*

- i. Under British law a doctor is under no obligation to disclose all information to the patient, even if he/she asks specific questions. It is enough that the amount of information given is as much as a "reasonable doctor" would decide to tell¹⁸ in the context of the doctor's relationship with a particular patient.¹⁹ However, major treatment risks (such as a 10% risk of stroke) must be disclosed. In contrast, American case law defines a "reasonable" amount of information as what a "prudent patient" would want to know in order to make an informed choice.²⁰ There is a significant body of ethical and legal opinion in the UK that is critical of the standard of the "reasonable doctor" because it fails to give proper recognition to the ethical principle of respect for autonomy and is excessively paternalistic. On these grounds, the "prudent patient" perspective is regarded as providing a more appropriate basis for assessing the adequacy of information given.^{1,21} The Medical Ethics Committee of the BMA support this view, suggesting that: "ideally, the doctor should inform the patient about any risks inherent in the treatment which might be particularly important to that patient, as well as explaining the risks and benefits of alternatives and of non-treatment."²²

1.2.4 *The extent of consent*

- i. Consent is not a once and for all decision but a continuing process linked to the evolving nature of the treatment. At the same time, consent is valid insofar as it applies to the precise treatment in question, or at least to acts of a substantially similar nature. When a patient agrees to a particular operation, the surgeon is not justified in departing from instructions and performing a different one. The only time when doctors are justified in proceeding without prior authority is when it is necessary to do so to save the life or preserve the health of the patient and it is not possible to obtain that person's consent but the doctor has no convincing evidence that the patient would object.²²

1.3 **Evidence about informed consent in practice**

- i. There appears to be relatively little systematic empirical evidence available about how well the process of obtaining informed consent is actually carried out in practice. However, those research data that do exist appear to indicate problems in a number of areas. Examples include:

* problems with the readability of informed consent forms for research, especially for those with low literacy skills²³

- * concerns that learning-disabled patients are disadvantaged in situations where it is left up to them to ask for information they want or need²⁴
- * evidence that the task of obtaining informed consent is often left to the most junior member of the surgical team, whose understanding of the surgical procedures involved may be very limited²⁵
- * evidence that the consent procedure may often be haphazard²⁶ and speculation on the likelihood of wide variations for similar patients across the country in respect of what their doctors tell them, or believe they should be told²⁷
- * widespread concern about the inadequacy of healthcare professionals' communication skills and the need for nursing staff to act as patient advocates²⁸
- * concern about the extent to which doctors may become desensitised to patients' fears and concerns with regard to routine procedures (such as blood transfusion to neonates) and may, in consequence, see no need to obtain (parental) permission²⁹

2. INFORMED CONSENT IN THE CONTEXT OF CHILDREN UNDERGOING COMPLEX HEART SURGERY

This section:

- * explores the potential information needs of children and their parents and draws attention to aspects of the care of children undergoing complex heart surgery which may complicate the process of giving and obtaining such information in this context
- * identifies factors which affect the amount, content and quality of discussion between patients, parents and hospital staff and the value to patients of the information they get

2.1 Patients' information needs for informed consent

- i. To give informed consent to proposed treatment, patients need information which is timely, accurate, reliable, relevant, understandable and sufficient to meet their needs and wishes. For a number of reasons, these criteria may arguably be particularly difficult to meet in the context of children undergoing complex heart surgery. Written information may be particularly helpful for patients and parents in these circumstances.

2.1.1 *The nature of the problems and their treatment*

- i. Lesser³⁰ points out that any type of treatment can differ in at least five ways:
 - * likelihood of success
 - * degree of success possible
 - * seriousness of side effects
 - * seriousness of harm if things go wrong
 - * degree of risk that things may go wrong
- ii. In complex paediatric heart surgery, where the treatment involved is highly technical, dangerous, uncertain, non-standard and multi-faceted (involving a combination of major and minor, heroic and routine procedures), each of these factors may be particularly hard to estimate. For example, Alderson⁷ points out that:
 - * If a new operation has been performed on very few, and perhaps very sick, patients, percentage mortality rates for average cases will not be known;
 - * If patients survive for a few weeks after surgery, the cause of death, and therefore where to place the patients in the surgery statistics, may be uncertain;
 - * Success rates for the same operation vary between different hospitals and surgeons, and they change over time;
 - * Recent figures may look very promising, but they cannot include long term effects;

- * Morbidity rates are even more complicated than mortality rates. A single effect may cover a wide spectrum of symptoms and severity, which do not all fall into agreed, neat categories of "moderate" or "severe".
- iii. In addition, criteria for assessing severity of risk may vary according to the priorities and values of different lay and professional perspectives. Thus, Alderson⁷ cites as an example the varying answer she was given by different staff in response to the question "What is the risk of neurological damage from cardiac bypass surgery?" A surgeon, looking for long-term overall success rates, assumed that only serious lasting damage need be considered. He estimated the risk at half to one per cent. A physician gave an estimate of two to five percent "but it might be something very slight, maybe just affecting movement in the little finger". A nursing sister, aware of the effect on families of even minor and temporary symptoms, estimated "maybe up to ten per cent". Any attempt to weigh up the overall risks and benefits of the treatment for any particular patient has to be done in the context of that person's individual circumstances, values and aspirations.
- iv. Even where there is agreement on what risks matter, and the likelihood of occurrence can be accurately assessed, the communication of that risk to individual patients is not straightforward. Problems have been identified, for example in:
- * understanding how probabilistic estimates of risk based on population data can be applied to the prospects for a single individual patient³¹
 - * the extent to which people's perceptions of risk and the choices they make vary for any given risk according to how the data are presented (eg as chances of survival or as risk of death; as percentages or ratios; in verbal or numeric form; in terms of size (large or small risk), severity (major, minor) or acceptability (excessive or reasonable))^{4,32}

2.1.2 *The location and process of care*

- i. For children undergoing complex heart surgery, care is fragmented over time and place and shared by many different people in a range of different settings. What patients or their parents may want or need to know will change over time, perhaps in unpredictable ways, over the whole period of care. In such circumstances, Alderson⁷ comments that, even though much effort is put into giving medical information, "so many people are involved that the effect is like a mosaic in which the parts do not all tessellate. They are not all clearly defined, they overlap and leave gaps. There is uncertainty about who said what, when and where and who should provide each part. Families receive a detailed picture sometimes in ways which confuse rather than inform. In return, families cannot ensure that all the staff directly concerned know their views and needs."

2.1.3 *The involvement of children and families*

- i. Where parents and families are involved in making decisions, either alone or together,

with or on behalf of their children, there will be additional issues of:

- * how information is shared and exchanged among everyone concerned
- * and how to take account of the needs and wishes of both patient and family (which may not always be the same)

2.2 Factors affecting the amount, content and quality of discussion

- i. The quality, amount and content of discussion with patients and parents preceding consent are influenced by the adequacy of information available (as discussed above), by patients' and families capacity to ask for information and by the extent and type of information given to them by staff. Each of these will, in turn, be affected by the attitudes and policies of the hospital and its staff and the way in which care is organised.

2.2.1 Asking for information

- i. Factors that affect parents' capacity to ask for relevant information include:
 - * whether they are physically present and involved with their children's care (may depend on distance of hospital from home, and the cost and availability of transport; the availability of comfortable, convenient and affordable accommodation to stay or sit near their child; support at home or work)
 - * whether they feel able and empowered to ask (will depend on own confidence, but also on the extent to which they feel their presence and participation is welcomed or discouraged by staff; whether they are given the privacy, time, opportunity and encouragement to ask questions; whether concerns they express are taken seriously and answered clearly)
 - * whether they know what to ask (will depend on own background knowledge and experience, but also on being adequately informed about the general routines and procedures within the hospital as well as the specific details of individual treatment and care)
 - * whether they know whom to ask (depends on clear information as to which staff are responsible for which aspects of care and information giving, and when and where they can be contacted)
 - * whether they are in a fit state to ask (feeling psychologically prepared and adequately supported to cope with information (may depend on personal/family circumstances and availability of professional support)

In addition, for children, the opportunity to ask questions will also depend on the extent

to which they are actively included in discussions by both parents and staff and encouraged to feel their views and feelings are important.

2.2.2 *Being given information*

i. Factors that affect the amount and nature of information offered by staff to patients and their families include:

- * the extent of staff knowledge or uncertainty about the patient's problems, treatment plans, prognosis etc
- * the status, responsibilities and professional perspectives of staff involved (Alderson distinguishes between the professional approaches and priorities of cardiac surgeons (more concerned with cardiac issues and technical expertise) and paediatric cardiologists (more concerned with the child and family as a whole))
- * individual and hospital-wide attitudes to the importance of parental and patient involvement and understanding and perceptions of their capacity to understand and cope with any information given
- * staff awareness of patients' needs and concerns (influenced by extent and continuity of contact with patients and their families; social knowledge of the child's daily life and family dynamics etc)
- * availability of staff with time, confidence, communication skills and appropriate places and opportunities to talk with patients or parents
- * extent of co-ordination and team-working between staff

2.2.3 *Making use of information*

i. The value to patients of any information they are given about proposed treatment will be affected by the extent to which they are able to understand and remember what they are told. Written information may allow them to take in information more easily at their own pace. There is a considerable research literature which shows that neither recall nor understanding can be taken for granted. Key findings⁴ in this area include:

- * patients often do not understand what they are told
- * patients often interpret what they are told within their own framework of ideas
- * patients are often reluctant to ask for further information even if they want it
- * patients often forget a great deal of what they are told
- * patients recall best what they are told first
- * the proportion of material recalled diminishes as more information is given
- * perceived importance of information is positively related to recall

- * level of medical knowledge is positively related to recall
- * patients with a high level of anxiety recall best
- * intellectual and educational levels have a small, but relatively consistent, positive relationship to recall
- * there is no consistent relationship between recall and age

ii. A key factor affecting patients' capacity to give informed consent will be the extent to which they trust those who give them advice or information. As Alderson points out, this includes both trust in the medical knowledge and competence of those providing care and in their personal commitment towards the interests of the particular patient. She suggests that trust is nurtured by medical concern and willingness to listen, and is undermined if these responses are missing. In addition, trust is encouraged when patients and staff:

- * can talk without deceit or concealment;
- * respect each other's viewpoint;
- * risk giving confidential information;
- * feel free to ask "silly" or critical or intimate questions;
- * can admit ignorance;
- * do not need to be defensive or hostile;
- * are willing to re-examine beliefs;
- * can agree to differ;

while trusting that they will not lose the respect of the other.

2.2.4 *Conclusion*

- * The consent process is a key element in supporting respect for patients' autonomy and establishing an appropriate relationship between patient and doctor. Ethically valid consent has three distinct requirements - competence, information and voluntariness. For each of these requirements there may be difficulties (conceptual, legal and practical) in establishing precisely what is required and whether it has been achieved.
- * Broad guidelines relating to the consent process exist, but they do not provide a blueprint for good practice, since they do not go into detail about how the consent process should be undertaken or who should be involved. In addition, present expectations in the UK - which depend on the judgment of the "reasonable doctor" rather than the "prudent patient" - have been criticised as being insufficiently respectful of patient autonomy.
- * For children undergoing complex heart surgery, the requirements for consent present a number of additional difficulties associated with the fact that parents are involved with a wide range of health professionals in making decisions with and for children in respect of treatment that is complicated, highly technical, uncertain and potentially life threatening. The quality of the consent process is

not determined simply by the giving and getting of appropriate information. Rather it is affected by the skills, resources and ethos of the organisation at every level and the extent to which these support and facilitate optimal communication and positive relationships between staff, patients and their families.

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