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Rationing potentially inappropriate treatment in newborn intensive care in developed countries

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SUMMARY

In newborn intensive care, parents sometimes request treatment that professionals regard as 'futile' or 'potentially inappropriate'. One reason not to provide potentially inappropriate treatment is because it would be excessively costly relative to its benefit. Some public health systems around the world assess the cost-effectiveness of treatments and selectively fund those treatments that fall within a set threshold. This article explores the application of such thresholds to questions in newborn intensive care: (i) when a newborn infant's chance of survival is too small; (ii) how long treatment should continue; (iii) when quality of life is too low; and (iv) when newborn infants are too premature for cost-effective intensive care. This analysis yields some potentially surprising conclusions. Newborn intensive care may be cost-effective even in the setting of very low probability of survival, very poor predicted quality of life, for protracted periods of time, or for the most premature of newborns.

1. Introduction

Health practitioners usually have a very strong desire to provide life-sustaining treatment to a newborn infant. Yet there are various situations when doctors could regard that treatment as potentially inappropriate. Consider the cases in Box 1.

Professional guidelines endorse the idea that health professionals are not obliged to provide treatment that would be 'futile' or 'potentially inappropriate' [1,2]. However, there is no existing agreement on how to define futile or inappropriate treatment, nor any clear way to use the concept to answer the questions outlined in the box [3]. There are often different views about what would be in the patient's interests, based on differing evaluations of the possible outcomes, as well as on different value-theories about what grounds such a judgment [4]. The difficulty in defining futility has led many ethicists to reject the concept, and dismiss its use in treatment decisions [5–7].

However, distinct from concern for the patient's interests, a separate reason not to provide treatment may be because of concern for distributive justice and the need to limit expensive and scarce medical resources. Although most discussion about life-sustaining treatment in newborn infants focuses on the child's best interests (and perhaps on the interests and wishes of parents), resources are of central importance in intensive care, for newborn infants as for older patients [8,9]. Unfortunately, it is sometimes necessary to ration potentially beneficial treatment on the grounds of distributive justice [10].

One widely used method of deciding between different priorities for funding in a public health system is to compare their cost-effectiveness. Modeling based economic evaluations usually assign probabilities to branches emanating from chance nodes with end-points of each pathway given values or payoffs, such as costs, life-years or quality-adjusted life years (QALYs). The QALY is a preference-based measure of health outcome that combines length of life and health-related quality of life in a single metric. This allows analysts to express the cost-effectiveness of new treatments in terms of incremental cost per QALY gained. Such calculations can be used to decide whether the incremental benefit of an individual treatment is sufficiently great, relative to the incremental cost, to provide it. Some countries and policy-makers have used cost-effectiveness thresholds to efficiently and consistently decide between different priorities. In the UK, for example, interventions that cost less than a threshold level of £20,000 to £30,000 per QALY are usually funded by the National Health Service, whereas those that cost more than £30,000 are not usually provided [11,12].

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Box 1
When are health professionals justified in declining to provide desired treatment?.[a]

A A newborn infant has a very severe congenital lung malformation. Doctors have attempted to stabilize the infant with specialized forms of breathing support; however, he has not responded. Doctors believe that there is a >95% chance that he will die despite maximal treatment. His parents are requesting that full active treatment (including, if needed, extracorporeal membrane oxygenation) be provided.
- What chance of survival is too low to provide expensive life-support?

B A newborn infant, born extremely prematurely, has had severe lung problems since birth. He has required support with a breathing machine in intensive care continuously for six months, and appears unable to breathe without support from the machine. Doctors and nurses in the intensive care unit feel that further treatment is futile, but his parents wish treatment to continue.
- How long is too long to provide intensive life-prolonging medical treatment?

C A newborn infant has been diagnosed after birth with complex congenital heart problems that would usually be treated with major cardiac surgery. However, she also has been found to have a chromosomal disorder, and if she survives she will have severe intellectual disability. Specialists have suggested that surgery is not clinically appropriate, but the infant's parents are adamant that it should be attempted.
- What level of disability is too great for life-saving surgery to be provided?

D A mother goes into premature labor several months before she is due to deliver. She has requested that doctors attempt to save her baby, but current guidelines do not recommend resuscitation. At this gestation there is a very low chance of survival if intensive care is attempted, infants require months of expensive treatment, and a substantial proportion of survivors have long-term illness or impairment.
- When is a newborn infant too premature for resuscitation to be attempted?

[a]These cases are composite versions of real cases encountered by D.W.

There is considerable ethical debate about the use of cost-effectiveness thresholds, and about QALYs for deciding between different treatments [13–17]. It is not the aim of this article to review those arguments, nor to assess whether the incremental cost per QALY metric should be used to decide between medical treatments. Rather, the point is that cost-effectiveness thresholds are already widely used in many public health systems to decide between different treatments. If that approach is justified, on the grounds of consistency, it appears that these same thresholds should be applied to other medical interventions. What would be the implications of such an approach for decision-making in neonatal intensive care? One frequent objection to cost-effectiveness analysis is that it might lead to rationing of life-saving treatment. The results of the analysis below might be used to inform debate about what the implications would be of applying cost-effectiveness thresholds to clinical decisions around potentially inappropriate treatment.

The focus here on the neonatal intensive care unit (NICU) allows us to set aside some issues that might be thought to make decisions more complicated for older individuals (e.g. it removes the question of whether priority should be given to those who have previously been worse off, or who have experienced a shorter life already). However, none of the analysis in this paper should be taken to imply that cost-effectiveness thresholds should be applied only or preferentially in the NICU. Indeed, one feature of standard cost-effectiveness thresholds suggests that resource limits far less often provide a justification for withholding treatment in the NICU than in adult or pediatric intensive care. If the duration of survival after intensive care is longer, the cost-effectiveness of providing life-sustaining treatment will be correspondingly greater.

Since the aim of this article is to explore ethical questions, we will make some assumptions that simplify analysis, but that would not be part of a formal economic evaluation. We will focus on the costs and effects of providing intensive care, compared with the option of withdrawing or withholding life-prolonging treatment (i.e. the clinical setting for a determination that treatment is potentially inappropriate). We will assume that infants not treated will die and make the simplifying assumption that an infant who dies in intensive care will not have generated economic costs or health consequences. Empirical data for examples are drawn from a range of different countries and time-points, reflecting the availability of data. We will convert currencies to UK pounds (using relevant purchasing power parities), but will not adjust for inflation over time. We will not apply discounting to future costs or the value of future life-gains. Finally, we will assume equal age-weighting for the potential health consequences of treatment (i.e. that a year of life saved for a newborn infant is equivalent to a year of life saved for an adult).

2. Low-probability treatments

The general formula for assessing cost-effectiveness is given by the following:

$$\text{Incremental cost-effectiveness} = \frac{\overline{C}_2 - \overline{C}_1}{\overline{E}_2 - \overline{E}_1} = \frac{\Delta C}{\Delta E}$$

where C_2 and E_2 refer to the mean cost and mean effectiveness of a comparison intervention, and C_1 and E_1 refer to the mean cost and mean effectiveness of the reference intervention. We are interested in comparing the alternatives of continuing intensive care versus withdrawal of intensive care. If we assume that all patients who have treatment withdrawn die (and that this is not associated with costs), the formula may be simplified:

$$\text{Cost} - \text{effectiveness} = \frac{\overline{C}_2}{\overline{E}_2}$$

The effectiveness of continuing intensive care will depend upon the mean probability of survival ($\overline{p}$), duration of survival (if the patient survives, $\overline{d_s}$) and his/her health-related quality of life (hereafter 'quality of life' for brevity) ($\overline{q}$).

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