The tyranny of a kilogram: should we untie rather than cut the Gordian Knot?

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Pectora roborant cultus recti

I, the undersigned, hereby declare that the work contained in this assignment is my own original work and I have not previously in its entirety or in part submitted it at any university for a degree.

Abstract

The number of babies requiring neonatal intensive care exceeds the facilities available. The assignment questions the perceived shortage of resources and investigates methods of resource allocation.

The first chapter addresses the development of technology and reflects briefly on the romance between medicine and technology. The second chapter addresses the issue of prognosis of the small preterm neonate and reflects on how these data are derived and the assumptions that are often made based on prognostic data. Chapter three concentrates on how outcomes discussed in the second chapter may be quantified. Individual utility quantification plays a role in decision making for the individual neonate, while comparative utility quantification addresses some of the issues concerned with the macroallocation of resources.

This leads into chapter four that addresses macroallocation and challenges some of the assumptions that resource allocation is based upon. Are resources scarce? Are there financial constraints? What is the role of medicine in health? Will redistribution of wealth necessarily improve the health of the population?

Who should make decisions for individual sick neonates regarding neonatal intensive care is addressed in the next chapter. The tension between sanctity-of-life and quality-of-life ideologies, created by life sustaining technology has been legally and ethically settled in favour of the patient's right to self-determination, based on the principle of respect for patient autonomy. It will however be argued that the traditional four principles cannot be utilised as the neonate is at best pre-autonomous. Moral obligations towards the neonate are dependent on the beneficence and non-maleficence obligations of the parents and the caregivers. Both these principles are prima facie and may have to be tempered by distributive justice.

Plato's absolutist thinking and Descartes mathematician's perspective, have influenced medicine's romance with certainty. If knowledge and certainty are necessary for decision making and it is shown that absolute certainty is elusive, should we be nihilistic about decision making in neonatal intensive care? Chapter 6 critically assesses three approaches to decision making in the presence of prognostic uncertainty.

In contemporary medicine there is a constant tension between the traditional commitment to the patient on the one hand and the awareness that resources are finite on the other, this tension is an unfortunate reality of medicine. To constrain the growth of medical expenditure, doctors are now asked to serve simultaneously as society's agent of cost containment and as the patient's agent for maximum health. There is increasing pressure on doctors to serve two masters, society and the patient. Acting on behalf of society as a gatekeeper, while for the patient the doctor is expected to act as advocate. Chapter seven investigates both gate-keeping and advocacy and attempts to answer the question whether doctors can and indeed should try to serve two masters simultaneously?

The final chapter brings together the threads of the various extended arguments and attempts to give solutions to some of the conundrums.

ABSTRAK

Die hoeveelheid babas wat neonatale intensiewe sorg benodig oorskry die beskikbare fasiliteite. Die taak bevraagteken die waarneming van 'n tekort aan hulpbronne en ondersoek dus metodes van hulpbronallokasie.

Die eerste hoofstuk bespreek die ontwikkeling van tegnologie en reflekteer kortliks oor die romanse tussen medisyne en tegnologie. Die tweede hoofstuk handel oor die uitslag van die prognose van die klein voortydse neonaat en reflekteer hoe die data afgelei word en die veronderstellings wat dikwels gemaak word, gebaseer op prognostiese data. Hoofstuk drie konsentreer op die bespreekte uitkomste van hoofstuk twee en hoe dit bepaal kan word. Nuttige individuele bepaling speel 'n rol tydens besluitneming ten opsigte van die individuele neonaat, andersyds, vergelykende nuttige bepaling spreek sommige van die punte ten opsigte van die makro-allokasie van hulpbronne aan.

Laasgenoemde gee inleiding tot hoofstuk vier, wat makro-allokasie aanspreek en sommige van die aannames waarop hulpbronallokasie gebaseer is uitdaag. Is hulpbronne skaars? Is daar finansiële beperking? Wat is die rol van medisyne in gesondheid? Sal herverspreiding van rykdom noodwendig die gesondheid van die populasie verbeter?

Wie verantwoordelik is vir besluitneming ten opsigte van die siek neonaat in intensiewe sorg word in die volgende hoofstuk bespreek. Die spanning tussen onskendbaarheid-van-lewe en kwaliteit-van-lewe ideologië, moontlik gemaak met behulp van lewens-onderhoudende tegnologie is wettig sowel as eties vasgestel ten gunste van die pasiënt se reg tot selfbeskikking, gebaseer op die beginsel van respek vir die pasiënt se selfbeskikking. Dit sal egter betwis word dat die tradisionele vier beginsels nie aangevoer kan word nie omdat die neonaat pre-outonomies is. Morele verpligtinge teenoor die neonaat is afhanklik van die weldadigheid en onskadelike verpligtinge van die ouers en versorgers. Beide hierdie beginsels is *prima facie* en sal moontlik deur verdelende reg getemper moet word.

Plato se absolutistiese denke en Descartes se wiskundige perspektief het die medisyne se romantiek met sekerheid beïnvloed. Indien kennis en sekerheid nodig is vir besluitneming en dit is bewys dat absolute sekerheid misleidend is, moet ons nihilisties wees oor besluitneming in neonatale intensiewe sorg? In Hoofstuk 6 word die drie benaderings tot besluitneming in die teenwoordigheid van prognostiese onsekerheid krities beraam.

In die hedendaagse medisyne is daar 'n konstante spanning tussen die tradisionele verpligting teenoor die pasiënt aan die een kant en die bewustheid dat hulpbronne beperk is aan die ander kant – hierdie spanning is 'n tragiese werklikheid in die medisyne. Om sodoende die mediese uitgawe te beperk, word medici versoek om gelyktydig te dien as die gemeenskap se agent om koste te beperk asook die pasiënt se agent vir maksimum gesondheid. Daar is toenemende druk op Medici om twee meesters te dien – die gemeenskap en die pasiënt. Om op te tree as hekwagter namens die gemeenskap, terwyl daar van die dokter verwag word om namens die pasiënt as sy advokaat op te tree. Hoofstuk sewe ondersoek, beide die hekwagter en advokaat en daar word gepoog om die vraag te beantwoord of dokters kan en inderdaad durf poog om twee meesters gelyktydig te dien?

Die finale hoofstuk dien as samebindende faktor van die verskeie uitgebreide argumente en pogings om oplossings te bied tot sommige van die vraagstukke.

Contents

Chapter

Chapter 1

Adumbration

The Priorities in Perinatal Care Conference is a conference that has been held annually since 1981. Delegates at the Conference are predominantly state employed health care workers, mainly doctors and nurses, interested in the perinatal period. They are dedicated to improving pregnancy and neonatal care to indigent patients dependent on public health facilities. Most, but not all the delegates while working for the state are employed at academic hospitals.

The majority of state funded neonatal intensive care beds in the country are situated in academic hospitals. In their normal line of duty conference delegates are regularly confronted by neonates requiring neonatal intensive care within the public health system. In March 1991 delegates of the 10th Priorities in Perinatal Care Conference adopted a consensus statement restricting neonatal intensive care facilities to those neonates weighing 1000g or more[1]. The allocation of resources has always been of interest to the author. Since becoming aware of the consensus statement, the author has always wished to have the opportunity to reflect on the allocation of neonatal intensive care facilities and critically evaluate the consensus statement.

There are essentially two co-existing neonatal intensive care allocation processes. Resource allocation at the global level of decision-making, called macroallocation, is usually distinguished from microallocation or rationing decisions about which individuals receive what services. Macroallocation decisions determine how much money is allocated to health care in the country. Macroallocation decisions determine how much of a given resource ultimately is made available to ration among individual patients. Rationing occurs at the level of the patient, where it is decided whether or not a patient should receive a treatment that is in limited supply. The different allocation processes each have their own decision-making process. As the consensus statement embraces both macro- and microallocation the dissertation will examine resource allocation and appropriate decision making at both levels.

The first three chapters are largely introductory in nature. The first chapter addresses the development of technology and reflects briefly on the romance between medicine and technology. This leads into the second chapter, the introduction of which outlines the development of neonatal intensive care.

Despite drastically different foundations both deontologists and utilitarians would argue that knowledge of outcome must be available for clinical care. The second chapter addresses the issue of prognosis of the small preterm neonate and reflects on how these data are derived and the assumptions that are often made based on prognostic data. Chapter three concentrates on how outcomes discussed in the second chapter may be quantified. Individual utility quantification plays a role in decision making for the individual neonate, while comparative utility quantification addresses some of the issues concerned with the macroallocation of resources. Chapters two and three leave one with a feeling of prognostic uncertainty, uncertainty whether it is indeed possible to prognosticate for the individual patient and uncertainty as to how to quantify outcomes.

Chapter three concludes with a discussion on comparative utility, discussing ways of quantifying outcome for groups of patients. This in turn can then be used as one way of deciding which therapy should be given. This leads into chapter four that addresses macroallocation and challenges some of the assumptions that resource allocation is based upon. Are resources scarce? Are there financial constraints? What is the role of medicine in health? Will redistribution of wealth necessarily improve the health of the population?

Who should make decisions for individual sick neonates regarding neonatal intensive care is addressed in the next chapter. The tension between sanctity-of-life and quality-of-life ideologies, created by life sustaining technology has been legally and ethically settled in favour of the patient's right to self-determination, based on the principle of respect for patient autonomy. Although there are numerous ethical approaches, principlism has been utilised in the dissertation, due to its widespread use in medical ethics and easy understanding by the medical profession. It will however be argued that the traditional four principles cannot be utilised, as the neonate is at best pre-autonomous. Moral obligations towards the neonate are dependent on the beneficence and non-maleficence obligations of the parents and the caregivers. Both these principles are prima facie and may have to be tempered by distributive justice.

Plato's absolutist thinking and Descartes` mathematician's perspective, have influenced medicine's romance with certainty. Conventional medical education fosters doctors with the notion that uncertainty is a manifestation of ignorance, weakness or failure. If knowledge and certainty are necessary for decision making and it is shown that absolute certainty is elusive, should we be nihilistic about decision making in neonatal intensive care? Chapter 6 critically assesses three approaches to decision making in the presence of prognostic uncertainty.

The consensus statement restricts admission to neonatal intensive care to neonates weighing more than 1000g and as such has a gate-keeping function. In contemporary medicine there is a constant tension between the traditional commitment to the patient on the one hand and the awareness that resources are finite on the other. This tension is an unfortunate reality of medicine. To constrain the growth of medical expenditure, doctors are now asked to serve simultaneously as the patient's agent for maximum health and as society's agent of cost containment and as the patient's agent for maximum health. There is increasing pressure on doctors to serve two masters, society and the patient. Acting on behalf of society as a gatekeeper, while for the patient the doctor is expected to act as advocate. Chapter seven investigates both gate-keeping and advocacy and attempts to answer the question whether doctors can and indeed should try to serve two masters simultaneously.

The final chapter brings together the threads of the various extended arguments and tries to justify why the delegates at a Priorities in Perinatal Care Conference, individuals known for their dedication to the indigent patient, issued the consensus statement.

Reference

1. Wainer S, Khumalo H. Attitudes of mothers, doctors, and nurses toward neonatal intensive care in a developing society. Pediatrics 1993;91:1171-1175.

Chapter 2

A brief history of technology

Technology has revolutionised medicine. Once life could only be established in the womb and when established could only be suppressed at the cost of drastic danger to the women. Death was indisputable and unpostponable. Technology has changed all this; life can now be created in a laboratory test-tube, the nature of life can be altered by gene therapy. Those facing death as a result of the failure of a vital organ can have their lives prolonged by organ transplantation. Those unable to eat can be fed intravenously, those unable to breathe can be ventilated and when death is inevitable, the process of dying can be indefinitely prolonged. Technology is perceived as helping man in the struggle against nature and in so doing blurring many conventional distinctions.

Technology is a major cultural determinant, no less important in shaping human lives than philosophy, religion, social organisation, or political systems. In the broadest sense, these forces are also aspects of technology. The French sociologist Jacques Ellul has defined *la technique* as the totality of all rational methods in every field of human activity, so that, for example, education, law, sports, propaganda, and the social sciences are all technologies in that sense. At the other end of the scale, common parlance limits the term's meaning to technological innovation.

The terms science and technology are often confounded. The confusion arises because so much of contemporary technology is based on the natural sciences--such disciplines as physics, chemistry, biology, and other branches of knowledge that deal with the study, measurement, and understanding of natural phenomena. The achievements of the medical, pharmaceutical, electronic and plastics industries are based on a huge body of scientific investigation.

In simplest terms, the concern of science is "why," and of technology, "how." The relationship between the two is actually much more complex, however, and it varies from industry to industry: some technologies are science intensive, whereas the manufacture of such items as furniture depends much less on science. In fact, much of modern technology developed without any scientific input whatever, and there are many examples of entire sciences arising from earlier technologies or developing in an effort to explain findings made by scientifically naive artisans. For instance, gunnery led to ballistics; the steam engine, to thermodynamics; powered flight, to aerodynamics; primitive metalworking, to metallurgy; and communications, to radio astronomy.

The history of technology is the study of the changes through which economic, cultural, and military techniques have evolved and of the social, economic, and political consequences those changes have produced. To reach a full understanding of the history of technology, one cannot consider instruments and techniques in isolation but must also consider many events, some of them seemingly remote, that have had a bearing on the evolution of technology: the role of the technologist and engineer and their status and training; geography and climate; division of labour; the processes of invention and innovation; the diffusion of knowledge; the technical consequences of research; the relationship between technology and science; traditions of art; and the development of crafts.

According to Greek mythology the first technological innovation was fire. Legend has it that fire was brought to man by Prometheus, who stole it from the God's for the benefit of man. Technology was introduced to man by a true humanitarian act. This is almost ironic as now technology often represents the antithesis of humanity. Prometheus was punished by the Gods for this - he was tied to a rock and every night a vulture devoured his liver. However such was the regenerative function of the liver that it regained it's function daily. Prometheus's torture continued for thirty years until he was rescued by Hercules. Fire has been turned to technological advantage in many ways. Cooking made foodstuffs more palatable, the clearing of forest lands made ground available for habitation and cultivation and the baking of pottery lead to functional crafts, to name but a few.

The history of technology begins with the use of stone tools by the earliest humans--and perhaps even by their prehuman ancestors. The field of study may be divided into four major periods: the Palaeolithic (Old Stone Age), beginning about 2.5 million years ago; the Neolithic (New Stone Age) transition, dating from about 9000 BC; the Agricultural Civilisation, which originated with the invention of the plow in the 4th millennium BC; and Industrial Civilisation, which covers the past 250 years. These divisions are approximate and sometimes extensively overlapping; even today, with agricultural and industrial civilisations existing side by side and each incorporating technology that is characteristic of the other, there also exist isolated groups of people who still employ Stone Age technology. Similarly, rudimentary forms of agriculture, or at least horticulture, may have been practised occasionally during the Palaeolithic, which was characterised by hunting and gathering.

The Palaeolithic era and the Neolithic transition, which jointly constitute more than 99% of the time span of technological history, lie properly in the domain of the prehistorian--mainly the archaeologist, anthropologist, and palaeontologist. Palaeolithic technology was the creation of both modern humans (Homo Sapiens) and at least one extinct species, Homo Erectus. Hunting of animals and gathering of eggs, insects, and edible plants were the dominant economic activities. On the evidence of surviving hunting-gathering societies, it may be supposed that a dual economy existed in which men hunted and women gathered. By the end of the Palaeolithic, humanity's technological repertoire included the use of fire, stone tools, spears and spear throwers, the bow and arrow, simple oil lamps, pigments, mortars and pestles, and bone sewing needles. The Neolithic transition is characterised by the origins of food production through the development of plant and animal husbandry, wild cereal plants were domesticated, plant and animal husbandry was developed, and small farming communities were formed. Cultivation was accomplished with the use of the digging stick and the wood hoe. Neolithic crafts included pottery, spinning and weaving, basketmaking, and house building.

The invention that marked the beginning of Agricultural Civilisation was the ox-drawn plow. Plow agriculture was accompanied by an array of momentous developments. Writing evolved; the political state came into being, possibly through the conflicting pressures of expanding population and limited fertile land in the river valleys, chronic warfare set in; and copper and bronze metallurgy was devised. Bronze and iron found their widest use in the paraphernalia of war. The substantial technical and cultural progress of these early civilisations, the emergence of crafts whose practitioners were relieved of the need to participate in food production, the increase in population, and the rise of many urban societies centred in impressively wealthy cities were entirely based on the productivity, and hence on the food surpluses, of plow agriculture. At first, surpluses adequate to sustain civilisation were possible only on irrigated land, so that the earliest civilisations were confined to alluvial river valleys. As the technology of plow agriculture improved, civilisation spread to rain-fed lands away from the river valleys. The introduction of the horseshoe and the horse collar permitted the substitution of the horse, with its greater speed and endurance, for the ox, completing the agricultural revolution that the heavy plow had initiated.

The Middle Ages in Europe were in general prodigiously innovative. In the 8th century iron became widely available and once again was adapted to military needs. In the 12th century water mills, which had not been widely used until then, and windmills, the concept of which was only then reaching Europe from the East, brought a revolution in the production of power. On a small scale muscle power could be replaced by alternative sources. By the middle of the 16th century, English founders had perfected the casting of iron, instead of bronze, guns, thereby sharply reducing the cost of warfare. From the 15th through the 17th century, the period designated by cultural historians as the Renaissance, the new warfare employing guns and armed ships changed Europe from a provincial region to a centre of world power.

During certain periods in history innovations in technology have grown at such a rapid pace that they have produced what have become known as industrial revolutions. The term Industrial Revolution originally referred to the developments that transformed Britain, between 1750 and 1830, from a largely rural population making a living almost entirely from agriculture to a towncentred population. The Industrial Revolution--based initially on water-power and later on steam engines and other energy converters--had the effect of replacing human and animal muscle as the principal source of power with machines. This change put much vaster resources at society's disposal and substantially raised living standards in all societies capable of taking advantage of technological innovations. Certainly, these triumphs also had their darker side, such as the misery that attended the initial displacements of industrialisation and the pollution and despoliation of the environment. It can be said that the Industrial Revolution gave rise to the engineering profession as it is recognised today. Where previously engineers had risen through the ranks of craftsmen, in the 18th century it was becoming apparent that the act of design should be codified in the form of technical training. Technical studies penetrated the established universities slowly, and it was in new institutions--such as the Ecole Polytechnique in Paris and the University of London--that engineering first took root in university education.

A transformation of comparable significance began in the middle of the 20th century with the emergence of science-intensive industries, which were based on chemistry, modern physics, and especially mathematics. The electronic computer was the most prominent technological development of the time; another was the amazing proliferation of artificial materials, many of which were developed for specific purposes. This transformation has been called the Second Industrial Revolution, in which many of the functions performed by the senses and the human mind have begun to be replaced by machines, some of which greatly extend the range of possible achievements. It is sometimes also called the Scientific and Technical Revolution. As examples of this transformation, approaching aircraft are guided safely to a fogged-in airport by means of radar and radio, and the exact dimensions and quality of metal products are maintained during mass production by means of electronic sensors and controls. Previously computers made use of formal logic where only dichotomies were accepted. Artificial intelligence, used in newer computer systems involved in decision analysis, utilises fuzzy logic. The advantage of using fuzzy as opposed to formal logic in decisions about neonatal intensive care admission will be discussed in more detail elsewhere.

Many innovators in medicine, like Prometheus, had to pay a heavy price for their innovations. In the fifteen hundreds Michael Servetuas a physician-theologian fell foul of the Church when he described the pulmonary circulation. At the same time William Harvey faced criticism and rejection for his description of the circulation of blood, yet eventually his book, *De Motu Cordis* (the abbreviated and familiar title!) became one of the most influential books in the history of medicine.

The first instrument generally used in diagnosis was the stethoscope described by Lanennec in

1819. The invention was prompted by his contact with a young women whose symptoms suggested heart disease. He could not apply his ear directly to her chest because of her obesity and for moral reasons. Recalling that sound was amplified when transmitted through some solid structures, he rolled a sheath of paper into a cylinder, placed one end on her chest and listened at the other. The sounds were clear and the stethoscope was born. The first instrument developed in patient management was also the first step in separating the patient from the doctor. They were not only physically separated but now the distracted doctor was immersed in the mystique of sounds inaudible to the patient.

One piece of equipment that had a modest unexpected beginning has developed into a highly effective, complicated and expensive machine. The imaging capabilities of modern radiology could hardly have been prophesied a century ago when Roentgen visualised the bones of his wife's hand. Imaging technology changed the one on one doctor-patient relationship. No longer did the doctor and patient have to be present simultaneously. With X-ray, a technician took the picture in the absence of the doctor and later a whole group of doctors could see the result and discuss the diagnosis without the physical presence of the patient. A multitude of medical developments have paralleled the technological explosion, however these two are paradigmatic of the growing chasm technology has brought to the doctor-patient relationship. Sceptics teach medical students that when all else fails examine the patient.

In the first half of the century, the place of delivery shifted from home to hospital with the growing realisation that hospital deliveries could reduce the toll of complications for the mother. This move accelerated the medicalisation of a normal physiological process, birth. Until recently birth in hospital offered little survival advantage for the preterm infant as care of the new-born infant was limited to the well-meaning gestures of the parents, midwives or doctors. Following the Second World War, many of the environmental causes of infant mortality (past the first month of life) could be reduced by improved sanitation, immunisation and antibiotics. Deaths in the neonatal period began to exceed infant mortality and the spotlight fell upon improving neonatal care.

Antibiotics developed during the Second World War could be used to protect preterm infants from infection. Computer technology, the development of synthetic materials like plastic and miniaturisation, necessitated by the Space Race, could be utilised to miniaturise medical technology designed to save adults` lives. Neonatal intensive care is a progeny of the technological age, successful equipment joined with miniaturisation and computer technology.

Like the Sorcerer's broom in Walt Disney's film *Fantasia* technology has almost taken on a life of it's own.

Technology and philosophy

In describing a model for culture, van Peursen in, The Strategy of Culture, describes three broad cultural traditions of thinking, the mythical, the ontological and the contemporary functional tradition. In the ontological phase man asked; what are phenomena? now in the functional phase the question is; how do things function?. The functional approach well describes contemporary medical science. A scientist looking through a microscope symbolises this approach, the distance and the difference between the observer and the observed, the effort to intensely examine the smallest detail of the observed isolated from its context, and the use of reliable hard data.

Functionalism runs the risk of deteriorating into operationalism where phenomena are defined in terms of how they function or operate. Medical personnel tend to see disease as some malfunction of the individual and if they can isolate (diagnose) and eradicate (treat) the malfunction then the individual will be better. This reductionalist view can be observed when doctors, talking to each other, refer to patients in terms of the patient's malfunction rather than by the patients name. `We admitted two breeches and one post-partum haemorrhage last night`, is the type of statement often heard in a morning meeting discussing the previous nights admissions to a labour ward. Operationalism reduces everything to measurable functions or operations, leading to a loss of identity, where nobody is really anybody anymore. Overcoming this loss of identity is extremely difficult.

In 1819 Laennec`s stethoscope was the progenitor of medical technology and was specifically designed (for moral reasons!) to place a distance between the male doctor and the female patient's chest. A knowledge gap also developed as now the doctor could hear something (the patient's heart sounds), that the patient could not hear. The analogy of the microscope describing functionalism could also be used to illustrate the physical and emotional distance between doctor and neonate, the patient, in the neonatal intensive care unit. The extremely small premature infant can be described as humanoid at best, overwhelmed by an incubator with intravenous and arterial lines and tubes in virtually every natural orifice. The small neonate lies on the megacrib, developmentally and intellectually unable to communicate and due to the technology unable even to cry, hopefully unable to remember. Wiring and attachments monitor every monitorable bodily function, the data produced by the technology becomes a surrogate form of communication. The neonate communicates through urine output, pulse rate, blood pressure, oxygen saturation and blood culture results. The technocrats know `eveything` about the baby down to the finest detail. Due to the fragile skin and the risk of infection, even unnecessary touching of the baby is discouraged. The neonatal intensive care, one of the pinnacles of medical technology, has widened the gap created by the stethoscope to a chasm.

Neonatal intensive cares are usually high pressure busy units in hospitals. Goals are often short term, improving the arterial oxygenation or increasing the output may obsess the staff involved for the better part of a day. Although they are doubtless caring people, the staff will often slip into the operational mode and refer to a patient by the short term physiological goal that they are trying to attain. They will refer to the baby operationally, although they will claim pragmatically, by the malfunction. Alternatively babies are often referred to by either their or their mother's major pathology.

Modern medicine was developed on certainties with well demarcated boundaries like motherhood, or as in the binary system used in computers, dichotomies like life and death with distinct boundaries. Modern medical technology has blurred many of these cherished distinctions. Technology in the form of reproductive technology has long challenged some of the traditional concepts of motherhood. Life and death certainties are now challenged on a daily basis by intensive care technologies. Medicine, while creating some of the first cracks in modernity's certainties, is slow in even acknowledging postmodernity. Modernity has a tendency to try to simplify extremely complex data. Although to be addressed in more detail elsewhere, the idea of simplifying the admission criteria to neonatal intensive care to an easily measurable birthweight reflects a typical modern approach. Simplicity and certainty are forced onto complexity and uncertainty.

An asymmetry has developed between the prolific growth and expansion of the technological explosion and the seedling state of ethical and societal considerations. Philosophy has had a long running romance with the is/ought distinction, how things are opposed to how they either should be or it is desirable for them to be, in essence a fact - value distinction. Two similar distinctions the could/should and the possible/probable often need to be addressed in the neonatal intensive care.

Doctors may feel compelled to use equipment merely due to its presence or availability as a technological imperative. Something can be done, so there is an obligation to intervene. The mere presence of the technology is interpreted as a moral warrant necessitating its application. The technoculture approach of, `you could do something therefore you should do something` is apocryphal. On reflection the decision to utilise this type of expensive technology, where the prognosis is guarded, just as any decision to forego technology, should be backed by rigorous ethical reasoning. Neonatal intensive care may have solved many physiological problems.

However, many philosophical questions remain unaddressed.

It is often not the technology itself that inspires fear but the approach of the people that develop and use it. Fallible people lose sight of their own fallibility in their scramble to expand the frontiers of science or knowledge, to redesign or overcome nature and to outwit the ultimate foe, death. In the case of neonatal intensive care, some may perceive the race to be on to push back the boundaries of viability, to be able to pull through the smallest of babies, irrespective of the consequences. The psychology of some of these technocrats may lead to confusion between means and ends. The small patient in the neonatal intensive care unit should never be used as a means towards ultimately developing the doctor's ego or reputation. Alternatively the intensive care therapy should never be an end unto itself. The medical effort and the technology utilised in the neonatal intensive care unit should be a means to be used only when the patient, the ends, may conceivably benefit from the therapy.

When considering technology, particularly in neonatal intensive care, the expression, `every cloud has a silver lining`, should perhaps be modified to `every silver lining has a cloud`. The silver lining being the intensive care and its perceived advantages. The cloud being the problems with distributive justice as a result of the expenses; where intensive care has merely prolonged dying and not saved life and where lives saved may conceivably not be worth living. These essentially ethical issues will be addressed in greater detail later in the dissertation.

Bibliography

Due to the fact that this chapter has been written in an open format and is a synthesis of information from the sources utilised no direct references have been given. The following sources were utilised:

Hodgkin P. Medicine, postmodernism, and the end of certainty: Where one version of the truth is as good as another, anything goes. BMJ 1996;313:1568-1569.

Greaves D. What is medicine?: towards a philosophical approach. J Med Ethics 1979;5:29-32.

Alderson P. The importance of theories in health care. BMJ 1998;317:1007-1010.

Almond B. Philosophy, medicine and its technologies. J Med Ethics 1988;14:173-178.

Tarnas R. The Passion of the Western Mind. Pimlico London 1996

Dunbar R. The trouble with Science. Faber and Faber London 1995

Russell B. History of Western Philosophy. Routledge London 1946

van Peursen CA. The Strategy of Culture. North-Holland Publishing Company, Amsterdam 1974.

Chapter 3

Prognostic prediction

The major killer of preterm infants is pulmonary complications. The immature lungs do not produce enough surfactant, a chemical substance that stabilises the small alveoli during expiration. This means that at the end of expiration the neonate has to use an inordinate amount of energy to re-expand the lungs. Due to extreme prematurity these babies seldom have adequate energy supplies and they have small muscle volumes. The effort required at the beginning of each inspiration soon exhausts the babies. Once exhausted they can no longer expand the alveoli, leading to alveolar collapse, which in turn diminishes oxygen uptake. The condition of the babies steadily declines until they die. Other problems encountered by the extremely preterm infant include intracranial haemorrhage from the delicate vascular system of their developing brains, temperature and fluid homeostasis.

The outcome of preterm infants is preceded by a brief resume of the history of neonatal intensive care[1]. The resume is important for a few reasons. Firstly the poor outcome of vulnerable neonates prior to the introduction of neonatal intensive care corresponds to the poor outcome of contemporary vulnerable preterm neonates denied admission to intensive care facilities. Secondly it shows the temporal nature of any research describing the outcome of neonates admitted to neonatal intensive care. New innovations and procedures improve outcome of the most vulnerable infants. This often means that the prognostic data presently available is already outdated and contemporary admissions are likely to fare better than their predecessors did. Due to the time period between study and publication, most results in the literature reflect outcomes of babies managed in intensive care units three to five years prior to publication. Finally morbidity and mortality data need periodic reassessment as the survival and outcome of low birth weight infants continues to improve.

The move from home to hospital, while medicalizing a natural process, improved maternal outcome in labour but did little to improve neonatal outcome. Immunisation programs, improving socio-economic conditions and sanitation improved the survival of infants. The spotlight then fell onto neonatal care. Early facilities did little more than to warm infants. Improvements on this included antibiotics and the development of more sophisticated incubators. The lungs however remained the limiting factor. Miniaturisation allowed ventilators developed for adults to be adapted to the needs of the neonates, this lead to a substantial improvement in outcome in the seventies. The realisation that the administration of exogenous corticosteroids to pregnant women enhanced the secretion of surfactant by their babies improved the outcome of preterm babies in the eighties. The early nineties saw the introduction of commercially artificially produced surfactant, which further diminished morbidity and mortality from lung complications.

The prognosis of large cohorts of preterm infants administered artificial surfactant are now starting to appear in the medical literature.

Sound ethical reasoning, like clinical decision making is based on reliable information. Knowledge of neonatal morbidity and mortality rates is fundamental for the management of high-risk obstetric patients. It is essential then to access the information available on the outcomes of preterm infants and to assess it's validity.

On what is the medical profession's knowledge of premature infant survival based? Intuitive knowledge would be considered impossible and anathemic. Personal knowledge based on personal experience while helpful is too limited. Most would probably resort to the medical literature for information. Since the medical literature is usually utilised as the resource for prognostic prediction it is important to assess the methodology of the literature in obtaining and interpreting information.

1. Traditional outcomes evaluated in the literature.
2. Clinical criteria used for prognostication.
3. Statistics
4. Probability

1. Traditional outcomes evaluated in the literature.

Traditionally the paediatric literature has identified death and clinical morbidity as the two outcomes they wish to evaluate for the very small preterm infant[2]. These outcomes have been chosen, as they are considered medically relevant and easy to identify. As they are easy to identify, they are considered 'solid endpoints' in the sense that they are considered trustworthy. These are endpoints chosen by medicine, based on their medical relevance and ease of collection. They are not necessarily the endpoints that would interest the patients themselves or their surrogate decision-makers.

Death is usually referred to as a solid endpoint. A child either dies or survives, thus data on death should be trustworthy. However the questions is, Is this always so? A liveborn infant is defined as any infant that shows signs of life at birth, these include a heart beat, pulsation of the umbilical cord, respiratory movement or movement of the voluntary muscles[3]. If a baby is classified as live born the baby will have to be registered as such and if it dies requires a funeral with all the concomitant expenses. If an extremely small liveborn preterm infant dies in the very early neonatal period there is a tendency to classify the infant as stillborn so as to spare the parents the inconvenience and expenses of birth registration and funeral costs. Not including very small live borns that die in the early neonatal period gives the impression of a better prognosis for extremely small live borns for survival.

The numerous studies show variation in their results as regards morbidity and comparison between studies can be difficult. These difficulties are as a result of variations in diagnosis and definition of disabilities and the rigour, duration and timing of follow-up.

As a group low birth weight children experience more health problems than normal birth weight children do[4,5]. These include prolonged stays in neonatal intensive care units and greater dependency on oxygen at one month after birth. There is also a tendency to more rehospitalisation and health-related limitations on daily activity. Asthma, respiratory tract infections and ear infections tend to be far commoner in these children. Preterm delivery is more prevalent in socially disadvantaged mothers and preterm infants from socially disadvantaged backgrounds fare worse than those from a socially advantaged population are. Children that were of low birth weight also have a tendency to remain smaller and lighter than their peers do.

Neurodevelopment disability is possibly the worst outcome for survivors born at extremely early periods of gestation[1,4]. Disabilities found in surviving graduates of neonatal intensive care include spastic diplegia, spastic hemiplegia and quadriplegia with or without intellectual impairment. Other neurological problems include blindness, deafness and severe epilepsy. Minor motor and co-ordination problems, specific learning disorders and attention deficit disorders are commonly recognised among school age survivors. Table 2, however shows the majority of survivors at 24 weeks have no major residual neurological handicap.

Infants where a poor outcome is anticipated may be allowed to die. This also effects the interpretation of data as one then overestimates mortality while underestimating major morbidity.

As can be seen outcome data can be difficult to interpret.

2. Clinical criteria used for prognostication:

Once `relevant` outcomes have been identified, the next question is: Are there clinical criteria that we can us to predict the outcomes that we are interested in?

Probabilities of specific outcomes are traditionally based on either gestational age or birth weight[6]. Gestational age is divided into completed weeks of pregnancy duration for example 27 weeks would include all neonates born between the onset and completion of the 27th week of gestational age. Birth weight categories have pragmatically been divided into 100g divisions for example from 501-600g. As will be discussed later inadvertently classifying a neonate in the incorrect category could mean the difference between life and death for that infant. Both gestational age and birth weight, as prognostic indicators are not without their problems.

Theoretically and empirically the better predictor of outcome is gestational age, as this reflects organ maturity[6]. Preterm infants are heterogeneous and all babies of the same gestational age can obviously not have exactly the same organ maturity. This heterogeneuosity of organ maturity can be seen in non-identical twins where following preterm delivery only one may develop complications of prematurity while the other does not[6].

Organ maturity is determined from the date of conception. Gestational age is conventionally calculated from the first day of the last menstrual cycle and it assumed that conception followed this by 14 days. This may well be so in patients with 28 day cycles. In babies delivered from women with either shorter or longer cycles gestational age would not accurately reflect organ maturity. Babies born of women with shorter cycles would be maturer, while those born from women with longer cycles would be less mature than anticipated. While the discrepancy may only be a day or so, this could inadvertently classify the baby into another prognostic group. From one category to the next changes the prognosis, even known gestational age really dependent on date of conception and easily from 22 to 23 weeks which could be of critical significance, especially at the lower categories as it could be the difference between futility and treatment. Classification into the incorrect gestational age category could make the difference between futility and a decision to treat.

A large percentage of pregnant women are unsure of the date of their last menstrual period for various reasons. Early ultrasound may help date the pregnancies, however early ultrasound alone also has it's inaccuracies. Additionally many women present too late in pregnancy for ultrasonic estimation of gestational age. Paediatricians utilise clinical scoring systems to estimate gestational age after delivery. However they are less accurate thn menstrual dating or early ultrasound and should not be used to place an infant in a prognostic category.

As there is a correlation between gestational age and birth-weight in normal pregnancies, birth-weight is often used as a surrogate predictor of outcome where gestational age is either unknown or uncertain[5,6]. Unfortunately even in normal pregnancies the correlation between gestational age and birth-weight is not particularly good[7]. A large 28-week baby may weigh the same as an appropriately grown 30-week baby or a small 32-week infant. Any correlation between gestational age and birth weight only holds for normal pregnancies and by implication preterm delivery cannot be considered normal. Prematurity is often associated with other obstetric pathology, distorting any correlation between gestational age and birth weight even further.

It is generally assumed that birth-weight is an easily obtainable, reliable and objective measurement that is available directly after the birth of the child. In larger neonates there is a tendency of the nursing staff to round of the birth weight to the nearest 10g. In small neonates it has been reported that there is a tendency to round off the birth weight to the nearest 50g. Thus the outcome of a neonate with a birth weight of 880g may be rounded of to 900g placing it into a totally different prognostic category.

Other than the problems discussed with regards to gestational age and birth weight, further factors complicate the combination of data between different units and hence their interpretation. Preterm infants are by no means a homogeneous group, even those of identical gestational age or birth-weight. There are many different reasons for preterm delivery and the prognosis is to a certain degree dependent on the aetiology of the preterm delivery[8,9,10]. Girls tend to outperform boys and small black babies do better than small Caucasian babies. Growth retarded preterm infants have a better prognosis than appropriately grown babies do. As delivery of very small infants is a relatively rare event, most studies are small and their results prone to error. So as to increase sample numbers to make the data more significant, there is a tendency to extend data collection over a large number of years, where earlier deliveries would not have reaped the benefits of later innovations.

Obstetric decision making makes a considerable difference to outcome[11,12,13]. Administration of corticosteroids to enhance lung maturity, intrapartum monitoring, route of delivery, condition at birth and immediate neonatal resuscitation may all play a considerable role in outcome. There are some articles that suggest the greatest determinate of outcome in near viable pregnancies, is the decision by the obstetrician as to whether the baby will survive or not. If the obstetrician decides that the baby is viable it receives optimal pre- and intrapartum care, followed by vigorous neonatal resuscitation and pressure on the paediatric staff to admit the infant to the neonatal intensive care unit. It has been shown that for infants of 500-750g the decision by the obstetrician that the baby was viable increased the chance of survival eighteen-fold[9]. The fact that the subjective perception of survival by the obstetrician reflects the best prognosis makes somewhat of a mockery of using either gestational age or birth weight to prospectively predict prognosis or act as a gatekeeper to a neonatal unit.

Unfortunately for the obstetrician, clinical estimation of fetal weight is difficult and inaccurate, especially in small babies where there is a tendency to underestimate eventual birth weight[5]. Ultrasonic estimation of birth weight tends to be less inaccurate and actual birth weight tends to be within 10% of the estimated birth weight. As tables 3 and 4 show prognosis for birth weight is conventionally expressed in 100g categories and a 10% difference between the estimated and actual birth weight means that the two can fall into different prognostic categories. Additionally ultrasound facilities are not always available. These factors make it difficult to translate prognostic data based on birth-weight into information that will be helpful in prenatal decision making[14].

3. Statistics:

Science is only possible, as things tend to vary in an unvarying way. If all things were the same, then prediction would be superfluous, while if they were totally different prediction would be impossible.

Traditional predictive science follows an observation, inductive and deductive prediction process[15,16,17]. Singular phenomena are observed. The unprejudiced observer records all the conditions under which the observation occurred and all the outcomes. The recorded outcomes can be regarded as statements that have been empirically derived. Since these statements represent the observation of a single phenomenon they may be referred to as singular statements. Singular statements refer to a particular outcome at a particular time and under particular conditions. If following repeated observations under identical circumstances the same outcomes are found there is a tendency to generalise or universalise the statements. The method of basing universal statements on accumulated singular statements is known as induction. These universal statements soon attain the status of laws. Using deductive reasoning these laws are then used to predict the outcome if similar circumstances recur.

Extensive critique of the inductive process is beyond the scope of the dissertation. Some of the major criticisms will be mentioned. The idea that science begins with observation is apocryphal. The observer does not describe all the circumstances under which the experiment occurs, nor all the outcomes. Ideas of what should be recorded and what outcomes are measured are founded in theories of what is important. Thus theories precede observation in science and theories bias the observer.

Extrapolation from singular to universal statements, the problem of induction also known as `Hume's problem` and has been addressed by Hume, Popper and others. Science assumes the regularity of nature, thus that the future will be like the past. There is no way that this can be established, as we cannot predict the future. The belief that universal statements arrived at by induction can be used to predict future events is a reflection of human psychology and not of logic. Inductivists aware of this criticism attempt to take refuge behind a probabilistic reformulation of induction. One cannot be one hundred percent sure that, just because one has observed the specific outcome of a phenomenon on many occasions, the same outcome will occur under similar conditions in the future. Universals arrived at by induction cannot be guaranteed to be absolutely true, however they are probably true. The greater the number of observations and the greater the variability under which the observations are made, the greater the probability that the resulting universal statement is true. Now the naïve principle of induction has been replaced by a probabilistic version. The reformulation being that if a large number of singular phenomena have been observed under differing conditions, resulted in a particular outcome without exception, then all similar phenomenon will probably result in the same outcome. The implication of the probabilistic formulation being that on the basis of a finite number of observations, a universal conclusion can be made that is probably true. The reformulation does not overcome the problem of induction as a universal statement is still generated from singular statements. The probability of a probabilistic universal statement being true can be easily refuted mathematically. The probability of the inductive universal being true is the number of finite singular observations divided by the number of infinite observations possible, thus the mathematical probability of truth remains zero however many finite observations are performed.

Traditional science then predicts future events by deduction from induced truths. The universal statements derived by induction are then used to predict the outcome of phenomena in similar conditions. Now there is the extrapolation from the universal to the specific.

Prediction of the prognosis of babies admitted to neonatal intensive care follows exactly the same process; observation, induction and predictive deduction[18]. Exactly the same criticisms can be leveled here. The observers are not unbiased; they select relatively easily obtainable `objective` information such as gestational age or birth weight as prognostic criteria. They also select easily obtainable medically relevant outcomes to observe. They conveniently ignore a multitude of other data about the neonate, contingencies that occur may and do occur during the intensive care stay and limit outcomes to those that they can quantify relatively easily.

In naïve inductive science observations under identical conditions give rise to identical outcomes and laws can be formulated. The inductivist reasoning so far has concentrated on the study of nature and the development of natural laws, where under similar circumstances, experiments will have similar outcomes. The probabilistic formulation of induction only addresses the probability of the truth of the outcome and should not be confused with probability theory.

Due to patient differences prior to therapy and random occurrences during therapy, some patients will improve; some deteriorate while others will show no change. Despite medicine's romance with modernity, empirical observation has shown that groups of patients never have an all or nothing outcome. Medicine has attempted to overcome the resulting uncertainty by utilising probability theory.

4. Probability:

Probability is a branch of mathematics that deals with the likelihood of observing one of several possible outcomes that can occur in an event[19]. In probability an event is a single happening, often referred to as a trial, and an outcome is one of several possible results. For example, one toss of a coin is an event, whereas a head or a tail is an outcome.

Probability theory was originally developed to make predictions in games of chance. In its most straight forward case probability theory deals with a set of outcomes that are equally likely to occur. For example if a card is drawn from a deck (a random event), the outcome is equally likely to be a heart, a diamond, a spade or a club. In this random event the probability of the card drawn being of a specific kind is found by dividing the number of outcomes of the specific kind (say spades) by the total number of possible outcomes.

Probability theory has developed and there are now two main interpretations, the subjectivists and the frequentialists[20]. The former depends on our expectations and observations of events. The later dominates in medical statistical and epidemiological analysis at present. Here probability can be viewed as the relative frequency of an outcome in a long string of events. The frequentialist view is also referred to as the empirical approach to probability, as probabilities are based on outcome data from a number of random sample events taken from a defined population. The law of large numbers implies that as sampling becomes larger, observed frequencies of outcomes of events approach theoretical probabilities. Large populations show inherent stability and perturbations due to individual variations becomes smoothed out.

Probability theory has merely been designed to address the uncertainty of outcome and while acknowledging the complexity of the phenomena, contingencies and outcomes studied has done nothing to resolve these problems.

Individual studies usually report point probabilities for specific outcomes in the population studied. If in the population studied there were 400 infants weighing between 700g-800g and 40 died, the point probability for the outcome death in the 400 events (patients) would be 0,1. This point probability refers only to the outcome death in the population studied. Medical scientists often wish to know if a similar trial was repeated under similar circumstances how similar would the results be? For this reason point probabilities are usually accompanied by 95% confidence intervals. Ninety five percent confidence intervals are mathematically calculated and were a similar trial repeated 100 times, then theoretically the point probability would be between the 95% confidence intervals. Following the law of large numbers the larger the trail the closer the 95% confidence intervals as the closer the trial results will be to the natural frequencies.

Probability theory may tell us what the probability of an outcome is in a population. Using the example alluded to above the probability of death in the population studied was 10%. Two major issues however remain unresolved. Point probabilities derived from medical research refer to populations of patients and not individual patients. How can we extrapolate population-derived data onto individual patients? Also although the probability of a particular group of patients for death may be 70%, for a particular patient it can only be 0 or 100%. In essence what we communicate to the patient is our perception of the probability of the outcome.

The problems of extrapolating from populations to individuals can be illustrated by the following cases. The smallest surviving unaffected infant was a severely growth restricted female delivered in 1991 at a gestational age of 27 weeks. Her birth weight was 280g; her 120-day sojourn in intensive care was followed by an uneventful early childhood. She is at present progressing well at school and has no identified sequelae of her extremely low birth weight[21,22]. This normal outcome occurred despite the fact that her mother did not receive steroids prior to delivery and the infant did not receive artificial surfactant in the neonatal period. The same authors have reported another case with a birth weight of 380g and a similar excellent outcome. Futility will be discussed in detail later, however all large population based studies would have considered management of these cases to be futile.

Synthesis:

There can be little doubt that for the individual patient there is considerable uncertainty about outcome. This uncertainty is based upon the inherent mistrust in the inductive method. We live in a world of complexity, diversity and ultimately uncertainty. The uncertainty may be denied by authoritative dogmatism. An example of this is the 1000g threshold for neonatal intensive care admission. An alternative approach to the uncertain prognosis of the extremely small neonate is discussed in the chapter on individual and comparative utility.

The data in the tables (Appendix A) show the survival of infants admitted to neonatal intensive care. What other research and historical reflection has shown is that those neonates refused admission to neonatal intensive care fare far worse. The smaller the infant the worse the prognosis. There can be little doubt that small preterm neonates are extremely vulnerable.

While absolute prognostic certainty is elusive, the outcomes of infants at the extremes of the spectrum appear to be relatively stable. Despite new technologies and innovations that continue to push back the boundaries of viability, cases exist in which all the known evidence lead the decision-makers to conclude that aggressive intervention is futile. In cases of probable futility it is morally legitimate to withhold or withdraw therapy[23]. In contrast to the cases of probable futility, cases also exist where prevailing knowledge and experience suggest an excellent outcome. It is that group of babies between the extremes where uncertainty prevails.

Axioms

A 280-g baby has survived with no residual morbidity.

There have been improvements in morbidity and mortality over time.

The smaller or more preterm the infant the more likely it is that there will be either mortality or morbidity.

All data are based on population studies and any probabilities are for populations. For the individual the risk of outcome for death cannot be given as percentage, it is either zero or one hundred percent.

Prognostic data should be used as a road map.

Basically have to accept that while when evaluating the chances of survival of a population we can be reasonably accurate when attempting to prognosticate for the individual we are confronted with prognostic uncertainty.

Babies above 1350g or 31 weeks should have a survival of virtually 100%.

Even the majority of survivors at 24 weeks have no major residual neurological handicap.

References

1. Hack M, Klein NK, Taylor HG. Long-term development outcomes of low birth weight infants. The Future of Children 1995;5:1-20.

2. Muraskas J, Bhola M, Tomich P, Thomasma D, McDonald R. Neonatal viability: pushing the envelope. Pediatrics 1998;101:1095-1096.

3. Taitz T, Clow S. Effect of the legislative definition of the terms `stillbirth` and `viable` a medicolegal impasse. S Afr Med J 1988;73:240-241.

4. Hack M, Fanaroff AA. Outcomes of extremely immature infants – a perinatal dilemma. N Engl J Med 1993;329:1649-1650.

5. Allen MC, Donohue PK, Dusman AE. The limit of viability – neonatal outcome of infants born at 22 to 25 weeks` gestation. N Engl J Med 1993;329:1597-1601.

6. Cooper RL, Goldenberg RL, Creasy RK, DuBand MB, Davis RO, Entman SS, James JD, Cluver BA. A multicenter study of preterm birth weight and gestational age-specific neonatal mortality. Am J Obstet Gynecol 1993;168:78-84.

7. Stevenson DK, Goldworth A. Ethical dilemmas in the delivery room. Semin Perinat 1998;22:198-206.

8. Worthington D, Davis LE, Grausz JP, Sobocinski K. Factors influencing survival and morbidity with very low birth weight delivery. Obstet Gynecol 1983;62:550-555.

9. Vas R, Vidyasgar D, Winegar A, Peterson P, Spellacy WN. Perinatal factors influencing the outcome of 501 to 1000g newborns. Clin Perinatol 1986;13:267-284.

10. Wolf EJ, Vintzileos AM, Rosenkrantz TS, Rodis JF, Salafia CM, Pezzullo JG. Do survival and morbidity of very-low-weight infants vary according to the primary pregnancy complication that results in preterm delivery? Am J Obstet Gynecol 1993;169:1233-1239.

11. Shaup AHP, Wolf H, Bruinse HW, de Ouden AL, Smolders-de Haas H, van Ertbruggen I, Treffers PE. Influence of obstetric management on outcome of extremely preterm growth retarded infants. Arch Dis Child 1997;77:F95-F99.

12. Reuss ML, Gordon HR. Obstetric judgements of viability and perinatal survival of extremely low birthweight infants. Am J Pub Health 1995;85:362-366.

13. Vansteenkiste MAL, Pattinson RC, Kirsten GF. The role of obstetric factors in determining fetal viability. S Afr Med J 1992;81:508-511.

14. Finer NN, Barrington KJ. Decision-making in delivery room resuscitation: a team sport. Pediatrics 1998;102:644-645.

15. Dunbar R. The trouble with science. Faber and Faber. London 1995.

16. Magee B. Popper. Fontana Press. London, 1985.

17. Chalmers AF. What is this thing called science?. Open University Press. Bristol 1982.

18. Morrison JJ, Rennie JM. Clinical, scientific and ethical aspects of fetal and neonatal care at extremely preterm periods of gestation. Br J Obstet Gynaecol 1997;104:1341-1350.

19. Anonymous editorial. Clinical practice, statistics, and philosophy. Lancet 1982;911-912.

20. Edwards A, Prior L. Communication about risk – dilemmas for general practitioners. Br J Gen Pract 1997;47:739-742.

21. Muraskas JK, Myers TF, Lambert GH, Anderson CL. Survival of a 280 gram infant. N Engl J Med 1991;324:1598-1599.

22. Muraskas JK, Myers TF, Lambert GH, Anderson CL. Intact survival of a 280g infant: an extreme case of growth retardation with normal cognitive development at two years. Acta Paediatr 1992;382:16-20.

23. Pierce SF. Neonatal intensive care - decision making in the face of prognostic uncertainty. Nurse Clinics N Am 1998;33:287-297.

Chapter 4

Individual and comparative utility

There are essentially two co-existing neonatal intensive care allocation and decision-making processes. On the one hand, microallocation decisions at the level of the individual patient involving clinical decisions. In neonatology the patient is unable to make these decisions and hence they are made by surrogate decision-makers. On the other hand, macroallocation decisions. These are the planning decisions made on behalf of the community by health care jurisdictions. These decisions include issues such as whether or not facilities should be provided, where provided facilities should be located and who qualifies to utilize them.

Decisions have to be made at both levels. Although decision-makers and factors influencing decision-making differ between the two levels, essentially both utilize a similar process. Both require some idea of the anticipated outcomes of alternative decisions that can be made. Assessment of potential outcomes, expressed quantitatively and qualitatively, is best explained by decision analysis theory. Decision analysis theory suggests that three questions should be addressed when comparing decisions[1,2,3]:

1. What decisions can be made?
2. What are the probabilities (ρ) of a particular outcome for a particular decision? This represents a quantitative assessment.
3. What is the utility (u) of each outcome? This is a qualitative assessment.

If these questions can be answered then it is relatively easy to calculate the anticipated utility of each decision $\Sigma(\rho \times u)$.

While appearing straight forward, there are obviously problems with this approach. It is beyond the scope of the thesis to analyze decision analysis in full. However it will be briefly addressed. Appropriate alternative decisions that can be entertained are usually relatively easy to identify. Probability determination of outcomes is difficult and has been more comprehensively discussed under prognosis. Problems with qualitative assessment of outcome and quantification of qualitative assessment of outcome are addressed below. The limitations of decision analysis must also be remembered. Decision analysis is merely a method to allow comparison of the anticipated outcome of alternative decisions available. Final decision making is far broader and other than taking cognisance of potential outcomes also tends to involve, amongst others, personnel, social, political, ethical and philosophical issues[4].

Individual utility:

How does one qualify outcome for an individual? If the patient were competent then the patient would assess qualitative utility according to their own beliefs and values. Health related quality of life can be measured in many ways, perhaps the simplest and most time honoured is the simple question by the doctor to his patient, `How are you? `. In the absence of competence, these judgements are far more difficult.

If one wishes to compare outcomes qualitatively, some form of standardization is necessary. Utility measurement is one such approach[5,6]. The term utility may potentially lead to confusion. Utility does not refer to the usefulness of the individual or of the health state in which the individual is found. Utility refers to the desirability or preference that individuals exhibit for a condition or outcome. Utility is a cardinal measure of the strengths of an individual's partiality for a condition or outcome.

Medicine has a tendency to attempt to numerically quantify qualitative assessment; there are numerous ways of doing this. The desirability of health states can be arbitrarily standardized on a scale from zero to unity[5]. This means quantifying the qualitative outcome between zero and one. The quantitative value of the qualitative outcome is a reflection of the decision-makers preference for an outcome. Utility values for outcome are usually assessed relative to two extremes, referred to as anchor states. The commonly used anchor states are death, assigned a value of zero and full health, assigned a value of one. Even the most solid end-point, death, allocated a score of zero is questionable. Not all deaths are the same; if they were then euthanasia would not be an issue in medicine.

Different decision-makers can be utilised to assign utility values to particular health states[7]. Utility value assignees may include patients or their surrogates, medical personnel, the general public or politicians. At the level of individual utility and decision-making, the patient is probably best qualified to assign quantitative values to utilities. The patient is informed about the different outcomes and utility scores are assigned according to the patient's beliefs and values. Alternatively patients with particular conditions may be requested to determine their utility for their particular state. The potential for subjectivity can be appreciated when one considers the commonly observed phenomena that two patients with the same clinical condition often have dramatically different responses.

Qualitative assessment of long term outcome in surviving preterm neonates is obviously more difficult than in adults. Firstly, competent adults can assign utility scores according to their own beliefs and values. In neonates, surrogate decision-makers have to assign utility scores. In assessing neonatal outcome and individual utility, thought experiments have be performed with surrogates in which particular health states are described to the surrogates and those individuals allot a utility score to each health state. Secondly in competent adults the potential outcomes can be compared to the normality that they used to enjoy. The preterm neonate that survives with sequelae will have had those sequelae for the whole of their cognitive life. How does one quantitatively assess a condition such as blindness for somebody that has never experienced vision? Are they worse or better off than individuals that could previously see?[8] Some may assume handicapped children experience suffering and this causes torment in the family. Alternatively they may assume that individuals with sub-average intelligence must be miserable. When quantifying utility as a surrogate one must be careful not to merely project our own desires and fears. Some of the lost quality of life may also be more a reflection of society's interaction with the individual, rather than an inherent problem with the individual themselves.

Utility assessments are essentially a quality of life assessment and assigning a score between zero and one may be philosophically extremely difficult for some decision makers[9]. To the vitalist, mere biological life alone is an end-point that is not only acceptable. It is an outcome worthy of striving for. To the non-vitalist mere biological life of the permanently comatose patient is not beneficial unless there is a real possibility of either a diagnostic or prognostic error. To anyone but vitalists, balancing benefits and burdens pre-supposes the concept of quality of life. One has to have some concept of the type of life that a patient would live after a medical intervention. Surrogate decision-makers should be extremely careful with quality of life judgements and remember that quality of life for the patient should not be confused with the quality or the value of the patient's life to others. The criticism has been made that quality of life decisions shifts the focus away from whether treatment is beneficial to the patient, to whether or not the patient's lives are beneficial to them[10]. Quality of life judgements are not about the social worth of the patient, but about the value of life for the person that must live it. One way to for surrogate decision-makers to focus on the value of life for the person who must live it may be the concept of best interests.

Decision analysis on the individual level facilitates normative quantification of the anticipated outcomes of particular decisions[2]. Outcomes of clinical decisions can now be semi-quantitatively compared. Anticipated outcomes are now available. The final decision taken, while obviously taking cognisance of the outcomes of the available decisions, is usually based on variable combinations of social, political, ethical or philosophical inputs. Outcome analysis where the results of the outcomes analyzed directly and solely influence management is necessarily utilitarian in nature.

Individual utility and treatment obligations:

Macroallocation determines provision of facilities or not. If the facility is available and an individual requires the facility then evaluation of individual utility is important for clinical decision making. How can individual utility analysis influence surrogate decision making? In neonatal care surrogate decision-makers utilize decision analysis to evaluate the likely outcome of different management options. The best interest standard determines that they should make their decision based, in a utilitarian manner, on the balance of benefits over burdens.

Beauchamp and Childress have suggested that when considering treatment on the individual level there are three moral categories[10]:

1. Obligatory to treat (wrong not to treat).
2. Optional whether to treat or not.
3. Obligatory not to treat (wrong to treat).

In the vast majority of patients there is an obligation to treat. It will be argued that in the face of uncertainty as is often the case in neonatal care, there is also an initial obligation to treat. The second category they subdivide into neutral and supererogatory. The neutral sub-category refers to it being morally neutral whether or not a doctor provides therapy or a surrogate authorizes or refuses therapy. In the supererogatory sub-category providing treatment is considered supererogatory, while not providing it would not be morally blameworthy. It has been suggested and will be expanded upon below that treatment may be morally optional if considered futile or if the burdens of treatment are deemed to exceed the benefits. The category of obligation not to treat is rare and would include the refusal by a competent, autonomous individual not to treat. It may also be argued that in the presence of scarcity of resources, futility or where burdens considerably outweigh benefits, that there is an obligation not to treat.

Futility

The word futility is derived from the Latin *futilis,* that literally means `that which easily pours out`, which has come to mean serving no purpose in English. Futilis is a word associated with Greek Mythology, in which the daughters of Danaus, king of Argos murdered their husbands on their wedding night, on his instruction. They were condemned by the gods to collect water for eternity using leaky sieves. A futile action is one that cannot achieve the goals of the action, no matter how often repeated[11]. Futile acts are ineffective and incapable of achieving a desired result or goal.

Futility has to be distinguished from similar terminology[12]. Futility should not be confused with impossibility, where actions are either physically or logically impossible. Futility should also not be confused with acts that are so complex, that though theoretically possible, are at present implausible. The production of an infant entirely outside the uterus may be theoretically possible, but with current technology is implausible. Hopelessness should also be distinguished from futility. Futility refers to the objective quality of an action; hopelessness describes a subjective attitude. Hope and hopelessness bear more relation to desire, faith, denial and other psychological responses than to the objective possibility or probability that actions being contemplated will be successful or not. Something plausible, although unlikely, is never hopeless, because hope is what human beings summon up to seek a miracle against overwhelming odds. It is logically acceptable to say that you know that an action is probably futile, but that you have hope. Such a statement would express two facts. The first about the perceived outcome of the situation and the second about the psychological state of the speaker. The distinction between futility and hopelessness may lead to conflict between medical personnel and parents.

Earlier this century all medications were considered to be effective. They brought about the effect that their names described. Emetics could be relied upon to cause vomiting, purgatives to cause laxation; sudorifics to cause sweating. According to the medical theories of the time, medication when prescribed was always considered to be beneficial. Failure of a patient to get better was a defect of nature, not of the doctor or of the treatment.

Modern medicine however, through improved statistical analysis, has come to recognize the important distinction between effect and benefit[13]. Therapy may be effective, however the goals that will be achieved may not desirable. The goal of medical therapy is not merely to cause some effect on either the patient's anatomy, physiology or biochemistry, but to benefit the patient as a whole. The ultimate goal of any therapy should be to either improve the patient's prognosis, comfort, well being or general state of health. Any therapy that fails to provide such benefit, even if it does produce measurable effect, may be considered to be futile. Futility is temporally unstable as new innovations make the previously futile possible.

Like decision analysis the term futility has a quantitative and qualitative element. Futility may refer to an improbability of an event occurring, a semi-numeric evaluation, or to the quality of an outcome that treatment will produce. Determining futility is similar to decision analysis, with one important distinction. In decision analysis, the decision to use a particular procedure is based on the joint product of the probability of success and the quality of the outcome $\Sigma(\rho \times u)$[12]. In the case of futility probability and utility are independent final determinants. Either a poor probability of any successful outcome or a good probability of poor outcome may be used to declare an action futile.

Burdens outweigh benefits

While the concept is self-explanatory, for a surrogate decision-maker it can be extremely difficult to adjudicate. Like futility the evaluation of benefits and burdens is subjective.

Treatment optional or wrong?

Beauchamp and Childress feel that futility changes the relationship between doctor and patient, there is no longer an obligation to treat[10]. The concept is not new[14]. Hippocrates felt that it was improper for doctors to engage in practices that are hopeless. He also felt it improper to cause more burden than benefit. In both instances he felt that there could come a time when we should stop treating. The first notion was more concerned with protecting the virtue of the profession, while the second focused primarily on concern for the good of the patient. Plato felt that the responsible doctor should not pander those that should not be treated no matter how rich they were.

The principle of nonmaleficence does not insist on the maintenance of biological life, irrespective of the patient's pain, suffering or discomfort. If on the balance of utilities the burdens outweigh the benefits there is no obligation to treat[10].

We have now established that there is no obligation to treat in the presence of futility or when the burdens outweigh the benefits. The question is; is it ever wrong to treat under these circumstances? This opinion may be supported by appeals to distributive justice. Distributive justice will be addressed in more detail later. The argument to support an obligation not to treat are briefly detailed below.

Resources can be considered wasted from society's point of view if it is known beforehand that either the chance of a good outcome is poor or the chance of a bad outcome is good[15]. The concept of waste here should not be confused when health resources have been used for an infant with a real likelihood of a good outcome, that subsequently dies[16]. Limiting care with marginal utility fits into the scheme of fair allocation of scarce resources or distributive justice[10].

Futility and burdens outweighing benefits are extremely important concepts if they oblige non-treatment, especially if the non-treatment will probably lead to death. These terms are not value neutral. There are uncertain probabilities and no consensus how seldom treatment has to work to be deemed futile[16]. Utility quantification is a value judgement made by surrogate decision-makers. These judgements should never be used as a moral trump card, if there is not consensus amongst decision-makers the whole situation should be reconsidered.

Comparative utility:

The discipline of health economics has developed so as to evaluate and compare the resource consumption of healthcare programs[17,18]. Health care is dependent on resources that are not infinite, be they provided by the recipient of the care, a third party insurer or the government. It is no longer enough to claim that interventions merely work or are effective, they have to be economically competitive. They have to compete for the finite healthcare resources. When third party financiers consider an intervention they consider the costs of paying for it. Is a particular health procedure or service program worth doing when compared with other things that we can do with the same resources? In deciding to use resources in one health program or treatment, the community foregoes the opportunity to use those same resources in another competing activity. It is generally accepted that neonatal intensive care improves outcome of preterm neonates, however neonatal intensive care must compete with other health programs for allocation of healthcare funding. The distribution of expenditure within health care services must be justified. As can be seen, economic evaluations are predicated by a number of assumptions. Resources are scarce, relevant alternatives have to be identified, alternatives can be qualified, quantified and compared. Rational choices can be made and justified on economic grounds.

The perceived scarcity of resources will be challenged and choices of distribution of resources will be addressed when discussing distributive justice. Methods of economic comparison will be further addressed here. In order to compare different health programs there has to be a single unit. As the comparisons are for economic evaluation, the numerator is inevitably in monetary units.

Economic evaluation, which relates mainly to planning decisions, strives to obtain comparative assessments of costs and consequences of a wide range of health care programs, the logic being that, if it is accepted that resources are limited, priorities for health services investments need to be assigned[10]. There are several forms of economic evaluation, but all forms compare inputs into a health care program with some combination of outputs. Inputs include costs to the health care sector and to patients and their families in providing care as well as indirect costs such as revenue lost due to individuals not being able to work. There may also be an attempt to calculate intangible costs associated with therapy, such as pain and suffering. Whereas the valuation of costs is relatively straightforward, though not without controversy, the evaluation and quantification of the qualitative benefits of health care, particularly the intangible benefits is a source of debate

Outputs of health care programs can be assessed in many ways[10]. Firstly, they may be measured fairly simply as number of cases treated or number of years of life gained. Secondly the outputs may be measured in monetary terms. Economic evaluation where outputs are measured in monetary terms is referred to as cost-benefit analysis. Some categories of benefit are relatively easy to quantify monetarily, especially if financial in nature themselves, such as saving in health care as a result of improved health. Other more intangible benefits, such as the value to the patient or their families of feeling healthier, are obviously far more difficult to quantify. If patients requiring the health intervention could die either if they did not receive the intervention or as a result of the intervention, those performing cost-benefit analysis would be in the difficult position of having to allocate a financial value to human life. Cost-benefit analysis is unpopular as outcome is measured in financial terms. Health should be seen as an end in itself and not as a financial commodity. To overcome these problems the outputs of health care may be measured according to the value of the recipient's health state, in other words utility is measured. Evaluation with utility as the denominator is referred to as cost-utility analysis.

The lifetime of an individual can be considered to consist of two major components: quantity of life and quality of life[5,6]. Quantity of life is the time interval from birth to death, while quality of life refers to life's quality at each point between birth and death. Quality of life is a broad concept that incorporates all aspects of an individuals existence. Many factors external to the health domain such as economic, cultural, political, environmental and spiritual contribute to quality of life. There should be a distinction between quality of life as an all-inclusive concept incorporating all the factors that impact upon an individual's life and health related quality of life, which includes only those factors that are part of an individual's health. Health related quality of life is a less broad concept than the all-embarrassing quality of life and only relates to the health aspects of an individual. The unit conventionally used to report utility in comparative assessment is quality of life, although a more appropriate term would be health related quality of life.

The principles of quantification of quality of life assessment are similar to those of individual utility assessment. The desirability of outcomes is standardized on a scale from zero to one. The quantitative value of the qualitative outcome is a reflection of the decision-maker's preference for an outcome. Utility values for outcome are assessed relative to two extremes, or anchor states. The least desirable anchor states are allocated a value of zero and the most desirable anchor state, usually full health, assigned a value of one. People seek health; thus each year of good quality healthy life expectancy is allocated a value of one. Each year of poor quality unhealthy life expectancy is then allocated a value of less than one. The value below one of each year of poor quality life expectancy is dependent on the degree of incapacity, the greater the incapacity the greater the loss[5,6]. When quality of life values are combined with prognostic information, it allows calculation of quality adjusted life years (QALYs). QALY is a composite indicator that combines morbidity and mortality to provide a quantitative measure of losses from a condition or gains from an intervention.

Factors determined and quantified in neonatal survival evaluate neurological function like physical mobility and coordination, intellectual capacity and ability to interact socially[19,20]. Respiratory dysfunction is also qualified and quantified. In individual utility assessment the patient or a surrogate assigns values to outcomes. In comparative utility assessment patients with particular outcomes may be requested to assign values for their outcomes relative to full health. Alternatively thought experiments may be performed in which particular health states are described to individuals and those individuals allot a utility score to each health state. It may be argued that when economic analysis seeks to inform planning decisions the relevant utility values are those of either the general public or their elected representatives.

The concept of QALYs is based on numerous assumptions[10]. These include that the only function of health services are health maximization and that healthy life is equivalent to quality life. Only selected utilities are evaluated and these are often based on the ease of identification and numeration of the qualitative short-fall. Qualification and quantification of any dysfunction is subjective and dependent on the opinion of the groups whose opinion was solicited. Qualitative assessment is normative and interpretation of the good life and the allocation of a numerical value may give a false impression of objectivity to the unwary. QALYs is an egalitarian concept as each year of life is equal. QALYs values individuals in direct proportion to their expectation of life at their current age and advantages the young and discriminates against the elderly as saving the life of a young person will produce more QALYs than that of an older person.

In cost-utility analysis, the input or numerator is the financial cost and is reported in a monetary unit and the denominator or utility unit is the quality adjusted life year. Thus, cost-utility analysis is reported as cost per quality adjusted life year. Cost-utility ratios have little intrinsic meaning by themselves but can be compared with ratios for other health interventions. Because many evaluations have been performed, it is hardly surprising that there has been a tendency to construct ` league tables` of interventions in terms of their costs per quality adjusted life-year[21,22]. Most league tables present data for debate and do not specify any cut-off point beyond which programs should not be provided.

League tables are usually constructed using studies performed at different times, by different investigators on different patients, often in different countries. A study performed at a particular time, merely represents a snapshot of the situation at the time of the study. Making provision for inflation is one way of trying to allow for comparison of studies that are not contemporaneous. Presumably different methodologies for calculating utility and costs of utilities would have been utilised. Finally comparisons are made across disparate fields.

League table analysis is further complicated in the case of neonatal care. The advantage to younger patients where QALYs are utilised in the denominator has already been discussed. Neonatal technology is rapidly changing and costing changes concurrently. The introduction of artificial surfactant has dropped the cost of initial intensive care and increased the number of survivors, both intact and impaired. The increase in number of impaired survivors leads to increased long-term care costs. As smaller infants require more care and have a worse outcome despite this, the cost per QALY gained, increases as the gestational age or birthweight drops[23].

Cost-utility comparisons, comparing neonatal care to other forms of health care have been performed in the United States[24]. It was found that the cost per QALY gained for an infants weighing between 1000g and 1499g was less than that for treating hypertension in 40 year old men. Even though cost per QALY gained increases with decreasing birthweight, the cost for infants weighing between 500g and 999g is less than that for coronary artery surgery or renal dialysis. In the USA the total annual direct costs of neonatal intensive care for small infants is less than one third of the costs of health care of smoking related disease and less than two thirds of the direct health costs of alcohol abuse.

Despite all the criticism it is essential to bear in mind that decisions have to be made about the allocation of resources. Cost-utility analysis is probably the most sophisticated form of economic evaluation available at present and from the health economy viewpoint has an important role to play[25]. Those utilising cost-utility analysis league tables for economic evaluation and comparison of health interventions for economic advice on determining resource allocation should always bear the criticisms in mind. Advisors and macroallocation decision-makers should exercise caution, care and intelligence when using cost-utility analysis.

References

1. Lane DA. Utility, decision, and quality of life. J Chron Dis 1987;40:585-592.

2. Lindely DV. Making decisions. London: John Wiley, 1971.

3. Schwartz WB, Gorry GA, Kassirer JP, Essig A. Decision analysis and clinical judgement. Am J Med 1973;55:459-472.

4. Sisson JC, Schoonmaker EB, Ross JC. Clinical decision analysis; the hazard of using additional data. JAMA 1976;49:149-164.

5. Torrance G. Utility approach to measuring health-related quality of life. J Chron Dis 1987;40:593-600.

6. Drummond MF. Discussion: Torrance's utility approach to measuring health related quality of life. J Chron Dis 1987;40:601-603.

7. Testa MA, Simonson DC. Assessment of quality of life outcomes. N Engl J Med 1996;334:835-840.

8. Magee B, Milligan M. On Blindeness. Oxford University Press, Oxford, 1995.

9. Mitchell RG. Objectives and outcomes of perinatal care. Lancet 1985:931-933.

10. Beauchamp TL, Childress JA. Principles of Biomedical Ethics - Fourth Edition. Oxford University Press, New York; 1994.

11. Oxford English Dictionary. Clarendon Press, Oxford;1980.

12. Schneiderman LJ, Jecker NS, Jonsen AR. Medical futility; its meaning and ethical implications. Ann Intern Med 1990;112:949-954.

13. Tyson J. Evidence based ethics and the care of premature infants. The Future of Children 1995;5:1-20. Http://www.futureofchildren.org

14. Edelstein L: In: Ancient Medicine; Selected Papers of Ludwig Edelstein. Temkin O, Temkin CL (eds). Johs Hopkins Press, Baltimore;1967.

15. Emmanuel EJ, Emmanuel LL. The economics of dying - the illusion of cost saving at the end of life. N Engl J Med 1994;330:540-544.

16. Avery GB. Futility considerations in the neonatal intensive care unit. Sem Perinat 1998;22:216-222.

17. Tee GS. Cost utility analysis of taxane therapy. Am J Health Syst Pharm 1997;54:11S-15S.

18. Tudehope DI. Economic evaluation in medicine. J Paediatr Child Health 1997;33:185-186.

19. Stolz JW, McCormick MC. Restricting access to neonatal intensive care; effect on mortality and economic savings. Pediatrics 1998;101:344-362.

20. Rogowski J. Cost-effectiveness of care for very low birth weight infants. Pediatrics 1998;102:35-43.

21. Williams A. Economics of coronary artery by-pass grafting. BMJ 1985;291:326-329.

22. Mason J, Drummond M, Torrance G. Some guidelines for use of cost effectiveness league tables. BMJ 1992;306:570-572.

23. Neil N, Sullivan SD, Kessler DS. The economics of treatment for infants with respiratory distress syndrome. Med Dec Making 1998;18:44-51.

24. Bregman J. Development of outcome in very low birthweight infants: current statistics and future trends. Ped Clin N Am 1998;45:673-691.

25. Robinson R. Economic evaluation and health care: cost-utility analysis. BMJ 1993;307:859-862.

Chapter 5

Macroeconomics

We have no money so we must think

Rutherford, British physicist

Resource allocation at the global level of decision-making, called macroallocation, is usually distinguished from microallocation or rationing decisions about which individuals receive what services[1]. Macroallocation decisions determine how much money is allocated to health care in the country. These decisions determine how much the central or provincial government is willing to allocate to health care as opposed to education, defense, the environment or other social goals. Macroallocation decisions determine how much of a given resource ultimately is made available to ration among individual patients. Rationing occurs at the level of the patient, where it is decided whether or not a patient should receive a treatment that is in limited supply.

The dissertation in essence addresses microallocation decisions; which babies should and should not receive neonatal intensive care? However it would be naïve not to briefly address macroallocation in a discussion of this nature. The reason for the brevity is that many articles have been written on the issue and final decisions are probably more motivated by political than philosophical theory.

Few would dispute that there is a need for reorganisation of health care in South Africa. The system is inequitable and does not provide for the health care needs of the majority of the population, particularly those in remote rural areas[2,3]. There is at present a two-tier system: the private sector for those with a degree of financial freedom and the public sector for those that cannot afford private care. By the 1990s health expenditure in South Africa consumed almost 8% of the gross national budget. By 1992 in the private sector, 60% of the country's doctors spent 64% of the health budget on the 17% of the population that could afford private health care[2]. The private service continues to expand and change demographically as many young blacks are employed and join the insured. The public sector serving 83% of the population utilises only 36% of money spent on health and requires urgent redress[2].

Buchanan argues that there are nine elements necessary for a fair and just healthcare system[4]. The core three being; access, that is universal, of adequate level and without undue burden to the patient are based on the United States President's Commission on Medical Ethics. Fair distribution of financial costs of ensuring universal access of adequate care, fair distribution of rationing and a capacity for improvement to a more just system are three further necessary elements proposed by Buchanan. He describes three further elements: the system should educate and train appropriate numbers and types of health workers, should enable the effective pursuit of appropriate high quality biomedical research and implement in a cost-effective manner findings of relevant research.

Buchanan`s nine elements appear reasonable and will not be further debated, other than to briefly address the following issues: What is basic medical care? and How should health care be distributed? Basic medical care may either be interpreted as the bare minimum of medical care or that level of medical care necessary for survival and adequate functioning. Basic health services may thus mean the minimum of primary health services or it may mean highly sophisticated neonatal intensive care to support and allow the survival of small preterm neonates[5,6,7]. Definition of basic medical care is important to give content to Buchanan`s elements and as will be seen later to give content to patients right's in terms of the Constitution. As neonatal care units supported by public funding are available, I have taken basic health services to extend beyond the bare minimum and to be interpreted as those services basic to survival and adequate functioning.

Unspecified claims to fair distribution are extremely broad as different theories of distributive justice advocate different material principles that identify relevant properties that individuals must possess to qualify for benefits or burdens. As there is no overarching theory of social justice to balance competing claims between morally relevant criteria such as need and benefit: fair, open and publicly defensible resource allocation procedures are critical[8]. Any theory of distributive justice for health care leading to government policy should also be well published, coherent and consistent, as should be any government policy emanating from the theory. An example of lack of consistency between theory and policy may be the coercion of newly qualified doctors to perform community service. If a decision is made to concentrate on primary health care and diminish the role of medical personnel in the system then coerced employment of graduates may be more a reflection of political expedience than theory initiated policy. Surely engineers and builders of basic infrastructure should precede the doctors?

Some issues have to be addressed prior to continuing[9]:

1. Is there a shortage of medical resources?
2. Are there financial constraints?
3. What is the role of medicine in health?
4. If poverty plays a role in sickness, will redistribution of wealth result in more health?

Since the thesis discusses the issue of macroallocation of health services, the first issue to resolve is: Is there a shortage of medical resources? If rationing is the allocation of scarce resources, then prior to deciding whether and how to ration, the threshold question must be; Are the resources scarce? If not, there is no need to ration as there is plenty for all. If resources are indeed scarce, the question whether to ration is no longer relevant. The question now becomes how to ration?

Very few health care goods or services are inherently limited by scarcity of supply in nature. The most obvious example is organs for transplantation. Even this may be an artificial scarcity; there may be enough organs, but a reluctance to donate them. Some drugs are limited in supply as they are derived from nature. However, most drugs can be created by synthetic means and the natural limit disappears. Limitations on most medical supplies is almost inevitably a function of the money available to be spent on them.

The other major component in the health care sector is the individuals that deliver the services: the health care workers. There is no shortage of people to fulfil these services. If we are told there is a shortage of nurses, it is not because there are not enough people to serve as nurses. It is either as not enough people have been trained to provide nursing services, due to a reluctance to finance nursing colleges or not enough money is being paid to nursing personnel to persuade people to train as nurses, or for trained nurses to remain in the profession. The raw materials, people, exist. It is money that turns human resources into health care workers, money to pay for training, money to pay for delivery of services, just as money ultimately turns raw materials into products.

If there is no natural shortage of drugs, technologies or health care workers why are health care services often considered scarce resources? Economists believe that money is merely a means of valuing capital, labour or raw materials and how we allocate our money reflects how we value our resources. Financial limits on specific resources are the functional equivalent of natural limits on the resources. Natural limits impose absolute scarcity, while financial limits create artificial or relative shortages. Health care restrictions are thus in reality artificial restrictions and reflect the value that society places on health care when compared to other resources.

It has been established that in essence there is no absolute shortage of health resources. Any health care shortage is artificial and economic in nature. The question that then has to be addressed is; Are there financial constraints? Internally a recession, limited tax base, an inefficient and large public service and corruption are all threatening the economy[10]. Externally foreign aid to developing countries has been decreasing since the mid-1980s. The waning superpower rivalry and the increased need for help in Eastern Europe following the collapse of communism has made Africa even less significant in the eyes of Western aid agencies[10]. The low gold price, almost unsustainable debt burden, weakening foreign exchange and world recession have exacerbated the financial situation. There can be little doubt that there are severe financial constraints. Also, theoretically, health care could consume most if not all of even a booming economy, thus there must be financial restrictions[11,1,2,13].

Our health service shortages are artificial and a reflection of our economic woes. From this one would presume that if we could improve economically we could improve our health services and improve the health of the nation. This reasoning is based on the classical key assumption that health services are the major determinants of health status, so that inequalities in the latter are largely a result of differential access to the former. The salient question prior to implementing a policy based on this reasoning is, What is the contribution of medical care to health improvement?

The assumption that improved health services improve national health is based on the fact that there were impressive reductions in mortality in the last century. These reductions have benefited almost all countries in the world and all social groups, although with enormous disparities in the extent and the pace of the progress. The coincidence of this fall in mortality with the explosion in medical technologies led to the almost obvious conclusion that the latter had to be the reason for the reduction in the former. This certainty was short lived.

In the 1950s, precisely when most countries were beginning to report important decreases in mortality, criticisms began to be leveled against conventional wisdom. In 1959, Rene Dubos published his now classic book *Mirage of Health*[14]. In it he demonstrated that mortality had begun to decline in the West long before the formulation of the microbial theory of disease and the introduction of the magic bullets in the form of antibiotics. At the same time the physician and demographer Thomas McKeown looked at what was responsible for health in a population. He came to the conclusion that the reasons for declining mortality were to be found primarily in better living conditions, especially clean water, nutrition, housing, sanitation and environmental improvement[15]. It would appear that medical services have a small effect on health status, compared with socio-economic determinants. Progress in reducing health inequalities will be achieved not so much by increasing access to medical care as changing the social conditions and lifestyles that account for the persistence of such inequalities. Better public health, housing, sanitation, electrification, education, roads, public transport, pollution control and campaigns against tobacco and alcohol abuse, can probably do much more than curative medical services in extending quality of life and life expectancy.

If poverty plays a role in sickness, will redistribution of wealth result in more health? The `Black report' showed that inequalities in health are based on socio-economic position[16]. Poor health is clearly associated with poverty, a term that is often mixed up with other terms such as inequality, disadvantage, alienation and marginalisation. Reports equating poverty with poor health have lead to the deprivation model of sickness[16]. The deprivation model assumes that deprivation is an absolute state with causes sickness and early death through malnutrition, overcrowding, starvation, disease and other identified and unidentified factors. The deprivation model's proponents claim that redistribution of wealth and financial resources would abolish poverty and improve the health of community. They feel that redistribution of wealth is the single most effective strategy for improving public health and egalitarian policies flow directly from and are justified by this philosophy. Equality is good for national health.

The deprivation model assumes that at higher levels of income and wealth, health benefits plateau. Further increases in income or wealth produce diminishing levels of returns in health gain. Thus if money is redistributed from the wealthy to the poor, the poor will gain health but the rich will not loose health as they have already crossed the threshold of financial health and are some distance along the plateau. Man is born well and that health should be maintained. Poverty is caused by human agency; deprivation is an infringement of the right to health.

An alternative model to the health deprivation model to explain socio-economic differentials is the salutogenic model[16,17,18]. Salutogenesis is the process of health creation; as opposed to pathogenesis which is the process of disease causation. Rather than regarding pathological breakdown as an unusual situation, salutogenesis regards health as an abnormal state. Life is maintained in the presence of endemic environmental hostility to the organism. Health, far from being a natural state or a universal right is an achievement, a privilege and often the consequence of good luck.

People fortunate enough to enjoy the advantages of a higher socio-economic position are more able to build up resilience and resistance than those below them. This makes a longer life span more probable, as they are able to accumulate more positive health. Instead of sickness being caused by deprivation, salutogenesis sees health as caused by socio-economic advantage. Man is conceived and delivered in a vulnerable state, good health is possible by social arrangement. Positive health is the achievement of a positive environment.

If health is salutogenic and made possible by advantage, then the redistribution of resources is not an attractive option for improving the health of the nation, as redistribution works by removing advantage. If the relationship between socio-economic position and health is progressive and positive then redistribution of wealth may merely transfer health from the rich to the poor. There would be losers as well as gainers. Egalitarian policies do not so much create health, as move it around. Such redistribution may or may not be desirable; the point is that it is not self-evidently the right solution.

Inequalities in health may be less a sign of failure to address deprivation than an unintended consequence of success. Instead of redistributing a fixed quality of health from rich to poor, it may be more meaningful to create more health. This can be done by stimulating the economy and reducing the proportion of the population at the lower end of the socio-economic scale and increasing the proportion with higher socio-economic positions. This would continue the prevailing social trend towards financial betterment and presumably also the health trend of increasing average life expectancy. There would not be redistribution of wealth and with it health, but a net economic and health gain. Everybody would gain and nobody would loose. This type of strategy would allow many to gain the advantages at present only enjoyed by the few, rather than leveling the few down to the disadvantage of the many.

The implications are that a highly educated, highly skilled, high waged, economically expanding predominantly middle class is good for the health of the nation, despite its accidental promotion of inequality. Redistribution of income, resources and consequences has little to offer as regards improving the health of the people; it merely robs Peter to pay Paul. Whether such an economically expanding middle class society is desirable is a far broader social, political and philosophical debate.

It has now been established that financial constraints are responsible for artificial shortages in health care. That transfer of wealth from the rich to the poor will merely redistribute and not create health and that social upliftment and primary health care should take preference over curative services. It would appear that there are two major issues that will have to be addressed. One financial in nature and the other social, a shift from hospital based to primary health care system.

Monetary resources may either be generated internally by taxation or sourced externally from foreign donors[10,11]. A recession and a small tax base, restrict internal fund generation. Externally foreign aid to developing countries has been decreasing since the mid-1980s. The waning superpower rivalry and the increased need for help in Eastern Europe following the collapse of communism has made Africa less significant in the eyes of Western aid agencies. Amongst other things public funds are unnecessarily drained by corruption, the almost unsustainable foreign debt burden and a large and inefficient public service. Less money is available and the weak currency has further diminished the governments buying power of imported material.

According to the salutogenic model merely redistributing the wealth from the rich to the poor will not resolve the problem[16,17,18]. Additionally due to the vast number of poor people very little could be redistributed for health to each individual. The recession has also decreased the number of wealthy individuals.

The government has to be innovative in financial procurement for health[11,19-22]. A leaner, more efficient public service would diminish costs of the public service. Broadening the tax base and innovative financing, for example a lottery to supplement health costs, would augment the government coffers. The World Bank and donor countries are advocating community financing for primary health care, where users are charged a small fee for service. The arguments are that user payment gives a perceived value to services, deters frivolous demand and decreases the opportunity for hidden unofficial charges levied by unscrupulous health workers. Payment would also contribute towards the delivery of health care and overall payment of a small fee may improve health services[23]. Interestingly South Africa has bucked the international trend, with a change in the opposite direction, that is from user charges to free primary health care services. Increased accountability and limiting corruption could do much for the morale of the country[24].

Wealth creation is important as it would broaden the tax base and as individuals become wealthier they would be able to afford to pay for their own health care. This has the double advantage of increasing revenue and decreasing government costs. According to the salutogenic model of health and disease there would be the additional advantage of increased health[16].

Providing primary health care for all with no increase in spending involves redistribution of the health budget. As the previous budget was primarily hospital based, this means creating a new balance between hospital based and primary care services[2,3,25]. A hospital-based system is curative in nature and depends to a large extent on the traditional health care workers, doctors and nurses. As hospital's goals largely focus on the development of specialised activities, they may become a 'fortress ' to protect those working inside their walls from responding to the needs of the community. Primary health care concentrates on preventative strategies and decreases the role of the traditional deliverers of health care, specifically the medical personnel and particularly specialists. Because of the change in emphasis, development of a good primary health care system in South Africa necessarily means a direct challenge to the hegemony of the medical profession. Any Minister of Health not irritating the medical fraternity is not doing her/his work!

The government driven reform of health care is taking place predominantly in the public sector, where the major focus is on developing community facilities accessible through the district based primary health care. The rural poor are the most disadvantaged at present and this should improve accessibility to them. The public health care system will emphasise the promotion of healthy lifestyles, the co-ordination of the health services and community participation in planning. Primary health care will be delivered free of charge. The government will work towards efficient administration and effective systems of referral to secondary and limited tertiary levels of care. There will be collaboration with other factors effecting health such as housing, electrification, clean water and sanitation. There will be an improvement of environmental health services. They will attempt to involve the populace in their own health promotion. One of the issues to address may be how to bring ethics back into society and health care in particular.

The complexity of social transformation and specifically of health precludes any simple plan. The change from hospital to primary based health care in the absence of financial resources to fund both simultaneously will lead to hardships in the short-term. The government of the day has a political and moral responsibility to inform the public of the trade-offs involved in withdrawing existing services in order to benefit future generations.

Distributive justice demands that there should be a shift towards primary health care in its broadest sense. It would appear from the foregoing that an argument has been leveled against hospital based medicine and by implication neonatal intensive care. Poverty and deprivation continue in the country. The socio-economically disadvantaged are more prone to bad health[6]. Low birth weight and preterm labour is unequivocally more prevalent amongst socially disadvantaged populations. In 1990 the infant mortality rate for whites was 7,4 per 1000 births, compared to 48,3 per thousand for blacks[22]. This is important, as the social costs of rationing neonatal care must also be considered. Withholding care from liveborn infants will increase the infant mortality rate. Neonatal intensive care rationing has the potential to increase the already disgraceful disparity in neonatal deaths between the have and the have nots[5,25]. Improving access to neonatal intensive care is a move in the direction of trying to rectify some of the injustices of the past. Like Rawls we could utilise the concept of fair opportunity as a rule of redress to attain greater equality.

When considering allocation of health resources the government may also have to consider factors other than distributive justice. Given the country's political past, it is not surprising that the new government has introduced a constitution with a bill of rights. Rights are based on the theory of liberal individualism and rights are claims that individuals or groups may make on others or on society[26]. A positive right is a right of provision, while a negative right is a right of freedom. Unlike the principles some rights are absolute, however most are prima facie. Like the principles all rights should be specified and prima facie rights may have to be balanced. The unjustified action against a right or its violation must be distinguished from justifiable overriding or infringement of a right.

Rights can be defined in terms of claims that are justified by moral or legal principles and that allow individuals to make claims that ought to be respected or indeed demand respect by others[26]. The significance of rights is that the person with the rights is able to justify the infringement of another's autonomy, for the claim determines the duty or obligation owed to the claimant.

There is a self-imposed obligation on behalf of the South African Government following the implementation of Act 200 of 1993, the Constitution of South Africa that includes a Bill of Rights (Chapter 30 of the Act)[27]. Paragraph 30 of the Bill of Rights entitles every child under the age of 18 to basic nutrition, shelter, basic health services and social services. In June 1995, the South African Government ratified the 1989 United Nations Convention on the Rights of Children, the idea being to ensure that the rights of children were not violated[28].

The importance of specification of basic health services can now be understood. The assumption of the author is that these are those health services required for survival and adequate functioning, thus including specialised services like neonatal intensive care. The assumption is based on the premises that the government already supplies these services and there should be universal and equal access to care. If the service is available then to make access to neonatal care equal and universal the government has an obligation to expand the service. The alternative is to make the service available to nobody.

From the perspective of macroallocation it is the opinion of the author that neonatal intensive care facilities should be improved. Not only can this opinion be supported by distributive justice but it is also conforms with the governments self-imposed obligations to children as formulated in the Bill of Rights.

References

1. McKneally MF, Dickens BM, Meslin EM, Singer PA. Bioethics for clinicians:13. Resource allocation. Can Med Assoc J 1997;157:163-167.

2. Benatar S. Health care reform in the new South Africa. N Engl J Med 1997;336:891-895.

3. Coughlan FJ. Primary health care organisation in South Africa: some conceptual issues. S Afr J Sociol 1995;26:9-14.

4. Buchanan A. Privatization and just health care. Bioethics 1995;9:220-239.

5. Landman WA, Henley LD. Tensions in setting health care priorities for South Africa's children. J Med Ethics 1998;24:268-273.

6. Eddy DM. What services are basic? JAMA 1991;265:782-790.

7. Veatch RM. What counts as basic care? Private values and public policy. Hastings Centr Rep 1994;2:20-21.

8. Engelhardt HT, Rie MA. Intensive care units, scarce resources, and conflicting principles of justice. JAMA 1986;255:1159-1164.

9. Mariner WK. Rationing health care and the need for credible scarcity: why Americans can't say no. Am J Pub health 1995;85:1439-1445.

10. Anonymous editorial. Structural adjustments and health in Africa. Lancet 1990;335:885-886.

11. Maxwell RJ. Resource constraints and the quality of care. Lancet 1985:936-939.

12. Colman KC. Equity, poverty and health care for all. BMJ(SA Edition) 1997;5:460-464.

13. New B. The rationing agenda in the NHS. BMJ 1996;312:1593-1600.

14. Dubos R. Mirage of Health; Utopias, Progress and Biological change. Harper Colotron Books, New York, 1979.

15. Normand C. Economics, health and economics of health. BMJ 1991;303:1572-1577.

16. Charlton BG. Is inequality bad for national health? Lancet 1994;343:221-222.

17. Kelly MP, Davies JK.. Healthy cities a modern problem or a post-modern solution? In Davies JK, Kelly MP; eds. Healthy Cities: Research and Practice. Routledge, London, 1993.

18. Kelly MP, Charlton BG. A scientific basis for health promotion; time for a new philosophy? Br J Gen Pract 1992;42:223-224.

19. Abel-Smith B. Financing health services in developing countries; the options. UN News on Health Care in Developing Countries 1993;7:8-15.

20. McPake B. User charges for health services in developing countries: a review from the economic literature. Soc Sci Med 1993;36:1397-1405.

21. Einterz E. Reorientating health care in Africa - can the elite believe in equality? World Health Forum 1996;17:261-265.

22. Pinker R. Falling back on charity. BMJ 1996;313:1566.

23. Costello A. Commentary: should mother and child health services in developing countries be free? BMJ (SA edition) 1997;5:441-442.

24. Wright J, Walley J. Assessing health care needs in developing countries. BMJ (SA edition) 1998;7:127-131.

25. Malcolm L. Primary health care and hospital: incompatible organisational concepts? Soc Sci Med 1994;39:455-458.

26. Beauchamp TL, Childress JA. Principles of Biomedical Ethics - Fourth Edition. Oxford University Press, New York; 1994.

27. Act 200 of 1993, the Constitution of South Africa, Bill of Rights (Chapter 30 of the Act.

28. United Nations Convention on the Rights of Children.

Chapter 6

Consent, who should decide?

Fictional autonomy changes guard; parentalism replaces paternalism.

The tension between sanctity-of-life and quality-of-life ideologies, created by life sustaining technology has been legally and ethically settled in favour of the patient's right to self-determination, based on the principle of respect for patient autonomy[1]. The principle of respect for autonomy can be justified by both deontologists and utilitarians. The deontological viewpoint is given by Kant who argues that respect for autonomy is based on the concept that all persons have unconditional worth, as they are sentient and have the capacity to determine their own destiny. To violate an individual's autonomy is to treat them as a means, in accordance with another's goals. Treating persons as a means and not as ends is a fundamental violation of the Categorical Imperative. Mill representing the utilitarian approach argues that the greatest good for the greatest number will be achieved if individuals are allowed to develop according to their own personal convictions, as long as they do not interfere with the personal convictions of others[1].

The moral rule that one should always obtain consent for interventions with patients is derived from the principle of respect for autonomy. The right to self-determination is not lost in the absence of decision-making competence. It is considered appropriate for surrogates to make decisions about life-sustaining technology. There are different standards by which the surrogates may decide for incompetent patients. These include the strong autonomy based pure autonomy standard; the weaker autonomy based substituted judgment standard and the beneficence/non-maleficence based best interest standard[1].

Potentially there are five parties that could act as decision-makers[1,2,3].

1. The patient: According to the principle of respect for autonomy from which the moral rule of taking informed consent is derived consent should be obtained from the patient. Competence is a threshold element or precondition for giving informed consent. Competence judgments serve a gatekeeping role, distinguishing between those whose decisions should be solicited or accepted from persons whose decisions need not or should not be solicited or accepted. Competence for decision making requires the individual to have the capacity to understand the material information, to make a judgment in view of their values, to intend a certain outcome and freely communicate their decision to care givers. In the normal doctor-patient relationship competence is presumed and is seldom challenged in the absence of a conflict of values between doctor and patient.

There are rival standards of competence and it should be remembered that competence judgments and grading are normative. In cases of borderline competence this may lead to moral and legal conflict. The neonate's cognitive development is at the sensory-motor level, sensory stimuli precipitate motor responses without higher mentation. The newborn infant obviously does not fulfill any of the criteria for decision-making competence and is not intellectually or physically competent to make decisions or to give consent.

2. The family: Conventionally the patient's closest family member is the first choice as surrogate. In the case of a neonate, the parents would usually be the primary decision-makers as they engaged in a series of actions that resulted in the birth of the child and are presumed to have the baby's best interests at heart. Possible conflicts of interest include desire for a perfect child, an inability or unwillingness to accept a mentally or neurologically impaired child. Fear of financial burdens, the impact of the impaired child on the stability of the marriage or concern about the impact of the child on other siblings or potential siblings may all influence parental decision making. Parents may also request management that is considered futile and may cause pain and suffering. Requests for futile treatment may be based on parents` religious convictions, fear of impact of the loss of a child on a marriage, the inability to let go or a state of denial. Cognisance must never be lost of the incredible psychological strain that the parents must be under when taking these difficult decisions.

3. Health-care professionals: Historically in the neonatal intensive care unit paternalistic decisions have been made by health-care professionals. This may be the prevailing sentiment in many South African state hospitals, where neonatologists seek refuge behind parental ignorance or perceived parental ignorance.

The principle of respect for patient autonomy has appropriately displaced the doctor as the primary decision-maker in the normal doctor-patient relationship. The primary role of the doctor now is to ensure that informed consent occurs, so as to facilitate the patient's decision-making. In the absence of conflicting principles, respect for patient autonomy has elevated the patient to the role of primary decision-maker.

In cases where the patient is incompetent, however, the doctor retains a fiduciary obligation towards the patient and has an obligation to act as the patient's advocate. This will be discussed below under obligations of the health professionals towards the baby.

4. Institutional ethics committees: In facilities caring for the chronically infirm or aged, where

family members are not available, institutional ethics committees may be called upon as the primary surrogate decision-maker. Unless the preterm neonate has been abandoned, this situation seldom occurs in the neonatal intensive care scenario. In the case of neonatal care institutional ethics committees like the judiciary, may act as independent source of review.

Somewhat removed from the doctor-patient relationship and the emotional atmosphere in the intensive care unit they generate open discussion and debate about issues and may help resolve disagreements between health professionals and parents.

5. The judiciary: On occasions it is necessary to resort to the courts for decision making. This is an expensive route to follow and there is no proof that decisions made are any more satisfactory than the other potential decision-makers. An advantage of the courts is that although the correct decision may not be made procedural justice will be followed.

Legal concerns

Traditionally parents are recognised as the natural surrogate decision-makers for children. This presumption is premised by the notion that the child is not competent to make such complex and far reaching decisions[4]. In South African Law there is an irrefutable presumption that a child under six years of age is incapable of making legally binding decisions[5]. The choice of parents as the primary decision-makers is based on the facts that they bear responsibility for the children and that they are likely to bear the best interests of the child to heart.

Historically this was a right based on the right of ownership; children were seen as the property of their father. In contrast to the previous proprietary situation, the relationship between the parent and child is now seen as a fiduciary relationship. Parents no longer enjoy the absolute right to make decisions. In South Africa the Minister of Health or one of the Minister's surrogates may intervene[5]. The right has almost evolved into a duty. Parents have a duty to maintain, protect and educate their children and from this they have a duty to provide care.

The power of the state has also been transformed from seeing the child as property of the state, towards acting in the best interests of the child. The State will always attempt to follow the principle of perceived best interest.

Ethical concerns

It has been established that the neonate does not have competence for decision making. In the situation of decision-making for incompetent individuals surrogates are expected to make decisions. There are different standards of surrogate decision-making[1,2]. In the strongly autonomy based pure autonomy standard, the explicit autonomous decision of a previously competent patient is respected. The surrogate merely conveys rather than substitutes the now incompetent patient's decisions. In the less strongly autonomy based substituted judgement standard, the surrogate decision-maker makes the decision that the surrogate believes the now incompetent individual would have made under similar circumstances were they competent. Obviously both standards require that the individual was previously competent and the standards differ in whether explicit instructions were left or not. Neonatal decision making incompetence differs substantially from decision-making incompetence of previously competent individuals. Here there is no life history to paint a picture of personal preferences and the infant has never spoken[6]. Another approach has to be taken. Because of an insufficiently developed central nervous system, the neonate has no values or beliefs that are necessary for an individual to have a perspective on their best interests.

Neonatal incompetence is a class of incompetence where individuals have never been competent. Competence and autonomy are not synonymous and the fact that the neonate is not competent to make decisions does not necessarily mean that the neonate is not autonomous. Gillon describes three types of autonomy[7]. Autonomy of thought refers to intellectual activity and thinking for oneself. Autonomy of will is the freedom to decide to do things on the basis of one's deliberation; autonomy of thought is a necessary prerequisite for autonomy of will. Autonomy of action is the freedom to act on the basis of one's deliberation and will. Autonomy of action is dependent on autonomy of thought and autonomy of will. The neonate's cognitive development is at a pre-intellectual sensory-motor phase and the neonate does not have a deliberative process. It would appear, utilising Gillon`s approach, that the neonate is at best a potentially autonomous individual.

The neonate is not only incompetent to make decisions but has never previously been competent, so decision making cannot be extrapolated from the previously competent individual. The neonate is also not autonomous in the true sense of the word. Like the fetus obligations to the neonate have to be understood exclusively in terms of the principles of beneficence and non-maleficence[8,9]. They generate the moral status of the neonate and the obligations it is owed.

The parents have a beneficence and non-maleficence based obligation to the neonate, as they are its moral fiduciaries. They are expected to promote the neonate's best interests and that of the child it will become. Health care workers also have beneficence and non-maleficence based obligations towards the neonate.

The standard of surrogate decision making usually utilised in the never previously competent is the best interest standard[10,11,12]. Concerning neonatal care the term `best interests` appears to be ambiguous to some and criticism has been leveled against it. To have best interests a baby must have interests[13]. A newborn like all other individuals can have an interest not to be wronged in the sense that it should not be used as a means to somebody to satisfy someone else's ends. The child probably has interests in being fed, kept warm and possibly also to be loved and cared for. While the child is conscious in the medical sense the child has no memories of self-consciousness and is probably not orientated towards the future[13]. Given these limitations a newborn cannot be said to have an interest in it's own future existence. Brody considered the notion of the infant's best interests as sensible but unknowable beyond it's interests in nutrition and warmth[14]. We cannot know what an individual's interests are let alone their best interests without knowing a considerable amount about the individual. We kneed to know their plans and desires. Such knowledge is only possible after the parents and others have guided the development of the child.

Alternatively the term `best` may be viewed as the obligation to maximize the net benefit to the patient[6]. The surrogate decision-maker weighs up the potential benefits and burdens of various treatments and alternatives to treatment, including withholding or withdrawing treatment. Under these circumstances the decision process is unquestionably utilitarian in nature. If we interpret best interest standard as maximizing the net benefit to the patient, possibly a better term would be the utilitarian standard of surrogate decision-making. While the moral rule to have informed consent is primarily derived from the principle of respect for autonomy, the utilitarian standard of surrogate decision making is driven by a combination of obligations of the principles of beneficence and non-maleficence.

There can be no autonomy-based interests for the neonate. The assumed interests include food, warmth and not to be harmed. The parents and the health professionals both have beneficence and non-maleficence based obligations to the neonate[8,9]. The life of the newborn are intertwined with that of the family and it is unrealistic to suppose that parents can decide for the newborn without making a choice for the family. For them the baby does not live in isolation. In the doctor-patient relationship, doctors should be primarily concerned with the interests of the patient. Societal and family interests should not be considered except for the effect that these have on the interests of the patient[6]. Utilitarian standards of surrogate decision making are inescapably quality-of-life decisions and normative in nature. It should be stressed to surrogate decision-makers that these quality-of-life decisions should not be made subject to the perceived social value of the individual to the surrogate, but on the perceived value of the life of the person that must live it. Due to the normative nature of the decisions to be made and the different perspectives from which decision making is viewed, there is an inherent tension between the parental and medical decision-makers. It should be remembered that neither the parents nor the health professionals are necessarily unanimous units and there is the potential for moral disagreement between the parents themselves or the different health care workers involved. Balancing the potential outcomes of the utilitarian standard of surrogate decision making is undoubtedly extremely difficult.

For the sake of the thesis the parents and health care workers will be seen as separate, but individually unanimous units (parents as one unit and health care workers as the other), each unit having its own unanimous values and unanimous decisions. Often the parents and medical personnel are in agreement as to what plan of management provides the greatest benefit of goods over harms. Should the balance go clearly in one direction and all parties agree then there are seldom problems. However balancing benefits and burdens are value judgements and there may be conflicting views between the parents and doctors about what is in the best interest of the neonate. Ultimately best interest decisions may have less to do with what is in the child's best interests than the level of comfort that the decision-makers have with one another's decisions. Best interest decisions are seldom questioned unless there is a conflict between decision-makers[15].

Conflicts about treatment decisions usually result from one or a combination of the following factors[6,16]. Firstly there are differing perceptions of the facts. This is understandable considering the degree of prognostic uncertainty. Secondly there are differing emotions and the parents may need time to adjust to the concept of impending death or survival of an impaired infant. Finally differing normative values can play a major role. If either the parents or the doctors have strong ethical foundations in vitalism, this will play a major role in decision making in the presence of possible death. Value decisions become far more varied when morbidity data enter the equation. The perception and values attached to individual morbidity is inherently subjective and will vary between individuals, families and cultures. Conflicts usually revolve around parents refusing what doctors consider to be reasonable care or parents demanding maximal care in the presence of what the doctors consider to be a futile outcome. Both of these problems are discussed in more detail in the chapter on utility and futility.

Most conflicts can be resolved at the bedside using shared decision making where values and motivations for decisions made are openly discussed. It is essential for the doctor to be aware and sensitive to the possible reasons for the conflicts. The medical profession should also take cognisance of the inherent uncertainty of the prognosis and the normative nature of all judgements. It may be necessary for an ethics consultation if available, or the assistance of an institutional ethics committee. Both may be viewed from the parent's perspective as coercive in nature, especially if they are in conflict with the parent's decision. Occasionally resolution can only be found in the courts.

The moral rule requiring consent for medical intervention or non-intervention is derived from the principle of respect for autonomy[1]. If the neonate is not an autonomous individual does this mean that consent is unnecessary? Some may reject Gillon`s definition of autonomy and argue that the patient is indeed autonomous. Some may argue that the principle of respect for autonomy should include pre-autonomous individuals. If individuals that where previously autonomous are entitled to the respect of autonomy based on their previous autonomy, why not extend this respect for autonomy to individuals that subsequently will be autonomous? If respect for autonomy can be extrapolated back in time, why not forward in time also? This temporal extrapolation of respect for autonomy should not be confused with standards of consent.

If we postulate that the neonate is not autonomous is there still an obligation to have informed consent? Legally the answer must be yes[4,5]. Morally if the neonate is not autonomous then the principle of respect for autonomy is fictitious. Beauchamp and Childress feel that the principle of respect for autonomy is not so broad that it can extend to non-autonomous individuals[1]. They do however feel that the principle can be used as a canopy to protect non-autonomous individuals. If the principle of respect for autonomy is rejected in neonatal decision making, moral obligations to the neonate are driven by the principles of beneficence and non-maleficence and tempered by the obligations of distributive justice[8,9]. Parents and health workers adhering to these principles are morally obliged to make decisions for the neonate. In the decision making process both have authority and responsibility. Morally emphasis should be laid on responsible decision-making, while legally emphasis may be on the process of authorization by informed consent.

If there is conflict between parents and caregivers, how should the conflict be resolved? Caregivers need to remember they are not the holders of the absolute truth[16,17]. Independent assessment either by a neutral individual, an institutional ethics committee or the judiciary is necessary. Possibly the best interest standard for the parents should be substituted by the rational parent standard. A rational parent standard would require that the parents demonstrate the ability to prioritize options for their child within the context of their own value system[2]. The absence of a definable value system or the absence of consistent decision making would bring the parents` decision-making capacity into question. The problem is what is a reasonable decision and who should adjudicate the reasonableness of a decision.

The law attempts to define reasonability in terms of what the majority of people would choose under similar circumstances[18]. This may appear straightforward where there are concrete data on mortality rates. Obviously these data run all the risks of extrapolating group outcomes onto an individual. Mortality data can also lead to conflict if either the parents or the doctors have strong ethical foundations in vitalism. Decisions on reasonableness become far more difficult when morbidity data enter the equation. The perception and values attached to individual morbidity is inherently subjective and will vary between individuals, families and cultures.

Treatment and non-treatment decisions for never previously competent incompetent patients is difficult and all we can hope for is imperfect procedural justice[1]. Here the procedure is just but we cannot guarantee the right outcome, as judged by some independent standard. Decisions themselves are normative, however the procedure must be transparent, fair and reliable.

There are basically three counseling approaches. Firstly there is parental compliance, where the parents are coerced to follow the course that the health professional recommend and prescribe. At the opposite end of the spectrum there is an ethic of health professional abdication where the health professional stands aside and abides by whatever decision parents make. In contrast to these two extremes is an ethic of engagement[19,20]. Engagement differs from a good discussion in that all parties in engagement are granted equal status and are assumed to have equal decision making capacity, although using different data sets. Health professionals principally utilize scientific data, while parents use their knowledge of the self. The ethic of engagement recognizes the moral agency of all involved and synthesizes the medical knowledge with the parent's autonomy and insight. Engagement is a movement away from universalism, an approach that takes a stance of distanced objectivity, a right or wrong that applies to everyone. Engagement suggests that the right thing to do is created in the narrative, created by the open dialogue. Decisions are particular and contextual to the case and are not generalisable to other cases. Engagement should not be seen as a turn from universalism to relativism, in which no ethical theories or principles bear any weight and each moral agent renders an acceptable opinion. Engagement is an effort to jointly work out how a particular case contextually relates to ethical theories.

In the engagement model the health professionals do not simply recommend what to do next, as they only have knowledge of objective scientific data and not off the unique and particular views of the family. The family is also not confronted by a myriad of options that they only minimally comprehend. Engagement is a holistic process of assessment and decision making, in which all the data, views and resources of all the moral agents are brought to bear.

The principle of respect for dignity and personhood of the neonate requires a careful assessment of both actual and potential pain and suffering of the infant as well as the potential for pleasure and satisfaction. The assessment should be based on the worth and the goodness of life to the child and not on parental utilitarian considerations such as emotional and financial burdens. Well-being is not static and must frequently be revisited; continuously involving the parents in an on-going assessment of the infant's prognosis is essential.

Cognisance must be taken of parental vulnerability[21,22]. Health professionals in neonatal units deal with these dilemmas regularly. The parents are suddenly and unexpectedly confronted with a totally unanticipated outcome to the pregnancy, the possible imminent death of a small baby or a survivor with sequelae. Parental reaction is often similar to the stages of grief - shock, denial, guilt, sadness and then some degree of adaptation. Health professionals, however, should not underestimate parental abilities, moral agency and sense of responsibility.

Procedural Ethics

When confronted by ethical problems in neonatal care, it is probably advisable to follow certain procedures[22-24].

1. Determine who the surrogate decision-makers are. Both parents and caregivers have moral obligations to the child and both should be involved in decision making. Surrogate decision-makers must give fully informed consent according to the same rigorous requirements necessitated under the informed consent doctrine. In the normal consent taking process competence is usually presumed. Where surrogate decision-making is to be made, medical personnel must be certain of the legal and ethical acceptability as well as the decision-making competence of the surrogate. Beauchamp and Childress have suggested that surrogate decision-makers should have the following qualities[1]. Firstly competence in the sense that they have the ability to make judgements. They should be emotionally stable, which may be difficult under the circumstances. They should have a commitment to the patient's interests and be free from conflicts of interest. They should understand the concept of neonatal best interest and be able to distinguish the concept from their own best interests. The decision-maker should have adequate knowledge and information and this should be based on informed consent.
2. Establish rigorous informed consent. There should be full disclosure and the doctor should explain the benefits and risks of all treatments under consideration as well as all reasonable alternatives, including the option of no treatment. The doctor should volunteer and motivate her recommendations. The decision-maker must demonstrate comprehension of the various choices that have been disclosed and the implications of the various options. The decision-maker should be free from external influences to choose one option over another. Authorization or declining of treatment should be explicit and clear.
3. Consideration of decision, resolution of conflicts if necessary.
4. Authorization of intervention or none intervention. The final step of informed consent is

authorization. Legally authorization is necessary and legally the parents have a presumption towards being allowed to give the authorization. .

5. Transparency. The whole process should be transparent and open to review.

Summary

This chapter examines on what grounds and by who should decision-making occur for the neonate. Although there are numerous ethical approaches, principlism has been chosen, due to its widespread use in medical ethics and easy understanding by the medical profession. It is easily understood by the medical profession due the vertical nature of it's reasoning, which is similar to the vertical deductive nature of diagnostic and therapeutic reasoning.

The argument has been made that the traditional four principles cannot be utilised, as the neonate is at best pre-autonomous. Moral obligations towards the neonate are dependent on the beneficence and non-maleficence obligations of the parents and the caregivers. Both these principles are prima facie and may have to be tempered by distributive justice. The role of distributive justice was argued in the chapter addressing the issue.

Informed consent is a legal if not a moral obligation. A definite moral obligation however is surrogate decision-making on behalf of the neonate. Parents and health-professions have obligations, responsibilities and authority. Neonatal best interests are difficult to define and may reflect negotiation between the decision-makers. Tensions between the parental and health-professionals interpretations of utility and values, serve to protect the neonate.

References

1. Beauchamp TL, Childress JA. Principles of Biomedical Ethics - Fourth Edition. Oxford University Press, New York; 1994.

2. Cooper R, Koch KA. Neonatal and pediatric critical care - ethical decision making. Crit Care Clinics 1996;12:149-164.

3. Moor S. Euthanasia in relation to newborn babies - a comparative study of the legal and ethical issues. Med Law 1996;15:295-317.

4. Schewchuk TR. The uncertain `best interests` of neonates; decision making in the neonatal intensive care unit. Med Law 1995;14:331-358.

5. Personal communication with Mr John Young, attorney at Rooth and Wessels, Pretoria.

6. Peabody JL, Martin GI. From how small is too small to how much is too much? Clin Perinat 1996;23:473-490.

7. Gillon R. Philosophical Medical Ethics. John Wiley and Sons, Chichester, 1985.

8. Chervenak FA, McCullough LB. Perinatal ethics; a practical method of analysis of the obligations of the mother to the fetus. Obstet Gynecol 1982;66:442-448.

9. Harman CR. Moral obligations in perinatology: problems with systemized approaches. Semin Perinat 1987;11:240-243.

10. Poland RL. Russel BA. The limits of viability; ethical considerations. Semin Perinat 1987;11:257-261.

11. Kraybill EN. Ethical issues in the care of extremely low birth weight infants. Semin Perinat 1998;22:207-215.

12. Morrison JL, Rennie JM. Clinical, scientific and ethical aspects of fetal and neonatal care at extremely preterm periods of gestation. B J Obstet Gynaecol 1997;104:1341-1350.

13. Stevenson DK, Goldworth A. Ethical dilemmas in the delivery room. Semin Perinat 1998;22:198-206.

14. Brody H. In the best interests. Hast Centr Rep 1998;18:37-38.

15. Tyson J. Evidence based ethics and the care of premature infants. The Future of Children 1995;5:1-20. Http://www.futureofchildren.org

16. Pinkerton JAV, Finnerty JJ, Lombardo PA, Rorty MV, Chapple H, Boyle RJ. Parental rights at the birth of a near-viable infant, conflicting perspectives. Am J Obstet Gynecol 1997;177:283-288.

17. Hammerman C, Kerrbuth E, Lavie O. Parental vulnerability; decision making in the critically ill neonate: cultural background versus individual life experiences. J Med Ethics 1997;23:164-169.

18. Clark FI. Making sense of State v Messenger. Pediatrics 1996;97:579-583.

19. Pierce SF. Neonatal intensive care - decision making in the face of prognostic uncertainty. Nurs Clin N Am 1998;33:287-297.

20. Sexson WR, Overall SW. Ethical decision making in perinatal asphyxia. Clin Perinat 1996;23:509-518.

21. Rogers AC. Vulnerability, health and health care. J Adv Nurs 1997;26:65-72.

22. Pellegrino ED. The anatomy of clinical judgements in perinatology and neonatology: a substantive and procedural framework. Semin Perinat 1987;11:202-204.

23. Steinberg A. Decision making and the role of surrogacy in withdrawal or withholding of therapy in neonates. Clin Perinat 1998;25:779-791.

24. Logan RL, Scott PJ. Uncertainty in clinical practice; implications for quality and costs of health care. Lancet 1996;347:595-598.

Chapter 7

Uncertainty and how decisions should be made

Plato's absolutist thinking and Descartes mathematician's perspective has influenced medicine's romance with certainty[1]. Traditional medical education fosters doctors with the notion that uncertainty is a manifestation of ignorance, weakness or failure. To avoid these stigmata students study hard to acquire knowledge and technological skills, thus providing themselves with what they perceive to be a reassuring cloak of certainty.

Uncertainties in medical practice tend to be obscured or ignored. Patients tend to be unnecessarily overinvestigated in the doctor's desire to reduce diagnostic uncertainty to a minimum. Patient's personal, social and psychological concerns that all intensify uncertainty, tend to be downplayed.

There is an urge to resolve uncertainty through selection and simplification. Selective focus is placed on those aspects of disease most amenable to investigation or intervention, allowing doctors to ignore and avoid the more uncertain aspects of medical problems. Unfortunately these untidy areas of uncertainty, selectively ignored by the medical profession, often encompass the patients` main concerns. Simplification is best exemplified by the extrapolation of outcomes from research, directly to individual patients. Protocols and guidelines are other manifestations of simplification. Repeated denial of uncertainty leads to forms of dogmatic authoritarianism. A prime example of dogmatic authoritarianism being the formulation of the guideline denying infants of less than 1000g admission to a neonatal intensive care unit. Proceduralism follows for all those that then follow this guideline. They have a procedure to follow that tells them what to do and absolves them of any moral responsibility.

Those making the final decision are faced with uncertainty[1]. This uncertainty entails:

1. Technological uncertainty: Technological innovations devised to improve patient outcome and reduce clinical uncertainty, have only contributed to its increase.
2. Quantitative uncertainty: The uncertainties inherent in medical practice are the result of clinical variability and an enormous range of interchanges between a host of factors.
3. Qualitative uncertainty: Despite the shortcomings medicine has been able to give an approximation of the quantitative risk that these infants have. A qualitative risk is exponentially more difficult. One must remember that unlike others that may have been normal and then disabled, these infants are disabled from birth.
4. Moral uncertainty: Who should decide? what are the infants best interests?, what should be considered harm and how should resources be distributed? Uncertainty generated by the fact that there are few right or wrong answers.

5. Legal uncertainty ie passive euthanasia.
6. Holistic uncertainty: It is important that the doctor should take cognisance of factors beyond the direct medical problem. The should include personal, social and psychological concerns of the patient and the patient's family. Addressing these issues tends to increase rather than diminish uncertainty.

The accelerating pace of change within society has intensified all of the above.

Resolution of uncertainty

Karl Popper proposed the idea of propensities in which the world is not seen as a predictable causal machine, but as an environment continually offering new possibilities with many factors affecting outcomes[2]. In the medical context, outcomes can be influenced by many factors, ranging from the individual patient's response to treatment to external influences within the environment and society, as well as advances in medical knowledge, skills and technology.

There are three approaches that can be utilised to address uncertainty in clinical practice[3-7].

Limiting care based on probability of survival - the statistical prognostic approach. This approach seeks to define, by gestational age, birth weight or other criteria, a group of infants for whom the outcome is considered futile. For those whose outcome is considered futile, they are denied admission to neonatal intensive care. This strategy seeks to minimise the number of infants that die slow deaths or who live with profound handicaps and is willing to sacrifice some potentially intact survivors. This approach does not consider the death of an individual baby that may have been saved as the worst error. A characteristic of this strategy is that it accepts the probability that it will fail to save some infants that would be individually, socially and economically worthy, in order to avoid saving those lives that would be accompanied by great cost, both short term in the neonatal intensive care and long term in rehabilitation and remedial education. This conservative approach minimises the number of infants that survive neonatal intensive care with profound impairment, but denies a chance of life for other infants that may have been able to survive with little or no impairment. Fewer infants should also die in the neonatal intensive care unit as those infants most likely to die are denied access to the facility. This approach tends to flatter a neonatal intensive care's morbidity and mortality statistics.

What should the fate be of those infants denied admission to neonatal intensive care? In essence there are two options; active or passive euthanasia[8,9]. The first option, acting deliberately to cause direct and deliberate death is based on the assumption that one of the primary roles of the doctor is to avoid pain and suffering. Active killing of defective or even normal newborn infants is not a new phenomenon. In antiquity, killing defective new-borns was normal practice, and in Sparta it was a legal obligation. Aristotle claimed that defective new-borns had no right to live. Plato said that even normal children of socially undesirable parents should be killed. In Rome defective new-borns were killed, as were normal children so as to reduce family size. In ancient Arabic societies it was an obligation to kill defective new-borns. All major religions and most contemporary modern societies strongly oppose the active killing of any neonates.

Neonates denied admission to neonatal intensive care should be given comfort care[10,11]. Comfort care is basic supportive care such as warmth, oxygen and appropriate hydration and feeding. All should be accorded human dignity and receive love and attention. If possible their parents should spend as much time as possible with them. In essence comfort care is passive euthanasia as there is the deliberate withholding of life sustaining treatment.

The method is just in withholding or providing care for similar infants and is socially aware of resource allocation[12,13,14]. Having a statistical threshold for initiating therapy undoubtedly makes these decisions psychologically easier for medical personnel. It is psychologically more difficult to begin and then terminate treatment than never to begin it. For those that accept the concept of a threshold value, they can take psychological and moral refuge behind it. They did the best that they could; they were not allowed to do any more. Decision-makers are relieved of the psychological burden of having to make difficult decisions.

A positive aspect about the conservative approach is that it minimises the expenditure of resources on infants that are judged to have little or no chance of survival. There is a tendency to utilise this approach in developing countries. The role of distributive justice under these circumstances has been discussed in detail under distributive justice.

This approach is only as good as the statistics upon which it relies. At the extremes these statistics would appear to be relatively reliable, for more borderline cases the data are less compelling. The problems associated with the interpretation of data and the extrapolation from generalisations was argued in the chapter on prognosis.

Another problem with the a priori approach is that some infants survive despite the withholding of treatment and by the time that life-sustaining treatment is initiated they have sustained significant neurological insults that may have been avoided with immediate treatment[10]. Failing to attempt to save lives of neonates on the border of viability, means that there is no opportunity to refine and improve on neonatal technology to save small infants in the future. The whole history of neonatal intensive care has been one of gradual modifications that decrease the iatrogenicity of technology and allow smaller and smaller infants to survive without handicapping sequelae.

The a priori approach also minimises the role of parents as the decision to decline admission of the neonate to intensive care is beyond their control. Exclusion of parental decision making is not inevitable. However, as in units that have a cut-off, parents could be informed of their babies' statistical chances of death or severe disability and they could participate in the decision making process. Time constraints however may preclude parental decision making if this approach is followed.

The 'wait until certainty' approach: Here all liveborn babies are aggressively resuscitated and provided with necessary intensive care from the moment of birth. Intensive care measures are not withdrawn unless the infant improves sufficiently to take over the vital functions in question or dies. Barring iatrogenic complications this approach offers all infants the greatest opportunity of survival. This approach ensures that all errors are in one direction - on the side of life. It resembles the criminal law approach, which holds that it is better to acquit ninety-nine guilty defendants than to convict one innocent person. This approach is often followed by the Americans, many of whom believe implicitly in the concept that everyone deserves a chance. Once resuscitation is initiated and the baby admitted to the intensive care unit, fear of litigation is often the reason that treatment is continued until imminent death.

Erring on the side of life is in general an appropriate principle, even though in individual cases some may consider prolonging of a hopeless existence as a greater tragedy. The wait until certainty approach is a policy that works on the perceived worst outcome, death, and avoids it at all costs. This type of policy may be referred to as a maximum strategy.

The maximum strategy has numerous advantages. As doctors will err only on the side of life, each neonate's right to life is respected to the greatest possible extent. Management policy is set in advance, psychologically doctors will never have to agonise over whether or not to initiate treatment, whether to stop treatment nor wonder afterwards whether they gave up to soon, denying the chance to a baby that may have survived. Parents will also never have to live with the guilt that they had to participate in the decision that allowed their child to die; they did everything possible. Treatment will only be terminated if the child gets better or if death or certainty of death intervenes. The approach yields a comforting degree of certainty. The maximum strategy does have the advantage that care is given to all and thus ongoing improvements in the outcome of very small infants will continue.

A maximum strategy is obviously the approach to follow in complete ignorance of potential probabilities. The less that is known about the baby's prognosis, the more compelling the policy. However, in the presence of more information and when the chances of severe impairment increase, the maximum strategy will at some point clash with the substantive principle that parents can legitimately view the outcome worse than death. Parents while initially elated with the idea of doing everything to save the infant may become disillusioned as the reality of the outcome dawns on them. The maximum approach disenfranchises them. The maximum strategy will inevitably maximise the number of infants that have protracted deaths over days, weeks or months, as well as those that survive severely impaired. It seems appropriate when knowledge about an infant's outcome is absent, but increasingly inappropriate when the data suggest that the child's risk of profound handicap is extremely high. A drawback of this approach is that it ignores any reasonable medical basis for predicting that severe impairment is highly probable if not certain.

Likewise the approach pays insufficient cognisance to any suffering that neonatal intensive care may cause. The neonate's existence in intensive care often consists of painful and invasive medical procedures and innumerable crises. As the chances of a successful outcome wain, it becomes more and more difficult to justify forcing the child to endure the care and for the parents to watch it.

The approach denies the ethical complexity of the situation. Those that follow it will be increasingly governed by technology instead of employing it like a tool. Likewise the role of the parents is reduced to that of onlooker since the decisions as long as there is uncertainty have been predetermined.

Resources are not limitless and in the South African public situation where there is a shortage of neonatal intensive care beds, a bed occupied by an infant that eventually will not survive or if it does survive will be severely impaired, is a bed that an infant with a better chance of survival will not be able to occupy[14,15,16].

Provisional intensive care for all – the individualised prognostic approach: For this approach all neonates will be aggressively resuscitated and the baby will be admitted to the intensive care unit, unless following counseling there has been a justified prior request by the parents not to resuscitate the infant and that life support should be withheld. This type of request by the parents would only be justified at the extremes of birth weight or gestational age where futility can be anticipated. For all infants resuscitated and admitted to neonatal intensive care continuation of support would be contingent on decisions made by further assessment of the infant and after thorough deliberation with the parents. This individualised prognostic strategy is typical of the British approach. The reassessment can be time limited as with severe asphyxia, where the decision to cease further resuscitation may be made 20 to 30 minutes after delivery if resuscitation has not been successful at that point in time. In the case of extremely preterm infants there may be no time limited and the infant's condition is regularly re-evaluated.

Due to varying neonatal care and differing illness severity in neonates it was necessary to develop measures of disease severity so as to be able to compare care between different neonatal intensive care units. Numerous systems have been developed. These include the Paediatric risk of mortality (PRISM), Score for neonatal acute physiology (SNAP) and Clinical risk index for babies (CRIB)[17-20]. Scoring systems that quantify risk have an important role to play in research, planning and clinical audit. They facilitate more reliable comparison of disease severity to outcome and allow monitoring of quality of care between units and in the same unit over time. They are substantially more accurate than single parameters like birth weight or gestational age in predicting mortality.

Like birth weight or gestational age, predicting outcome using these systems also makes use of the observation, induction, and predictive deduction methodology. The universalisation problem also persists as the individual's outcome is compared to a group of infants that had a similar response to neonatal intensive care. If the methodology used to obtain and extrapolate data is identical to that used in birth weight or gestational age, why should predictive scoring systems be more acceptable? Firstly these limitations are present in all situations where statistics are used. When choosing a new car, information about the reliability of the car is based on the reliability of the manufacturer and past models. If one wishes to purchase a reliable car it is reasonable to use this information, however one must also be alert to the fact that the car purchased is different from all the other cars. Secondly it is ethically appropriate to make management decisions based on clinical judgement[19]. Research has shown that empirically derived scoring systems project probabilities more accurately and more consistently than clinical judgement. They incorporate the experience of numerous experts and bolster the judgement of less experienced neonatologists.

Unlike birth weight and gestational age the scoring systems are not used as gatekeepers, but to assess the response of the neonate to intensive care and from this to predict outcome[17-20]. There are two advantages. Firstly they are based on the individual infant's response to intensive care. The second advantage is that prognosis is based on multiple objective criteria as opposed to a single objective criterion like birth-weight or a single semi-objective criterion like gestational age.

Scoring systems will tend to recalibrate over time. Predictions made of a group of patients a few years earlier may overestimate the risk of death or disability, owing to technological advances. It is important to continuously validate scoring systems.

The individualised prognostic strategy avoids the extremes of treating all infants until the outcome is certain or withholding all treatment as the neonate falls into a group where the prognosis is perceived to be grim. Neither type of mistake - sacrificing a potentially intact infant or saving a severely impaired one is necessarily to be avoided at all costs. Doctors employing this strategy err in both directions, though they seek through clinical observation to minimise each type of mistake. They optimistically initiate treatment in borderline cases to give the babies a chance. However while there is an ethical reason to initiate treatment, there is no compelling reason not to withdraw treatment should the child's prognosis subsequently be found to be poor. Ethically there is no distinction between not initiating and withdrawing treatment[9,13,21,22].

The individualised prognostic strategy allows the parents to be actively involved in decision making as the decisions have not been predetermined. It allows a wide, perhaps too wide variation in treatment decisions. Sometimes treatment will yield an infant so devastatingly disabled that death may have seemed more preferable. Likewise decision-makers may withdraw treatment from a baby that possibly could have involved relatively intact. Doctors and parents will agonise and may later regret or be tormented by their decisions. Their agonising however is only commensurate with the tragic nature of their dilemmas. The alternative approaches that limit the agonisation may be inappropriate for exactly that reason. The individualised prognostic strategy allows confusion, uncertainty and errors. When medical uncertainty leads to moral uncertainty, it seems preferable, albeit harder, to confront these dual ambiguities rather than to bury them under either statistical criteria or moral certitude.

The individualised prognostic strategy seems to be the best. It is consistent with contemporary clinical practice, sensitive to the parent's role and unconstrained either by an oversimplistic vitalism, excessive fear of legal liability, or an emotionally appealing but ethically untenable distinction between withholding and withdrawing treatment. The strategy both recognises and reflects the complex nature of these dilemmas. The approach accepts the uncertainty of prognosis, that there is more than one possible outcome and many choices.

Flaws include those inherent in the informed consent process, particularly in surrogate decision making. Parents can decide based on their own best interests and not the best interests of the child. Health care providers may fail to fully disclose all the risks, benefits or treatment alternatives including no treatment other than comfort care. They may impose their own biases during the disclosure process; potentially being more pessimistic for socially disadvantaged couples.

The distinction between the individualised prognostic strategy and the wait until certainty strategy is the degree of certainty that has to be sought. The degree of certainty that allows the parents to opt to terminate treatment or that requires the overriding of their wishes.

While absolute prognostic certainty is elusive, the outcomes of infants at the extremes of the spectrum appear to be relatively stable. Despite new technologies and innovations that continue to push back the boundaries of viability, cases exist in which all the known evidence lead the decision-makers to conclude that aggressive intervention is futile. In cases of probable futility it is morally legitimate to withhold or withdraw therapy[23]. In contrast to the cases of probable futility, cases also exist where prevailing knowledge and experience suggest an excellent outcome. It is that group of babies between the extremes where uncertainty prevails.

References

1. Logan RL, Scott PJ. Uncertainty in clinical practice: implications for quality and costs of health care. Lancet 1996;347:595-598.

2. Popper KR. A world of Propensities. Thoemmes Antiquarian Books, London, 1996.

3. Rhoden NK. Treating baby Doe: the ethics of uncertainty. Hastings Centr Rep 1986;16:34-42.

4. Kraybill EN. Ethical issues in the care of extremely low birth weight infants. Semin Perinat 1998;22:207-215.

5. Goldsmith JP, Ginsberg HG, McGettigan MC. Ethical decisions in the delivery room. Clin Perinat 1996;23:529-550.

6. Penticuff JH. Defining futility in neonatal intensive care. Nurs Clin N Am 1998;33:339-352.

7. Kinlaw K. The changing nature of neonatal ethics in practice. Clin Perinat 1996;23:417-428.

8. Moor S. Euthanasia in relation to newborn babies - a comparative study of legal and ethical issues. Med Law 1996;15:295-317.

9. Steinberg A. Decision making and the role of surrogacy in withdrawing or withholding therapy in neonates. Clin Perinat 1998;25:779-790.

10. Sexson WR, Overall SW. Ethical decision making in perinatal asphyxia. Clin Perinat 1996;23:509-518.

11. Sidhu H, Heasley RN, Patterson LL, Halliday HL, Thompson W. Short-term outcome of infants refused perinatal intensive care. BMJ 1989;299:647-649.

12. American Academy of Pediatrics. Ethics and the care of critically ill infants and children. Pediatrics 1996;98:149-152.

13. Harris J. Are withholding and withdrawing therapy always morally equivalent? - a reply to Sulmasy and Sugarman. J Med Ethics 1994;20:223-224.

14. Ho HK. Priorities in neonatal care in developing countries. Singapore Med J 1996;37:424-427.

15. Lipman J, Lichtman AR. Critical care in Africa. Crit Care Clin 1997;13:255-265.

16. Smith J, Barnes JM. Neonatal intensive care - an undervalued discipline with a real place in South African medicine. S Afr Med J 1994;84:797-798.

17. Richardson DK, Tarnow-Mordi WO, Escobar GJ. Neonatal risk scoring systems. Can they predict mortality and morbidity? Clin Perinat 1998;25:591-611.

18. The International Neonatal Network. The CRIB (clinical risk index for babies) score: a tool for assessing initial neonatal risk and comparing performance of neonatal intensive care units. Lancet 1993;342:193-198.

19. Luce JM, Wachter RM. The ethical appropriateness of using prognostic scoring systems in clinical management. Crit Care Clin 1994;10:229-241.

20. Teres D, Lemeshaw S. Why severity models should be used with caution. Crit Care Clin 1994;10:93-110.

21. Beauchamp TL, Childress JA. Principles of Biomedical Ethics - Fourth Edition. Oxford University Press, New York; 1994.

22. Campbell AGM, McHaffie. Prolonging life and allowing death: infants. J Med Ethics 1995;21:339-344.

23. Pierce SF. Neonatal intensive care. Decision making in the face of prognostic uncertainty. Nurs Clin N Am 1998;33:287-297.

Chapter 8

Advocate and gatekeeper or advocate or gatekeeper?

In contemporary medicine there is a constant tension between the traditional commitment to the patient on the one hand and the awareness that resources are finite on the other[1]. This tension is an unfortunate reality of medicine. The tension, far from being relieved by modern technological medicine is in fact exacerbated by it. The demands of patient advocacy confront the constraints of limited budgets. In response, to constrain the growth of medical expenditure, doctors are now asked to serve simultaneously as the patient's agent for maximum health and as society's agent of cost containment. There is increasing pressure on doctors to serve two masters, the patient and society[2,3]. For the patient the doctor is expected to act as advocate, and for society as gatekeeper. Can the doctor serve two masters simultaneously?

Advocacy

The etymological root of the word `advocacy` can be traced to the 15th century and means `pleading for support`. The linguistic routes stem from Latin `Ad` being `to` and `Vocare` meaning `to call`. In the legal profession the role is clearly defined and determined with the advocate as one whose profession is to plead the cause of anyone in a court of law; a counselor or counsel. The United Kingdom Central Council for Nursing considers advocacy as promoting and safeguarding the well being and interests of the patient[4]. Others perceive the advocate's role as supporting and protecting the rights and interests of the patient[5].

The fully competent autonomous individual should be able to protect their own interests and rights. The assumption that advocacy is required in health care implies that there is a reduction of patient autonomy and that the patient's interests or rights may not be protected. In the normal patient-doctor relationship, where the patient is competent the patient may be disadvantaged, if only by virtue of their condition[5]. The principle of beneficence asserts an obligation to help others further their important and legitimate interests. Rules derived from the principle include protecting and defending others, preventing harm occurring or removing conditions that will cause harm to others as well as helping persons with disabilities and protecting and defending the rights of others. From this we can see that advocacy is justified by the principle of beneficence. It has been established that the autonomy of the preterm neonate is diminished. Thus the principle of beneficence now obliges the doctor to act as an advocate for the neonate

The core condition most frequently cited as demanding an advocacy action is patient vulnerability. If one accepts the premise that the vulnerable are entitled to advocacy, one has to decide; who is vulnerable? In health care there are many reasons why a patient may be considered vulnerable[5]. The mere presence of disease places the autonomous patient as being vulnerable to the condition. The poor and those at the extremes of age are usually considered to be most vulnerable. Few would disagree that the small preterm neonate is especially vulnerable. If vulnerability is a prerequisite for advocacy then the small preterm neonate also qualifies according to that criterion.

Advocacy is justified by the principle of beneficence. The principle of beneficence requires positive action or intervention. It is impossible to extend beneficence to everyone and hence beneficence is an imperfect obligation. Specific beneficence is directed at specific parties such as children, friends and patients, while general beneficence is directed beyond these special relationships to embrace all persons. Specific beneficence is based on special moral relationships, while general beneficence is usually derived from some form of moral reciprocity. Specific beneficence may be extended partially, to those with whom we have a special relationship. Health care professionals - a broad term that includes doctors, have an obligation of beneficence to their patients which is over and above the requirements of general beneficent duty owed to society in general[2,3]. When dealing with an individual patient, as is the case when considering a baby for neonatal care, specific beneficence should take preference over general beneficence. Under these conditions the doctor has an obligation of advocacy for the patient.

In caring for an individual patient the doctor should do everything to benefit that particular patient without regard to cost to society[2,3]. In caring for the individual patient, the doctor must act solely as the patient's advocate against the apparent interests of society as a whole, if necessary. An analogy can be drawn with the role of a lawyer defending a client against a criminal charge. The attorney is obligated to use all ethical means to defend the client, regardless of the cost of prolonged legal proceedings or even the possibility that a guilty person may be acquitted through skillful advocacy.

Society also benefits if all doctors follow this principle. All patients can be expected to be treated humanely, decently and fairly. In a just society 'the physician who withholds care that it is within his power to give because he judges it wasteful to provide to a particular person breaks faith with his patient'[2]. A just society must have a group of professionals whose sole responsibility as health care practitioners is to their patients as individuals. The distinction must be made here between doing everything technically possible and doing what the doctor believes is best. Doing everything technically possible is a vitalist approach as opposed to doing what the doctor thinks is right.

The last two decades have witnessed a wealth of nursing literature devoted to the subject of patient advocacy[6]. The nursing literature tends to view patient advocacy to be the unique role of the nursing profession. Some even contend that the need for patient advocacy is due to medical staff transgressions. The basis for the assumption of a unique role for the nurse as advocate is unclear as is any evidence to suggest that nurses are any more virtuous than doctors in this respect. On the contrary in the third world the nurse may be the least virtuous individuals in the health care team. There is also no evidence that patients want or indeed have requested the nursing profession to represent their views or protect their rights. The hierarchical structures and authoritarian-style management makes it extremely difficult for the nurse to have the autonomy and influence necessary for the patient advocate. It may be argued that due to their power and authority in the medical hierarchy the doctor may make a more effective advocate[7].

Gatekeeping?

The term gatekeeper is metaphorical in nature[8]. The implication being there is a gate and there is something worth having beyond the threshold of the gate. As there is something worth having beyond the gate's threshold there are a group of individuals that wish to pass through the gate. It is the responsibility of the gatekeeper to decide who qualifies to pass through the gate and gain the benefits. Gatekeeping by implication is concerned with distribution, in this case the distribution of goods. Distribution of goods by a virtuous gatekeeper would be fair and according to standards derived from the principle of distributive justice.

By inference gatekeeping must refer to microallocation decisions. The macroallocation decision has already been made; the benefits are available; however, the applicants exceed the vacancies. Extrapolation of the metaphor of gatekeeper to neonatal intensive care facilities in South African public health facilities is easy to follow. Neonatal intensive care beds are available; however they are in short supply and applicants exceed vacancies. Somebody has to decide who may and may not be admitted. Pressure is applied to neonatal intensive care medical staff to decide which patients should be admitted to the limited facilities and hence the staff are expected to act as gatekeepers.

While a virtuous gatekeeper would distribute goods according to the principles of distributive justice any justification for the role of gatekeeping would have to be derived from general beneficence, - beneficence directed beyond the individual patient to other, future and potential patients. The advocate-gatekeeper tension is not a tension between two-prima facie principles, beneficence and distributive justice, but between specific and general beneficence. It is the feeling of the author that when confronted by the individual patient that specific beneficence supercedes general beneficence.

By interpreting specific beneficence to supersede general beneficence it becomes obvious that it is not possible for the doctor to serve the dual masters of advocacy and gatekeeper[2,3]. The doctor's obligations are primarily to the individual patient. When practicing clinical medicine the doctor cannot serve two masters. The master must be the individual patient. The doctor's duty to the individual patient is not an antiquated concept but one that preserves respect, confidence and the proper functioning of the medical profession. If the medical profession becomes more interested in societal concerns than the patient's own needs, the drive for finding reversible illness, a correct diagnosis, or new potentially expensive new technologies will lessen or disappear.

The argument does not imply that in caring for individual patients doctors should disregard the escalating costs of medical care[9,10,11]. To help resolve the conflict between the roles of social agent and patient advocate one resolution is to eliminate waste from the system. To use cost effective treatment. Doctors can help control costs by choosing the most economic ways to deliver optimum care for the patients.

Resource allocation:

Resources belong to society and therefore society expects a certain order in their allocation and utilization. It should be society and not the individual doctor that makes decisions to limit the availability of expensive but effective care[12,13,14]. Society and not the health care personnel must make the decisions and create the guidelines limiting the availability of life-sustaining treatments. If society, through their politician's decide to ration health care then the politician must take responsibility for the decision.

Society controlling the distribution of society's resources is not without it's problems.

Societal decisions about the correct allocation of resources are highly subjective and open to bias. An example may be the distribution of health care to the elderly. Cost-benefit analysis tends to discriminate against the elderly and may turn this age discrimination into health policy. A large part of increasing health costs is due to expenditure on health care for older people and the majority of most people's health care expenses occur in the last six months of their lives[15]. Negative attitudes towards aging and the elderly may influence our willingness to cover these costs. Society may discourage doctors to utilize effective expensive treatment in the health care of the elderly.

Any intervention for the good of the community must still be weighed up against a possible loss of personal autonomy. It should be remembered that the most murderous and totalitarian regimes have often acted in the so-called interest of the greater public good.

Society as the owner of resources is an extremely broad concept. Who decides on behalf of society?[16] The decisions are almost always made by politicians. Even in a democracy it is doubtful whether the decisions made by the politicians necessarily reflect the wishes of the people. Politicians often make decisions based on politics, especially when it comes to the distribution of resources. They are more likely to tend to distribute resources to voters than non-voters. Those most vulnerable to health rationing are the politically disenfranchised and this often includes the poor and those at the poles of the age spectrum.

The concept `the greatest good for the greatest number` assumes a utilitarian health policy. If such a policy were embraced a significant number of individuals would suffer. While the concept of `the greatest good for the greatest number` seems theoretically appealing, in reality society continues to care for the severely handicapped, the chronically ill and recidivists, at considerable expense. Society does not view the greater good in purely utilitarian terms, but in a mixture of competing philosophies. While society demands the wise expenditure of its resources, it is aware of its responsibilities to all its members.

Society owns the resources and should be responsible for their distribution[16]. What is the role of the doctor in this process? Based on general beneficence doctors have a duty towards the community and should assist in setting of policies as experts. More importantly however based on both general and specific beneficence the role of doctors is to lobby vigorously in the political arena for the resources needed for high-quality health care for the population at large and for individual patients.

Doctors should also play a role in educating the public so that they understand that doing everything is not necessarily the best for a patient. Our problem may lie not in our failure to cure disease but in our success; the unbridled pursuit of health jeopardizes both our personal lives and other important social goals, such as assurance of adequate education and housing. Callahan has suggested that calls for restraint should not be made to the medical profession as to the public[17]. Most proposals to cut costs of medical care call for changes in supply, especially services supplied by doctors. Callahan argues that the greater challenge is to change the demand for medical care, by urging the public to be realistic about the role of medicine in improving quality of life. Callahan calls for more caring and less curing to help counter the image of herd hearted arbitrary limits on care.

The analogy between a lawyer representing a defendant and a doctor representing a patient was made earlier. This is not an unreasonable approach as long as individual patients and doctors understand that in the court analogy there is a jury and a judge, probably best represented by society and politicians respectively[14]. The judge (in this case politicians) has to make a decision after having heard the evidence and doctors and patients are ultimately bound by that decision. Politicians should be held responsible for their decisions made on behalf of society and if society is unhappy with their decision making they should be replaced. For this to happen clear policy has to be formulated and made available to society and politicians have to stand by their decisions made[18].

Summary:

The patient-society, advocacy-gatekeeper tension is a reflection of the tension between specific and general beneficence. Decisions about who should be admitted to neonatal intensive care units are microallocation decisions, taken at the level of the individual patient. At this level specific beneficence obligations should outweigh general obligations of beneficence. The doctor should be the patient's advocate and not society's gatekeeper.

Resources belong to society and society should adjudicate their distribution. Although doctors may advise society, the eventual decisions and responsibility for them should be taken by society or society's representatives. Due to problems with society's decision making process and the fact that the system can always be improved doctors have an advocates role to vigorously lobby for the resources needed for quality health care.

References

1. Fuchs VR. The `rationing` of medical care. N Engl J Med 1984;311:1572-1573.

2. Levinsky NG. The doctor's master. N Engl J Med 1984;311:1573-1575.

3. Spring CL, Eidelman LA, Steinberg A. Is the physician's duty to the individual patient or society? Crit Care Med 1995;23:618-620.

4. UKCC. Exercising Accountability. UKCC 1989.

5. Willard C. The nurse`s role as patient advocate: obligation or imposition? J Adv Nurs 1996;24:60-66.

6. Mallik M. Advocacy in nursing - a review of the literature. J Adv Nurs 1997;25:130-138.

7. Berman S. Training pediatricians to become advocates. Pediatrics 1998;102:632-636.

8. Pearn JH. Gatekeeping and assisted reproductive technology. The ethical rights and responsibilities of doctors. MJA 1997;167:318-320.

9. Ubel PA, De Kay ML, Baron J, Asch DA. Cost-effective analysis in setting of budget constraints: is it equitable? N Engl J Med 1996;334:1174-1177.

10. Garner P, Kale R, Dickson R, Dans J, Salinas R. BMJ 1998;318:531-535.

11. Kleinert S. Rationing of health care - how should it be done? Lancet 1998;352:1244-1246.

12. Hope T, Hicks N, Reynolds DJM, Crisp R, Griffiths S. Rationing and the health authority. BMJ 1998;318:1067-1069.

13. Warnock M. Ethics, ideology and rationing in the NHS. J R Col Med 1998;32:118-120.

14. Klein R. Puzzling out priorities. Why we must acknowledge that rationing is a political process. BMJ 1998;317:959-960.

15. Lewis PA, Charnay M. Which of two individuals do you treat when only their ages are different and you can't treat both? J Med Ethics 1989;15:28-32.

16. Beauchamp TL, Childress JA. Principles of Biomedical Ethics - Fourth Edition. Oxford University Press, New York; 1994.

17. Callahan D. What kind of life: the limits of medical progress. Simon and Schuster, New York, 1990.

18. Knaus WA. Rationing, justice and the American physician. JAMA 1986;255:1176-1177.

Chapter 9

Synthesis

The underlying theme of the dissertation is resource allocation and the accompanying decision making. Medical resource allocation, specifically neonatal intensive care is addressed. Essentially resource allocation occurs at both the macro- and microallocation levels in neonatal intensive care. At the macroallocation level decisions are made as to the necessity for neonatal intensive care beds and if they are necessary, where they should be situated. Microallocation decisions are concerned with allocation of specific beds to specific patients.

The consensus statement of the 10th Priorities in Perinatal Care Conference addresses both of these levels. Reading the consensus statement macroresource-allocators may decide to budget for neonatal beds based on the requirements of neonates weighing more than 1000g. For the individual patient 1000g has become the threshold weight for neonatal intensive care admission.

Prior to addressing resource allocation it is necessary to address the appropriateness of the consensus statement. The consensus statement of the 10th Priorities in Perinatal Care Conference is explicit in advising the restriction of neonatal facilities to neonates weighing more than 1000g. The implication being that birthweight alone is an appropriate prognostic criterion and that 1000g is the appropriate threshold weight. The chapter on prognosis has shown that birthweight alone is an inappropriate criteria and a threshold of birthweight of 1000g is extremely inappropriate, as many babies considerably lighter can survive without neurological sequelae.

As regards macroallocation it was noted that there is no shortage of medical resources and if there is a resource scarcity, money is the scarce resource. Socio-economic factors have more to do with population health than health care and improving the health of the nation is probably more dependent on wealth generation rather than wealth redistribution. Government has an important role to play in stimulating wealth generation as well as procuring funding for health care.

The present public health system is inequitable and does not provide for the needs of the population. Buchanan's nine elements for a fair and just health care system are advocated. Despite the new emphasis on primary health care, neonatal intensive care can be justified by a number of factors. Cost-utility analysis shows neonatal intensive care to be extremely cost effective. The Bill of Rights advocates basic health care for children, the understanding of the author being that basic health care being that required for adequate functioning and survival. Finally if we believe in equity of health care and neonatal care facilities are available for some, they should either be available to all that need them or to none at all.

At present admission to neonatal intensive care, using the statistical prognostic approach is based on the probability of survival, albeit the threshold weight being inappropriate. Microallocation is relatively simple; if a bed is available and if the weight of the neonate exceeds 1000g then the neonate may be admitted. Obviously if there is no bed available the baby cannot be admitted. Alternatively if the baby weighs less than 1000g then admission is denied. Resource allocation is governed by a rule derived from the consensus statement. If we accept the rule then resource allocation and decision making is easy to understand simple, objective and dependent on birthweight. Psychologically those involved in microallocation decisions may take refuge behind the rules.

It has been argued that in the presence of prognostic uncertainty the individual prognostic approach allowing provisional intensive care admission for all neonates, would be more appropriate. If all neonates are initially admitted then decision making becomes more complex. Issues such as who should decide and on what grounds should decisions are made become important. Neonates cannot decide for themselves and obligations to the neonate are dependent on the principles of beneficence and non-maleficence. Both the parents and the health care workers have these obligations to the neonate. Although difficult to determine, decisions should be made in the perceived best interests of the neonate.

Finally doctors have an obligation of advocacy to their patients that exceeds general beneficence to society as a whole. Doctors and interest groups should act as patient advocates and not society's gatekeeper.

As can be seen it is the opinion of the author that the consensus statement is questionable. Both the use of birthweight to determine prognosis and the 1000g threshold if birthweight is used, are inappropriate. Additionally the profession's and particularly the individual doctor's obligation of specific beneficence to the patient should exceed the obligation of general beneficence to society. The consensus statements should be used in advocacy rather than gatekeeping roles.

One can only speculate why a group of individuals dedicated to the wellbeing of pregnant patients and their progeny issued the consensus statement. They are confronted daily with the reality of demand for neonatal intensive care beds exceeding availability. Utilizing birthweight as the decisive criteria was probably an attempt to introduce a single, simple objective criteria that can be easily evaluated, and allow equitable access of neonates to units. The choice of the threshold weight must have been selected more on historical than scientific grounds.

Appendix A:

Tables showing survival for different gestational ages and birthweights.

Table 1

Year	23 weeks	24 weeks	25 week	26 weeks	Reference
1986-1990	12/32 (37%)	28/75 (37%)	54/90 (60%)	72/113 (64%)	Ferrara
1988-1990		6/14 (43%)	9/19 (47%)	18/23 (78%)	Grey
1988-1991	6/40 (15%)	19/34 (56%)	31/39 (79%)		Allen
1988-1991	2/28 (7%)	13/40 (32%)	11/44 (25%)	35/62 (56%)	Holtrop
1989-1991	0/21 (0%)	5/11 (46%)	14/22 (64%)	18/35 (72%)	Katz
1990-1991	3/15 (20%)	8/18 (44%)	14/22 (64%)	27/40 (68%)	Hagan
1985-1992	1/ 9 (12%)	13/28 (45%)	26/55 (47%)	43/80 (54%)	Rennie
1991-1993	1/37 (3%)	27/97 (28%)	38/104 (36%)	73/132 (55%)	Bohim
1987-1994	11/33 (33%)	31/65 (48%)	35/74 (47%)	57/84 (68%)	Morrison
1990-1994		18/37 (49%)	31/41 (76%)	45/54 (83%)	Kilpatrick
Total	**36/215 (17%)**	**144/368 (39%)**	**223/450 (50%)**	**325/536 (61%)**	
95% CI	12%-22%	33%-45%	44%-56%	55%-67%	

Table 1 shows the probability of survival at different gestational ages. As can be seen at a gestational age of 25 weeks 50 % of neonates can be expected to survive.

Table 2

Year	23 weeks	24 weeks	25 weeks	26 weeks	Reference
1983		0/1 (0%)	2/6 (33%)	2/17 (17%)	Wariyer
1982-1986		2/5 (40%)	1/2 (50%)	2/8 (25%)	Weissman
1884-1986			6/9 (66%)	12/31 (39%)	Johnson
1984-1987			2/7 (29%)	2/1 (11%)	Eg-Anderson
1985-1987		2/3 (60%)	0/7 (0%)	2/6 (33%)	Ruys
1983-1989	6/9 (66%)	16/43 (37%)	25/77 (32%)		Synnes
1985-1992	2/2 (100%)	3/13 (23%)	8/27 (30%)	10/43 (23%)	Rennie
1986-1990	7/12 (58%)	8/28 (29%)	16/54 (30%)	27/32 (32%)	Ferrara
1980-1993		3/8 (38%)	12/46 (26%)	16/73 (22%)	Cooke
Total	**15/23 (65%)**	**34/101 (34%)**	**72/235 (31%)**	**69/263 (26%)**	
95% CI	34%-96%	23%-45%	24%-38%	20%-32%	

Table 2 shows the probability of major sequelae in survivors. At a gestational age of 24 weeks the majority of survivors are unimpaired.

Table 3

Year	<500g	500-599g	600-699g	700-799g	800-899g	900-999g	Reference
1983-1994	18/382						Sauve
1991-1992		9/56*	27/72*	40/83*	78/108*	93/143*	VICSG
1991-1992		106/321	176/346	243/374	330/407	355/403	Fanarof
1994-1995		103/322	250/410	296/394			Tyson
Total	18/382 (5%)	218/966 (31%)	453/828 (68%)	579/851 (68%)	408/515 (79%)	448/546 (82%)	

* Survival at 2 years (others are survival to discharge from hospital)
VICSG = Victoria Infant Collaborative Study Group

Table 3 shows the probability of survival at different birthweights. Sixty eight percent of babies weighing more than 600g can be expected to survive.

Table 4

Year	500-749g	750-999g	References
1987-1988	43/127	21/39 (54%*)	van Steenkiste
1989-1991	58/177	148/227	Meadow
1985-1994	77/173	169/266	Morrison
1991-1992	382/869	793/982	Fanaroff
Total	**490/869 (36%)**	**1131/1514 (75%)**	

This unit subsequently reported a 76% survival for these neonates.

Table 4 shows the probabilities of survival in two groups of birthweight.

Appendix B:

Combined Bibliography (In alphabetical order and not according to appearance)

1. Abel-Smith B. Financing health services in developing countries; the options. UN News on Health Care in Developing Countries 1993;7:8-15.
2. Act 200 of 1993, the Constitution of South Africa, Bill of Rights (Chapter 30 of the Act.
3. Alderson P. The importance of theories in health care. BMJ 1998;317:1007-1010.
4. Allen MC, Donohue PK, Dusman AE. The limit of viability – neonatal outcome of infants born at 22 to 25 weeks` gestation. N Engl J Med 1993;329:1597-1601.
5. Almond B. Philosophy, medicine and its technologies. J Med Ethics 1988;14:173-178.
6. American Academy of Pediatrics. Ethics and the care of critically ill infants and children. Pediatrics 1996;98:149-152.
7. Anonymous editorial. Clinical practice, statistics, and philosophy. Lancet 1982;911-912.
8. Anonymous editorial. Structural adjustments and health in Africa. Lancet 1990;335:885-886.
9. Avery GB. Futility considerations in the neonatal intensive care unit. Sem Perinat 1998;22:216-222.
10. Beauchamp TL, Childress JA. Principles of Biomedical Ethics - Fourth Edition. Oxford University Press, New York; 1994.
11. Benatar S. Health care reform in the new South Africa. N Engl J Med 1997;336:891-895.
12. Berman S. Training pediatricians to become advocates. Pediatrics 1998;102:632-636.
13. Bregman J. Development of outcome in very low birthweight infants: current statistics and future trends. Ped Clin N Am 1998;45:673-691.
14. Brody H. In the best interests. Hast Centr Rep 1998;18:37-38.
15. Buchanan A. Privatization and just health care. Bioethics 1995;9:220-239.
16. Callahan D. What kind of life: the limits of medical progress. Simon and Schuster, New York, 1990.
17. Campbell AGM, McHaffie. Prolonging life and allowing death: infants. J Med Ethics 1995;21:339-344.
18. Chalmers AF. What is this thing called science?. Open University Press. Bristol 1982.
19. Charlton BG. Is inequality bad for national health? Lancet 1994;343:221-222.
20. Chervenak FA, McCullough LB. Perinatal ethics; a practical method of analysis of the obligations of the mother to the fetus. Obstet Gynecol 1982;66:442-448.
21. Clark FI. Making sense of State v Messenger. Pediatrics 1996;97:579-583.
22. Colman KC. Equity, poverty and health care for all. BMJ(SA Edition) 1997;5:460-464.
23. Cooper R, Koch KA. Neonatal and pediatric critical care - ethical decision making. Crit Care Clinics 1996;12:149-164.
24. Cooper RL, Goldenberg RL, Creasy RK, DuBand MB, Davis RO, Entman SS, James JD, Cluver BA. A multicenter study of preterm birth weight and gestational age-specific neonatal

mortality. Am J Obstet Gynecol 1993;168:78-84.

25. Costello A. Commentary: should mother and child health services in developing countries be free? BMJ (SA edition) 1997;5:441-442.
26. Coughlan FJ. Primary health care organisation in South Africa: some conceptual issues. S Afr J Sociol 1995;26:9-14.
27. Drummond MF. Discussion: Torrance`s utility approach to measuring health related quality of life. J Chron Dis 1987;40:601-603.
28. Dubos R. Mirage of Health; Utopias, Progress and Biological change. Harper Colotron Books, New York, 1979.
29. Dunbar R. The trouble with Science. Faber and Faber London 1995
30. Eddy DM. What services are basic? JAMA 1991;265:782-790.
31. Edelstein L: In: Ancient Medicine; Selected Papers of Ludwig Edelstein. Temkin O, Temkin CL (eds). Johs Hopkins Press, Baltimore;1967.
32. Edwards A, Prior L. Communication about risk – dilemmas for general practitioners. Br J Gen Pract 1997;47:739-742.
33. Einterz E. Reorientating health care in Africa - can the elite believe in equality? World Health Forum 1996;17:261-265.
34. Emmanuel EJ, Emmanuel LL. The economics of dying - the illusion of cost saving at the end of life. N Engl J Med 1994;330:540-544.
35. Engelhardt HT, Rie MA. Intensive care units, scarce resources, and conflicting principles of justice. JAMA 1986;255:1159-1164.
36. Finer NN, Barrington KJ. Decision-making in delivery room resuscitation: a team sport. Pediatrics 1998;102:644-645.
37. Fuchs VR. The `rationing` of medical care. N Engl J Med 1984;311:1572-1573.
38. Garner P, Kale R, Dickson R, Dans J, Salinas R. BMJ 1998;318:531-535.
39. Gillon R. Philosophical Medical Ethics. John Wiley and Sons, Chichester, 1985.
40. Goldsmith JP, Ginsberg HG, McGettigan MC. Ethical decisions in the delivery room. Clin Perinat 1996;23:529-550.
41. Greaves D. What is medicine?: towards a philosophical approach. J Med Ethics 1979;5:29-32.
42. Hack M, Fanaroff AA. Outcomes of extremely immature infants – a perinatal dilemma. N Engl J Med 1993;329:1649-1650.
43. Hack M, Klein NK, Taylor HG. Long-term development outcomes of low birth weight infants. The Future of Children 1995;5:1-20.
44. Hammerman C, Kerrbuth E, Lavie O. Parental vulnerability; decision making in the critically ill neonate: cultural background versus individual life experiences. J Med Ethics 1997;23:164-169.

45. Harman CR. Moral obligations in perinatology: problems with systemized approaches. Semin Perinat 1987;11:240-243.
46. Harris J. Are withholding and withdrawing therapy always morally equivalent? - a reply to Sulmasy and Sugarman. J Med Ethics 1994;20:223-224.
47. Ho HK. Priorities in neonatal care in developing countries. Singapore Med J 1996;37:424-427.
48. Hodgkin P. Medicine, postmodernism, and the end of certainty: Where one version of the truth is as good as another, anything goes. BMJ 1996;313:1568-1569.
49. Hope T, Hicks N, Reynolds DJM, Crisp R, Griffiths S. Rationing and the health authority. BMJ 1998;318:1067-1069.
50. Kelly MP, Charlton BG. A scientific basis for health promotion; time for a new philosophy? Br J Gen Pract 1992;42:223-224.
51. Kelly MP, Davies JK.. Healthy cities a modern problem or a post-modern solution? In Davies JK, Kelly MP; eds. Healthy Cities: Research and Practice. Routledge, London, 1993.
52. Kinlaw K. The changing nature of neonatal ethics in practice. Clin Perinat 1996;23:417-428.
53. Klein R. Puzzling out priorities. Why we must acknowledge that rationing is a political process. BMJ 1998;317:959-960.
54. Kleinert S. Rationing of health care - how should it be done? Lancet 1998;352:1244-1246.
55. Knaus WA. Rationing, justice and the American physician. JAMA 1986;255:1176-1177.
56. Kraybill EN. Ethical issues in the care of extremely low birth weight infants. Semin Perinat 1998;22:207-215.
57. Landman WA, Henley LD. Tensions in setting health care priorities for South Africa's children. J Med Ethics 1998;24:268-273.
58. Lane DA. Utility, decision, and quality of life. J Chron Dis 1987;40:585-592.
59. Levinsky NG. The doctor's master. N Engl J Med 1984;311:1573-1575.
60. Lewis PA, Charnay M. Which of two individuals do you treat when only their ages are different and you can't treat both? J Med Ethics 1989;15:28-32.
61. Lindely DV. Making decisions. London: John Wiley, 1971.
62. Lipman J, Lichtman AR. Critical care in Africa. Crit Care Clin 1997;13:255-265.
63. Logan RL, Scott PJ. Uncertainty in clinical practice: implications for quality and costs of health care. Lancet 1996;347:595-598.
64. Luce JM, Wachter RM. The ethical appropriateness of using prognostic scoring systems in clinical management. Crit Care Clin 1994;10:229-241.
65. Magee B, Milligan M. On Blindeness. Oxford University Press, Oxford, 1995.
66. Magee B. Popper. Fontana Press. London, 1985.
67. Malcolm L. Primary health care and hospital: incompatible organisational concepts? Soc Sci Med 1994;39:455-458.

68. Mallik M. Advocacy in nursing - a review of the literature. J Adv Nurs 1997;25:130-138.
69. Mariner WK. Rationing health care and the need for credible scarcity: why Americans can't say no. Am J Pub health 1995;85:1439-1445.
70. Mason J, Drummond M, Torrance G. Some guidelines for use of cost effectiveness league tables. BMJ 1992;306:570-572.
71. Maxwell RJ. Resource constraints and the quality of care. Lancet 1985:936-939.
72. McKneally MF, Dickens BM, Meslin EM, Singer PA. Bioethics for clinicians:13. Resource allocation. Can Med Assoc J 1997;157:163-167.
73. McPake B. User charges for health services in developing countries: a review from the economic literature. Soc Sci Med 1993;36:1397-1405.
74. Mitchell RG. Objectives and outcomes of perinatal care. Lancet 1985:931-933.
75. Moor S. Euthanasia in relation to newborn babies - a comparative study of the legal and ethical issues. Med Law 1996;15:295-317.
76. Morrison JL, Rennie JM. Clinical, scientific and ethical aspects of fetal and neonatal care at extremely preterm periods of gestation. B J Obstet Gynaecol 1997;104:1341-1350.
77. Muraskas J, Bhola M, Tomich P, Thomasma D, McDonald R. Neonatal viability: pushing the envelope. Pediatrics 1998;101:1095-1096.
78. Muraskas JK, Myers TF, Lambert GH, Anderson CL. Intact survival of a 280g infant: an extreme case of growth retardation with normal cognitive development at two years. Acta Paediatr 1992;382:16-20.
79. Muraskas JK, Myers TF, Lambert GH, Anderson CL. Survival of a 280 gram infant. N Engl J Med 1991;324:1598-1599.
80. Neil N, Sullivan SD, Kessler DS. The economics of treatment for infants with respiratory distress syndrome. Med Dec Making 1998;18:44-51.
81. New B. The rationing agenda in the NHS. BMJ 1996;312:1593-1600.
82. Normand C. Economics, health and economics of health. BMJ 1991;303:1572-1577.
83. Oxford English Dictionary. Clarendon Press, Oxford;1980.
84. Peabody JL, Martin GI. From how small is too small to how much is too much? Clin Perinat 1996;23:473-490.
85. Pearn JH. Gatekeeping and assisted reproductive technology. The ethical rights and responsibilities of doctors. MJA 1997;167:318-320.
86. Pellegrino ED. The anatomy of clinical judgements in perinatology and neonatology: a substantive and procedural framework. Semin Perinat 1987;11:202-204.
87. Penticuff JH. Defining futility in neonatal intensive care. Nurs Clin N Am 1998;33:339-352.
88. Personal communication with Mr John Young, attorney at Rooth and Wessels, Pretoria.
89. Pierce SF. Neonatal intensive care - decision making in the face of prognostic uncertainty. Nurse Clinics N Am 1998;33:287-297.

90. Pinker R. Falling back on charity. BMJ 1996;313:1566.

91. Pinkerton JAV, Finnerty JJ, Lombardo PA, Rorty MV, Chapple H, Boyle RJ. Parental rights at the birth of a near-viable infant, conflicting perspectives. Am J Obstet Gynecol 1997;177:283-288.

92. Poland RL. Russel BA. The limits of viability; ethical considerations. Semin Perinat 1987;11:257-261.

93. Popper KR. A world of Propensities. Thoemmes Antiquarian Books, London, 1996.

94. Reuss ML, Gordon HR. Obstetric judgements of viability and perinatal survival of extremely low birthweight infants. Am J Pub Health 1995;85:362-366.

95. Rhoden NK. Treating baby Doe: the ethics of uncertainty. Hastings Centr Rep 1986;16:34-42.

96. Richardson DK, Tarnow-Mordi WO, Escobar GJ. Neonatal risk scoring systems. Can they predict mortality and morbidity? Clin Perinat 1998;25:591-611.

97. Robinson R. Economic evaluation and health care: cost-utility analysis. BMJ 1993;307:859-862.

98. Rogers AC. Vulnerability, health and health care. J Adv Nurs 1997;26:65-72.

99. Rogowski J. Cost-effectiveness of care for very low birth weight infants. Pediatrics 1998;102:35-43.

100.Russell B. History of Western Philosophy. Routledge London 1946

101.Schewchuk TR. The uncertain `best interests` of neonates; decision making in the neonatal intensive care unit. Med Law 1995;14:331-358.

102.Schneiderman LJ, Jecker NS, Jonsen AR. Medical futility; its meaning and ethical implications. Ann Intern Med 1990;112:949-954.

103.Schwartz WB, Gorry GA, Kassirer JP, Essig A. Decision analysis and clinical judgement. Am J Med 1973;55:459-472.

104.Sexson WR, Overall SW. Ethical decision making in perinatal asphyxia. Clin Perinat 1996;23:509-518.

105.Shaup AHP, Wolf H, Bruinse HW, de Ouden AL, Smolders-de Haas H, van Ertbruggen I, Treffers PE. Influence of obstetric management on outcome of extremely preterm growth retarded infants. Arch Dis Child 1997;77:F95-F99.

106.Sidhu H, Heasley RN, Patterson LL, Halliday HL, Thompson W. Short-term outcome of infants refused perinatal intensive care. BMJ 1989;299:647-649.

107.Sisson JC, Schoonmaker EB, Ross JC. Clinical decision analysis; the hazard of using additional data. JAMA 1976;49:149-164.

108.Smith J, Barnes JM. Neonatal intensive care - an undervalued discipline with a real place in South African medicine. S Afr Med J 1994;84:797-798.

109.Spring CL, Eidelman LA, Steinberg A. Is the physician's duty to the individual patient or society? Crit Care Med 1995;23:618-620.

110.Steinberg A. Decision making and the role of surrogacy in withdrawal or withholding of therapy in neonates. Clin Perinat 1998;25:779-791.

111.Stevenson DK, Goldworth A. Ethical dilemmas in the delivery room. Semin Perinat 1998;22:198-206.

112.Stolz JW, McCormick MC. Restricting access to neonatal intensive care; effect on mortality and economic savings. Pediatrics 1998;101:344-362.

113.Taitz T, Clow S. Effect of the legislative definition of the terms `stillbirth` and `viable` a medicolegal impasse. S Afr Med J 1988;73:240-241.

114.Tamas R. The Passion of the Western Mind. Pimlico London 1996

115.Tee GS. Cost utility analysis of taxane therapy. Am J Health Syst Pharm 1997;54:11S-15S.

116.Teres D, Lemeshaw S. Why severity models should be used with caution. Crit Care Clin 1994;10:93-110.

117.Testa MA, Simonson DC. Assessment of quality of life outcomes. N Engl J Med 1996;334:835-840.

118.The International Neonatal Network. The CRIB (clinical risk index for babies) score: a tool for assessing initial neonatal risk and comparing performance of neonatal intensive care units. Lancet 1993;342:193-198.

119.Torrance G. Utility approach to measuring health-related quality of life. J Chron Dis 1987;40:593-600.

120.Tudehope DI. Economic evaluation in medicine. J Paediatr Child Health 1997;33:185-186.

121.Tyson J. Evidence based ethics and the care of premature infants. The Future of Children 1995;5:1-20. Http://www.futureofchildren.org

122.Ubel PA, De Kay ML, Baron J, Asch DA. Cost-effective analysis in setting of budget constraints: is it equitable? N Engl J Med 1996;334:1174-1177.

123.UKCC. Exercising Accountability. UKCC 1989.

124.United Nations Convention on the Rights of Children.

125.van Peursen CA. The Strategy of Culture. North-Holland Publishing Company, Amsterdam 1974.

126.Vansteenkiste MAL, Pattinson RC, Kirsten GF. The role of obstetric factors in determining fetal viability. S Afr Med J 1992;81:508-511.

127.Vas R, Vidyasgar D, Winegar A, Peterson P, Spellacy WN. Perinatal factors influencing the outcome of 501 to 1000g newborns. Clin Perinatol 1986;13:267-284.

128.Veatch RM. What counts as basic care? Private values and public policy. Hastings Centr Rep 1994;2:20-21.

129.Wainer S, Khumalo H. Attitudes of mothers, doctors, and nurses toward neonatal intensive care in a developing society. Pediatrics 1993;91:1171-1175.

130.Warnock M. Ethics, ideology and rationing in the NHS. J R Col Med 1998;32:118-120.

131.Willard C. The nurse's role as patient advocate: obligation or imposition? J Adv Nurs 1996;24:60-66.

132.Williams A. Economics of coronary artery by-pass grafting. BMJ 1985;291:326-329.

133.Wolf EJ, Vintzileos AM, Rosenkrantz TS, Rodis JF, Salafia CM, Pezzullo JG. Do survival and morbidity of very-low-weight infants vary according to the primary pregnancy complication that results in preterm delivery? Am J Obstet Gynecol 1993;169:1233-1239.

134.Worthington D, Davis LE, Grausz JP, Sobocinski K. Factors influencing survival and morbidity with very low birth weight delivery. Obstet Gynecol 1983;62:550-555.

135.Wright J, Walley J. Assessing health care needs in developing countries. BMJ (SA edition) 1998;7:127-131.