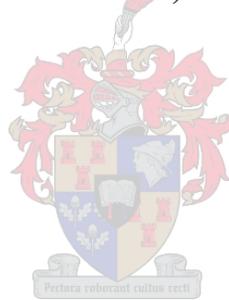


ETHICAL ISSUES IN PRE-ECLAMPSIA: HURRY UP AND WAIT

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DECLARATION

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SUMMARY

Pre-eclampsia is a common and dangerous condition of pregnancy. During clinical care the sensitive obstetrician will frequently recognise moral ambiguity and ethical conflicts. It is important to understand the pertinent issues and find ways of resolving them.

Counselling is an important element of modern medicine. In deciding which counselling model to apply, clinicians must consider many variables including the particular clinical scenario, strength of evidence, and the justifiable limits of paternalism and autonomy in a position of shared responsibility. Couples have a moral right to procreate even when the pursuit of pregnancy involves significant risks. However, with their understanding of care ethics as well as rights ethics, informed women are well placed to negotiate the extremes of these positions when deciding whether to risk a pregnancy or not. The concept of the “fetal patient” is a helpful one. An autonomous woman may choose to confer or deny this status to her pre-viable fetus, while obstetricians must balance autonomy- and beneficence-based obligations to the pregnant woman with beneficence-based obligations to her fetus.

Maternal behaviour that harms the fetus and future child is categorised as maternal-fetal conflict. However, any pregnant woman is morally required to avoid harming the fetus, if this can be done without sacrificing her own important interests. The term non-compliance implies a hierarchical nature in the doctor-patient relationship. This reduces patient agency, erodes trust and conflicts with informed choice. Although sometimes justified, this “label” generally does more harm than good.

Expectant management of early pre-eclampsia recognises that neonatal intensive care is an expensive and limited resource. The ultimate goal of expectant management remains the safety of the mother and the delivery of a live infant who will not require intensive and prolonged neonatal care. This judicious use of neonatal intensive care improves distributive justice but by

consenting to expectant management as an inpatient, the pregnant woman voluntarily restricts her freedom. The decision is morally undergirded by the value accorded to the viable fetus and the scientific evidence informing the decision. When an extremely preterm, growth restricted fetus requires delivery, resuscitation may become an issue for consideration. The distinction between withholding resuscitation in such cases, or initiating but later withdrawing care is morally irrelevant. Categories of optional and obligatory treatments are more helpful, but perinatologists must determine treatment thresholds through understanding the relevant data and ethics issues.

Finally, women do not lose their rights when they become terminally ill. When an undelivered woman is declared brain dead following complications of pre-eclampsia, her doctors and family must formulate clear plans for her and her living fetus. She must still be treated with respect and her right to die with dignity not forgotten. Extension of somatic support to optimise the outcome of her fetus can be supported ethically provided that the fetus is at the threshold of viability, the support is not prolonged (distributive justice), advanced level support is available with a successful outcome likely, and that doctors and family are in clear agreement.

OPSOMMING

Pre-eklampsie is ‘n algemene en gevaarlike toestand van swangerskap. Die verloskundige met ‘n fyn waarnemingsvermoë sal dikwels morele dubbelsinnigheid en etiese konflik tydens kliniese sorg erken. Dit is belangrik om die kernaspekte te verstaan en maniere te vind om dit op te los.

Berading is ‘n belangrike komponent van moderne geneeskunde. Tydens besluitneming oor watter model van berading toegepas moet word, moet klinici ‘n aantal veranderlikes teen mekaar opweeg insluitend die spesifieke kliniese senario, sterkte van die getuienis, die geregverdigde perke van paternalisme en outonomie in ‘n posisie van gedeelde verantwoordelikheid. Die egpare het ‘n morele reg om voort te plant selfs wanneer die verlange na swangerskap betekenisvolle risiko’s inhou. Vrouens wat goed ingelig is, het die vermoë om die uiterstes van etiek van sorg en regte teen mekaar op te weeg wanneer hulle besluit om die risiko van swangerskap te loop. Die konsep van “fetus as pasiënt” kan wel tot verdere besluitneming bydra. Die outonome vrou mag self besluit of die fetus daardie status het. Aan die ander kant moet die verloskundige outonomie en goedwilligheid- (“beneficence”) gebaseerde verpligtinge teenoor die swanger vrou opweeg teen die goedwilligheid-gebaseerde verpligting teenoor haar fetus. Moederlike gedrag wat die fetus en toekomstige kind skend, word as ‘n moeder-fetus konflik beskou. Enige swanger vrou is egter moreel verplig om nie die fetus skade te berokken nie, mits dit gedoen kan word sonder die prysgawe van haar eie noodsaaklike belange. Die term “nie-inskiklikheid” (“non-compliance”) impliseer hiërargie in die dokter-pasiëntverhouding. Hierdie hiërargie doen afbreuk aan die besluitneming van die pasiënt, ondermyn vertrouwe en bots met ingeligte keuses. Alhoewel besluitneming op grond van hiërargies-gebaseerde gesag soms geregverdig is, veroorsaak hierdie kategorisering gewoonlik meer kwaad as goed.

Afwagtinge hantering van vroeë pre-eklampsie gaan van die standpunt uit dat neonatale intensiewe sorg ‘n duur en skaars hulpbron is. Die uiteindelige doel van afwagtinge hantering bly die veiligheid en gesondheid van die ma en die verlossing van ‘n lewendige baba wat nie

verlengde intensiewe- en neonatale sorg benodig nie. Hierdie oordeelkundige gebruik van neonatale sorg bevorder distributiewe geregtigheid, maar wanneer sy toestemming gee tot afwagterende behandeling as binnepasiënt, beperk die swanger vrou vrywilliglik haar vryheid. Hierdie besluit word moreel ondersteun deur die waarde wat aan die lewensvatbare fetus toegevoeg word en die wetenskaplike gronde waarop die besluit berus. Wanneer 'n erge voortydse, groeivertraagde fetus verlossing benodig, word ressussitasie soms iets wat oorweeg moet word. Die onderskeid tussen die weerhouding van ressussitasie in sulke gevalle en die onttrekking van sorg waar dit aanvanklik begin is, is moreel irrelevant. Kategorieë van opsionele en verpligte behandelings is meer behulpsaam, maar perinatoloë moet die behandelingsdrempels bepaal deur die relevante data en etiek te verstaan.

Laastens, vroue verloor nie hul regte wanneer hulle terminaal siek word nie. Wanneer die komplikasies van pre-eklampsie breindood van die vrou veroorsaak voor die verlossing van haar baba, moet haar dokters en familie duidelike planne vir die hantering van haar en haar fetus ontwikkel. Sy moet nogsteeds met respek behandel word en haar reg om met waardigheid te sterf, mag nie uit die oog verloor word nie. Verlenging van die ondersteuning van lewensfunksies om die uitkoms van haar fetus te verbeter, kan eties ondersteun word, mits die fetus na aan lewensvatbaarheid is, die ondersteuning nie te lank duur nie (distributiewe geregtigheid), gevorderde ondersteuning beskikbaar is met 'n goeie kans vir suksesvolle uitkoms en dat die dokters en familie ten volle saamstem.

DEDICATION

Both Kant and Aristotle insisted on the duty of self-improvement. In so doing, I have presumed upon the good will of my wife Heather, and my sons Jonathan and Justin. I wish to dedicate this work to them.

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I wish to express my gratitude to my supervisor Professor Anton van Niekerk as well as the members of his department. In addition, I thank Stellenbosch University and my medical colleagues for their support.

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CHAPTER ONE: INTRODUCTION

1.1 Pre-eclampsia in context

Pre-eclampsia is a heterogeneous, pregnancy specific, hypertensive disorder which occurs in 2-5% of pregnancies (Kenneth et al., 2010; Petit & Brown, 2012). Although the aetiology is multifactorial and still not completely understood, a key component is inadequate placentation in the first trimester and defective trophoblast infiltration of the spiral arteries in the second trimester. Through different pathophysiologic pathways such as immune maladaptation to paternal antigens, the process leads to exaggerated systemic inflammation affecting the maternal vascular endothelium, maternal organs and the placenta (Redman et al., 1999). Thus the clinical findings of pre-eclampsia can manifest either as a maternal syndrome, a fetal syndrome or both (Sibai, 2008).

Pre-eclampsia and other hypertensive disorders of pregnancy are leading causes of maternal and perinatal morbidity and mortality both in developed and developing countries. The World Health Organisation estimates that at least one woman dies every seven minutes from hypertensive disorders of pregnancy (von Dadelszen & Magee, 2008). In South Africa and the United Kingdom, pre-eclampsia and other hypertensive disorders of pregnancy have had a persistent and strong association with maternal mortality (Saving Mothers 2008-2010; Saving Mother's Lives, 2011). Complications of pre-eclampsia also constitute important causes of severe acute maternal morbidity in South Africa (Pattinson et al., 2003; Hall et al., 2006). Pre-eclampsia exacts a toll on the fetus and neonate as well. Hypertensive diseases of pregnancy have been shown to be important causes for delivery of very low-birth weight babies and perinatally related losses in South Africa (Odendaal et al., 2003; Taliep et al., 2010).

The duration of normal pregnancy is generally accepted as nine months, but because periods of weeks, or even days can become critical in terms of outcomes, obstetric specialists and maternal-fetal sub-specialists refer to gestation in terms of weeks (w) and days (d). Normal pregnancy

lasts 40w and one week spans e.g. 39w0d – 39w6d. The terms fetus and baby are used interchangeably here but both refer to the undelivered child. Viability is defined where necessary. After birth, reference is made to the neonate or child. While it is not necessary to discuss the classification of pre-eclampsia in detail, in this thesis, it is usually graded into mild and severe forms (von Dadelszen et al., 2003). More recently certain authors have emphasized the gestational age at presentation, sub-dividing the condition into early- (< 34w) and late-onset pre-eclampsia (\geq 34w0d). Early onset pre-eclampsia is almost always severe and being the more dangerous form for the mother and baby, such cases are usually referred to specialised centres (Hall et al., 2006; van der Merwe et al., 2010).

The clinical course of women with early onset, severe pre-eclampsia may be associated with progressive deterioration of the maternal and fetal conditions. Thus, because delivery is the only definitive way of arresting and reversing (curing) this pregnancy-associated disease, there is broad agreement on delivery (aggressive management – *hurry up*) in the presence of multi-organ dysfunction, fetal distress or once a gestation of 34w0d has been reached (Hall et al., 2000). Once pre-eclampsia has developed, delivery is always in the best interests of the mother, thus the beneficent doctor would always want to deliver the baby. On the other hand, delivery at early gestations holds particular dangers for the baby being associated with high perinatal mortality and morbidity resulting from prematurity, as the most important factor for survival of a healthy baby is gestational age (Derham et al., 1989). At the threshold of viability, careful prolongation of the pregnancy (expectant management – *wait*), under the care of tertiary specialists, by periods as short as several days to a week can make a significant difference in the perinatal outcome (Hall et al., 2000a). Ultimately the potential benefits for the baby must be balanced against the potential dangers to the mother. Expectant management of carefully selected patients with early onset, severe pre-eclampsia has been shown to be safe for the mother and beneficial for the baby (Hall et al., 2000; Hall et al., 2000a; Hall et al., 2006). These findings have since been replicated in developed countries such as France (Haddad et al., 2004) and endorsed widely (Frias & Belfort, 2003), yet other experts still regard the magnitude of maternal risks associated with

expectant management as unclear (Steegers et al., 2010) highlighting one of several areas of professional, moral decision making in the clinical management of pre-eclampsia.

The author of this dissertation has been managing women with pre-eclampsia at a tertiary referral hospital for more than 25 years and has led research on the same condition for 17 years. In 1999 he obtained his doctorate at Stellenbosch University entitled “Expectant management of early onset, severe pre-eclampsia” (Hall, 1999). With this level of exposure to the clinical management of pre-eclampsia I have become acutely aware of many sensitive, even vulnerable “areas” where ethics and clinical practice impinge on each other. This thesis will address such areas in more-or-less chronological fashion, beginning with dilemmas that arise prior to pregnancy, then from the start to the end of pregnancy and finally, relevant issues that persist long after the pregnancy has passed. The morally astute clinician will certainly benefit by being mentally prepared for the various ethical dilemmas that pre-eclampsia will present to him or her. In most cases the initial management decisions will require considered, expeditious execution - *hurry up!* After this initial evaluation and stabilisation period, some pregnancies will need to be delivered (*hurry up*) while for others that are remote from term (term = 37-41w), and where the mother and fetus are stable, the more prudent course will be to offer expectant management – *wait!*

1.2 A framework for ethics in clinical practice

Ethics is the result of a systematic and theoretical reflection on the phenomenon of morality. In terms of morality we believe that people, in this case doctors and patients, may be held responsible or accountable for their actions. Such actions should be guided by moral norms and principles. Humans are rational beings that can act freely by making informed choices. This brings about the obligation to act in a morally correct fashion. In ethics we are not dealing with factual enquiry but rather we reflect on the moral status of acts through the application of theories and principles to distinguish between good or bad actions. This leads us to normative ethics that

provide guidelines tested for moral acceptance which in turn lead to moral choices (Hall, 2012:1). When this type of theoretical ethics is super-imposed on everyday life or e.g. clinical medicine we have “applied ethics”. Actions may also be right or wrong in terms of the law but this does not mean that ethics and the law are synonymous. There are many generally agreed actions that are wrong but not illegal; however, ethically correct behaviour sometimes does become enforceable through professional bodies such as medical councils.

Ethical dilemmas occur when we have to choose between two or more compelling obligations in circumstances that prevent us from doing both. Action in compliance with one obligation will cause contravention of the other, which leads to moral perplexity as we are forced to choose. The philosopher Peter Geach denied that such conflicts occur, appealing to the providence of God, but in real life such conflicts certainly happen in clinical medicine (Geach, 1969:128). When confronted with such ethical dilemmas we deliberate the issue and are required to provide justification for our considered final position while understanding that such justification is seldom compellingly conclusive. In this sense we grapple with uncertainty.

We examine an ethical dilemma using the illumination of the major moral theories. A moral theory may be defined as “a conceptual framework in terms of which action guides or norms for action are formulated, as well as certain rules in terms of which those action guides are to be applied” (van Niekerk, 2011:19). Moral theories are applied to moral problems or dilemmas in order to guide our actions. We may justifiably ask the question: at which level of abstraction do the various theories operate, is there a specific hierarchy? Utilitarianism (a form of consequentialism) through the account of Mill and deontology through the account of Kant have both been systematically elaborated and are very influential in bioethics (Beauchamp & Childress, 2009:357). Despite the robustness of these two best-known theories there are several competing theories such as virtue, communitarian, social contract and rights-based ethics that demand careful attention. The fact that one particular theory is not universally accepted indicates that strong affiliation with any single ethical theory is precarious. Defects and excesses appear in

all the major theories and therefore knowledge of the insights and arguments within them is indispensable for the practice of bioethics. Beauchamp and Childress state this position as follows: “We accept as legitimate various *aspects* of many theories advanced in the history of ethics. However, we reject both the hypothesis that all leading principles of the major moral theories can be assimilated into a coherent whole and the hypothesis that each of the theories offers an equally tenable moral framework” (2009:334).

The field of bioethics is a wide one and certain theories may better fit certain sub-divisions thereof e.g. utilitarianism may be more suited to public health than clinical medical ethics. For their part, Beauchamp and Childress argue that almost all of the theories accept the four principles upon which they base their own theory, often referred to as principlism (2009:362). The initial position of Beauchamp and Childress was that established ethics theories such as utilitarianism are the highest level of abstraction, followed by principles, then specified rules and finally particular moral judgements.

Beauchamp and Childress drew from the work of W.D. Ross in the formulation of their own views (2009:15). Ross was a “pluralist” and in the 1930’s he formulated the idea that “principles” are moral guidelines that arise from an intuitive sense of right and wrong actions (Dancy, 2002:411). He drew a distinction between prima facie and actual obligations. “A prima facie obligation is one that must be fulfilled unless it conflicts, on a particular occasion, with an equal or stronger obligation” (Beauchamp & Childress, 2009:15). As moral agents we look at all sides of the issue, assessing the merits of different approaches in order to locate, what Ross called “the greatest balance” of right over wrong to determine our actions (Ross, 1930:19-36). Again, it is important to state that when evaluating the theories that influence bioethics it is almost impossible to consistently and coherently defend a single moral theory. Therefore we should rather seek to understand the different approaches well and then utilise ethical pluralism. By not choosing one theory to the exclusion of others we are able to employ the best aspects of each theory. This provides our basic framework.

The theoretical background discussed has been further assimilated into models such as this five step example.

1. Identify the moral dilemma – what are the conflicting values?
2. Establish all the necessary information – medical, legal, ethical, socio-political norms; patient preferences; practitioner’s personal value system.
3. Analyse the information obtained.
4. Formulate possible solutions and make recommendations or take action.
5. Implement the necessary policies in institutions/private practice (Moodley, 2011).

1.3 Obstetrics, maternal-fetal medicine and pre-eclampsia

“Sound clinical reasoning and moral judgement are essential to the work of an obstetrician” as they are required to “make ethically complex decisions on a daily basis” (DiGiovanni, 2010). These unavoidable ethical debates particularly in maternal-fetal medicine are neither insoluble, nor a matter of personal opinion. “In situations that seem to pit the interests of pregnant women against the interests of their fetuses, clinicians must be prepared to identify the key issues and relevant clinical aspects in cases encountered to find a solution in the mother-fetus dyad” (DiGiovanni, 2010). Ethics in obstetrics and maternal-fetal medicine are unique in that the clinician is dealing with two “interwoven” patients who may at times have different interests. Unlike the general practitioner, the obstetrician may only meet the patient once she is pregnant and so trust must be developed quickly. This is even harder in state institutions where the chances that the patient will be seen by the same doctor continuously are slim. Outside of the private sector and particularly in developing countries, pregnant women and neonates are particularly vulnerable groups that pose unique ethical dilemmas (Wilkinson et al., 2011).

Ethics, professional values and behaviours are intrinsic to obstetric competency, and medical training institutions are now acutely aware that training in professionalism must be incorporated

into the curriculum. However, due to the lack of consensus on a definition of professionalism, training institutions should at least provide institutional definitions (Hall, 2013). Certain authors argue that “medical professionalism should reflect the values of a virtue-based ethic that stresses compassion and beneficence, rather than the values of a duty-based ethic” (Swick et al., 2006). Chervenak and others have promoted the “professional responsibility model of leadership” based on the concepts of John Gregory (1724-1773) and Thomas Percival (1740-1804), with a core component of ethical values that subordinate self-interest. In addition professional physicians must be committed to intellectual excellence, and practice medicine according to exacting scientific standards (Chervenak et al., 2013).

Van Niekerk and Benatar have pointed out that there are very few well trained bioethicists in South Africa with the skills and credibility to provide effective and appreciated bioethics consultations in the clinical care setting (van Niekerk & Benatar, 2011). If clinicians develop an understanding of the critical elements of clinical medical ethics they will become more confident in addressing the ethical issues in clinical cases. However, clinicians often express the view that the bioethics literature is too general, vague and principlist in nature. They would prefer easily applied case-specific references. Indeed Beauchamp and Childress emphasize that abstract principles must be further specified, adding content into case-specific guidance (2009:17). In this regard the analytical and clinical arguments of philosophically and legally aware clinicians are enlightening in moving from hypothetical scenarios to real clinical situations. When using principlism or other moral theories, we may be uncertain about which principles to apply. If more than one principle applies we are urged to weigh them and apply Rawls’ idea of reflective equilibrium. Thus principles need to be made specific (specified) in each case and reciprocally, case analysis requires illumination from principles. However, “There is no reason to expect that the process of revising moral judgements and specifying and balancing principles will come to an end in a perfect equilibrium. Particular moralities are, from this perspective, continuous works in progress rather than finished products” (Beauchamp & Childress, 2009:383).

In biomedical ethics, agreements providing clarity in precedent cases are inordinately useful but a literature search using the search engines Scopus, PubMed, EBSCOhost and Philosopher's Index, as well as the search functions within eminent journals such as Bioethics; South African Journal of Philosophy; Journal of Law, Medicine and Ethics; Journal of Medicine and Law; Journal of Applied Philosophy and others revealed scant information on “ethics AND pre-eclampsia”. It is therefore the aim of this thesis to highlight specific regularly encountered problem areas and discuss them in a bioethics context. By assisting clinicians with the resolution of real-life ethical dilemmas presented by clinical decision-making, I hope to make an original contribution to this field of study.

1.4 Chapter overview

The chapters that follow the introduction deal with the ethical issues involved in the clinical management of pre-eclampsia and related matters, before, during and after the pregnancy. Actual cases have been adapted for use in anonymous fashion. Once the pertinent issues have been examined a “summary position” is assumed at the end of each chapter. Full references follow the final chapter of the document.

Chapter Two begins by unpacking the ethics of pre-conception counselling. It unmask the tension in the funder-obstetrician-patient relationship and considers the justifiable limits of paternalism and autonomy, demonstrating how over a relatively short period of time counselling has changed from a paternalistic and directive approach based on beneficence, to a non-directive “doctrine” resting on respect for autonomy, and currently finds itself moving on to a “shared responsibility” position somewhere between the first two. Reproductive autonomy represents a strong individual right that includes the freedom to procreate and the freedom not to do so. Both are important for individual liberty. This subsection also deals with two perplexing questions: when is it morally wrong to procreate, and is there a duty not to procreate? The potential to lower the incidence of pre-eclampsia by fortification of staple foods consumed even before a woman becomes pregnant is alluring. Once again beneficence, paternalism and autonomy are

relevant but ultimately a conception of public health with a strong commitment to social justice provides moral direction.

There is currently a concerted effort in biomedical research to construct an early screening test for pre-eclampsia to detect women at high risk of developing the disease. The first section of Chapter Three examines the ethics issues at the core of implementing such a program. The differences between the better considered scenario of genetic screening e.g. Down's syndrome, and screening for pre-eclampsia are elaborated, and counselling reappears in a new context. Impressive advances continue to be made in the treatment of fetal conditions. These treatment options have promoted the concept of the fetus as a patient in perinatal medicine, but we need to understand the functions and applications of this concept. The termination of a pregnancy with severe pre-eclampsia at <24 weeks is not uncommon in tertiary referral practice. The moral considerations are explained with and without granting the pre-viable fetus the status of personhood and the concept of futility is interrogated.

In Chapter Four we first return to the theme of counselling in different contexts. Most women are prepared to make great personal sacrifices for the welfare of their pregnancies, thus demonstrating supererogatory attitudes. In addition, many do not feel unwell in the early stages of pre-eclampsia. These two factors together with evidence and risk influence the counselling. Healthcare in South Africa is certainly challenged by resource constraints. This raises the issue of justice, specifically distributive justice when considering the management of scarce, extraordinary resources. Just how expectant management of early pre-eclampsia facilitates this process is explained. Pregnant women have a unique disadvantage in that they cannot be separated from their fetuses but expectant management of early pre-eclampsia is only offered as inpatient management. Therefore, if a woman does want to approximate this benefit for her fetus, she must voluntarily suffer restriction of her freedom until delivery and eventual discharge with her baby. This subsection will examine the premises of such a decision.

In Chapter Five we begin by examining the concept of maternal-fetal conflict. Social stereotypes expect women to be self-sacrificing and judge women especially harshly if they exhibit behavior that is harmful to the fetus and future child. The theme is continued as the concept of non-compliance is expounded and the reasons for behaviors that are often categorized as such, are explored. In the final section of this chapter, a case is used to illustrate maternal-fetal conflict and non-compliance, in the context of competent maternal refusal of delivery by medically indicated caesarean section.

I begin Chapter Six by providing succinct data on survival and neurocognitive outcomes of babies born at or just beyond the threshold of viability. Next I draw together generic elements of counselling discussed in earlier chapters and integrate them into four options described in the literature to prepare for the “high stakes” discussion on the resuscitation of extremely premature, new-born babies. Considering resuscitation will lead us to consider the moral relevance of the distinction between withholding and withdrawing care. Some of the babies born to mothers with early pre-eclampsia will survive with neurocognitive and/or other impairments. In the final section I discuss the perils of expecting a perfect baby and the relationship between society and disabled persons.

The practice of obstetrics involves different types of care. In Chapter Seven the focus falls on the palliative and comfort care of the pregnant woman. When a woman who has suffered major complications of pre-eclampsia before delivery is subsequently declared brain dead, her doctors and family are faced with challenging medical and ethical decisions regarding the living fetus.

Anti-hypertensive agents are essential to control maternal blood pressure in the acute or expectant phase of pre-eclampsia management, but the choices are very limited. Chapter Eight highlights the lack of clinical research amongst pregnant women as the main cause of this problem. The reasons behind the reticence for inclusion, and the ethical principles justifying greater participation in biomedical studies are explored.

In Chapter Nine we discover that pre-eclampsia has lifelong implications for the mother and her infant. The particular danger is the development of cardiovascular disease in later life. This leads us to consider the obligation of preventive care and the ethics principles invoked by this approach.

Finally, in Chapter Ten, some future frontiers for pre-eclampsia are identified.

CHAPTER TWO: POWER AND THE PRE-CONCEPTION PERIOD

2.1 Pre-conception counselling

Counselling is a theme that will permeate this thesis, resurfacing on many occasions, but each time in a different clinical context. This section begins with a case which proceeded (as far as is known) without the benefit of pre-conception counselling.

Case 1: A 37-year-old, mother of three children booked late for antenatal care. In her previous pregnancy she developed early, severe pre-eclampsia that was complicated by haemolysis, elevated liver enzymes and low platelets (HELLP) syndrome. She was delivered at 32 weeks' gestation but developed renal failure during the post-partum period and was managed in an Obstetric Critical Care unit. In the next pregnancy she developed gestational hypertension at 24 weeks' gestation and was referred to a level 2 (specialist care) hospital but defaulted care. At 33 weeks' gestation she presented to the emergency area of a community-level institution with acute, severe pre-eclampsia. Shortly after admission, and before she could be transferred to a higher level of care, she developed pulmonary oedema (heart failure) and collapsed. Resuscitation was performed immediately but was unsuccessful. A post mortem examination revealed failure of five maternal organ systems.

All women who have developed pre-eclampsia should be counselled about the risks for recurrence of the condition in a subsequent pregnancy before discharge from the hospital, after completion of the pregnancy. “Patients want necessary medical information and honest assessments of what to expect with clear acknowledgement of uncertainties” (DiGiovanni, 2010). Ideally, women who have previously experienced early, severe pre-eclampsia and who are considering another pregnancy should present to a specialist or maternal-fetal sub-specialist for counselling on rates of recurrence. The doctor must take into account that because pre-eclampsia is a heterogeneous disorder, the pathogenesis can differ in women with various risk factors. In the

case presented the risk of recurrence of any form of pre-eclampsia was approximately 65% and 21% for early severe pre-eclampsia (Barton & Sibai, 2008). If a woman with previous pre-eclampsia decides to proceed with a pregnancy after counselling, she should proceed in the safest manner possible. There are several modifiable risks factors such as inter-pregnancy interval, diet, body mass index, smoking, immune competence if HIV positive and exposure to seminal antigens that can all decrease the chances of recurrence (Hall, 2007; Barton & Sibai 2008; Shachar & Lyell, 2012). Discussing matters of sexual activity, when to fall pregnant, obesity, HIV status and social drug habits need to be approached sensitively. Once pregnant other interventions will be considered from as early as the first trimester and a higher level of surveillance will be applied. In the case above, no mention was made of pre-conception counselling. That woman had experienced severe complications of pre-eclampsia, first hand and had three living children. We can only speculate as to why she proceeded with another pregnancy that cost her life.

When couples do present for pre-conception counselling, on what principles should such counselling proceed? This sub-section on the ethics of pre-conception counselling will demonstrate how over a relatively short period of time counselling has changed from a paternalistic and directive approach based on beneficence, to a non-directive “doctrine” resting on (some would say intimidated by) respect for autonomy which is a fundamental value in bioethics. Baily summarises the position saying that indeed “The birth of bioethics as a field was closely associated with a conceptual and practical shift away from paternalism and towards respect for patient autonomy as the core value in the physician-patient relationship” (2011). Counselling of the patients currently finds itself moving back to a flexible position of shared responsibility (patient and doctor) somewhere between these two positions.

Power in the funder-obstetrician-patient relationship

By virtue of their position, doctors exercise power through their ability to take and implement decisions directly or through others. The political philosopher Thomas Hobbes (1588-1679) is

well known for advocating the constraint of power through a social contract. Exploring this familiar tension within the above-mentioned relationship will lead us to consider the justifiable limits of paternalism and autonomy. Although it is sometimes hidden, the field of clinical medicine, both public and private is a contested area when viewed in the socio-political context. In order to counteract a monopoly of power, Chervenak et al., advocate a professional leadership model that proposes constraints on organisational and individual power (2013). But, even if monopolies are addressed, asymmetrical power relationships are certainly present. The battle for dominance between doctors, patients, public and private healthcare funders is not always clearly perceived and shifts in power occur regularly over time.

A short summary of the asymmetrical power relationships is appropriate in order to understand who is involved, how the power relationships are made manifest and the consequences thereof. The power has generally resided in the hands of the doctors who provide the service upon which the public depends. The state (as the public healthcare funder) and private healthcare funders, as genuine and proxy employers have an agenda to wrest this authority back from medical professionals. A form of organisational exploitation (power) currently occurs in both the public and private sectors where unfunded mandates are issued to doctors or clinical services for quality improvement or patient satisfaction (Chervenak et al., 2013).

Until recently doctors practiced a patriarchal form of medicine but recently the autonomy of the patient as a medical consumer has gained much ground and patients (in obstetrics women) are gaining power. However, in an ironic full circle, this shift in power sometimes suits certain doctors by enabling them to maintain the power they seek, but how can this be?

Using deliberative clinical ethical judgement it is not consistent with beneficence-based obligations, for doctors to offer therapy or interventions in the absence of evidence of improved outcomes (Wielgos, et al., 2013). Caesarean section is a method of delivery for the mother and baby. The onset of spontaneous labour and natural birth is a painful process that lasts for many

hours and may begin or end at any time of the day. Elective caesarean section can be conveniently scheduled, is completed in less than one hour and is performed under full analgesia with post-operative analgesia provided. Traditionally caesarean section has only been performed when there is a medical indication to do so. However with the strong emergence of patients' autonomy and the right to make an informed choice, certain women are "demanding" ("caesarean on demand") delivery by caesarean section without a medical indication. Thus in the case of caesarean section the power is perceived to have shifted from the doctor to the patient, but what many fail to see is that this is exactly what many doctors want other parties to believe. In actual fact this maintains the power of the doctors who understandably prefer shorter, predictable deliveries to uncertain drawn out affairs in the middle of the night. The issue of the physician's or patient's power will surface again in other sections of the thesis.

Having explored the familiar tension of power in the funder-obstetrician-patient relationship leads us to consider the justifiable limits of paternalism and autonomy. In fact, paternalism may be an "unfortunate" term. One may ask "how far should a feminist obstetrician go in imposing *opinions or* treatment on women in the name of their own best interest and/or that of the fetus" (Dickenson, 2002:4).

Paternalism and conflicts between beneficence and autonomy

According to Beauchamp and Childress "beneficence provides the primary goal and rationale of medicine" (2009:207). Physicians have a long history of using their own judgements to determine their patient's needs for information and treatment, but in the current era, autonomy rights of patients have set limits on "beneficent" actions by doctors, thereby raising the problem of paternalism. As a father acts beneficently in deciding what is best for his children, the analogy is that the professional doctor with his knowledge and training can best decide on his patient's interests. The normatively neutral definition of paternalism chosen by Beauchamp and Childress is "the intentional overriding of one person's preferences or actions by another person, where the person who overrides justifies this action by appeal to the goal of benefitting or preventing or

mitigating harm to the person whose preferences or actions are overridden” (2009:208). Paternalism challenges doctors especially when e.g. a patient makes an informed choice to pursue a harmful course of action e.g. not to undergo a caesarean section for fetal distress (see Chapter 5). So Beauchamp and Childress argue that “beneficence sometimes provides grounds for justifiably restricting substantially autonomous actions” (2009:209). On occasion limited rationality restricts the capacity of a person to act autonomously and we are justified in arranging their choice to correct for cognitive biases. This is “soft” paternalism e.g. discouraging the action of smoking, but if we manipulate persons into doing what is good for them e.g. taxing cigarettes we practice “hard” paternalism. Soft paternalism involves less conflict between autonomy and beneficence but in hard paternalism the informed beneficiary defines her own best interests by different values. I will return to beneficence and non-maleficence in clinical judgement and counselling after discussing respect for patient autonomy. Soft paternalism appears again in the final sub-section of this chapter. In pre-conception counselling paternalism can be justified by two positions:

- *Paternalism justified by consent or prospective benefit.* Here we deal with hypothetical consent which implies that persons would accept beneficent paternalism when psychological pressures lead them to take unreasonably risky actions. Regarding benefit, major benefit with minor infringement of autonomy would be acceptable, but not vice versa.
- *Justified hard paternalism.* Minor hard paternalism is common in hospitals according to Beauchamp and Childress, but to be justified it needs to satisfy certain conditions: significant but preventable harm; action will probably prevent harm; benefits outweigh risks; action is the least autonomy-restrictive alternative and, no substantial autonomy interest is compromised. As the risk to a patient’s welfare increases the likelihood of a justified paternalistic intervention increases, so a doctor must balance her beneficence with the patient’s autonomy. However hard paternalism in professional practice is risky as it disrespects personal autonomy and invites abuse (Beauchamp and Childress, 2009:216,233).

One *de novo* factor that increases the risk of pre-eclampsia is the use of assisted reproduction techniques. It has already been stated that the aetiology of pre-eclampsia is multi-factorial and that one of the pathophysiologic pathways functions through immune maladaptation to paternal antigens. Short (< six months) exposure to new seminal antigens (sperm and secretions) has been shown to increase the risk of pre-eclampsia (Verwoerd et al., 2002). Sperm or ovum donation used in assisted reproduction increase the risks through the same pathways, while multiple pregnancies that frequently result from assisted reproduction are also at increased risk of pre-eclampsia through hyperplacentation (Barton & Sibai, 2008). In a thought provoking publication, Gillian Lockwood, a philosophically trained director of an infertility unit in Oxford, has discussed the following case (Lockwood, 1999).

Case 2: A 34-year-old woman was referred for in vitro fertilisation (IVF). Both her first and second pregnancies were complicated by early pre-eclampsia and ended in early neonatal deaths due to extreme prematurity. She had been born with only one poorly developed kidney and accepted sterilisation after the second pregnancy. She subsequently suffered end-stage renal failure but after dialysis and a renal transplant, returned to good health. She maintained good kidney function on a combination of immune-suppressive drugs, steroids and anti-hypertensive agents that are not absolutely contraindicated in pregnancy. She was “so distressed by her childlessness” that she underwent a reversal of the tubal ligation but failed to conceive due to blocked tubes. The IVF was successful, resulting in a twin conception. At 20 weeks’ gestation she developed deep vein thrombosis. Her twins were born at 29 weeks and survived.

This woman received full pre-conception counselling, chose autonomously to fall pregnant despite significant risks for herself and the fetuses, was managed at a high level of care and had a complicated but successful outcome. The decision to accept the couple onto the IVF programme

required balancing the risks (already explained) and safety, but the ethical aspects were contentious. Great emphasis was laid on obtaining true informed consent. However in the tertiary referral clinic of the author of this dissertation, many women with similar high-risk backgrounds fall pregnant, spontaneously and intentionally without counselling but knowing the risks. Should the IVF clinic have declined to help the couple in Case 2? The risks involved were significant and may even have resulted in early death due to complicated pre-eclampsia or deterioration/rejection of the renal transplant. Lockwood argued that “as long as the risks associated with fertility treatment and pregnancy were thoroughly explained to, and accepted by, the woman (and her partner), then to refuse treatment on the sole ground that her health may deteriorate was unacceptably paternalistic” (1999). I agree with this position and support the moral right of this couple to proceed with a pregnancy. There were certainly risks involved for the mother and fetus/child but there was also the potential for a fulfilling result as demonstrated by the outcome. Ultimately autonomy and safety need to be balanced. Both the patient and her partner fully understood and accepted the risk-benefit equation and in this scenario the couple were not denying others the use of scarce resources. The shared decision making avoided paternalism as the physicians did not prescribe how this woman should utilise the health benefits she already enjoyed as a renal transplant patient. I also consider their approach to be more responsible to themselves, their pregnancy and society than that of couples who simply present for care already some way into a very high risk pregnancy having bypassed pre-conception counselling and interventions to ameliorate risks, as well as the benefits of care during early gestation.

Maternal-fetal sub-specialists are acutely aware that the desire to bear a child is often still very strong, perhaps irrationally so, in women with severe, chronic diseases or reduced life-expectancies. “The desire to achieve the normality of pregnancy and motherhood, if only for a short while, can be overwhelming and must be recognised and treated sympathetically by physicians working in this field” (Lockwood, 1999).

Respect for autonomy

Recently in bioethics, autonomy or self-rule has received inordinate emphasis, but autonomy itself is multi-faceted and some facets can even become rather “dangerous”. The current dominance of autonomy over the much older principles of beneficence and non-maleficence is largely the result of recent abuses of power by physicians e.g. Nazi experiments, the Tuskegee syphilis trial and the Steve Biko debacle. Space limits long quotes, but it is Isaiah Berlin who has most eloquently expounded the essence of autonomy in his famous passage that contains negative and positive conceptions of freedom (Young, 2012). Using negative and positive obligations, respect for autonomy supports specific moral rules: a) tell the truth, b) respect the privacy of others, c) protect confidential information, d) obtain consent for interventions with patients, e) when asked, help others make important decisions (Beauchamp & Childress, 2009:104). Two other eminent philosophers have influenced autonomy; Kant insists that persons should always be treated as “ends”, and J.S. Mill states that power may only be exercised over persons against their will, to prevent harm to others (Rachels & Rachels, 2010:137; Mill, 1997). Kant’s interpretation of justice requires us to respect the rights of all persons regardless of their situation because as reasoning human beings they are worthy of respect. This categorical imperative, where acting morally requires acting out of duty, overrides considerations of utility or even virtue (Sandel, 2009: 123). However, as has been previously stated, Beauchamp & Childress believe that respect for autonomy should be regarded as *prima facie* rather than absolute, as it may be justifiably overridden on occasion by an equal or stronger rule or principle.

In essence, full autonomy is the right of every individual to make decisions for herself. A person is autonomous when she chooses intentionally, with understanding and without controlling influences. While the first criterion is definite, the second and third are incomplete. The obstetrician might not want the woman to become pregnant, or a husband might strongly desire another pregnancy from his wife irrespective of the risk to her health. Furthermore, respect for autonomy creates important obligations for counselling that are very similar to those functioning for informed consent. Patients have a fundamental right, but not a mandatory duty to choose.

Patients “have the right to accept or decline information. Forced information and forced choice are inconsistent with this obligation” (Beauchamp & Childress, 2009:107). Valid informed consent contains the following elements that are also important to keep in mind when counselling:

A. *Threshold elements*

- Competence to decide and understand
- Voluntariness in deciding

B. *Information elements*

- Disclosure of information
- Recommendation of a plan
- Understanding of information and plan

C. *Consent elements*

- Decision against or in favour of plan
- Authorisation of plan (Beauchamp & Childress, 2009:120-121).

I will make brief comments on each element.

Competence. The criteria for autonomy and competence are very similar. Patients are competent to make a decision if “they have the capacity to understand the material information, to make a judgement about this information in the light of their values, to intend a certain outcome, and to communicate freely their wishes” (Beauchamp & Childress, 2009:113). Certain authors propose different standards or levels of competence (the sliding-scale strategy) e.g. a higher level is required to refuse treatment. However Beauchamp & Childress believe that it is “confusing to blend a decision’s complexity with the risk at stake” and recommend “placing only the required standards of evidence for determining decision-making competence on a sliding scale” (2009:117).

Voluntariness. This element removes coercion, including informational manipulation and rewards. It takes the right of refusal seriously.

Disclosure. Physicians are obliged to disclose relevant information but in recent times the focus has shifted from the physician's obligation to disclose information to the quality of the patient's understanding according to Beauchamp and Childress (2009:117-118). According to Chervenak and McCullough the general rule for clinical practice is for the physician to disclose the major factors of the reasoning process, with neither medical law nor medical ethics requiring the patient to be provided with a complete medical education (Chervenak & McCullough, 2009). Three named standards are proposed to govern the norms of disclosure of information.

- *The professional practice standard.* This is determined by the professional community's custom. Difficulties here include the questionable existence of a standard for each situation, the awareness of that standard by the doctor and the skill to serve the patient's best interests. Perhaps damningly, Beauchamp and Childress state that this standard "subverts the right of autonomous choice" of the patient (2009:122).
- *The reasonable person standard.* This self-explanatory standard has conceptual and practical difficulties. Interestingly, there is research to indicate that "patients generally make their decisions prior to, and independent of the process of receiving information" (Faden & Beauchamp, 1980:313-336).
- *The subjective standard.* Information is adequate insofar as it meets the specific informational needs of the individual and for this reason it is the preferred moral standard of disclosure.

"The ethical principles of autonomy would suggest that patients should always be fully informed but sometimes information can increase the cognitive and emotional burden. The right to autonomy must therefore be balanced with the ethical obligation to do good (beneficence) and not to harm (non-maleficence) (Epstein et al., 2010). "Beneficence-based clinical judgement makes an important claim: to interpret reliably the health related interests of the patient from medicine's perspective. This perspective is provided by accumulated scientific research, clinical experience and reasoned responses to uncertainty." (Chervenak & McCullough, 2009).

Rigorous, evidence-based judgements move beyond an individual clinician's clinical perspective, justifying a move away from pure non-directive counselling. On the other hand, non-maleficence "should be incorporated when the physician approaches the limits of beneficence-based clinical judgement, that is, when the evidence for expected clinical benefit diminishes and the risks of clinical harm increase" (Chervenak & McCullough, 2009). Here the cautious physician should be non-directive.

In pre-conception counselling, non-disclosure would be restricted to "therapeutic privilege" where a doctor may legitimately withhold information if, based on sound judgement, such information would harm an unstable patient. Counsellors should consider how information will enhance or reduce patient's autonomy and judge how much they can reasonably assimilate. Counsellors should certainly concentrate on providing beneficial information as simply dumping large amounts of information may undermine the ability to choose wisely.

Recommendation. Recommending a plan on the basis of the information and shared responsibility is particularly important in pre-conception counselling, but more than one session may be necessary.

Understanding. This may be impeded by immaturity or irrationality, as well as poor communication skills and information overload. Patients exhibit wide variations in understanding but Beauchamp and Childress state that "understanding need not be complete" because a grasp of the relevant, central facts is generally sufficient (2009:127).

Decision and authorisation. Sometimes patients decide against a medical plan because of a false belief e.g. a woman with early, severe pre-eclampsia may not feel sick and therefore decline hospitalisation. According to Beauchamp and Childress "as long as this patient continues to hold a false belief that is material to her decision, her refusal is not an informed refusal" (2009:131).

Autonomy has stood accused that it is informed by liberal individualism that disregards the role of culture, family and community, particularly in the African context (Hellsten, 2001). Within communitarian societies the contribution of the family and community has greater influence on the decision or choices of a patient. This has been termed “a different view on autonomy” and a “different perception of illness” (van Bogaert, 2006). Here the response is that no one is “truly” autonomous. Rather autonomy results from a process of formative interactions and the principle’s “precise demands remain unsettled and open to interpretation and specification” (Beauchamp & Childress, 2009:140). A person may even decide autonomously to surrender their autonomy to a third party.

An important criticism of autonomy in terms of pre-conception counselling is that it leads counsellors to adopt a “non-directive” stance. This is appropriate if the data on a particular clinical issue are equivocal e.g. when the benefits of early screening for pre-eclampsia are unclear. However, this “doctrine” of non-directiveness is now under challenge particularly when robust, evidence-based medicine provides clear answers. Professional counselling entails showing respect to the patient and enhancing her autonomy. “Providing neutral information may fulfil the formal requirements of informed consent; nevertheless this does not encompass all of what respecting patients as persons entails” (Quill & Brody, 1996). In a relationship centred model of autonomy, information need not always be provided in a neutral fashion to enhance that autonomy. When the evidence of benefit is strong, the facts must be stated clearly by the doctor using a in a respectful, deliberative yet directive approach. In this manner power and responsibility are shared by the patient and her doctor.

2.2 The decision to fall pregnant

The moral duty or obligation not to fall pregnant, if it exists at all, is usually raised in the context of severely debilitating genetic (inherited) diseases such as Huntington’s disease. However I want to shift the focus of the question to the context where a woman has an extremely high

chance of developing pre-eclampsia with its severely debilitating complications such as renal failure, cerebral haemorrhage or even death. When examining Cases 1&2 several difficult questions arise.

- In the light of the likely severe complications, was it in these patient's best interests to fall pregnant?
- Did they neglect their duties to their husbands/partners, surviving children, and relatives?
- Should doctors make judgements about a woman's capacity to parent? A mother with a chronic debilitating disease e.g. renal failure after pre-eclampsia or with a shortened life expectancy may perform less well as a parent. Infertility legislation in the United Kingdom places great emphasis on the "interests of the child" who may be born through assisted reproduction (Lockwood, 2002:165).
- Infertility services are a scarce resource. In Case 2, how do we balance autonomy, justice and utility?

In addressing the issues we will first interrogate reproductive autonomy, and then consider freedom to procreate and freedom not to procreate. Thereafter we will discuss the related questions of "when is it morally wrong to procreate?" and "is there a duty not to procreate"?

Reproductive autonomy

Reproductive autonomy represents the strong interest or right to make choices regarding reproduction even when others might regard such choices as unwise or against public interest. Ronald Dworkin, an American philosopher and legal theorist describes the reproductive autonomy of persons as "a right to control their own role in procreation unless the state has a compelling reason for denying them that control" (1993:148). However we live in a world where *medical* information is increasingly available and where society is "policed" by those who advocate responsible motherhood according to the British medical lawyer Jean McHale (2002: 101-112). Thus society may become increasingly critical of those who, in its opinion make the wrong reproductive decisions although this does not in itself make the decisions immoral.

Freedom to procreate

What makes the freedom to procreate valuable, or put another way, why do individuals value having genetically related children through ordinary (natural procreation) so highly? Carson Strong provides five reasons to answer this question (2002:19-20).

- First, he rejects the notion that men need to prove their virility and that women must bear children to prove their femininity. Although such views have apparently been held in certain cultures, Strong finds these stereotypic roles selfish, confused and indefensible (2002:19). Rather than looking at descriptive reasons given, we should concentrate on the normative question of reasons given to justify the desire for genetic offspring.
- Second, we may value having genetically related children because it involves participation in the mystery of the creation of a self-conscious person like ourselves.
- Third, genetically related children might affirm a couple's love and acceptance of each other.
- Next, through procreation we provide a link to future persons and make a personal contribution to the future human community.
- Finally, the experiences of pregnancy and childbirth are regarded as deeply meaningful and valuable in themselves. Pregnant women are esteemed by the community while pregnancy provides an experience of personal development and an opportunity for altruism for many. Then, there is the joy experienced at the birth of a baby.

Strong believes that these reasons can be used to defend the desire for genetic offspring and suggests that procreation can contribute to both self-fulfilment and self-identity (2002:21). It follows therefore that interference with these rights may deny the necessary respect due to individuals. However "this does not mean that freedom to procreate is never outweighed by other ethical concerns" (Strong, 2002:21). It means that we would require compelling reasons to override reproductive autonomy. Women themselves may be torn between their emphases on concrete caring relationships characterised as feminist "ethics of care", while on the other hand

desiring to exercise individual rights to satisfy the sometimes overwhelming desire for motherhood (Hall et al., 2013).

Freedom not to procreate

As in the section above, I will answer the question of why freedom not to procreate carries value. Each of these points is closely linked to the one that follows.

- This “negative” freedom (not to procreate) helps a person direct the course of her life. Having children places major demands on the parent’s lives in terms of time and all resources. Autonomy and self-determination are enhanced by the freedom to decide whether or when to have a child. The same freedom is needed when considering additional children. I regularly see women in my tertiary referral obstetric clinic who have an underlying medical disease such as diabetes mellitus or permanent organ impairment such as partial renal failure following pregnancy-associated diseases like pre-eclampsia. When a subsequent pregnancy would significantly threaten the existing health, or even life of a woman, the freedom not to procreate is important. Sadly, in my experience, many husbands (partners) are willing and sometimes even encourage their wives (partners) to take this risk. The freedom not to procreate is particularly important for women in order to direct the course of their lives.
- Freedom not to procreate is closely linked to bodily self-determination. Women have the right to decide on the use of contraceptives and especially sterilisation. Although men also have this right, it is especially important for women due to their previous “oppression” and the fact that they directly bear the burdens of pregnancy (Hall et al., 2013).
- The next reason has already been alluded to in the previous points and is articulated by many feminist authors. These writers postulate that male-stream moral theory has both feminised and looked down upon the role of care and relationship in moral decision-making. Carol Gilligan juxtaposes ‘care ethics’ with what she calls ‘justice or rights ethics’ and sees them as loosely feminine and masculine respectively (1997:146-152).

Joy Kroeger-Mappes argues that a single system consisting of two ethics, with one presiding over the other (rights over care ethics), is seriously flawed when viewed from women's perspective, as women but not men, are held accountable to both ethics. (1994:108-131). Women are held to the requirements of the care ethic, especially as it pertains to the home and family life, in ways that men are not. For example, if one's child is ill, feminised care and relationship ethics and responsibilities imply that the mother but often not the father is morally obligated to stay at home and look after the child rather than to go to work (Hall et al., 2013: 29-33). Thus the current system that subordinates women according to Kroeger-Mappes, treats the same caring activities as obligatory for women and as supererogatory for most men (1994:108-131). This is why freedom not to procreate is especially important for women.

When is it morally wrong to procreate?

“The idea that it might be a moral crime to have a baby, that it might be wrong to bring a new human individual into the world is to many people simply bizarre. Having a baby is a wonderful thing to do, it is usually regarded as the unproblematic choice from the moral if not from the social or medical point of view. It is only having an abortion and perhaps also refraining from having children that is regarded as requiring justification” (Harris, 1998:99).

At the heart of this debate lies the question of whether a child could be better off if he or she had never been born, known in legal terms as “wrongful life”. This term is usually made in reference to being born impaired rather than unimpaired, existing and not existing (Bennett & Harris, 2002:322), but in the pre-eclampsia scenario the additional issues here are the unintended but foreseen consequences of an extremely high-risk pregnancy.

The question that I want to ask is, is it morally wrong to deliberately proceed with a pregnancy when the baby might survive disabled (due to being born extremely preterm), or if the baby survives intact, where the mother dies shortly after labour, or perhaps a few years later? In other

words, when a mother (and father) have fair warning of these dangers through pre-conception counselling, is it morally right or wrong to proceed with such a pregnancy spontaneously or even request fertility treatment to become pregnant? I contend that when all of the parties with an interest in the pregnancy (the parents, the potential child, family and society) have received due consideration, it is not wrong to proceed responsibly. The answer must also depend on the value that we place on life itself and what we regard as a worthwhile life. We generally regard life as valuable and positive but a fully autonomous couple would have to carefully consider the positive and negative predicted scenarios after the pregnancy (e.g. an impaired child; children without a mother; a husband with a chronically impaired wife or a maternal death).

In terms of the baby that might lose its mother in childbirth, the argument comparing existence with non-existence is problematic. If a person was never born, never was, then it is illogical to contend that they could be said to be better or worse off (Steinbock, 1992:117). On the other hand it seems reasonable to consider lives that are worth living and “those that are so blighted by suffering that they may be considered ‘unworthwhile’” (Bennett & Harris, 2002:323). A utilitarian could argue that it would be cruel to intentionally create suffering, thereby increasing unhappiness, but how would society prevent such pregnancies without invading individual privacy, bodily integrity and civil liberties?

I find Bennett and Harris’s arguments enlightening and persuasive. They defend reproductive autonomy and the “powerful interest or right in the freedom to make reproductive choices, even where these choices may be thought unwise, frivolous or contrary to the public interest” (2002:332). Both agree that as long as a life is worthwhile, i.e. valued by the person whose life it is, it is equal to any other life regardless of its quality. This applies to all actual lives but Bennett extends it to all possible lives. Both authors agree that only a life of overwhelming suffering has a different value (2002:331). Very few lives reach this “standard of awfulness”.

Is there a duty not to procreate?

Having considered when it might be morally wrong to procreate, I will briefly discuss the opinions of Jean McHale, a British medical lawyer on whether a duty not to reproduce exists. There is increasing pressure in modern society on pregnant women to behave responsibly and make correct reproductive choices, but how far does this argument extend down the “slippery slope”? Is it limited to choosing to avert significant handicap in a child, or does it include maternal safety as well? McHale points out that assisted reproductive technologies already provide a means of controlling access to reproductive services and that clinicians act as gatekeepers according to pre-determined criteria (2002:101). However such control does not apply outside the walls of infertility clinics and a general application would at present seem “ludicrous”. We may ask who should bear the costs of caring for chronically ill mothers or affected children. For indigent parents the cost may have to be carried by the state but does this equate to imposing a duty not to procreate? Some are concerned about modern society’s attitude towards vulnerable community members.

In the introductory paragraph of section 2.2 I asked whether a moral duty not to fall pregnant exists when a woman has an extremely high chance of developing complicated pre-eclampsia as reflected by clinical Cases 1&2. I have argued that reproductive autonomy is a fundamental human right that must be respected. Procreation allows humans to participate in the valuable process of creating self-conscious persons that link us to the future. Properly informed parents are best able to determine their own best interests. Almost all forms of human life carry value and it is very difficult to predict with certainty (when judged by the person whose life it is), those that will not be worthwhile. I am therefore sceptical about whether a person could ever “ever be regarded as being under a duty not to reproduce” and as McHale has pointed out, if such a duty existed, it could not be legally enforced (2002:101).

2.3 Fortification of foods to prevent pre-eclampsia

Background

Pre-eclampsia is a leading cause of maternal and perinatal mortality and morbidity globally but developing countries and vulnerable populations in developed countries are affected most (WHO, 1998; Sibai et al., 2005; de Graaf et al., 2013). I have already alluded to the fact that pre-eclampsia has multi-factorial aetiology. In 1980 Belizan and Villar observed that Mayan Indians in Guatemala who soaked their corn in lime before cooking had a low incidence of pre-eclampsia and eclampsia (1980). The link between poverty and pre-eclampsia may therefore lie in dietary calcium deficiency. Subsequently, studies linking pre-eclampsia to calcium deficiency have been summarised in a systematic review. Calcium supplementation of at least one gram/day beginning around mid-pregnancy was associated with a modest reduction of pre-eclampsia among women at increased risk or with low dietary calcium intake (Hofmeyr et al., 2010). It is believed that calcium supplementation in the second half of pregnancy may decrease blood pressure without directly addressing the underlying pathology. Thus calcium supplementation provided before pregnancy might be a more effective strategy. At the present time, a team of international research obstetricians, including myself, are conducting a large, powered, multi-centre randomised controlled trial to investigate whether low dose, pre-conceptual calcium will lower the rate of pre-eclampsia. Historically, some of the most effective public health interventions have been achieved through the fortification of food e.g. iodine and fluoride. If the results of this study are positive they could inform the decision on whether to fortify basic foods with calcium, but what are the ethics issues?

The principle of beneficence requires us to take positive actions to contribute to the welfare of persons, something more demanding than non-maleficence. For Beauchamp and Childress beneficence includes the virtue of benevolence, and utility in the form of balancing benefits and risks. This utility is constrained by justice and differs from classic utilitarianism. In their view classic utilitarianism “is systematically arranged on a principle of beneficence” but they consistently reject any “sole principle” for ethics, neither does beneficence override their other

three principles (2009:197-8). Although the fortification of basic foodstuffs may be seen to diminish the autonomy of indigent persons who cannot afford to buy non-fortified (usually more expensive) products, the previous, tested, effective public health intervention examples lead one to believe that an intervention of this nature would be accepted by the community. The argument is further enhanced when one considers that the benefits would extend beyond pregnancy (see Chapter Nine).

Obligatory and ideal beneficence

Medical practice has an ancient history of embracing beneficence. While discussing paternalism in section 2.1, I pointed out that beneficence can provide grounds for justifiably restricting autonomy. However, to protect persons from harm caused by conditions beyond their control, i.e. beyond an autonomous decision, is not controversial. The principle of beneficence supports certain moral rules of obligation such as: prevent or remove harm e.g. prevent pre-eclampsia (Beauchamp & Childress, 2009: 168-9). Beneficence requires both positive motives and actions, although the line between obligatory and ideal is often unclear. According to Beauchamp and Childress “we are obligated to act non-maleficently toward all persons at all times, but it is generally not possible to act beneficently toward all persons” at all times e.g. outside of special relationships (2009:199). This is too demanding! If beneficence was an absolute ideal there would be no need to distinguish between obligatory and supererogatory acts. General obligations are stronger when an action is necessary to prevent significant loss, with such action having a high chance of success without significant risks or harms to the person acting.

Public health ethics

The relatively new domain of public health ethics has strong utilitarian roots and assumes a population rather than an individual focus. Here civil liberties and individual autonomy may bow to utilitarian, paternalistic and communitarian orientations (Callaghan & Jennings, 2002). Powers and Faden have argued that it is social justice that provides the moral foundation for public health ethics (2006). The difficulty is to balance what is best for the population with individual protection. Although soft or hard paternalism is sometimes justified in health care and

policies, caution must always be exercised. Even soft paternalistic health care policies are susceptible to abuse if they lack scientific and public scrutiny, while there is always the “slippery slope” argument to consider. A positive result from the research trial on pre-conception calcium supplementation (mentioned above), will provide robust scientific evidence for the formulation of public health policy. The traditional field of public health includes the activities of water sanitation, disease surveillance and health education, including interventions to promote health and prevent disease (Dawson & Verweij, 2007). Other fortification projects such as those with iodine and fluoride have already been successfully implemented in the past and as I have shown the ethical dilemmas in this case are easily resolved. Such interventions are aimed at the public as a whole (high coverage), thus the effect or outcome measure should be apparent at population level. However, Powers and Faden caution that public health “gets it wrong” if it is solely concerned with outcomes. They state that “unlike either beneficence-based or utilitarian justifications for public health, by situating the focus on well-being within a theory of social justice, we capture what we believe are the twin moral impulses that animate public health: to improve human well-being by improving health and to do so in particular by focusing on the needs of those who are most disadvantaged. A commitment to social justice, as we explicate it, attaches a special moral urgency to remediating the conditions of those whose life prospects are poor across multiple dimensions of well-being. Placing a priority on those so situated is a hallmark of public health” (Powers & Faden, 2006:82).

Balancing benefits, costs and risks

Beneficent health policies and research must balance benefits against cost and risks. Formal cost-benefit analysis tools that lead to policy formulation are widely used. They have the advantage that they avoid subjective and political decisions, yet they remain controversial. Cost is calculated in monetary terms but benefits are more difficult to measure. Quality-adjusted life years (QALYs) evaluate quality of life rather than only survival years. As with other cost-effectiveness analyses, utilitarianism is the “philosophical parent” and so certain well known challenges also occur. Is a QALY equally valuable to old and young patients (pregnant women

are generally young), and what about non-health benefits that affect quality of life? The danger is that “these techniques concentrate decision making authority in the hands of narrow, technical professionals e.g. health economists, who often fail to understand moral, social, legal and political constraints that legitimately limit use of these methods” (Beauchamp & Childress, 2009:222). According to Beauchamp and Childress, “no form of analysis has the moral power to dictate the use of a particular medical procedure” simply by virtue of the lowest cost-effectiveness ratio (2009:223). Doctors use scientific evidence to take decisions, but when conclusive evidence is lacking, the “precautionary principle – better safe than sorry” is ethically justifiable in order to avoid serious or irreversible harm.

Large numbers of indigent, fertile women in South Africa are powerless to acquire a medically balanced diet. It is reasonable to assume that if low dose calcium fortification (supplementation) of staple foods carries low risks and decreases the incidence of a major disease such as pre-eclampsia, then most women would accept this action to be in their best interests. This would remove the conflict between respect for autonomy and beneficence and represent only soft paternalism. Social justice would then require public health to expedite such fortification if it is within its power to do so. At the moment the most practical way to achieve this would be for the state through the Health Ministry to require producers of basic staple foods such as flour, maize meal and bread to add 500mg of calcium per average daily portion or amount of the product consumed by an individual.

2.4 Summary position

In this chapter I have discussed pre-conception counselling, power relationships, the decision to procreate and fortification of staple foods in the context of pre-eclampsia. I have proposed that where evidence-based information is robust, pre-conception counselling be conducted in a respectful, yet directive manner of shared responsibility that makes space for the doctor and the patient. I have argued that reproductive autonomy is a fundamental human right that gives

couples the moral right to procreate. Human life is valuable and it is only at extremes that are difficult to predict, that procreation becomes contentious. I conclude that because women understand the social connectedness of care ethics as well as rights ethics, they are well placed to negotiate the extremes of these positions and make the right autonomous (in the noblest sense of the term) decision on whether to risk a pregnancy or not. My argument here is for a relationship-centred model of autonomy where a woman's decision is informed by her values, including her relationship with her potential progeny, superimposed on information provided by a respectful, professional counsellor. Fortification of staple foods with calcium in order to prevent pre-eclampsia and its complications is at worst an example of soft paternalism. If it is shown to be safe, effective and affordable, then social justice requires public health to expedite this intervention.

CHAPTER THREE: EARLY PREGNANCY - LESS THAN 24 WEEKS' GESTATION

3.1 Screening for pre-eclampsia

The importance of pre-eclampsia has been set out in section 1.1. Avoiding pre-eclampsia is considered to have important health benefits by such august organisations as the National Institute of Clinical Excellence (NICE) in the United Kingdom, and the World Health Organisation (WHO) (NICE, 2008; Conde-Agudelo et al., 2004). Although the pathogenesis of the disease begins very early in pregnancy, the clinical manifestations only become apparent after the 20th week. Despite the large amount of scientific and clinical effort that has been expended in the management of pre-eclampsia, delivery of the placenta (and necessarily the baby) remains the only definitive treatment that leads to resolution of the condition. Apart from the primary prevention already discussed, many clinical trials have addressed secondary prevention of pre-eclampsia i.e. once the patient is pregnant. Interventions have included anti-hypertensive agents, fish oil supplementation, calcium supplementation, supplementation with vitamins C and E, and antithrombotic agents (Barton & Sibai, 2008). Of these, low dose aspirin has shown the most benefit, but the magnitude of this benefit is only small to moderate. Early (≤ 16 weeks' gestation) use of low dose aspirin is more effective at preventing early onset pre-eclampsia (Roberge et al., 2012). Another benefit is that low dose aspirin has a good safety profile (Askie et al., 2007).

Modern public health care focuses not only on prevention of disease through lifestyle modifications but also through population-based screening programmes. Such screening tests utilise biophysical and/or biochemical parameters together with personal information that are used to calculate the risk of developing a specific disease. In contrast to diagnostic tests that are offered to individuals with disease, screening tests are offered to apparently healthy individuals.

What are the criteria to be met by screening tests and how does pre-eclampsia perform?

- The disease should pose an important health problem – pre-eclampsia certainly does.

- The disease should have a well understood aetiology – pre-eclampsia is still not fully understood.
 - There should be a recognisable early stage – an understanding of a biochemical imbalance of angiogenic and anti-angiogenic factors in the maternal blood is developing.
 - Early effective treatment should be available – early low dose aspirin is a partial answer.
 - There should be a suitable test that is accurate, rapid, non-invasive, inexpensive and easy to perform in early pregnancy – the proposed combined test performs well but will take time to become available in developing countries and will not be cheap.
 - This test should be acceptable to the population – the combined test would be.
 - There should be adequate facilities for the management of cases – this is important in developing countries where the greatest burden of disease is found.
 - The physical/psychological harm to those screened should be less than the benefits - yes.
 - The programme should be cost-effective – this must still be properly determined.
- (Adapted from Wilson & Junger, 1968).

When screening in obstetrics is mentioned, many automatically think of the well debated screening programmes for fetal chromosomal diseases such as Down's syndrome. Jørgensen et al., have opined that the genetic screening programmes have largely been technology driven, ignoring the moral questions that should be asked before implementation. They question whether new clinical methods enhance patient autonomy or simply realise technologically achievable socio-economic goals (Jørgensen et al., 2006). Screening based on history and biophysical risk factors such as weight, blood pressure and proteinuria is standard practice in obstetrics but only identifies about 30% of cases that will develop early, severe pre-eclampsia (DiGiovanni, 2010). No other single screening test has proven to be accurate enough to replace this practice.

Recently a new combined test utilising biochemical parameters (including angiogenic and anti-angiogenic factors [proteins influencing blood vessel formation] in the maternal blood), biophysical parameters and personal information e.g. race and age, has performed well in

predicting the risk of pre-eclampsia, long before the clinical syndrome becomes manifest. Because the prevalence of pre-eclampsia in the general population is “relatively low”, such a test must have a high detection rate (DR) and a low false positive rate (FPR) according to Conde-Agudelo et al., (2004). I will return to this point with regard to pre-eclampsia specifically. Public health policy generally relies on utilitarian principles, so is it problematic if only a small number of the population benefit? The answer is no, if the benefit to those persons is great and the harm caused to those for whom the test was unnecessary, is minimal. In this sense there is still a greater benefit for the population (Jørgensen et al., 2006). The proposed advantages of the combined screening test for pre-eclampsia are:

- Begin early preventative treatment with aspirin – unfortunately only moderate benefit.
- Refer to a higher level of clinical care and surveillance.
- Promote distributive justice by allowing the most effective distribution of medical resources to those who will benefit most by early detection.
- Lower rates of pre-eclampsia and its complications.

In terms of accuracy, the combined test has achieved a sensitivity (true positive) of 94.1%, a specificity (true negative) of 94.3%, with the likelihood ratio of 16.5 (high) for a positive test and 0,06 for a negative test, thus easily meeting the WHO standards (Poon et al., 2009). WHO criteria expect a high detection rate (DR) and a low false positive rate (FPR). In utilitarian terms this comes from comparing the population benefit with the harm of the same test. However this rationale is derived from genetic screening tests where a false positive test for Down’s syndrome may have the devastating result that a normal baby is aborted. In the context of pre-eclampsia, a false positive test would currently result in the patient receiving aspirin therapy (which is safe, cheap and widely available), increased surveillance and perhaps anxiety. Thus the false positive result in pre-eclampsia is less “dangerous” than the false positive result for Down’s syndrome. However, in the future some women might use the screening test for pre-eclampsia to decide whether or not to continue with the pregnancy where abortion is an option (DiGiovanni, 2010). When formulating a screening test for pre-eclampsia, it therefore seems wiser to aim for a higher

detection rate and accept the trade-off of a higher false positive rate, as the risks of a false negative result, which deprive a patient at high risk of pre-eclampsia of prophylaxis and increased surveillance, are greater.

Counselling and consent

To end this sub-section I will return to the theme of counselling and consent, this time in the context of antenatal (prenatal) screening. Angus Clarke has stated that “the decision of a health-care system or of individual professionals to offer prenatal screening for any condition inevitably conveys a recommendation to pregnant women that accepting the test is the responsible course of action” (2012:253). So although the language of choice, autonomy and consent is used, the mere fact that a structured screening programme exists, conveys a message that contradicts the “veneer” of neutrality. Those who choose not to comply with the “standard” screening policy may be regarded as irresponsible and later blameworthy if a complication does occur. In my own clinic, I prefer my trainees to state that a patient declined rather than “refused” a test that was offered. When performed professionally, counselling before screening shows respect and enhances a woman’s autonomy. As discussed earlier, beneficence and non-maleficence are always “in the mix” when counselling is performed, as “respecting patients as persons (*a categorical imperative*) involves more than viewing them as autonomous persons, it involves providing good and avoiding harm (*in this case through screening*)” (Jørgensen et al., 2006). In pregnancy women seek medical care precisely to avoid adverse outcomes.

One of the fundamental moral obligations expected of physicians is to seek a greater balance of clinical benefit over harm for their autonomous patients. This is done through meeting the requirements of informed consent as discussed in section 2.1. But what type of consent is required in each context? If a test is good, does it matter if consent is not “fully informed”? The United Kingdom General Medical Guidance on consent to screening states:

“You should explain carefully the purpose of screening; the likelihood of positive or negative findings and the possibility of false positive or negative results; the

uncertainties and risks attached to the screening process; any significant medical, social or financial implications of screening and follow-up plans, including the availability of counselling and support” (General Medical Council, 2008).

Clearly women must be actively involved in the decision making process which, in truth, sometimes invokes the least infringement principle in order to achieve population-based health goals. Yet the level of consent required for a screening test for pre-eclampsia has been debated. If the test provides population-based health benefits that allow resources to be allocated where they are most needed, is it necessary to seek individual consent, or could an opt-out approach be justified (Jørgensen et al., 2006)? To answer this question, the public goal of screening for pre-eclampsia must be very well defined while balancing the deontological respect for autonomy with the net population utilitarian-based benefits that are still to be accurately determined in this case. Regarding individual consent, I have already argued that providing neutral, non-directive information can be less respectful and fail to enhance autonomy. If the combined test offers robust benefits, and the harm of a false negative test is minimised, doctors should be obliged to recommend it. However this recommendation may never be coercive or deceptive. Despite the currently limited methods for secondary prevention, the benefits of a screening programme for early, severe pre-eclampsia seem to far outweigh the risks but the level of consent will still need to be determined.

3.2 The ethical concept of the fetus as a patient

While the moral (and legal) status of a new-born baby is clearly established, the moral status of the fetus has elicited much debate. Does a fetus have full moral status and if so at what stage of development is it acquired?

“To have moral status is to deserve the protection afforded by moral norms” but “such protections are afforded only to entities that can be morally wronged by actions” (Beauchamp & Childress, 2009:66). How do we identify those who have full moral status? Does it require

human dignity, sentience or rationality? Beauchamp and Childress argue that the properties put forward in prominent theories alone are not enough to resolve the issue but that “collectively these theories can be used to provide us with a general, though untidy framework for handling problems of moral status” (2009:67). They list five theories which despite their strengths, all fail to give an adequate account when considered alone.

- A theory based on human properties.
- A theory based on cognitive properties.
- A theory based on moral agency.
- A theory based on sentience.
- A theory based on relationships.

Beauchamp & Childress are concerned that parties select their criteria for moral status to match their pre-theoretical orientations, including political and religious ones. The proposed solution is to accept as general, the criteria advanced in the first four theories, while adding the fifth theory as another relevant dimension.

Next the issue of potentiality, which is prominent in theories of moral status merits mention. Some hold that “it is morally wrong to intentionally cause a being with the potential to develop status-conferring properties to lose or fail to realise that potential” with the fetus being a case in point (Beauchamp & Childress, 2009:83). However, individual rights may sometimes be justifiably overridden by the rights of others, and not all individuals with moral status, have it without qualification. It is also not valid to argue that all potential must be fulfilled. This question is, for example, raised by the phenomenon of a young child with excellent hand-eye coordination. Such a child undoubtedly has the potential to become an excellent pick-pocket. But we will agree that the latter is a kind of “potential” that, morally speaking, should not be fulfilled. Using the fourth theory (sentience), moral status may be proportional to the quality of sentient life. By applying this approach, the moral standing of zygotes, embryos, fetuses and new-borns increases continuously, and a pregnant woman would have a higher status than her fetus (Strong,

1997:457-478). On this theme, John Harris has stated that “what we need to know is not when life begins, but rather when life begins to matter morally?” with the correlated question being “not when does life end, but when does life cease to matter morally?” (Harris, 1985). Both of these questions may be relevant in section 3.3. Ultimately, with the help of specification, “a plausible, philosophically defensible, practical theory of moral status is the most we can expect” (Beauchamp & Childress, 2009:85).

In the last few decades two apparently opposing positions have emerged in obstetrics and gynaecology. On the one hand, the termination of pregnancy has become a clinically, legally and ethically accepted option; while on the other hand impressive advances have been made in the treatment of fetal conditions. These treatment options have promoted the concept of the fetus as a patient in perinatal medicine, but how does this concept function and when does it apply? Chervenak and McCullough have written extensively on this concept which is based on two ethical principles, namely beneficence and respect for autonomy (2008). Through beneficence the obstetrician has an obligation to seek the greater balance of clinical benefit over clinical harm. Chervenak and McCullough see beneficence as a first principle dating back to Hippocrates and importantly, non-maleficence in the form of *primum non nocere* as a more recent and second principle. They argue that if *primum non nocere* was made the primary principle then all invasive aspects of perinatal medicine would become unethical due to their risks (Chervenak & McCullough, 2008). The pregnant patient has her own set of values and beliefs through which she makes health related judgements. This is translated into clinical practice through respect for autonomy and informed consent. The obstetrician has an obligation to act beneficently towards the pregnant woman and to respect her autonomy.

Now we turn our attention to the fetus. “The fetus cannot be said to possess moral values and beliefs, because of its insufficiently developed central nervous system. We cannot say with confidence that the fetus possesses independent moral status and generates its own rights” (Chervenak & McCullough, 2008). The obstetrician therefore has no autonomy-based

obligations towards the fetus. However, the obstetrician does have a perspective on the health of the fetus and therefore has beneficence-based obligations to the fetus, but only if that fetus is a patient! According to Chervenak and McCullough the fetus becomes a patient when:

- the mother confers that status by presenting it to the obstetrician and
- there exist interventions whether diagnostic or therapeutic that are reliably expected to result in a greater balance of clinical good over harm for the child that the fetus is expected to become in the future. (Chervenak & McCullough, 2008).

An advantage of the “fetus as a patient” concept is that it bypasses the language of fetal rights, which in South African law, and according to Chervenak and McCullough, has no application to the fetus in obstetric ethics (Chervenak & McCullough, 2008; Moodley, 2011). How does viability influence this concept? Viability can be loosely defined as the ability of the fetus to live after delivery, even if technological support is needed, and subsequently become a child. The gestational age equated with viability varies according to the availability of skills and technology. Although exceptions are made, the threshold for viability has moved from 28w0d gestation in the 1990s to 26w0d at Tygerberg Academic Hospital where the author of this thesis practices. The threshold in many developed countries is at 23-24 weeks’ gestation (DiGiovanni, 2012; Chervenak & McCullough, 2008). We should also note the clear conditional threshold of 20 weeks’ gestation for termination of pregnancy in South African law (Government Gazette No. 30790; Moodley, 2011a:257). Viability is important because it heralds a threshold at which the moral/ethical perspective changes. From a moral perspective, the pre-viable fetus is not a patient unless its mother, through her autonomy bestows that status, which she is free to confer or withdraw according to her values and beliefs. In contrast, the viable fetus is a patient from an ethical perspective, independent of a pregnant woman’s autonomy to confer that status (Chervenak & McCullough, 2008). Despite this change the pregnant woman’s autonomy over her own body and the pregnancy that is part of it, still has priority. The challenge for the obstetrician is to balance the autonomy- and beneficence-based obligations to the woman with the beneficence-based obligations to the fetus. These obligations that will sometimes clash are

discussed further by way of clinical examples in Chapter 5 and commentary in Chapter 6, page 83.

3.3 Termination of pregnancy (<24 weeks)

Background

Pre-eclampsia that develops in the mid-trimester (< 28 weeks' gestation) is a challenging problem as explained in Chapter One (Hall et al., 2001). I re-iterate that pre-eclampsia only becomes clinically manifest at ≥ 20 weeks' gestation, so in this section we are dealing with pregnancies from 20w0d-23w6d. In 1988 Pattinson et al., reported no fetal survival when mothers presented with pre-eclampsia before 24 weeks (1988). In practice this means that the pre-viable pregnancy could not be extended forward to viability. Subsequently, the largest reported study on expectant management of early pre-eclampsia, only offered expectant management from 24 weeks' gestation (Hall et al., 2000a). In a review of studies in the literature on expectant management of pre-eclampsia remote from term, Sibai and Barton reported that the overall perinatal mortality rate at < 25 weeks was extremely high (83%) and maternal complications were substantial (57%). Based on this review they recommended that patients at ≤ 23 weeks should be offered termination of pregnancy, whereas those at ≥ 24 weeks could be offered expectant management following extensive counselling (Sibai & Barton, 2007). This recommendation was confirmed by Bombrys et al., one year later (2008). In Chapter One I explained that expectant management of early, severe pre-eclampsia is offered to patients in tertiary institutions by maternal-fetal sub-specialists who meticulously monitor the mother and her fetus in order to gain 1-2 weeks' of gestational age, because even this short period of time gained *in utero*, remote from term, markedly improves perinatal outcome. However, if the chances of reaching viability are dismal, then there is no clinical reason to continue the pregnancy when the mother remains at high risk of further complications. In this scenario the interests of the woman and her fetus appear to be in conflict. The pre-viable pregnancy will be terminated (aborted) and the fetus will die, either during the process or shortly after birth. If both

had equal status, treatment of the one most at risk should be given priority (Adams et al., 2003); however in this case the pregnant woman's autonomy has priority (DiGiovanni, 2010). When a pregnant woman is critically ill, the doctor's duty of beneficence in saving her life and health overrides the duty of beneficence to the fetus.

The futility issue

In the paragraph above I make the statement that "if the chances of reaching viability are *dismal*, then there is no clinical reason to continue the pregnancy". This raises the concept of medical futility. Futility may be at issue in many clinical scenarios but it is most often framed in the end-of-life context. During the mid-1980s' to mid-1990's period, the futility debate raged back and forth. In their article on the rise and fall of the futility movement, Helft et al., made the following observations "The movement to establish a policy on futile treatment was an attempt to convince society that physicians could use their clinical judgement or epidemiologic skills to determine whether a particular treatment would be futile in a particular clinical situation. The idea was that once such a determination had been made, the physician would be allowed to withhold or withdraw the treatment, even over objections of a competent patient" (2000).

Schneiderman, who has made important contributions to the debate, has used common sense notions and statistical assumptions regarding outcomes in order to frame a broadly acceptable definition of futility (2011). He has also argued that a treatment effect is not necessarily a benefit. A recent formulation of his definition of futility is therefore: "that medical futility is the unacceptable likelihood of achieving an effect that a patient has the capacity to appreciate as a benefit" (Schneiderman, 2011). The argument follows that once a treatment is accepted as futile the doctor will have no ethical obligation to provide it.

Implicit in the definition of futility is that it has quantitative and qualitative components. These two components can be traced back to writings by Hippocrates and Plato. "Whenever the illness is too strong for the available remedies, the physician surely must not expect that it can be

overcome by medicine ... To attempt futile treatment is to display an ignorance that is allied to madness” (Hippocratic Corpus, 1977). This illustrates the quantitative aspect. Although philosophers such as Hume and Popper have pointed out that even if A follows B, a hundred times, one can never be absolutely certain that the same thing will happen again (Popper, 1961), reasonable physicians must accept the evidence that they have observed, as this forms the foundation of clinical medicine. For example, rigorous quantitative physiology-based systems such as the APACHE score have been developed to predict which patients will die in the critical care environment. On this basis statisticians build in thresholds of significance (typically < 5%) supported by confidence intervals (typically at 95%). However these systems provide accurate prognostication for groups rather than individuals (Helft et al., 2000). Although the physician is never absolutely certain the quantitative approach helps physicians overcome the paralysis of uncertainty. There is also a qualitative component to futility. “For those whose lives are always in a state of inner sickness Asclepius (a physician) did not attempt to prescribe a regime to make their life a prolonged misery. A life with preoccupation with illness and neglect of work is not worth living” (Plato, 1981). The patient must have the capacity to appreciate the treatment as a benefit. To merely preserve a vegetative state or prolong significant suffering without the prospect of improvement is qualitatively futile. When treatment serves no purpose, the focus must shift from futility to the ethics of care, specifically comfort care. The physician always has an obligation to alleviate suffering, enhance well-being and support patient dignity in the final stages of life (Schneiderman, 2011).

In Chapter 2, I raised the issue of the battle for power. One may ask the question of who has the right to decide whether medical care is futile or not. Here one may observe that the autonomy of patients is in conflict with the autonomy of doctors. Although doctors might believe that they are best placed to make this judgement on objective grounds, others have argued that it is incorrect to regard futility as an objective entity and that patients, with their subjective views and goals are best able to judge what is beneficial to them (Lantos et.al., 1989). This position carries the support of authors such as Veatch, Brett and McCullough (Veatch, 1994; Brett and McCullough,

1986), while Youngner states that doctors should only “frame the choices by describing prognosis and quality of life” (Youngner, 1988). The counter-argument is that doctors are not obliged to provide care with no proof of benefit and that complete respect for patient autonomy reduces a doctor “from a moral agent to an extension of the patient’s wishes” (Paris and Reardon, 1992). Doctors should act with the virtue of integrity, exercising their knowledge through honest appropriate counselling and practice. They should not provide false hope by discussing futile options as this only undermines patient autonomy. Brody has stated categorically that “society cannot dictate to medical professionals the practice of their integrity” (Brody, 1994).

Next, there is the principle of distributive justice. In clinical medicine, respect for the patient’s autonomy is a fundamental value. In fact a competent adult has “a close to absolute moral and legal right to refuse treatment, with limited exceptions in situations in which refusing treatment harms others” (Baily, 2011). However there is a difference between refusing treatment and demanding it. The right to receive an appropriate standard of health care is well accepted, but this right is not unlimited. Medical treatment is almost always an expensive limited resource. Mary Ann Baily has put it this way: “Currently concern about ethics in medical decisions is too easily portrayed as in opposition to concern about cost: the ethical physician or advocacy group heroically faces off against the amoral bean-counters. This is a false picture. The truth is, cost is an ethical issue” (2011).

In this sub-section (3.3) we are dealing with the counselling of a pregnant woman with severe pre-eclampsia before 24 weeks’ gestation, who will be offered a termination of pregnancy because of the extreme risks to her own life and health, and because the hope for the fetus reaching viability is “futile”. Consensus definitions on futility have proved elusive and ranking levels of autonomy has not helped. In the clinical scenario, professionalism and virtue moves beyond these disputes. Honest communication in an environment of trust is required. Experienced doctors recognise clinical situations in which treatment is futile and they should inform patients and their families thereof. These important decisions should not be taken by

individuals alone but rather with multi-disciplinary input. In addition, the principle of distributive justice has led to the establishment of hospital and regional policies to guide treatment. Finally, the judgement that treatment is futile is not the end of care. The obligations to alleviate suffering and support dignity remain in the form of comfort care.

Applied clinical ethics

The issues surrounding termination of pregnancy “on demand” or following patient requests have been well described and debated. I want to focus on the particular and different clinical scenario just described and extrapolate the insights of some authors in the field. I will first examine moral issues concerning three variations on the recommendation to terminate the pregnancy in this clinical situation.

- The pregnant mother accepts the medical recommendation to terminate the pregnancy, the fetus is previable and not a patient. This is the standard position.
- The moral dilemma if the fetus is regarded as a person.
- The moral dilemma if the mother declines termination of the pregnancy.

My purpose is to discuss the ethical issues but I will first state the legal background in South Africa. There are three medical indications for termination of pregnancy after 20 weeks, of which two apply in this context:

- Where continued pregnancy would endanger the woman’s life (main focus).
- Where continued pregnancy would pose a risk of injury to the fetus (Moodley, 2011a).

An important aspect of the abortion debate concerns the personhood or moral status of the fetus. For the purposes of this focussed discussion the point has been sufficiently elaborated in section 3.2. Abortion is often considered as a paradigm example of maternal-fetal conflict but this only makes sense if the fetus has interests (moral status~personhood). As I have pointed out, this is debatable in varying degrees up to viability. If one accepts the latter position then abortion does not pit the interest of the pregnant mother against her fetus up to that stage (Steinbock,

2012:150). I will now move past the debates surrounding early abortion of unwanted pregnancies that have been carefully discussed in texts such as the one by Mary Anne Warren (2012) to the first version of our scenario, which is not uncommon in the context of tertiary referral practice.

Case 3: A pregnant woman with severe pre-eclampsia is referred in at 22 weeks. The mother is stabilised and the diagnosis confirmed. Because the fetal prognosis is dismal (futile) at this stage and pre-eclampsia holds significant risks to the mother, she is counselled and consents to termination of pregnancy.

The situation satisfies two South African legal requirements for late termination mentioned earlier. This anguished decision usually occurs in the context of a wanted pregnancy. The ethical issues involved in scenarios where the pregnancy is “wanted” may be thought to be different from those where the mother has no concern for the fetus. Eileen McDonagh, an American political scientist has previously sought to unite opponents and proponents of abortion through an argument that justifies abortion not in terms of a woman’s right to choose, but in the granting of her consent to the further continuation of the pregnancy (2002:222). This argument where maternal autonomy comes out “trumps” is similar to that of Chervenak and McCullough, where a pregnant woman and not her fetus has autonomy, and that through this maternal autonomy she is free to confer or withdraw “patient” status on her pre-viable fetus according to her values and beliefs (Chervenak & McCullough, 2008). In Bonnie Steinbock’s opinion “the long-term interests of a pregnant woman in preserving her life and health surely outweigh the interests of a doomed fetus even if it temporarily experiences unavoidable pain” (2012:151). In this scenario the doctors have acted with beneficence, respected the autonomy of the competent patient and reasoned along utilitarian lines of thinking with regard to the greatest amount of happiness. In the somewhat similar and famous case of Angela Carder the initial reasoning of the hospital administrator was that it is morally preferable to save one life than to lose two (van Niekerk, 2011). In the process of termination in the described clinical scenario, the fetus usually dies

during the induced labour (termination) due to pre-eclampsia-induced placental dysfunction and the limited fetal reserves of severe prematurity. We now encounter the rule of double effect (RDE) that “incorporates a very influential distinction between intended effects and merely foreseen effects” (Beauchamp & Childress, 2009:162). The rule is rooted in the moral theory of Aristotle that emphasises a person’s intention, and in Bentham’s theory on the consequences of actions. If the physician, through the termination of pregnancy, intended to save the life of the mother and did not intend to cause the death of the fetus, then such an act was not morally wrong according to the RDE. However “slippery-slope” arguments must always be considered seriously.

I now consider a different twist in the same case scenario. What if we grant this fetus the moral status of personhood from conception? The 22 week fetus would already be severely damaged through pre-eclampsia mediated placental dysfunction, but I will also ignore that fact for now. Would this change our moral perspective? The fundamental principle of non-maleficence imposes the obligation not to harm others (*primum non nocere*) that is generally more stringent than the obligation of beneficence. However, according to Beauchamp and Childress, mainstream moral philosophy does not draw a sharp distinction between the obligations of not harming, and helping others (2009:151). The specifications of non-maleficence lead to moral rules which again are prima facie and not absolute such as do not kill and do not cause pain or suffering. In clinical medicine the line between non-maleficence and beneficence can be blurred as in this case the doctor must harm (*kill*) the fetus in order to save the mother. If the fetus is a person, are we treating it merely as a means to the end of saving the mother’s life or are we working toward the overall best outcome? In this sense deontology and consequentialism clash but Beauchamp and Childress would remind us of the prima facie nature of moral rules.

In a well-known paper, introducing the model of the “famous violinist”, Judith Jarvis Thomson argued that even assuming full moral status for the fetus, there are sometimes morally sound reasons to sanction abortion (1971). If mother and fetus had equal rights, some would argue that

abortion/termination (killing the fetus) would be wrong even if the mother's life was at risk and we were letting her die. But it is difficult to find a moral difference between "killing" and "letting die" (Rachels & Rachels, 2010). Part of the problem lies with the focus on what the "third party", namely, the doctor may or may not do, when an abortion is requested, as the doctor is seen to be the one who is "killing or letting die". Judith Jarvis Thomson is anxious not to refuse to grant the mother the very status that is so firmly insisted on for the fetus. When looking at the mother, she asks "does a mother not have the right to decide what happens in and to her body?" On this basis, her right to life and bodily autonomy outweigh the fetus's right to life. "It cannot seriously be said that she must sit passively by and wait for her (*own*) death"; and with reference to her model Thomson states "if anything in the world is true, it is that you do not commit murder, you do not do what is impermissible if you reach around your back and unplug yourself from the violinist to save your life" (Thomson, 1971). The point is also elaborated by Eileen McDonagh who points out that a major justification for killing a living thing, including a person, is self-defence (2002:223). In this regard even the law recognises persons' right to use deadly force to protect themselves from certain types of harm including death and serious bodily injury e.g. renal failure. In her opinion, self-defence (with deadly force) in this context does not merely excuse the action; it justifies it (McDonagh, 2002:225)! Ultimately, though with some qualifications, Thomson argues that the right to life does not guarantee the right to use another person's body, even if that body is needed for life itself. In this scenario, the fetus's rights are only violated if it is killed unjustly.

In the final version of this clinical scenario, certain mothers decide to decline the offer of termination, often based on their own religious values or beliefs. Again this is not an uncommon occurrence in tertiary clinical practice. Such decisions place enormous stress on professional doctors who are acutely aware of the serious, potential complications for the mother but must respect her autonomous decisions and continue with the highest standard of care. Decisions are of course only autonomous if patients are properly informed and have processed that information. When patients initially decline, doctors should allow time for such processing and then return to

ensure that there is adequate understanding and not simply false hope. Part of the disclosure process is to involve not just the father of the pregnancy, but also (with the woman's consent) other family members and authority figures such as ministers of religion, thereby acknowledging communitarian values. Informed refusal will be discussed further in section 5.3. In most cases the pregnant woman will reconsider her position over time or as her condition deteriorates. When the fetus dies spontaneously *in utero* this also resolves the personal ethical dilemma for most women.

In the case of early pre-eclampsia at < 24 weeks' gestation, there are grave risks for the mother and a dismal prognosis for the fetus. Under these circumstances, the fetus should not be regarded as a patient.

3.4 Summary position

In this chapter I have discussed antenatal screening for pre-eclampsia, the ethical concept of the fetus as a patient, futility and the termination of a non-viable pregnancy with early, severe pre-eclampsia in order to save the mother's life or prevent severe complications. The ethical issues related to a screening programme are influenced by factors such as methodology and the availability of a "curative" intervention. I have argued that the ethical matters be considered before possible implementation of this promising combined test. Utilising the concept of "the fetus as a patient" is helpful in perinatal medicine. An autonomous pregnant woman may choose to confer or deny this status to her previable fetus. Obstetricians have to balance the autonomy- and beneficence-based obligations to the pregnant woman with the beneficence-based obligations to her fetus. Although it is always an anguished decision, most often in the context of a wanted pregnancy, the termination of a pregnancy with severe pre-eclampsia at <24 weeks is not morally problematic. This remains the case even when considered from the (unusual) position of considering the previable fetus as a person.

CHAPTER FOUR: AGGRESSIVE OR EXPECTANT MANAGEMENT OF EARLY, SEVERE PRE-ECLAMPSIA

4.1 Background, counselling and consent

All pregnant women experience some form of discomfort during pregnancy and undergo direct risks to their health and life, the physiologic hypercoagulable state being just one example. Treatments vary in levels of discomfort from taking a short course of antibiotics to long hospital admissions. While few parents will die through caring for their small infants (despite exhaustion), many women become ill and die in pregnancy (Bewley, 2002:135). It is however common knowledge that pregnant women with wanted fetuses are often prepared to jeopardise their own health and even life prospects for sake of their pregnancies. In this sense their actions are clearly supererogatory.

In section 1.1 I explained the serious nature of pre-eclampsia. When early, severe pre-eclampsia develops it is always in the mother's interests to end the pregnancy. The clinical course may be associated with progressive deterioration in both maternal and fetal conditions. Thus, because delivery is the only way of arresting the disease, there is broad agreement on delivery in the presence of organ failure, fetal distress or once a gestation of 34 weeks has been reached. However, there are high rates of perinatal mortality for babies born very prematurely (remote from term). When women diagnosed with severe pre-eclampsia, are stabilised and delivered within 48 hours, this is termed *aggressive management* (hurry up). Additional complications or fear of progressive deterioration informs this approach. In many tertiary units around the world, *expectant management* (wait) is offered to carefully selected women with early pre-eclampsia (24w0d – 33w6d) who respond to stabilisation (usually 24-48 hours), have no other maternal or fetal complications and who consent to tertiary, non-invasive maternal and fetal surveillance on a continuous in-patient basis. Expectant management is then performed by a dedicated team of doctors until discharge after delivery (Hall et al., 2006; SMFM, 2011). The gestational time gained by expectant management varies but is usually about two weeks (Hall et al., 2000). The

ultimate goal of expectant management remains the safety of the mother and the delivery of a live infant who will not require intensive and prolonged neonatal care (Hall et al., 2000a).

This background provides the basis for the next clinical application of *counselling and consent*. Although expectant management is now more widely advocated, particularly in developing countries where neonatal intensive care facilities are limited (Frias & Belfort, 2003), experts in the field have emphasized that expectant management should only be offered after “extensive counselling” (Sibai & Barton, 2007). Why do they use the adverb “extensive”? Having earlier examined beneficence, non-maleficence, autonomy, deontological and utilitarian perspectives, I have argued that clinical counselling is also influenced by: risks (maternal and fetal), asymmetric power within the doctor-patient relationship (section 2.1), the level of evidence for an intervention and the supererogatory nature (see preview of Chapter 4 in chapter overview of Chapter 1) of women with welcome pregnancies. In an extensive review of the management of severe pre-eclampsia before 34 weeks’ gestation, the Society for Maternal-Fetal Medicine (SMFM) found that expectant management of selected patients can improve neonatal outcomes (SMFM Clinical Opinion, 2011). In order to determine our mode of counselling we need to ask what level of evidence informed this conclusion. In fact the highest level of evidence (randomised trials - category I) is small, although there are several large reassuring observational studies. When considering expectant management we therefore have a situation with significant risks (for both mother and fetus), a paucity of category I evidence, good lower category evidence and mothers who have a supererogatory attitude. Another independent factor that influences the decisions of these women is that even with severe hypertension they do not feel unwell, and may therefore underestimate the risks. This adds to the responsibility of the doctor. The mode of counselling should therefore be non-directive (due to the level of evidence), clear and thorough, while at the same time not overloading the patient with information. This is how I interpret the term “extensive counselling” in this context. In an attempt to improve patient comprehension before this emotionally charged decision, my clinical unit designed and tested a patient information sheet in a randomised, controlled trial. Although this improved patients’

understanding, it did not alleviate their anxiety (van der Merwe et al., 2011). It remains incumbent upon doctors to act calmly and professionally when counselling these women.

4.2 Scarce advanced (extra-ordinary) resources

A critical moral relationship exists between the doctor and a patient because he/she is well placed to act beneficently. As such physicians experience an obligation to rescue. In the context of early pre-eclampsia, doctors are obliged to “rescue” the mother and fetus if at all possible but to do this, tertiary medical care is required. This takes the form of inpatient management by a team of sub-specialists and sometimes requires further admission to an adult or neonatal intensive care unit (Hall et al., 2006).

High care and especially intensive care represents what has been called *extra-ordinary* treatment (Beauchamp & Childress, 2009). Healthcare in South Africa is certainly challenged by resource constraints. This raises the issue of justice, specifically distributive justice in resource management. For Beauchamp and Childress, justice is explicated as “fair, equitable and appropriate treatment in the light of what is due or owed to persons”. To this, distributive justice adds: appropriate distribution of resources “determined by justified norms that structure the terms of social co-operation” which includes the “distribution of all rights and responsibilities in society” (2009:241). In South Africa, access to quality healthcare is largely limited by the ability to pay. The issue of distributive justice only arises when there are conditions of scarcity and competition. Tertiary and specifically intensive care services are scarce resources. I will return to this point in later chapters.

Principles of justice

There are several principles of justice of which one is *formal* and the others, *material*. In their application they must be specified and balanced. *Formal* justice requires that equals must be treated equally and unequal's, unequally. This principle lacks substance because it does not

qualify how persons should be treated equally or how to determine their equality, e.g. should all SA citizens have equal access to free healthcare or should pregnant women have priority? “Principles that specify the relevant characteristics for equal treatment are called *material* because they identify the substantive properties for distribution” (Beauchamp & Childress, 2009:242). Sometimes the *relevant properties* needed for a particular distribution are well established but in other contexts new policies require formulation. In healthcare this finds particular relevance when new highly specialised (extra-ordinary), usually expensive forms of therapy become available in limited quantities. Thus abstract principles of justice can only provide rough guidelines for specific actions or policies. Further moral argument, specification and balancing, as well as the utilisation of experience and judgement are still required.

Theories of justice

According to Beauchamp and Childress, various theories “succeed only partially in bringing coherence to our fragmented visions of social justice” (2009:244). Current health care policies have competing objectives where one goal may undermine another e.g. seeking to provide expensive tertiary care but protecting public funds through cost-containment programmes. At best these theories can help to delineate competing objectives acting to reduce the importance of some while promoting others to reach a balance.

- *Utilitarian theories*. Utility demands that we maximise social welfare and that maximum utility constitutes maximum justice, but individual rights may be compromised. It seems unjust to maximise utility while denying health care to the sickest, most vulnerable populations.
- *Libertarian theories*. Here “health care is not a right and the ideal system is privatised” (Beauchamp & Childress, 2009:245). Robert Nozick believes that a theory of justice should affirm individual rights rather than create patterns of economic distribution e.g. equal distribution of health resources. Justice is seen in the operation of just procedures, not in the production of just outcomes, (Nozick, 1974:149-182). Denial of access to care through lack of finance is seen as unfortunate but not unjust, but libertarians do not oppose utilitarian patterns of distribution if they are freely chosen. “The problem with

libertarian justice is that it disadvantages individuals and clinical services that do not generate large revenues but are essential to the organisation's mission" (Chervenak et al., 2013).

- *Communitarian theories.* Whereas Mill, Rawls and Nozick promote models of society based on rights and contracts and a single theory of justice, "communitarians regard principles of justice as pluralistic, deriving from as many conceptions of the good as there are diverse moral communities" (Beauchamp & Childress, 2009:246). The community is for the individual and the individual for the community, but the needs of the community are given priority over those of individuals.
- *Egalitarian theories.* In this just society everybody should receive an equal distribution of healthcare irrespective of their ability to pay.

Chervenak et al., advocate a model of professional responsibility (see section 2.1) that invokes the corrective force of egalitarian justice to prevent the inequities of utilitarian and libertarian justice (2013).

Tertiary care and specifically intensive care may be regarded as extra-ordinary treatment. A widely referenced rule is that "extra-ordinary treatments can legitimately be foregone whereas ordinary treatments cannot legitimately be foregone" but the distinction is often vague and according to Beauchamp Childress, morally irrelevant (2009: 158). The key is the balance of benefits and burdens to the individual.

In specifying the principles of justice, knowledge of the effectiveness of treatment is essential in determining resource allocation. In early pre-eclampsia, the randomised trials and observational studies already mentioned have demonstrated the particular benefits of expectant management for the fetus, in carefully selected cases. The ultimate goal of expectant management remains the safety of the mother and the delivery of a live infant who will not require intensive and prolonged neonatal care. What is important to note is that by safely prolonging the pregnancy, thereby increasing gestational age at delivery, excellent perinatal and neonatal survival rates can be

achieved, and the need for expensive neonatal intensive care support is markedly decreased (Hall et al., 2000a; SMFM, 2011). This judicious use of neonatal intensive care improves distributive justice. Further developments in the care of very premature babies without adequate recourse to neonatal intensive care include avoiding mechanical ventilation by the use of continuous positive airways pressure (CPAP), and “kangaroo” care by the mother. The kangaroo position for the premature baby is an upright, prone position on the mother’s bare chest, between her breasts and under her clothes, thereby forming the maternal pouch (Hall & Kirsten, 2008).

4.3 Restricting the freedom of pregnant women

This unorthodox and aggressive intervention is usually considered in the context of the dangers posed by hard drug abuse in pregnancy. In the field of severe hypertension and maternal-fetal medicine the culprits include cocaine and more commonly methamphetamines (“tik”) in the Western Cape. However there are many other ways in which women put their fetuses at risk such as smoking, drinking alcohol or failing to attend clinics. In this chapter I want to shift the focus and context to the related but different scenario of a woman offered expectant, inpatient management for early, severe pre-eclampsia. As stated earlier, this partial “restriction of freedom” (i.e. inpatient management) is necessary to perform the clinical surveillance required to ensure the safety of the mother and fetus during the process. The dedicated medical team managing these women must be able to respond quickly to early signs of impending complications. In this group, a moral relationship exists between the mother and her wanted fetus upon which she has conferred personhood (rights) and for that reason she voluntarily offers up her “outpatient freedom” for an undetermined period (usually about two weeks) before delivery, as well as after delivery to assist with the care of her small, premature baby until it is ready for discharge. The inpatient stay after delivery often takes the form of “kangaroo care” once the maternal condition has resolved.

Being an inpatient for an undetermined period of time is challenging. Compared to parents, pregnant women have a unique disadvantage in that they cannot be separated from their fetuses, but does this intimacy increase their obligations (Bewley, 2002)? Many women are referred in from rural areas, and are thus far away from home. They often come from low socio-economic circumstances making it difficult for their family members to visit, they have to change their habits in the hospital e.g. stop smoking and they are anxious about their pregnancies. These women temporarily lose control over the circumstances in their homes, such as care of other children and the collection of finance and grants. What makes it even more difficult is that in many cases these mothers do not feel physically unwell. These facts illustrate the point that in order to understand women's choices we need to grasp what Engel has termed the biopsychosocial model (Engel, 1982). This means that comprehensive clinical judgement requires attention to both clinically relevant biomedical and psychosocial aspects of a pregnancy. Expectant management thus represents a multi-faceted "sacrifice" by the mother. If she does not consent to this "restriction of freedom" package, expectant management is not possible and aggressive management (as previously described) is offered.

Expectant (inpatient) management makes two important assumptions:

- *The fetus in this context has moral status and rights.* According to the "fetus as a patient" model (see section 3.2) the mother has conferred this status. However, even if a woman declines expectant management, her viable fetus can still be regarded as having moral rights, although its mother is not prepared to accept trying to improve the neonatal outcome by prolonging the pregnancy. In this case the mother's claims of autonomous choice and bodily integrity outweigh the interest of the fetus in being born at a greater gestation. The fact that a mother chooses to rank her interest above that of the viable fetus "trumps", but does not remove fetal rights. These mothers still care about their fetuses despite choosing not to "restrict their own freedom" for whatever reason. Thus the obligation to care for the fetus, even through aggressive management remains. Both the mother and the medical team have a duty to take reasonable steps to ensure that the

fetus is born in good health. “The rights it possesses in the future impose duties on us now to care for it, so as to ensure that it may achieve this personhood later” (Bewley, 2002).

- *Sufficient justification for this “restriction of freedom” exists.* When involuntary restriction of freedom is considered e.g. for a cocaine addict, a powerful justification for overriding a person’s right not to be interfered with, must exist. However, if a mother has obligations to her fetus, then so has society (Bewley, 2002). In our context of voluntary “restriction of freedom” during expectant management of pre-eclampsia, we still need sufficient justification. This is provided by the scientific evidence that has been discussed.

4.4 Summary position

In this chapter I have discussed counselling in a new context, the utilisation of scarce, advanced resources and the issue of restricting the freedom of pregnant women. Based on the available scientific evidence, counselling stable women with early pre-eclampsia should be performed in a professional, calm, non-directive and thorough manner that takes account of the supererogatory nature of pregnant women. Neonatal intensive care is an expensive and limited resource. The ultimate goal of expectant management remains the safety of the mother and the delivery of a live infant who will not require intensive and prolonged neonatal care. This judicious use of neonatal intensive care improves distributive justice. By consenting to expectant management, the pregnant woman voluntarily restricts her freedom. This decision is morally undergirded by the value accorded to the viable fetus and the scientific evidence informing the decision.

CHAPTER FIVE: JUDGEMENTS OF NON-COMPLIANCE IN PRE-ECLAMPSIA

5.1 Background and maternal-fetal conflict

Women have moral obligations to avoid harming their fetuses. “Just as parents have obligations to avoid exposing their born children to substantial risks of serious harm, so pregnant women have comparable obligations to the children they will bear” (Steinbock, 2012:158). During pregnancy women do need to make sacrifices and take risks and while some actions are clearly morally wrong, such as using methamphetamines, other actions are morally equivocal. Even amongst women with severe chronic illnesses that may accelerate if they become pregnant e.g. renal failure after previous pre-eclampsia, the desire to achieve pregnancy and motherhood can be overwhelming (Lockwood, 1999). Falling pregnant against clear medical advice or failing to attend clinics is not uncommon behaviour and is frequently categorised as “non-compliance”. Doctors do well to ask themselves if this term is value-free or used to “reinforce the physician’s power and to label the patient as an object of concern rather than a partner in the clinical relationship” (Dickenson, 2002:6). Generally patients can choose whether to heed professional advice, or not. However, sometimes “failure to follow professional recommendations elicits pejorative judgements of non-compliance, and while these judgements are provoked by a failure to comply with specific advice, typically they are applied to the patient as a whole” (Baylis & Sherwin, 2002).

A pregnant woman is more than a “fetal container” (Annas, 1986). She is a person with her own interests and needs under the restrictive influence of pregnancy. Maternal behaviour that harms the fetus and future child is categorised as maternal-fetal conflict but Bonnie Steinbock insists that this term is often misleading (2012:152). Society and the medical profession are particularly sensitive about maternal harmful behaviour because such a patient is risking not only her own

health, but also that of her future child. Social stereotypes expect women to be self-sacrificing and judge women especially harshly if they fail to make all reasonable efforts to protect the health of their developing fetuses (Bayliss & Sherwin, 2002:293). Although the child harmed by maternal behaviour during pregnancy, had different rights at the time that the injury was inflicted, it does not lessen the obligation to avoid injuring a fetus that will develop into a child. For Steinbock this is a continuous argument and thus the conflict here is not really with the fetus but with the future child (2012:152). Although women have prima facie obligations to avoid inflicting prenatal harm on future children, this moral obligation finds little expression in the law. Steinbock supports her argument that we have obligations to individuals not yet born by using the example of improper canning of baby food today that would harm a child born next week (2012). According to this reasoning, one may however legitimately question whether maternal harmful behaviour (e.g. drug abuse) is morally wrong when an abortion is planned, because in that case a child will not come into being.

If we accept the “potentiality” argument of Steinbock, one model of understanding women’s obligations to their fetuses is to consider what is required from parents of children already born. “Our moral obligations to our children may be particularly broad and deep, but they do not overwhelm all other moral considerations in all circumstances” according to Murray (1991:107). This generally translates into protection from substantial risks of serious harm. There are many ways in which women put their fetuses at risk such as smoking, drinking alcohol or failing to attend clinics, but when it comes to specific risks such as occasional drinking during pregnancy, there is often disagreement amongst the experts. Ultimately, any woman who will have a child is morally required to avoid harming the fetus, if this can be done without sacrificing her own important interests.

5.2 Understanding non-compliance

Pregnant women and those considering pregnancy are bombarded with advice ranging from mere suggestions to professional recommendations. In section 4.3, I introduced the biopsychosocial model of Engel which helps us understand the reasons for a patient's behaviour. Certain types of behaviour are not inherently problematic but merely informed or uninformed refusals. Those that are problematic and thus likely to be judged as "non-compliance" are those where the patient fails to comply with her own choices (Baylis & Sherwin, 2002:286). Despite this, medical professionals should deal with these situations in ways that still attempt to enhance autonomy, respect and integrity within the doctor-patient relationship.

Case 4: A 36-year-old, mother of one child, first presented for care very late in her pregnancy (28w5d gestation). The patient lived in a town outside a secondary hospital in the Western Cape, approximately 100 kilometres away from the tertiary referral hospital. A diagnosis of pre-eclampsia was made. The mother, an obese smoker, had severe hypertension and the placenta of the fetus was functioning poorly. After a period of stabilisation she consented to expectant management of her condition as an inpatient at the tertiary hospital.

Shortly after admission the mother received news that her 11-year-old son had not arrived at school. According to the patient she had been transferred to the tertiary hospital before being able to make domestic arrangements and was now unable to contact family or friends as her phone's battery was flat. The understandably anxious patient wanted to return home. The social worker was consulted and reported back to the managing registrar (trainee specialist). The head of the Special Care Unit (Prof. Hall) then contacted the specialist obstetrician at the secondary hospital to make specific individual arrangements for the patient. The plan was that she would return home to address the pressing domestic issue and then present to the

secondary institution (closer to her home) the next day, if not for admission, then for full evaluation.

Although ambulance transport from the tertiary hospital was arranged for the patient, she left without informing the staff, taking a taxi home. According to her “fellow” patients in the tertiary hospital, the patient arrived home safely, quickly located her son at a friend’s house but then decided not to return to either hospital.

The interpretation of non-compliance

As stated above, women are likely to receive a range of advice before, during and after pregnancy. For example, if the woman in Case 4 had presented before pregnancy, she would have been advised to stop smoking, lose weight, take folate supplements, consider the effect of the inter-pregnancy interval, and have received counselling regarding chromosomal anomalies. From the woman’s perspective, this advice though sound, might have been impossible to follow. Those who fail to follow sound medical advice may be labelled as “non-compliant”. Given the large amount of medical advice directed at pregnant women, it is likely that all women will diverge from the plan to some extent, but when do doctors evaluate this divergence as non-compliance and when do they not?

It seems that in order for the term non-compliance to be used, a doctor patient relationship must exist. If the woman in Case 4 had not presented for preconception counselling, she would still have known that smoking and obesity are unhealthy as such knowledge is widely available. If she had fallen pregnant without addressing them there may have been some disapproving moral judgements, but her omissions would not be regarded as non-compliance. On the other hand “The label non-compliant is readily assigned in cases where there is a perceived risk of serious harm for the fetus or the woman that is avoidable but for the woman’s failure to comply with her physician’s recommendations” (Baylis & Sherwin, 2002:290).

The term non-compliance might imply that the power in the doctor-patient relationship is inherently unequal. In that sense labels of compliance or non-compliance are assigned by those with greater power (doctors) on those with lesser power (patients). Doctors give directives but patients can only make requests. Although this is often the *de facto* case, doctors must comply with professional norms and could be reported as non-compliant for failure to do so.

The real problem with the label of non-compliance is that it often involves more than justified concern on the part of the doctor, it also expresses or implies disapproval. Something has gone seriously wrong in the relationship and blame is assigned (Baylis & Sherwin, 2002:291). In the increasingly litigious medical environment, the doctor may be concerned that the unnecessary risks taken by the patient might lead to complications with legal consequences. For this reason medical staff are very quick in “demanding” that women sign the “red card” (a self-discharge document) when discharging themselves against medical advice. It is interesting to note that there are opinions that rest the blame for patient non-compliance on doctors rather than on patients, as it is their responsibility to properly inform, educate and explain the importance of conscientiously following medical advice (DiMatteo & DiNicola, 1982, 251). Once a label of non-compliance has been given, essential trust between the doctor and the patient is eroded and the patient’s agency is reduced in that she “is discouraged from determining her behaviour on the basis of her own perception of what constitutes a good outcome and how best to achieve it” (Baylis & Sherwin, 2002:292).

Why might patients not comply?

There is a wide variation among doctors in the use of the term non-compliant. I have argued that the term is not value-free and may even be harmful. Baylis and Sherwin believe that it is useful to identify behaviours and to understand whether doctors and patients agree about the nature of the problem (2002, 293).

- *Deliberate refusals: value conflict.* Here patients reject medical advice that is contrary to their own values. A woman with severe pre-eclampsia at <24 weeks’ gestation may

decline termination of pregnancy because she is opposed to abortion. She is unlikely to be labelled non-compliant but may feel less support from doctors who are anxious about potential complications associated with her choice.

- *Deliberate refusals: epistemological conflict.* In the current era there is a vast amount of medical information in the public domain. Apart from this, women's judgements are also influenced by personal experiences and those of family and friends. In this case the woman may not agree with the information that informs her doctor's recommendation.
- *Deliberate refusals: distrust.* Some women, particularly minority groups, different faiths or vulnerable groups such as refugees, see doctors as representing a culture that is hostile to them.
- *Lack of understanding.* Here patients do not follow medical advice because they do not fully comprehend it. Disclosure of information takes time and requires patience. Language may also present a barrier which is why the author's unit has designed a patient information leaflet to be used in combination with counselling (van der Merwe et al., 2011). Lack of understanding could also apply to incorrect use of medication or missed appointments.
- *Inadvertent non-compliance.* Sometimes the doctor and patient agree on the goals and yet the patient still does not act in accordance with the advice. This might reflect too much advice or that she is unable to control her circumstances such as work environment, work hours or domestic circumstances. This is a particular problem for women from low socio-economic groups. Hence the need to understand the biopsychosocial model.

Application

As stated earlier, expectant management of early pre-eclampsia requires inpatient management. This "restriction of freedom" is necessary to perform the clinical surveillance required to ensure the safety of the mother and fetus during the process. The alternative is aggressive management as explained in Chapter Four. In Case 4, the woman who initially consented to expectant management was free to withdraw that consent and request the alternative path without any

prejudice. However, her psychosocial concerns for her 11-year-old son, led her to discount both medical options, thereby endangering her own health and that of her fetus. The medical team did not label her as non-compliant, but sought to understand her moral dilemma more comprehensively and then made a medically compromising, individualised decision to assist her. Her decision not to accept either of the standard medical options was distressing to the staff who have witnessed cases where such women discharged themselves only to be brought back convulsing with eclampsia, intra-cerebral haemorrhage, placental abruption or an intra-uterine death. The “sting in the tail” for the medical team in this case was that even when her evident social problem had been solved, the patient still did not return for care. At this stage a label of non-compliance would seem to have been justified, but there may still have been other factors which the patient chose not to reveal.

“In the ideal physician-patient relationship, responses to medical advice should be mutually satisfactory, based on mutual respect, mutual understanding and mutual responsibility” (Baylis & Sherwin, 2002:292). This is of course not always possible. However, the patient must not perceive the doctor as pressuring her into compliance or unfairly judging her to be irresponsible. When patients do choose not to comply with medical advice doctors must:

- seek ways of providing health care that will still preserve patient integrity,
- respect the patient’s choice, as decision-making authority is ultimately theirs,
- examine all options in a sense of shared decision-making (see sections 2.1 & 4.1),
- and empower women to pursue their chosen goals.

As in Case 4, “this is not about better educating or motivating patients or more effectively counselling or persuading them to pursue a particular course of action, but is rather about developing creative strategies for dealing with obstacles that may not be evident or acknowledged by either the patient or her physician” (Baylis & Sherwin, 2002:299). Ultimately the term non-compliance does more harm than good!

5.3 Refusal of caesarean section

Most women will adopt supererogatory actions to ensure that their babies are born in a healthy condition. Caesarean section is a major operation that may be life-saving for a mother and/or her baby. I have explained that by consenting to expectant management, a woman with early pre-eclampsia is making sacrifices for-, or put another way fulfilling beneficence-based obligations to her viable fetus. During the careful counselling process she is informed of the high probability of delivery by caesarean section, as the fetal condition may deteriorate rapidly. I begin this subsection with an adapted case that I managed personally.

Case 5: A 19-year-old, woman in her first pregnancy was referred to a tertiary hospital with pre-eclampsia at 28w2d gestation. After stabilisation and evaluation of the mother and her fetus, she was counselled and accepted expectant management. The mother had severe hypertension and the fetus was growth restricted. Eight days after admission the heart rate monitoring test on the fetus revealed ominous cardiac decelerations and the woman was counselled to undergo emergency caesarean delivery to save the baby. She however declined to give consent for the operation.

This case of informed refusal clearly illustrates points used in the debate on maternal-fetal conflict and non-compliance. The patient first accepted care for herself and her fetus but then refused a therapeutic intervention to protect her endangered fetus. How should we understand this? The informed refusal may be explained by a different perception of autonomy and illness in communitarian-based societies as proposed by van Bogaert (2006), but I will propose a different explanation.

In the past two decades, cases of legally enforced caesarean section have occurred in the United States (US) and in the United Kingdom (UK), but judging by Appeal Court decisions, they are now very unlikely (Savage, 2002). In my opinion recourse to judicial authority should be avoided as it is clearly adversarial and leads to total breakdown in the doctor-patient relationship.

An ethical dilemma is not “solved” by a court’s decision. The FIGO recommendations state that “Resort to courts is inappropriate and usually counterproductive. No woman should be forced to undergo any procedure in order to preserve the life or health of her fetus, as this would be a violation of her autonomy and fundamental human rights” (Schenker & Cain 1999). However, doctors face a serious challenge when a pregnant woman makes choices that are inconsistent with the beneficence-based obligations the doctor has to the fetus or the woman. McCullough and Chervenak have proposed “a clinical strategy that does not involve simply acquiescing to the pregnant woman’s decision or simply seeking to coerce her compliance, namely respectful persuasion” (153:1994) . This involves reviewing the case information with the patient; explaining the doctor’s own reasoning as well as how other doctors might differ; explaining how to meet these objectives and showing the patient that her own values and beliefs are inconsistent with her decision, if this is indeed the case.

Refusal of an emergency caesarean section for fetal distress causes consternation amongst medical staff because refusal seems irrational and they generally perceive the viable baby to have high moral status. Indeed, the refusal of caesarean section presents a moral dilemma only if two conditions apply.

- First, the right of a competent patient to refuse a medical intervention.
- Second, the fetus must lack the status of a full legal person (Steinbock, 2012:155-156).

Of course, the line between competent refusal and inability to consent can be difficult to distinguish in certain cases, a good example being fear. Fear of an operation may be a rational reason for refusal to undergo it, but fear may also paralyse the will and thereby destroy the capacity to make a decision (Savage, 2002:270). If the latter is the case then overriding her refusal does not violate her autonomy. Beauchamp and Childress have pointed out that “our obligations to respect autonomy do not extend to persons who cannot act in a sufficiently autonomous manner” (2009:105). But what if the patient is competent but unreasonable? Pellegrino and Thomasma believe that in such a case the doctor should override an irresponsible refusal (1988:25,32,46-47). Supporters of the “waiver theory” claim that once a woman has

waived her right to abortion, she is duty bound to do what is necessary to promote the best interests of the fetus (Nocon, 1999). In this sense, her duty of beneficence to the fetus overrides her own right to autonomy. However, the legal decisions in “forced caesarean” cases from the US and UK have more recently been described as “paternalistic” and “placing the non-existent legal rights of the fetus above the woman’s autonomy” (Savage 2002:277). The concept of “best interests” applies to parties with legal rights. The fetus does not possess legal rights but this does not mean it merits no protection as it certainly has interests. In South Africa, the National Department of Health’s, Patient’s Charter does make provision for general informed refusal of treatment by a patient, thus providing general grounds for maternal refusal of a caesarean section (2000).

In advancing arguments for the overriding of an informed refusal of e.g. caesarean section to save an endangered fetus, van Bogaert 2006) uses a well-structured approach based on the “fetus as a patient” principle advocated by McCullough and Chervenak (1994). According to these authors, the mother may convey the status of personhood to the fetus. What is not clear is whether this status is permanent? In Case 5, the mother accepted expectant management in the hospital, thereby indicating her concern and the granting personhood to her fetus. However, when she declined caesarean section, was this status still operational or had it been revoked by her? I have already indicated (in section 5.2) that consent can be autonomously withdrawn without the expectation of prejudice.

Some would argue that the moral permissibility of refusing a caesarean section depends on the strength of the reasons given (Steinbock 2012:155). An ugly scar would not be sufficient justification, but religious beliefs, or as stated above genuine fear would be. Fear of the operation was a strong influence for the young woman in Case 5. McCullough and Chervenak have argued that a case can be made for compulsory caesarean sections in cases of major placenta praevia. This is because the procedure unequivocally produces benefits for the woman and her fetus/baby.

In this scenario they consider any other judgement as irrational (McCullough & Chervenak 1994:249-250).

The current position of the legal profession and professional medical societies in the UK, US, Canada and others is that overriding the refusal of caesarean section by a competent woman is almost never justified (Savage, 2002:269,272; Steinbock, 2012:156). The South African position is similar in that the fetus is without legal rights until birth, while maternal autonomy is strongly endorsed (Moodley, 2011a:254). These positions are based on the following considerations.

- A competent adult has the right to refuse treatment.
- Caesarean sections, though safe still carry risks.
- The imposition of compulsory surgery is viewed as an assault on bodily integrity.
- It is possible for a doctor to be wrong about the need for surgery. However McCullough and Chervenak argue that the question is not whether doctors are infallible but whether their clinical judgement is reliable (1994:249-250).

I conclude that the overriding of informed refusal of a medically indicated caesarean section, by a competent woman is almost never morally justified and I am uncertain how one would physically force the procedure on a woman. If a woman does make the decision to decline a medically indicated caesarean section she must live with the consequences that must be clearly explained to her.

5.4 Summary position

In this chapter I have discussed the related concepts of maternal-fetal conflict and maternal non-compliance that find application in the informed refusal of caesarean section. Maternal behaviour that harms the fetus and future child is categorised as maternal-fetal conflict. However, any woman who will have a child is morally required to avoid harming the fetus, if this can be done without sacrificing her own important interests. The term non-compliance implies a hierarchical nature in the doctor-patient relationship. This reduces patient agency, erodes trust

and conflicts with informed choice. Although there may be specific circumstances in which use of the term is justified, ultimately this “label” does more harm than good. The refusal of a medically indicated caesarean section, by a competent woman often places doctors in an agonising dilemma but overriding this decision is almost never justified.

CHAPTER SIX: DELIVERY OF EXTREMELY PRETERM BABIES

6.1 Background and counselling

“The potential delivery of an extremely premature infant presents a clinical situation that raises a complex combination of medical, social, ethical, religious and economic issues. It is a unique medical encounter such that it is not about curing the patient. Rather it is an encounter where counselling is assisting families in deciding between life and death underscoring the stressful nature for both patients and providers” (Srinivas, 2013).

In the preceding chapters I have explained that dealing with early pre-eclampsia entails making decisions on delivery at and just beyond the threshold of viability. In these circumstances survival and intact neurological survival, or put another way, survival without moderate to severe morbidity (handicap) become critical considerations. There is an inverse relationship between gestational age at delivery and moderate to severe impairment (Moore et al., 2012). In addition to the greater risk of permanent, significant morbidity associated with extremely preterm birth, fetuses from mothers with pre-eclampsia are often affected by severe growth restriction, which further increases these risks. This represents a form of double jeopardy.

Survival data and morbidity after birth at 22-26 weeks’ gestation

A recent follow-up study from the United Kingdom evaluated medium-term outcomes after birth in this category. It showed an encouraging improvement in survival but no significant reduction in the prevalence of severe disability (Moore et al., 2012). The data from the United States although different, shows the same trends (NICHD, 2009; Mercurio, 2009). Survival of a neonate born at 22-23 weeks is possible but the cost in terms of severe morbidity such as neurodevelopmental impairment is great. Neurodevelopmental impairment has been defined as a Bayley mental developmental index or psychomotor developmental index < 70, moderate/severe cerebral palsy, bilateral blindness, and/or bilateral hearing loss requiring amplification (Mercurio, 2009). In Chapter Four, I explained that there is broad consensus that the perinatal outcome for

the specific condition of pre-eclampsia at gestations < 24 weeks is dismal. Moving to the other end of this specified category, the general neurologically intact survival i.e. survival free of moderate or severe impairment is close to 60% at 26 weeks (Moore et al., 2012). Thus < 24 weeks and ≥ 26 weeks represent important lower and upper thresholds for counselling. I will return to this point in section 6.2.

Counselling, the ethics of decision making, useful models

In earlier discussions on counselling I alluded to factors influencing the mode of counselling and the importance of a flexible approach determined by the clinical situation. Counselling extremely stressed parents regarding resuscitation and or the possible outcomes of an extremely pre-term infant is very challenging. In this clinical scenario, I will draw on generic principles discussed earlier but also incorporate a useful document from the American College of Obstetricians and Gynecologists (ACOG, 2004). To begin with, the doctor must have a good understanding of the scientific evidence for and against the decision at hand. I have provided a succinct summary above to illuminate some applied ethics applications that will follow in this chapter. During counselling and decision making (consent), the doctor must show respect for the patient (deontology, autonomy and respect for communitarian values), through beneficence and non-maleficence ensure the greatest balance of benefit over harm (includes consequentialism), consider aspects of justice (e.g. scarce resources such as intensive care) and demonstrate virtues such as veracity or truth telling. Chervenak and McCullough warn against ethical reductionism that occurs when “ethical reasoning appeals exclusively to one ethical concept in clinical circumstances that by their very nature require consideration of multiple, complementary concepts if those circumstances are to be adequately understood and responsibly managed. Rights-based reductionism commits the fallacy of reasoning about ethical issues in perinatal medicine on the basis of exclusively the rights of the fetus or the rights of the pregnant woman” (2012). The rights of women are important in perinatal ethics but they are not exclusive.

A fully informed decision by an autonomous patient must be respected, even if it cannot be supported by the doctor when it clashes with his or her own ethical principles e.g. abortion. I have made the point that in almost all situations the patient has the right to decline/refuse unwanted treatment but a point that I have not yet made is relevant to section 6.2. That is, a patient does not have “a parallel *right to demand treatment* that the physician believes is not beneficial, unwise or overtly risky” (ACOG, 2004; Beauchamp & Childress, 2009:220). Throughout the chapters of this thesis I have emphasised that the approach to counselling must be flexible. I have already referred to modes of counselling but the ACOG document proposes four useful models, all of which may be used according to the patient and the decision involved (2004). The models will be applied to the case scenario in section 6.2. The paternalistic and informative models represent opposite ends of the spectrum, while the other two are pragmatic, middle ground options.

- *The paternalistic model.* Here the doctor might only present information on risks and benefits that she believes will lead that patient to make the “right” decision. I have discussed this in section 2.1. This approach/mode/model may be the best way to balance the ethical principles of beneficence and non-maleficence when patient autonomy is impaired.
- *The informative model.* In this model “the patient has complete control and the physician’s values are not discussed”. A detailed description of risks and benefits is given without prioritisation or recommendation of any option. This model has a serious disadvantage in that it assumes that the patient can integrate complex medical information and “removes” the role of the doctor as a caring, expert partner in the decision making process. The ACOG document states that “one of the many unfortunate consequences of the professional liability crisis is the unsubstantiated belief of some physicians that the informative model reduces the physician’s risk of liability” (2004). Actually this model has limited application, as a doctor’s professional judgement is of considerable value and it is very difficult to counsel with complete objectivity.

- *The interpretive model.* In this mode the doctor provides information and aids the patient's self-understanding. She (the doctor) helps the patient clarify and then integrate the patient's own values into the decision, while being careful not to impose her own values.
- *The deliberative model.* This model is similar to the interpretive model "in that it includes a discussion of not only the medical benefits and risks, but also the patient's individual priorities values and fears". Where it goes beyond the previous model is that "the physician must consciously communicate to the patient his or her health values" (ACOG, 2004). This must be done without pressurising the patient, thereby maintaining a balance of power in the doctor-patient relationship.

Within the counselling scenario the doctor must judge whether the information presented is adequate. Beauchamp and Childress state that a grasp of the relevant central facts is generally sufficient (2009:127). In the practice of "evidence-based medicine" the strongest evidence must be utilised but where strong evidence is lacking, this must be honestly acknowledged. "There is no ethical imperative to initiate discussion of treatment options that are unproven" (ACOG, 2004). In addition doctors must guard against personal conflicts of interest such as the financial gain sometimes associated with innovative treatment techniques. When looking at the broad picture, surgical and medical guidance in obstetrics is based in part on scientific evidence, in part on the doctor's understanding of a patient's values and preferences and in part on the experience and values of the doctor (ACOG, 2004). With regard to a patient's values and preferences, medical professionals ought to be attuned to what individual patients deem as important in their lives. Olthuis and colleagues believe that this facilitates "good and caring" medical decisions that take into account the "lived experience of being ill" (2014).

6.2 Resuscitation of new-born babies

Resuscitation of new-born babies occurs every day in the labour wards of hospitals. In most cases the practice is well accepted and rests on a firm scientific basis, but there are difficult cases too. “It is widely believed in neonatology and obstetrics that there are situations in which it is inappropriate to attempt new-born resuscitation, and other times when new-born resuscitation is obligatory despite parental refusal. In each case an ethical justification for the decision needs to be identified” (Mercurio, 2009). When resuscitation is performed, the goal or intent is to save the infant’s life and to minimise morbidity but when resuscitation is not performed the goal is to provide as peaceful a death as possible for the baby while providing emotional support for the parents. There seem to be three positions regarding resuscitation.

- Always resuscitate – this avoids a difficult ethical decision.
- Always allow the parents to decide – this seems to avoid a difficult ethical decision.
- Doctors must exercise judgement – this requires a difficult ethical decision.

Decisions made in these circumstances are fraught with personal, conceptual and ethical difficulties (Kluge, 2012:274).

- Personal difficulties include the psychological responses of parents as well as doctors who are trained to save and not to “let die”.
- Conceptual difficulties include notions of disability, suffering and quality of life.
- Examples of ethical questions are: who makes the decision, or, is there a difference between withholding and withdrawing care?

In philosophy concepts are used to identify and classify our fields of experience. Using class characteristics we recognise different types within the same concept. Concrete concepts such as bird or building are not controversial. On the other hand, abstract concepts such as those mentioned in bullet two above, are more difficult to deal with and often “represent matters and values that are of the gravest importance for people”. We use ideas to interpret our fields of

experience which is clearly different to identification and classification. Through interpretation we establish the value, importance and relevance of the things we encounter (Van Niekerk, 2011:8). Over time, certain ideas may become clear enough to become institutionalised as is the case with professional boards (Hall, 2013). For example the American Academy of Pediatrics (AAP) acknowledges that there are circumstances in which resuscitation at birth can be withheld:

Where gestation, birth weight, and/or congenital anomalies are associated with almost certain early death, and unacceptably high morbidity is likely among the rare survivors, resuscitation is not indicated, although exceptions may be appropriate in specific cases to comply with parental request. Examples include.... In conditions associated with uncertain prognosis, where there is borderline survival and a relatively high rate of morbidity, and where the burden to the child is high, some parents will request that no attempt be made to resuscitate the baby. In such cases, the parent's views on either initiating or withholding resuscitation should be supported (Katwinkel, 2006).

The basic principle is this: when early death is very likely and survival would be accompanied by unacceptably severe morbidity, resuscitation and intensive care are not indicated. When survival is likely and the risk of severe morbidity is low, resuscitation and intensive care are indicated. For cases that fall between these two positions, the parents should determine the treatment based on the child's best interests. The latter represents a consequentialist calculation of benefits over burdens (Mercurio, 2009). This still leaves the evaluation of the chance of survival and the interpretation of "unacceptably severe morbidity" to the doctor.

Just how do doctors decide which extremely premature new-born babies to resuscitate? A general answer might be: when there is a net benefit that does not represent an injustice to others. My approach to this question is to use the two components that I have advocated throughout this thesis. First, understanding the relevant data and second, applying ethical reasoning. Regarding the first point, I have given a summary of the data in section 6.1. In addition to gestational age at birth, there are several factors that determine the survival and neurocognitive outcome of a baby.

These include, growth and birth weight, gender, whether antenatal corticosteroids were administered and single versus multiple pregnancy. All of these confounding variables must be integrated into the decision by the doctor. However, even if objective disability could be accurately predicted for an individual case, it is far more difficult to predict the “subjective perception of that disability by the parents, and most importantly by the child herself” (Mercurio, 2009). Saigal et al., have found that doctors have a worse perception of quality of life for those with severe disability than adolescents, parents of extremely low birth weight infants or parents from the community (1996). This illustrates the point that we need the personal perspectives of persons with disabilities and should avoid imposing our own values.

Rights of the new-born baby

In section 3.2 I noted that whereas the rights of the fetus are limited, the new-born baby does have rights that must be taken into account. There is almost universal consensus that newborn babies have clear moral and legal status although Goss has stated that “how absolute such status is, differs globally” (2002). The South African Bill of Rights (Chapter 2 of the South African Constitution) states in 28(1)c that “*Every child has the right to ... basic health care services*” (1996). Although this concept is not further specified it should be noted that in 1995 South Africa ratified the United Nations Convention of the Rights of the Child. This Convention recognises the rights and best interests of all children, including the right to life, optimal survival and development (Unicef 1989). As always, each right is not absolute and must be weighed against others when taking a decision but such basic rights would include the following:

- The “unalienable right” to life. With the right to life comes a right to basic medical treatment to preserve life.
- The right to mercy. In the case of the new-born baby this is the right not to be subjected to pain that is unlikely to yield a net benefit. Adults clearly have this right and new-born babies should be accorded it as well.
- The right to justice. Patients should be treated fairly and equally unless there is a morally relevant difference between them. In a study using qualitative analysis to examine factors

that influence obstetric decision making at the threshold of viability, Edmonds et al., found that thresholds varied and that doctors managed in vitro fertilisation pregnancies more aggressively (2012). Expressing similar concern regarding unjust, unequal treatment Janvier et al., found a greater willingness to withhold resuscitation from premature new-borns than from other people such as term new-borns, older children and adults (2008). Although it may be argued from a psychological perspective that a deeper relationship exists with an older child than with a new-born baby, it is not evident whether this difference is morally relevant (Mercurio, 2009).

Rights of the parents

Parents have a right to be informed of their baby's condition, prognosis and reasonable therapeutic options available (Mercurio, 2009). This right does not depend on their intellectual capacity. However, the right of a parent to decide is not absolute; it can be limited by the right of the child. For example an adult can refuse recommended treatment for herself on religious grounds (Jehovah's Witness) but does not have the right to deny her child a treatment that is likely to prevent serious harm, suffering or death (Beauchamp, 2003:269-274; McQuoid-Mason, 2005:29-30). The United States Supreme court stated a long time ago that "parents have a right to make martyrs of themselves, but not of their children" (Massachusetts, 1944). The general position is that when the baby's best interests are unclear, then parents have the right to decide whether resuscitation is attempted or not. However, beyond a threshold when the likelihood of benefit becomes high enough, treatment becomes obligatory (Mercurio, 2009). Chervenak and McCullough put it this way: "When the fetus is a patient and the evidence for obstetric management for fetal and neonatal benefit is reliable, counselling of the pregnant woman is justifiably directive" (2102).

Parents do not have the right to demand a treatment (in this case resuscitation), and doctors have no obligation to provide that treatment when it offers no benefit to the new-born baby. In these circumstances the parental right to decide is outweighed by the baby's right to mercy and the

doctor's obligation not to inflict pain without benefit (non-maleficence) (Mercurio, 2009). In another qualitative study, this time assessing parent's experiences and satisfaction with care during the birth of their very preterm babies, Sawyer et al., identified the importance of staff appearing calm, portraying confidence and taking control during the birth process (Sawyer, 2013). In essence the parents in that study seemed happy to relinquish some autonomy for medical paternalistic direction in an existential crisis. I now refer back to the four models (section 6.1, 82-83). The environment where the decision on delivery and resuscitation of extremely preterm babies is made is highly stressful for some parents and overwhelming for others. These parents have a right to guidance that is more than an informative menu of choices. As illustrated by Sawyer et al., when patient autonomy is impaired, a paternalistic approach may be the best way to balance the ethical principles. However under these circumstances it is important for the parents to know when the presentation of the data is complete and when the presentation of the doctor's opinion has begun (Mercurio, 2009).

Withholding and withdrawing treatments

At one time the action of removing a patient from a ventilator, thereby allowing him to die was unacceptable. This meant that there was a great reluctance to begin ventilation in unclear cases. Currently, the opinion of Beauchamp and Childress is that the distinction between withholding and withdrawing life-sustaining treatment is "outmoded and untenable" and sometimes even "morally dangerous" (2009:155). There is a psychological problem in that stopping ventilation can be more difficult as emotional attachment to a baby grows each day. Doctors and parents may believe that this action renders them responsible for the baby's death, whereas they are "not responsible" if life-sustaining treatment was not initiated and a "natural" death occurred. However the intent behind not performing resuscitation and stopping ventilation is to bring about the death of the baby and so the distinction, though perhaps psychologically comforting becomes morally irrelevant. Wilkinson and Savulescu support this position stating that "Ethical analyses, professional guidelines and legal decisions support the equivalence thesis for life-sustaining treatment: if it is ethical to withhold treatment, it would be ethical to withdraw the same

treatment” (2012). In practice limited resources have been used as a justification for withholding treatment but the above-mentioned authors believe that the same reason (resource allocation) plays a much smaller role when withdrawal of treatment is considered. Reasons given by Wilkinson and Savulescu (2012) for this latter position include:

- Fairness. Here doctors act on the basis of the “first come, first served” rule which is endorsed by some medical societies as a fair manner of distributing intensive care (Persad et al., 2009).
- Conflict of interest. Doctors have a relationship with their existing patients and their families. This makes it difficult to choose between their patients and the prognosis of others with whom they do not yet have a professional relationship, but who are competing for the same scarce resource.
- The slippery slope. The concern here is that treatment withdrawal for justified reasons might pave the way for treatment withdrawal for morally unjustified reasons in the future.
- Consent. When treatment withdrawal is contemplated, potentially difficult consultation with families and consent is required. This does not apply when requests for intensive care admission from doctors working outside the intensive care unit (ICU) are made to doctors managing the ICU. The decisions are made between the doctors themselves.
- Legal vulnerability. Doctors may feel more vulnerable to legal sanction upon withdrawing treatment than when treatment is withheld.

Brown et al., have investigated whether professional orientation of obstetric and paediatric specialists towards fetuses and pregnant women differs. Their findings suggested divergent ethical sensitivities with paediatric specialist having more optimistic attitudes (2012). Upon reflection there is moral justification for withholding resuscitation at birth, and performing it but later withdrawing life-sustaining treatment such as ventilation. However, there are two situations that we want to avoid.

- In withholding resuscitation in uncertain cases, a baby who might have survived with what the parents or child would perceive as a good outcome, will die. This is an irreversible decision.
- Providing resuscitation at birth, followed by ventilation might initially save a baby that subsequently dies after a painful course in the intensive care unit. The baby's right to mercy is thereby violated. There are also the dangers of overtreatment, consumption of scarce resources and survival with profound impairment which the parents and/or child would consider unacceptable.

Providing resuscitation and ventilation in borderline cases, does have advantages. It avoids hurried decisions at a time of great stress, allows time for more prognostic indicators to be assessed, while some parents take comfort in having tried and then withdrawn support, than never having tried at all. Indeed, the moral burden of proof seems heavier when the decision is to withhold, than when it is to withdraw treatment. Beauchamp and Childress have proposed moving away from the morally irrelevant distinction between withholding and withdrawing treatment to the concept of optional and obligatory treatments (2009:166). These categories are:

- I. Obligatory to treat (wrong not to treat)
- II. Obligatory not to treat (wrong to treat)
- III. Optional whether to treat (neither required nor prohibited – morally neutral).

These categories can be superimposed on our clinical scenario.

- I. Deferring all decisions regarding resuscitation of the baby to the parents “is inconsistent with professional obligations to act as moral agents” (Mercurio, 2009). Beyond an upper threshold (with a good chance of intact survival) it is wrong to withhold resuscitation even if the parents request this. In this scenario Chervenak and McCullough state that directive counselling for resuscitation is ethically justified (2013). The baby's right to life prevails over a parent's right to decide. The position of this upper threshold is influenced by many variables, but in moderately resourced tertiary settings it lies around 26 weeks' gestation.

- II. Below some threshold the chance of survival is so low that the baby's right to mercy prevails over a parent's right to decide. Here, Chervenak and McCullough state that directive counselling for withholding resuscitation is ethically justified (2013). In moderately resourced tertiary settings this lower threshold lies below 24 weeks' gestation.
- III. Between categories I & II there is an area of uncertainty. This is where the will of informed parents should direct the doctor after non-directive counselling.

I must repeat that the thresholds are not "cast in stone" but are open to revision. Maternal-fetal subspecialists and neonatologists at a facility should determine them by consensus, through understanding the relevant data and ethics issues. Once decided upon, the approach must be applied consistently.

6.3 Normality and impairment in an era of enhancement

The birth of a baby should be a joyous event but sometimes it can be a tragedy. In the pregnancy-related condition of pre-eclampsia, delivery is often necessary at or just beyond the threshold of viability, raising the possibility of survivors with major and minor impairments. On the other hand we live in an era of enhancement when e.g. screening and diagnostic tests for genetic conditions with cognitive impairment such as Down's syndrome have become a routine part of antenatal care in many countries. Once the diagnosis of Down's syndrome is confirmed termination of pregnancy is considered. Where does the balance between accepting impairment and trying to eliminate it, lie?

Using the moral principles that undergird modern medical practice, it is not difficult to support opportunities of making less-than-normal children normal, but should we go further? Is society becoming less tolerant of children and adults with neurocognitive impairment? Rosemarie Tong,

a philosopher from North America, believes that “although parents have a limited right to enhance their already normal children genetically, and, conceivably, also a limited duty to do so, they should not be encouraged to do so (2002:88). Indeed, society should actively discourage parent’s quests and expectations of perfect babies rather than imperfect mortals to love as ends in themselves (Chervenak et al., 2010; Alderson, 2002:210). In a study designed to test whether there are differences in the level of maternal-fetal attachment (early affection) before and after fetal imaging echocardiography which is used to investigate cardiac abnormalities, Ruschel et al., concluded that diagnosis of fetal heart disease increases the level of maternal-fetal attachment (2014).

The most recent Federation of International Gynecology and Obstetrics (FIGO) Committee Report on “Ethical issues in the management of severe congenital anomalies” (includes all forms of impairment from birth) emphasizes that anomalies range from insignificant to severe. The document acknowledges the lack of a medical definition of both severity of fetal disease and normal life (2013:307). Indeed, the very notion of normal is often regarded by disabled persons as a form of discrimination. Using qualitative research methods among disabled persons, Priscilla Alderson found that they suffered more from the general stigma of disability than from their actual condition (2002:206). However she only included persons with the ability to be interviewed. Most of these appeared to value and enjoy their lives. When examined from the important perspective of the affected child and its parents, Bennett and Harris find nothing morally wrong with “bringing into existence” an impaired but worthwhile life (2002:323). I agree with this position and have discussed the pertinent ethical issues in section 2.2 (36-37).

Returning to the FIGO document, it further states that delivering and raising a severely impaired baby may impact on the physical, mental and social life of a family (2013:307). There is also the not inconsiderable financial cost of caring for an impaired child or adult. Where families cannot afford the cost themselves, these would have to be carried by the state. This would hardly satisfy

utilitarian or libertarian perspectives but communitarian and specifically egalitarian theories of justice would seek to address, and if possible correct unjustified, arbitrary impairments.

There are those who argue that selecting who may survive and utilise society's resources devalues disabled persons and inappropriately sets the standards that must be met in order to count as a person (Kluge, 2012:279). "This approach deprives society of the opportunity to develop virtues such as compassion, tolerance and understanding, and thereby impoverishes the moral life of society in general (Ashley & O'Rourke, 1982). It is my opinion that even in an era of enhancement, we have no obligation to "eradicate" unavoidable impairment, although doctors and patients must always seek to prevent it. We may reasonably ask what price society will pay if it does not protect its weakest members who cannot help themselves.

6.4 Summary position

In this chapter I have discussed counselling in yet another pre-eclampsia scenario, resuscitation of an extremely preterm new-born baby and asked whether we have devalued impaired children in an era of enhancement. The modes or models of counselling are further refined by placing pragmatically flexible interpretive and deliberative models between the less frequently applicable paternalistic and informative models. The environment where the decision on delivery and resuscitation of extremely preterm babies is made is highly stressful for some parents and overwhelming for others. These parents have a right to guidance that is more than an informative menu of choices. Under these circumstances the paternalistic model becomes the best method of balancing the ethical principles. The distinction between withholding resuscitation from the extremely premature new-born baby and initiating but later withdrawing care is morally irrelevant. Using the categories of optional and obligatory treatments is more helpful but maternal-fetal subspecialists and neonatologists need to determine treatment thresholds through understanding the relevant data and ethics issues. Modern society is pursuing enhancement while at the same time grappling with the position of impaired persons. My conviction is that impaired

persons offer society the opportunity to develop virtues such as compassion, tolerance and understanding, and thereby deepen its moral life.

CHAPTER SEVEN: SOMATIC SUPPORT AFTER MATERNAL BRAIN DEATH

7.1 Background

The moral character of medicine is based on three values central to the doctor-patient relationship. They are:

- Patient benefit. Care is provided where benefits outweigh burdens or harms. Doctors have no obligation to continue treatment where it is their clear, professional opinion that such treatment would provide no clinical benefit (Chan & Tipoe, 2014).
- Patient self-determination. In an environment of individual autonomy, professional counselling enables the mutual identification of the operative goals of care. The patient has a right to control what happens to her body and treatment may not be administered without her consent. Treatment goals may change according to the considered choice of the patient or an appropriate surrogate decision maker.
- Ethical integrity of the health care professional. Doctors too are autonomous agents and may not be compelled to violate personal ethical or religious values in the service of the patient. Doctors have a moral commitment to avoid risks to the patient that are greater than the potential benefits and are therefore not obliged to provide untested, medically contra-indicated or futile treatments (Beauchamp & Childress, 2009; Pellegrino & Thomasma, 1988).

The practice of obstetrics involves different types of care ranging from preventative care to medical and surgical interventions, and even to palliative care for patients whose illnesses offer no chance of cure. Each type of care is linked to definable goals including the relief of symptoms, pain and suffering, and the optimisation of pregnancy outcomes. I have already explained how the goals are identified through counselling and shared decision making between the patient and her doctor. These goals must be clear for the following reasons.

- Assumptions about the objectives of care inevitably shape perceptions about the appropriate course of treatment.
- These objectives may be understood differently by the patient and her caregivers.
- Unarticulated commitments to certain goals may lead to misunderstanding and conflict.
- The goals of care may evolve and change in response to clinical and other factors (ACOG, 2004).

In this chapter the focus falls on the palliative and comfort care of the pregnant woman and the interests of her fetus. Women do not lose their rights when they become pregnant or terminally ill (van Bogaert & Dhai, 2008). In 1772 John Gregory stated that “it is as much the business of a physician....to alleviate pain, and to smooth the avenues of death as to cure diseases” (Pernick, 1983). In end-of-life decision making, obstetricians must attempt to follow the wishes of their pregnant patients, or appropriate surrogate decision makers when the patient is no longer able to make her own decisions. Somatic support refers to the continuation of measures to support the respiratory and circulatory functions of the patient and to provide nutrition.

7.2 Maternal brain death and perimortem caesarean section

In section 5.3 I have argued that a pregnant woman with decision making capacity has the same right to refuse treatment as a non-pregnant woman. Although she did not suffer from pre-eclampsia, the case of Angela Carder in the United States, in 1987 had a major influence in this area of obstetric management. When medical complications occur, a pregnant woman may lose her decision making capacity, either temporarily or permanently. In pre-eclampsia/eclampsia, major cerebral complications such as intra-cerebral haemorrhage or massive cerebral oedema occur regularly in South Africa (Saving Mothers, 2008-2010). These complications cause maternal collapse that may be rapidly followed by death. However, with improved resuscitation techniques, patients are sometimes saved and transferred to intensive care units (ICU) where advanced support and further evaluation is possible. Unfortunately, a subsequent diagnosis of

brain death is made in certain cases. Once a patient is mentally incapacitated, medical decisions must be taken by a surrogate decision maker. The usual order of priority for determining this person is: a legally appointed person with power of attorney, spouse, an adult child of the patient, either parent of the patient, adult brother or sister of the patient or adult close friend of the patient (DiGiovanni, 2010). The surrogate decision maker is required to participate in formulating explicit care giving goals for the patient and her fetus. According to Beauchamp and Childress there are three standards that surrogate decision makers may use.

- *The substituted judgement standard.* The aim here is to make the decision the incompetent person would have made if competent.
- *The pure autonomy standard.* This standard compels us to respect the preferences of formerly autonomous patients but in the absence of explicit instructions the proxy may choose selectively.
- *The best interest standard.* Here the highest net benefit among the available options is chosen, and may even override advance directives and refusal by incompetent patients. This is the best standard for previously competent or never competent patients (Beauchamp & Childress, 2009:139).

With the broader acceptance of the “fetus as a patient” principle (section 3.2) consideration has been given to extending somatic support to the brain dead mother, usually in an ICU setting in order to improve the outcome of the fetus/baby. Different scenarios are illustrated by the following four adapted cases.

Case 6: A 20-year-old, woman in her second pregnancy was referred to a tertiary hospital after being diagnosed with pre-eclampsia and suffering acute collapse at 34 weeks’ gestation. Special investigations revealed a large intra-cerebral haemorrhage and brain death was subsequently diagnosed. After consultation with the family a caesarean section was performed and a live, stable baby delivered. Thereafter ventilation was withdrawn and the mother demised.

Case 7: (not pre-eclampsia) A 28-year-old, woman in her third pregnancy was referred to a tertiary hospital with stridor (obstructed respiration at the level of the larynx) of unknown aetiology. She was 25 weeks pregnant. A tracheostomy procedure was performed but two days later she developed exsanguinating haemorrhage from the surgical site. In order to assist a difficult resuscitation, a perimortem “caesarean section” was performed but the mother and fetus both demised.

Case 8: A 27-year-old, woman in her second pregnancy developed eclampsia (pre-eclampsia complicated by generalised convulsions) at 31 weeks’ gestation. She was stabilised at a Community Health Centre, intubated and referred to a tertiary hospital where she was subsequently declared brain dead due to a massive intracerebral haemorrhage. The family was counselled regarding the mother’s condition and they accepted her inevitable death. From their side there was no wish to deliver a premature baby who might have suffered significant brain damage while the mother was hypoxemic. Advanced support was withdrawn and the mother demised with her baby in utero.

Case 9: A 22-year-old, woman in her second pregnancy was referred to a tertiary hospital with severe pre-eclampsia at 28 weeks’ gestation. She required intubation due to her depressed level of consciousness. After appropriate investigation in the Intensive Care Unit she was declared brain dead. In consultation with the family a decision was taken to optimise and then deliver the baby. The plan was to administer corticosteroids (to enhance fetal pulmonary maturity); gain one week of maturation in utero for the baby, while providing somatic support to the brain dead mother and then to deliver by caesarean section. Five days later, heart rate monitoring of the baby showed signs of distress and delivery of a live baby was performed by caesarean section. After the operation maternal support was withdrawn and the mother demised.

For most pregnant women and their families, the welfare of the fetus is of the utmost concern. This maternal interest in the welfare of her fetus forms the basis of the fundamental ethical commitment of the obstetrician (ACOG, 2004). The obstetrician is responsible for both the patient and her fetus and must optimise benefits and minimise risks for both parties. When a pregnant woman is dying or is brain dead, the International Federation of Gynecology and Obstetrics (FIGO) affirms that the life and well-being of the fetus becomes a matter of urgent consideration (FIGO, 2006). Excruciating choices have to be made that respect the woman's recent and clearly expressed wishes and incorporate the views of the woman's partner and family who will need to care for the baby. In sections 7.1 and 7.2, I have emphasised the importance of the patient-doctor relationship, or in the case of brain death, surrogate/proxy-doctor relationship in setting clearly understood goals. I have also explained how the decision making process of the surrogate should be informed.

Perimortem caesarean section and resuscitation

During cardio-pulmonary resuscitation (CPR) with the pregnant woman lying on her back, chest compression does not deliver sufficient cardiac output to accomplish resuscitation (Katz, 2012). Therefore when a mother has a resuscitatable cause of death, her life might be saved by prompt (four minutes after collapse) delivery of the fetus (Katz, 2012; Einav et al., 2012). This is performed primarily to save the mother but in the process (rule of double effect, see section 3.3) the life of the baby might be saved as well. In Case 7, the perimortem caesarean section was performed in the acute scenario as part of the resuscitation effort to save the mother, not to save the pre-viable fetus.

When a woman who has collapsed medically, is successfully resuscitated with her fetus still alive in utero, difficult choices have to be made. "During initial management of a pregnant woman with evolving brain death, it must be decided whether to deliver the fetus immediately, to initiate supportive care to allow further fetal maturation, or to allow the fetus to die as the mother is removed from mechanical ventilation" (Powner & Bernstein 2003). When the gestational age is

compatible with a good outcome, immediate delivery is preferred but for the fetus at the threshold of viability, prolonging the gestation to optimise neonatal outcome may be considered while the mother is stable.

In the case of maternal brain death, extended somatic support has been provided for > 100 days for the sake of the fetus alone (Powner & Bernstein, 2003) but with pre-eclampsia it is unlikely that the mother would remain “stable” for that length of time even in an ICU setting. Haemodynamic instability and organ failure poses challenges to maintaining adequate utero-placental blood flow. A bed in an ICU is an expensive, extra-ordinary and scarce resource, particularly in developing countries. The growing demand for ICU services requires continuous triage of the adults and children most likely to benefit from such care, raising another set of ethical dilemmas (Levin & Sprung, 2008). When the prognosis of the mother is not considered, as in the case of brain death, it is the fetus, who has no legal rights and whose right to life is a matter of ethical debate that is effectively competing with rights-bearing adults and children for an ICU bed. Nonetheless, even when the pregnant woman is brain dead with no cognitive function and no prospect of recovery (dead in strict legal terms – Lane et al., 2004), her body is still biologically alive, and must be treated with respect and her right to die with dignity or in peace, not forgotten. Although the disputable phrase “best interests” is often used to motivate the right to die with dignity Chan and Tipoe believe that one can easily reach the same decision by considering the futility of treatment only (2012). The question that I want to answer is whether it is ethically appropriate to provide maternal organ supportive measures (somatic support) to optimise the fetal outcome in a case of maternal brain death.

Prolongation of maternal somatic function is being described more frequently but it still constitutes experimental care (Lane et al., 2004). As such, doctors are not under an obligation to offer or provide it (see section 7.1). The gestational age of the fetus is central to the argument. In Chapters 4 & 6, I made the point that a gain of 2-7 days in utero can be critical for the neonatal outcome when delivery is effected around the threshold of viability. In Case 6 the gestational age

was already relatively advanced (34 weeks) and so extended support was rightly not considered. In Case 8, the family accepted the death of the mother and chose not to save a possibly compromised but viable fetus, while in Case 9 the family accepted the death of the mother but wanted the fetus to have the best possible chance of survival. I would argue that the decision to extend somatic support to a brain dead pregnant woman can be supported ethically provided that the fetus is at the threshold of viability, the support is not prolonged (issues of distributive justice), advanced level (ICU) support is available with a successful outcome likely, and finally that the doctors and family are in clear agreement as to the goals.

7.3 Summary position

Women do not lose their rights when they become pregnant or terminally ill. When a woman who has suffered major complications of pre-eclampsia before delivery is subsequently declared brain dead, her doctors and family must formulate clear plans for the dying mother and her living fetus. Although she may be regarded as dead in strict legal terms, the patient's body is still biologically alive, and must be treated with respect and her right to die with dignity not forgotten. The decision to extend somatic support to a brain dead pregnant woman in order to optimise the outcome of her fetus/baby can be supported ethically provided that the fetus is at the threshold of viability, the support is not prolonged (issues of distributive justice), advanced level (ICU) support is available with a successful outcome likely, and finally that the doctors and family are in clear agreement as to the goals.

CHAPTER EIGHT: LIMITED CHOICE OF ANTI-HYPERTENSIVE MEDICATIONS

8.1 Background

Obstetricians face the challenge of knowing how best to prevent or treat illnesses in their pregnant patients on a daily basis. This is a challenge because of a chronic reluctance to conduct research in pregnant women resulting in inadequate data to guide many treatment decisions. By way of example “The global H1N1 influenza pandemic disproportionately affected pregnant women, drawing attention to the fact that although they need safe and effective medical treatment, they have always been a marginalised study population” (Goldkind et al., 2010). During the 2009/10 H1N1 influenza pandemic pregnant women suffered higher morbidity and mortality than the general population. It is well known that the physiology of pregnant women differs from that of non-pregnant women and men. This begs the question whether the correct antiviral agent was prescribed to those pregnant women, and if so was it prescribed at the correct, effective dose, to meet their particular medical needs?

In section 1.1, I highlighted the importance of pre-eclampsia and other hypertensive diseases of pregnancy. Hypertension and specifically acute severe hypertension are dangerous conditions that require definitive medical treatment (Hall et al., 2000b). While some of the largest research trials in recent medical history have involved anti-hypertensive agents, very few have been conducted amongst pregnant women, thereby severely limiting the choice of obstetricians or forcing them to adopt “off label/licence” prescription practices (Expert Opinion, 2007). This means that the prescription e.g. of an anti-hypertensive agent takes place outside the indications for which that agent/drug was registered, placing greater responsibility on the prescribing doctor. With regard to anti-hypertensive medications in pregnancy, progress has been extremely slow. Methyl-dopa, an “old” drug is still widely used because research performed during pregnancy does exist and there are follow-up data showing no short-or long-term problems in children followed to the age of 7 years, following in utero exposure (Redman et al., 2010:173). However

methyl-dopa has poor potency and causes side effects to the mother. It is therefore hardly ever used outside of pregnancy because better agents are available. Although no one doubts the importance of preventing harm to pregnant women, their fetuses and future children there are sound arguments to “justify the inclusion of pregnant women in a greater number of biomedical studies” than is currently the case (Macklin, 2010).

8.2 Lack of research in pregnant women

The reluctance to include pregnant women in clinical research follows from medical disasters and lawsuits such as that with thalidomide, a mild anti-emetic that was never tested in pregnancy and resulted in the birth of around 10 000 babies with severely deformed limbs after their mothers had used the medication for “morning sickness”. The general result of this and other similar disasters is aptly summarised by Lyerly et al. “Due to ethical complexities and concerns about research risks, pregnant women and their interests have been under-represented in research. A consequence has been a dearth of information about the safety and appropriate dosing of medications and vaccines during pregnancy and a limited understanding of how illness during pregnancy affects women’s health over time” (Lyerly et al., 2012). In the 1970s and 1980s the prevalent attitude was to exclude women of childbearing potential and pregnant women from research (ACOG, 2004). This was due to the following reasons:

- Fear that an undiagnosed pregnancy might place an embryo at risk.
- Fear that a fetus would be harmed in a known pregnancy.
- The view that pregnant women are vulnerable and require protection.
- Fear that the liability risk would be increased. This fear affects Institutional Review Boards and drug manufacturers (ACOG, 2004).

However what is ethically acceptable often changes over time. In properly conducted trials the risk of harms can be minimised. Thus the existence of risk in itself, does not justify the exclusion of women from the research needed to provide valid evidence for treatment. Recently there have been many calls for greater inclusion of pregnant women in clinical trials in order to obtain valid,

evidence-based rather than empirical information, applicable to this population (ACOG, 2004; Macklin, 2010). This information is needed to fill in the “gaps” in medical knowledge needed to treat common conditions encountered during pregnancy, such as hypertension. According to Macklin, “an evolution in ethical thinking has undeniably occurred” (2010). Despite the current calls for greater inclusion, there are those who argue that the exclusion of pregnant women from clinical trials is not automatic, not unethical, nor arbitrarily determined (Allesee & Gallagher, 2011). Commenting on the situation in the United States, the latter authors state that the current regulatory framework is “based on sound ethical and legal reasoning that demonstrates when inclusion is appropriate or when clear and compelling reasons for exclusion” exist (Allesee & Gallagher, 2011). The position of the South African, Department of Health, Research Ethics Guidelines is that “no pregnant woman may be involved as a participant in any research activity unless the purpose of the activity is to meet the health needs of the mother, and the foetus will be placed at risk only to the minimum extent necessary to meet such needs” (DOH, 2004). A similarly worded statement applies to research involving fetuses.

The rationale for specifically including pregnant women in research begins with the physiologic changes during pregnancy and lactation, which makes these women different from non-pregnant women and men. Other factors include:

- Medical conditions such as HIV, that frequently affect pregnant women.
- Certain medical conditions such as pre-eclampsia that are specific to pregnancy.
- Certain conditions such as preterm labour that threaten the course of pregnancy.
- Certain conditions such as growth restriction that affect the fetus.
- Medical conditions related to pregnancy that may affect the future health of women (see Chapter 9).
- The safety of medication during pregnancy and breast feeding (ACOG, 2004).

What do women say?

There is little evidence to explain why women agree or decline participation in research during pregnancy. Lynn Jansen states that research participants “regularly overestimate the likelihood of gaining therapeutic benefit from a clinical trial”. She believes that this “mistake” needs to be studied and informed consent re-evaluated (2014). On the other hand, Lyerly et al., have recently reported on a small sample of pregnant women with high levels of education and socio-economic status who were participating in a National Institutes of Health, phase II, multicentre, randomised H1N1 vaccine trial. These women “construed participation as a benefit rather than a risky endeavour from which they needed protection, and even articulated reasons that such participation is preferable to clinical care when pregnant” (2012). Several women reported feeling safer as part of a research study, while others cited altruistic motivations for study participation. The latter findings counter the entrenched view that pregnant women need protection from research, but although they are certainly helpful, they cannot simply be generalised to other populations or trials involving greater risks e.g. fetal surgery for spina bifida.

What are the ethical requirements for research?

For research on any human subject to be justified there needs to be a reasonable prospect of the acquisition of useful knowledge while maintaining a favourable balance of benefits over risks. Strategies for risk mitigation include first obtaining adequate preclinical information e.g. toxicology studies, and a safety database with information from non-pregnant women (Goldkind et al., 2010). Macklin (2010), is of the opinion that it is also ethically necessary to first have data from animal studies before using human participants, a position supported by research ethics directives in South Africa (MRC, 2013). Still, it is important to remember that animal studies do not always accurately predict results in humans. In the case of thalidomide, had this mutagenic agent been taken through rigorous phase I or phase II clinical trials the effect would have been quickly discovered and the number of deformities much smaller. This is easily understood from a utilitarian perspective. Research subjects must be carefully monitored and protected and there must be a fair distribution of burdens and benefits among potential research subjects. Doctors

who assume the dual roles of clinician and investigator must be particularly wary of conflict of interest because each role has different goals (Beauchamp & Childress, 2009:139). The goal of the investigator is to generate beneficial knowledge for the future, whilst the clinician must act in the best interests of the current patient. The ACOG Committee on Ethics points out that the potential for role conflict is particularly apparent when innovative therapies are introduced (ACOG, 2004).

What ethical principles support the inclusion of pregnant women in research?

The call to include more pregnant women in clinical research is justified by the following ethical principles.

- *Autonomy*. In civil society and medical practice women have the capacity and the right to make decisions regarding their own lives. This includes the right to weigh the risks and benefits associated with participation in research projects and decide for themselves. This autonomous right is however limited “by the right of investigators and Institutional Review Boards to take precautions to limit the risk for pregnant women and their fetuses” (ACOG, 2004:88). Autonomy is applied through informed consent, which in research should meet the highest standards and be presented in understandable verbal and written language. Participants need a careful explanation of the type of research protocol that they will be participating in e.g. how a randomised controlled trial is conducted. The researcher and caregivers should guard against therapeutic misconception where participants/patients have inflated perceptions of therapeutic benefit. This is a particular danger when the patient’s doctor is also the researcher. Another limit on autonomy is when it infringes on the rights of others. Some authors extend this “infringement argument” to the maternal-fetal relationship, arguing the decisions by the mother may infringe on the rights of her fetus (Allesee & Gallagher, 2011). The maternal-fetal relationship has already been discussed. In my opinion respect for the fetus may not come at the cost of the pregnant woman’s autonomy. The interests of the fetus are better served by helping the pregnant woman to make a better informed decision. Whether the

father of the pregnancy needs to be involved in the consent process for research is controversial. For most research the consent of the pregnant woman alone is sufficient and the ACOG Committee on Ethics does not support recognition of distinct paternal rights before the birth of a child (2004). The positions of the South African Medical Research Council (MRC) Guidelines on Ethics in Medical Research and the South African Department of Health (DOH) Research Ethics Guidelines, are similar to the ACOG in that paternal consent is not automatically necessary, but the ACOG and DOH guidelines do require maternal and paternal consent when research has the prospect of direct benefit to the fetus alone (ACOG, 2004; DOH, 2004; MRC, 2013). In my opinion the South African position does need to take communitarian (Ubuntu) ethics into account (Hall et al., 2013). The DOH and MRC documents limit paternal participation when the research activities are primarily directed towards the mother (DOH, 2004; MRC, 2013). The mother is encouraged only to involve the father of the pregnancy in making the decision. Although it is only the signed, informed consent of the pregnant patient that is legally necessary to proceed when the health needs of the mother and fetus are involved, I would argue that time must be made by the woman (and if necessary by the researchers) to involve and seek the opinions of her partner and/or her family before official participation. This approach allows the woman to determine the extent of paternal and family involvement in the consent process. In a communitarian society, participation without such support only weakens the moral position of the participant and researchers, and often results in an “unexplained” withdrawal from the study. While women do have the autonomous right to withdraw from a study at any time (MRC, 2013), this decision is often “made for them” through pressure by the community if sufficient prior consultation was lacking.

- *Beneficence.* Pregnant women can benefit from the valid results of research designed to provide specific answers to their health needs.
- *Non-maleficence.* Pregnant women may actually suffer harm when data from studies on men and/or non-pregnant women are extrapolated to them. Systematic evaluation of risks

and benefits is particularly important when vulnerable populations are involved. According to the MRC Guidelines on Ethics in Medical Research, one of the characteristics of a vulnerable community is the “limited availability of treatment options” (2013). I have argued that this certainly applies to pregnant women.

- *Justice*. It is widely held that health care is a “special good” with a special need for a theory of justice (Beauchamp & Childress, 2009:242). In section 4.2, I discussed formal and material principles of justice. A dilemma with the principle of distributive justice is that it does not specify the characteristics of a “health need” or whose needs are more important but in the opinion of the ACOG “The systematic exclusion of women from research violates the ethical principle of justice, which first requires that persons be given what is due to them” (2004). Pregnancy is a condition valued, even encouraged by society, and as such it may not become the basis of unjust denial of benefits according to the “fair opportunity” rule. Justice requires that women do not have results from different study populations imposed on them. Medical research may be viewed as a limited resource but the benefits of scientific advancement should be shared equally. Thus researchers should be required to address obstacles to the participation of specific groups such as pregnant women. Consideration must be given, not just to those who should benefit but also to those who bear the burden. The Belmont Report advises that “medical research on any given group should not unduly affect persons from other groups unlikely to be among the beneficiaries of subsequent applications of research” (2010). However, at a practical level, the economic considerations in the allocation of resources are difficult to ignore. Clinical trials are generally expensive; the “market” of ill pregnant women is small and the risks of legal liability for pharmaceutical companies, high.

Research versus post-marketing surveillance

Although it is important to prevent harm to pregnant women, their fetuses and future children, it is debatable whether participation in research holds more risks than clinical care. In fact, “because the evidence base for current treatments is so weak, standard practice can be more like

experiment than validated treatment” according to Lyerly et al., (2010). The argument stating that despite the lack of clinical research, women are still protected by post-marketing surveillance is unconvincing. Although official surveillance activities have value they lack the rigor of randomised or other carefully conducted scientific trials and control over post-marketing surveillance is more difficult due to the wider scope of activities and role players. Advantages of properly conducted research include the following:

- “The quality of informed consent *including detailed information about risks and benefits* will be better in the research setting than in the clinic when physicians prescribe a medication that has never been tested in pregnant women” (Macklin, 2010).
- The participants/patients will be monitored more carefully.
- Phase I and/or phase II trials will discover serious mutagenic effects quickly. The numbers of pregnancies thus exposed to harm are far smaller than the numbers of exposures with post-marketing surveillance. This makes good utilitarian sense.

Despite the moral and clinical justifications for a greater participation of pregnant women in biomedical studies, support for this process would be irresponsible without having properly trained Institutional Review Boards and researchers practicing with rigorous ethical scrutiny. Biomedical research in developing countries must develop and/or maintain high standards and beware of the pervasive commercial influence of multi-national conglomerates. In the South African context it is encouraging to note the recent comments by van Niekerk and Benatar who opine that “a lot of what is currently done in bioethics in South Africa deals with capacity building in research ethics, in particular capacity to participate in the ethical review of research protocols” (2011). South Africa has a number of excellent research units that must continue to explore the deep reserve of opportunities present in clinical medicine in this country. This includes involving pregnant women in clinical research.

8.3 Summary position

The limited choice of anti-hypertensive agents for use in pregnant women can be viewed as a direct result of limited research studies involving pregnant women. Although it is important to prevent harm to pregnant women, their fetuses and future children, it is debatable whether participation in research holds more risks than clinical care. In addition ethical principles justify research in this group. Researchers have several strategies for risk mitigation at their disposal and robust research protocols that are meticulously implemented provide security for the clinician/researcher and pregnant woman alike. I therefore support the calls for increased representation of pregnant women and their interests in research, as the initiative is morally justified and will improve clinical management.

CHAPTER NINE: PRE-ECLAMPSIA BEYOND PREGNANCY

9.1 Mother and child

In Chapter One I stated that pre-eclampsia is a pregnancy-specific disease that resolves after delivery of the placenta. While this is still largely true, research during the last decade has shown that this disorder has lifelong implications for the mother, and her infant if it is born with a low birth weight (Pettit & Brown, 2012). Pre-eclampsia and other hypertensive disorders are common complications of pregnancy. Observational studies have now shown a relationship between these disorders and cardiovascular disease, renal disease, and diabetes later in life (Sattar & Greer, 2002; Pettit & Brown, 2012; Hermes et al., 2013). This is important as cardiovascular disease and diabetes are leading causes of morbidity and mortality in women in developed countries. Certain authors believe that pregnancy acts as a cardiovascular “stress test” by unmasking underlying pathology, while others have demonstrated that it may be the disease condition (pre-eclampsia) itself that begins the long-term pathological process (Pettit & Brown, 2012; Bytautiene et al., 2013). With regard to children, Chan et al., investigated the effects of preterm birth and growth restriction (both common in pre-eclampsia) on cardiovascular, renal or metabolic dysfunction in adolescents. Using a retrospective, cohort study design, they demonstrated that preterm birth and low birth weight increased the risk of arterial stiffness and metabolic dysfunction (2010).

Whether pre-eclampsia is the cause or simply a disease that unmasks women with vulnerable vascular systems, it does provide an opportunity to identify women at increased risk of cardiovascular disease. The next step will be to address the modifiable risk factors through lifestyle and medical interventions in order to prevent morbidity and mortality. This would include regular exercise, cessation of smoking, prevention or management of obesity, as well as medical treatment of hypertension and metabolic dysfunction if required. To date there are no properly structured studies that answer this question but doctors have a strong obligation to

advocate a healthy lifestyle for women who experienced hypertensive diseases during their pregnancies.

9.2 Ethics in prevention and primary care

When seeking to prevent disease we move into the domain of primary care within public health. Traditional bioethics teaching tends to emphasise the perplexing dilemmas usually encountered in hospitals and tertiary care settings. In contrast to hospitals where staff appropriately trained in ethics, or even a clinical ethics committee are available to provide guidance, support in primary health care is sparser while the need for ethics support is probably no less (Lillemoen & Pedersen, 2012). In fact ethical issues in primary care occur frequently and affect the quality of care. A case in point here is the influencing of individuals to change their behaviour through lifestyle modification, in order to prevent cardiovascular morbidity and mortality. Moon et al., state that “the complex nature of primary care can make it difficult to define a clear and consistent process for managing ethical conflicts” (2008:478). Roberts and Reich agree that ethical dilemmas are regularly encountered in public health, citing the examples of influencing changes in patient behaviour, rationing scarce resources and limiting individual freedom to diminish disease transmission. Their framework for analysing these dilemmas distinguishes three philosophical views “often invoked in public health discourse: positions based on outcomes (utilitarianism), positions focussed on rights and opportunities (liberalism), and views that emphasize character and virtue (communitarianism)” (Roberts & Reich, 2002).

Many other philosophical views can also be distinguished in primary care. The interconnected network of needs and care, as well as the prevention of harm are expressions of the “Ethics of Care” that originated in feminist writings (Hall et al., 2013). The principle of beneficence directs that we should actively prevent harm from occurring to others (Beauchamp & Childress, 2009:199). While W.D. Ross had a wide and demanding interpretation of general beneficence that rested on the mere fact that “there are other beings in the world whose condition we can

make better” (Ross, 1930), this has been described as romantic, impractical and sometimes perilous because the “more widely we generalise obligations of beneficence, the less likely we will be to meet our primary responsibilities” (Beauchamp & Childress, 2009:199). Yet although common morality sets limits to the demands of beneficence, doctors have a specific duty to prevent disease and harm. Apart from the moral obligations of care, the principle of beneficence requires doctors to balance costs, risks and benefits. This is as applicable to primary care as it is to hospital care. Statements of risk are evaluative as they attach a value to the prevention of events such as cardiovascular complication. The benefit may refer to cost avoidance or risk reduction “but more commonly in biomedicine it refers to something of positive value, such as life or health” (Beauchamp & Childress, 2009:222).

I have already stated that although a plausible argument (on the basis of pathophysiology) can be made to advocate lifestyle modification for the woman who experienced pre-eclampsia during her pregnancy, there are currently no properly structured studies that answer this question conclusively. In these circumstances beneficence is implemented through precautionary measures. Although it has many different formulations, the “precautionary principle” encapsulated in the maxim “better safe than sorry” has been widely applied, including to the domain of public health. “Depending on what is valued and what is at risk, it may be ethically justifiable and even obligatory to take steps in the absence of conclusive scientific evidence, to avoid a hazard where the harm would be both serious and irreversible” (Beauchamp & Childress, 2009:229). However, if the precautionary principle is to be applied responsibly, doctors should be careful not to distort or inflate risks to health.

In the medical field with its limited resources, the principle of justice requires continual attention. While some believe primary care to be critical to healthcare “providing most care for most people, for most conditions most of the time” (Moon et al., 2008:475), the vexing question remains: should priority be given to treatment or prevention? Our moral intuitions may send us in opposite directions but in most systems the balance lies, understandably on the side of

expenditures for treatment rather than prevention. This is because treatment deals with concrete situations whereas the benefits through prevention are more abstract. We would do well to remember that in many cases preventive care is more effective in saving lives. It remains the responsibility of research scientists to provide robust evidence regarding the efficacy (or lack thereof) of prevention programmes in order to provide just and equitable allocation of resources.

In its ideal form Starfield believes that primary care must be accessible, patient-centred, continuous and comprehensive (1998).

- *Accessibility* often implies that the local clinics are in the community. This gives these practitioners insight into the “multiple dimensions of patients’ preferences, including the influence of personal history, family and community” (Moon et al., 2008:475).
- *Patient-centred care* incorporates the needs, values and goals of patients who are accorded “Kantian” respect as real people. Kant argued that the basis for this respect is a person’s capacity for moral action, that is, for acting on the basis of impartial rules derived by reason. The approach of shared decision making has already been addressed in the sections on counselling and consent. The challenge for clinicians in primary care is to deal with patient goals, values and behaviour that are detrimental to health, e.g. working with the woman who will not stop smoking, control her weight or take medication. Here again, respect for autonomy wrestles with beneficence and paternalism comes into consideration. Non-compliance that often seems to conflict with other values and behaviours, has been covered in Chapter Five, but continuous care allows the clinician time to revisit the situation.
- *Continuous care* helps establish the doctor-patient relationship, but once the pregnancy is past, the role of the obstetrician comes to an end, although the obstetrician-gynaecologist may continue primary care in the latter role. If this is not the case, the doctor is obliged to arrange for continuity of care through another provider so that the patient does not experience “abandonment”. This is challenging within state health care systems with

rigid boundaries, but working relationships can be established amongst colleagues as illustrated in Case 4 (Chapter Five).

- *Comprehensive care* requires the integration of the physical, psychological and social elements, as well as prevention into the care provided.

9.3 Summary position

The conditions of pre-eclampsia and other hypertensive diseases of pregnancy provide a unique opportunity to identify women and children at increased risk of cardiovascular and metabolic diseases in later life. Cardiovascular morbidity and mortality represent end-points important enough to merit the application of beneficence in the form of the precautionary principle while still awaiting robust scientific support. Prevention provided through primary care is well supported by many ethics principles.

CHAPTER TEN: THE PATH FORWARD

Ethics in obstetrics is confounded by the complex relationship between a pregnant woman and her fetus. In this thesis I have emphasised that pre-eclampsia is one of the most important conditions that an obstetrician will face, with many interfaces between clinical medicine and ethical principles that arise even before a pregnancy has begun and continue long after it has ended. The aim of this thesis has been to highlight specific regularly encountered problem areas and discuss them in a bioethics context in order to assist clinicians in their decision-making and resolution of dilemmas in real-life.

The most important frontier for pre-eclampsia remains effective prevention and/or curative therapy. Both will bring peculiar ethical considerations to the pre-conception period and first trimester of pregnancy. Pre-conception counselling and care is an area ripe for further developments. Much attention has been focussed on genetic markers for pre-eclampsia but no strong, simple predictive genetic test has yet been identified. Although genetic testing is widely applied in general obstetrics it remains a contentious topic. In the future genetic screening for pre-eclampsia may become a reality and would therefore need to be incorporated into counselling.

There is no medical cure for pre-eclampsia at present. Delivery is the only definitive way of arresting and reversing this pregnancy-associated disease. Research with e.g. anti-angiogenic factors or statins may hold the key to unlocking medical therapy. Should such therapy become a possibility, all the ethical dilemmas of where and how to conduct the research in pregnant human subjects would need to be considered. There would also be a moral responsibility to make effective treatment easily accessible in poor, developing countries that carry the greatest burden of disease. On-going human research and the roll-out of antiretroviral medications for HIV/AIDS have provided the world with some salient lessons in this regard.

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