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Gillian Craig, M.D.

Paradise lost: The Devolution of Medical Practice

Many British doctors will have been shocked by the editorial 'When learned doctors murder' in *Ethics and Medicine*.[1] C. Ben Mitchell referred to the devolution of medical practice, and warned of the dangers of using euphemistic language to make murder seem respectable. His warning is timely, but the word 'murder' does not trip easily off the tongue when speaking of medical practice.

Time was when I was blissfully ignorant and knew nothing about the practice of sedation without hydration. My peace was shattered when I visited a hospice as a member of the public some years ago. I saw how the management of death can take over and dominate thought. 'Death', wrote one patient 'is becoming a little noisy, a little too obvious'. My glimpse of the unacceptable face of palliative medicine was a painful shock that gave rise to the hydration debate.[2]

Some palliative medicine colleagues have been offended by my suggestion that sedation without hydration can be considered as euthanasia.[2] They do not see their clinical practice in that light. Others feel that my criticism has struck at the whole ethos of palliative medicine. I hope it has! The death-orientated approach must be replaced by a life-orientated approach, and due regard paid to matters of hydration. There are hopeful signs that attitudes to hydration in the hospice movement have become more flexible in recent years. If so, my effort has not been in vain.

However, progress within the hospice movement is counterbalanced by worrying developments elsewhere. I have drawn attention to the dangers of advance directives.[3] If these are made legally binding, people will be able to opt for death by dehydration simply by signing an advance directive that prohibits the use of artificial hydration under certain circumstances. This happens already in some states in the USA. Competent patients can of course refuse artificial hydration or medical treatment simply by saying 'No'. Sometimes old people who are tired of life take matters into their own hands and stop eating and drinking.

James Hoefler, an American associate professor of political science, has written a sinister guide to foregoing treatment at the end of life. He talks quite openly about dehydration, describing this as 'a time-honoured, foolproof alternative to tube feeding for terminally ill patients who are prepared to die'. He also discusses dehydration as an alternative to physician-assisted suicide. 'The key' (to managing death), suggests Hoefler, 'is knowing when to shift the focus from curing to caring . . . If we really care we will think long and hard about whether to impose artificially provided nutrition and hydration'.[4] Few doctors would disagree with that statement. However, I would stress that hydration must never be withheld with the deliberate intention of ending life.

Difficult quality of life considerations are an important part of medical decision making. It may be acceptable to withhold artificial hydration if the means of administering it is too great a burden for the patient.[5] This could apply to tube feeding or gastrostomy feeding in many clinical situations, including advanced dementia and some stroke patients. Many very difficult decisions have to be made in younger people with 'learning difficulties'. There is no easy answer to these problems.

The British Medical Association (BMA) recognize that there are 'substantial and unresolved issues concerning the withdrawal and withholding of treatment from patients . . .'[6] Their Medical Ethics Committee issued a consultation paper on 'Withdrawing and Withholding Treatment' in July 1998 and invited comments for three months. Their aim was to seek views as widely as possible, from doctors, other health professionals, patients and the general public. Guidelines are now being prepared and are awaited with some apprehension. The task of the BMA Medical Ethics Committee is a difficult one. It is crucial that they refuse to be pushed into unwise or hasty decisions by pressure from politicians or the legal profession.

There may well be economic advantages to be gained from the early death of ill or disabled people, as the Federal Government in the USA noted some years ago.[7] This message will not have been lost on those responsible for our cash-strapped Health Service and could well be part of the covert thinking behind moves to make advance directives legally binding in the UK. The British Government, like that of the USA, could stand to gain financially from the early death of patients who might otherwise be a burden on the health service. No politician would admit this in so many words, but economic arguments are powerful and the temptation to act must be strong.

Many people were appalled in 1996 when the British Medical Journal (*BMJ*) published an editorial 'Jack Kevorkian: a medical hero', written by the North American Editor of the *BMJ* and a Professor of Medicine and Bioethics from Canada.[8] Dr Kevorkian, an unemployed pathologist, was killing patients at their request in the back streets and garages of Michigan, and dared the law to stop him. He was convicted of second degree murder in 1999.

One of the key principles of medical ethics, as agreed at an international conference held in Paris in 1987, is set out in Article 2 of Principles of Medical Ethics in Europe.[9] This

states, 'The doctor may use his professional knowledge only to improve or maintain the health of those who put their trust in him; in no circumstances may he act to their detriment'. The conference report was unanimously adopted by all participants, including the General Medical Council representing the United Kingdom. The *BMJ* editorial flouted Article 2 and undermined professional integrity. It is ominous that there was no public reprimand about this editorial from the BMA or the General Medical Council. Editorial freedom, it would seem, is more important than professional morality and respect for the law.

The law on euthanasia was very carefully reviewed by Parliament at the time of the Bland case, and the result of the carefully reasoned debate was that euthanasia remains illegal in the United Kingdom. That decision should be respected, but there are constant attempts to undermine the law. Those who break the law are not heroes. The true medical heroes are those who truly care for their patients and support them through pain and distress, until life comes to a natural end.

Many letters of protest were written about the editorial and several were published in the *BMJ* of July 27th, 1996. Some were from palliative medicine specialists at the forefront of the fight against euthanasia.[10,11] Dr. Ilora Finlay and colleagues from the University of Wales College of Medicine stressed many practical reasons why killing a patient, even when problems seem insurmountable, must remain prohibited by law. In summary, they said that the law protects vulnerable patients, it protects doctors from themselves, and it protects doctors from relatives and managers who may stand to benefit from a patient's early death.

A Geriatrician, Dr C. A. Crowther[12], drew attention to Pope John Paul II's letter *Evangelium Vitae*, which upholds the value of human life and exposes the prevailing 'culture of death' in which we are immersed.[13] Robert Balfour, a Consultant Obstetrician[14], quoted Dr Everett Koop, a former Surgeon General in the USA who predicted a euthanasia programme for various categories of citizens and pleaded, 'Let it never be said by historians... that there was no outcry from the medical profession'.[15]

Intentional and deliberately planned death should have no place in medicine, yet the concept has been introduced into public debate quite deliberately. The *BMJ* editorial was a blatant example of this. Others have introduced the issue more subtly and unobtrusively. In recent years, several influential people have helped to promote euthanasia. One such, John Hams, a Professor of Applied Philosophy who advocates doctor-assisted suicide, was chosen by Age Concern to chair a study group that prepared a statement on values and attitudes in an ageing society. Their views, advocating doctor-assisted suicide and euthanasia, have been presented to the public in a glossy brochure, and on the internet, as part of the Age Concern Millenium Debate of the Age.[16]

This initiative—said to be independent, but rumoured to have government funding—aims to raise awareness about the implications of our changing demography, in particular the increasing number of old people in our society. Another aim is to achieve policy changes, and help to set personal and national priorities through a national programme of events. Those who cooperate and interpret the theme according to operational policy can use the 'age speech—bubble logo!' The Debate of the Age is proudly presented as the 'largest, most involving social campaign ever envisaged outside government'.[6] Feedback will be presented to the Government in Spring 2000. The organizing committee includes several representatives from the world of finance and insurance, the Editor of the *BMJ*, Professor John Harris, some media experts, a token Bishop and others. The debate is of course, very wide ranging and covers many areas that are unrelated to medical ethics. Nevertheless, the views expressed on euthanasia in the interim papers are sinister and dangerous. Meanwhile the Lord Chancellor and the Government assure the public that there are no plans to legalize euthanasia! However subtly the spin doctors work, the public must not allow themselves to be fooled.

From time to time a General Practitioner, the Chairman of Doctors for Assisted Dying, is invited to speak on radio or television, or writes to the Times. He is proud that he has killed terminally ill patients in the course of his medical career. The police have decided not to prosecute him as the crimes were committed many years ago. Yet ageing war criminals are still prosecuted. Why should this doctor have immunity from prosecution?

In 1992 a Consultant Rheumatologist was convicted of attempted murder. Having found himself unable to control his patient's severe pain, he gave her a lethal injection of intravenous potassium chloride, and she died within minutes.[17] Despite the conviction, he was allowed to continue to practise by the General Medical Council (GMC). Yet his action contravened both the law, and Article 2 of Principles of Medical Ethics in Europe to which the GMC had been a signatory. Had they forgotten about this, or did they choose to overlook the fact? Where now is the resolve to see that these ethical principles are put into practice? Where is the resolve to respect the law of the land?

In his book *A Preface to Paradise Lost*,[18] C. S. Lewis commented on Milton's epic poem and was fascinated by mankind's ability to argue ourselves into a course of action that we know to be wrong. Eve, is tempted to eat the forbidden apple. She has dubious reasons for offering to share the apple with Adam in the Garden of Eden.[19] Lewis wrote:

> I am not sure that critics always notice the precise sin which Eve is now committing, yet there is no mystery about it. Its name in English is Murder. If the fruit . . . means death, then he must be made to eat it, in order that he may die . . . And hardly has she made this resolve before she is congratulating herself upon it as a singular proof of the tenderness and magnanimity of her love . . .
>
> The whole thing is so quick, each new element of folly, malice and corruption enters so unobtrusively, so naturally, that it is hard to realise that we have been watching the genesis of murder.. . . Thus, and not otherwise, does the mind turn to embrace evil. No man perhaps ever at first described to himself the act he was about to do as Murder, or Adultery, or Fraud, or Treachery, or Perversion; and when he hears it so described, by other men he is (in a way) sincerely shocked and surprised. Those others 'don't understand'. If they knew what it had really been like for him, they would not use those crude 'stock' names. With a wink, or a titter, or in a cloud of

> muddy emotion the thing had slipped into his will as something not very extraordinary, something of which rightly understood and in all his highly peculiar circumstances, he may even feel proud.[18]

How well these thoughts of C. S. Lewis describe the varied reactions to the hydration debate. We all have a responsibility to ensure that withholding hydration is not used as a means of ending life. The hydration needs of patients should be met in a way that is morally acceptable, medically acceptable, and in keeping with the law of the land. How sad it would be if the celebration of 2000 years of Christianity should coincide with an age when human life became disposable in civilized society.

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David Schiedermayer, M.D.

'Where am I Going from Here?' The Ethical and Spiritual Issues of Estrangement

THE STORY

Some people pray when they are ill. Some take to calculating the statistics. Others go into hostile denial, railing against the cruelty of biology, of tumours and ischemia and viruses. Dr. Epstein takes a purely intellectual approach.

Dr. David Epstein was born on June 13, 1920. His father was a general practitioner, and it was obvious that young David was an intelligent child. His father took him on rounds with him, explaining the early 20th century models of disease, and David became fascinated with physiology. He soon found the need to apply his interest to his own situation, for he noted sudden spasms of his hands and an inability to walk long distances without severe spasms and weakness. He began what would be his lifelong research quest: the diagnosis and treatment of his own rare disease, myotonia congenita.

Myotonia congenita is an autosomal recessive disease occurring in about one in a million people. It causes severe muscle spasms, making it difficult for the patient to walk, shake hands without letting go, or speak without a clenched jaw. Most patients with myotonia congenita die of iatrogenic complications, for they are often exquisitely sensitive to anticholinergic drugs, cholinesterase inhibitors, and CNS depressants, all of which are commonly used in the clinical setting and especially in the operating room. So young David Epstein began his odd relationship with the medical profession. He asked his father for medication, but he also was wary of side effects. He was also always searching outside of medicine for other chemicals which might help his condition.

His father gave him thyroid medication, which he felt helped him. David also found that alcohol in large doses helped him, so as a teenager he was drinking a fifth of

whisky a day. He cut down on this amount when he no longer found the alcohol helped the myotonia. Over the next forty years he tried an array of medications including ACTH, chlorothiazide, cortisone acetate, prednisone, testosterone, and many others. I remember in 1983 when he became my patient that he asked me to obtain acetyl-COA from Sigma chemicals in Germany, such was his ferocious quest for medications which might help his disease. But I digress. Young David was an intelligent youth, and he went on to be well educated at a fine university and law school. He began practising law in Chicago and was quite successful until years later when he had significant problems with the IRS. He was married, had one son, but is now estranged from both his wife and son. He says that his wife married a doctor and he doesn't know her whereabouts, and that his son is a hippie who doesn't want to contact him. He quit law in the late 1970s and went to medical school in Germany, completing most of the training.

Over the last fifteen years I have known him, a clinical encounter with Dr. Epstein (as I call him in respect for his education) goes like this:

'Good morning, Dr. Epstein'.

'Good morning, Doctor. They tried to take my weight out there and my blood pressure but I couldn't stand it. Doctor Schiedermayer, I have pulmonary venous hypertension and edema, and palpitations. I have been taking cortisone acetate for it, and ginkgo biloba, and my emphysema seems better but I wonder if I need to increase my oxygen'.

I scan the chart. He does have severe emphysema with pulmonary function tests showing an FEV1 of 22 percent of predicted. His arterial blood gases on room air show a pO2 of 67 but he drops below 60 with minimal exertion. He is on home oxygen and spends most of his day in a recliner chair.

I read other notes. He also has risk factors for heart disease, including his age, his gender, and a history of smoking three or four packs of cigarettes a day for most of his adult life. He quit smoking five years ago when he developed cancer of the base of the tongue, but admits he still smokes one to two cigarettes per month. He has no history of hypertension, diabetes, or known lipid abnormaliiies. His self-medication with corticosteroids has resulted in severe osteoporosis and one hip fracture requiring hip pinning in February 1996.

'Dr. Epstein, did you go see Dr. Hansen (the cardiologist)?'

'I did, doctor, and he told me that I have emphysema, and that I don't have any heart disease he can help me with'.

'Hmmm. How is your myotonia doing?'

In reply, Dr. Epstein reaches out and shakes my hand. When we end the handshake and he tries to release, he can't let go.

'You see, doctor. I have cut way back on the cortisone. But I need to try a shot of ACTH. Can you prescribe it for me?'

When I politely decline, he shakes his head and says he'll have to get it from his friend in Chicago, an older doctor he helped with a lawsuit many years ago.

Dr. Epstein treats me with some disdain, both because I am just a general practitioner (not that he doesn't also treat the specialists with disdain) and because I am very conservative about giving him the various medications he continually requests. Nonetheless, he continues to see me as my patient. At one point he offered me his possessions and his inheritance, which I firmly refused of course, saying that I could no longer be his doctor. He said if I didn't take them the IRS would anyway. Although the offer seemed sincere, he made it more than a year ago and has accepted my refusal without a second request.

On examination, Mr. Epstein has very thin features, with tight muscles around the face. He has quick movements and a ready but sardonic smile. He has graying hair with severe seborrheic dermatitis. He is 5 feet 8 inches tall and estimates his weight to be 115 pounds. He is in a wheelchair. His blood pressure is 120/76. The neck has some skin changes consistent with radiation therapy. A right carotid bruit is present. The lungs have decreased breath sounds throughout but no rales, rhonchi, or wheezes. The first heart sound is very soft and the second heart sound is not split. The abdomen is scaphoid, and the extremities show 1+ edema. His skin is dry with much flaking. Neurologically he is oriente x3. His reflexes are difficult to elicit. His muscle tone is increased throughout and he does have some evidence of muscle wasting in the thenar areas. He also has some dysarthria, presumably from muscle weakness in the muscles of phonation.

After each examination, Dr. Epstein gives me an update on the latest treatments for myotonia, often noting that he has discovered that a treatment would work many years before the scientists discovered it would be effective. He does not expect me to know this material, although after more than forty office visits it often feels to me that we are actors in a play and we each read our lines. On the other hand, he is always full of surprises, on each visit telling me some detail about his life which he knows I may find interesting. He tells me of his calls to the head of the FDA (true stories). He describes the various regimens he has tried for impotence (amazing hormonal manipulations, actually). He adds to the parts of the history I thought I knew. For example, I knew that he drank heavily, but I didn't know until he mentioned it on the last visit that he drank a fifth of whisky a day as a teenager because it helped his myotonia.

The generalist physician becomes accustomed to his or her patients doing fairly well over the years, with office visits, phone calls, medication refills, and then, every once in a while, sadly, disaster. I count on about a disaster a week. This is one of the great sadnesses of general medicine, that even with almost everyone doing well, someone will be doing poorly. Lately, it has been Dr. Epstein.

In July 1997, he considered suicide because of his deteriorating condition. My office notes indicate that he had a seconal and a revolver. However, his 'hobby used to be hypnotism, and so he hypnotized himself out of his depression'. I arranged for home health care agencies to see him, but he accused one home health aide of stealing his money (it is difficult to determine if she did, but there is no evidence to support his claim). I asked another agency to see him, and things were going well until he began constantly speaking to the nurse, Ruth Jones, about his loaded pistol. She reported the pistol to her agency, and after several meetings, Ruth called me and said they would have to notify the police about Mr. Epstein's danger to self.

I was reluctant to get the police involved, but agreed that given the situation it was probably the best things.

Ruth and the social worker confronted Dr. Epstein about

the pistol, and when they asked for it, he became very angry, getting up out of his wheelchair and tearing the social worker's dress. The police arrived shortly and Dr. Epstein was taken to the psych unit. The psychiatrist examined him, finding him to be highly irascible but fully competent, and he asked me to come to see him so they could send him back home. I talked to him, and found him to be his usual self.

'Doctor', he said to me, 'If I was going to commit suicide I wouldn't talk about it. You know that.'

A nurse and the chaplain from the agency were there in the hallway of the psych unit, so we discussed Dr. Epstein's case and agreed to go to see him together. I mentioned to the chaplain, standing at the bedside, that Dr. Epstein was estranged from his wife and son and that I thought this was an important spiritual issue for him. I saw Dr. Epstein shake his head. He moved his head quickly from side to side. 'Here is his spiritual problem', I thought to myself. The chaplain moved his head in the opposite direction, up and down. I moved my head up and down.

'This is a great spiritual discussion', I thought to myself as I looked around the room. 'Everything is right here, in the body language alone. There is a doctor and a chaplain who believe in God, both of their heads nodding up and down, the patient we are trying to help, who doesn't even believe in his own son, and the nurse who, still angry with him about the gun, purses her lips slightly but appears ready to forgive and take him back.'

Spirituality in the clinical setting is embedded in the details of cases such as Dr. Epstein's. Every office visit, every request for a consultation, for a medication refill, for a referral to a home health agency, is a spiritual event. Every crisis point, from the crisis of worsening illness to a major ethical crisis, is a spiritual event. One simply cannot separate out an aspect of the patient's history, for example, the social history or spiritual inventory, and say that this is the only spiritual aspect of the case.

And sometimes the most important spiritual details are seen at the margins, at the refusals, at the disappointing juncture of the case.

A logical question, of course, is what is the patient's faith tradition. But we are often too impatient when we ask this. I always ask it as part of the patient's social history. But sometimes asking the exact type, the exact denomination, is rushing to a conclusion. For if we believe in spirituality, that is, in the basic sense that human beings are spiritual, then we know already that Dr. Epstein is a spiritual being. Based on his history, we already knew that when asked by the admissions clerk about his religion he was going to say that he had none. This, of course, was exactly what he said.

It is after asking a patient's social history that we turn to the chart to try to glean an answer regarding their faith tradition. We found Dr. Eptstein's social security number, his address, and that he is a white non-hispanic male, who is divorced. He listed himself as retired/disabled. He lists no one, no one at all, as someone to contact in case of emergency. Under 'relation to emergency contact', someone typed, 'OTHER'. Under 'relation to responsible party', someone had typed 'SELF'. So we had someone who was estranged even from himself, who was an other. I looked through several inches of notes. The cardiac surgeon, cardiologist, another internist, an ENT physician, and ENT cancer surgeon made no notation of his religion. The cardiothoracic physician's assistant completed a long form, and Dr. Epstein told the PA his mother died at age 72 of lung cancer and his father died at age 71 of diabetes. Dr. Epstein told the PA he was single and has no children.

Pages and pages of my notes were present, noting that 'his hobby is hypnotism. He hypnotized himself out of a depression', or 'Pt considered suicide at the end of July. He had Seconal, and a revolver, drank Schnapps, and smoked cigarettes, but didn't go through with it.' I treated him with testosterone, B12, Paxil over the course of time. I found a hand written letter from Dr. Epstein, requesting an EKG ('since 1936 I have intermittently taken class I antiarrhythmic drugs to relieve my muscular problems and provide me with mobility'). He also requested a T3 and T4, Prostate cancer test, cholesterol with HDL and LDL, triglycerides, and alkaline phosphatase. He wrote, 'over the past year I have had an insidious and gradually progressive loss of short-term memory, reaching serious proportions at this time'. I was on sabbatical during the year he wrote this letter, so another physician saw him and referred him to a neurologist for the memory loss.

The neurologist noted that 'the patient studied at the University of Heidelberg and at the Goethe Institute in Frankfurt where he apparently received two Ph.Ds. Since then, he has forgotten the content of his two Ph.Ds and has also forgotten German, French, and Spanish. During the interview, he states that he has no personality changes although he admits to being a difficult patient. He denies any verbal or physical aggressiveness. He states that although he is anxious, he has no problems with misplacing objects. He denies accusatory, suspicious, hiding, and hoarding and paranoid ideation. When asked whether a caregiver is present, he states that he is alone and needs nobody to take care of him. He admits to having recently prescribed himself Hydergine to treat his memory and feels this has been useful with the addition of Niacin. He is also interested in procuring Piracetam in Europe, as well as Ascar.'

The only other salient note on the chart was from the urologist. 'Dear Dr. Schiedermayer: I had the pleasure of evaluating one of your patients, David Epstein, in the Prostate Center today. Mr. Epstein presented to the Prostate Center with a request for a prostate ultrasound. He had recently overheard a radio talk show which advocated the use of transrectal ultrasound as a method for screening in benign prostatic hyperplasia. Mr. Epstein refused a PSA and a digital rectal examination, stating that he had recently completed a PSA and was uninterested in a digital rectal examination. Mr. Epstein was very specific and exact in his demands.' Later on, however, Dr. Epstein did allow the urologist to do an examination, which was negative for cancer.

So I looked through the entire chart without finding one iota of spiritual history in the clinical record—unless you consider that Dr. Epstein's whole life history was a spiritual history, and that his basic spiritual problem was that he was estranged and alone and preferred it that way. Not enough? So I decided to call him, both to see how he was doing since he was home from the psych ward where he was for assaulting the home health care social worker who was trying to take away his gun.

When I called him at home I heard him coughing as he picked up the phone. He told me he was having thick, viscous yellow sputum, up to one-half cup a day, streaked with blood. He said he was short of breath even while he talked, and he was having decreased appetite. He said he was alert and lucid and had 'all my cognitive abilities'. He requested that I complete the paperwork for an electric wheelchair, which I said I would do. He noted that he increased his home oxygen to 6 litres a minute, and that on one litre a minute his heartrate was 120 beats a minute but on 6 litres it was down to 70 beats a minute. He asked if that dose of oxygen had any side effects, and I told him that drying was the main side effect. He said, 'where am I going from here?'

I said that nothing dramatic would happen, but that he might have gotten a pneumonia and may have needed to get some antibiotics if that were to happen. I asked him if he had enough help at home, and he said that once or twice a week he had someone come and cook for him. She was an African-American woman, who made spicy food which he liked. He enjoyed everything but chitlins. He asked again what I think he may have needed, and I said, how about prayer. He laughed and said, 'prayer is out of my jurisdiction. Hell no.' I asked, 'were you ever a religious person?' He replied, 'I am an unbeliever. A disbeliever.' I asked, 'well, how about hypnotism?' He answered that he had read every book on hypnotism, including those in the library of congress, that he had taken 2 college courses on hypnotism, and that he had hypnotized over 10,000 people in his life.

I said, 'well, when we had the home health service in, we had that chaplain to see you. I wonder if we could get you in contact with your wife, your son . . .'

'Doctor, let me tell you a story', he said. 'One year ago I told a friend to buy Merck stock at 34 dollars a share, and he bought it and it went up to $124 a share. He made $15,000, and he sent me a check. Well, he later ran into my ex-wife, and he gave her my number. She called me and we talked for over a half hour. She told me that she had called my son, and asked him to contact me, but he won't call me.'

'I am sorry', I said.

'I am too', he said.

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Redefining the Active/Passive Euthanasia Debate: Introducing New Categories to Aid Proper Moral Contemplation

In part one of this article, I argued that the 'active/passive' terminology and categorization confuses rather than helps the euthanasia debate. In part two, I argue that 'situation' and 'intention' are necessarily required in any euthanasia discussion, and I offer a new categorical structure that incorporates these concepts more fully than has traditionally been the case.

THE RELEVANCE OF SITUATION

The factor of situation is used to identify whether there are any other factual concerns that are of moral relevance, ignored by the active/passive distinction. The situation in which one may find one's self can have a moral bearing on the decision to be made. Concerning the issue of killing and letting die, Judith Jarvis Thomson realized that 'morally speaking it may matter a great deal how a death comes about'.[1] She evaluated several killing/letting die situations in which it can be concluded that, when all other things are equal, the situation alone can determine the morality of an action. She first looks at an example very similar to Rachels' Smith/Jones example:

> (1) Alfred hates his wife and wants her dead. He puts cleaning fluid in her coffee, thereby killing her.
>
> (2) Bert hates his wife and wants her dead. She puts cleaning fluid in her coffee (being muddled, thinking it's cream). Bert happens to have the antidote to cleaning fluid, but he does not give it to her; he lets her die.[2]

Thomson agrees with Rachels that in situations such as this there is no moral difference between killing and letting die. Both Alfred and Bert, out of a desire for the death of their spouse, act in morally culpable ways to secure it. As commonly accepted, it is better to let die in some cases than to kill. Thomson writes:

> David is a great transplant surgeon. Five of his patients need new parts—one needs a heart, others need, respectively, liver, stomach, spleen, and spinal cord—but all are of the same, relatively rare, blood-type. David can take the healthy specimen's parts, killing him, and install them in his patients, saving them. Or he can refrain from taking the healthy specimen's parts, letting his patients die.[3]

It is intuitively correct that David may not justifiably kill one to save five. The primary reason is because the healthy specimen has claim to those parts above any claim the others have to them. More controversially, however, Thomson sees that in some cases it is morally better to kill than to let die. She writes:

> Frank is the passenger on a trolley, whose driver has just shouted that the trolley's brakes have failed, and who then died of shock. On the track ahead are five people; the banks are so steep that they will not be able to get off the track in time. The track has a spur leading off to the right, and Frank can turn the trolley onto it. Unfortunately, there is one person on the right-hand track. Frank can turn the trolley, killing the one; or he can refrain from turning the trolley, letting the five die.[4]

Most people would probably consider it morally acceptable to turn the trolley onto the one killing him (thus saving the five) rather than do nothing and let the five die. Each of the above cases can be decided on moral grounds other than the act itself as well as the intention of the agents involved. Each turns on the specific circumstances of the individual case. It shows, for example, that sometimes the moral status of the consequences are the only way to decide what is morally acceptable to do.

One argument against the category of 'situation' could be that it does not contain specific moral criteria with which we can evaluate. This category is not a specific rendering of a moral principle; rather, it is a general catch all for external factors which are relevant to making a moral decision on an action. Though this is true, it does not pose a problem. There are many moral guidelines and theories that we could possibly include in a debate over euthanasia, probably too many in fact even to easily count. Only the issue of intention (discussed next) is, especially in circles that support the traditional view of euthanasia (see Part I), almost always integral to the debate over euthanasia. In relation to judging the morality of an action, the way intention is viewed often relies on aspects of the actual situation, such as what the agent is 'free to do'. The broad category that I called 'situation' allows for exceptions to any a priori moral categories.

In addition to embracing the capacity of broad moral expression in the debate over euthanasia, 'situation' provides a chance to examine each case for information that precludes the formation of a moral decision without it. In any circumstance where the debate can turn on a piece of information or knowledge, the category of situation is how those exceptions are noted. The concept of situation is admittedly broad. However, I hope that it will indicate an open avenue for both the information of each individual situation to be more readily considered and that other moral criteria can have an expression, perhaps previously impeded by the complexity of the active/passive definitions and categorization.

THE RELEVANCE OF INTENTION

Intention is a primary moral element used by those who defend the traditional view of euthanasia in almost every debate. It is used in considering almost all individual circumstances where an action must be evaluated. Those who defend the traditional active/passive distinction recognize that the actions in and of themselves alone do not determine their own morality. Rather, actions are a synthesis with intention. Thomas D. Sullivan, who defends the active/passive distinction in its traditional form, also contends that the active/passive categories are not based solely on the actions of agents. He argues that action is a synthesis with intention. On intentions, Sullivan argues, 'The traditional view [of euthanasia] is that the intentional termination of life is impermissible, irrespective of whether this goal is brought by action or inaction.'[5] This corresponds directly to the AMA statement which reads, 'The intentional termination of life of one human being by another—mercy killing—is contrary to that for which the medical profession stands and is contrary to the policy of the American Medical Association.'[6] Those who defend the traditional view usually believe that passive euthanasia can be murderous.

Teresa Isaacs, while agreeing with Rachels' methodological premise, that the action of killing is no worse than the action of letting die, asserts that there are other moral grounds upon which the issue of euthanasia turns. She defends this conclusion by saying:

> We cannot draw the distinction [between killing and letting die] so that it is at once clear and coincidental with our intuitive moral judgments about cases. Since it cannot fulfill both of these criteria at the same time, it is not what is doing the moral work in any given case.[7]

Isaacs insists that there are *other* moral criteria doing the moral work. Of those moral grounds she does list, all of them could easily be classified as falling under a broad category of intention.[8]

Richard Higginson also agrees with Rachels' conclusion that action cannot be the deciding moral factor. Yet, he also asserts that intention does have that moral relevance, thereby making it his central focus. In his article 'Euthanasia Reconsidered', he writes:

> The crucial criterion for deciding whether something constitutes euthanasia lies not in whether it is active or passive, not whether it is doing something or not doing it, but *whether the death of the patient is deliberately sought*, through whatever means.[9]

If intention is vital to include in determining the morality of active and passive euthanasia, it is necessary to answer

those who disagree with that contention. Rachels believes all this discussion about intention is irrelevant. He directly responds to Sullivan's argument above, but his arguments weigh against all who believe intention to be a relevant moral consideration in the euthanasia debate. Rachels correctly believes that the arguments against him concerning intention primarily turn on the assumption that it is (or at least can be) wrong to terminate life intentionally. Thus, if it can be wrong to do so, intention is a relevant moral factor and it should be a part of the equation—something that Rachels has left out of his categories. Rachels disagrees as to its relevance, and therefore he builds his case using the bare-difference argument:

> A massively necrotic bowel condition in a neonate is out of control. Dr. White realizes that further treatment offers little hope of reversing the dying process and will only increase the suffering; so, he does not submit the infant to further treatment—even though he knows this decision will hasten death. However, Dr. White does not seek, choose, or plan that death, so it is not part of his intention that [the] baby dies.
>
> Dr. Black is faced with a similar case. A massively necrotic bowel condition in a neonate is out of control. He realizes that further treatment offers little hope of saving the baby and will only increase its suffering. He decides that it is better for the baby to die a bit sooner than to go on suffering pointlessly; so, with the intention of letting the baby die, he ceases treatment.[10]

It is Rachels' contention that those who believe intention is a morally relevant factor would assert that Dr. White's action would be morally acceptable, while Dr. Black's action would not. Both did exactly the same thing but did it with different intentions. It would not make logical sense, then, to assert that the bare difference of thought or disposition makes identical actions acceptable in one case (Dr. White) and unacceptable in another (Dr. Black). Rachels writes, 'A pure heart cannot make a wrong act right; neither can an impure heart make a right act wrong.'[11]

There are many philosophers who assume that motive has no bearing on the moral status of an action. John Stuart Mill asserts, 'Utilitarian moralists have gone beyond almost all others in affirming that the motive has nothing to do with the morality of the action, though much to do with the worth of the agent.'[12] However, motive (desire) is an important informative piece that can help explain the morality of acts. For those who support the traditional view of euthanasia, intention is one of the key elements that helps to determine the morality of specific cases of euthanasia. It is the motive of the agent that confers moral status on those causes which are amoral in and of themselves. As Rachels pointed out, the action of killing is no worse than the action of letting die when all else is equal. If these causes are amoral, the intention of the agent helps us to decide under what circumstances the rule against killing innocent life should not apply. The morality of the agent and the morality of the action the agent does are inseparable as long as the agent is free to act.

In evaluating any action, we must look to the intention of the agent to inform us as to the true nature of the action. It is the agent's freedom that will guide us to know how we should view the intention of the agent in each individual situation. It is necessary to separate the motive from the act and evaluate it separately because the morality of the motive with which someone carries out an act of euthanasia does not transfer to the act and make that act right or wrong when the agent is not free to act.

The problem of freedom is what causes Rachels' necrotic bowel condition example to fail to do the mission he wants it to do—namely, to prove that intention does not matter. The fact is, that neither Dr. White nor Dr. Black was free to try to save the baby's life. The baby was going to die. As long as it was not immoral for the baby's death to be 'accelerated' by the stoppage of treatment, the actions that both doctors made to stop treatment are the only choice they were able to make. In order for Rachels to be able to prove his point (that intention is irrelevant), both doctors would have to have had a free choice to continue treatment (and possibly save the baby) or not continue treatment (when the baby could possibly have been saved). Since the baby was dying and could not be saved, the intention of the agents did not change the moral stance of their actions.

While the issue of intention is contained in most definitions of active and passive euthanasia, it is not possible to define clearly this relationship in any form. The complexity of defining these categories, with their myriad conditions, prevents their viable use in moral assessment by competing moral theories. For intention to be relevant in the debate, a coherent expression of any categories and their relation to intention is required. The categories which I will propose subsequently seek to give intention its proper consideration for moral assessment of euthanasia.

PROPOSAL FOR NEW CATEGORIES

I wish to propose four categories for the debate. Because of the importance people place on intention in the traditional definitions, I have chosen to structure the argument around the four possible *causes of death* that I see in euthanasia; each cause is associated with a related intention. The categories I will propose attempt to redefine the active/passive categories into a more usable form allowing the cause of death and its related intention to be criteria for the moral evaluation. These categories are intended as a tool to address the general situations we can identify.

The first of these categories is *Natural Termination* (NT). This is when someone dies without human action or omission. The cause is amoral. There is not a moral aspect to this category because the cause of death is not human, but nature. For example, Joe Snuffy is 94 years old and is suffering from malignant tumours in both his liver and pancreas. He has not responded to chemotherapy, and the physicians believe that radiation will kill him because of his frail condition. Mr. Snuffy also has a history of heart problems. During the night, he has a cardiac arrest and dies within a minute. The doctor does not have the freedom to save him and is not morally culpable for his death.

The second category is *Human Termination* (HT). This is the functional equivalent of acts of commission or 'active euthanasia'. When someone actively intervenes into the process of nature, death is not natural. Rather, it is the deliberate act by someone taking the place of nature. The

person doing the act is morally culpable for the person's death. This is true even if the person killed is in a terminal condition, because the person dies from something other than his ailment. (This category is not intended to cover situations where a person dies as a result of an accident.) Thus, if Mr. Snuffy had not died from cardiac arrest, but the physician had administered a lethal injection, the physician would then have been responsible for the death. The point here is that with HT the person is intentionally the direct physical cause, the overall action then requiring moral assessment. HT is intentional killing.

The third of these categories is *Human Termination using Nature* (HTN). This category covers those omissions in which someone allows a person to die, where the person could have recovered from their ailment and not died (when they are not irreversibly dying). This category is distinct from Natural Termination (NT), because with NT the person who dies is unable to be saved. HTN is another form of intentional homicide. If HT is direct killing because someone acts to end a life before it is nature's time (by commission), then HTN is just as much an act of intentional killing (by omission) if the person who dies could be helped but was allowed to die. There is no moral difference between the two (i.e., they are functionally identical). For example, Ms. Snowy is a 21 year old prostitute who has been brought into the emergency room after a car accident. She has some broken ribs as well as some cuts and bruises. After being preliminarily treated, she is admitted to the hospital and given a narcotic to ease her extreme chest pain. A night intern checking on her later recognizes an increasing shallowness of breathing. He discovers that her broken ribs in fact made a small puncture in each of her lungs. As a result, her lungs are now filling with blood. Under the influence of the narcotic, the patient is asleep and slowly drowning in her own fluids. Having a religious conviction against prostitution and harbouring anger toward prostitutes (whom he believes are destroying his neighbourhood), the intern decides not to act. The patient dies within a couple of hours. The night intern is causally responsible for the death of Ms. Snowy because she can hardly be considered 'irreversibly dying'. The prostitute's condition is treatable. She has the capacity to survive, and he has the freedom to save her. The night intern is responsible for the homicide because his motive was to kill using an omission as his method.

A case cannot fit into this category if the person who is in danger of dying will not allow themselves to be helped. If someone does not allow someone else capable of intervening to do so, the death will not fall under either of the upper two categories. What category it does fall under, depends on whether the person is committing suicide (which would be a case of HT and the decision of the morality of it depends on the motive of the one who dies) or if the person, through a state of confusion, withdraws from/refuses assistance and dies as a result of their 'involuntary' actions (HTU—discussed next).

The fourth category is *Human Termination Unintentionally* (HTU). This category describes those situations in which the cause is human but the motive is not to intend death. Rather, the death either happens unintentionally, accidently, or as a result of another motive. Here the Principle of Double Effect can play a role. Mr. Snuffy is in a great deal of pain, and the doctor gives him some morphine to ease it. The doctor would not be morally culpable for his death if Mr. Snuffy dies as a result of the morphine, because the doctor's motive is not to kill, but to ease pain. Even though the cause is human, the motive tells us that the death was unintended and the action that caused death is amoral.

It might appear that these four categories could easily be combined into two categories: intentional and unintentional. However, the problem with this concept is that anything that falls under Natural Termination has nothing to do with intention and cannot really be considered 'unintentional'. Rather, because an agent is not free to act and the termination is amoral, the intention of the agent has no relevance on the morality of the act itself. This is different from Human Termination Unintentionally because with HTU, it is the fact that the agent acted 'unintentionally' that makes the termination amoral. Thus, they are not equal because in one category it is the intention that makes the moral difference (HTU) and in the other it is the lack of freedom to save someone from death that makes the moral difference (NT).

However, this is not to say that there are *no* moral decisions to be made when deciding to withhold/withdraw treatment. On the contrary, it may be that there are moral reasons to either withhold/withdraw treatment or continue treatment based on the situation (consequences) that are existent. The mere fact that the termination itself will be amoral does not necessitate a freedom to do whatever we want. On the contrary, the way we approach an amoral termination may be moral or immoral.

Let's look at a hypothetical case to see how each of these four categories works. Martha Sniffy wants her husband Joe to die. He is a whiny old man who gets on her nerves from morning to night, demanding that she get him coffee and dance incessantly, and she waits for the day she will be free of his presence. Joe is not known to be in a terminal condition. He is still living at home, has a minor heart condition, and can eat solid food as long as it is cut up into small enough pieces to fit through his small, swollen throat. Joe has found that eating the smallest piece of food first and then increasing them in size helps his windpipe to open and allows him to eat larger pieces. Certainly he will die eventually, but it is not apparent that it will be soon. How he will die is the question. Assuming he does not die in some other way (e.g. car crash), he will probably die in one of four ways (and they correspond to the four categories above): Mr. Sniffy will die either as a result of some natural event, be actively and intentionally killed, die as a result of someone intentionally failing to stop nature from killing even when capable of doing so, or he will die as the result of an unintended action.

Possible Outcome 1—Natural Termination: Martha cuts up Joe's breakfast into small pieces as usual. As Joe is eating, Martha leaves the room for a moment. She returns to find Joe face down in his plate from a heart attack. She grabs his nitro pills from the cabinet, but being unable to rouse him, she cannot get him to take the pills. She calls 911 and requests an ambulance. However, the paramedics do not arrive in time. Joe dies in minutes. This is a result of NT because he dies from a natural event and no one could help him recover.

Possible Outcome 2—Human Termination: Martha cuts up Joe's breakfast into small pieces as usual. She adds a fast-acting poison to the smallest pieces of food, knowing he eats them first. In case Joe doesn't finish his meal, he will have still ingested the poison. As Joe is eating, Martha leaves the room for a moment. She returns to find him face down in his food dead from poisoning. This is a case of HT because she intentionally acted to kill Joe.

Possible Outcome 3—Human Termination Using Nature: Martha cuts up Joe's breakfast into small pieces as usual. As Joe is eating, Martha leaves the room for a minute. She returns to find him choking on a piece of food, but happily stands aside and watches. He dies within minutes from suffocation. This is a case of HTN because she could have tried to help save him. Had she tried to help, but been unable, it would be a case of HTU (next).

Possible Outcome 4—Human Termination Unintentionally: Mary cuts up Joe's food as usual, but she does not cut them up small enough; she was not paying as close attention as she should have. Mary leaves the room while Joe, thinking the pieces are small enough, begins to eat. A piece of food catches in Joe's throat and he suffocates before Mary returns. Since the cause is human, her intention shows us that this is an accident.

Of the four optional outcomes, only in the first and last outcomes does Mary *not* have an active motivational role in her husband's death. Joe's death in outcome 2 was as a result of commission and was not an accident. Outcome 3 was a result of an omission of help and Mary let Joe die intentionally. Mary is culpable because she could have tried to help. In outcome 1 Mary is not culpable for her husband's death because her attempt to help was unsuccessful. In outcome 4, Joe dies as a result of Mary unintentionally cutting the pieces of food too big.

With the following steps, one can use these categories to examine an euthanasia situation. First, we must judge the freedom of an agent to act. If there is no freedom to act, then the death is NT. Second, if the agent is free to act, then we judge the motive and situation. Though the categories match more directly with the general moral foundations of those who defend the traditional moral principles in the active/passive debate, they do provide a means for moral evaluation that other moral foundations do not use. I do believe that the four category structure allows for the situation to bring forth further moral and factual elements, giving them an adequate place.

As is clear, these new categories cover the spectrum of possibilities traditionalists use for making moral judgements on how we die, and they allow for extended moral discussion concerning various methods by which we do die. It is not asserted that these categories will cover the moral issues on every way that we die, nor do we deny that there will be many cases in which this category scheme will not make it any easier to reach moral conclusions. Rather, I am merely claiming that these categories *can* help people reach general moral conclusions about euthanasia which will apply in *many* cases. I also believe that in *some* of those difficult cases where this category scheme does not directly apply, it may still be of help in the moral evaluation process. Hopefully, the morality or immorality of a death can be more clearly determined than when using the categories 'passive euthanasia' and 'active euthanasia'.

MORAL IMPLICATIONS OF THE NEW CATEGORIES

There are a few moral implications of the new category structure that I would like to describe. The first is that in whatever case a death caused (commission) by another human being is considered immoral by a moral foundation, then death resulting from an omission to act when another human being is able to preserve life by acting is also immoral as long as that omission was motivated by a desire to kill. These are morally equivalent. Second, no one is morally responsible for deaths that result from an accident or because they could not intervene to stop a death. These are morally equivalent. Inability to prevent death cannot place moral responsibility of that death on to the one unable to intervene or stop it from occurring. The agents are not free to act.

The result of these moral implications is that an act can be deemed immoral only when someone either actively kills another or intentionally fails to give help. Given any other conditions, no one would be morally culpable.

CONCLUSION

In this article I have attempted to show that the traditional passive/active or omission/commission distinctions are inadequate for moral debate. The necessary elements of any categories that enable us to establish general moral conclusions are intention and situation. In light of this, I have offered the new categories to address this need:

Natural Termination—any situation in which a person dies because of an omission by an inability to act, insufficiency of an act, or futility of an act. The cause is amoral.

Human Termination—any act where someone actively intervenes into the process of nature to cause a person's death. The cause is human in nature, and thus moral conclusions are based on the motive.

Human Termination Using Nature—any situation in which someone who is able to save someone from death but instead allows nature to kill. The cause is human (for failure to intervene) and moral conclusions are based on the motive.

Human Termination Unintentionally—any situation in which the death of someone is the result of intentional action, but the result was not driven by the motive to kill. Rather, the motive was to do something else. The action is amoral.

This is intended as an introduction into new ways to redefine the traditional view and create a framework in which those who defend that view can, as well as their opponents, profitably discuss the morality of euthanasia. Though the prospect of actually replacing the active/passive terminology is daunting indeed, I hope that this is a start towards a more profitable debate.

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Ethical Issues in Cochlear Implantation of Children

Of the four million children born in the U.S. every year, somewhere between 12,000 and 24,000 have some degree of hearing loss. Many will not have their hearing loss detected until they are two years of age or older.[1] Many children will have a profound loss not correctable by hearing aids and have one alternative for (partial) hearing restoration, the cochlear implant. This highly technical neural prosthesis for hearing restoration has created ethical controversies, beginning with adults. Surprisingly, the controversy heightened as the technology has improved and children down to two years (recently 18 months) of age were approved for cochlear implantation. Cochlear Corporation reports that as of May, 1998, a total of 11,883 children world wide have been implanted with the Nucleus-22 cochlear implant and 1,684 children have been implanted with the Nucleus-24 device. Advanced Bionics Corporation reports that as of June, 1998, they have 760 children implanted with their Clarion Multi-Strategy cochlear implant device, which at this time includes North and South America and Europe.

The cochlear implant is a class III implantable medical device that electrically stimulates the auditory nerve fibres in the deafened ear. In profound sensorineural deafness the transducing hair cells of the inner ear are gone, but the residual VIIIth cranial nerve fibres of the auditory pathway remain. The Cochlear Implant (CI) utilizes an electrode array, surgically placed into the inner ear, where the electrical stimulation takes place. The channels (electrode pairs) are assigned to transmit certain frequencies of a sound when received by a microphone and changed to an electrical signal by the processor. The auditory brain sorts the mixed frequency stimulations and patients learn to hear words.

First clinically tested in the 1970s, this device has improved steadily in electronic sophistication and its ability to provide meaningful sound information to the brain of deaf individuals.[2] Approximately 6 different CI devices exist worldwide, with the greatest number of recipients in the U.S. and a greater number of children are appearing as CI candidates for implantation. The Nucleus 22-channel cochlear implant developed by Cochlear Corporation was approved by the FDA for use in children 18 months of age and older on December 28, 1997. Cochlear Corporation has also developed the Nucleus 24-channel cochlear implant which was cleared for use in children 18 months of age and older on June 25, 1998. The Clarion cochlear implant developed by Advanced Bionics Corporation was approved for use in children 24 months and older on June 26, 1997. The 18–24 month old protocol for this device is currently under clinical investigation. Currently, only the Nucleus and Clarion devices are approved for use in the United States.

The last five years have shown a tremendous increase in the number of cochlear implants implanted in children. The total number of children implanted to date with both the Nucleus and Clarion cochlear implant devices is 4,821. The pre-implant process consists of extensive audiological testing and evaluation designed to determine an appropriate cochlear implant candidate and to select the ear to implant. This decision is not taken lightly by the medical professionals who determine candidacy. The selection protocol has changed significantly over the years. A profound bilateral sensorineural hearing loss with minimal or no speech discrimination ability in either ear is the usual circumstance. Little or no benefit is expected from the use of conventional hearing aids. After an appropriate hearing aid trial, the cochlear implant evaluation is conducted.

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Ethical Issues in Cochlear Implantation of Children

Of the four million children born in the U.S. every year, somewhere between 12,000 and 24,000 have some degree of hearing loss. Many will not have their hearing loss detected until they are two years of age or older.[1] Many children will have a profound loss not correctable by hearing aids and have one alternative for (partial) hearing restoration, the cochlear implant. This highly technical neural prosthesis for hearing restoration has created ethical controversies, beginning with adults. Surprisingly, the controversy heightened as the technology has improved and children down to two years (recently 18 months) of age were approved for cochlear implantation. Cochlear Corporation reports that as of May, 1998, a total of 11,883 children world wide have been implanted with the Nucleus-22 cochlear implant and 1,684 children have been implanted with the Nucleus-24 device. Advanced Bionics Corporation reports that as of June, 1998, they have 760 children implanted with their Clarion Multi-Strategy cochlear implant device, which at this time includes North and South America and Europe.

The cochlear implant is a class III implantable medical device that electrically stimulates the auditory nerve fibres in the deafened ear. In profound sensorineural deafness the transducing hair cells of the inner ear are gone, but the residual VIIIth cranial nerve fibres of the auditory pathway remain. The Cochlear Implant (CI) utilizes an electrode array, surgically placed into the inner ear, where the electrical stimulation takes place. The channels (electrode pairs) are assigned to transmit certain frequencies of a sound when received by a microphone and changed to an electrical signal by the processor. The auditory brain sorts the mixed frequency stimulations and patients learn to hear words.

First clinically tested in the 1970s, this device has improved steadily in electronic sophistication and its ability to provide meaningful sound information to the brain of deaf individuals.[2] Approximately 6 different CI devices exist worldwide, with the greatest number of recipients in the U.S. and a greater number of children are appearing as CI candidates for implantation. The Nucleus 22-channel cochlear implant developed by Cochlear Corporation was approved by the FDA for use in children 18 months of age and older on December 28, 1997. Cochlear Corporation has also developed the Nucleus 24-channel cochlear implant which was cleared for use in children 18 months of age and older on June 25, 1998. The Clarion cochlear implant developed by Advanced Bionics Corporation was approved for use in children 24 months and older on June 26, 1997. The 18–24 month old protocol for this device is currently under clinical investigation. Currently, only the Nucleus and Clarion devices are approved for use in the United States.

The last five years have shown a tremendous increase in the number of cochlear implants implanted in children. The total number of children implanted to date with both the Nucleus and Clarion cochlear implant devices is 4,821. The pre-implant process consists of extensive audiological testing and evaluation designed to determine an appropriate cochlear implant candidate and to select the ear to implant. This decision is not taken lightly by the medical professionals who determine candidacy. The selection protocol has changed significantly over the years. A profound bilateral sensorineural hearing loss with minimal or no speech discrimination ability in either ear is the usual circumstance. Little or no benefit is expected from the use of conventional hearing aids. After an appropriate hearing aid trial, the cochlear implant evaluation is conducted.

between the hearing community and the Deaf Culture. The deaf need not be cut off from the world and can function in society in spite of their deafness.

Regardless of how the medical ethics conflicts with the Deaf Culture, 90% of deaf children are born to two hearing parents and 97% to at least one hearing parent. Such loving parents are aware of the technology of cochlear implants for deafness and their clinical outcomes. Bioethical dilemmas have arisen irrespective of the surgeons who implant and audiologists who rehabilitate with the CI. Bioethics often deals with medical issues brought about by evolving technology. Cochlear implant technology has grown considerably since its inception in the 1970s with a single channel analog stimulator. It has been only a little over 7 years since the U.S. FDA gave pre-market approval to implant children with the multichannel CI. Since our clinic began with the single channel CI, we have implanted over 320 patients. With today's multiple channel, digitally programmable devices, both stimulation and reverse-telemetry are available.

Questions have arisen as to the appropriate time to implant a child. Suppose there is a tremendous technological improvement 1 or 2 years away that will be unavailable to a child if he is implanted with today's device. How young should a baby be implanted with this surgically risky procedure? Indeed, developmentally and neurophysiologically, it is in the best interest of a deaf child to receive auditory stimulation to the brain in the early years of language acquisition. It is then that auditory and associative cortical neural pathways are developing. Sensory systems continue to develop after birth and without stimulation, maturation of the auditory and language brain is impaired. If this early stimulation of the brain is unavailable in early childhood, effective use of the stimulation provided by the cochlear implant in later life will be compromised. For the above reasons over 50 children have been implanted with the CI in Germany, under 2 years of age.

An extension of this bioethical dilemma concerns the cochlear implantation of prelingually deafened children. Auditory (temporal lobe) development also takes place *in utero* and a congenitally deaf baby, that subsequently receives the implant, does not receive the benefit from electrical cochlear stimulation as does the post-lingually deaf child (deaf before language development). That is to say, if a certain amount of hearing has taken place before the onset of deafness, the CI technology is remarkably more beneficial because the brain has circuitry that can be matured and trained by the CI. Speech and language development in pre-lingually deafened children is relatively poor compared with post-lingually deafened children. Thus the question arises, 'Is the risk-benefit ratio for the CI sufficient to warrant this risky and expensive procedure in pre-lingual deafness?'

Evidence is substantial that the benefits of cochlear implantation, especially in post-lingually deaf individuals, are well worth the procedural costs and risks. Consensus statements from the National Institutes of Health have affirmed 'With thousands of CI patients worldwide now, safety and efficacy are established for children and adults'.[14,15] Numerous clinical studies have shown that the great majority of children with CIs have the ability to hear and understand words without lipreading.[10,16] Even those children born deaf or who lost hearing early in life due to meningitis and who receive CIs before age 3, most often use oral language as their primary method of communication, have as high as 86% word understanding and average 63% open set speech discrimination.[16] Audiometric and speech language data indicate that the earlier a child is identified and given an implant, the better.

DEONTOLOGICAL PERSPECTIVES

The American Deaf Culture is largely reasoning from the deontological or consensus platform. They are stating that the consensus of (their) culture would have no implantation on children with the cochlear device. Children born deaf are automatically in their culture, not that of the baby's hearing parents. Consequently, the decision to not implant should emanate from that child's culture, which believes ASL is an acceptable mode of communication and aural-oral communication is not. The failure in this ethical reasoning of what is the right decision based on consensus is that the Deaf Culture is not a majority. 'Since the overwhelming majority of deaf children are born to hearing parents and live in a hearing family, in an overwhelmingly hearing society, to suggest that an outsider, a member of a small minority, should be empowered to speak for the child is unthinkable. The parent has the right and the responsibility to make this sort of decision for the child.'[9]

The larger Hearing Culture, also reasoning from the deontological perspective, states that hearing is the norm and therefore all should take any means possible to be restored to or enter into the hearing community. Of course the conflict arises between the Deaf and Hearing Cultures because both believe they are correct and both are speaking for all of their culture.

TELEOLOGICAL PERSPECTIVE

There are those who endorse the cochlear implantation of children and adults simply from the pragmatic and practical viewpoint, stating hearing is better than not hearing. Such teleological reasoning for correcting any medical problem is often adhered to in today's technological world. Teleological decision making is pervasive in medicine. If we can fix it, fix it. The general medical mind set is toward restoration if not cure. Deafness, perceived as a disability, is not practical, is costly, and impairs one from productivity in mainstream society. Thus, fixing deafness by cochlear implantation is the right thing to do for the individual and for society. 'Cost-effectiveness in children will also be influenced by the degree to which the costs involved in the education of profoundly deaf children can be decreased by the cochlear implant. Education in a school for the deaf is estimated to cost at least $35,000 per child per year, well over twice the average cost of public education of a hearing child. If we carry out a simple cost-benefit analysis ignoring quality of life benefits, a 13% annual savings in education costs of a deaf child implanted at age 3 would result in a net gain.'[17]

The physician-knows-best mentality has been

complicated today by highly technical and sophisticated medical devices, simply because most patients cannot adequately comprehend how such devices work. Indeed, most patients and families of patients today have a very simplistic understanding of how the CI actually works to restore sound. To provide that understanding fully before surgery, the otologist and audiologist need to spend an extraordinary amount of time with the candidates and their families. Otherwise the overwhelming complexity of the technology can encroach upon the decision making process of the patient or parents in the case of pediatric cochlear implants. When biomedical science data strongly support the safety and efficacy of a device like the CI, the professional response is usually to endorse its application strongly in all patients fitting the criteria. This teleological perspective has been the origin of controversy and tension between Deaf Culture and the otolaryngologic surgeons. Just because a device is safe and efficacious doesn't mean that every deaf patient wants to have it implanted in them.

THEOLOGICAL PERSPECTIVE

There is little doubt that the theological basis of deciding whether a child should receive the cochlear implant is based on love for the child. Scripture is replete with examples of and encouragements for unconditional love of others. Within one's family there is both familial love and unconditional love, expecting nothing in return. In both Matthew chapter 22 and James chapter 2 we are instructed to love our neighbours as ourselves, as it is presented in context with the greatest commandment of all, to love God with all our heart, soul and mind. Certainly such unconditional love would apply also to those within our own families. I John 4:7 says, 'Beloved, let us love one another, for love is from God . . .' and any act toward one's children with their best interest at mind is an act of love.

Then there are the acts of compassion toward those we come in contact with, especially the 'least' among us. The Matthew 25 passage of caring for the least in the kingdom is affirmed in Paul's letter to the Colossians (3:12) where we are told to 'put on a heart of compassion'. Hellen Keller summed up the suffering of deafness when she compared blindness to being cut off from 'things', whereas, deafness cuts on off from 'people'. Hence, the compassion of a parent for a deaf child seeks the best means of restoring their connectedness with family and mankind. Such is a noble act, made in love. Such ethics are based on a higher authority of absolute moral truths. For these are the statistical evidences that children indeed improve their hearing with the cochlear implant, their speech and language is enhanced, they usually can become mainstreamed into public schools and their overall life is improved. Since hearing and oral communication are so much a part of us, as created in the image of God, wanting to restore those abilities to our children is both a natural and loving parental desire.

SUMMARY AND CONCLUSION

The multi-channel cochlear implant gives children the opportunity to live in more than one culture. 'Many deaf people believe deafness is a "culture" that comes with its own language, traditions, values, schools, theater, art, writings and social and political structure.'[18] However, the world is made of many different cultures: American; European; Asian; Russian etc . . . and yes, one may even concede that the deaf are a culture. But the bottom line is that no matter what culture we live in, we must all communicate with and live in harmony with one another. We must respect the beliefs and values of every culture in order that choices may exist and each may choose options with which they are comfortable. The cochlear implant is a choice. It is not a statement that to be deaf is not good. There are many choices during one's life. To limit one's choice is to take away opportunities. The cochlear implant is one choice that must be made available for those who value the hearing opportunity it so richly provides.

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The Impact of the Pill on Implantation Factors—New Research Findings

For health consumers and health care professionals of an orthodox Judeo-Christian or Islamic tradition, as well as those authentically concerned with the universal respect of unqualified human rights, the asserted capacity of the pill to act as an abortifacient, both in its once-a-day and 'morning-after' permutations, is one of significant moral weight.

The research on 'break-through' ovulation[1,2] leads moralists, philosophers and human rights' advocates to question the use of the title 'contraceptive' to describe the pill. There is tension in this nomenclature. The term 'contraceptive' refers to a drug, device or chemical that prevents the joining of the sperm with the female secondary oocyte (commonly referred to as the ovum).[3]

The problem arises because the female sex cell, the secondary oocyte, may be present in the reproductive tract at or near the time of coitus, hence there exists the possibility that fertilization may occur. Yet, as we will see, the pill alters the receptive structure of the endometrium, making implantation problematical.

But are concerned groups justified in moving from a position which states that the pill sometimes fails to prevent 'ovum' fertilization, with the result that new human life may begin, to the position of claiming that the pill has an abortifacient capacity? The first position notes that ovulation occurs in women on the pill and fertilization may occur, but claims there is no evidence that implantation is impeded. The alternate view considers that because ovulation has been detected and the lining of the womb is in an undeveloped state, human life is imperilled.

This is a seismic shift in outlook. What merit is there in this latter claim other than supposition or suspicion? Is the pill tarnished with the title of abortifacient on conjecture rather than on fact?

This paper will seek to clarify these issues. I will concentrate in some depth on a variety of the implantation factors associated with the microenvironment of the endometrial epithelium. Discussion will also be focused on the mechanism(s) of hormonal dialogue between the 5–7 day old human embryo (the blastocyst) and the cells which line the endometrium. I will also cover the impact of above normal (supraphysiological) levels of estrogen and progesterone on these implantation factors and the role of the pill hormones on the integrity of the endometrium. Particular attention will be given to the impact of the pill on cyclical development of endometrial thickness, and the relationship of this uterine feature to the success of implantation of the human embryo. Central to these issues will be a review of the research on 'break-through' ovulation (also known as 'escape-ovulation'), an event which must occur, otherwise all concerns concerning the pill as an abuser of human rights would be shown to be empty.

This paper is of necessity detailed. I hope that the employment of suitable analogies, as well as bracketed discussion of medical terms or concepts, will make it accessible to the scholar and lay reader alike.

1.1 EXECUTIVE SUMMARY

The process of implantation of the human embryo into the lining of the womb is a very complex and delicate one.[4] Proper attachment and successful implantation is under the guidance and control of a vast array of 'implantation factors' such as interleukin-1 β[5] platelet-activating factor (PAF),[6,7] insulin-like growth factor (IGF),[8] leukemia inhibition factor (LIF),[9] tumor necrosis factor α (TNF α).[10]

Many of these chemical factors participate in a process referred to in the medical journals as 'cell-signalling', a process which involves the new human embryo and the cells of the lining of the womb chemically communicating with each other.[11,12,13,14] The purpose of this chemical communication is to create an optimally advantageous endometrial environment at the time the human embryo attempts to implant.

Aside from this bio-chemical embryo/uterine-cell communication, successful implantation of the human embryo is dependent also upon a class of molecules known as integrins. Integrins are cell-adhesion molecules found in a 'mirror' fashion on both the human embryo and the lining of the womb.[15,16] These integrins bind onto each other, via gluco-proteins (e.g. fibronectin). The success or otherwise of this binding process is intimately linked to the ongoing success or otherwise of the pregnancy.

The reader will note that I am using the orthodox understanding of the term 'pregnancy'. This definition dates the beginning of the pregnancy from the moment of fertilization. I do not use, nor do I accept the minority view,

influenced as it is by the politics of abortion, that dates a pregnancy from the time of implantation.

1.2 THE RE-DEFINING OF PREGNANCY TERMINOLOGY

Notwithstanding the embryonic, linguistic and time-honoured orthodoxy of 'pregnancy', increasingly frequent attempts have been made to redefine all aspects of pregnancy, but most particularly, when pregnancy begins. The reason for this move is clear; by redefining pregnancy—when it begins, the nature of the embryo etc—the way will be made smooth for the more rapid introduction of RU-486, the morning-after pill, anti-HCG vaccines, anti-implantation factor drugs and other embryocidal drugs. Unwittingly or otherwise, the end result is a semantically based desensitization of the moral conscience of the community.

The following is an indicative selection of quotes to illustrate my point.

> The prevention of pregnancy before implantation is contraception and not abortion.[17] (Glasier, *NEJM*, 1997)

> Predictably, some opponents of abortion allege that emergency contraception is tantamount to abortion . . . even if emergency contraception worked solely by prevention the implantation of a zygote, it would still not be abortifacient . . . Pregnancy begins with implantation, not fertilization . . . fertilization is a necessary but insufficient step toward pregnancy.[18] (Grimes, *NEJM*, 1997)

> Emergency contraception works by inhibiting or delaying ovulation or by preventing implantation. Despite some assertions to the contrary, it is not itself a form of abortion.[19] (Guillebaud *Lancet* 1998)

These opinions are starkly at odds with embryology[20] and etymology.[21]

Before examining these features in more detail, and the relational involvement of the pill, it may be of some benefit to propose an analogy to assist in the understanding of the various implantation factors and the role of integrins.

Consider the example of a space shuttle, low on fuel and oxygen, urgently needing to dock with the space station. The mother ship and the shuttle communicate with each other so that the shuttle knows which docking bay to go to. Importantly, the mother ship knows which bay to make ready. Successful communication is imperative. If this electronic communication fails (disrupted embryo-uterine 'cell-talk') the shuttle may go to the wrong docking bay, fail to attach to the mother ship, drift away, with the result that the crew dies from a lack of food and oxygen. Alternatively, the shuttle might go to the right bay but find that all the docking apparatus is not in place. Again, the attachment between the two fails due to faulty communication and the crew dies. This role of embryo/endometrium communication is fulfilled by implantation factors such as interleukin, TNF, NDF and PAF. To continue the analogy, integrins could be thought of as grappling hooks that 'hold' the human embryo onto the womb whilst the process of implantation is completed.

This then is a brief overview of this review paper. I would like now to analyse these issues in more depth, looking at the specific role and activity of the main implantation factors covered in the research literature. As well, I will expand on the interaction between these factors and the steroidal hormones: estrogen, and its artificial copies (principally ethinylestradiol, ingested via the pill) and progesterone, plus its artificial copies (norethisterone, levonorgestrel, gestodene and desogestrel).

1.3 THE INTERLEUKIN SYSTEM

The interleukin (IL) system, composed of IL-1α, IL-1β and IL-1ra, is both hormonally regulated and of endometrial origin (Simon, 1996).[22] Under *normal* physiological conditions, progesterone increases the production of IL-lα and IL-1β from the endometrium[23] and levels of the IL system reach their maximum during the luteal (post-ovulatory) phase of the menstrual cycle.[24]

Of the various components of the interleukin system, research suggests that IL-1β plays a key role in the proper orientation of the embryo to the uterine lining, a process known as apposition. Recalling our earlier analogy, apposition could be likened to pre-docking maneuvers responsible for correctly aligning the docking ports of mother ship and shuttle.

Within this framework, the role of IL-1β is thought to that of a 'signal system' between endometrium and embryo.[25] '. . . [S]uccess of embryonic implantation relies on a perfect dialogue between good quality embryos and a receptive endometrium'.[26]

Huang and co-workers (1997) have also reported that the IL system is 'an important factor in embryo-maternal molecular communication during the implantation process'.[27]

Whilst normal levels of the ovarian hormones estrogen and progesterone have a beneficial effect on the levels of IL-1β, excessive hormonal levels, known as supra-physiological steroid levels, have been shown to cause a reduction in the levels of IL-1β. As a result, the rate of implantation drops significantly. Simon and co-workers (*J Reprod Immun*, 1996) have shown that there is an inverse relationship between estrogen and progesterone levels, and the levels of IL-1β (as estradiol levels increase, implantation success decreases).[28]

The direct consequence of these findings, as they relate to the maintenance of pregnancy, are set out by Carlos Simon:

> . . . we have shown prospectively that suprahysiological serum E2 (estradiol) levels during the pre-implantation period are responsible for the impairment of embryonic implantation in patients undergoing I.V.F. It is possible that above normal (supraphysiological) serum E2 levels impair implantation through disrupting regulation of uterine paracrine factors; specifically, the IL-1 system is one possible candidate when considering what is reported in the present study.[29]

The term 'paracrine' refers to the effect(s) that are caused by hormones but are localized to cells only in the immediate vacinity,[30] i.e., the endometrium, rather than the more normal, wider area of bodily influence that characterizes hormones.[31]

Simon's research indicated that excessive estradiol (an estrogen) levels interfere with implantation as a consequence of disruption to the IL-1 system. I.V.F. research has shown that high levels of estradiol (E2) result in a poor implantation rate of 8.5% whereas reduced E2 levels increased the successful rate of implantation to 29.3%.[32]

As Simon and co-workers noted, 'High E2 levels, which are known to be interceptive, and altered E2/progesterone ratios, which also are associated with the impairment of endometrial receptivity, are the main factors affecting endometrial receptivity in high responders.'[33]

The use of the word 'interceptive' is significant. Professor Rahwan, professor of Pharmacology and Toxicology, Ohio State University, defines interception as the 'interference with the implantation (nidation) of an already fertilized ovum, and, from a biological standpoint, must therefore be an early abortifacient approach'.[34]

This research by Simon finds its importance within the context of the emerging use of the pill in high doses as a post-coital or 'morning-after' pill (MAP). The MAP regime comprises the ingestion, within a time-frame of 12 hours, of approximately 10 times more estrogen and 10–20 times more progesterone than a woman would take via the normal once-a-day pill (depending on the brand used). These increased levels are obviously supra (above) physiological levels.

As previously outlined by Simon, the disruptive effect on implantation rates caused by high levels of estradiol, or incorrect estradiol/progesterone ratios, means it is biologically plausible to suggest the 'morning-after pill' (MAP) is an abortifacient-empowered medication because of its capacity to interfere with the interleukin system.

Further supporting this assertion is research by Swahn *et al.* (1996), which showed the administration of the MAP caused a suppression of the LH surge, decreased the pregnandiol levels and increased the estrone levels (Fig 1, p. 741).[35] These alterations to the normal menstrual cycle hormonal patterns had an impact on the development of the endometrium.

> An endometrial biopsy was taken one week after treatment. Although it was difficult to date the biopsy in some women because of the absence of a discernible LH peak, the conclusion was that the endometrium showed significant alterations in endometrial development with a dissociation in maturation of glandular and stromal components.[36]

The authors then, in a seemingly contradictory manner, suggest that the 'relatively minor changes in endometrial development does not seem sufficiently effective to prevent pregnancy'.[37] This statement would appear to undermine any claim that the MAP acts in part via an abortifacient mechanism. Further reading reveals that the researchers did not investigate the 'biochemical effects (of the pill) on molecular levels on the endometrium'.[38] That is, the researchers did not investigate the hormonal impact of the MAP on the various implantation factors.

In my view, this omission negates their attempts to minimize the abortifacient significance of the 'relatively minor changes in endometrial development' caused by the MAP. As will be seen later, relying only on measures of endometrial thickness cannot accurately assess the precise conditions needed for successful implantation—this exclusive approach fails to take heed of the implantation factors which are the second, vital characteristic associated with successful implantation.

1.4 PLATELET-ACTIVATING FACTOR (PAF)

Another implantation factor which is associated with successful uterine receptivity of the human embryo is platelet-activating factor(PAF).[39] PAF interacts with PAF receptors located on the endometrium. To recall, receptors are bio-chemical binding sites, located on the surface of cells, which are specifically designed to interact exclusively with a specific chemical, in this case PAF. When PAF attaches to the receptor, a message is conveyed to those cells.[40]

The effect of PAF upon the endometrium is to cause a release of nitrous oxide (NO), leading to vascular dilation and increased vascular permeability of the blood vessels of the endometrium[41] The fact that chemical blockage of the PAF binding site (receptor) on the endometrium inhibits implantation supports the view that the PAF receptor has a critical role in uterine receptivity[42]

PAF is also involved in the cyclical development of the endometrium.[43,44] Not surprisingly, the levels of the receptors for PAF vary throughout the menstrual cycle, with the highest endometrial levels detected during the mid-late proliferative phase (i.e., the days preceding ovulation) and the late secretary phase,[45] when the endometrium is approaching or at its state of maximum monthly development. These findings are consistent with PAF having a preparatory role for uterine reception of the human embryo.

As was the case with the interleukin system, control of PAF is under the control of ovarian hormones, estradiol and progesterone.[46] As Ahmed has noted: 'PAF production has been shown to be regulated by ovarian hormones . . .'[47]

Given the role of ovarian hormones on the activity of PAF and its receptor within the endometrium, it is biologically plausible to suggest that irregular uterine hormone levels, caused by the pill, may have a negative impact on uterine preparedness for implantation. Supporting this view is the work of Rabe and co-workers, who reported a decrease in endometrial thickness in women taking the pill, during the days when implantation would occur.[48]

Specifically, these researchers showed that there was, for some pill users, a 50% reduction in endometrial development when compared to that seen in the control (non-pill using) group.[49] Therefore, it is reasonable to conclude there is an adverse impact upon the express of PAF receptors. Indeed, given the hormonal influence exerted by estrogen, it would be biologically illogical to conclude no damage to the expression of endometrial PAF receptors.

1.5 THE EFFECT OF MISSED PILLS ON OVULATION

For the pill to exhibit the characteristic of an abortifacient, one biological event is essential: ovulation. The crucial

question is this—does break-through (or escape) ovulation occur during regular pill ingestion?

Grimes *et al. (Obstet Gynecol,* 1994) had previously reported that 'suppression of follicular development is incomplete with contemporary low-dose pill'.[50]

Grimes' study was characterized by a high rate of patient compliance, meaning that the women involved in the study adhered to the research protocol of daily ingestion of the pill.[51] Yet, escape-ovulation was detected even within the context of a rigorously scrutinized scientific study.

These facts argue strongly in favour of escape-ovulation also occurring within the general populace of women on the pill. This latter group of women are not necessarily as highly motivated as those participating in a scientific study. To adhere to a tedious daily, monthly, yearly regime of pill ingestion, without supervision is, in the words of one feminist writer a 'bore and a chore'.[52] Because daily pill ingestion is so onerous, patient compliance will be less than the necessary ideal. However, does the occasional failure to take the pill mean that 'escape ovulation' will increase in some proportional fashion?

In an attempt to determine the frequency of escape-ovulation under more realistic conditions, researchers have constructed experiments that required women in the study to deliberately miss one or more days of the pill. A variety of tests, including ultrasound of the ovaries, estradiol (E2), progesterone (P) levels and LH (leutinizing hormone) measurements were used to determine if ovulation had occurred.

Hedon and co-workers (1992) tested 47 young, healthy women who missed between 1 and 4 days tablets starting from day 1 ora new cycle. 'None of the patients experienced normal ovulation' though one, who missed 3 tablets at the beginning of the cycle, 'had a follicular rupture', but no LH surge or progesterone increases, factors usually associated with normal ovulation[53] Note that this study was for only one cycle. Limiting the study to one cycle was a study weakness, because any follicles which may have ruptured during the normal 7 pill free days between cycles would not be detected.

Earlier, Hamilton (1989) had performed a similar study but extended the observations for two consecutive months. Of 30 women in the study, one had a probable ovulation, due to one deliberately omitted tablet on day one of the *second* cycle.[54]

More recently, Letterie (1998) published the results of a study employing a new, reduced dosage formulation of the pill. Ten women, divided into 2 groups, used two slightly different formulations comprising a delayed start, limited midcycle use of estrogen and progesterone. Each of the two treatment groups was monitored for 2 consecutive cycles. In total, 30% of cycles exhibited ovulation, all of which occurred in the *second* cycle.[55]

It is revealing to look more closely at the data for the two groups. In group one, ovulation occurred in 10% of cycles (1 in 10 cycles). This group took 50mcg ethinyl estradiol/1mg norethinodrone for days 6–10 and 0.7mg norethinodrone for days 11–19. Group two took 50mcg ethinyl estradiol/1mg norethinodrone for days 8–12, and 0.7mg norethinodrone only for days 13–21, 'five ovulation(s) occurred in 10 cycles'.[56] This is an ovulation rate of 50%. This study did not investigate implantation; all participants used barrier contraceptives, or abstinence (Private correspondence).[57]

It should be noted that these research findings, conducted under ideal research conditions, represent the best possible outcome in terms of ovulation suppression by the pill. Yet these results do not faithfully replicate real-life because they do not take into account such common events as gastro-intestinal illness or drug interactions. Stomach upset decreases drug absorption, thus loosening the hold over ovulation otherwise exerted by the pill hormones. Likewise, drug interactions decrease the amount of active pill hormone available to act in a suppressant manner upon the ovaries.[58,59] Other researchers and I are of the view that these two issues would contribute to an increase in the frequency of escape-ovulation.[60]

1.6 PILL CONTROL OVER OVARIAN FOLLICULAR DEVELOPMENT

Based upon my 20 years experience as a community pharmacist, I believe the commonly held view is that the pill fully stops ovulation (anovulation). Yet this view is wrong. The recent work by Rabe *et al.* (1997) contradicts this common misunderstanding. Following are some salient points from this research.

- Pre-ovulatory follicular cysts (> 20mm) occurred in 7.3% of 329 pill users enrolled in the study.[61] This size of follicle is identified with an increased rate of escape-ovulation.[62]
- For non-pill users, the rate of follicular cysts was 13.9%.
- Some women, notably those on triphasic formulations, had follicles measuring 60mm.
- Estradiol was present at higher levels (in pill users with enlarged follicles) than in non-pill users (who also had enlarged follicles). The respective levels were 153 pg/ml and 126 pg/ml.[63]

The estradiol level of 153 pg/ml, seen in pill users with enlarged follicles, is important, as it is close to the 'threshold level 150 to 200pg/ml', which, if persisting for approximately 36 hours, triggers ovulation.[64]

As a summary of their research, Rabe noted: 'Analysis of the ovarian activity in the current study demonstrated that the total number of developing follicles increased rather than diminished during OC use, without marked differences between OCs'.[65]

This research underscores the pill's precarious hold over ovulation suppression. It is an event endeavouring to occur. The intervention of a variety of 'lifestyle' factors such as missed doses, drug interactions or gastro-intestinal upset, can act to loose the hold exerted by the pill over natural ovarian function.

As a footnote to this discussion, the FDA approved, in late 1998, a low dose estrogen formulation of the pill (norethinodrone acetate, 1 mg; ethinyl estradiol 20 mcg). Similar low-dose estrogen formulations are also now available in Australia.[66] The frequency of escape ovulation can only be expected to increase in this situation of reduction hormonal ingestion.

1.7 ENDOMETRIAL THICKNESS AND IMPLANTATION

Thus, the question arises: will a low dose pill, more inclined than not to permit escape-ovulation, increase the frequency of implantation failure due to a under-developed endometrium? The medical literature indicates that there is a critical thickness of the endometrium needed to sustain implantation of a human embryo.

Issacs (*Fert Steril*, 1996) reported that an endometrial thickness of at least 10mm or more, around the time of ovulation, 'defined 91% of conception cycles'.[67] Spandorfer (*Fertil Steril*, 1996) noted that 97% of abnormal pregnancies, defined as Fallopian tube lodgment or spontaneous abortion, had endometrial thickness of 8mm or less. 68 Shoham (*Fert Steril*, 1991) reported that a mid-luteal thickness of 11 mm or more 'was found to be a good prognostic factor for detecting early pregnancy' but no pregnancies were reported in an ovulation induction programme 'when the endometrial thickness was less than or equal to 7mm'.[69]

The mid-luteal phase of the menstrual cycle, around day 20, is referred to in the medical literature as the window of expected implantation.[70,71]

Gonen (*Journ In Vitro Fert Embryo Transf*, 1990) also reported that 'endometrial thickness was significantly greater in the group of patients who achieved pregnancy than in the group who did not'.[72] Implantation failure was associated with endometrial thickness of approximately 7.5mm, success with endometrial thickness of approximately 8.5–9mm.

These study results, which indicate a normative endometrial thickness of around 8.5mm for successful implantation, are central to any claimed interceptive/abortifacient capacity of the pill. Research findings from Rabe and co-workers (1997) underscore this point.

Rabe reported that study subjects who took the triphasic levonorgestrel/ethinylestradiol formulation had the highest percentage of follicular cysts with a diameter greater than 20mm,[73] but they failed to develop a median endometrial thickness in excess of 6mm.[74] To recall, follicles of this size are 'thought to be associated with increased risk of escape ovulation'.[75]

The importance of these events is clear; follicles of a suitable size can develop in women taking the pill daily, but endometrial thickness has been shown to be underdeveloped. In the event of follicle rupture and release of an 'ovum', implantation of a human embryo would be greatly hampered. Rabe confirms this very point: '. . . the occurrence of pregnancy would be unlikely because accessory contraceptive mechanisms such as cervical hostility and endometrial suppression are usually in effect'.[76]

It must be pointed out that in this quote Rabe has falsely defined pregnancy as beginning at implantation. Pregnancy begins with the fertilization of the female sex cell (ovum) by sperm, the restoration of the full complement of 23 pairs of chromosomes and thereby the creation of a new human person.

Based upon these findings, a number of issues present themselves:

- An endometrial thickness around 8.5mm has been shown to be associated with successful implantation.
- Low dose triphasic formulations of the pill, the most popular in Australia, fail to completely stop follicular development, the precursor stage to the release of a female sex cell.
- Break-through ovulation is an event straining to occur, even with daily pill ingestion.
- If break-through ovulation were to occur, implantation might fail, because of an endometrium that is too thin.

It is important to note that these four observations exist independently of the impact of the pill on the various implantation factors involved in cell-signaling.

1.8 INTEGRINS

As the aforementioned research indicates, the last few years have seen a remarkable unveiling of the process of implantation of the human embryo into the uterine tissue. A large body of evidence now exists which demonstrates that the process of implantation, rather than being an accidental event dependent on chance, is in fact a multi-factorial, cascading bio-molecular,[77] physiological and hormonal event of spectacular intricacy, complexity, refinement and interdependence.[78] Implantation is not, as one might suppose, akin to two pieces of Velcro fortuitously touching and gripping together. Rather, implantation is, in every sense, as complex, and therefore susceptible to interference, as is the clotting mechanisms of the cardiovascular system.

Beside PAF, the interleukin system and other factors mentioned briefly in the introduction, the class of cell adhesion molecules known as integrins also play a critical role in successful implantation of the human embryo into the endometrium.

As the description of the molecule suggests, the role of integrins is to bind cells together. Etzioni has suggested that integrin facilitated cell adhesion is 'a process that is essential for anchorage' of cells to each other (*Lancet*, 1999).[79]

There are a variety of different types of integrins found within the body—one that plays an essential role in implantation is known as $\alpha v\beta 3$. The medical literature now contains many research papers demonstrating the vital role of this integrin in the process of binding the 5–7 day old human embryo to the endometrium (lining of the womb).

Somkuti and co-workers (*Fert Steril*, 1996) for example reported that integrins 'might prove useful as markers of normal endometrial receptivity'[80] because they have been shown to be absent in women with unexplained infertility and endometriosis.[81]

Similarly, Lessey (*Am J Reprod Immunol*, 1996) reported 'aberrant expression of this integrin is associated with infertility in women'.[82] Widra (*Mol Hum Reprod*, 1997) noted 'the absence of endometrial ctv133 during the critical period of implantation . . . in women with unexplained infertility and endometriosis'.[83] Others had also commented on the absence or diminution of $\alpha v\beta 3$ in women with recurrent pregnancy loss[84] or unexplained infertility.[85]

Assessing the role of the pill, Somkuti (1996) compared endometrial sampling from women on the pill with samples from non-users and reported integrin expression 'to be altered grossly in OC users'.[86]

Complementing this work were the observations of Yoshimura (1997): '. . . a loss of normal αvβ3 expression is associated with primary infertility and milder forms of the disease. These observations suggest that this integrin plays a significant role in the implantation process'.[87]

Eric Widra and colleagues (1997), at Georgetown University investigated the role of physiological levels of estrogen and progesterone on the endometrial levels of αvβ3. They reported that estrogen caused a down-regulation in the expression of αvβ3,[88] an important finding in the light of the fact that 'expression of the αvβ3 integrin may, in fact, be necessary for normal implantation to occur.[89]

Castelbaum and co-workers (*J Clin Endo Metab*, 1997) reported the endometrial expression (presence) of αvβ3 was 'reduced by E2 treatment and further suppressed by E2 plus P. . .'[90]

These results indicate a link between the impact of hormones on the expression of integrins, and the role of integrins in implantation. Whilst the inter-relationship between hormones, integrins and implantation is not yet fully understood,[91] sufficient evidence exists to conclude that the inter-relationship is significant from the perspective of implantation. This is because implantation occurs only 'on or about day 20 of an idealized 28-day menstrual cycle'[92] and the αvβ3 integrin 'is expressed on endometrial epithelial cells only at the opening of the implantation window, on postovulatory day 6'.[93]

1.9 INSULIN-LIKE GROWTH FACTOR (IGF)

The IGF system is an important growth factor, playing a key role in the monthly development of the endometrium and in the process of implantation.[94] There are two subsets, IGF-1 and IGF-2. The first is believed to facilitate the mitotic action of estradiol [E2] in the endometrium, whilst IGF-2 'expressed abundantly in mid-late secretory endometrium, may be a mediator of progesterone action'.[95] Aside from this hormonal aspect, the most abundant expression if IGF-11 is in the columns of the invading trophoblast in the anchoring ville.

From this it can be seen that IGF has a promotional effect upon the process of implantation. But IGF is in turn regulated. 'The biological actions of IGFs are modulated by a family of binding proteins (IGFBPs). The demonstration of IGF and IGFBP transcripts [copying facilities] in pre-implantation embryos indicates that the influence of IGFs and IGFBPs in fetal development begins even prior to implantation'.[96]

Thus far, it can be seen that these factors have a key role to play in both the preparation for and process of implantation. As Han *et al.* have noted: 'Presumably, IGF-II and IGFBPs are used for cell to cell communications between fetal trophoblasts and maternal decidual cells at the feto-maternal interface for placental development and/or function'.[97]

Against this background, the role of the hormones in the pill, particularly their influence over implantation, is important. A number of researchers have shown that the pill causes an increase in IGFBP-1 levels and a decrease in plasma concentrations of IGF-1.[98,99] More specifically, during the pill free-week 'IGFBP-1 was significantly lower on the medication-free day than on day 14 of the cycle . . . The short absence of exogenous estrogen and progestin during the medication-free week also affected IGF-1 levels, which were significantly increased'.[100]

The superabundance of IGFBP induced by the pill has, from an implantation perspective, significance. Giudice has reported that: 'IGFBP's bind IGF's with high affinity and, for the most part, inhibit IGF bioavailability to their receptors for action in their target organs'.[101] Thus, the supraphysiological levels of IGFBP, induced by the pill, may be detrimental to the process of implantation via an inhibitor action on the levels of IGF. Giudice highlights this point: 'IGFBP-1 has been shown to inhibit trophoblast invasion into decidualised endometrial stromal cultures, suggesting that this IGFBP-1 is a maternal "restraint" on trophoblast invasion'.[102]

Aside from the indirect anti-implantation effect of excessive levels of IGFBP upon IGF, IGFBP also has a direct, anti-attachment effect upon the human embryo. 'IGFBP-1 specifically binds to first trimester trophoblast and that it binds to the 'α5β1 integrin in trophoblast. Furthermore, it inhibits trophoblast attachment to fibronectin; another RGB ligand found in the placental bed.'[103]

In summary, the pill causes an increase in IGFBP levels, leading to a decrease in IGF levels. This may have a negative impact upon implantation. IGFBP also may have a direct effect at the level of trophoblast/endometrial integrin binding. More research is required to understand fully the roles of IGF and IGFBP. This represents a new, emerging field of research into the multitudinous factors involved in the process of implantation. Whilst the above research indicates that the pill facilitates anti-implantation endometrial environment, confirming evidence is yet to be found. Hence there exists a reasonable suspicion only, a point made by key researchers in the field.[104]

1.10 CONCLUSION

This discussion has had as its focus the multifactorial nature of embryo implantation. On occasion, this discussion has required detailed analysis of the relevant factors influencing the success of this event. Sometimes it is not possible to speak of these events, centred as they are on the maintenance of human life, without a certain measure of complexity and detail. To those readers who have struggled with this material I apologize.

This paper does not presume to be the final word on this complex and evolving branch of medical knowledge. New research appears almost monthly to illuminate further and sometimes confuse this emerging medical discipline. Nevertheless, I hope I have briefed the reader on issues related to the first right of all humans—the right to stay alive. Some may seek to discount the interceptive/abortifacient capacity of the pill. For three reasons, this would be a scientifically precarious position to adopt.

First, I am of the view that the preceding evidence strongly argues the case in favour of the pill possessing an interceptive/abortifacient capacity. At the very least, the evidence is repetitive and circumstantial. Indeed, how more clear and straightforward could the issue be than the following statement from Eric Widra and colleagues? 'Demonstration of complimentary integrin expression on preimplantation embryos has further buttressed the argument that these molecules are important for the initiation of pregnancy'.[105]

Second, even researchers view as the new arena of 'contraceptive' research the interrelated system of implantation factors. Carlos Simon and colleagues (*Fertil Sterility*, 1998), after discussing the interdependent relationship between the interleukin-1 system, the αvβ3 integrin adhesion system and implantation, conclude by stating that the interleukin-1 system would be a promising new area of research apropos the development of new 'contraceptives'.[106] Given this sentiment, I am of the view that anti-interleukin chemicals will be the RU-486 of the next decade.

Third, and most tellingly, the abortifacient capacity of the pill is recognized by those who support abortion. Consider the following, taking from the *Guttmacher Report*. 'The best scientific evidence suggests that ECP's [emergency contraceptive pill] most often work by suppressing ovulation. But depending on the timing of intercourse in relation to a woman's hormonal cycle, they—as is the case with all hormonal contraceptive methods—also may prevent pregnancy either by preventing fertilization or by preventing implantation of a fertilized egg in the uterus' (my emphasis).[107]

Need any more be said?

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The Abortifacient Effect of the Birth Control Pill and the Principle of 'Double Effect'

INTRODUCTION

Christians are increasingly being exposed to the medical and theological debate concerning the potential abortifacient effect of the birth control pill (the Pill). Some argue that the Pill, in both of its forms (the oral combined oral contraceptive [COC], containing estrogen and progesterone hormones, and the oral progestin only pill [POP], containing only progesterone hormone) has an abortifacient effect, at least some of the time.[1,2,3,4,5,6,7,8] By 'abortifacient effect'. they mean that the Pill causes the unnatural and unrecognized death of preborn children sometime between conception and 'patient recognized pregnancy'—the time when the woman realizes that she is pregnant, either by signs or symptoms. A patient-recognized pregnancy can be clinically confirmed by physical examination, ultrasound or laboratory testing. By 'preborn child', is meant the developing human life that secular physicians medically label, depending upon the stage of development, as a morula, a zygote, a blastocyst, a pre-embryo(sic), a conceptus, or an embryo.[9]

Other physician experts argue that the possibility of the Pill causing an abortifacient effect is either 'non-existent' or 'infinitesimally small'.[10,11,12,13] For the purposes of this paper, the former group will be called the 'abortifacient theory proponents' or 'proponents' and the latter group will be called the abortifacient theory opponents' or 'opponents'. It appears to this author, that among practising physicians and among those obstetrician-gynecologists who have studied the subject and written opinions, the majority are in the 'opponent' camp. However, it also appears that more information has been published and distributed by the 'proponents'. Further, the only studies which have been accepted for publication in national and peer-reviewed medical journals represent the 'proponent' position.[2,7,8]

Some opponents use the term 'mini-abortion' to refer to the abortion of a preborn child prior to or just following implantation. Proponents have objected to this term, declaring that it appears to devalue the preborn. Opponents say that the term 'mini-abortion' is only meant to indicate that the microscopic preborn child is much, much smaller than at later stages of development. For the purposes of this paper the term 'abortifacient effect' or 'abortion' will be applied to the death of human life from conception to the point of that life being able to live outside of the mother's womb.

National groups, ministries, commissions or publications have published information which appears to favour one of several positions: (1)The 'proponent' view appears to be supported by the American Academy of Natural Family Planning,[14,15] the American Life League,[16] Eternal Perspective Ministries,[1] Human Life International,[17] One More Soul,[18] Pharmacists for Life,[19] the Study of Abortion Deaths Commission,[20] and the journal *Life Advocate*;[21] (2) A 'neutral' view seems to be supported by the Christian Medical and Dental Society[22] and the WELS Lutherans for Life.[23] (3) The 'opponent' view is supported by a group consisting of twenty-three well-respected academic and private-practice, pro-life, obstetrician-gynecologists[5] and has been expanded by a group of four obstetrician-gynecologists.[10,11] National groups that are currently discussing or debating the issue, but have yet to publish or publicly release an opinion, include (but may not be limited to) the National Right to Life. the American Association of Prolife Obstetrician-Gynecologists (AAPLOG), the American Association of Prolife Family Physicians (AAPFP), the Physicians' Resource Council of Focus on the Family, the Family Resource Council (FRC), the Center for Bioethics and Human Dignity and the Catholic Medical Association (CMA).

PREMISES

For most Christians, the value of human life is measured by the value placed on that life by the God who created it. Because God's word, the Bible, says that he values human life in a way that is distinct from any other life that he created, most Christians hold that God's valuation of human life supersedes any assignment of value based on human choice, society, law or any human institution. Scripture teaches that human beings are made in the image of God, by God, for his purposes, and live at his pleasure. Therefore, most Christians hold that human beings do not have the right before God to terminate the life of any other fellow human being, except as explicitly delegated by God in his word.

Scientists have been able to delineate the biological mechanisms by which God creates a new human being. The joining together of a male sperm and a female egg to produce human life is the process called fertilization and can take as long as twnety-four hours.[9] Most Christians believe that the point in time at which a new human being is created is at the moment of conception (Num. 5:28; Ps. 139:15–16). Any interruption of the process of develpment of the human being after fertilization (or conception) is felt by most Christians to be the moral equivalent of an abortion and is called by Christian physicians a 'post-fertilization effect'[2] or an 'abortifacient effect'. [1,3] Therefore, an intentionally caused abortion, whether recognized by the mother or not, at any point after fertilization (conception) would carry the same moral significance as the taking of a human life at any time in the life-span of that human being.[25]

A number of verses in the Bible make it clear that conception is the time at which God creates a human being (in this case a preborn child): including the conception of Jesus (Isa. 7:14; Lk 1:31; Matt. 1:20), Isaac (Heb. 11:11), Samson (Judg. 13:3,7), Job (Job 3:3), David (Ps. 51:5), David's son (2 Sam. 11:5) and John the Baptist (Lk. 1:36).

Therefore, physicians should protect human beings from conception to the end of their life as determined by God.

The term 'contraception' is the process by which conception is prevented ('contra' 'against'; 'ception' = a root word for the word 'conception').[24] Some would differentiate 'natural' contraception (such as modern, medical natural family planning) and 'artificial' contraception, based on the concepts of cooperating with versus suppressing natural fertility processes.[14,15] 'Birth control' is a process by which birth is prevented, whether conception occurs or not. For example, a medical abortion is birth control but not contraception. Using these definitions, birth control methods that are 'natural contraceptives' include abstinence, periodic abstinence, natural family planning (a variety of methods) and birth control methods that are 'artificial contraceptives' include the diaphragm, condom (male or female) and spermicidal sponge, creams and gels.

Among Christians there are a variety of theological views concerning the morality of contraception.[25] There are those who would contend that it is unethical to use any contraceptive mechanism or method.[26] Others believe it is unethical to use most 'unnatural' or 'artificial' forms of contraception.[27,28,29] Still others believe virtually any form of contraception is ethical.[9] It appears that the majority of those who have published on this issue (at least since 1950) would allow for ethical reasons to contracept.[30,31,32,33] This paper is not meant to discuss the ethics of contraception, as this has been done elsewhere,[25] but makes the assumption that birth spacing using contraception can be ethical, following the principles outlined by Meilaender and Turner.[32] However, for those who hold that valuable human life begins at conception, then ethical birth control must be exclusively contraceptive: e.g., it must (1) work exclusively (or, some would say nearly exclusively) by preventing conception from occurring and (2) cause no harm to the conceived but preborn child.

Finally, for the purposes of this paper, it is assumed that the principle of 'double effect' is more likely to help Christians determine moral or ethical actions in medicine than the principle of utilitarianism.[34,35]

THE MEDICAL EVIDENCE

Both proponents and opponents seem to agree that the risk of an abortifacient effect with the POP and Norplant® (subcutaneously implanted progesterone rods) are such that. in general, it would be unethical to use. or prescribe these products as a contraceptive.[1,2,10,11] In other words. the POP and Norplant® appear to have an abortifacient or post-fertilization effect, at least some of the time. Of POPs, opponents have stated, for example, that 'POPs are much less effective birth control . . . although they have potential advantages for select patients'.[11] They go on to say, 'POPs . . . are associated with higher ectopic (tubal) pregnancy rates, exposing the user to increased potential for morbidity and even mortality. This may constitute an unacceptable risk for the use of these products'.[11] Proponents have said, 'For POPs . . . postfertilization effects are likely to have an increased role'.[2] However, proponents and opponents derive different conclusions when it comes to the COC's or injectible progesterone (i.e., Depoprovera®). Since COC's are used much more frequently than Depoprovera®, this paper will examine the COC. The following arguments for and against an abortifacient effect of the Pill were distilled from four excellent reviews on the subject.[1,2,10,11]

The 'Hostile' or 'Unreceptive' Endometrium Theory

Proponents cite a large number of medical studies which document that the uterine lining (endometrium), the 'home in which newly conceived human life implants and develops',[1] is dramatically changed by the Pill.[1,2,3] They cite scores of studies that seem to document that the endometrial structure, biochemistry and function are all dramatically changed by the Pill. They feel that most of these studies conclude that the pill-induced endometrial changes render the endometrium 'hostile'[1,3] or 'unreceptive'[2] to implantation 'at least some of the time'.[2] Proponents also point to secular research opinion that these endometrial 'changes have functional significance and provide evidence that reduced endometrial receptivity does indeed contribute to the contraceptive efficacy of (the Pill)'.[36] Proponents believe that no published studies have refuted these findings.

Although proponents admit, and opponents point out. that this is not direct proof of an abortifacient effect of the Pill, it is felt by the proponents to be indirect proof of 'a very high order'.[1,2] They state[1,2,3] that the presumption that these pill-induced endometrial changes reduce the chance of implantation and increase the chance of an unrecognized, pill-induced abortion of the preborn is so well-accepted in the medical world that the Food and Drug Administration's (FDA's) approved product information for the Pill in the *Physicians Desk Reference*[37] (PDR) says, '*Although the primary mechanism of action is inhibition*

of ovulation, other alterations include changes in the cervical mucus, which increase the difficulty of sperm entry into the uterus and changes in the endometrium which reduce the likelihood of implantation'.[37] To proponents, this is an FDA admission of the abortifacient effect of the Pill.[1,2,3]

Further, proponents cite Magnetic Resonance Imaging (MRI) studies which show that the endometrial lining of Pill users is significantly thinner than that of non-users.[2,3] They also cite nine recent and fairly sophisticated ultrasound studies which have all concluded that endometrial thickness is related to the 'functional receptivity'[2] of the endometrium in women who are infertile. Some of these studies, they say, show that when the endometrium becomes too thin, at least in infertile women, implantation of the preborn child does not occur.[2,3] They point out that the minimal endometrial thickness required to maintain a pregnancy in infertile patients ranges from 5 to 13mm, whereas the average endometrial thickness in women on the Pill is 1.1 mm.[2] They feel that these data lend credence to the FDA approved statement that there are Pill-induced *'changes in the endometrium which reduce the likelihood of implantation'.*[37]

Opponents reply that the assertion that any 'hostile' endometrium causes unintended abortions of preborn children in women on the Pill has absolutely no direct supporting medical evidence.[10,11] Opponents claim that the 'hostile endometrium theory is unproven assertion'.[10,11] Further, they state that the FDA approved statements about the Pill-induced changes to the endometrium are accurate only when the woman does not ovulate ('ovulation' is the process whereby the ovary releases an egg [ovum] into the abdominal cavity). They believe that if the woman taking the Pill has a 'break through ovulation', that a whole new hormone environment comes into play.[10,11] They feel that the hormonal changes occurring after ovulation have seven days to act on the lining of the uterus (the endometrium) to prepare it for implantation.[10,11] They feel that these hormones will normalize the endometrium whether the woman is on the Pill or not.[10,11] They feel this is the reason that unexpected pregnancies on the Pill do as well as any other pregnancies (at least after the pregnancy is clinically recognized).[10,11]

Proponents counter that the opponent's theory that a breakthrough ovulation on the Pill will normalize the endometrium has no supporting medical studies.[2] Further, they point out that after a woman stops taking the Pill, it can take several cycles for her menstrual flow to increase to the volume of women who are not on the Pill,[38] suggesting to them that the endometrium is slow to recover from its Pill-induced thinning.[2] They also cite an older study that looked at women who ovulated on the Pill.[39] This study showed that after ovulation the endometrium did not appear to be receptive to implantation. Proponents feel that this study directly refutes the theory that a breakthrough ovulation on the Pill will normalize the lining of the uterus and supports the potential that the Pill causes unrecognized loss (death) or preborn children, at least some of the time.[2]

Ectopic Pregnancy Risk on the Pill

Another argument proposed by the proponents is this: They argue that if the Pill has no abortifacient (postfertilization) effect, then the reduction in the rate of intrauterine pregnancies (IUPs) in Pill-takers should be identical to the reduction in the rate of extrauterine (ectopic or tubal) pregnancies (EUPs) in Pill-takers.[2] They argue that if there is an increased extrauterine/intrauterine pregnancy (EUP/IUP) ratio, this would constitute conclusive evidence for an abortifacient effect.[2]

Proponents cite at least two medical studies that have shown an increased EUP/IUP ratio.[40,41] They point out that these data came from seven maternity hospitals in Paris, France[41] and three in Sweden[40] and involved a total of 380 women with ectopic pregnancies and 380 *pregnant* controls (women who become pregnant while using the Pill).[2] Proponents point out that secular researchers who have reviewed these studies have suggested that at least some of the Pill's birth control effect is provided via a postfertilization (or abortifacient) effect.[41,42]

Opponents point out,[11,12] and proponents admit,[2] that EUP studies that compare women with EUP to a *non-pregnant* control group do not show an increased risk of EUP for Pill-users.[11] Opponents feel that comparing EUP patients with pregnant controls results in unreliable data and conclusions.[11] Therefore, opponents totally discount the EUP data which compares EUP patients with pregnant controls. However, there is, as yet, no published, peer-reviewed researcher that substantiates the opponents' opinion. Further, proponents assert that only the data comparing EUP patients to pregnant controls is valid. They substantiate their claim by pointing to published secular research opinions which state that, '. . . when considering the situation where a woman became pregnant during contraceptive use, one should focus (exclusively) on pregnant controls'.[41,42] Therefore, proponents say, the elevated IUP/EUP ratios in women on the Pill is strong evidence that the Pill is associated with an abortifacient effect, at least some of the time.[2,3]

Conclusions About the Medical Evidence

Proponents and most opponents seem to agree that the use of POP's and Norplant® as contraceptives are, in general, unethical. Thus, the debate and controversy seem to swirl around COCs, which are the most common form of birth control (exclusive of sterilization) used by women.

Concerning the EUP data, even proponents have to admit that the risk is very small. They estimate that the absolute risk of an EUP in a woman on the Pill would be 1 to 20 per year for every 1000 women using a COC for an entire year.[2] Only one study in the medical literature, from Zimbabwe, has reported an absolute risk of EUP in women on COCs and it reported a rate of 1 per 2000 women who used the COC for one year.[43] Assuming that these data could be generalized to other women, if a woman took the Pill for 20 years, then she would have only a 1% risk of EUP. Proponents point out that there are women who would never choose a medical abortion even once in 20 years and they point out that this data 'proves' that the risk of an abortifacient effect of the Pill is not 'infinitesimally small' and, certainly not 'nonexistent'. Further, proponents argue that the unreceptive endometrium in Pill takers is much more likely to cause unrecognized abortion of the preborn child than the recognizable EUP.

However, for the most part, proponents and opponents agree that their arguments about the data are qualitative and not quantitative. In general, both sides agree that there is no direct proof—no 'cause and effect' proof—that the endometrial changes cause unrecognized abortions in women on the COCs. The proponents clearly believe the evidence is strong, in that, extremely strong. The opponents believe the evidence is nonexistent or extremely weak. Both sides admit that it is not possible from the current data to predict just how often it might occur.

Proponents argue that even if the effect is rare, there are so many millions of women on the Pill, that even a very rare effect could abort countless preborn children. Further, they say that the abortifacient effect can potentially occur to any woman who is taking the Pill: e.g., that when a woman takes the Pill that she is playing a 'form of Russian roulette with her preborn child'.[1] They feel that the longer a woman takes the pill, the greater the chance she has of the Pill causing an unrecognized abortion. Opponents point out that for any particular woman they would predict that the risk of an unrecognized abortion is 'infinitesimally small'.

Should Women be Informed About This Controversy?

Many reproductive scientists have defined pregnancy as occurring at the point of or at some point after implantation.[44,45] However, this definition does not change the fact that many patients identify the start of human life as beginning with fertilization. For many of these patients, a form of birth control that may allow fertilization and then cause loss of the preborn child is unacceptable. Regardless of the personal belief of the physician or provider about the mechanism of the action of the Pill, it is important that patients have information relevant to their own belief and value systems. Some physicians have suggested that postfertilization loss attributed to the Pill would not need to be included in an informed consent until it is either definitely proved to exist or proven to be a common event. However, rare but important events are an essential part of other informed consent discussions in medicine, primarily when the rare possibility would be, judged by the patient to be important. For example, anesthesia-related deaths are extremely rare for elective surgery (<1:25,000 cases); nevertheless, it is considered appropriate and legally necessary to discuss this rare possibility with patients before such surgery because the possibility of death is so important to patients. Therefore, the women to whom the induced loss of a preborn child is important, failure to discuss this possibility, even if the possibility is judged to be remote, would be a failure of informed consent.

There is a potential for negative psychological impact on women who believe human life begins at fertilization, who have not been given informed consent about the Pill, and who later learn of the potential of postfertilization effects of the Pill.[46] The responses to this could include disappointment, anger, guilt, sadness, rage, depression or a sense of having been violated by the provider.[47]

DO INTENTIONS MATTER?

Opponents seem to agree with proponents that if the Pill does have an abortifacient effect, that this effect would be a bad effect, a bad consequence.[11] Proponents say this bad consequence of taking or prescribing the COC is probable, at least on occasion. Further, they point out that the longer a woman takes the Pill, the greater her chance of having an unrecognized, caused abortion. Opponents say this bad consequence is very unlikely. Therefore, those not versed in the technical intricacies of these medical arguments and unable to decide 'which side is right', are left with the dilemma of deciding whether to take or prescribe the COC until or if the medical controversy is resolved.

Opponents have argued that physicians who prescribe the Pill and women who take the Pill do so almost universally to prevent ovulation and that the Pill prevents ovulation the vast majority of the time it is taken (although they concede that there is breakthrough ovulation on the Pill). Opponents point out that physicians who prescribe the Pill and patients who take it intend that the BCP be contraceptive. Opponents argue that this intention, which is good and ethical, supersedes any potential rare and unintended bad consequence—such as a possible abortifacient effect. Proponents have argued that the effect is bad, no matter what the intention.

Indeed, intention is viewed as important in medical ethics since it can not only help to determine whether an action is right or wrong, but intention has been used to help define the nature of the act itself and the kind of person who is performing the act.[34,35] Therefore, Christian ethicists point out that it is not always bad to produce bad consequences.[34,35] They point out that morality is not just about consequences. There are times when good consequences can actually be ethically bad, based upon a bad or unethical intention. On occasion, bad consequences can be ethical if based upon good intention. However, to know when it is morally possible to produce bad consequences, Christian ethicists often resort to an ethical principle called the principle of 'double effect'.[24,48]

The Principle of the Double Effect

The principle allows the performance of an act (such as prescribing or taking the Pill) which has good and (potential or actual) bad consequences only if the following conditions are met:[34,48]

1. The act of prescribing or taking the Pill must be ethical—it must be morally good (or, at the very worst, morally neutral). In other words, the act itself must not intrinsically be a bad act.
2. The person prescribing or taking the Pill must intend for the action of the medication to be moral (or good). In other words, he or she in no way intends a bad effect or consequence.
3. The good effect of the Pill (its birth control effect) does not follow a bad effect (i.e., an abortifacient effect). In other words, a bad effect cannot be a means to a good effect.
4. If there is a bad effect or consequence, then there must be sufficiently serious moral reason(s) for allowing the bad

effect to occur. In other words, the good effect that is intended has sufficiently moral and ethical value to justify allowing or tolerating the bad effect.

5. And further, as a corollary to number four, there must be no other way of producing the good effect.

This principle has a long and rich history in western ethics and medicine and is increasingly called upon in modem medical ethics to determine the rightness or morality of actions with good and bad effects.[48] The principle of double effect is often opposed by the principle of 'consequentialism' or 'utilitarianism'.[34] The later principle is increasingly popular in medical ethics and teaches that the rightness or wrongness of an act is determined primarily by its consequences or results.[34]

Application of the Principle of Double Effect to the Pill Data

Based upon the principle of double effect, then, is it ethical or not to take or prescribe the Pill during this scientific controversy? To be an ethical action, all of the above conditions will need to be met.[48] With the COC, are they?

As discussed in the assumptions section of this paper, for the purposes of this paper it is assumed that birth spacing with good intention and with contraceptive agents can be ethical. Therefore, by definition condition one is met. In addition, for the purpose of this discussion, it is conceded and/or assumed that virtually all prescribing physicians and women taking the Pill are doing so with good intention. Therefore, condition two is also met.

Since most proponents and opponents agree that an abortifacient effect of the Pill, should it occur, is likely to occur only a minority of the time (if at all, say the opponents), then condition three is met—in the sense that the vast majority of the time the good effect of the pill does not depend upon a possible (or even probable) bad effect (an abortifacient effect). Therefore, for this discussion, it is declared that condition three is met; however, it is also conceded that this is a debatable point.

Condition four of the principle of double effect is hotly debated by the proponents and the opponents. It is not the purpose of this paper to repeat the fullness of this discussion: however, to summarize two of the arguments:

1. Opponents argue that women who do not have access to the Pill are more likely to become pregnant and then more likely, in industrialized societies, to choose abortion and in primitive societies to die from pregnancy. Thus, they imply, condition four is met. Proponents argue that this premise is not true, as only a small minority would choose not to take the Pill because it causes early abortions, and these same people (presumably Christians and other theists) would in all likelihood be the very last ones to try to obtain a medical abortion.
2. Opponents state that studies indicate that up to 80% of conceived embryos naturally fail to implant and they point out that the Pill, by lowering the rate of conception, will lower the total absolute numbers of deaths of the preborn. They seem to be saying that if the Pill kills some children, consolation can be had under condition four in knowing that the Pill prevents many other preborn children from ever being conceived and therefore from dying 'naturally'. Proponents argue that if there are fewer abortions because of the Pill, it is not because the Pill brings any benefit to a preborn child, but only because it results in fewer preborn children being conceived. They imply that it is not that lives are being preserved, but simply that there are fewer lives to preserve and that humans are instructed in Scripture to take responsibility for their choices, not for God's.

Were our discussion to end at this point, the controversy certainly might be considered 'unsettled', or 'debatable'. It certainly could be considered to fall under the category of 'disputable matters'[12] discussed in Romans 14:1–21. Objective, knowledgeable Christian observers would in all likelihood line up on one side or the other of the argument, based upon a variety of subjective and objective criteria. However, the principle of double effect has one last condition that must be considered and that condition relates to alternatives. In other words, the principle makes the condition that there must be no other way to produce the good effect. Indeed, there may be.

Natural Family Planning—A Viable Option to the Pill

Only over the last decade has modem, scientific natural family planning (NFP) become established in the medical literature. Nevertheless, many physicians and most women view natural family planning only as the old fashioned and mostly ineffective rhythm method. The old joke goes something like this: 'What do you call a couple who uses the rhythm method for birth control?' The answer, 'Parents!'

Many are surprised to learn that one form of NFP, developed at Creighton University (called the NaPro™ method), has been medically studied over the last 20 years and has been reported in one meta-analysis to be even more effective than the Pill at preventing pregnancy.[49] This meta-analysis reported five studies that recorded 1,876 couples who used the NaPro method for a total of 17,130.0 couple of months of use. The method and use effectiveness rates for avoiding pregnancy were 99.5 and 96.8 at the 12th ordinal month and 99.5 and 96.4 at the 18th ordinal month, respectively. The discontinuation rate was 11.3% at the 12th ordinal month and 12.1% at the 18th ordinal month. Obviously, in the populations studied, the method is highly effective as a means of avoiding pregnancy in both its method and use effectiveness. The method effectiveness has remained stable over the years of the studies, but the use effectiveness for avoiding pregnancy appears to have improved over the study period. Another form of NFP, the Billings Ovulation Method, is so simple to teach and use that it is taught around the world, even to people who cannot read or write.[50,51,52,53]

NFP is said to promote love, romance, communication, prayer, spirituality and learning about natural, God-created reproductive mechanisms. A very great advantage of NFP is that it is said to foster communication and understanding between the man and the woman, develop cooperation between them and a sharing of the responsibility in this important matter of their children. In all these ways it is said to improve a couple's relationship and help them to grow in love and fidelity to each other.[54]

These medical and sociological facts about NFP appear to nullify condition five of the principle of double effect. Since there is a viable, safe and effective alternative to the Pill, this fact would appear to dissolve most arguments that the Pill, until proved to be non-abortifacient, should be or can morally be used by Christians. In fact, assuming that NFP is only as effective as the Pill (and not more effective), it would appear that most arguments to use the Pill, in view of the fact that it may have an abortifacient effect, would be reduced to arguments of convenience at the potential expense of preborn human life.

Future Research

Without question, more medical research on this controversy is needed and would be instructive to physicians, ethicists and theologians. Others have begun to call publicly for such research to be done.[1,2,10,13,22] In particular, studies are needed that evaluate women who get pregnant while taking the Pill. Medically, two separate types of research need to be done with these women: One type would evaluate the development of the preborn child from the point of conception to the point of implantation: the second would evaluate gestation from the point of implantation onward.

From the Point of Conception to Implantation

Direct evidence of a postfertilization, preimplantation abortifacient effect would require methods to measure directly the rate of fertilization and the loss of the preborn child before implantation in women on the Pill. Transcervical tubal washings have been used in women on IUDs to quantify the rate of ova fertilization[55] and could theoretically be done in women on COCs. However, it is probable that most Christians would view such research as unethical.

Other than the washings, there is no currently accepted and proven method to measure the loss of the prebom child prior to implantation. However, a number of techniques and methods to quantitate preimplantation conception are being investigated. Promising research involves the measurement of maternal hormones that appear to be produced or altered after fertilization.[56,57,58] The most promising research involves the identification and measurement of a substance called the 'early pregnancy factor'.[59,60,61] It is reasonable to predict that this research will assist in the answer of this question in the very near future.

From the Point of Implantation

Direct evidence of an abortifacient effect on the preborn child after implantation and prior to signs or symptoms of pregnancy would require measurement with ultrasensitive assays for βHCG (a hormone that can be measured in the blood or urine of the mother).[2] There is also the possibility of being able to measure other pregnancy-related hormones.[62] Studies using these ultrasensitive assays have been done with normally fertile women not using birth control,[63,64,65,66] as well as with women using nonhormonal methods of birth control.[67]

Using these established methods to detect very early pregnancy, women on the Pill (the COC) could be studied and the loss of their preborn children (from implantation onward) could be demonstrated and compared to already published studies of the 'natural' losses of normally fertile women using no birth control.[68,69] Studies such as these, in women on the Pill, would be expensive and would necessarily have to involve a large number of women. An additional obstacle is that it is unlikely that pharmaceutical companies would fund such research. Nevertheless, it would appear reasonable for the proponents and opponents to join together to carry out such research.

If this study showed that there is increased loss of the preborn in women on the Pill, as compared to women not using any birth control, then the case of the proponents is established. If this study showed that there is no measurable loss of the preborn in women on the Pill, then the case of the opponents is established. However, a third possibility exists: the proposed study could show that there is a significant loss of the preborn in women on the Pill, but that the loss is less than that seen in noncontracepting women. If so, then another ethical debate would be forthcoming and appropriate. Such a discussion is beyond the scope of this paper.

CONCLUSION

There is currently a significant controversy about whether the Pill causes early, unrecognized abortions of preborn children. It does appear theoretically possible (even probable) that research could be done to begin to settle the controversy and this research is critically needed. However, until such research is available, those who feel ethically comfortable with prescribing the Pill should inform their female patients of this possible effect and allow their patients to decide whether they should or should not use this form of birth control. Further, physicians or pharmacists who feel ethically constrained from prescribing or dispensing the Pill should be supported. Whether they should be encouraged or compelled to inform patients who still desire to use the Pill to a healthcare provider who can prescribe or dispense the Pill is beyond the scope of this discussion.

There appear to be viable, safe and effective forms of NFP. NFP is a natural method of contraception that never causes an abortifacient effect. It appears that most physicians and patients are not aware of this option and that the vast majority of those who prescribe the Pill have never been educated about modern medical NFP. Efforts should be undertaken by national groups to educate Christian women and physicians about these options.

Finally, based upon the principle of double effect, it appears reasonable to conclude that the Pill should not be used or recommended to those who believe life begins at conceptions unless and until the Pill is proven not to be an abortifacient. It appears to be a reasonable conclusion that such studies could be done and that proof could and should be forthcoming: however, to date. that proof clearly does not exist.

Until such proof is available, one way or the other, the Pill should be considered a possible cause of death to

preborn children. It is reasonable to hypothesize that if the Pill was in development today and if the preborn child was considered truly human under the law, then it would be unlikely that the FDA would allow the Pill to be approved for public use until the manufacturers had studied and established whether or not (and, if so, how often) the Pill causes the death of preborn children.

Since, in the final analysis, the choice to prescribe or use the Pill may be legitimately considered a potential life and death decision for the preborn, it seems reasonable to let God's Word be the final one: 'This day I call heaven and earth as witnesses against you that I have set before you life and death, blessings and curses. Now choose life, so that you and your children may live' (Deut 30:19).

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Book Review

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Last Rights: Assisted Suicide and Euthanasia Debated
Michael M. Uhlmann, Editor
Washington, D.C.: Ethics and Public Policy Center; Grand Rapids, MI and Cambridge, UK: Eerdmans, 1998
ISBN 0-8028-4199-6, x + 677 pp., paperback $35.00

In the aftermath of the 1997 U.S. Supreme Court decisions dealing with assisted suicide, a variety of anthologies on the subject appeared on the market. This volume, edited by Michael Uhlmann of the Ethics and Public Policy Center, is clearly the best. If you are in search of one volume that captures the debate over assisted suicide, this is it. I have recently finished using it as a text for a graduate seminar in bioethics and I did not have to look any further than this text for the most up-do-date and relevant material on the subject. It contains most of the central figures in the academic and public policy debate on the issue, and though one could always suggest an addition here and there, the overall breadth of this volume is difficult to improve on.

This book contains helpful introductory material on the history of suicide (an original piece by Uhlmann) followed by extended sections that deal with the moral/theological perspectives, medical perspectives, and legal perspectives. Linking the moral and theological perspectives together could be seen as somewhat redundant, since each section has significant moral overtones and the entire debate can be seen as fundamentally a moral one. However, the theological perspectives are a helpful addition, and distinguish the book from other anthologies which either ignore theological views or given them a token mention. That is not the case here. The theologians included are Gilbert Meilander, Pope John Paul II, the Ramsey Colloquium (which goes beyond just making a strong theological argument), and Jewish views. Even the piece in this section by Leon Kass, though not a theologian, makes a very powerful theological argument rooted in the biblical material on the image of God and the resulting notion of human dignity. Also included here are critics of the theologically grounded notion of the sanctity of life, such as Peter Singer and Margaret Battin.

The medical perspectives include some of the most visible proponents of assisted suicide, such as Jack Kevorkian and Derek Humphry, though neither piece was particularly well argued. A more cogent and compelling piece defending the practice came from Timothy Quill, the physician-defendant in *Vacco v. Quill* which the Supreme Court ruled on in 1997. Also included in this section was the classic anonymous 'It's Over Debbie', which first brought the prospect of abuses in the practice to public attention. Pieces on the potential abuses of assisted suicide are included as well as principled arguments against it (Leon Kass and Edmund Pellegrino). Unfortunately only one selection deals with another critical issue: the Dutch experience. Though the piece addressing this is very good (Herbert Hendin), a wealth of available empirical data and its interpretations could have been included. Examples of other works include those of British law professor John Keown, physician Carlos Gomez and the ongoing debate in both the *Journal of the American Medical Association* and the *New England Journal of Medicine*.

The selection on legal perspectives is invaluable and in my view, the most helpful aspect of the book. It makes the major appeals court and Supreme Court decisions in the landmark Glucksburg and Quill cases accessible to the reader in one place and includes commentary on those decisions as well. It also includes a model law should the practice be legalized (Charles Baron) and a general critique of plans to allow but carefully regulate it (Daniel Callahan and Margot White).

Overall, the selections are well chosen and representative not only of the variety of perspectives on the issue, but include most of the major figures in the debate. Any reader who is familiar with the debate on this issue will readily recognize many if not all of the contributors. Michael Uhlmann has done the academic community a great service in gathering these resources into one volume that enables the reader to access the broad spectrum of the debate over physician assisted suicide.

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