

Extended Project Dissertation

Can the lack of medical consent ever be justified?

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Abstract

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The Nuremberg Trials in 1947 led to the promotion of medical consent as an essential patient right. With doctors increasingly practicing 'defensive medicine', consent and the surrounding bureaucracy form a fundamental part of medical practice.

The domain of consent is vast and relies on ethical and philosophical considerations and arguments in its investigation.

The aims of the project are to explore the history of consent and to track its progression, examining the differing circumstances in which lack of consent occurs; in medical treatment in a clinical sense, and during human experimentation. The project compares these separate, but nonetheless broad areas of consent and seeks to determine whether they should be appraised together or separately. Looking at both case studies and hypothetical situations the project presents arguments for and against justification for the lack of consent; the importance of autonomy versus the progression of human knowledge and the potential benefits of overruling consent as supported by a utilitarian framework.

The project concludes that lack of medical consent can never be justified but for a few exceptions falling into the category of medical treatment. Mill's harm principle supports overruling parental wishes concerning their children's medical treatment, if parental beliefs counter what is seen as best for the child - providing this has been deemed ethically suitable by an appropriate body. Other than such exceptions, in medical treatment autonomy should be regarded with utmost importance providing the patient has displayed sufficient understanding of what their actions, such as refusal of treatment, will cause. The argument for autonomy is used to reach the conclusion that regardless of any eventual furtherance of knowledge carrying out medical research on unwilling people can never be justified.

Introduction

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Consent is the formal permission given for something to happen. The past sixty years has seen significant progress in establishing medical consent as a patient's right. The discovery of Nazi atrocities during their experimentation on unwilling concentration camp prisoners during World War Two shocked the world into action, and has subsequently led to the development of a legal framework to cater for issues of medical consent.

With the recognition of autonomy, the right for a person to make choices for themselves, came many legal battles between patients and doctors over the ethics of actions taken by doctors, where a lack of informed consent led to consequences previous unknown to the patient. Medicine today is becoming increasingly patient orientated; however are still instances when patient wishes are ignored or overruled by courts and doctors. In most cases this occurs when a patient refuses life prolonging, vital treatment. The concern for beneficence, to do what is best for the patient, is upheld by healthcare professionals as their reasoning behind overriding autonomy.

Often the demands of patients regarding their treatment, when contrary to that recommended, put great strain on the healthcare system both economically and in terms of resources and time. Should doctors go to great lengths to provide for medical patients who for certain reasons cannot consent to regular medical treatment? The right for autonomy would argue that yes; only the patient themselves should have the right to decide what happens to their own body, as it is them alone who will have to deal with the consequences.

Consent first interested me after first hand viewing of a controversial situation in clinical practice. On a work experience placement in a large teaching hospital, whilst shadowing an anaesthetist on ward rounds we came across a patient who was going in for surgery, however due to her religious beliefs- she was a Jehovah Witness, she would not accept blood transfusions if needed during her surgery. I found this fascinating, firstly due to my unfamiliarity with such a situation where somebody would refuse life saving treatment and,

perhaps more worryingly due to the patient apparent particular lack of knowledge regarding the various consequences of such a decision. This is something the doctor did not seek to fully amend. My realisation of this however has only come since looking closely at the process and requirements of informed consent. Patient central care is now a main focus within medical education and practice, and wanting to pursue a medical career myself the topic is one that will no doubt become prominent in my working life.

Consent itself does not concern science; but has a great importance within scientific practice as it is fundamental within medicine and scientific experimentation. Greater are the philosophical and ethical issues that support consent and lie at the very heart of its creation, such as autonomy and beneficence. Examining consent brings into play many philosophical frameworks. Relativism, the idea that every situation needs to be assessed separately and thoughts surrounding this tailored accordingly. Absolutism the opposite of relativism – that one overall rule should govern. And utilitarianism, the belief that ethically superior actions are those that result in overall benefit or happiness for a greater number of peoples. Thoughts such as those of John Stuart Mill's on when one should be able to overrule another individual's wishes can also be applied to consent as can the ideas of Kant and Nietzsche are relevant when discussing the pros and cons of human research. Nietzsche argues that we too easily 'give up' when blocked by long established morals and ethics, and instead we should strive to reassess and revalue these, not allowing our morals to get in the way of our progression as a race. Such thoughts would therefore support human experimentation when consent has not be gained, in favour of the eventual results gained rather than concern for inhumane actions taken.

Literature Review

(2,990)

What is Informed Consent?

Informed consent is, as the name suggests, permission given by a patient concerning medical treatment having been informed of matters surrounding the treatment. It has been defined as ‘an autonomous authorization by an individual regarding a medical intervention or involvement in biomedical research.’¹

In today’s world, used to freedom of speech and democracy we fully expect that any of our medical treatment is firstly approved by us, the patient. Informed consent allows us to make decisions about our body’s medical needs with knowledge and understanding about what those choices will result in. ‘At the centre of informed consent remains the critical primary of the right for a patient to understand any medical treatment, medical procedure, or participation in medical research.’²

The Components of Consent

Informed consent can be broken down into three basic parts; ‘voluntariness, capacity and knowledge’³. The patient must be willing for the proposed medical treatment to take place, they must be deemed to have the mental capacity to deal with making decisions regarding

¹ Beckerman, N. *Informed Consent* [online]. The Encyclopaedia of Death and Dying. Available from: <http://www.deathreference.com/Ho-Ka/Informed-Consent.html> [17/10/08]

This source is a secondary source from an online encyclopaedia about death. No information is provided on the qualifications of the writer; however as a factual source it does not contain any one-sided views. Some of the information from this source concerning the Nazi experiments was inaccurate which makes me doubt the reliability of the source slightly. Nonetheless the source has been useful in gaining a basic knowledge about informed consent

² Kiefer, J. *The History and Importance of Informed Consent in Clinical Trials* [online]. Available from: <http://serendip.brynmawr.edu/biology/b103/f01/web2/kiefer.html> [17/10/08]

This is an essay posted on Serendip’s Exchange, a website which hosts scientific and social science essays, although many have a strong opinionated focus this is factual, no information is provided as to the qualifications the author has, other than that they were studying at Bryn Mawr College, Pennsylvania, which is a highly selective, women’s liberal arts college.

³ Schwarc, C (ed.) (1994) *The Chambers Dictionary*. Chambers Harrap Publishers Ltd, Edinburgh. A dictionary, therefore a reliable source.

treatment; this therefore excludes children and the mentally ill, and they must also have been presented with a satisfactory amount of information about the proposed treatment.

These three parts can be further explained through the following necessary components:

1. Competence –The doctor must decide whether the patient is competent both to understand and decide upon their medical treatment
2. Disclosure – The doctor must ensure the patient has an adequate knowledge by disclosing a set of ‘core disclosures’⁴
3. Understanding – The patient must understand the information given to them
4. Voluntariness
5. Consent (Beckerman, www.deathreference.com)

The driving force behind *informed* consent is that the patient is given adequate knowledge of their proposed treatment and thus ‘substantially understands the nature of the procedure he is authorizing.’ (Donnelly, 2000, Ch 2, p.21) However, it is impractical to give the patient absolutely *all* the information available surrounding the procedure they hopefully will consent to, therefore a set of ‘core disclosures’ are given to the patient. ‘This is the information which patients...usually consider material in deciding whether to consent and also the information that the medical professional believes to be material about the proposed intervention or research.’ (Donnelly, 2000, Ch 2, p.23)

Core disclosures include:

- Risks
- Success rates
- Uncertainties
- Benefits and side effects
- Doctor’s recommendation

⁴ Donnelly, M (2002) *Consent: Bridging the Gap between Doctor and Patient*, Cork University Press, Cork, Ch 3, p.23

This is a book written about consent within Irish healthcare, it is one which argues for patient rights to information and understanding, however the information that I have sourced are purely factual, although due to the location of the author the information may be more tailored to Irish healthcare. The author is a solicitor and lecturer in medical law at University College, Cork and therefore the information within the book comes from an expert in the field of medical consent.

- Alternative recommendation
- The experience of the doctor in dealing with this specific procedure
- The role of the rest of those included in the medical team
- The costs of the treatment
- The presence of medical students is also something which the patient must consent to (Donnelly, 2000, Ch 2, p.23)

The points listed above are those which surveys have identified as factors patients consider most important regarding informed consent.⁵

With medical research the additional core disclosures include:

- The purpose of the research
- How it will be funded
- How the research will be carried out
- If placebos will be used (Donnelly, 2000, Ch 2, pp.23-24)

However these are merely guidelines, ‘Unlike in legal discourse relating to information disclosure, there is no reference to the ...patient or professional.’ (Donnelly, 2000, Ch 2, p.23)Therefore it is up to the doctor to listen to the patient and decide what information is relevant. ‘This focus on the individual patient regards communication of information as a two-way process.’ (Donnelly, 2000, Ch 2, p.24)

It is evident that today the interests and decisions of the patient lie at the heart of medical treatment, but this has not always been the case, indeed only in the past hundred years has this become the norm. Informed consent as we understand it has developed and evolved throughout the history of medicine. In particular, the notion of consent is historically linked to, and revolves around two ethical concepts.

The ethical concepts behind medical consent

Autonomy

⁵ O’Flynn, Norma et al, (1997) ‘Consent and Confidentiality in Teaching in General Practice: Survey of Patients’ Views on Presence of Students’ *BMJ* 315 (1142)

This was a survey which was published in the medical journal the BMJ. Publication of work within reputable journals such as the BMJ requires an extensive process of peer review and therefore I feel the data is reliable.

Autonomy has been defined as ‘personal freedom to make moral choices’⁶

Logically it seems obvious that people should have the right to choose what happens to their own body. Going back to the ‘doctor knows best’ attitude which formed the basis of medicine, the idea of autonomy is entirely contrary to this. ‘ This in no way denies the importance of the doctor’s expertise but it acknowledges that the patient is an expert too in relation to how she lives her life and the consequences and risks she is prepared to take.’ (Donnelly, 2000, Ch 2, p.16)

The patient’s right to choice over their body means they now work *with* the doctor to make their own decisions. The right to exercise free decision, and the capacity for it was recognised as a key human right in the seventeenth and eighteenth centuries.(Polani, 1983) However, the Hippocratic Oath which is still seen as a guideline for all those in the medical profession states: ‘I will [not] give a deadly drug to anybody who asked for it’⁷. This lack of regard for the patient’s demands (though yes in this instance it *may* be for the patient’s own benefit) shows the lack of autonomy patients at one point had.

The idea of autonomy and informed consent has only been fully developed within the past century, the development and origins of informed consent will be explored later in this essay. It is interesting to note however that ‘it was not until the middle of the sixth century AD in Italy that patients were encouraged to question their physicians.’⁸

Patients are allowed to refuse treatment ‘which could prolong their lives, but has no direct impact on the lives of others’(Mayberry and Mayberry, 2003, Ch 1, p.12) An example of this would be Jehovah Witnesses, who due to their religious beliefs refuse blood. The Jehovah’s Witness doctrine, written in 1945 states, ‘blood was reserved for only one special use, the

⁶ Polani, P (1983) *The Development of the concepts and practice of patient consent*. In: GR Dunstan and MJ Seller (eds) *Convergence and divergence in tradition*. King Edward’s Hospital Fund for London, London

This information has been quoted in *Consent in Clinical Practice* which suggests it is a reliable source to use

⁷ Edelstein, L. (1943) *The Hippocratic Oath: Text, Translation, and Interpretation* [online]. Johns Hopkins Press, Baltimore.

Available from: http://www.pbs.org/wgbh/nova/doctors/oath_classical.html [26/11/08]

The text is quoted from a translation of the Hippocratic Oath, which having gone through the process of publication suggests that the translation is accurate and valid.

⁸ Mayberry, M and Mayberry J. (2003) *Consent in Clinical Practice*, Radcliffe Medical Press, Abingdon, Ch 1, p.17

This is a guide aimed at those working within the healthcare service to provide them with information on consent as applicable in their job. The authors are a doctor and nurse who have both spent extended time working within the healthcare system in Britain, and having been published by Radcliffe Medical Press it is likely that the facts and figures displayed in the book are valid.

atonement for sins, which led up to Jesus' shed blood.'⁹ The doctrine also states, 'Even in the case of an emergency, it is not permissible to sustain life with transfused blood.'¹⁰ The followers of the religion believe that blood cannot be removed from the body, therefore blood/organ transfusion/transplant and storage is not an option for them. This of course brings up many ethical issues and controversial cases have arisen revolving around this. In 2007, the story of a woman's death, due to refusal of blood transfusions during labour made headlines nationally.¹¹ The patient in question, Emma Gough, having signed an advance directive, legally prevented doctors from providing her with blood which would have saved her life. Advanced directives 'allow a competent person to express who should be a decision maker and what preferences the patient may have.' (Beckerman, www.deathreference.com) In some cases, such as with terminally ill patients, there can be seen to be many advantages to this decision. However in the Gough case her newlywed husband was left to deal with both the death of a wife and the upbringing of baby twins. As mentioned earlier, patients can reject treatment 'which could prolong their lives, but has no direct impact on the lives of others' (Mayberry and Mayberry, 2003, Ch 1, p,12) but clearly in this instance the patient's death has direct impact on many, namely her husband and children. This is an example of where lack of autonomy can be seen as the *greater* of two evils. This is recognised by the law and sometimes patient's wishes are often overruled by a court. An example of this is 'M ... a gravely ill 15-year-old... the courts decided that her refusal to undergo a heart transplant could be overridden.' (Mayberry and Mayberry, 2003, Ch 1, p,12) In direct contrast to this Hannah Jones, a terminally ill 13 year old has been granted permission to refuse a heart transplant. Hannah has decided that, rather than prolong a miserable life in and out of hospital, she will 'let nature take its course' at home, surrounded by her friends and family.¹²

⁹ Woods, A. (2007) *Why do Jehovah's Witnesses refuse blood transfusions?* [online]. Available from: <http://www.digitaljournal.com/article/246961> [26/11/08]

This is an online article; however the information provided matches up with that which is included in the Witness's doctrine.

¹⁰ Wikipedia, *Jehovah's Witnesses and Blood Transfusions* [online]. Available from: http://en.wikipedia.org/wiki/Jehovah%27s_Witnesses_and_blood#cite_note-8 [27/11/08]

Although the information is from Wikipedia that which has been referenced this can be backed by reading the Witness's doctrine.

¹¹ Pavia, W. (2007) *Jehovah's Witness mother dies after refusing blood* [online]. Available from: <http://www.timesonline.co.uk/tol/news/uk/article2809423.ece>

A news article from The Times, as it is a broadsheet newspaper it has a reputation to uphold and therefore it would be in the paper's interest to reproduce accurate information.

¹² De Bruxelles, S. (2008) *I'll take my chances, says Hannah Jones after refusing heart swap*. The Times, London.

Available from: http://www.timesonline.co.uk/tol/life_and_style/health/article5134048.ece [27/11/08]

A news article from The Times, the information from this source used in this document is factual and not opinion based, and as it is from the Times it is likely to be very reliable.

This case brings in many other ethical topics, not only those surrounding autonomy and consent, the complexity of which will be explored more fully in the discussion.

Beneficence

‘[T]he term ‘beneficence’ includes acts of mercy, kindness and charity...it concerns the motivation to act in the best interests of others.’ (Mayberry and Mayberry, 2003, Ch 1, p.16)

Despite being mentioned earlier, that patients in sixth century Italy were encouraged to question their doctor, this was very uncommon and ‘throughout most of antiquity and the Middle Ages the physician was expected to provide the patient with the best treatment available and this was to be accepted by the patient without question.’(Mayberry and Mayberry, 2003, Ch 1, p.17)

This sets beneficence as the primary goal of medicine and healthcare, however completely disregards the morals and ethics which autonomy serves. Beneficence and autonomy do not blend well,

‘Whether respect for the autonomy of patients should have priority over professional beneficence directed at those patients is a central problem in biomedical ethics’¹³

‘Since the time of Hippocrates the moral basis for the practice of medicine has been to help at least to do no harm’(Mayberry and Mayberry, 2003, Ch 1, p.16) Doctors obviously try to provide treatment that has a positive benefit to the patient as per the Oath which encourages doctors, ‘To practice and prescribe to the best of [their] ability for the good of [their] patients’¹⁴ Nowadays, however, many treatments that help ‘alleviate disease and injury’ (Mayberry and Mayberry, Ch 1, p.16) may also cause harm, the harm being pain and suffering.

¹³ **Beauchamp, TL. and Childress, JF. (2001) *Principles of Biomedical Ethics* (5e). Oxford University Press, Oxford**

This guide to biomedical ethics has been published by Oxford University Press and has gone through review by experts in the field, therefore a reliable source.

¹⁴ **Hippocratic Oath. Available from: http://en.wikipedia.org/wiki/Hippocratic_Oath [27/11/08]**

This online Wikipedia article summarises accurately the elements of the Hippocratic Oath

‘The use of life-sustaining treatments occasionally violates patients’ interests...pain can be so severe and...so burdensome that these factors outweigh anticipated benefits, such as a brief prolongation of life.’(Beauchamp and Childress, 2001)

Due to this a patient may refuse treatment, as shown above in the section about autonomy. If the patient’s refusal is overruled then this would reject the patient’s autonomy; however it could be in the patient’s best interest. Going back to the foundation of ethics for many doctors, the Hippocratic Oath, this ‘medical paternalism’ (Mayberry and Mayberry, 2003, Ch 1, p.16) is a key idea. Therefore striking a balance between allowing the patient’s own requests to be granted and to act in the patient’s best interest medically causes great problems when dealing with consent. The tradition of patients having complete trust in their doctors, when patients were encouraged to ‘confidently entrust themselves to him for treatment.’¹⁵ Is ultimately counterbalanced by the developing tradition of making a patient’s decisions equal, if not more important than the doctor’s.

We could flip the ancient idea of a beneficence-central outlook on healthcare to an autonomy centric one; however allowing merely patient autonomy raises severe ethical issues and ultimately goes against what is seen as the core of a doctor’s role; to help patients and cure and treat their illnesses.

¹⁵ **Jones, WHS (trans.) (1967) *Hippocrates. Vol. 11. Decorum XVI. Heinemann, London***
This translation, published by Heinemann will be a reliable, reviewed translation of the Hippocratic Oath.

Origins of Informed Consent

The nature of consent within medicine has changed enormously from its outset. In the past a 'doctor knows best' attitude was adopted, however today's society is very much human-rights centred. (Beckerman, www.deathreference.com)

'Hippocrates's oath which granted physicians the right to practice in the patient's best interest, has conflicted with the twentieth-century trend towards patient rights' - British Museum (Beckerman, www.deathreference.com)

In the past there was a 'preferred conception that physicians should protect their patients from information about their diseases or treatment options' (Beckerman, www.deathreference.com) that is, the doctor knows best attitude. But 'since the mid-twentieth century there has been a trend toward patient's rights' (Beckerman, www.deathreference.com)

Medical advances within the last few centuries also put pressure on doctors, unsure what information to pass on to their patients 'physicians began to disclose basic information without necessarily outlining all potential risks.' (Beckerman, www.deathreference.com)

In most documents on the history of informed consent, the Nuremberg Trials of 1947 are seen as the basis for the development of medical consent. However, before explaining how the Nazi experiments lead to the principle of consent being outlined in the Nuremberg code, it is important to note that the Nazi's treatment of experimental subjects is not the only instance in which unethical and inhumane medical research has been carried out.

During World War II the Office of Scientific Research and Development was created by President Roosevelt, its aim was to combat diseases which commonly affected soldiers. A potential vaccine for dysentery was developed by one of the research teams and this was tested on orphans and the mentally ill. (Kiefer, <http://serendip.brynmawr.edu/exchange/>) This is just one example of many similar experiments that took place in America and Britain.

The case of Mohr vs. Williams in 1905 is important in the development of the notion of informed consent; a doctor had obtained consent from a patient to operate on her right ear,

but during surgery the surgeon determined that the left needed surgery instead and proceeded to operate on it. The judge's conclusion to the case is very similar to the way informed consent works today:

'a physician needs to advise a patient of all the information related to a particular procedure and must review all the risks and benefits. Only after this ...does the patient enter into a contract...that authorizes the physician to operate only to the extent of the consent given.'

(Kiefer, <http://serendip.brynmawr.edu/exchange/>)

The Nazi Experiments

Finding information on the details of the experiments is difficult; no doubt due to their taboo nature, however the book 'Doctors from Hell' has been useful. It outlines the various experiments that were undertaken at the concentration camps during the 1940s. The High Altitude Experiments are just one of the many.

In May 1941 the Luftwaffe physician Dr. Sigmund Rascher proposed high altitude experiments to be made, a proposal that was willingly authorized by Heinrich Himmler.

Four experiment types were conducted:

- Slow descent without oxygen
- Slow descent with oxygen
- Falling without oxygen
- Falling with oxygen

The first two were to simulate descent with the parachute open and the other two a free fall before the chute had opened.

The experiments took place at Dachau concentration camp (a short distance from Munich) between March and August 1942 for the German Air Force.

The experiments were carried out by placing the victim in an airtight pressure chamber, high altitude atmospheric conditions were then simulated in the chamber and the victim's responses recorded.

Those who took part in the experiments were referred to as ‘Versuchspersons’, or VPs, meaning experimental person¹⁶ There were approximately 180-200 inmates chosen at random to partake in the experiments, they included:

- Jews who had been condemned for *Rassenschande* -racial shame i.e. marriage or intercourse with non Jews
- Russians and Russian prisoners of war
- Poles
- German political prisoners (Spitz, 2005, Ch 2, pp. 65-83)

At the Nuremberg Trials ‘The defendants claimed the experiments were to be performed on habitual and condemned criminals, referred to as ‘volunteers’.’ (Spitz, 2005) However only around ten inmates volunteered for the experiments, they had promised that they would be released from the camp if they did so, and were often promised more favourable work as a reward. Only one man is thought to have been released from the camp after the high altitude experiments; he underwent the most experiments and was also in an experiment conducted in the presence of Himmler.

In the first of the experiments, ten prisoners were selected and taken to the station as permanent experimental subjects; they were told that nothing would happen to them. Therefore they were not even given the chance to know about what was to happen to them. Medical doctors undertook the research, which considering medical professionals are normally associated with moral and ethical values is very disturbing. Not only this but all those conducting the parachute fall experiments knew the experiments on the involuntary inmates were likely to result in death- they were not conducting these experiments with any sense of naivety. Certain individuals were also murdered directly in order to conduct autopsies to examine the affects of the experiments.

¹⁶ **Spitz, V. (2005) *Doctors from Hell, The Horrific Account of Nazi Experiments on Humans, Sentient Publications*, Ch 5, pp. 65-83** This book is written by a court reporter for the Nuremberg war crimes trial, it therefore contains her own eye witness reports of the trials themselves and their transcripts. The details of the experiments come from evidence presented at the trial. The source is mainly factual, however there is, understandably a bias against the Nazi’s. The research is deemed medically useless by the author, indeed it may be but little argument is put forward for this, the statement is simply made. Regardless of this it is the information concerning the happenings of the experiments that I have used this source for, and as actual trial transcripts are included in the source these provide accurate information about the experiments.

At the Nuremberg Trials the defendants argued that although subjects had been killed, the experiments did not involve torture or pain, but this was proven very wrong by the photographs taken of prisoners during experiments.

It is hard to imagine that doctors, let alone anyone could carry out these experiments on any human, consenting or not. The shock factor of the inhumanity lack of consent can bring, as shown by the Nazi experiments alerted people to the need for a system of informed consent, hence its swift development in the latter part of the twentieth century.

Development of Consent following the Nuremberg Trials

There was a ‘comprehensive movement toward informed consent ...after World War II with the 1947 Nuremberg Trials.’ (Kiefer, <http://serendip.brynmawr.edu/exchange/>) The Nuremberg Code of 1948 which was a result of the trials,

‘abandons the earlier paternalistic perspective of medicine and research and replaces it with the centrality of patient self determination by asserting that the voluntary consent of the human subject is necessary under all circumstances of medical research.’

(Kiefer, <http://serendip.brynmawr.edu/exchange/>)

The Nuremberg Code laid out the principle that ‘The voluntary consent of the human subject is absolutely essential.’¹⁷ The Nazi trials re-defined the notion of consent by alerting the world to its need within medicine. By hearing of such inhumane practices within Nazi medicine suddenly the need for consent was recognised.

In the legal sphere, informed consent eventually emerged as a right in 1972 following a series of legal cases in California during 1950s. A woman sued her physician because the effects of radiation treatment he had proposed and administered ‘far exceeded the side effects described by the physician.’ ‘The court found that unless such consent was based on full information, and ...the patient fully understood all the risks of the procedure, the doctor was not protected for liability.’ (Kiefer, <http://serendip.brynmawr.edu/exchange/>)

¹⁷ U.S Government, (1949) *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, pp. 181-182.* [online]. Available from: <http://ohsr.od.nih.gov/guidelines/nuremberg.html> [27/11/08]

This is from the website for the National Institutes of Health, in the Office of Subjects of Human Research section of the website, it is a national company and therefore the information is reliable.

Through tracing the historical developments of the notion of consent it is clear that there has been a move from a medicine in which the doctor is seen as the decision maker and mastermind to one in which the doctor must ensure the patient's wishes and demands are met as best possible.

Discussion

(4,141)

Introduction

In an era where the right to free will and in some cases the right to free medical care is the norm one could expect to be granted the right to medical consent. I am going to argue that a lack of consent is never justified; however, I will also point to exceptional examples which show when lack of consent could be overridden.

It is important to establish that there are two very distinct categories concerning consent that I am considering in this essay; medical treatment for the purpose of caring, and medical experimentation for the furtherance of scientific knowledge. I will develop my thoughts concerning my proposal in application to both categories. I believe that lack of consent in regards to medical experimentation can never be justified; the exceptional case in which lack of medical consent can be justified falls under refusal of treatment within medical treatment.

Autonomy

A right to autonomy is now considered both essential and natural in life and therefore many would ask; how can we ever justify the lack of it? How can anyone be the judge over which situations require doctors and the law to intervene, and what gives a certain individual the right and the power to be such a judge and to deny a human being choice over their own body?

The notion of autonomy is that the individual has the right to what happens to their body, if they wish to have a certain treatment then it should be provided. I see no reason why the person should not have the right to refuse treatments when fully aware of the consequences and having presented a level of understanding of this to their doctors. It is after all the patient's body and life that will be affected, and who other than the patient themselves should have authority over this?

By law a patient can refuse treatment if this will affect nobody but the patient themselves, John Stuart Mill supports in his famous 'harm principle' which states that,:- 'the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others.'¹⁸

However allowing full autonomy in regards to medical treatment could have serious consequences ethically. Perhaps in certain circumstances a medical professional, with best interests in the patient's health, supreme medical knowledge and experience could and should override patient's decisions. Only in the past century have we seen a move away from a 'doctor knows best' approach to medicine. It is in the doctor's best interest to do what is right for the patient and it is also the doctor who has the knowledge of the patient's condition, the available treatments and the consequences. He may transmit much of this information to the patient, as required to ensure the patient is fully informed. However, the patient can never be on the same level in terms of experience, so perhaps the doctor should have a greater say in their patient's treatment, as had previously been the case throughout the history of the practice of medicine.

However regarding the founding principles of consent, autonomy and beneficence, making the doctor most important in the decision process regarding patient care causes problems. As will be explored later in this essay, medical cure, although medically may be best for the patient it may not present the best solution overall. Although a doctor has the supreme medical knowledge and experience, to put themselves in the patient's position and understand their situation fully is impossible. Who other than the patient ultimately has a right over the treatment their body receives? Although sometimes difficult to comprehend patient's refusal of treatment autonomy must be respected as a basic yet vital patient right.

Utilitarianism

Utilitarianism is the idea that an action can be justified if it is for the greater good. The argument that an action is for the greater good is often used when overriding autonomy. Utilitarianism encourages judgement of ethical situations in terms of what promotes the

¹⁸ Mill, J.S (1859) *On Liberty*, Penguin, London, 1984 ,p68

This is John Stuart Mill's own writings and therefore the quotes regarding his thoughts I have used are accurate.

greatest good for the greatest number of people, it does not focus on individual needs and it is concern for the individual that forms the basis of autonomy. The right to choice often does not result in positive benefit for the largest number of people, as it will often have a negative impact on others connected to the person involved.

Mentioned earlier in this essay was the case of a Jehovah Witness woman who died after refusing a blood transfusion whilst in labour. Had doctors gone against her wishes and invalidated her lack of consent this would have not only saved her life but prevented a grieving husband from bringing up a daughter single handed. Although the patient's prior wishes were ignored and therefore her autonomy not given, such an action would have benefited the lives of both husband and daughter and so could be seen as an overall benefit; the lesser of two evils. In such a situation a doctor is not only faced with a moral dilemma but an economic one too; providing alternative treatments is both costly and time consuming and creates unnecessary difficulty for those providing care for the patient.

There are indeed problems with a utilitarian approach; there are many different factors that need to be considered, particularly in the realms of consent. This weakness to utilitarian thought does not make it practical to then apply it to consent, due to its reliance on the ability to weigh out different consequences with clarity and ease.

For the greater good?

The foundations of medicine are that a doctor does what is best for their patient. Some patient's beliefs and desires are so far removed from that of the healthcare professional that actions are forced upon that patient which although they may help medically, psychologically they do not. Surely the mental wellbeing of a person is at least equal if not *more* important than physical, unfortunately it is very hard to accept and understand viewpoints so diverse from our own. One of the arguments for the justification of lack of consent was that a Jehovah's Witness mother should have been legally forced a blood transfusion during her caesarean in order that she could have remained alive to bring up her daughter, instead of leaving that responsibility with her grieving, widower husband. On the surface this appears preferable. However mentally what would the impact of such actions be? If she had believed so strongly in the sin that surrounded accepting transfused blood, then to have had her body accept what in her eyes was an impure substance, and sinful in practice would have had enormous effects psychologically. She herself would have also been shunned by the rest of

her religious community, who are infamous for such behaviour, and her husband, also a follower of the religion would no doubt treat her in a different light. Would *he* want to live with a woman whose body had been tainted with a substance whose presence is one of sin? It was a terrible situation her husband found himself in, but grief is transient. For the child to be bought up in a single parent family – until, and indeed if the father finds a new partner – is not an unusual predicament, arguably far more healthy than an upbringing in a family shunned by fanatical followers of a Christian sub – sect. Too often do we treat a situation, understandably as if it were our own, but in any medical context there are far more things to consider than just a patient's physical health.

Utilitarianism thus presents the problem of a slippery slope; it is very hard to draw a line at whether something can be done for the greater good. This is because, as seen from the example above, the ability to assess and measure ethics in practical and simple ways is problematic. Moreover, if we were simply to carry out actions 'for the greater good' the focus would shift towards overall benefits and immoral actions overlooked and ignored. As expressed above, what we sometimes deem is for the greater good is entirely the opposite in regard to the patient. In a short article in the Times titled '*Some decisions are too important to be left to medics*', written by consultant anaesthetist Andrew Hartle, chairman of the clinical ethics committee at Imperial College Healthcare Trust, the point is made that,

'Some decisions are too important to be left to the doctors. We are highly trained and skilled but we may have a different view of things, perhaps because we are too close to it. You have to respect patients' autonomy. As long as the decision is genuine, informed and entirely voluntary, then you should go with it.'¹⁹

Utilitarianism has been shown counter to autonomy in its focus on gain for the overall population and not the individual. Ironically however, it could be seen to support the idea of autonomy, by the very denial of autonomy in the first place. If, adhering to utilitarianism frameworks healthcare professionals were to constantly overrule patient autonomy, arguably for the greater good, a knock on effect of mass decrease in population satisfaction may occur, as a result of people in fear of what could happen to their own bodies despite their desires.

¹⁹ Hartle, A (2009) '*Some decisions are too important to be left to medics*', *The Times*

The information expressed is of a personal nature and is presented in the essay as an opinion on the topic of autonomy. Hartle is a consultant doctor and as a member of an ethics committee is therefore in a very appropriate position to comment on this subject.

This therefore invalidates utilitarianism as a justification of denial of patient consent by default.

Exceptional Case

Currently autonomy has great focus within medicine, however children and the mentally ill are not deemed capable to decide for themselves, instead a family member is granted this responsibility. I see such situations as this as ones which perhaps could give rise to exceptional circumstances under which it could be ethically superior for healthcare professionals to disregard the views of the patient's family. A thought experiment to explain this could be if the parents of a child refused to give consent for a treatment for their child on the grounds of their own religious faith. The parents legally are responsible for providing consent on behalf of their child, however surely if the child is not mentally mature enough to be considered able to give his or her consent they are also not mature enough to choose to belong to this religion in the first place. If a child cannot be seen fit to decide for themselves on medical grounds what difference is there in their choice of religious beliefs? It is contradictory of the parents to provide consent on behalf of their child when they are based on religious views which their child technically could not have the authority to hold themselves. It therefore follows that their parents should not be able to prevent their child from accepting a treatment based on religious grounds as it is not in the patient's best interest as the decision is influenced by parental, rather than patient beliefs. As the refusal of treatment will result in harm of the child then the denial of consent should be in this case overridden.

Another example of an exception case could be when a woman refuses to have a Caesarean, a choice will affect her child's life. It is not uncommon for doctors to perform Caesarean sections on women despite their objections; an example of this was described to a graphic degree in the Times;

A Nigerian woman expecting triplets...taken to hospital... [in] the final stages of her pregnancy, repeatedly said she was unwilling to have a caesarean. The hospital obtained a court order once she had gone into labour. When both parents were

informed ... they objected strenuously. The woman was put in leather restraints and her husband ejected from the hospital.²⁰

For a woman to refuse Caesarean puts her unborn child at severe and most certainly lethal risk. There is added complexity in this situation in that the child is yet to be born. Arguments on the topic of abortion show the mixed views scientists and the public as a whole have about ending the life of unborn children and whether or not this amounts to murder. It is interesting to observe that, 'While it is considered acceptable for an unborn child to be killed (aborted) if mother and doctor agree...it is not regarded as acceptable that an unborn child be allowed to die if its birth would require medical intervention of a kind unacceptable to the mother'²¹.

This is something that Mill's harm principal would object to.

Although patient autonomy is being disregarded, I believe this is a situation with exceptions due to a number of circumstances. The process of labour is both emotionally and physically, stressful, the patient may not be of the right mind set to decide on her treatment, in other words she could be seen as not mentally capable to make decisions at this time. Normally where mental capacity is questioned it is seen as ethically right for doctors to take actions as they see fit. The doctor may also not have *time* to fulfil the requirement of *informed* consent in regards to letting the patient know what their refusal of treatment will result in. Most importantly this situation differs to that of a patient refusing treatment for themselves only, such as the Jehovah's Witness blood transfusion, because the action does not hold consequences for the patient alone, but also her child. Intervention in this instance is supported by Mill's harm principle that 'the only purpose for which power can be rightfully exercised over any member of a civilized community... is to prevent harm to others.' (Mill, 1859)

²⁰ **The Times, 7 October 1992, quoted in Tassano, F. (1999) *The Power of Life or Death*, Oxford Forum, Oxford, Ch 9, p.121**

²¹ **Tassano, F. (1999) *The Power of Life or Death*, Oxford Forum, Oxford, Ch 9, p.136**

This book is written for those with a general interest in involuntary treatment and non- treatment and the surrounding ethics and issues, it has been praised by reputable publications such as the BMJ and Nature and this suggests it is a reliable source.

Relativism

This response to the question posed by this essay so far, that *sometimes* lack of consent could be more ethical, adheres to the relativist framework. This is the rejection of the idea that one rule can govern every situation; instead supporting that actions should be tailored accordingly. I feel that a relativist way of thinking must be applied to consent. Logically this does appear the more sensible option; tailoring rules for every situation seems rational considering events are never the same twice. Consent is such a broad topic and events that arise from it are not in black and white, so why should our laws be? The philosopher Nietzsche is a firm supporter of this; ‘Anyone who still judges “in this case everybody would have to act like this” has not yet taken five steps toward self knowledge.’²²

Absolutism

The flip-side to the relative argument is absolutism. The idea behind this set down a firm rule, always applicable to every example of the instance it describes; lack of medical consent can never be justified, or it always can. Relativism as an ideal does work, but in reality it would be incredibly impractical. Society could not function on laws that were not fixed; the consequences of laws on consent with ill defined boundaries would make medical practice for doctors impossible. Decision making for doctors and patients would be far more difficult not knowing where lines lie and the legal system would explode with cases surrounding consent. There are disadvantages to absolutism; the idea that a universal law can hold in all situations intensely over simplifies matters and fails to do justice to the complex nature of certain situations.

The counter argument above does appear to squash the credibility of the relativist response to the question, but then does absolutism provide a viable alternative? I do not believe it does. The idea that a universal law can hold in all situations intensely over simplifies matters and fails to do justice to the complex nature of certain situations. Although practically relativist views pose many problems, an absolutist approach is less ethically sound. Relativism may

²² F. Nietzsche (1887) *The Gay Science*, W. Kaufmann (trans); Vintage Books, Random House, New York, 1974

This is a published translation of Nietzsche’s *Gay Science*, for it to have been published the translation would have had to be approved and made sure of its accuracy.

not be perfect but is better than absolutism. Indeed the exceptional cases show that absolutism would be an unwise and narrow minded route to take. Moreover, in this essay consent has been split into two themes; consent in medical treatment and consent in medical experimentation. This again shows that different considerations need to be made for consent, something absolutism does not allow.

Medical Experimentation

To this point the essay has dealt with matters of consent concerning medical treatment, I believe this to be an issue which should be viewed in a context separated entirely from that of consent in medical research. I aim to examine the arguments for and against justification of lack of consent in medical research. Medical experimentation does not fall into the 'exceptional cases' of medical treatment because the concern is not that of the patient making decisions that harm others, but not allowing patients the knowledge over what is happening to their bodies or the power to object to it. The importance of autonomy is strongly supported when investigating medical experimentation because it is fundamental in arguing that lack of consent in this instance can never be justified despite any benefits in the end.

Knowledge and progression

Human experimentation is infamously associated with Nazi doctors; much to the advantage of other nations who too have disregarded moral and ethical conduct in pursuit of knowledge, but have allowed their own misdemeanours to fall into darkness behind the much publicised Nazi atrocities.

However, it has never been doubted that the Nazi doctor's actions were a severe breach of human rights and moral medical practice. The length to which they took their investigations, be it inconceivable to the ethically and morally aware society we are part of, can, one would hope, never be replicated. The results of such research therefore will never be gained, and here ends the progression of human knowledge in set field. This creates a dilemma; our concerns for ethics and morals have created a barrier preventing human knowledge and progression. The lack of medical consent within medical research has seen discoveries which are used for positive benefit and many such discoveries may have not been possible without the use of human subjects. Nietzsche stated that we allow our concerns for morality to interfere with our own race's progression and knowledge. Only if we disregard our moral obligations will we be fully able to partake in research and discovery which could ultimately help us as a species.

Nietzsche puts forward the valid point - that our progression as a race is hindered by our regard for morals, more specifically *established* morals. Nietzsche stresses that we should not

assume one way of thinking in regard to morals simply because we are told, but instead we should strive to determine for ourselves what is right and wrong. The philosopher Immanuel Kant however believes that man should 'never [be used] as a means only'²³. Disregarding our morals would be an incredibly dangerous route to take; we cannot waste human lives merely for progression of human knowledge. How far can we go in order to progress as a race, if we were to accept this way of thinking? If we did not allow morals to interfere with medical research and research in general we may on one hand progress our race in terms of our scientific understanding and knowledge but we would back step generations in human rights. When 'civilised' cultures compare themselves to primitive ones lack of regard for human rights and barbarity are often the grounds most often cited, and usually the example used to charter our progression socially.

The context of person

The Nazi's saw no wrong in their actions because they were carrying out their experiments on people who they saw as second class, non human, citizens. The Nazis did not believe they had any right to object to their treatment, or whether there was anything wrong with the treatment they were being given.

Today certain people are denied consent, for example children and the mentally ill. If it is ok to disregard the wishes and views of such people then would it be such a great leap to treat criminals or those condemned to death similarly? Many of the Nazi research subjects were those condemned to death, it could be said that there was no harm in such actions as they were on route to death anyway. Their actions have earned them punishment, but what if this punishment could benefit future generations of law abiding human beings. Providing punishment in the form of loss of human right and providing scientific advancement would be killing two birds with one stone, a prime example of utilitarianism thinking. But what gives one man the right to carry out inhumane actions on another? The argument that they have committed crimes so terrible that they deserve it does not think justify this. To treat a person in such a way would be entirely contradictory and would to de-humanise both victim

²³ **I. Kant, (1785) 'Fundamental Principles of the Metaphysic of Morals', reprinting in B. Mackinnon Ethics, Wadsworth, 2001**

This book features the direct writings of Immanuel Kant and therefore is entirely accurate when wanting to show the views of Kant.

and perpetrator. To do this to a person, to deny them dignity regardless of actions they may have taken would only bring the perpetrator down to the condemned person's level.

Use of data

The argument put forward for not gaining consent in regards to medical research is that ultimately it could be used to benefit the lives of a great number of people. But I do not believe, however great the benefits, that research on unwitting subjects can be justified. To perform such actions on another human being takes away the humanity of the perpetrators. There are no circumstances that give one man the right to take out such actions on another. Using such data could be seen as justifying the actions taken to gain it, showing a severe lack of respect and consequential desecration for the memories of the victims of the research, giving the actions of those who carried it out purpose. Focus would shift to the benefits of the data rather than the unethical way in which it was gained.

This would not have been the outcome if the data was cited and used responsibly, use of data does not have to go hand in hand with justifying the experiments. To use data gained in unethical circumstances gives meaning and purpose to those who suffered. If noted as being gained in such a way I think that it should be used, to not use the results would be putting waste to the pain and suffering those who endured the sadistic actions of their 'doctors'. However it should be made clear that this statement in no way justifies the initial experiments themselves, but gives use and purpose to their findings.

By doing this we are not vandalizing the memories of those who had to participate in these experiments, but instead we are appreciating the pain and suffering they went through in order to progress human knowledge and increase our understanding of the human body, which in turn will benefit our healthcare.

Under no circumstances can lack of medical consent be justified for medical research, no matter the gain at the end. To violate patient rights, using them as a research means, without permission is classed as assault and goes against basic ethical and moral code. Autonomy is a basic human right; there is no instance in which overruling that for scientific gain could be seen as ethically appropriate. Other methods will have to be taken to gain such results.

The use of results already gained in this way should be treated as a different matter. If used correctly they do not justify the research itself, but give purpose to those who unwittingly took part in the research and suffered as a result.

Ultimately decisions on patient care should rest with the patient as long as they are fully aware of the treatments available and the consequences of accepting and refusing them, and of a mental capacity to understand them.

Healthcare professionals need to understand and accept that what is best for the patient is often what the patient believes is best, not simply an improvement in medical health. Again providing they are mentally capable of such decisions and at an age where law deems them mature enough to decide for themselves. An instance in which I believe doctors should be able to override their patient's decisions is in the case of parents choosing for their children, in a literal context or indirectly by refusal of a caesarean. A child who is seen as too immature to decide for themselves in terms of consent should surely not have extreme denials of treatment forced upon them by their parents purely because of their own beliefs. In such cases I believe it is up to the healthcare professionals and the legal services to decide on behalf of the child putting their best interests, and not that of the parents, first.

Consent encompasses a vast range of issues each requiring individual investigation, an overall absolutist view on constant is illogical and inappropriate. Views on consent have changed with time and this is a reason why investigation such as that carried out in this essay is necessary in order to maintain levels of upmost ethical appropriateness within healthcare and scientific experimentation.

Conclusion

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It would have been unwise from the outset to assume that I would have come to an absolute answer to my research question due to the vast range of issues and situations medical consent concerns. Autonomy, the right to choose for what happens to ourselves is now seen as the very basic of human rights. Medical actions, even in research, that oppose this right can therefore never be justified, save for a very few exceptions. Not only does this view benefit the patient but also doctors and the legal system, giving them logical laws to abide to and work with. Relativism is key here in assessing the differing nature of various events and circumstances which allow such a conclusion to be reached. The right to choice, is that who other than the individual themselves should choose what happens to their own body, however if their choices affect someone else, to the extent of harming them then autonomy is no longer ethically and morally right. It is in instances where this is the case the justification of lack of medical consent can occur.

The project has allowed me to explore to a great depth a topic not only of great interest to me, but one that will bear great important during my future as a medical practitioner. I have gained knowledge not simply of the laws and practices of consent, but the reasoning and history behind them. This strengthens my belief and understanding that movement away from paternal medicine has advantageous. By fully showing the counter arguments to my beliefs, however strong, it has allowed me to construct an even more powerful response, thereby strengthening my initial argument and by using not only my own thoughts, but those of renowned philosophers gives greater weight to these arguments. The need for a well planned layout, to make full benefit of the points expressed within an essay has become clear whilst writing my discussion.

During the research I referred to books of many kinds, from autobiographical accounts of the Nazi war trials to guides aimed at practicing healthcare professionals. The importance to analyse and assess not only the information presented in the source but the credibility of the author has become apparent, most particularly when using information sourced from the internet. A topic like consent can provoke strong viewpoints, and with no limits or restrictions as to what can be posted online the ability to access the validity of a source is of great importance.

Consent offers almost endless examples to be investigated; in this project I barely scrape the surface, the project could be extended to no end to encompass these, however this would of course not be at all practical. Because I cover a broad basis in the essay, examples of medical experimentation have been limited to that of the Nazis, this is no bad thing, as the Nuremberg trials played a very important role in the development of informed consent, but I would have liked to extend my investigation to other nations.

The project could be extended to look more closely at the exceptional cases I have drawn up, such as the questions surrounding the refusal of the caesarean, extending this to discussions over what rights an unborn person should and could have. Looking at the reasoning for autonomy; whether we *are* autonomous people who have complete control over what happens to our bodies and whether we should always have a say in what happens to us. In doing so greater strength could be added to the conclusion of why, particularly in medical research lack of medical consent can never be justified.

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Project Proposal Form

Level 3 Project Proposal Form for <i>Unit 1: Dissertation</i> .	Learner name :
Centre name :	
Tutor-assessor name :	
Proposed title of project : Can the lack of medical consent ever be justified?	
Date : 24 September 2008	

Section One: Title, objectives, responsibilities

Title or working title of project (in the form of a question) :
Can the lack of medical consent ever be justified?

Project objectives (eg, what is the question you want to answer? What do you want to learn how to do? What do you want find out?)

The ethics surrounding the subjects to be tackled are in some cases fairly obvious. Medical war crimes are an ethical disaster. However have they actually turned out to benefit human kind and if so could the experiments, however incomprehensible result in something positive and beneficial?

The ethics surrounding contemporary cases of consent are more open to discussion. I would like to address the question of whether we should go to great lengths to provide for medical patients who for certain reasons cannot consent to regular medical treatment.

I would also like to define consent and the variations of it in certain circumstances. And look at the nature of consent, whether we can simply restrict it to putting a name on form.

Looking at the Nazi's ideology I would like to explore the views of philosopher Hannah Arendt and also discuss whether we are autonomous people who have complete control over what happens to our bodies and whether we should always have a say in what happens to us, the belief of this may well have convinced the Nazi's that there was nothing wrong with their actions.

Section Two: Reasons for choosing this project

Reasons for choosing the project (eg links to other subjects you are studying, personal interest, future plans, knowledge/skills you want to improve, why the topic is important):

My original reasoning for looking at the theme of medical consent was due to first hand viewing of a controversial example of consent in clinical practice. On a work experience placement in a large teaching hospital, whilst shadowing an anaesthetist we came across a patient who was going in for kidney related surgery, however due to her religious beliefs- she was a Jehovah Witness, she would not accept blood transfusions if needed during her surgery. I found this fascinating, in particular the lack of knowledge she appeared to have as to the various consequences of such a decision. It also made me think, observing the great deal of effort the doctors and nurses needed to fulfil this request whether or not medical consent in this instance is ethically correct. When researching about medical consent, having already decided on exploring the topic, I came across the book *Nazi Medicine and the Nuremberg Trial*, written by Paul Julian Weindling. This takes an in-depth look at the lack of informed consent given to the Nazi prisoners subjected to medical research during the second world war. Obviously there are fairly obvious ethical implications concerning the way the Nazi doctors carried out their medical research, and much of the research is seen to be entirely useless. However I wish to explore the subject deeper, broadening to other nations and their similar methods of experimentation on oblivious or unwilling subjects to see whether, perhaps benefits did arise from this horrific means of medical advancement.

I also want to explore the way such events have influenced the laws of consent used today, and looking at the laws themselves talk about the advantages, disadvantages of them. Like Jehovah Witnesses, there are other groups of people whom require specific concerns when dealing with consent, such as those who belong to certain religions, patients who are brain dead and also children. I want to discuss the conditions surrounding these social subgroups and also address the question 'should we provide specialist medical care for these people simply because of their personal beliefs?'

My intention is to pursue a career in medicine, and I am aware that during my career I will come across problems such as those above, particularly living in both a multi-faith society and one where everybody expects strongly to have high quality, and of course free, medical care. Doctors are increasingly practicing 'defensive medicine' and I realise that this will no doubt become more important during my own medical career.

Section Three: Activities and timescales

Activities to be carried out during the project (eg, research, analysis, writing, preparing for the presentation, etc) :	How long will this take?
<p>Project planning, completion of proposal forms</p> <p>Start to seek out relevant research in preparation for the literature review, gain basic and broad knowledge of consent. Prepare by seeking out relevant articles and books.</p>	1 week
<p>Mini Literature Review</p> <p>Write review of three sources related to title, in a narrative fashion.</p>	1 week
<p>Main literature review</p> <p>Expand on mini literature review, writing in a narrative fashion using many sources from many different origins to give an overview of consent, opening up opportunities for arguments later on in the project.</p>	4 weeks
<p>Discussion</p> <p>Embark on formulation of own opinion regarding the research question, using philosophical frameworks as well as further sources to support and counter my arguments.</p>	9 weeks
<p>Introduction, Abstract, Conclusion</p> <p>Use what has been written in the discussion and literature reviews to write these summary sections.</p>	1 week
<p>Bibliography and Final Revisions</p> <p>Assess the validity of the sources, proof read project and create bibliography.</p>	<p>Source analysis will be occurring throughout the writing process</p> <p>Final revisions will be done in the final week of writing, as will the bibliography</p>
<p>Oral Presentation</p> <ul style="list-style-type: none"> • Plan what will be included • Make Powerpoint slideshow • Plan what to say 	1 week
<p>Milestone one: Complete first draft of literature review <u>Target date (set by tutor-assessor): 4 Nov 2008</u> Milestone two: Complete first draft of discussion <u>Target date (set by tutor-assessor): 1 Dec 2008</u></p>	

Section Four: Resources

What resources will you need for your research, write up and presentation (eg libraries, books, journals, equipment)

I have bought various books of my own in relation to the project, as well as making use of the resources available from the school library. I already subscribe to the *studentBJM* journal and so will be looking out for any relevant articles. As far as articles go I will be using online archives such as JStore, and websites of the BMJ which keep a store of all published articles. My topic is one which is often in the news and so I expect that I will have a relatively large amount of sources from both newspapers and news published on the internet from newspaper websites and from large corporations such as the BBC.

What you areas of research will you cover?

The development and progression of decision making within medicine. The principals behind consent. The issues that have arisen surrounding modern day understandings of consent. What experiments have been taken out on humans without their consent - was anything gained from these? What laws are involved regarding a patient's refusal of medical treatment. What philosophical frameworks can be applied to consent?

Activity Log

September	
Progress	<ul style="list-style-type: none"> • I have had the idea of medical consent in mind for a while, browsing Amazon I came across the book '<i>Nazi Medicine and the Nuremberg Trials</i>' which I have now bought. • Am thinking about pursuing the project focusing on consent concerning unethical medical research.
	<ul style="list-style-type: none"> • Have begun to write research proposal up, specifically about why consent interests me.
	<ul style="list-style-type: none"> • Have started on the Literature review, looking at a source discussing whether Nazi data should be used which I found on JStore.
Plans/Ideas	<ul style="list-style-type: none"> • Find out more about what went on in the experiments, if they yielded any useful results.
Sources and Reading	<p>Weindling P (2004) <i>Nazi Medicine and the Nuremberg Trials</i>, Palgrave Macmillian Sheldon M. et al. (1989), Nazi Data: Dissociation from Evil. <i>The Hastings Centre Report</i>, Vol 15, No. 4, pp.16-18</p>
October	
Progress	<ul style="list-style-type: none"> • Reading <i>Nazi Medicine and the Nuremberg Trials</i> I have discovered how fundamental the Nazi medical experiments, and the investigations of them carried out at the Nuremberg Trials, were in terms of setting out contemporary laws on medical consent. • It has been difficult to obtain information of the experiments themselves-something I wanted to do so that I was able to see whether the arguments that all the Nazi research resulted in nothing of any medical/scientific use were actually valid or merely tainted by people's moral bias.
	<ul style="list-style-type: none"> • I have bought another book - <i>Doctors from Hell</i>. This has been written by a court scribe present during the Nuremberg Trials and is proving invaluable in explaining what the Nazi research actually entailed.
	<ul style="list-style-type: none"> • Have started to include the chapter about Nazi freezing experiments into my literature review
	<ul style="list-style-type: none"> • I have added information about the history of consent to my literature review, showing how important the Nazi medical experiments were in forming ideas of <i>informed</i> consent.
	<ul style="list-style-type: none"> • I want to understand more about the current laws on consent, I have bought, yet another, book – <i>Consent in clinical practice</i>, which is a guide book aimed at healthcare professionals outlining the current laws on consent as well as the principals behind it
Plans/ideas	<ul style="list-style-type: none"> • What is the current procedure with carrying out human experiments? – how much are they told, what are they consenting to do? • Look at the TGN 1412 drug trial (2006) that went wrong →if the experimental subjects had consented why were they rewarded such large amounts of compensation...what had they consented to? • How has the idea of consent changed throughout history? • Have we got a right over our bodies? – choice over treatment, state

	<p>control over our bodies ect.</p> <ul style="list-style-type: none"> • The laws and regulations on consent; look at age, mental limits • How do we class people as being able to make decisions for themselves...should we?
Sources and Reading	<p>Beckerman, N. <i>Informed Consent</i> [online] <i>The Encyclopaedia of Death and Dying</i>. Available from: http://www.deathreference.com/Ho-Ka/Informed-Consent.html [accessed 17 October 2008]</p> <p>Kiefer, J. <i>The History and Importance of Informed Consent in Clinical Trials</i> [online] Available from: http://serendip.brynmawr.edu/biology/b103/f01/web2/kiefer.html [17/10/08]</p> <p>Spitz V. (2005) <i>Doctors from Hell, The Horrific Account of Nazi Experiments on Humans</i>, Sentient Publications</p> <p>Donnelly, M (2002) <i>Consent: Bridging the Gap between Doctor and Patient</i>, Cork University Press, Cork</p>
December	
Progress	<ul style="list-style-type: none"> • Have completed first draft of literature review. The consent in clinical practice has been really useful in helping write this. • Having read more into the history of consent I have decided to broaden my project to looking at medical consent not just within medical research but as an overall theme within medicine.
	<ul style="list-style-type: none"> • I have decided to draw upon personal experience, of seeing a Jehovah Witness refuse a blood transfusion during my work experience, to explore examples within medicine when patients refuse to give consent to things such as blood transfusions.
	<ul style="list-style-type: none"> • I have decided to look at the Hannah Jones case recently in the news – the 13 year old has been given permission by the courts to refuse to have a life saving heart transplant • I have also looked at the case that occurred a few years ago, when a J.W woman in labour refused to have a blood transfusion which caused her to die.
Plans/ideas	<ul style="list-style-type: none"> • Having finished writing my literature review I am going to start thinking about my discussion, I need to look at philosophical ideas that can apply to my topic. For example Nietzsche's thoughts on our morality blocking the progress of human knowledge. I also want to look at Kant's thoughts on how people should not just be used as a means to find out something – both these can be used when talking about whether or not lack of consent within research can be justified • I plan to explore the importance for autonomy and whether doctors should be able to overrule it. • To read more about other examples of lack of consent other than the Nazi research.
Sources and Reading	<p>Pavia, W. (2007) <i>Jehovah's Witness mother dies after refusing blood</i> [online]. Available from: http://www.timesonline.co.uk/tol/news/uk/article2809423.ece [27/11/08]</p> <p>De Bruxelles, S. (2008) <i>I'll take my chances, says Hannah Jones after refusing heart swap</i>. The Times, London. Available from: http://www.timesonline.co.uk/tol/life_and_style/health/article5134048.ece [27/11/08]</p>
January	
Progress	<ul style="list-style-type: none"> • Am writing the discussion, with the view that lack of medical consent can be justified • Outlining situations such as that of the Jehovah's Witness mother, using utilitarianism to explain why doctors should have overridden her decisions

	<ul style="list-style-type: none"> Used Nietzsche's arguments for concern of morals blocking human progress in favour of medical research, counter this with Kant's beliefs that people should not be used simply as a means to a gain.
	<ul style="list-style-type: none"> I have changed my views in regards to the importance for autonomy. Originally I thought, and had been arguing that the J.W. mother should have had her wishes overruled by medical practitioners as, applying utilitarianism thinking, this would have had a greater overall benefit. However I have been writing and reading about the importance of patient autonomy which has made me more in support of allowing her to have her own decision. Also I think because I have looked into the situation more closely, I have come to realise that actually by intervening this may not be the best solution at all – actually it may be damaging mentally for the patient, therefore harming the child's upbringing This had led to talk about the importance not only of medical and physical health but also importance of doing what is best for the patient mentally.
	<ul style="list-style-type: none"> Have looked at J.S.M's Harm Principal in terms of when consent could be overruled.
	<ul style="list-style-type: none"> Have come across the book 'The Power of Life and Death' – if only I'd come across this book at the start of the project, it would have made things a lot easier! It describes an interesting case in which a woman was forced to have a caesarean when she had refused to give consent for it...
	<ul style="list-style-type: none"> I have deleted a section of the lit review – it was too long anyway – about whether or not Nazi data should be used (various people's views on this topic) I have decided this is something I can just integrate into the project as a whole, it does not need to be a separate thing.
Plans/Ideas	<ul style="list-style-type: none"> Finish off discussion and come to a conclusion
Sources and Reading	<p>F. Nietzsche (1887) <i>The Gay Science</i> W. Kaufmann (trans); Vintage Books, Random House, New York, 1974</p> <p>Mill, J.S (1859) <i>On Liberty</i>, Penguin, London, 1984</p> <p>Tassano, F. (1999) <i>The Power of Life or Death</i>, Oxford Forum, Oxford</p>
February	
Progress	<ul style="list-style-type: none"> Have changed focus with discussion, proposing that lack of medical consent can never be justified save for a few minor exceptions. Have changed my views about when doctors should intervene. Whereas before I believed they should in the case of the J.W mother because ultimately it would save her live, looking into it deeper it is apparent that this would not result in a positive; the woman would be shunned from her society etc. → Ultimately it is the patient's life and body and therefore why should others be able to make decisions over it? This view has been further enforced by reading Andrew Hartle's short article in The Times. The exception I have come up with is when parents have to act on behalf of their child. If their own radical views cause them to take actions which will end up harming the patient then doctors should be able to override these views in the best interests of the child. The book <i>The Power of Life or Death</i> has brought to my attention another situation which could be an exception, that of women in labour refusing C-sections...this will cause harm to the child and therefore lack of consent could be justified as supported by John Stuart Mill's harm principal. I have also split the discussion up into two separate categories – consent in medical treatment and consent in medical experimentation – hopefully this will highlight the need for a relativist approach to consent in the very separation of these.
Plans/Ideas	To finish the project!

	Tassano, F. (1999) <i>The Power of Life or Death</i> , Oxford Forum, Oxford Andrew Hartle, 'Some decisions are too important to be left to medics', <i>The Times</i> , 3 March 2009
March	
Progress	<ul style="list-style-type: none"> • Am writing intro, conclusion and abstract after making changes to the draft of my discussion and lit review • Have handed in this first 'final draft' of my project
Plans	To finish project and start on presentation
April	
Progress	<ul style="list-style-type: none"> • Have received the reviewed draft back and have started making amends to this. • Have started on presentation • Have booked a date for practice presentation, and have general idea of what to say, far too much for the 10 minute slot but this can be cut down • After the practice – the Powerpoint is fine, although the whole thing is too long, have decided to scrap the slide about medical experiments; it just seems to stick randomly on the end. Also have got rid of slide about utilitarianism which although quite a big part of the discussion wasn't needed in the talk • I have started writing a script of what to say as I rambled far too much in the practice, this will hopefully condense it • The real presentation has been done, it went fine, although the questions were pretty tricky and I didn't really know what to expect apart from the 'what changes have occurred in your project' one • Have proof read the project, made sure all sources have been appraised and made a bibliography, title page ect.

Presentation Slides

1

can the lack of medical consent ever be justified?

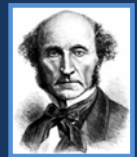
4

Autonomy

- Who other than the patient has the right to decide?



- John Stuart Mill's 'Harm Principle'



2

Informed Consent

'an autonomous authorization by an individual regarding a medical intervention or involvement in biomedical research.'

Crucial elements of Informed Consent:

Voluntariness

Capacity

Knowledge



5

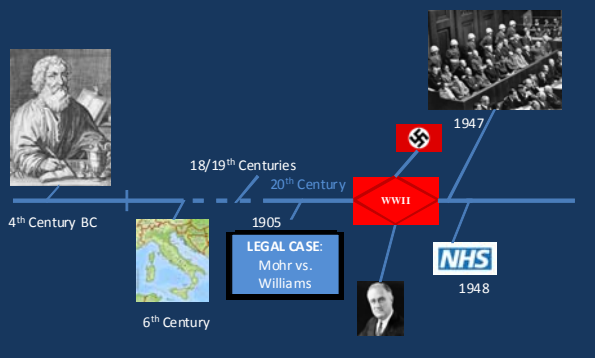
Exceptional Cases

Thought experiment
The parents of a child refuse to give consent for a treatment for their child on the grounds of their own religious faith



3

History of Consent



6

Exceptional Cases

Thought experiment
A pregnant woman refuses to have a caesarean vital for maintaining both her own life, and that of her unborn child



7

Relativism
vs.
Absolutism

8

can the lack of
medical consent
ever be justified?

Candidate Record Sheet

Learner Name	_____	Learner number	_____
Centre Name	_____	Centre Number	_____
Unit Name	<u>Perspectives on Science Extended Project</u>	Unit Number	_____

A form should be completed for each candidate and submitted with the work for moderation.

Project checklist

The final Project should include the following items:

- a Project Proposal Form
- a Project activity log or diary
- records of research carried out (which could be included within the project outcome or given separately)
- the Project Outcome*
- an evaluation
- evidence of the presentation

Project Contents

Please list the format of the items submitted as part of the Project, note whether this evidence is shared with other candidates and if so who (A4 Report, portfolio, sketchbook, CD of sound track, DVD of play/film, video, etc)

A4 Report

Authentication confirmation/consent

Candidate: I hereby certify to the best of my knowledge that this work:

- has been produced without any assistance beyond that recorded and allowed by the scheme of assessment.
- is not work which has been or will be submitted for another qualification.

I also agree to my coursework being used to support Professional Development, Online Support and Training of both Centre-Assessors and Edexcel Moderators.

Signature:

Teacher: I confirm that the learner's work was conducted under the conditions laid out by the specification. I have authenticated the learner's work and am satisfied that to the best of my knowledge the work produced is:

- solely that of the learner
- is not work that has been or will be submitted for another qualification.

Signature:

Print Name *in block capitals please:*

