INFORMED CONSENT – JUSTIFICATION AND PROBLEMS

[1] Any principle of the requirement for informed consent to medical research and treatment must be restricted in its scope to those who have and exhibit the requisite capacity to give and withhold consent.

The most important way in which this is done is by fixing an age of consent. In the UK this is 16. Below that age a minor has no moral power to give or withhold consent; above it full power.

[2] Problems with use of an age of consent

(A) Standard problem of where to fix the age, and also charge of arbitrariness at using age as a marker for competence

(B) Recognition that any age might be a defeasible presumption of incompetence can bring its own problems. Gillick is the classic legal case and benchmark for such recognition: as defined by Lord Scarman ‘the parental right to determine whether or not their minor child below the age of sixteen will have medical treatment terminates if and when the child achieves sufficient understanding and intelligence to understand fully what is proposed.’

Yet in its practical interpretation in the UK there was in subsequent legal cases a ‘retreat’: (a) parental consent not removed and could still trump even a matures minor’s consent; (b) a mature minor’s refusal of life saving or extending treatment was trumped by best interests (and especially value of life)

How to determine incapacity if not by simple age? Important principle in UK Mental Capacity Act [2005]: ‘A person is not to be treated as unable to make a decision merely because he makes an unwise decision’ (1 [4]). This principle should be
endorsed. Any assessment of a person’s capacity to consent should be made independently of an evaluation of the prudence of her choices.

Yet surely one critical evidential support for incapacity is the imprudence of a decision in respect of some particular matter. And yet – in response – in respect of adults where there is a general presumption of competence, the imprudence of a particular decision is not allowed to serve as a reason to defeat that presumption.

[3] Consent v informed consent

We might distinguish between consent *simpliciter* where there is a failure (*lack of consent*) if the person is completely ignorant that an action is being done to her. Someone does not even know that something is done

And cases of *deficient* consent where there is a lack of relevant information: person (patient) knows that a medical procedure is being performed but does not know enough about that procedure to give full consent.

What is the clinician obligated to inform the patient?

The plausible initial thought is that if the patient is not informed of something that would make a difference to the giving and withholding of consent then that information is material and relevant to the consent. The consent is not informed if that information is withheld or not known.

Thus, if a patient is not told that an operation carries with it a substantial risk – say of resultant disability – then her consent to the surgery is not informed. Had she known of that risk she would not have agreed to the surgery.

[4] Obligation to inform
What must the clinician tell the patient? Everything that is in this sense material and relevant.

However, in the first place it is important to provide the right justification for any obligation to provide information. A clinician arguably has a duty to tell a patient the truth - although the doctrine of *therapeutic privilege* allows that in – admittedly very uncommon – situations a doctor might withhold diagnostic and prognostic information if she judged that disclosure posed very real and serious problems to the health of the patient (such as possible suicide). Note also that there is a difference between responding honestly to requests for information and volunteering information even if not requested.

Not clear that obligation to provide information derives straightforwardly from obligation to secure informed consent. If a doctor intends to operate on a patient and knows that his doing this is impermissible unless the patient consents then he has a reason to obtain the patient's consent Further, he thereby has also a reason to do that which is a means to the obtaining of that consent, namely to give the patient relevant information. However this reason does not amount to an obligation on the doctor’s part to inform his patient. A doctor is obligated to do that which promotes the well-being of his patient and if he believes that a procedure does promote the patient's well-being then she ought to persuade the patient to have the operation, that is, give relevant information.

[5] Scope of obligation

What must the doctor tell the patient? Whatever is material and relevant – i.e. would make a difference? But by which standards? Note that there are three possibilities
- Objective reasonable: whatever any reasonable person would need to know in order to make an informed decision;

- Subjective reasonable patient: whatever a reasonable person with this patient’s beliefs and values would need to know, etc (so imagine that this patient is particularly worried about some possible side effects)

- Reasonable doctor: whatever a reasonable doctor would tell a patient. Bolam

[Bolam v Friern Hospital Management Committee [1957] 1 WLR 582] test: ‘that he is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art’

[6] Is a doctor obligated to inform a patient of what would not make a difference: the Afshar case Chester v Afshar [2004] UKHL 41

The case in outline is simple enough. A patient (Chester) is not warned about a small risk attendant on surgery (approx 1%) of cauda equina syndrome, which might result in serious disability. She consents to surgery and the risk eventuates, leaving her disabled. There was no evidence of medical negligence on the part of the surgeon (Afshar) in terms of the surgical procedure. Where some clinical negligence suits have rested upon the claim that had the patient been informed of certain risks he or she would not have given her consent to the intervention in question, the striking thing about Chester v Afshar is that Chester concedes that had she known of the risk she would have still consented to surgery, though perhaps not on that day, with that particular surgeon. Afshar’s failure to inform is thus not directly causally relevant to the occurrence of the harm. Afshar’s failure to warn subjected Chester to no more risk than she would have otherwise suffered, had he informed her of the risk. But the case
of negligence was nonetheless upheld in the House of Lords by majority decision against Dr Afshar, and in doing so a precedent has been set that seems to require clinicians to disclose information about very small risks, even if such information plays no role in the outcome of patients’ decision making.

Negligence requires

- Culpable failure or omission
- Attribution of harm as a result of the omission/failure

Now, Afshar did not fail at doing or to do something any reasonable clinicians would have done (Bolam test) either in his consultation or surgery

And the harm – the resulting disability – cannot be attributed to his failure since had he told her of the risk she would still have the operation albeit later.

Some of the judges tried to insist that the causation condition (but for) was met in this case but by fallacious causal reasoning.

Lord Steyn: [I]t is a distinctive feature of the present case that but for the surgeon's negligent failure to warn the claimant of the small risk of serious injury the actual injury would not have occurred when it did and the chance of it occurring on a subsequent occasion was very small. It could therefore be said that the breach of the surgeon resulted in the very injury about which the claimant was entitled to be warned.

The probability of the occurrence of the harm is the same whenever the operation is performed. It is false to claim that because it did occur at \( t_1 \) (when the operation did take place) its probability at the later hypothetical time \( t_2 \) is reduced.

Judges did think Afshar was wronged by Chester even though Chester’s actions and arguable failures did not materially affect the outcome. Thus they wanted to argue that a wrong is done in the failure to inform even if that failure did not vitiate the
consent inasmuch as - as argued earlier – what is needed for informed consent is only that which would make a difference

Afshar did not act paternalistically inasmuch as he did not withhold information on the grounds that he thought such withholding was good for Chester in the face of her own and different judgment. They agreed what was good for her.

He did – arrogance? Laziness? – deny her the chance fully to deliberate on the matter and to that end disrespected her as a deliberating agent. Imagine I move a chess piece of yours for you. I act paternalistically if I believe you would make a different (and in my view worse) move. But if I move your chess piece as I know you would anyway I still deprive you of something that is rightfully yours – the opportunity to make your move yourself. Afshar deprived Chester or making her own mind up herself – by and for herself.

[7] Information and understanding

Patients have not only to be provided with relevant information but be in a position to understand that information. Raises two issues

- Is the clinician obligated not only to provide relevant information but to ensure that it is understood? What does that require and what is it reasonable to demand of a clinician?
- How do we assess the relevant capacity of the patient? What is required in order to understand information?

False beliefs: patients may be able to consent but have false beliefs that lead them to misinterpret what they are told. Most obviously there is “therapeutic misconception”: that is, they assume that participation in non-therapeutic research is treatment.
Relatedly, many research subjects fail to understand the implications of trials involving placebos.

[8] Problem of referential opacity. Consent is not to a procedure or treatment as such; it is to a proposition that involves a particular description. And familiar problem from philosophy of language. I may know that something is the case under one description but not know that thing under another.

Example: in the Alder Hey case patients complained about the use by the hospital of the organs of their deceased babies. The clinicians claimed that the parents had consented to the posthumous removal, storage and use of what was referred to as ‘tissue’. However the clinicians understand this term broadly to encompass organs (hearts, kidneys etc) whereas the patients understood ‘tissue’ more narrowly and to exclude organs.

[9] Value of autonomy

Is consent rooted in value or principle of autonomy?

Three very different kinds of challenge

(1) Kantian: Kantians deny that Kant himself is a proper source of an answer to the question of why autonomy (as a source of consent) is valuable. What they understand as autonomy — namely the exercise of practical reason in conformity with the moral law — merits respect but it is some distance removed from what is meant by most of those who now use the term autonomy. ‘Contemporary accounts of autonomy have lost touch with their Kantian origins, in which links between autonomy and respect for persons are well argued; most reduce autonomy to some form of individual
independence, and show little about its ethical importance’ (Onora O’Neill). Kantian autonomy may give you a duty (of doctor) not to deceive and not to coerce, but nothing like the doctrine of informed consent.

If autonomy in the modern non-Kantian sense means personal independence in leading my life as I and not others sees fit then it is more likely to be properly subject to a consequentialist justification – and a prophylactic (negative protection against harms) rather than positive. And consequentialist justifications are subject to ‘on balance’ and ‘as a rule’ constraints; that is, it need not always be wrong to overrule an autonomous decision or consent.

(2) Relational: mainly due to feminist critics and those who appeal to cultures (such as Chinese) in which individuals do not choose alone. The critique is that the Western/male construal of autonomous choice requires a false (or simplified) view of the individual as an isolated solitary self-sufficient social atom, whereas the truth is that individuals are importantly bound up in relationships to others.

Need to distinguish two very different claims:

- Individuals are indeed in important relationships to others; how they understand themselves, how they are defined, involves reference to these relationships. Individuals are indeed embedded in such relationships.
- The normative power to consent is possessed and exercised by individuals and not by sets of related individuals.

So it may be true that somebody considers whether or not to agree to something only within a relational context (talking to and with others, such as family members), and a doctor may consult with the individual as a family member. Yet it is for the patient alone to give or withhold consent.
Distinguish from ‘joint account’ model of genetic information or diagnosis. Given that ‘Genetic information is, spontaneous mutations aside, essentially and unavoidably familial in nature,’ it would be wrong to restrict right to access to any genetic diagnosis to one information. E.g. disclosure – through genetic testing of one family member – of some particular abnormality/mutation cannot be restricted to that person tested.

(3) Autonomy versus bodily self-ownership.
I argue that the wrongness of – for example – taking a simple painless and harmless mouth swab is best understood as an invasion of another’s body and not as a violation of autonomy. The former does not reduce to the latter. For the latter construed as the power to make critical life choices or to lead a life as a whole as one chooses cannot explain what is wrong with the unconsented mouth swab.

Two attempts to explain the wrong of bodily trespass in terms of ‘personal sovereignty’:

(A) Arthur Ripstein (‘Beyond the harm principle’, *Philosophy and Public Affairs* 34:3 (2006): 215–245. For Ripstein ‘Use and injury exhaust the space of possible violations of sovereignty’. But a harmless bodily trespass such as a mouth swab need not be injurious nor motivated by the end of use by another. It may be wrong just because it is a trespass.

(B) Joel Feinberg (*Harm to Self*, Volume Three of his *The Moral Limits of the Criminal Law* (Oxford: Oxford University Press, 1986): 54-5) construes personal sovereignty and choice as where and how to move my body through public space’. However the wrong of bodily trespass is not a simple correlate of a right to love one’s own body through space. Moreover not all personal choice is about moving one’s
body through public space (Consider the freedom of thought and conscience).