Patient and Donor Consent

(In the era of Digital Health understanding and the dynamics in related and unrelated donors)

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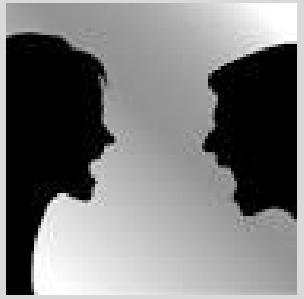
Gene, Stem cell science and organ transplant poses enormous healing potential to individuals and advances to our society.

The way forward demands **complex ethical** deliberation.

Procurement, allocation, words like ‘body parts’, embryos, haploid cells and future generation, research, donor payment, eugenics and where-do-we-stop, poses difficult ethical questions, even today.

Today we focus on informed consent

‘Body parts’



Building of arguments

There are <u>four</u> ‘kinds’ of arguments….

1. **Factual** arguments using true facts …. Best
2. **Emotional** arguments…. Goes nowhere !
3. **Rhetorical** arguments…. The clever use of words to persuade. Has a predetermined goal. Take care to recognise ! Common, dangerous and deceitful.
4. **Value** arguments….. Must weigh and balance human values. May be very difficult. Can go either way. In search the final good.

Indeed, **why** informed consent ?

1. The therapist has the latest knowledge and skills
2. .. the experience
3. .. wants to help and can help
4. .. wants to act in the best interest of the patient
5. .. knows contemporary 'best' care Rx options/outcomes
6. .. knows the possible poor outcomes of a 'wrong' decision by patient
7. Patient does not have above knowledge and insight– needs help, wants help, trust the therapist.
8. ….. many (most) patients not set on personal choice but rely on therapist

Non-paternalism a conscious 'must do' decisions by therapists

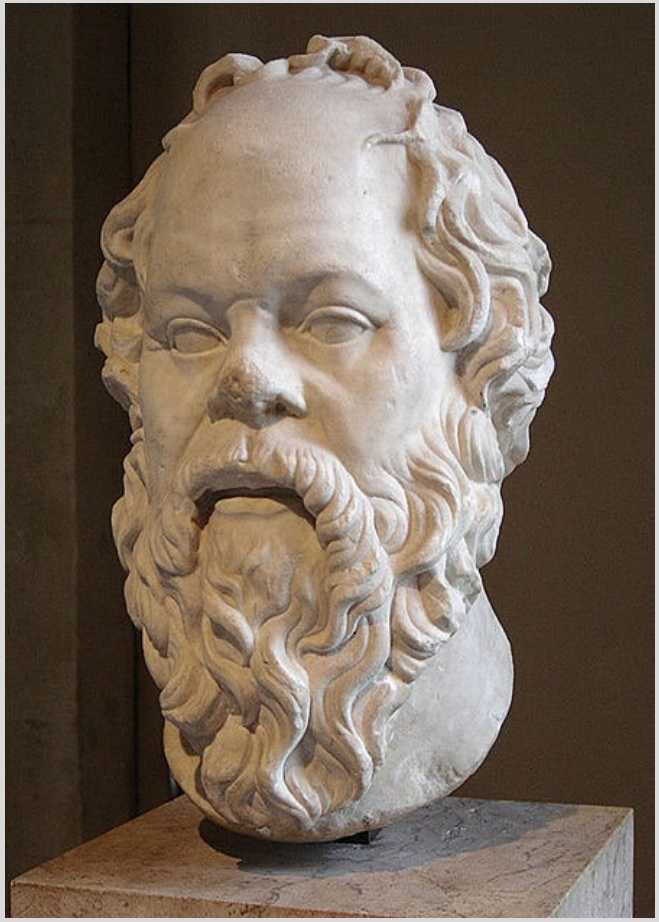
Please allow me five minutes on..

The Philosophy of Consent

Socrates 470-399 BC

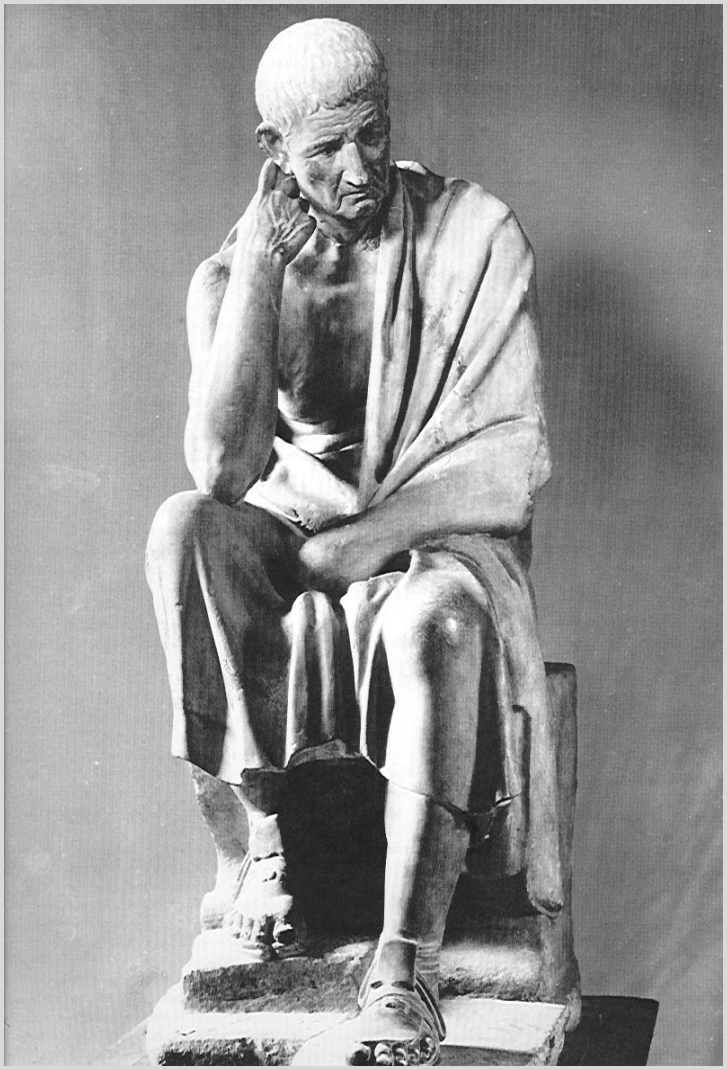
“ Should we not stop asking the questions we cannot answer? The metaphysical questions.
Is it not more important to ask the most fundamental question of all?
This question is -

“How should I live with my brother and my sister?”



Has something to do about our **connectedness**
Something about **harmony**

Aristotle 384-322 BC



"We want our lives to go well"

"A kind of life that, if we could, we would all choose!"

"A kind of life we would want for those we love"

'Eudaimonia' is a conceptual truth – a meaningful life that is an end in itself. Living this life has intrinsic value.

Do remember: My/your life can only be fulfilled others

Our journey, the good life, is spent in **search** of the good life"

In this process we must …….

Respect the decisions of others

Empower patients to self determination

Love our neighbor

Isaiah Berlin: (Latvian born British historian and liberalist 1969)

"I wish my life and decisions to depend on myself, not on external forces of whatever kind. I wish to be the instrument of my own, not of other men's acts or will . I wish to be a subject, not an object: to be moved by reasons, by conscious purposes, which are my own, not causes which affect me, as it were from outside. I wish to be somebody, not nobody, : a doer – deciding, not being decided for, self directed and not acted upon by external nature or by other men as if I were a thing, or an animal, or a slave… I wish, above all, to be conscious of myself as a thinking, willing, active being, bearing responsibility for my choices and able to explain them by references to my own ideas and purposes. "

By now you should be motivated to always secure informed consent from every patient or client

Our task today is to ……

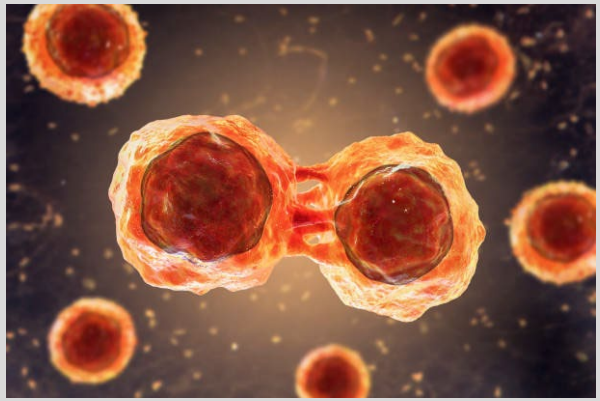
- Internalise the fact that we are still in **search** of the final truth, the final good, the final language.
- Socrates: “Now that we know, we do not know, we can start to make progress !”

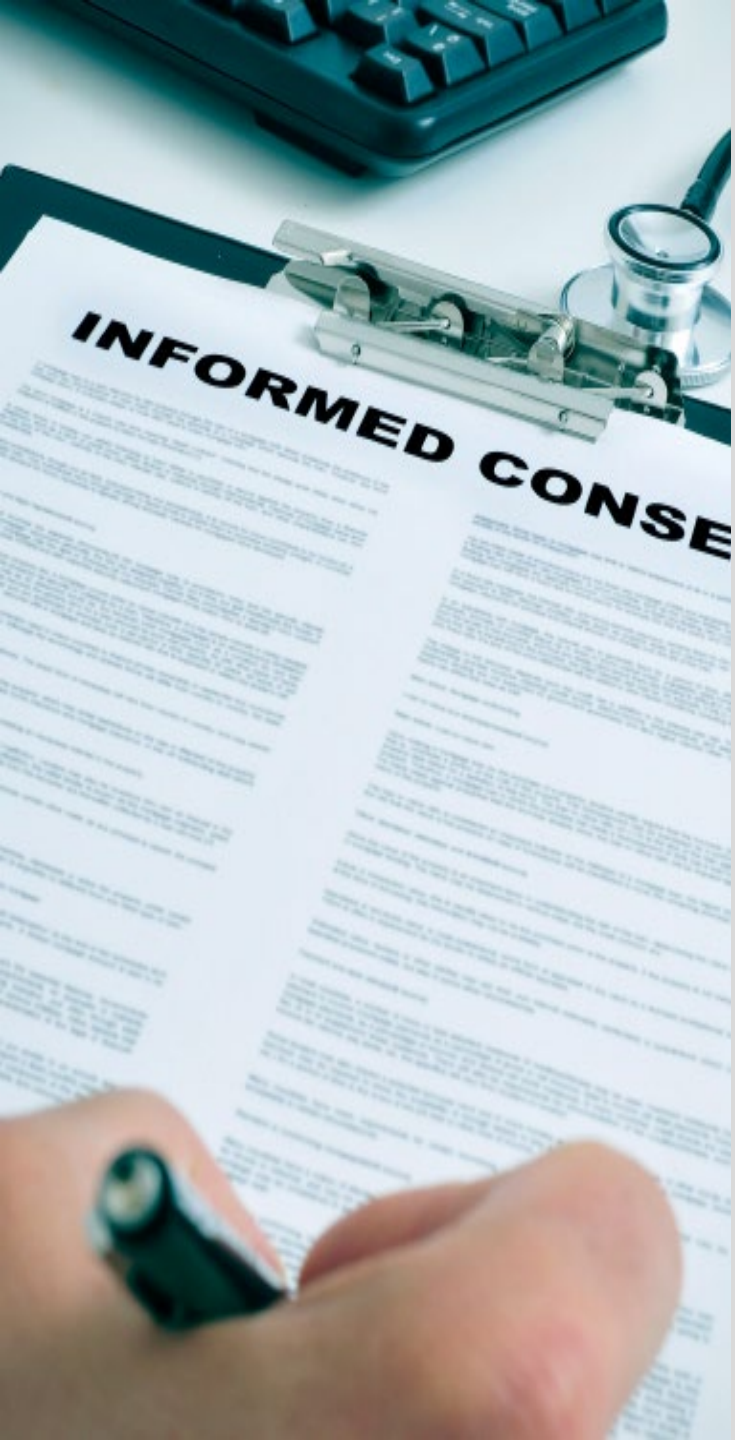
Respect Autonomy

Autonomy justifies:

- Telling the truth
- Respecting privacy of others
- Protecting confidential information
- Obtaining consent for interventions
- Helping others to make important decisions

- Thus, autonomy creates the following obligations:
  - **Informed consent**
  - **Confidentiality**
  - Truth telling
  - Effective communication





Informed Consent

- Process of understanding the risks and benefits of a procedure and treatment and agreeing to the treatment
- **Ethical** and **legal** requirement
- Based on principal of **autonomy**= the exercise of self governance, the ability to take intentional actions, patient has the right to make decisions about their medical treatment
- Patients can consent verbally, in writing or by conduct (nodding); written and oral consent are legally binding
- For many interactions e.g., a physical examination or blood test, implied consent is assumed
- For more invasive procedures or treatments (surgery)written consent is required

Elements of Informed Consent

- **Threshold elements**
  - Competence (to understand and decide)
  - Voluntariness (to decide)
- **Information elements**
  - Disclosure (of material information)
  - Recommendation (Action options)
  - Understanding (Information and action options)
- **Consent elements**
  - Decision (in favor of own choice)
  - Authorization (give go ahead for chosen plan)

Threshold element: 1. Competency

- Understanding, capacity, competency
- Understand the volume, content and context of information.
- Can use this information to build arguments.
- Can use this information to benefit own future (self-determination)
- Can use this information as a ‘reasonable’ person would.

More detail on competency later !

Threshold element: 2. Voluntariness

- Free of Coercion
- Wills the action
- No control/influence

  - Love, threats, lies, manipulation, emotional play, and half truths

FREEDOM

Be aware of following pitfalls

- Consent given…
  - Grudgingly, half-hearted, under pressure or unwillingly
  - Tacit, implied, presumed, deemed or ‘given no opposition’
  - ‘Routine practice’

Above consent can be contested

Informed Consent
Adequate Information (King and Moulton 2006)

Information that a reasonable person requires to make a decision:

1. Diagnosis and nature of the condition
2. Purpose of the proposed Rx
3. Reasonably expected benefits from the proposed Rx
4. Nature and likelihood of the risks involved, possible complications and adverse events
5. Inability to precisely predict results of the Rx
6. Potential irreversibility of the Rx
7. Risks, benefits, and results of alternative Rx
8. Consequences of not accepting the Rx

Information element: Disclosure

- Unbiased, not weighted, reasonable, tested in court
- Simple communication, language, friendly for age, religion and culture

COURT

Failure to disclose caused the injury

‘Being Autonomous’

- About personal capacity
- Competent people can be irrational and unreasonable
- Emotion can render a person incompetent #
- Incompetence can be temporarily (delirium)

One can be partially in/competent

Standards of Competence Beauchamp and Childress

1. Can express or communicate a choice
2. Understand immediate situation and consequences
3. Understand relevant information
4. Can use this information to reason
5. Reason rationally
6. Do risk/benefit reasoning - complex
7. Reach a reasonable persons decision

Who is competent? 1+2 or 6+7

Action depends on the…..

1. Degree of competency (1-7)
2. Weight of the decision

   Breakfast (1 is ok) - Survival decision (At least 5-6)
3. Time factor
   - If emergency save the life then…
   - If delirium – can you wait with therapy or not…

Value decisions

Weigh and balance

Do not get isolated

Competency Questionnaire: Testamentary capacity

Standard 1

1. Good day, how are you?
2. May I ask you a few questions?

} Can communicate

1

3. What is your name and surname, and where are we now? — 2
4. What have you been doing the past couple of hours? — 2
5. What is a testament and do you need to have one at this point? — 3
6. What assets should be in your testament? (Info correct - test) — 3
7. Who should be named in your testament ? (Info correct – test) — 3
8. How will this document benefit you and others? (Can argue) — 4
9. Who should manage your testament? (Can argue) — 4
10. Do you think your testament is reasonable and why? (Rational) — 5
11. Explain why certain assets should go to certain people (Rational) — 5

    1. Quest 8,9,10 and 11 <u>autonomous</u> and <u>benefit/risk</u> arguments — 6
    2. Would comply with <u>reasonable</u> persons' decisions — 7

Decision Making Capacity Assessment

- Decision-making capacity, make sure of the following:
    - Patient must be fully conscious - contact and orientated
    - Patient must be intellectual able to understand the task at hand
    - Hearing impairment
    - Visual impairment
    - Language barriers
    - Dysphasia
    - Dysarthria
- Ensure that the patient has received and understand all the relevant information to make an informed decision

Aid To Capacity Evaluation (ACE) – Administration

Name of patient: _____ Date: _____

Record observations that support your score in each domain, including exact responses of the patient. Indicate your score for each domain with a check mark.

1. Able to understand medical problem

(Sample questions: What problem are you having now? What problem is bothering you most? Why are you in the hospital? Do you have (name problem)?)

Observations: _____

_____

- ☐ **Yes**
- ☐ **Unsure**
- ☐ **No**

2. Able to understand proposed treatment

(Sample questions: What is the treatment for [your problem]? What else can we do to help you? Can you have [proposed treatment]?

Observations: _____

_____

- ☐ **Yes**
- ☐ **Unsure**
- ☐ **No**

3. Able to understand alternative to proposed treatment (if any)

(Sample questions: Are there any other [treatments]? What other options do you have? Can you have [alternative treatment]?

Observations: _____

_____

- ☐ **Yes**
- ☐ **Unsure**
- ☐ **No**
- ☐ **None Disclosed**

4. Able to understand option of refusing proposed treatment (including withholding or withdrawing proposed treatment)

(Sample questions: Can you refuse [proposed treatment]? Can we stop [proposed treatment]?

Observations: _____

- ☐ **Yes**
- ☐ **Unsure**
- ☐ **No**

5. **Able to appreciate reasonably foreseeable consequences of accepting proposed treatment**
   (Sample questions: What could happen to you if you have [proposed treatment]? Can [proposed treatment] cause problems/side effects? Can [proposed treatment] help you live longer?)
   Observations: _____

   _____

   ☐ **Yes**
   ☐ **Unsure**
   ☐ **No**

6. **Able to appreciate reasonable foreseeable consequences of refusing proposed treatment (including withholding or withdrawing proposed treatment)**
   (Sample questions: What could happen to you if you don't have [proposed treatment]? Could you get sicker/die if you don't have [proposed treatment]? What could happen if you have [alternative treatment]? *(If alternatives are available)*
   Observations: _____

   _____

   ☐ **Yes**
   ☐ **Unsure**
   ☐ **No**

(Note: for questions 7a and 7b, a "yes" answer means the person's decision is affected by depression or psychosis)

7a. The person's decision is affected by depression

(Sample questions: Can you help me understand why you've decided to accept/refuse treatment? Do you feel that you're being punished? Do you think you're a bad person? Do you have any hope for the future? Do you deserve to be treated?)

Observations: _____

_____

- ☐ **Yes**
- ☐ **Unsure**
- ☐ **No**

7b. The person's decision is affected by psychosis

(Sample questions: Can you help me understand why you've decided to accept/refuse treatment? Do you think anyone is trying to hurt/harm you? Do you trust your doctor/nurse?)

Observations: _____

_____

- ☐ **Yes**
- ☐ **Unsure**
- ☐ **No**

What makes our decisions unique to ourselves ?

- Patient competency, understanding, voluntary, necessary information ?

  NO !!

- Also things unique to ourselves at that moment
  - Lets us call it ‘Intuitive’ factors like emotion, anxiety, mood, wishes, hopes, fears, culture, personal values and our connectedness to others
  - How on earth are we to quantify or qualify above electronically ?

  It is so difficult for clinicians to accept the ‘wrong’ decisions of truly competent people

Related, unrelated donor challenges

- Related - also friend, acquaintance, spouse
  - strong emotional bond + the urgency of need
  - Family dynamics
  - Age

    Emotional pressure, undue influence, coercion
- Unrelated
  - Altruistic traits
  - Psychosocial benefits
  - Financial benefit ?? Donation financially neutral

    Necessitates a strong DONOR ADVOCACY TEAM

Surrogate Decision-Making

- Living will - respect autonomy
- Incompetent – no living will or emergency - surrogate decision maker
  1. Communicate the decision made by now incompetent person while still competent
  2. Communicate the decision that person ‘would have made’
  3. Make a best interest or reasonable persons decision

Secure Informed Consent in **four** situations

1. Consent to medical treatment – verbal most of the time (make a note in patient folder)
2. … to personal information sharing
3. … to research
4. … advance directives (Living wills)

Developing Digital Health

- eHealth is the delivery of health care using modern electronic information and communication technologies when health care providers and patients are not directly in contact and their interaction is mediated by electronic means. Patient signatures no longer compulsory. Tick box consent allowed. Currently patients still give written consent for Information sharing, agree to treatment or refusal, research and advance directives.
- HIS (Health Information Systems) A robust, integrated information system is the foundation for building a successful national healthcare delivery system. – Still a risk for unauthorised access to personal information.
- Enforced consent policies/laws Established: Protection of Personal Information Act (PoPI Act) Patient to permit or deny access.

Ongoing efforts to better security of information !

Informed consent in our digital era

Future digital communication **are** going to replace the paper trail past – fact!

1. May be time saving
2. Secure standardization of consent process (not customize)
3. Thus better overall quality control of **process** (process does not guarantee quality **consent**.
4. Secured patient consent banking (paper trail)
5. Standardize and better transfer of patient information (Use of multimedia).
6. Patient consent changes to that of a partnership and clinician the expert advisor

Patient-clinician interaction should remain an integral part of consenting especially to patient competency, comprehension and autonomy.

Challenges to E-consent

- Securing patient competency, understanding and true autonomy by e-consent very difficult
- Privacy and security measures - Access to e-consent
- How to **verify** consent – the signature – voluntary and free – time and date given
- 'Intuitive' factors –personal beliefs, wishes, mood, anxiety, values, time and situation, culture, language, education, intellect make one-fits-all e E-consent difficult
- Outside influencing of e-consent difficult to control
- Reversal of prior consent more difficult
- Not as 'personal' as the eye to eye contact
- Information overload – often not read or understood

Challenges of consent in research

- For many **lay** individuals our science is complex and hard to understand with the necessary insight.
- ‘Overload’ of complex info common.
- Versus the need to grasp ‘enough’ data to call it ‘informed’ consent
- Future risks often unknown
- NB It is not the **patient** that should determine whether this treatment or research is good or bad, safe or unsafe. The task of the profession and REC !

What needs to be done ?

- Constant revision of current practice to truly secure patient benefit – informed consent not merely to safeguard clinician for lawsuits !
- Keep it simple !
- Get into the habit of making short notes in patient notes. “After informative discussion the patient and I decided on the following action !”
- Respect patient self determination and best interest

“It is not about what I should do, it is more about who I am”

“ Do not be afraid of your weaknesses be afraid of your power.”

- We have the power to change social interaction.
- To strive towards what is good.
- To live my life in harmony with others

- Warburton (1999) “If you do not doubt the soundness of the assumptions on which your life is based, you may be impoverishing your life by not exercising your power of thought”

END

Most important human values

Love Starts with a positive regard for self, understanding weaknesses/strengths, only then you can truly love others.

Compassion An attitude or trait of active regard for the welfare of others. Empathy, tenderness and the sentiment of care

Discernment A sensitive insight and understanding for the needs of others (practical wisdom) and acting to that need without being influenced from outside.

Trustworthiness Centre stage to our patient – doctor relationship

Integrity Rests on healthy inner beliefs, values that will not be given up.

Our current moral Theories and Principals

1. Utilitarianism – The **moral** best action for most .
2. Rule based (E Kant) – Universal rules of good intent e.g. (Veracity)
3. Virtue based – To do the good because it is good (Character)
4. Social Contract Based – As summarized by our Constitution
5. Liberal Individualism – Human Rights (Life, Freedom, Basic needs and ownership of land and property)
6. Communitarianism – The common good
7. Ethics of Care – The good Samaritan
8. Casuistry – Gather all information, evaluate situation, time and future, weigh and balance all

Principle based ethics:

1. Respect Autonomy – self determination 2. Beneficence – do what is good. 3. Non-maleficence – do not harm 4. Justice – Be fair