Ethics in Rehabilitation Research

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Introduction

Efforts to make rehabilitation science and applications **more evidence based** have increased demand for human participants, raising **concerns** for their **safety** and **welfare**.

Rewards of biomedical research, such as advances in treatment and prevention of disease, are enormous

However, in some cases research can seriously harm participants, as illustrated by the Nazi atrocities committed on prisoners of war in the name of science and a series of well publicized scandals.

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Scandals in the United States.

These include the Tuskegee Syphilis Study, involving 399 poor African-American men who, without their knowledge, were denied treatment so that the natural history of their condition could be investigated

Experimentation on institutionalized children with mental retardation who were intentionally infected with hepatitis to determine the effects of a vaccine.

More recent examples include the death of an 18-year-old subject in a gene therapy trial and the death of a 24-year-old volunteer who was healthy in an asthma study.

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Why knowing the ETHICS is so important?

- Ethical codes

1. Provide standards of behavior and performance that form the basis of professional accountability to the public.

2. Provide guidance for rehabilitation specialists facing ethical challenges, regardless of their professional roles and responsibilities.

3. Educate rehabilitation specialists, students, other health care professionals, regulators, and the public regarding the **core values**, **ethical principles**, and **standards** that guide the research conduct of the rehabilitation researcher/practionaire.

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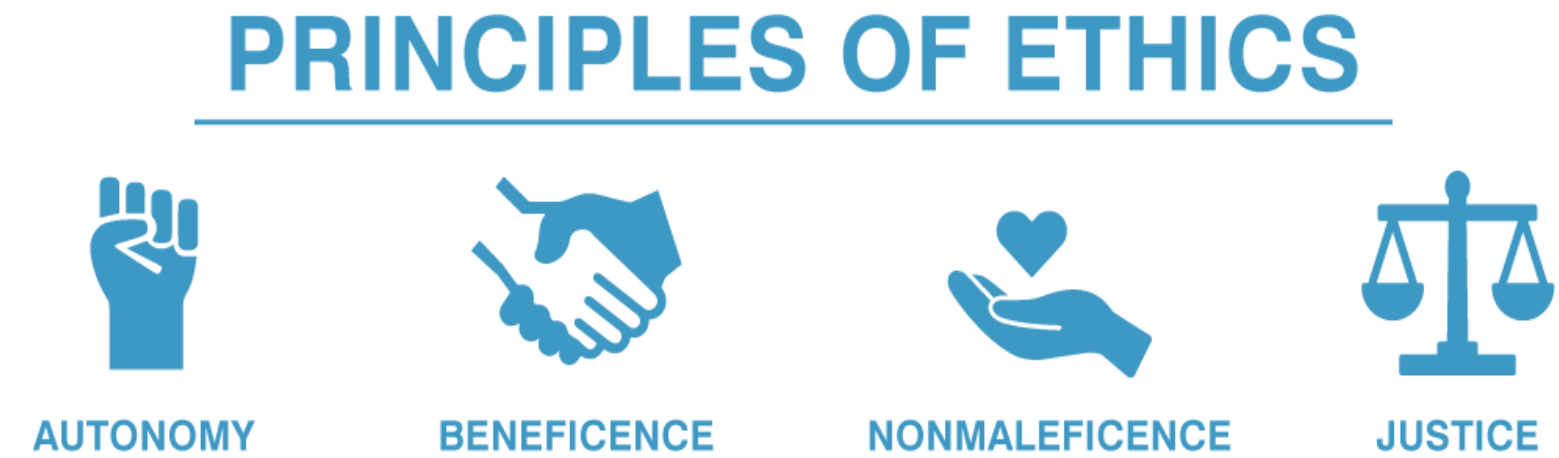
Four Key Bioethical Principles

Beneficence – doing what is best or right

Non-maleficence – do no harm

Autonomy – informed decisions

Justice – fairness



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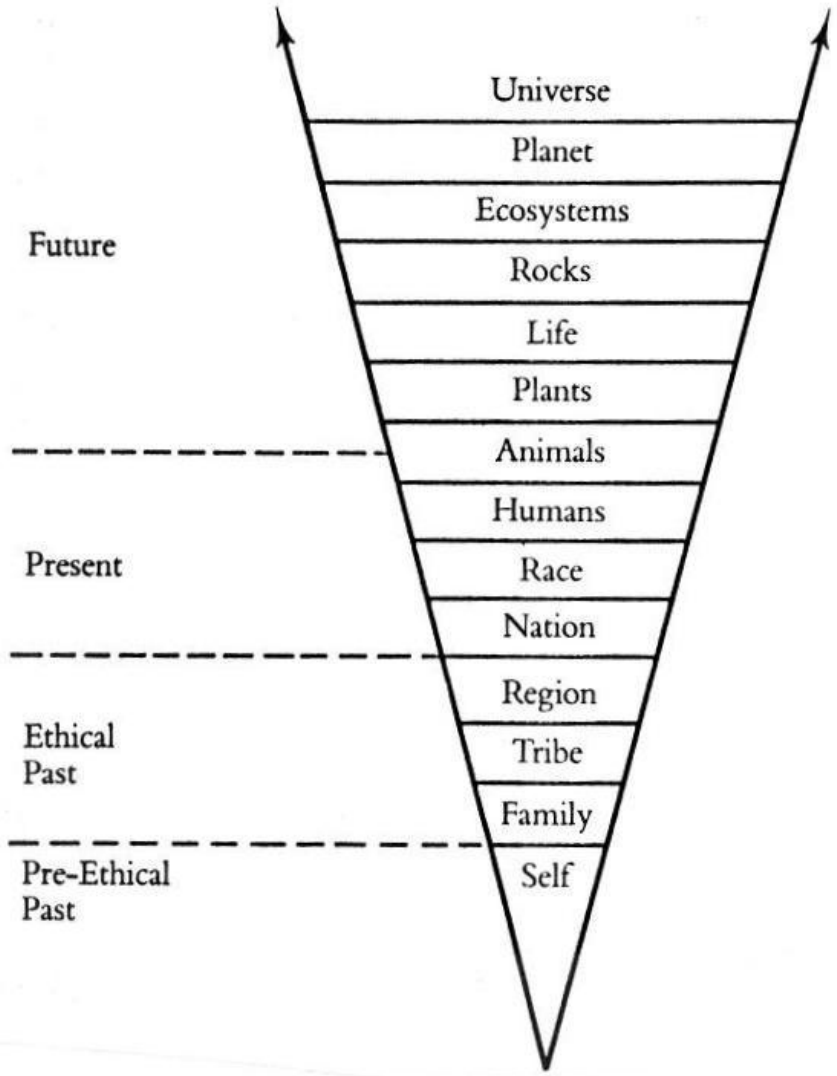
Ethics evolution

Moral Sensitivity – recognizing, interpreting, and framing ethical situations

Moral Judgment – deciding on right versus wrong actions

Moral Motivation – placing a priority on ethical values over other values

Moral Courage – implementing the chosen ethical action in spite of barriers



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Ethical Conflict

- When values, goals or duties conflict or are challenged.
- When you aren’t sure which action to take.
- When it isn’t clear what is the best thing to do

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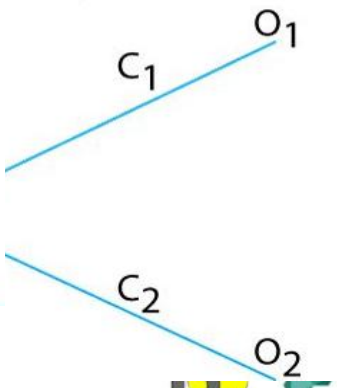
Ethical Dilemma

- When two or more clear principles or values apply but they support mutually inconsistent courses of action.
- When choosing one “good” clearly violates another principle or allows a negative consequence.
- When you cannot avoid the conflict of two competing principles

Ethical Dilemma

There are two (or more) courses of action, each of which is righ (or wrong). No matter which one I (the “agent”) choose, something of value will be compromised.



A = Agent
C = Course of Action
O = Outcome

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Ethical Distress

• When one knows the right thing to do, but organizational constraints make it nearly impossible to pursue the right course of action

Ethical Distress

I know which course of action I (the "agent") should take for the patient's benefit, but there is a structural barrier to my being able to do it.

A = Agent
C = Course of Action
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Ethical Temptation

- Involves a choice between a “right” and a “wrong”
- You may stand to benefit from doing the wrong thing

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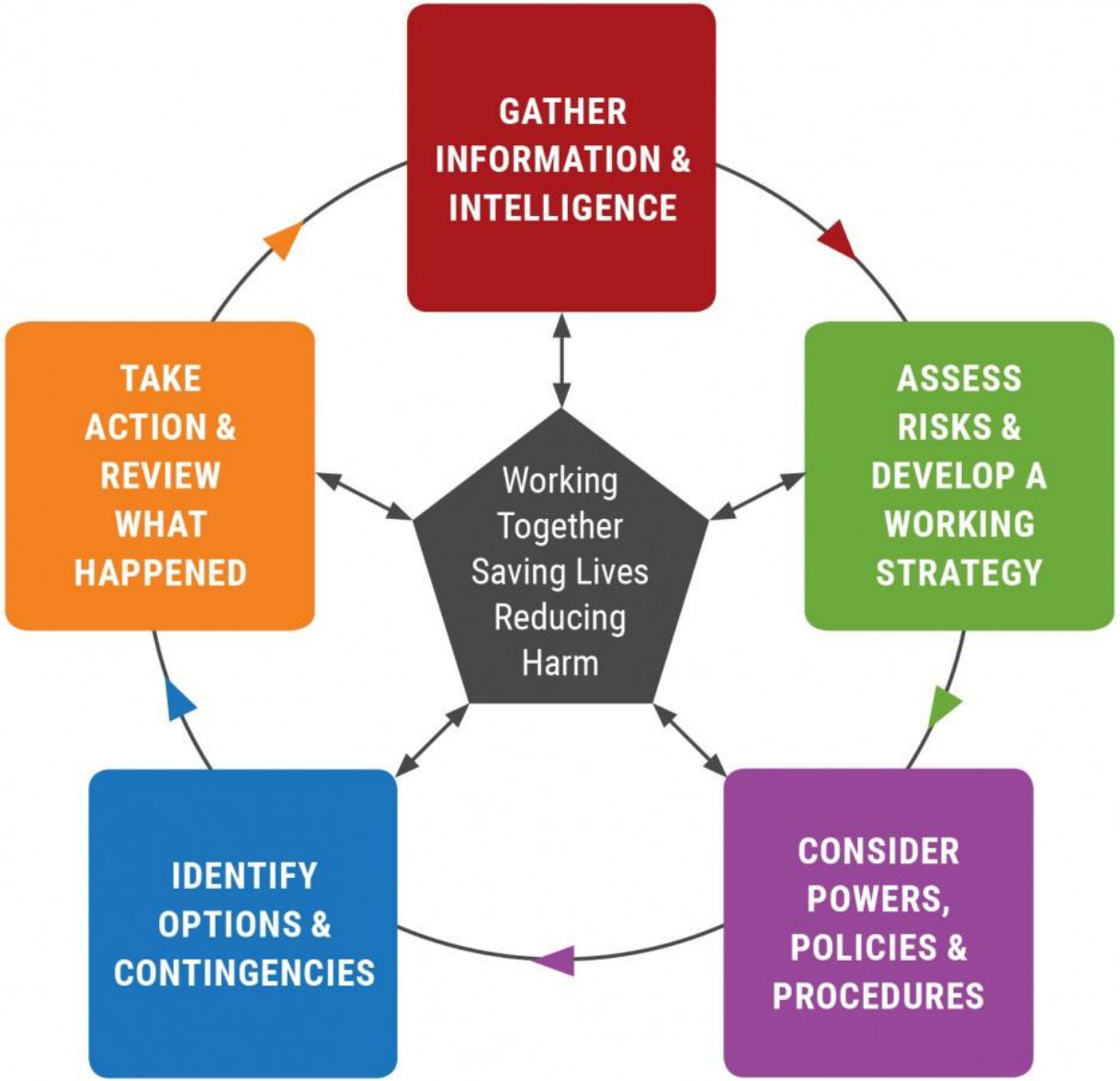
Silence

- Ethical values are challenged, but no one is speaking about this challenge
- This may be the course taken by an individual who is experiencing ethical distress

Ethical Decision-Making



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Challenges in Rehabilitation research ethics

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Traumatic Brain Injury (TBI)

- The severity of TBI can range from mild to severe.
- Persistent cognitive deficits can range from mild and temporary to severe and persistent.
- In cases of severe TBI, it may be obvious that the patient does not have sufficient decision-making capacity to be able to decide whether or not to participate in a research protocol,
- Alternative arrangements (such as proxy consent from a member of the family) may have to be sought.
- In other types (less severe) further capacity assessment may be required to ascertain a particular individual's level of decision-making ability.

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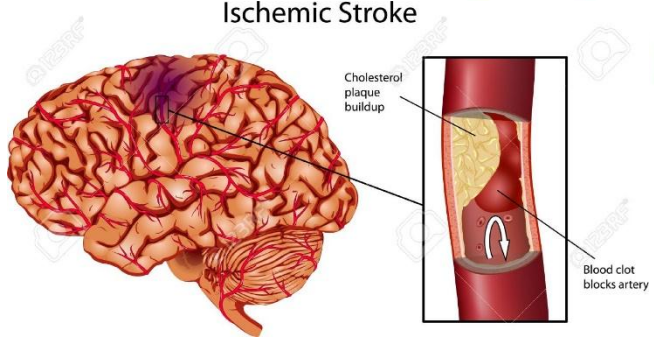
Stroke patients



- Stroke patients make up a large proportion of potential research candidates, both as inpatients and outpatients.
- Fairly significant number of stroke patients may recover neurologically to the point where they do not have any cognitive deficits which would interfere with the decision-making process,
- Many patients will continue to have damage to the parts of the brain involved in judgment and reasoning, and these patients might not be able to make a truly informed decision regarding participation in a research protocol.
- Again, if a concern exists, the patient may need to undergo further capacity assessment.

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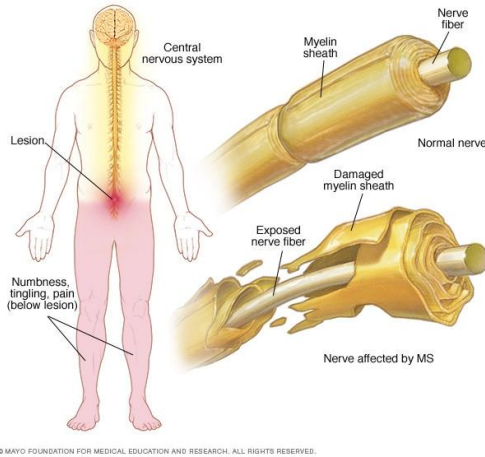
Multiple sclerosis (MS) and those w Parkinson's disease (PD)

- These patients often have very obvious physical impairments and limitations (such as tremor, weakness and incoordination) that tend to receive the majority of medical and therapeutic attention.
- However, a very significant proportion of patients in each group will go on to develop cognitive deficits that may affect decision-making capacity but might be quite subtle unless specifically tested for.
- Both groups commonly develop what is termed a subcortical-type dementia.
- These deficits often present as difficulties with higher-level cognitive functions such as reasoning, insight, judgment and abstraction.
- These difficulties, of course, are relevant to capacity and may be present in a degree sufficient to interfere with a patient's ability to decide whether or not to participate in a research protocol, but unless specifically tested for, will not always be apparent to the person obtaining informed consent.



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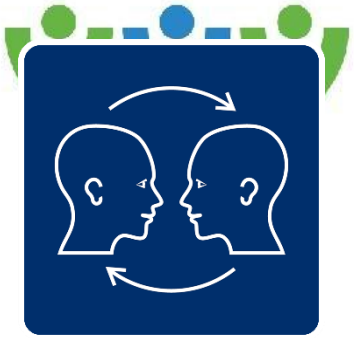
Communication issues



- In order to be able to consent to participate in a research study, the potential subject must be able to understand the nature and specific content of the protocol, as well as the risks and benefits which are involved in participation.
- In order to be a subject, the patient will generally also need to be able to communicate with the researcher.
- Both these areas can be impaired in patients with language deficits.
- The ability to use language to communicate with others, be it in a written or verbal (or other) form, requires the ability to comprehend information and to present information to others in a form that they can understand.
- Many patients in the rehabilitation population **may have varying degrees and types of aphasia.**

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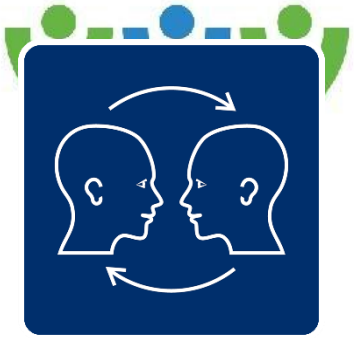
Communication issues (cont.,)



- If the language deficit involves comprehension, then informed consent will obviously be difficult to obtain from that particular subject, and they may have to be excluded from the study, or proxy consent sought.
- For patients with expressive deficits, they may be able to provide consent through non-verbal communication, but it may be very difficult for them to participate in the research protocol unless specific mechanisms are in place to accommodate their deficits.
- For example, some patients **might substitute one word for another** when they attempt to express themselves.
- In some cases the new word may be a nonsense word (or neologism) and it will be obvious to the researcher that the answer is not valid.
- However, some patients will substitute a true word, but one which has a different meaning then they wish to express.
- Some patients will the **use the word "yes" in place of the word "no"** because of their aphasia, and this substitution will obviously have significant limitation on the ability of the researcher to obtain valid and accurate data.

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Communication issues (cont.,)

- Therefore, in situations where a potential research subject is thought to have aphasia, a thorough assessment should be performed (usually by a Speech and Language Pathologist) to see if the patient is not only able to consent to participation, but whether or not their communication skills are sufficient to permit them to actually participate in the study.

- In addition, where possible the **Speech and Language Pathologist could assist in facilitating the participation of subjects** who have certain specific communication impairments which might otherwise preclude them from participating.

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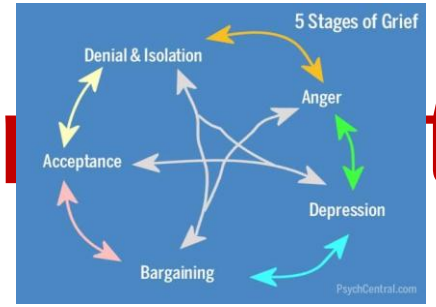
Timing of subject recr t



- Many patients have had serious, and sometimes devastating and life-altering, injuries or medical catastrophes.
- These patients need time to readjust to their new station in life, and there is often a certain amount of grieving that occurs.
- Within this setting, many subjects may be **hesitant to agree to participate** in research projects as they are still trying to cope with the new onset of a significant disability.
- With time to **readjust to the situation**, many patients **come to view things differently**, and go on to become **willing volunteers** after they have had some time to heal both physically and emotionally.
- Therefore, whenever possible, the researcher should take this into account, and should try and **approach the patient only after they have had time to adjust to their new disability**.
- In fact, this adjustment may not occur while the person is an inpatient (and sometimes, unfortunately, not at all), and if this is the case, their participation in a potentially time-consuming research protocol should probably not be sought.
- This must be determined on an **individual basis**, and **may require discussion and consultation with the patient's physician, the therapists involved**, the patient's family, and, whenever appropriate, the patient themselves.

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The potential for overuse of individual subjects

- The potential exists for individual subjects to be recruited for multiple different studies at various times and thus share a disproportionate burden for research participation.

- This can be a concern especially in one or more situations in rehabilitation medicine.

- Situation where patients are **residents of a particular facility for a long period of time.**

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The potential for overuse of individual subjects

- For patients whose stay exceeds a certain period of time, it might be reasonable to have **guidelines in place so that these patients will only be asked to participate in a certain number of research projects**, perhaps one per year or one every two years, to ensure they do not take on an excessive burden in this area.

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Hope for a cure

- There are some situations and diseases where no curative treatment is currently available.
- Increased funding to assist those involved in spinal cord injury research and has also contributed to the entrance of more scientists to this particular field.
- This have given hope to many individuals who find themselves in similar situations.
- **Between hopes and reality may be a huge gap. This may be ignored by researchers and not explained to study subjects.**

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Nature of the health care provider-research subject relationship

- The bond that develops between (patients) and their health care providers (such as physicians, nurses, and therapists) can be exceptionally strong and powerful.
- The patient may be totally dependent on the members of the care team.
- Deep emotional appreciation and gratitude for the care provided during this period
- In this setting, patients may be more likely to agree to participate in a research project out of a desire to please their health care team and because they may perceive their participation as being one way they can **"repay" the kindness** and care given to them by the members of the team.

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- This means that the researcher must be especially careful to ensure that the patient understands that their participation is entirely voluntary and that **their refusal** will not in any way impact not just the **quality of their health care**, but also their relationship with the members of their care team.
- The researcher must ensure that the patient understands they have **every right to refuse to participate without explanation** and that they are free to withdraw from the study at any point in time.
- Only after the researcher is completely confident that these requirements have been met should the patient be allowed to participate in the study.

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Take home mes

- Ethics are necessary to protect both subjects and subjects.
- Ethics is dynamic and ethical challenges/**Ethical Dilemma** evolve and should be deeply discussed.
- Decision making in ethical judgments is usually a systematic process.
- Rehabilitation research is essential and very useful ….. ethics also.
- Communications problems, HCWs-patients relationship, hope to cure, long term stay in rehabilitation centers are issues that should be carefully examined when recruiting research subjects.
- When I CONSENT, This means I do **understand, freely willing to participate.**

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Thank You

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