RESEARCH ETHICS AND CLINICAL ETHICS

HARMONY OR OPPOSITION?

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WHAT ARE ETHICS?

- DICTIONARY DEFINES ETHICS AS A CODE OF BEHAVIOR THAT IDENTIFIES THE MORAL THING TO DO.
- FUNDAMENTALLY, ethics is about determining the RIGHT THING TO DO.
- One can hypothesize that the objectives of research really conflict with the goals of clinical care, so one could suspect that the ethical approach differed between the two.
- Today, we can explore this idea, and understand similarities and differences.

ETHICS – BASIC PRINCIPLES

1. BENEFICIENCE - Must do things that are good or helpful
2. NONMALEFICENCE - Do no harm (other than the unavoidable burden of care)
3. AUTONOMY - Respect for the individual and their right to self determination
4. JUSTICE - Treat everyone the same, provide similar treatment to all

THE SURGEON AND THE MEDICAL STUDENT

- A Surgeon is presenting his work to a group of medical students . He is quite proud of an operation he has developed that he is convinced has vastly improved the health of his patients.

- A medical student asks " Doctor, did you perform a double blind randomized controlled trial to test whether it was better?" "NO," huffed the surgeon. "To have done so would have condemned half my patients to death."

- "Which half ?" Asked the student.

WAS THE SURGEON DOING RESEARCH?

- He certainly thought so!
- But, he failed to really follow the underlying principles of research ethics, although one could argue that he was providing ethical clinical care.

ETHICAL PRINCIPLES OF RESEARCH

1. Research must have social and clinical value: Ask a specific question that is important enough to justify asking people to accept some risk or inconvenience – BENEFICIENCE

2. Scientific Validity must be designed in a way that gets an understandable answer – BENEFICIENCE

3. FAIR SUBJECT SELECTION - The basis for recruiting is a scientific goal of a study. Participants who accept risk must be able to enjoy any benefits - JUSTICE

ETHICAL PRINCIPLES OF RESEARCH, CONT.

4. FAVORABLE RISK BENEFIT RATIO - non MALEFICIENCE

5. INDEPENDENT REVIEW – built in study from start. Ensure trial is ethically designed - JUSTICE

6. INFORMED CONSENT - accurate and free of bias, risks and ensuring voluntary nature

7. RESPECT - for potential and enrolled participants' AUTONOMY

PRINCIPLES ARE THE SAME IN ESSENCE

YET, THEY FEEL DIFFERENT - WHAT IS IT?

1. RESEARCH AND RESEARCH ETHICS FOCUSES BOTH ON A POPULATION *AND* ON INDIVIDUAL SUBJECTS

2. CLINICAL CARE FOCUSES ON THE INDIVIDUAL, ALONE

RESEARCH AND CLINICAL ETHICS

- RESEARCH GOAL IS TO FIND A SPECIFIC ANSWER, OFTEN BY COMPARING RESULTS, OR TESTING AGAINST A STANDARD OR A PLACEBO.

- RESEARCH, thus, requires EQUIPOISE - the researcher must not favor or believe one choice is superior to the other.

This is where the surgeon in our vignette failed.

RESEARCH AND CLINICAL ETHICS, CONT.

- CLINICAL CARE, unlike research, frequently questions issues for which there is no answer, or where rather answers are unclear.

- CLINICAL ETHICS is, therefore, designed to deal with uncertainty, using a best estimate of available information for guidance.

- RESEARCH to be ethical, must focus directly on finding an answer, and must be conducted according to a an unchanging protocol. There is specifically no room (in general) for alterations or individualization.

CASE 1

- A 65 year old man, MR. X, is enrolled in a study of hospitalized subjects testing whether DRUG A is superior to DRUG B in preventing worsening symptoms. Both drugs have been well studied for safety and they have identical safety profiles.

- A new physician takes over the care of MR. X, and she has never liked DRUG B.

- Should she change the patient's regimen and ensure that he is getting DRUG A? Is this ethically permissible?

- Why or Why not?

CASE 2

- A 65 year old man, MR. Y, is in the next bed over, being treated for heart failure. He is receiving DRUG B, and his condition is worsening.
- His physician decides to change him to DRUG A.
- Is it ethical for him to do this?

SO THE ETHICS ARE THE SAME BUT THE ANSWERS ARE DIFFERENT?

IN THE RESEARCH CASE

- THE SUBJECT IS BOUND TO THE STUDY PROTOCOL. THERE IS NO SAFETY REASON TO CHANGE, AND THE SUBJECT HAS NOT REQUESTED TO WITHDRAW FROM THE STUDY

IN THE CLINICAL CASE

- THE PATIENTS CLINICAL STATUS HAS CHANGED. THERE IS NO CLEAR ANSWER TO WHETHER A IS BETTER THAN B, BUT THE PHYSICIAN WHO IS CARING FOR HIM FEELS THAT THE CURRENT THERAPY IS NOT WORKING, AND CONSIDERS THE CHANGE IN DRUG TO POTENTIALLY IMPROVE CARE.

CASES

- WOULD THE RESEARCH CASE CHANGE IF THE PATIENT HAD DEVELOPED SEVERE HIVES WHILE TAKING THE FIRST DRUG?

- IS HE STILL PART OF THE STUDY? WHY?

DOES RESEARCH AND THE ANSWERS IT PROVIDES RESULT IN BETTER CLINICAL CARE? CAN IT CREATE ETHICAL DILEMMAS INADVERTENTLY?

- YES, THE REQUIREMENT THAT RESEARCH FOCUSES ON DISCRETE ANSWERABLE QUESTIONS MEANS THAT THE CONTROL AND STUDY POPULATIONS MUST BE ESSENTIALLY SIMILAR.
- THIS MEANS THAT THE STUDY POPULATION MAY HAVE TO BE NARROWLY DEFINED.
- IN ADDITION, RESEARCH ON HIGHER RISK THERAPIES IS OFTEN DONE FIRST ON THE SICKEST PATIENTS FOR WHOM NO OTHER THERAPY IS AVAILABLE.

CASE 3: DOES RESEARCH MAKE CLINICAL ETHICS HARDER?

- THERAPEUTIC HYPOTHERMIA IS A THERAPY USED FOR THE TREATMENT OF HYPOXIC ISCHEMIC BRAIN INJURY IN THE NEWBORN.
- NO OTHER POTENTIALLY HELPFUL THERAPY EXISTS.
- IN THE ORIGINAL TRIALS , ONLY THE SICKEST SUBJECTS WERE TREATED, BECAUSE THE RISKS WERE UNKNOWN AND POSSIBLY HIGH.
- EFFICACY WAS PROVEN FOR MODERATE TO SEVERE DISEASE.

CASE 3 CONT: RESEARCH AND CLINICAL ETHICS

- YOU ARE TREATING A NEWBORN WITH EVIDENCE OF MILD TO MODERATE BRAIN INJURY. A COLLEAGUE SUGGESTS USING HYPOTHERMIA. WHAT IS THE RIGHT THING TO DO?
- RESEARCH SUGGESTS A BENEFIT, BUT IT DOESN'T REALLY ADDRESS THE SAME PATIENT POPULATION?
- THE RISKS SEEM LOW, BUT ONLY A RELATIVELY SMALL NUMEBR Of PATIENTS WERE TREATED IN THE TRIALS. IF YOU TREAT MORE PATIENTS, MIGHT A LOW INCIDENCE BUT HIGH RISK COMPLICATION OCCUR?
- THE INFANT IS ALREADY 2 HOURS OLD - YOU HAVE ONLY TWO MORE HOURS TO DECIDE BEFORE STARTING THERAPY OR IT WILL BE OF NO VALUE.
- WHAT WILL YOU DO?

CONCLUSIONS

- THE ETHICS THAT GUIDE BOTH RESEARCH AND CLINICAL CARE ARE BASED ON COMMON PRINICIPLES.
- IN PRACTICE, RESEARCH REQUIRES EQUIPOISE AND A DEDICATION TO ENSURING THAT PROTOCOLS ARE FOLLOWED CORRECTLY IN ORDER TO ENSURE THAT A RELIABLE ANSWER TO THE RESEARCH QUESTION CAN BE OBTAINED.
- CLINICAL CARE IS COMPLICATED BY UNCERTAINTY AND CLIINCIAL ETHICAL DECSION-MAKING OFTEN REQUIRES CAREGIVERS TO USE THEIR BEST ESTIMATE OF CLINICAL BENEFIT AND HARM.

CONCLUSIONS CONT.

- CONTINUED CONDUCT OF ETHICAL RESEARCH IS THE ROUTE TO, ULTIMATELY, OBTAINING THE ANSWERS THAT WILL GUIDE CLINICAL CARE AND DECREASE THE UNCERTAINTY THAT PLAGUES ETHICAL DECISION-MAKING TODAY.

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