Ethical Dilemmas in Hematopoietic Cell Transplantation

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Disclosures

The following faculty and planning committee staff have no financial disclosures:

Name	Institution
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Name	Institution	Disclosure
Jackie Foster, MPH, RN, OCN	NMPD/Be The Match	Pfizer, stock owner (spouse)

Learning objectives

At the conclusion of this session, attendees will be able to:

- Define 4 ethical principles in relation to blood and marrow transplantation (BMT)
- Describe how each ethical principle pertains to the BMT process
- Discuss ethical principles as applied in case discussions related to BMT patients and donors
- Demonstrate an increased comfort level with applying ethical principles to practice

Theory of Medical Ethics

- Paradigm shift in medical practice
  - Focus on ***patient's interests*** are paramount in medical ethics
- "An applied branch of ethics or moral philosophy. It attempts to unravel the rights and wrongs of different areas of health care practice in the light of philosophical analysis"

  Campbell, Gillette, and Jones, *pg 2*

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Transparency

- Our practice is entrenched with ethical elements
- Multiple levels involved
- Complex care situations
- Complex process and medical procedure
- Donor and recipient
  - Autonomy
  - Confidentiality
  - Full disclosure
  - Right to withdraw

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Healing Ethos-professionalism

- Refers to ***a set of attitudes*** our professions have developed over many years, more than knowledge and skills. We learn that we must:
  - separate our own emotions and be able to develop an **objectivity** in our work.
  - detach our own emotions while still having **genuine concern** for our patients.
  - practice with an empathy and emotional concern that fosters a **profound respect for their individuality**

Campbell, Gillette, and Jones, p. 20

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Physicians Code of Ethics

- "A physician shall be dedicated to providing competent medical care, with compassion and **respect for human dignity and rights**
- A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health
- A physician shall, while caring for a patient, regard **responsibility to the patient as paramount"**

AMA Code of Medical Ethics, 2017

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Physicians Code of Ethics-Hippocratic Oath

- "Hippocratic oath discusses a code of ethics that transcends national boundaries and specific religious affiliations
  - Physicians using their **knowledge for good**
  - The regimen I adopt shall be **for the benefit of the patient** according to ability and judgement, and not for their hurt or any wrong
  - The health of my patient will be **my first consideration** rather than loyalty to colleagues"

Campbell, Gillette, and Jones, pg 31

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Nurses Code of Ethics

- **"Provision 1-** The nurse practices with compassion and respect for the inherent dignity, worth, and unique attributes of every person
- **Provision 2-** The nurse's primary commitment is to the patient, whether an individual, family, group, community, or population
- **Provision 3- The nurse promotes, advocates for, and protects the rights, health, and safety of the patient**
  - Protection of the rights of privacy and confidentiality
  - Protection of human participants in research
  - Importance of informed consent and the fact that participants can decline to participate or withdraw from any research
  - Professional responsibility in promoting a culture of safety
- **Provision 4-** The nurse has authority, accountability, and responsibility for nursing practice; makes decisions; and takes action consistent with the obligation to promote health and to provide optimal care "

ANA Code of Ethics, 2015

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Social Workers Code of Ethics

- Commitment to clients
  - Primary responsibility to promote the well-being of clients…clients' interest are primary. Responsibility to the larger society (report abuse, or harm to self or others)
- Self-determination
  - Social workers respect and promote the right of clients to self-determination and assist clients in their effort to identify and clarify their goals.
- Informed consent
  - Social workers (SW) should provide services to clients only in the context of a professional relationship based…on informed consent.
  - When patients lack the capacity to provide informed consent, SW should protect clients' interests…SW should take reasonable steps to enhance clients' ability to give informed consent
- Privacy and confidentiality
  - SW should protect right to privacy..confidentiality

NASW Code of Ethics, 2017

“It Takes a Village”

- Multidisciplinary team members all with dedicated roles of contribution
  - Recipient
  - Donor
  - Physicians
  - Nurses
  - Social Workers
  - Case managers
  - Chaplains
  - Pharmacists
  - Dieticians
  - Physical Therapists

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We all know it's a huge puzzle!

The Psychosocial Iceberg

- Multiple aspects involved in SCT. Develop long standing relationship with patient
  - Continuum of care along the transplant process
  - Explore patient wishes, concerns
  - Psychological ability to deal with situations and coping skills
  - Degree of patient cooperation
  - Family support and dynamics
  - Help overcome conflict- with patient and team

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Our Potential Conflicts

- Young age of most patients
- Life-threatening and often fatal disease
- Potential cure, often last chance at survival
- Living donors- younger, sometimes minor
- Selective process choosing donor
- High cost procedure- financial impact

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Ethical Involvement in Palliative Care

- When transplant patients do not respond to treatment, or incur severe complications, how do practitioners transition conversation from curative to palliative?
- Survivor may be cured but face lifelong complications- sterility, GVHD, secondary malignancy, or QOL
- Practitioners share decision-making process with others, and support is needed when the decisions are difficult and uncertain

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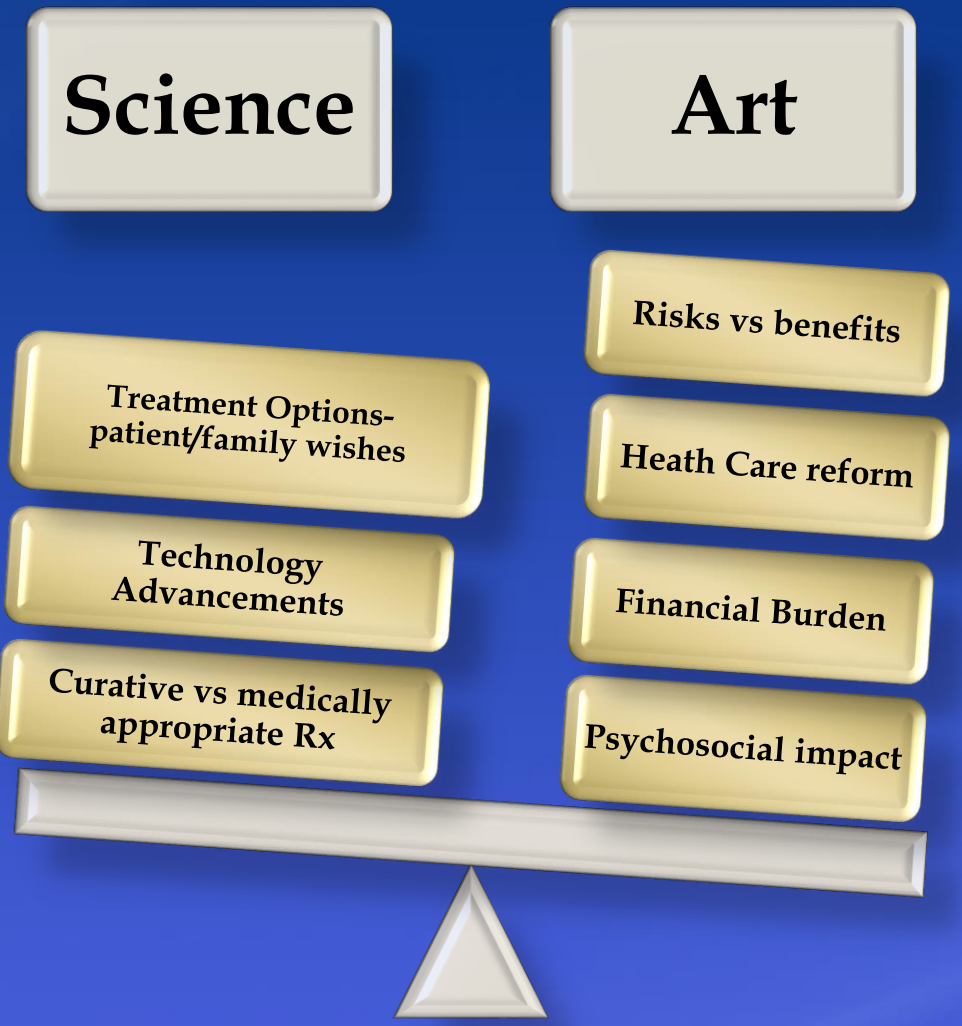
The balancing act…



The balancing act

- "Conflicts may arise between the rights of the individual, the rights of families, available accepted scientific and technological treatments, and economic realities…rights and needs of the potential recipient must be balanced with rights and needs of potential donors"

Transplant Nursing, pg 25

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Explore and assess psychosocial support system, coping skills, personal goals and wishes

Help patient find balance and foster balance within transplant team. Support team finding common ground and therapeutic goals.

The Patient is Our North Star…

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Ethical Principles

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Ethical Principles

- Informed Consent
- Benevolence
- Non-maleficence
- Distributive Justice

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Ethical Principle #1

- ***Informed consent***--Autonomy
  - Disclosure of risks and benefits
  - Laying out pros/cons
  - Information provided about the impact of the disease and treatment process.
  - Alternatives and options
  - Full disclosure
  - Free will to participate
  - Consent vs refusal

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Informed Consent and the Role of Psychiatry

- Mental illness vs physical illness
- Capacity vs Competency
- Patient Self Determination Act passed in Congress in 1990
- Durable Health Care POA
- Mental Health POA

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Surrogate Act- Decision-Making

- **HCPOA**--Surrogate medical decision-makers for incapacitated patients may be:
  - designated by the patient (a durable power of attorney for healthcare or healthcare proxy);
  - appointed by the court (a guardian); or
- **Surrogate**--a statutory surrogate selected according to state protocol in the following order:
  1. spouse
  2. adult child
  3. parent
  4. domestic partner
  5. sibling
  6. close friend
- If after "reasonable effort" none of these individuals can be located or if they decline to make the decisions, the attending physician may make the decision after consulting with the ethics committee, or if that's not possible, after consulting with another physician who concurs with the treatment decision (Arizona Revised Statutes {ARS} 36-3231).

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Informed Consent

- We assure patients give informed consent…but do they really consent? Physicians discuss the risks and benefits, but do patients really listen? They face fear of death and focus on life, then later on they live with complications, QOL issues, and financial distress
- When patients are faced with severe illness, we are faced with care decisions. How do we help them pursue aggressive treatment and then facilitate the transition to palliative care? Do they understand?

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Case Study A

Adult female with a cognitive disability, transplant candidate for Autologous stem cell transplant (SCT). MD states patient with seems able to make decisions, although asks team to speak to his brother as well. Psych consult for determination (documentation) of capacity and/or guardian, HCPOA or surrogate/proxy

Case Study B

- Adult male with DLBCL currently preparing for Autologous SCT. Patient is quiet and defers to his spouse throughout process. Spouse speaks during provider visits, and hinders contact with patient during calls. In presence of spouse, patient verbalizes agreement with transplant planning. During chemo, patient mentions to the nurse (when spouse is away) that he doesn't want to proceed to transplant

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Ethical Principles

- Informed Consent
- Benevolence
- Non-maleficence
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Ethical Principle #2

- ***Benevolence*** — a commitment to **do good** for others. Actions and intents have a positive affect, positive influence, and/or produce good patient outcomes. Decisions and choices have a positive impact on lives

Benevolence

- Treatment decisions- *pros* outweigh cons
- Risk vs benefit- *benefits* outweigh risk
- Seeking positive outcomes
- Weighing the greater good

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Professional Boundaries for TEAM

- We deal with very sick patients, often with transplant being their last chance at treatment and a cure. Donors are needed to move forward. Very emotional… pediatrics even more so.
- Physicians, nurses, transplant coordinators, CERs (community engagement representatives), social workers, chaplain, pharmacists, dieticians, physical therapists
- We get involved and sometimes our relationship can expand
  - Boundaries aren't always clear
  - Extended team and sometimes it's hard not to share information
  - Donor confidentiality and protection. Who tells the donor?

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Professional Boundaries for TEAM

- MRD…family dynamics can be burdensome
  - Family members agree to be donor, and pressure not to participate. Sometimes families pressure
  - Health concerns for donor-unsuitable donor, CA dx
  - What if patient relapses? Donor/family reaction
- MUD…how do we recruit **committed donors** to help
  - Agree to help **ALL** patients—not just one patient
  - College campus and concert events
  - Pediatrics pulls at heartstrings
  - Donor center coordinates potential donors, preliminary HLA donor

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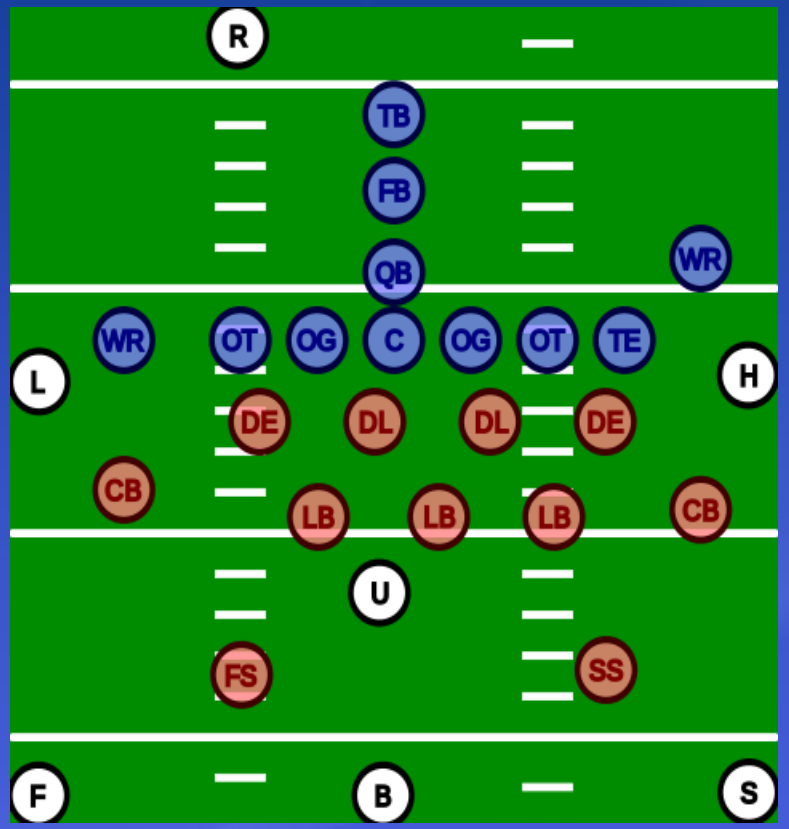
Professional Boundaries for TEAM

- TEAM roles- how do we respect each other's roles?



Case Study C

- Adolescent/young adult (AYA) male evaluated for Autologous SCT for refractory Hodgkins Lymphoma. Patient verbalizes being distraught over chemoRx side effects, and fear of stem cell transplantation. He said he "really only wants alternative medicine treatment"

- Similar scenario—Allo patient post-transplant who is growing weary and "throwing in the towel"

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Case Study D

- Patient with autoimmune syndrome comes in for transplant evaluation. Your site is contracted with insurance, but site doesn't have much experience with transplanting this diagnosis. Insurance won't consider allowing benefits. Do we treat patient where it is a covered benefit or refer to another more experienced center as non-contracted benefit?

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Ethical Principles

- Informed Consent
- Benevolence
- Non-maleficence
- Distributive Justice

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Ethical Principle #3

- ***Non-maleficence*** — to **do no harm**. Aspects of care may have a negative impact on our patients' lives or result in negative outcomes, albeit indirect or unintentional. We don't want to cause harm in whatever we do
  - Primum non nocere (first do no harm)

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Case Study E

- Adolescent male with Down's Syndrome diagnosed with AML referred for Allogeneic SCT. Father is legal guardian. Brother is MRD and cleared as donor with no significant medical history

- What if scenario is flipped?
  - Recipient had no other PMH, but sib donor had history of Down's syndrome
  - Similar in pediatric settings with parent consents for both recipient and donor

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Case Study F

- Adult patient with MDS (recipient) approved for Allogeneic SCT. Patient had several siblings, all screened for potential donor. Sib had a history of mental health issues, recently hospitalized for a psychotic break. Sib donor was screened by TC, not reporting any history of mental health issues. She, in fact, reported frequent head injuries from abuse and a MVA. Conversation was scattered, and TC communicated to MD, however MD felt she should still be HLA typed. HLA typing showed a 10/10 match, and was brought to workup. Psych consult was requested for input and donor was not cleared. Psych and donor MD both felt it could pose greater risk to be a donor given her fragile psychosis

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Case Study G

- Adult male with acute leukemia s/p 2 Allo transplants, presenting with chest pain upon exertion with + dobutamine stress echo
- Relapsed now with central nervous system disease with cranial nerve 7 involvement. Subdural hematoma with headache. Needed to undergo lumbar puncture for Methotrexate
- Recent MI (heart attack), on Plavix and ASA needing procedure. Complex patients with very complex care decisions

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Case study H

- Older adult with AML, s/p Allo SCT. Before transplant, patient had buy-in, but kept verbalizing to the physician that she "didn't want to go too far". Now, patient with fungal infection in sinuses, in ICU with brain abcess, CNS bleed, seizures on vent. How do we transition conversations?

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Case Study F or "TNTC"

- Psychosocial issues abound
- Financial impact/costs
  - Prescriptions
  - Travel/lodging
  - Insurance copay/max OOP
- Social impact
  - living away from home for months
  - Young families impacted
  - Family dynamics/relationship
- QOL
  - Side effects/complications/GVHD
  - Subjective vs objective (ADLs)

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Case Study I

- Adult patient with AML, candidate for Allogeneic SCT. Recipient's adolescent son is haplo related donor. Adult apheresis center can mobilize/collect a 17 year old, so feasible from logistics standpoint. BMT Coordinator expressed discomfort during some conversations that mother/wife would be coercive at times. Apprised donor MD. Referral to Ethics committee, reviewed and advised that minor donors should be collected in pediatric transplant center

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Case study J

- Adult male patient w/ AML, s/p Allogeneic SCT. Day +14 family changes their mind on caregiver plan. Wife refuses to take patient home as she doesn't feel she can handle this. Daughter is having kitchen remodeled after storm damage and can't take patient home. Medicaid insurance, denies SNF or subacute care facility.

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- “I believe everything was explained thoroughly and explicitly. But I don’t think that when you face a last option to have a decent quality of life that you process it. You hear, understand, and acknowledge it but only when you are on the other side of transplant, do you allow your mind and heart to process the knowledge that it may cost everything you own. When hope reappears, you process it because then you have a value to balance it against”

patient quote,

Kim, et al, pg. 1260

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Ethical Principles

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Ethical Principle #4

- ***Distributive justice*—**when we make decisions based on **the greater good**, or the equitable distribution of resources. How we decide allocation of limited resources

The old breadlines….

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Affordable Care Act

- The Affordable Care Act (ACA) bill was signed into law March 23, 2010. It is projected that the ACA will help reduce health care expenditures by approximately $600 billion over the first decade, and more than $1 trillion between 2020 and 2030 (Orszag, 2010, pg 601)
- This will entail reforming our health care delivery system overall for effective cost containment and total insurance coverage

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Distributive Justice…Triage

Triage is defined as follows:

- ***A process*** for sorting injured people into groups based on their need for or likely benefit from immediate medical treatment. Triage is used in hospital emergency rooms, on battlefields, and at disaster sites when limited medical resources must be allocated
- ***A system*** used to allocate a scarce commodity, such as food, only to those capable of deriving the greatest benefit from it

- Ethical foundation to do greatest good for the greatest number

Priest and Bahl, pg 160

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Case Study—Disaster Response

- Hurricane Katrina one of the deadliest storms in US history claiming 1836 lives with $150 billion of damage
- From Friday, August 26th to Sunday, August 28th
  - Katrina intensified from **category 2 to category 5** hurricane
  - Winds in excess of **160 mph**
  - Flood **waters up to 20 ft**
  - Helicopters arrived not to take patients, but to drop off sick, injured, or dead
- Hospitals left in utter chaos—temperatures excess of 100 degrees
- No running water source or electrical power
  - Non-functioning equipment
  - Scarce supplies- performed procedures by flashlight with little or no anesthesia

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Case study, cont'd

- LTAC unit inside of Memorial Hospital
- Triaged patients for evacuation. Rating of 1-3 with 3 being most critically ill
- Rating of 3 applied to 9 patients, need to be air-lifted
- Reviewed by MD helping, and deemed no reason to expect they would survive
- Plan to leave no *living* patients behind—abandonment
- Dr. Pou and 2 staff nurses administered lethal doses of Morphine and Versed. Sought staff to assist and "sedate" patients.
- Charged with 9 counts of homicide- grand jury declined to indict

Priest and Bahl, pg 158-161

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Case study K

- Pediatric patient with acute leukemia and has had several relapses while on chemotherapy. The possibility of undergoing a SCT to improve his condition has been suggested. This procedure is the only treatment that offers him a reasonable hope of survival at this point. Although he receives Medicaid assistance, the SCT is a costly procedure that would involve the family's travel to a distant medical center for weeks of treatment. It is not an experimental treatment, but it is not expected to offer a chance of *total* cure…The estimated cost of treatment would represent a considerable portion of the annual allotted Medicaid budget for his entire state
- Fry and Veatch, pg 81

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Case Study L

- Young adult undocumented female with relapsed AML, medically appropriate candidate for Allogeneic SCT. Young mother with 2 small children, husband works and unable to take time off work. One sister living nearby can help as caregiver, but doesn't drive (caregiver requirement). Patient is uninsured with no prescription coverage. Consider charity care, but to what end?

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Case Study M

- Pediatric patient currently in foster care, needing allogeneic transplant. MRD found in mother, currently incarcerated. Proceeded as haplo donor stem cell collection. Patient did well post-transplant. When mom was released from prison, she wanted to reconnect with child in foster care

- Family dynamics with split families/divorce, separation, abuse, legal custody

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We Can't Let Emotions Derail Care—The ASCT Breast Cancer Controversy

- In the 1990s more than 41,000 patients underwent autologous SCT for breast cancer, despite a lack of clinical evidence of its efficacy. Phase II studies were insufficient to show proof of SCT being superior to standard chemotherapy, which lead to insurers refusing to cover cost of transplant. Litigation and patient emotions lead to an avalanche of patients moving to ASCT. In addition, publication of falsified data in the first randomized controlled trial, skewed clinical evidence of its efficacy. Proceeding on to Phase III trials became increasingly difficult to recruit patients and eventually affected physician-patient relationships

Mello and Brennan, pgs 101-103

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In Conclusion…

- **4 Ethical Principles**
  - Informed Consent
    - Decision-Making Capacity
    - HCPOA, Surrogate
  - Benevolence
    - Do good
  - Non-Maleficence
    - Do no harm
  - Distributive Justice
    - Allocation of resources
    - Disaster care

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Our Role as Transplant Providers

- Fundamental role in complex process/procedure
- Engage with our patients throughout transplant process
- Unique situation to support and care for our patients during life crisis situations
- Facilitate communication thru palliative care transition
- Ability to objectively provide supportive discussion and patient/family education
- Foster healing ethos for ourselves, our peers, and our patients

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Special Thanks

NMDP/Be The Match Council Meeting

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Questions & Discussion

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Evaluation Reminder

Please complete the Council Meeting 2017 evaluation in order to receive continuing education credits and to provide suggestions for future topics.

We appreciate your feedback!