Ethical Considerations Regarding Disclosure of SUDEP

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Disclosures

None
Learning Objectives

• 1. Understand ethical underpinnings of clinical decision-making

• 2. Understand why clinicians should, with few unique and rare exceptions, disclose the risks of SUDEP
Understanding Ethical Underpinnings of Clinical Decision making and Applications Regarding Disclosing Risk of SUDEP

• Ethical Underpinnings of Clinical Decision making (includes Disclosure)
  – Bioethics and Clinical Ethics
  – Doctors Duty to Fulfill the Goals of Medicine
  – Paternalistic vs Shared Decision Making Models of Dr Pt Relationship

• Ethical Reasoning Why Clinicians Should Disclose Risks of SUDEP
  – Literature Supports Benefits Outweigh Worries about Harms Psychologically and in Quality of Life
    • Disclosure of SUDEP in Patients with Epilepsy
    • Delivery of “Bad News” or Uncertainty Disclosure in Other Medical Situations
    • Flawed QOL Reasoning in Other Medical Situations

• Ethical Reasoning For Not Disclosing risks of SUDEP in Rare and Unique Situations

• Conclusions and Recommendations
Ethical Underpinnings of Clinical Decisionmaking

• I. Bioethics and Clinical Ethics Principles and Applications

• II. Doctors Duty is to faithfully fulfill Goals of Medicine

• III. Paternalistic vs Shared Decision making models of Doctor Patient Relationship
I. 4 essential principles of biomedical ethics

1. *Respect for Autonomy: Autonomy* is the moral right to choose and follow one's own plan of life and action. Respect for autonomy is the moral attitude that disposes one to refrain from interference with others’ autonomous beliefs and actions in the pursuit of their goals.

2. *Nonmaleficence: Nonmaleficence* is the moral duty to do no harm.

3. *Beneficence: Beneficence* is the moral duty to assist persons in need.

4. *Justice: Justice* is the ethics of fair and equitable distribution of burdens and benefits within a community.

Beauchamp TL, Childress JF. Principles of Biomedical Ethics. Oxford University Press. 1979
### Ethical Underpinnings of Clinical Decision Making

### 1. 1980’s : Clinical Ethics Application of Biomedical Ethics

<table>
<thead>
<tr>
<th>Medical Indications:</th>
<th>Patient Preferences:</th>
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<tbody>
<tr>
<td><strong>Principles of Beneficence and Nonmaleficence</strong></td>
<td><strong>Principle of Respect for Autonomy</strong> (includes Truth telling/full disclosure)</td>
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<tr>
<td>What is the pt’s medical problem? History? Diagnosis? Prognosis?</td>
<td>• What are the pt's preferences for treatment?</td>
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<tr>
<td>What are the goals of treatment?</td>
<td>• Has the pt been fully informed of benefits and risks, understood this information, and given consent?</td>
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<tr>
<td>• In sum, how can this pt be benefited by medical and nursing care and how can harm be avoided?</td>
<td>Does pt have the capacity to decide? If not, who is the appropriate surrogate? Is the surrogate using appropriate standards for decision making?</td>
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<td></td>
<td>Is pt unwilling or unable to cooperate with medical treatment? If so, why?</td>
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<td></td>
<td>• In sum, is pt’s right to choose being respected to the extent possible in ethics and law?</td>
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<tr>
<th>Quality of Life:</th>
<th>Contextual Features:</th>
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<tbody>
<tr>
<td><strong>Principles of Beneficence and Nonmaleficence and Respect for Autonomy</strong></td>
<td><strong>Principles of Justice, Loyalty and Fairness</strong></td>
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<td>(introduces third party/observer bias; “best interest” reasoning)</td>
<td>Are there family issues that might influence treatment decisions?</td>
</tr>
<tr>
<td>• What are prospects with or without treatment for a return to normal life?</td>
<td>Are there provider issues that might influence treatment decisions?</td>
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<tr>
<td>• Are there biases that might prejudice the provider’s evaluation of the pt’s QOL?</td>
<td>Are there religious or cultural factors?</td>
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<td>Would pt’s present or future life might be judged undesirable?</td>
<td>How does the law affect treatment decisions?</td>
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<td>Is there any conflict of interest on the part of the providers or the institution?</td>
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Ethical Underpinnings of Clinical Decision making

II. Physician Duty to Follow the **Goals of Medicine**

- Prevention of untimely death
- Education and counseling of patients regarding their condition and prognosis (includes truth telling)
- Avoidance of harm to the patient in the course of care
- Promotion of health and prevention of disease
- Maintenance or improvement quality of life through relief of symptoms, pain, and suffering
- Cure of disease
- Improvement of functional status or maintenance of compromised status
- Assisting in a peaceful death

Ethical Underpinnings of Clinical Decision making

III. Duty to follow the Goals of Medicine and decide what should be done for the patient that would likely result in **optimum benefit** and **minimum harm**

- **Historically “Paternalistic”** (beneficence over autonomy; “best interest standard”; but perilous because it introduces observer/third party bias)

- **Today “Shared Decision making” is the ideal** (autonomy over beneficence)
Ethical Reasoning For Benefits of Disclosure of SUDEP Over Worries of Harms

• Benefits of Disclosure to Patients about SUDEP
  – Consistent with Principles of Autonomy and Goals of Medicine
  – Truth Telling is Preserved
  – Prevention of Harm
  – Follows Legal Precedent
  – Allows for the Natural Psychological Adaptation
    • Benefits of Disclosure of SUDEP
    • Benefits of Disclosure of “Bad News” of Uncertainty and Impact of Physician Caring Behavior: Examples from Other Medical Situations

– Worries about Catastrophic Psychological Harm and QOL are Unfounded in the Literature
  • Quality of Life Flawed Reasoning as Harm: Examples from Other Medical Situations
Benefits of Disclosure to Patients about SUDEP

• **Consistent with Bioethical Principle of Autonomy/patient preferences** Prinjha et al. 2005
  - Most pts want to know more

• **Consistent with Goals of Medicine** Helgeson et al. 1990, Shore et. Al. 2008
  - Pts can make their own informed choice to avoid harm, promote their own health, possibly prevent own untimely death
    - Decreased fear of seizures, decreased depression, increase med compliance; increased QOL, decreased worry

• **Truth telling**: builds trust in doctor and profession; prevents false sense of security; avoids feeling of betrayal pain for family by doctor withholding information

• **Prevention of harm**: Ryvlin P et al. 2011
  - 112 trials meta analysis of 18 SUDEP: 7 fold difference in SUDEP incidence: first controlled evidence that intervention with efficacious doses of AED’s may modify risk of SUDEP

• **Follow legal precedent**: absolute obligation to disclose even the most infrequent risk if that outcome has the severest of consequences, ie, death
Benefits of Disclosure to Patients about SUDEP Allows for the Natural Psychological Adaptation/Adjustment to Emerge and Eventually Adjust and Cope with It

- Anxiety can be a common behavioral response to nurses informing about SUDEP (49%), however, more commonly seen is improved adherence to treatment (62%) and avoidance of risk factors (59%) (Lewis et al. 2008)

- A majority of nurses informing patients of SUDEP noted patients’ quality of life remained the same (41%) or improved (42%) (Lewis et al. 2008)

- Majority of patients react with equanimity and positively emotionally/psychologically when receiving information from neurologists who frequently discuss SUDEP (Morton B. et al, 2006)

- **Reassurance:** if low risk; address the unasked ubiquitous worry/fear about death and thus, give a more realistic appreciation of risk; counteract bad internet information
Literature Shows Benefits of Disclosure of “Bad News” and Uncertainty in Other Medical Illnesses

• Allows for Short and Long Term Natural Psychological Adaptation/Adjustment
• Shows Single Most Important Factor: Impact of Physician’s Caring Behavior
  – Meta analysis of 54 studies: Huntington’s, AIDS, cardiovascular, cancer, diabetes, spinocerebellar ataxia - anxiety and depression initially but dissipated by one month (Shaw et al, 1999);
  – Narrative interviews 15 pts: Parkinsons disease when informed of unpredictability risks - pts and GP’s cope best with their own anxieties when GP’s interact with openness and partnership with the pt (Pinder R. 1990)
  – Cancer, studies of delivering bad news - HOW the news is delivered (not the specifics of the diagnostic tests) result in the best psychological adjustment.
    • Practices associated with lower anxiety (surveys to 131 pts with melanoma immediately, 4, 13 mos): setting the stage, have people in room that pt wanted to hear diagnosis, give as much information as pt desired, give written information, clear explanation, discuss pt’s questions same day; most of all, talking about pt’s feelings; being reassuring (Schofield PE, et al. 2003)
    • Best predictor of long term psychological adjustment, less PTSD, less depression and general distress (surveys of 60 pts with breast cancer): physician was caring and emotionally supportive (Mager et al. 2002)
Literature Shows Worries about Catastrophic Psychological and/or QOL Harm After Disclosure of SUDEP to Patients are Unfounded

- Belief by clinicians that, “in best interest of the patient” disclosure of risk of SUDEP will result in emotional distress in the patient, i.e. alarm/harm is not supported by the literature
  - Survey of UK neurologists: those neurologists who disclose SUDEP often report their patients react to information with equanimity, not with emotional distress (Morton et al, 2006)
  - Survey of UK nurses: anxiety common but majority of nurses noted QOL same or improved (Lewis et. al. 2008)
  - Information on risk of fatality including SUDEP as part of an overall 2 day educational program on epilepsy
    - reduced fear of seizures, significantly decreased hazardous self management behaviors, increased AED compliance, decreased depression in patients who were depressed (Helgeson et al 1990)
    - Families reported increased QOL and decreased worry at 1 and 6 months (Shore C, et al. 2008)
  - SUDEP information given to 67 parents (surveys immediately, 1,6 mos)
    - 91% wanted SUDEP information; 74% wanted it at diagnosis
    - No significant adverse effects on the parents’ emotional, physical, social functioning or employment immediately or 3 months after initial discussion. (Gayatri et al. 2010)
Quality of Life Flawed Reasoning as Harm of Disclosure: Some Examples from Other Medical Situations

- Third parties (physicians, care providers, families) often have a more dim picture than patients of the patient’s quality of life and apply their own values, bias and prejudice

  • Neonatologists hypothesized lowest QOL than parents and adolescents for 5 scenarios of progressively more severe learning or physically disabled hypothetical outcomes for babies born extremely low birth weight; (Saigal et al, 1999)

  • Physicians asked to evaluate living with certain chronic conditions such as arthritis, ischemic heart disease, chronic pulmonary disease and cancer judged life with these conditions to be less tolerable than the patients who suffered from them (Jonsen AR, Siegler M, Winslade WJ, Clinical Ethics 6th edition)
There are Rare and Unique Circumstances of Harms of Disclosure

• If the patient expresses the desire NOT to know, then their wishes should be honored, i.e., this respects their respect for persons/autonomy/patient preferences; and follows legal precedent they have the “right not to know”

• In a rare person with particular psychological/psychiatric makeup it might have an exaggerated emotional response such as PTSD

• In certain cultures (such as Navajo Indians) explanation of possible risk is interpreted as a prediction the undesirable events are likely to occur (Carrese, JA, et al, JAMA 1995)

• If the patient misunderstood low risk as no risk, i.e., the patient would have a false sense of security
If Not “If”, Then “How” To Discuss SUDEP:
Optimal Circumstances for Best Patient Understanding and Psychological Adjustment:

1. Information must be tailored to the individual patient/family’s current understanding about SUDEP, desire to learn more, and coping strategy
2. CARING, open demeanor of the physician, invitation to answer all questions
3. Separate nurse reiteration of information
   • Optimizes accuracy of patient/family recall; also changes power dynamic and enhances more questions and clarifications
4. Written supplementary materials
5. Include family (if patient agrees) in the discussion to optimize likelihood of accurate understanding and recollection of information; as well as emotional support and facilitate psychological adjustment
6. Recognition of potential physician bias of avoiding discussion to protect the patient emotionally and protect the physician from discomfort too.
Conclusions & Recommendations

1. The **benefits of disclosing risk of SUDEP to patients** with epilepsy (or to parents/proxy decision makers) **clearly outweigh the harms in high & low risk groups.**

   *exceptions include the rare patient with unique cultural, psychological or social contexts the physician is convinced by the patient it would be harmful*

2. Thus, it is not a matter of “IF SUDEP should be disclosed,” it is a matter of “HOW SUDEP should be disclosed.”
Partner Organizations

American Epilepsy Society
CURE
Epilepsy Foundation
Epilepsy Therapy Project
SUDEP Aware
FACES
Danny Did Foundation
RTI International
ICE Epilepsy Alliance
CDC
National Institute of Neurological Disorders and Stroke
LGS Foundation
Lennox-Gastaut Syndrome
The Pittsburgh Foundation