Was That Consent Informed?

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Disclosure

Member, AATS Ethics Committee and STS Standards and Ethics Committee

No conflicts related to this presentation
Informed Consent: Legal Definition

Assent to permit an occurrence, such as surgery, that is based on a complete disclosure of facts needed to make the decision intelligently, such as knowledge of the risks entailed or alternatives.
Informed Consent: Legal Definition

...a fundamental principle of law that a physician has a duty to reveal what a reasonably prudent physician in the medical community employing reasonable care would reveal to a patient as to whatever reasonably foreseeable risks of harm might result from a proposed course of treatment. This disclosure must be afforded so that a patient—exercising ordinary care for his or her own welfare and confronted with a choice of undergoing the proposed treatment, alternative treatment, or none at all—can intelligently exercise judgment by reasonably balancing the probable risks against the probable benefits.
Informed Consent: Ethics Definition

The willing and un-coerced acceptance of a medical intervention by a patient after adequate disclosure by the physician of the nature of the intervention, its risks and benefits, as well as of alternatives with their risks and benefits.

Informed Consent

1. Critical element of the preoperative process

2. Frequently the source of postoperative communications issues

3. Invariably a component in medico-legal issues
Elements of Informed Consent

1. Disclosure
   What a reasonable person would want to know
2. Capacity/Competence
   Ability to comprehend the disclosed information
3. Voluntariness
   Freedom from external coercion
4. Understanding
   Recognition of the impact/consequences of treatment
Understanding Information

Autonomous choice requires understanding
  – Engage patient in conversation
  – Informational needs, hopes, fears, values

Nature of understanding
  – Need not be “full”, only “adequate”—central facts
  – Appreciation of risks/benefits
Understanding Information

Problems of information processing

- Information overload
- Unfamiliar terminology (threatening)
- Special meaning to patient
- Framing risks
Understanding Information

Do all patients want all information?

• Refusal of info is itself an autonomous decision
• 60% don’t want to know details/risks
• 86% would consent without knowing the risks
• 88% don’t use information to make decision
• Courts: waiver permissible
Helping Patients Understand Risks

Physicians should recognize:

1. Challenges to effective communication
2. Emotions influence risk perception
3. Standardize descriptive terms
4. Avoid using relative risks
5. Provide positive & negative perspective
6. Use visual aids to convey risks

1. Challenges to Effective Communication

Patients
- Emotions may trump facts
- Unduly influenced by family, friends, media
- Desire for involvement varies widely
- Have insufficient background biology/medicine to navigate

Physicians
- Provide data rather than information
- Provide more detail than is needed (Goldilocks rule)
- Don’t understand framing
- Don’t use visual aids
Helping Patients Understand Risks

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6. Use visual aids to convey risks

2. Emotions Influence Risk Perception

Factors that decrease fear

- Less fear = less weight on risk
- Exhibit competence: engender trust
- Be responsive, supportive, and empathetic (patients want the surgeon “on my side”)
- More frequent (car crash vs plane crash)
- Less dreaded (heart disease vs cancer)
Helping Patients Understand Risks

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3. Standardize Descriptive Terms

Verbal inconsistency

– very high
– high
– moderate
– low
– very low
– minimal

Use frequencies, not odds

– which is more likely, 1:250 or 1:25?
– 40% pts think 1:250 is more likely than 1:25
– clearer: 4 out of 1000 vs 40 out of 1000
Helping Patients Understand Risks

Physicians should recognize:

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4. Avoid using relative risks
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6. Use visual aids to convey risks

4. Avoid Using Relative Risks

Relative risk causes confusion: Vioxx example
  – 1.50 CV events vs placebo 0.78 events /100 pt-yrs
  – Reported: Vioxx doubles risk of CV event
  – Actual: Vioxx increases risk by 0.72% (< 1 in 100)

Relative risk exaggerates perception of risk
Helping Patients Understand Risks

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Framing for Success: Nocebo Effects in Thoracic Surgery

- **Prospect theory:** people do not make decisions and judgments based on outcome probabilities
- Make them on the basis of gains and losses, and they weigh gains and losses differently
- In general, people are more strongly averse to losses than they are positively disposed to gains
- Overestimate the probability of unlikely events and excessively weigh unlikely events in their judgments
Framing for Success: Nocebo Effects in Thoracic Surgery

Overweighing results from 3 aspects of scenario evaluation:

• (1) focused attention
• (2) confirmation bias
• (3) fluency, or cognitive ease
(1) focused attention:
If an event is likely (survival without complications after an elective operation), people tend to focus on the alternatives (complications)
Framing for Success: Nocebo Effects in Thoracic Surgery

(2) confirmation bias:
People tend to retrieve evidence, instances, or images related to the focal alternatives that confirm their plausibility
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(3) fluency, or cognitive ease:
Weighing probabilities is influenced by the ease with which the adverse outcomes are perceived (complications suffered by a friend or relative after a similar procedure). The role of mathematical probability in weighing outcomes is reduced even more when the mental representation of the outcome is vivid
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- Using actual numbers rather than more abstract % increases the vividness effect, called denominator neglect.
- For example, an epidemic that “kills 1,286 people out of every 10,000” is perceived as worse than an epidemic that “kills 24.14% of the population,” even though the latter kills almost twice as many people.
Framing for Success: Nocebo Effects in Thoracic Surgery


- Nocebo response: when the suggestion of a negative effect of an intervention leads to an actual negative outcome
- For example, when clinicians instruct patients that a medical procedure will be extremely painful, the patients tend to experience more pain than those who were not similarly warned
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- Amanzio et al reviewed 73 clinical trials of NSAIDs, triptans, and anticonvulsant drugs (1988-2007), each comparing anti-migraine medications against placebos
- The negative side effects reported by the placebo groups in each study (nocebo effects) were the same as the drug being studied

Framing for Success: Nocebo Effects in Thoracic Surgery

- Frame preoperative discussions by emphasizing benefits and discussing risks (complications and death) honestly but in a way that minimizes the negative effect that loss aversion may have

- A thoughtful, fact-based informed consent process may optimize outcomes while honoring the principles that require serving our patients’ best interests and respecting their self-determination
2 incisions:

- Camera port: 1 inch
- Access incision: 2-3 inches
<table>
<thead>
<tr>
<th>Feature</th>
<th>Thoracotomy (n=284)</th>
<th>VATS (n=284)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least 1 Cx</td>
<td>49%</td>
<td>31%</td>
<td>0.0001</td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td>21%</td>
<td>13%</td>
<td>0.01</td>
</tr>
<tr>
<td>Atelectasis</td>
<td>12%</td>
<td>5%</td>
<td>0.006</td>
</tr>
<tr>
<td>Prolonged air leak</td>
<td>19%</td>
<td>13%</td>
<td>0.05</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>10%</td>
<td>5%</td>
<td>0.05</td>
</tr>
<tr>
<td>Transfusion</td>
<td>13%</td>
<td>4%</td>
<td>0.02</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>5%</td>
<td>1%</td>
<td>0.02</td>
</tr>
<tr>
<td>Death</td>
<td>5%</td>
<td>3%</td>
<td>0.20</td>
</tr>
<tr>
<td>CT duration (d)</td>
<td>4</td>
<td>3</td>
<td>0.0001</td>
</tr>
<tr>
<td>Length of stay (d)</td>
<td>5</td>
<td>4</td>
<td>0.0001</td>
</tr>
</tbody>
</table>
Conclusions

How Can the Surgeon Ensure Understanding?

• Provide information, not data, neutrally framed
• Convey competence, empathy, caring, trust
• Use frequencies, not odds
• Use actual risks, not relative risks
• Provide positive and negative perspective, but avoid the nocebo scenario
Ethics Bottom Line

• Consent is a process, not an event
• Disclosure of information enables capable persons to understand and accept or reject treatment
• Informed refusal by capable persons is ethically acceptable
• Framing of information and establishment of trust powerfully influence decision making
Ethics in CT Surgery: A Survey of Surgeons' Views

- A survey exploring the effects of ethics debates at annual meetings and ethics publications in CT journals was sent electronically to CT surgeons who belong to the Society of Thoracic Surgeons (STS) and the American Association for Thoracic Surgery (AATS)
- Of 3705 surgeons, 578 responded (16%)
Ethics in CT Surgery: A Survey of Surgeons' Views

- 66% attended ≥2 of the last 5 STS meetings
- 68% attended ≥1 of the last 5 AATS meetings
- 69% agreed that their own practices would benefit from better understanding of ethical issues
- 83% agreed that other CT surgeons would benefit from better understanding of ethical issues
- 61% agreed that demonstration of adequate understanding of complex ethical issues should be part of Board Certification
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- Iva Krabbe, a 65-year-old retired professor presents with a bx-proved 2-cm LUL NSCLC
- Professor Krabbe has full capacity to make health care decisions
- After pulmonary function testing, her thoracic surgeon, Dr S.F. Young, determines that the patient is a good surgical candidate and is prepared to offer her VATS lobectomy
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• Dr. Young also plans to mention the less desirable options of open lobectomy, stereotactic body radiation therapy, radiofrequency ablation, or observation (no surgery)

• Dr Young wants to provide Professor Krabbe with as much relevant information as is necessary for her to make a well-considered decision to go forward with the operation
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- The information should include the nature of the alternative operations and their expected benefits and risks, both short term and long term
- Short-term issues would include description of pertinent procedural details, normal expectations of pain, healing, and possible complications
- Long-term issues would include likelihood and duration of survival
Framing for Success: Nocebo Effects in Thoracic Surgery

• Dr Young describes how the VATS procedure is done, and complications relevant to the patient’s decision-making process are conveyed to her

• Dr Young uses numbers rather than percentages because numbers are more concrete and therefore easier to understand, or so he believes
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• He tells her that the likelihood of surviving the operation without complications is 75%, but also explains that many complications can occur

• Likelihood of air leak requiring chest tube drainage longer than a week is 8 out of 100 patients, cardiac arrhythmia 7 of 100, bleeding requiring transfusion 4 of 100, and pneumonia 3 of 100 patients
Framing for Success: Nocebo Effects in Thoracic Surgery

• Other complications are rare, each occurring in fewer than 1 of 1,000 patients
• In all, 25 patients of 100 undergoing this procedure have any complication at all
• Only 19 patients in 1,000 die after the operation
• Nearly 2/3 of patients have mild or no pain, and only 6 of 100 have severe pain, many fewer than after the open operation
Framing for Success: Nocebo Effects in Thoracic Surgery


- He also describes the likelihood and duration of long-term survival and cure after the operation.
- Dr Young has been thorough in discussing the possible results of surgery so the patient can make a well-informed decision about consenting to surgery, which she does without hesitation.
Framing for Success: Nocebo Effects in Thoracic Surgery

• Has the surgeon’s thoroughness served the patient well?

• It is possible that the patient may not have benefited from Dr Young’s carefully thought out, complete explanation

• Prospect theory and the nocebo effect can explain why the patient might have been harmed by the disclosure process
Framing for Success: Nocebo Effects in Thoracic Surgery

• Dr Young told his patient that she has a 75% chance of coming through the operation without complications, but its magnitude changes her focus to potential losses; cx and death

• She visualizes 8 patients with an air leak and a chest tube for over a week, 7 with abnormal heart beats, 4 bleeding from their chests, 3 with pneumonia, and 6 in severe pain, neglecting the denominator for each bad outcome
Framing for Success: Nocebo Effects in Thoracic Surgery

- Worse, 19 patients are dead; again, her calculus ignores the denominator of 1,000.
- Dr Young presented accurate evidence-based information but framed it in a way that may have increased the stress and anxiety that ordinarily accompanies imminent surgery.
- Some degree of postoperative nocebo effect is likely in the form of the nonspecific symptoms.
Framing for Success: Nocebo Effects in Thoracic Surgery

• A better approach for Dr Young would have been to provide the same information, but to frame it differently: keep the 75% survival without complications, and mention only the most frequent complications in general terms

• “The most common potential complications are an air leak lasting for a week, abnormal heart beats, bleeding, and lung infections, all uncommon, occurring in 1-7% like you.”
Framing for Success: Nocebo Effects in Thoracic Surgery


- Other problems can occur rarely, less than 1% of the time. Pain accompanies nearly all chest operations, but the vast majority of patients having this operation have only mild pain or no pain at all, far less than the older open operation.”

- He must mention survival outcomes as well, of course, but would not describe them as 19 deaths out of 1,000 patients
Framing for Success: Nocebo Effects in Thoracic Surgery

• Rather, he would frame them positively: “You will have a 98% to 99% chance of coming through the operation and leaving the hospital in good shape.”

• If Professor Krabbe wants more specific statistical details, Dr Young can easily provide them
Framing for Success: Nocebo Effects in Thoracic Surgery


- Patients in general attach greater weight to losses, adverse outcomes, than to gains.
- Effect is magnified when the positive aspects are dominant and losses are proportionately small.
- Using actual numbers rather than percentages tends to focus the subject’s attention on images of people who are suffering the adverse outcomes.
Framing for Success: Nocebo Effects in Thoracic Surgery

- Moreover, large numerators are seen as large #s rather than proportions, (denominator neglect), further accentuating the negative images
- Previous experiences the patient might have had with undesirable outcomes, (personally or in friends), add to the vividness of the images, resulting in even heavier weighing of adverse outcomes
Framing for Success: Nocebo Effects in Thoracic Surgery


- In this way, the threat of complications assumes proportions much greater than the actual statistics warrant, which can lead to increased anxiety and stress before the operation.

- Thoracic surgeons may be able to minimize nocebo effects after surgery by presenting a generally optimistic tone preoperatively, in the context of values and preferences of the individual patient.
Framing for Success: Nocebo Effects in Thoracic Surgery

- They should present relevant information accurately, according to the best evidence available, including description of Alternatives
- As surgeons, we should be mindful of the impact of our conversations on surgical outcomes
Weighting Composite Endpoints in Clinical Trials


Clinical trials comparing techniques for coronary revascularization (CABG vs. PCI) use MACCE as a composite endpoint:

– Death
– Stroke
– Myocardial infarction
– Need for repeat revascularization

- MACCE elements are treated as if of equal weight
- Non-inferiority margins are used to offset the deviation of the elements from equality and to consider unmeasured elements
- The magnitude of these margins is not evidence-based
## Study Attributes

<table>
<thead>
<tr>
<th></th>
<th>PCI</th>
<th>Intermediate</th>
<th>CABG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extent of procedure</td>
<td>2 hours</td>
<td>3 hours</td>
<td>4 hours</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>1 night</td>
<td>2 nights</td>
<td>4 nights</td>
</tr>
<tr>
<td>Recovery time (weeks)</td>
<td>1 week</td>
<td>3 weeks</td>
<td>6 weeks</td>
</tr>
<tr>
<td>Risk of death*</td>
<td>6%</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Risk of MI*</td>
<td>7%</td>
<td>5%</td>
<td>3%</td>
</tr>
<tr>
<td>Risk of stroke*</td>
<td>2%</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>Risk of revascularization*</td>
<td>20%</td>
<td>15%</td>
<td>10%</td>
</tr>
<tr>
<td>Change in life expectancy</td>
<td>No change in life expectancy</td>
<td>Live 6 months longer</td>
<td>Live 1 year longer</td>
</tr>
</tbody>
</table>

* During the procedure or within 3 years
## Sample Choice

<table>
<thead>
<tr>
<th></th>
<th>Procedure A</th>
<th>Procedure B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extent of the procedure</td>
<td>4 hour procedure 4 nights hospital stay 6 week recovery time</td>
<td>2 hour procedure 2 nights hospital stay 1 week recovery time</td>
</tr>
<tr>
<td>Risk of death during the procedure or within three years</td>
<td>2 deaths out of 100 patients</td>
<td>2 deaths out of 100 patients</td>
</tr>
<tr>
<td>Risk of heart attack during the procedure or within three years</td>
<td>1 heart attack out of 100 patients</td>
<td>1 heart attack out of 100 patients</td>
</tr>
<tr>
<td>Risk of stroke during the procedure or within three years</td>
<td>1 stroke out of 100 patients</td>
<td>1 stroke out of 100 patients</td>
</tr>
<tr>
<td>Risk of needing another procedure within three years</td>
<td>10 out of 100 need a new procedure</td>
<td>10 out of 100 need a new procedure</td>
</tr>
<tr>
<td>Change in life expectancy</td>
<td>Live 6 months longer</td>
<td>No change in life expectancy</td>
</tr>
</tbody>
</table>
Relative Weight of Attributes

Equal Weights = 0.1667
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Extent of the procedure</th>
<th>Risk of death during the procedure or within three years</th>
<th>Risk of heart attack during the procedure or within three years</th>
<th>Risk of stroke during the procedure or within three years</th>
<th>Risk of needing another procedure within three years</th>
<th>Change in life expectancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>4 hour procedure</td>
<td>3 deaths out of 100 patients</td>
<td>3 heart attacks out of 100 patients</td>
<td>3 strokes out of 100 patients</td>
<td>10 out of 100 need a new procedure</td>
<td>Live 1 year longer</td>
</tr>
<tr>
<td>B</td>
<td>2 hour procedure</td>
<td>6 deaths out of 100 patients</td>
<td>7 heart attack out of 100 patients</td>
<td>2 strokes out of 100 patients</td>
<td>20 out of 100 need a new procedure</td>
<td>No change in life expectancy</td>
</tr>
</tbody>
</table>

“A” = CABG (87%)  
“B” = PCI (13%)
Composite Results

Respondents more likely to choose CABG

– Value longevity
– Less concern with long hospital stay
– Familiar with CABG
– Unfamiliar with stents
– Lower income, rent home
– Consistent responses to conjoint choices
Composite Results

Respondents who switched to PCI when labeled as CABG or stent

- Younger
- Male
- Non-white
- Have CAD
- Have had previous PCI but not CABG
- Report feeling depressed
Conclusions

• MACCE elements do not have equal weight
• Patients may be biased by procedure labels
• Assigning relative weights to the composite elements strengthens the validity of the endpoint
  – Minimize speculation of alternate endpoint weights by editorialists
  – Minimize or eliminate the need for non-inferiority margin offsets