Communicating
Research-Related Risk

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Please note…

Benefit may make harms more tolerated, but benefit does NOT erase harm

To Discuss

• The duty to warn
• Harms and the risks in research
• How we communicate the risk of harm/s
• How what we communicate is ingested
What is Harm?

- Noun
  - Aggravation, balefulness, damage, damnum,
    deadliness, detriment, disablement, evil, hurt,
    hurtfulness, ill-consequence, ill-treatment,
    impairment, injury, malignancy, malignity,
    mischief, misfortune, noxiousness,
    penuriousness, ruin, scathe, scourge,
    virulence

http://legal-dictionary.thefreedictionary.com/harm

What is Risk?

- The potential that a specific action or activity *(including inaction)* will lead to a harm (an undesirable outcome).
- ‘Risk’ is often used to describe harm.
- Almost any human endeavor carries some risk, but some are much more risky than others.

The Risk of Daily Life

Drove to airport – Boston traffic
Risks: Car accident
Mental anguish

Airport Security
Risks: Loss of privacy
Embarrassment

Airline flight
Risks: Crash
Airline food
Deep vein thrombosis
To Discuss

• The duty to warn
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• How what we communicate is ingested
• Room for improvement

When we think we have a Duty to Warn

Why we warn

• To provide information so that an individual can make an informed decision
  – Ideally to protect themselves
  – Avoid mishap (harm)
• Legal protection (CYA)
  – Or so we think
Duty to Warn

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Who can be Harmed in Research?

- The individual
- Family members
- Community
What are Research Harms?

- Inconvenience
  - Parking
  - Getting to the site
- Physical
  - Discomfort
  - Downright pain
  - A variety of symptoms
    - Rash
    - Diarrhea
  - Loss of life or limb
- Psychological
  - Stress
  - Embarrassment
- Social
  - Stigmatization
- Financial
  - Insurance coverage
- Legal
  - Now they know you are a felon

Important Details of the harms

- Severity/seriousness
- Duration
- Reversibility
- Context
- Probability

This is a study of a new agent for the treatment of rheumatoid arthritis. Drug is an immune-modulator. Potential risks include:

- 20% have developed a transient rash
- 10% developed serious hypertension that required therapy
- 5% developed a serious infection
- 0.5% developed a neoplasm (cancer)
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Potential risks include:
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What if:
- Your mother has RA – and you have slight morning stiffness in one knee.
- You have bad pain in both knees and ankles that is reasonably controlled with NSAIDs
- You cannot walk up stairs
- You need a walker for ambulation

Important Details of the harms

Probability

- Almost always – in fact anticipated
- Frequent, common, often,
- Occasional, in some cases,
- Rare, very rare
- Has never happened but is theoretically possible

To Discuss

- Daily acceptance of risk of harm
- The duty to warn
- Harms and the risks in research
- How we communicate the risk of harm/s
- How what we communicate is ingested
The ‘Ideal’

- Unbiased presentation
- Straight-forward, simple language
  - That this is research
  - What the participant will be expected to do
- Potential benefits
- Potential harms – and risk for same
  - Clearly state that it is not possible to anticipate or list all risks – you will include the most likely
  - Provide meaningful ‘probability’

Simple Language

- Goal = “Just right”
- Avoid un-necessary big words
  - The risks include induration and ecchymosis at the injection site and rare events of asystole have been reported
    - You might get a bruise and die.
- Avoid un-necessary small words
  - The risks include some small red marks or bumps on your skin that may or may not be itchy.
    - You might get a rash

Benefits

- Avoid over-promise
- Example:

  This study, called GROUP (Get Rid of Your Pain) focuses on a new therapy for cluster headaches – specifically for patients who have failed all other therapies and have no where else to turn.

  We are extremely hopeful that this new drug will be ‘the answer’ for anyone suffering from CH.
**Benefits**

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**Of the known-risks – which to include?**

- Everything
- Only the likely ones
- All serious harms
  - Even if only hypothetical

  Consider some examples…

**Survey research**

- Research:
  - 4 page survey regarding cheating behavior
- Risks:
  - Sensitive questions may cause stress
  - Loss of privacy
  - Paper cut from handling the survey pages
  - Infection of the aforementioned paper cut
Research Cardiac Catheterization

- Risks:
  - May cause a serious arrhythmia
    - Resuscitation could be successful
    - Resuscitation could be unsuccessful
  - Catheter may puncture the heart and cause
    - Bleeding into the pericardial sac which
      - Can require emergency drainage of the blood by insertion of another catheter through the chest wall into the heart
      - Can require emergency surgery
    - Catheter could break and cause damage to any organ in the body
      - Stroke, heart attack, kidney damage, liver damage etc.
  - Catheter may damage a heart valve which
    - May require cardiac surgery
  - Problems at the catheter insertion site (femoral artery)
    - Bleeding
    - Rupture of the artery that
      - Could cause lack of blood flow to the leg and if artery cannot be fixed – loss of the leg
      - Could require surgical repair
  - The dye can cause:
    - Allergic reactions
      - Allergic reactions can kill
    - Worsen limited kidney failure
  - Pressure sore from lying on the cold radiology table
Clear communication of probability

- Recommendations
  - Do not use vague descriptive words (e.g. rare, common)
  - Use multiple formats (e.g. numbers, graphs)
  - Show pictorial representations as possible
  - Present comparisons with a common denominator
  - Use absolute as opposed to relative risks
  - Avoid small percentages (0.06%); use 6 per 10,000 instead
  - Individualize estimates if possible

Words vs Numbers

- Numbers preferred over words
  - 46.6% preferred numbers
  - 20.6% preferred verbal descriptions
  - 32.8% had no preference

> J Empir res Hum Res Ethics 2009;4:17-26

Words vs numbers

- European Commission recommended verbal descriptors

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<thead>
<tr>
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<tbody>
<tr>
<td>Common</td>
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> Aliment Pharmacol Ther 2011;33:23-32
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<table>
<thead>
<tr>
<th>Eur. Comm.</th>
<th>Students</th>
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So – everyone wants numbers
Do they know what they mean?

- 50% of people
  – could NOT convert 1% to 10/1000
- 80% of subjects
  – unable to convert 1/1000 to 0.1%
- Difficulty figuring out if 1 in 27 is higher or lower than 1 in 37
  – N.b., Medical students did not fare any better

Do not add confusion

Framing Bias
The potential benefit of this drug is that it will decrease your risk of developing kidney failure by 75%. *(relative risk)*

FYI: The potential effect on your absolute risk of developing kidney failure:

<table>
<thead>
<tr>
<th>Existing risk</th>
<th>Potential risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5%</td>
<td>0.125%</td>
</tr>
<tr>
<td>5.0%</td>
<td>1.25%</td>
</tr>
<tr>
<td>50%</td>
<td>12.5%</td>
</tr>
</tbody>
</table>

**Framing Bias**

- Hypothetical cholesterol lowering drug
  - Effect represented two ways:
    - 34% relative risk reduction of MI
    - 1.4% absolute risk reduction
  - Twice as many people enrolled when presented as a 34% relative risk reduction
- Best able to figure out benefit when given relative risk reduction AND baseline risk

*Aliment Pharmacol Ther 2011;33:23-32*

**Framing Bias**

- Study: surgery or radiation for lung cancer
  - When presented as surgical survival of 80%
    - 18% opted for radiation
    - 82% opted for surgery
  - When presented as surgical mortality of 20%
    - 44% opted for radiation
    - 56% opted for surgery

*McNeil et al*
This study, called GROUP (Get Rid of Your Pain) focuses on a new therapy for cluster headaches – specifically for patients who have failed all other therapies and have no where else to turn.

We are extremely hopeful that this new drug will be ‘the answer’ for anyone suffering from CH.

This new drug has already been studied at other institutions and some side effects have been reported. These include:

• Most people developed a transient rash
• About 25% had mild nausea
• And only a few had double vision and vertigo lasting several days

We do not expect that any of these potential side effects will be a problem for you, and we think that with careful dose monitoring serious side effects can be avoided.

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How our info is received

- Too long…too much
- Confusion with words
- Confusion with purpose
- Confusion with understanding risk
- Too often not read
- Too often not remembered

Effect of harm severity

- “Death and pneumonia are rare events”
  - Assumption that death much less likely than pneumonia
- “Visual impairment and dry mouth are rare events”
  - Students interpreted that as:
    - Risk of visual impairment: 2.3 +/- 2.7%
    - Risk of dry mouth: 8.8 +/- 7.7%

Frequency vs belief expectation

- ICF states: 90% of people receiving this drug will have no effect
- “It will be me” – I shall be in the 10%
  - This is belief expectation
Personalizing Risk

- Early-phase cancer study
- Participants asked to assess chances of long-term benefit
  - For all cancer participants: 12.6%
  - For themselves: 41.7%

Those expecting long-term benefit 17 times more likely to enroll

Availability Heuristic

- Research:
  - 4-page survey regarding cheating behavior
- Risks:
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Availability Heuristic

- Research:
  - 4 page survey regarding cheating behavior
- Risks:
  - Sensitive questions may cause stress
  - Loss of privacy
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  - Infection of the aforementioned paper cut

My father died from sepsis which started from a small cut in his finger...the risk of this study is too high for me! I’m outta here!