

***G - ELNEC Staff Education***  
*[End-of-Life Nursing Education Consortium]*

**Eliza Coffee Memorial Hospital**

***VI. Ethical & Legal Issues***

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# Objectives

- Understand what is required for informed consent and determining decision making capacity
- Understand what's required for advance directives
- Understand the definition of futile / non-beneficial care and how to avoid it

# Outline

1. The law and informed consent
2. Communicating risk & informed consent
3. Advance Directives
4. Ethics, stewardship & avoiding futile care

# 1. The Law & Informed Consent

- Federal and State
- Laws
  - Statutes – e.g. advance directives
  - Courts – e.g. landmark bioethics cases
  - Regulations – e.g. medical boards
- Resolving difficult cases
  - Ethics committees / consultations

# Ethics of an informed consent

- Information – legal standards

Professional standard

What a reasonable person would want

- Information – ethical goal to provide this in an understandable format to every patient

# Informed Consent Requirements

## Elements of Information in Informed Consent:

- nature of procedure
- benefits
- risks, common or severe
- alternatives

## For Consent to be Valid:

- **Voluntary** – must be free to choose
- **Patient must understand what's to be done**
  - Capacity to understand?

# Informed Consent

- **Definition:** The ideal that the patient should be informed about the pros and cons of a treatment and its alternatives, and on this basis should decide whether he or she wants to enter treatment.
- **Coined Oct.22, 1957 by Justice Bray of Calif. Court of Appeals :**
  - “In discussing the element of risk, a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an *informed consent*”

# Obtaining informed consent

- 1) It's a 3 part process of:
  - **Information disclosure (risks, benefits, etc)**
  - **Deliberation** [time to think about it]
  - **Shared decision making**
- 2) Communication of changes
- 3) Physicians have direct responsibility
  - but RN obtains signature
- 4) **Documentation – by MD**



## ...Obtaining informed consent...

- Doctor, ideally, uses best available evidence and considers patient's goals
- Physician & patient decide together:
  - doctor as *expert on possible treatment*;
  - patient as *expert on what she needs/wants*
- Risks/benefits often different for physician and patient: patients must be informed and be able to choose

# ...Obtaining informed consent

People should be offered information in a form that [ideally]:

- presents individualized risk and benefit scenarios
- presents the absolute risk of events numerically
- uses appropriate diagrams and text.

(See [www.npci.org.uk](http://www.npci.org.uk) )

# Is patient able to make decision?

- Can an informed decision actually be made?
- Decision-making capacity v. Competency

# Determining incapacity

Someone is “incapacitated” if limited in:

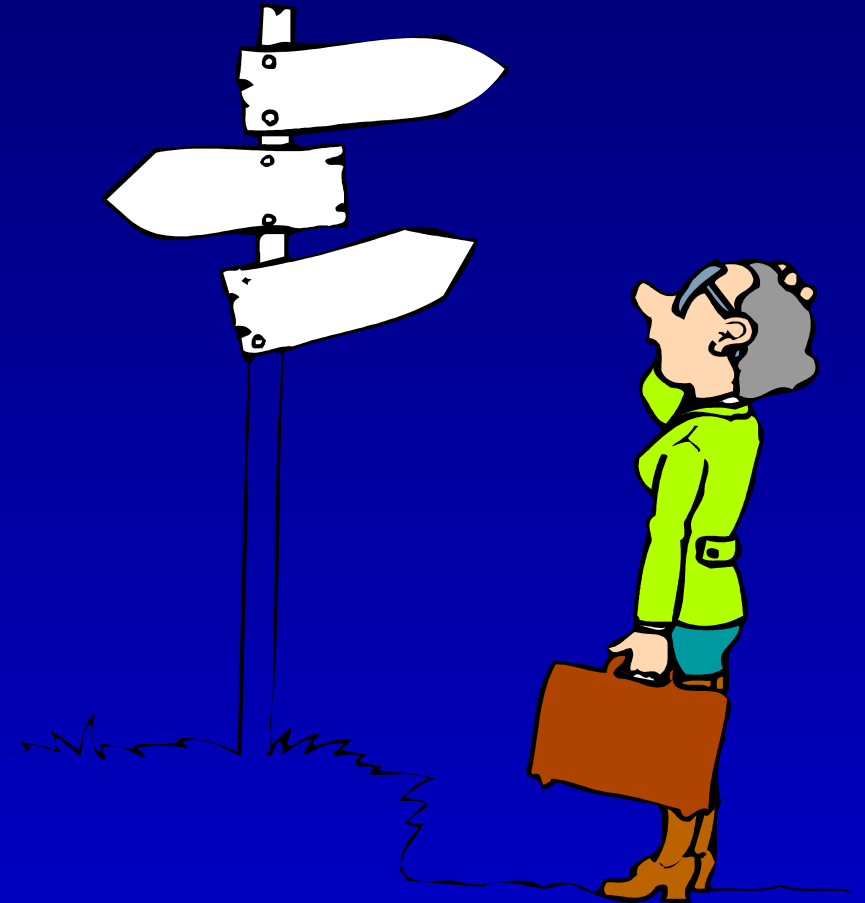
- 1) Ability to understand?
- 2) Ability to evaluate information, to reason, appreciate the consequences and to make a decision consistent over time?
- 3) Ability to communicate the decision?

Decision-making capacity is NOT related to “competency” [determined by judge].

One can have decision-making capacity while diagnosed with dementia.

# Capacity

- Clinically is not “all-or-nothing”
- Is not absolutely determined by one particular test
- Can differ according to the type of decision to be made



# Who Might Not Be Able to Make Decisions Include Those:

- With **advanced dementia**
- Who have had strokes that decrease their ability to understand or to speak
- Who are in a coma
- Who have a serious mental illness

# If incapacitated, there are standards for surrogate decision making

- **Substituted judgment:** decisions are based on surrogate's understanding of the older adult's values and priorities
  - **Prior competent choice:** decisions are based on what was indicated in **advance directive** under the particular circumstances
  - DPOA, Healthcare Proxy, Guardianship
- **Best interest standard:** objective assessment of the burdens and benefits of a particular treatment or course of action

# Who Can Make Decisions if the Older Adult isn't Capable?

(Listed in order of decreasing priority)

- Appointed guardian
- DPOA – HC/medical
- Spouse
- Adult (18+ years) children
- Older adult's parents (if still living & capable)
- Adult brothers and sisters
- If none of the above, guardian may be appointed



## 2. Communicating Risk

(for an informed consent) . . .

- Some people want “Illusion of Certainty”
  - Don’t want to know reality!! ??
- **Illusion of Certainty:** the belief that an event is absolutely certain although may not be ! Examples:
  - Treatments have only benefits but no harm
  - There’s only one best treatment
  - A diagnostic test is absolutely certain

# But, in reality...

- “In this life, nothing is certain but death & taxes”-  
Franklin’s Law
- Every healthcare decision is one between risks, not between a certainty and a risk
  - *All attempts to do good, also generate unwelcome side-effects !!*
  - If guidelines being debated, that usually indicates *uncertainty* !! e.g. HR Therapy, Vit.D,  
[Newsweek 1/24/11]

# Communicating Risk ...poorly

“The bad presentation of medical statistics such as the risk associated with a particular intervention **can lead to patients making poor decisions on treatment.**”

\* G.Gigerenzer. Simple tools for understanding risks. BMJ 2003;3:621

# Doctor-Patient Communication: seek same end?

- Patient wants “immediate” results & relief
  - Wants to trust doctor !
- Doctor wants to help patient “ASAP” and doesn’t like to give “bad results”
- “ASAP” can lead to miscommunication and problems [e.g. side-effects & ‘hurried tx’]:
  - If don’t know goals
  - Depending on ‘philosophies’ [Dr. v patient’s]

# Communicating Risk ...

- “**Risk**” [*the possibility of harm*] is an uncertainty that can be expressed numerically (via probabilities & frequencies)
- **Forms of Risk Communication:**
  - Probabilities [confusing]
    - Single event probability
    - Conditional Probabilities
  - Natural Frequencies [less confusing]

# Communicating & Common Sense:

- Public has right to clear information
- Use ‘natural frequencies’ to explain risks via
  - ARR & NNT - not RRR !
  - Frequency Tree
  - Population Visual aid [Paling Palette]

# Avoid Misleading Statistics

- **Relative Risk Reduction (RRR):**  
measure (as a %) of effect of treatment  
relative to number people improved/saved  
[typical in journal & newspaper articles]
  - RRR amplifies small differences and makes the insignificant appear significant
  - RRR doesn't reflect the baseline risk of outcome events

[\* *Henley. Edwards. Paling*]

## ...How to represent benefits & risks

- **Absolute Risk Reduction (ARR)**: measure of effect of treatment in terms of absolute number people improved/saved
- **Number Needed to Treat (NNT)**: number of people who need to be treated to improve/save one
  - desirable NNT for prevention is  $< 20-40$ ;
  - desirable NNT for treatment is 2 - 4.

Example: treatment to reduce CVA in A.Fib.



# Benefits of Warfarin v. ASA (in A.Fib)

## Treatment

## Risk of CVA

- No treatment: 3.5% (1-18%: CHAD2 risk score 0-6)
- ASA:
  - **RRR = 37%** ( $2.5/3.5 \times 100$ )
  - decreases  $\sim 1\%$  (**ARR**)
  - NNT = 100** ( $100/1$ )
- Warfarin:
  - **RRR = 71%** ( $1.3/3.5 \times 100$ )
  - decreases  $\sim 2\%$  (**ARR**)
  - NNT = 50** ( $100/2$ )
  - but, increases Bleeding Risk  $\sim 1\%$

# Risk & Benefit *Mis*-Communication

- It's how we present the information !
- “There are three kinds of lies: lies, damn lies, and statistics!”
  - Benjamin Disraeli
- Use visual aids – provide POS & NEG info
  - Paling Palettes – 1000 people
  - Bar charts

### 3. What is advance care planning?

- Process of planning for future medical care
- Values and goals are explored, documented
- Determine proxy decision maker
- Professional, legal responsibility

# . . . What is advance care planning?

- Trust building
- Uncertainty reduced
- **Helps to avoid confusion and conflict**
- Permits peace of mind

# Terminology of advance directives . . .

- Advance care planning
  - process of discussion, documentation, implementation
- Advance directives
  - instructional statement
    - living will
    - values history
    - personal letter - notarized
    - medical directive

# *Living Will / Advance Directive*

## Definition:

A form to make your wishes known (instructions or *directives*) to a health care provider before (*advance*) the need for medical treatment or other care is required, if you became too sick to speak for yourself.

# ... Terminology of advance directives

- Statutory
  - physician immunity [if follow Adv.Dir.]
- Advisory
  - patient wishes [verbal contract]
- Proxy designation
  - health care proxy
  - durable power-of-attorney for health care

# Values History “Example” of an Advance Directive

- I, **MAXINE**, being of sound mind and body, do not wish to be kept alive indefinitely by artificial means. Under no circumstances should my fate be put in the hands of pinhead politicians who couldn't pass ninth-grade biology if their lives depended on it, or lawyers/doctors interested in simply running up the bills.
- If a reasonable amount of time passes and I fail to ask for at least one of the following:



# Example cont'd...

- glass of wine, chocolate, a Margarita, chocolate, a martini, a cold beer, chocolate, chicken fried steak w. cream gravy, chocolate, Mexican food, chocolate, French fries, chocolate, Pizza, chocolate, ice cream, cup of tea, chocolate, sex, chocolate;
- **Then, it should be presumed that I won't ever get better.** When such a determination is reached, I hereby instruct my appointed person and attending physicians to pull the plug, reel in the tubes and call it a day.

# Use a validated advisory document

- A number are available
  - Alabama's deficiency re "No CPR"
  - "POLST" (Physician Order for Life Sustaining Treatment) – Oregon, Washington, +
- Easy to use
- Reduces chance for omissions
- Patients, proxy, family can take home
- "Don't require lawyer" - but hospital staff cannot witness [ need 2 non-family witnesses.]

# Document patient preferences

- Review advance directive
  - **Add patient's own preferences !!**
- Sign the documentation
- Enter into the medical record
- Read and interpret the advance directive
- Consult with the proxy
- **Ethics committee for disagreements**

# Common pitfalls

- Failure to plan
- Proxy absent for discussions
- Unclear patient preferences
- Focus too narrow
- Communicative patients are ignored
- Advance directives are not read

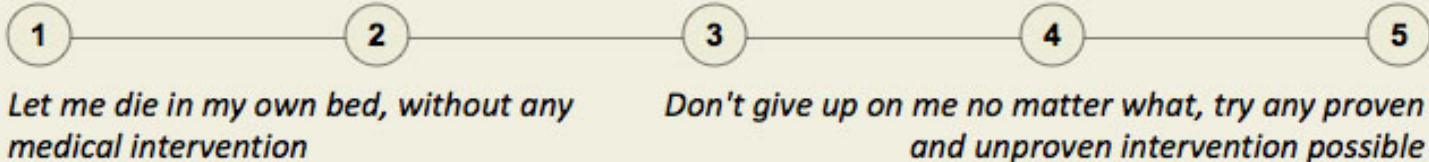
# Communication & Family Awareness

- Families have not discussed preferences among themselves
- Use *One Slide Project* – helps to guide discussion
  - go to [engagewithgrace.org](http://engagewithgrace.org)
- Use ParentsWish.com
  - Help adult children accept comfort focused care for their aging parents

# One Slide Project

## Can You and Your Loved Ones Answer These Questions?

1. On a scale of 1 to 5, where do you fall on this continuum?



2. If there were a choice, would you prefer to die at home, or in a hospital?
3. Could a loved one correctly describe how you'd like to be treated in the case of a terminal illness?
4. Is there someone you trust whom you've appointed to advocate on your behalf when the time is near?
5. Have you completed any of the following: written a living will, appointed a healthcare power of attorney, or completed an advance directive?



## 4. Ethics, Avoiding Futile Care... & Stewardship

- 1) What patients/families want
- 2) Mrs. Abigail Alzheimer – informed?
  - Using the Palliative Medicine Prognostic Tool to assist in making informed decisions
- 3) Mr. Charles Carcinoma – hope?
- 4) Stewardship
- 5) Conclusion

# Making choices: the ACP

## [Advance Care Plan]

- Choosing *M&M's* – caregiver's story
- *“My father's broken heart: how putting in a pacemaker wrecked my family's life”*  
– Katy Butler. NYT magazine, June 20/10
- *“Waging Peace in the War on Cancer”*  
[in *Treatment Options & Dilemmas* -  
[comfortcarechoices.com](http://comfortcarechoices.com)]



# Reminder: What do Patients & Families with Serious Illnesses Want ?

- ...
- Achieve a sense of control
- *Included in decisions & to be listened to*
- *Honest information*
  - Everyone wants adverse event info [1/100,000 - Ziegler. Arch Intern Med 2001]

\* Singer et al. JAMA 1999;281(2):163-168.

\* Tolle et al. Oregon report card.1999 [www.ohsu.edu/ethics](http://www.ohsu.edu/ethics)

## 2) Case - Mrs. Abigail Alzheimer

- 82 yof, Alzheimer's x 4 years
- HTN, PVD, OAB, OA, OP, GERD
- TIA's, CAD w/ stents, CHF
- Taking many prescriptions
- Widow, in ALF, 3 kids

# Informed Consent – Ms. Abigail

- OA of most joints, knees worse
- Orthopedic surgeon recommends TKA
- Goal = comfort - would TKA help?

# What's her PMPT\* Score?

- Sctn 1: 0
- Sctn 2: 0
- Sctn 3: 2 [Alz.Dem., multiple problems]
- Sctn 4: 2 [pain]
- Sctn 5: 1 [self-care usually]
- Sctn 6: 2 + 2 [AND + goals]
- Total: 9 [core sctns 2-5 = 7]

*\*Palliative Medicine Prognostic Tool*

# Informed Consent – Ms. Abigail

- Goal = comfort - would TKA help?
  - Family vs Patient preferences?
- Any risks? - Memory decline?
- Benefits? – Pain control? Mobility?
- Options?
  - Can her pain be controlled adequately w/o surgery?

# Informed Decisions

*Should Mrs. Alzheimer have a TKA - what's the process involved to make a decision?*

- To make decisions, people need credible and adequate information
- Because knowledge about their condition and prognoses affects decisions
- Information combined w/ skillful guidance may avoid futile interventions and improve QOL

# Avoiding Futile (Non-beneficial) Care

- During EOLC, we can be primary cause of suffering or, we can be primary cause of its relief !
- Only 10% people die suddenly
- 90% need some form of terminal care
- Providers must face decisions of “how many and what kind of interventions are needed”

# Defining Futile Care

- “clinical care that has a  $< 1-5\%$  chance of survival” [quantitative definition], or
- “when desired goals not met or desired results cannot be achieved” [qualitative]
- When treatment causes harm without benefit.



# Futile Care is **NOT** Quality Care

- Quality means the care:
  - **Must be warranted & efficacious for the condition in light of patient's values**
  - **Must maximize benefits, minimize risks**
  - **Must be cost-efficient**
  - **Should achieve individual's desired goals or results (when reasonable)**

# Reasons for Futile Care

- **Poorly defined**
  - **Decision processes faulty**
    - **Goals are not made known**
    - **Patients/families have insufficient info**
    - **Choices may not be clear**
    - **Leads to incongruity between patient goals and physician's offered choices**
    - **Results in mutual misunderstanding**
- e.g. Mrs. Alzheimer

# Mrs. Abigail Alzheimer

- Family chose TKA; **deteriorated post op .**
- Six mo. later, walker and 1 assist all ADL's
- Admitted to hospital w/ fx hip
- Delirium develops
- Surgeon says, “we need to fix her hip to control her pain and help walk again”
- **Family says, “do everything necessary”**

# The Futile “Do Everything”

- **Doctor’s assumption:** provide all surgery & drugs & tests to keep alive
- **Patient/Family’s assumption:** doctor will only do those things known to be effective in reaching their goals
- **“Do Everything” really means “Do everything that will help reach goals”**

# What's her PMPT Score Now?

- Sctn 1: 0 [?poor prognosis]
  - Sctn 2: 3 [alive in 1 yr?]
  - Sctn 3: 4 [CHF + dementia]
  - Sctn 4: 2+2+1 [pain + weakness + delirium]
  - Sctn 5: 3 [ADL: bed/chair >50%]
  - Sctn 6: 2 + 2 [AND + goals]
- Total: 19** (was 9) [**core sctns 2-5 = 15**(was 5)]

# “Futile” care – “would an ORIF be beneficial” – Questions?

- 1) What information should the surgeon have?
- 2) What information does the family need?
- 3) What are her/their goals?
- 4) What are the chances of her walking again?
- 5) Can her pain be controlled w/o surgery?
- 6) What’s the chance of her worsening, or dying, w/ the surgery vs w/o it?

# What Affects Decisions \* ?

- Unrealistic expectations / false hopes (lack of information)?
- “selfishness” of family?
- GUILT ?? - ‘seagull children’ [story]
- ‘Rescue’ mentality?
- “Learned helplessness” – family’s [W.Berry] ?
- No plan of care in place?

\* Read Hank Dunn’s “Hard Choices for Loving People”

# Medical 'dependency' & 'abandonment'?

- Has society become 'addicted' or dependent on pills/doctors and the 'quick fix', and can't care for family members any more?
- Does dependency and 'learned helplessness':
  - lead to frequent futile care ?
  - result in our 'abandoning' loved ones to medical care ?



# Ethics Addresses:

Ethics: the various methods that humans have for understanding the moral life; and questions

- What is the “right” or “good” act and why is it so?
- What is the meaning of “the good life” and how do we create “a good life”?
- How can we achieve fairness towards all people?
- How should people treat one another?

# Ethical Issues at the End of Life

- Who should make decisions for an older adult with dementia?
- How much should an older adult know about his/her medical condition?
- Is it ethical to withhold life-saving therapies like CPR?
- Is it ethical to withhold tube feeding?
- Is it ethical to administer morphine even if it may shorten the person's life?
- It is ethical to provide a person with the means to kill him/herself?

# Treatment limitations at the end of life...

- Right to refuse any intervention
- All patients have rights, even incapacitated
- Withholding / withdrawing
  - not homicide or suicide
  - orders to do so are valid
- Courts need not be involved
- Patient/family do NOT have right to demand futile care

## ...Limitations

### Opioids are appropriate in end-of-life care

- Recognition of role of opioids by regulatory agencies
- Principle of double effect
- Position Statements support comfort care

# ANA Position Statement

## Position Statement: RN's Roles & Responsibilities In Providing Expert Care & Counseling at the End of Life

“The nurse’s fidelity to the patient requires the provision of comfort and includes expertise in the relief of suffering, whether physical, emotional, spiritual or existential.”

# HPNA Position Statement

- No convincing scientific evidence that administering opioids, even in very high doses, hastens death
- Several clinical studies demonstrate **NO** significant associations among opioid use, respiratory depression, and shortened survival
- Respiratory depression and other changes in breathing are part of the dying process and are more likely to be from disease and organ failure than from opioids

# California State Law

## California Health & Safety Code:

- Inadequate treatment of acute and chronic pain originating from cancer or noncancerous conditions is a significant health problem
- For some patients, pain management is the most important treatment a physician can provide
- A patient suffering from severe chronic intractable pain should have access to proper treatment of his/her pain

[http://www.paincare.org/pain\\_management/advocacy/ca-bill.html](http://www.paincare.org/pain_management/advocacy/ca-bill.html)

# Summary: How to Make Informed Decisions & Avoid Futile Care

- 1) Discuss status of conditions and prognosis
- 2) Clarify goals
- 3) Understand all the options (read available material)
- 4) Ideally, physician recommends one option based on Goals – “we should aggressively do everything necessary for comfort”



## ...How to Make Informed Decisions & Avoid Futile Care

- 5) Formulate a plan, including response to crises; make an ACP & tell all family!
- 6) Confirm: can you live with the decision?
- 7) Ideally, patient has ACP written – if not, surrogate/proxy caregiver must decide what's in *best interests* of patient – and can say “enough” !

# Avoiding Futile Care - cont'd

- Provide reason why we should NOT do a specific tx, and provide options
- Never say “There’s nothing more we can do” !!!!
- Reinforce the link between Goal & Options
- Cultivate HOPE – that good will come from their decisions; that they won’t be abandoned; avoid FALSE hope.

### 3) Case - Mr. Charles Carcinoma

- 65 yom, adenocarcinoma L. lung stage IIIA
- COPD – smoker 1ppd
- Married, 4 grown kids, retired last year
- Cancer recurred despite Tx
- What are his goals?
- Does he have the right to choose?
  - Read *Treatment Options & Dilemmas* at [comfortcarechoices.com](http://comfortcarechoices.com)
- How do we protect his Hope?

# What is Hope?

- Is a feeling that can promote wholeness and healing
- May provide temporary respite from a frightening reality
- Is dynamic, changing with conditions
- Is not the optimistic view that all will be well if everyone just does what's needed!

# Hope cont'd

- Hope – arises from suffering which leads to endurance (quality allowing us to keep going when easier to quit), which produces character, which in turn produces the hope that even if things don't turn out ok, we will endure through and beyond the times that threaten us. [Gomes]

# Mr. Charles' Evolving Hope

## As Event Changes

- New dx cancer
- ChemoRx, still ca
- Stop chemo, join hospice
- Living w/ term.dis.
- Last few days, rain

## Hope

- A cure
- Disease w/ min. pain
- No admission to hospital
- Grandkids visit
- Sun will shine in am.

• *Hank Dunn*

# Preserving Hope while Avoiding Futile Care through PC

## Our Traditional Role

- To cure sometimes
- To relieve often
- To comfort always

*- anonymous 16<sup>th</sup> century aphorism [?Hippocrates]*

## 4) Stewardship in Healthcare

- Steward: “A person who manages the property or affairs for another entity.”
- Stewardship: “A [fiduciary & ethical] responsibility to take care of something one does not own.”
- Stewardship implies avoiding things which are non-beneficial for another person !



# Stewardship

- 5% of MC beneficiaries die each year
- 30% of MC budget is for last year of life
- Of those dying, 50% of costs spent on last 2 mo. of life [w/ no “gain in quality”]
- Do we (physicians & patients) not have a stewardship responsibility – to avoid futile or non-beneficial care?

\* 1. USA Today; 2. J. Lubitz, DHHS, report to US Congress 2004

# How to Improve QOL & Avoid Futile care: Be informed

- Internet information – Understand Risk
  - Cardiovascular Risk Calculator – University of Edinburgh – [cvrisk.mvm.ed.ac.uk/calculator](http://cvrisk.mvm.ed.ac.uk/calculator)
  - **Bandolier** - [www.medicine.ox.ac.uk/bandolier/](http://www.medicine.ox.ac.uk/bandolier/)
  - Paling Perspective Scale – [www.trci.info](http://www.trci.info)
  - Visual Rx - [www.nntonline.net/](http://www.nntonline.net/)
- Advance Directives & Discussions
  - **OneSlideProject** – [engagewithgrace.org](http://engagewithgrace.org)

# ...Improve *QOL*: Be informed

- Other information
  - Risk Charts for Men/Women – J Nat’l Ca Inst
  - **Comfortcarechoices.com** – R. Webb’s website w/ info about EOLC and palliative care choices
  - Gerd Gigerenzer. *Calculated Risks*. 2002
  - **Patient Decision Aids** - [http://www.npc.nhs.uk/patient\\_decision\\_aids/pda.php](http://www.npc.nhs.uk/patient_decision_aids/pda.php)

# Other Readings

- Hank Dunn. *Hard Choices for Loving People*. 2001. A&A Publishers. [[www.hardchoices.com](http://www.hardchoices.com)]
- Ira Byock. *Dying Well*.
- His Holiness the Dalai Lama's "Advice on Dying and Living a Better Life"
- Lawrence Schneiderman. *Embracing our Mortality*.

“Living is expressed through the struggle to understand more, listen better, and act without always being certain.”

*Samuel Klagsbrun, 1991*

**As you slide down the banister of life, may  
the splinters never point the wrong way.**

- Maxine

***G-ELNEC thanks Cathy Shelton –organizer,  
coordinator & editor !!***