Distinguishing Risks of Research From Risks in Therapeutic Clinical Practice

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A Proposition (rebuttable)

• The risks of an SOC intervention are the same whether the intervention is employed in clinical care or SOC research
  – SOC ⇒ risks well known
Limitations

• Only true if intervention is applied precisely the same in research as in clinical practice.
Examples in which SOC risks in research ≠ clinical

- Extremes of SOC range (if Rx targeted to continuous variable, e.g. $P_aO_2$ (good or bad))
- Provider not used to one SOC alternative, less skillful?
Examples in which SOC risks in research ≠ clinical

• Risk of study measures not used in clinical care
  – Genetic testing?

• Loss of patient/subject choice re: side effect profile
Common risk of clinical SOC

• The risk that you may receive a treatment which is ineffective and unnecessary.

• (Unfortunately, not lessened – for subject - by participating in SOC research)
The CAST Trial
Cardiac Arrhythmia Suppression Trial
NEJM 1991; 324:781

• Trial of 3 drugs to suppress ectopy in post MI patients
  – 2 drugs marketed, “SOC”

• Result:
  – RR of death for drug-treated groups was 3.6 vs. placebo
  – DSMB stopped trial at ~10 mo
Risks of SOC in research – different?

• Increased “spectrum” of risk exposure
  – Treatment A has risk X
  – Treatment B has risk Y
  – In research with A vs. B, I could be exposed to X or Y
  – Related to “loss of choice” issue
Risks of SOC in research

• You might be assigned to the group that does less well (and get treatment you wouldn’t have gotten in clinical care)

• How much this matters depends on the condition under study
Benefit of SOC research

• You might be in the group that does better (flip side)
• You might get better care in a study
• Most benefit probably to future patients
Summary

• SOC treatments may have greater, and/or different, risks in research vs. practice

• Research comparing SOC Rx can be ethical, but in general the difference warrants consenting subjects
“Be wary of the man who urges an action in which he himself incurs no risk”
-Joaquin Setanti
1540-1617
“If you don’t risk anything, you risk even more”

Erica Jong

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