

risk

burden

burden 1:
frustrating interests
motivating patients

burden 2:
theater of sham

risk

knowledge value

research ethics literature on
knowledge value:

“dark matter”

3 “value” questions re: sham*

* = no feasible, less burdensome means

Question 1:

are study objectives sufficiently “valuable”?

Question 2:

is study likely to meet objectives?

Question 3:

do sham methods advance study objectives?

Question 1(a):

Will use of sham significantly increase explanatory or predictive power of experiment?

Late stage:
downstream utility

(e.g. role in healthcare system,
morbidity of illness, etc.)

Early stages:
near term utility

(e.g. explanatory or predictive power,
given current state of knowledge)

Question 1(b-d):

does study ask the “optimal” question given current knowledge?

Question 1(b):

have parameters for eliciting intended properties
been nailed down?

(e.g. dose, delivery, co-interventions, formulation,
etc.)

If no, sham eliminates one of an infinite number of suboptimal regimes, thus valueless

Question 1(c):

Is study embedded within a network of previous,
robust findings?

every study potentially tests many hypotheses, e.g.

- i. agent has biological activity
- ii. human recapitulates preclinical

If well embedded, study informs more hypotheses,
thus stronger claim to knowledge value

Question 1(d):

Is orientation (explanatory v. pragmatic)
appropriate?

In research areas involving high degrees of uncertainty (e.g. attrition), explanatory studies more valuable

“negative studies” informative

Question 2:

is study likely to meet objectives?

- realistic accrual targets

- publication

- reporting quality

Question 3:

do sham methods advance study objectives?

Question 3(a):

Is choice of sham procedure matched to orientation and objectives?

Partial burr hole

Burr hole + injection of vehicle

Partial burr hole:
Causal role of expectation

Burr hole + injection of vehicle
Causal role of expectation + surgery + vehicle

Question 3(b):

Is study adequately powered?

Question 3(c):

Is sham procedure reliable given objectives?

-Will presence of sham arm cause selection bias in sample (e.g. select for expectant or optimistic patients)?

-Will blind of patients be maintained (and assessed)?

- Will blind of outcome assessors be maintained (and assessed)?

