

Blog

# RCTs and Exclusion of the Elderly

📅 March 22, 2017 👤 Bryn 🔖 clinical drug trials, elderly, participants, RCT, validity ✎ Edit

## Blog

Chercheuse en résidence / Scholar in Residence

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*Publié/Published:* 22 Mar 20172017 A Lippman, [Creative Commons Attribution 4.0 International License](#)

Conflit d'intérêts	Conflicts of Interest
Aucun déclaré	None to declare
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We've known for a long time, for too long a time, that what is formally called "external validity" is often lacking when there are randomized clinical trials of medical and pharmacologic interventions. Older trials, and some still today, have no female or otherwise gendered women enrolled. Some still think "marital status" has any meaning when probably knowing about sex partners (male, female,

both, neither) is more relevant – as it would be for STIs (sexually transmitted infections). And others provide financial inducements or patent extensions if children are participants.

But the one that right now irks me – perhaps because I have an interest in interventions which might be recommended for me or my peers – is the continuing exclusion of “older” people...with “older” starting variably at some age between about 60/65 and 80+ years of age. The latest evidence of this is the article just published in the Journal of the American Geriatric Society that examined the exclusion of “elderly adults” from trials of drugs for a fairly common condition among them, ischemic heart disease ([Bourgeois et al., 2017](#)).

So, once again an entire group is “profiled” and must therefore take medications or have other medical practices “off label” – and this with not only their effectiveness but also all the possible attendant “side” effects unknown. And this unknown is willful: researchers have not wanted to know it. A further example, perhaps, of what is becoming a popular focus of social sciences literature, epistemological ignorance. And from another viewpoint, probably a “knowable unknown.”

It is not easy to determine if this exclusion by age (too young; too old) stems from these populations being seen as too small to warrant investments into knowing what works for them: the financial returns aren’t “big enough.” Or if it is simple age discrimination. And with those otherwise possibly eligible (their ages are, as in the story of the “3 Bears,” “just right!”) too often themselves excluded because they have one or more chronic disorders which may, itself, be age-associated, the young and the “old” often, if not always, remain undocumented research participants. They must take their “steps into the unknown” ([Silverman, 1986](#)) without the “guidance” provided to those healthy enough to remain eligible.

Why don’t ALL committees reviewing protocols for funding reject those that cannot be applied to real people in the real world? Of course, “internal validity” is necessary, and while these may reduce type 1 and type 2 errors (false positives and false negatives), research is also open to what might be called type 3 errors. In these situations, we get the “right” answer but it’s to the wrong question – unlike work that leads to type 4 problems: the wrong answer to the wrong question.

To be clear: I am not now pushing for any expanded use of medications, not for those over 65, under 16, or of any age. Too many drugs already do too little good and too much harm for their alleged effectiveness. Nor will insisting on absolute rate reductions rather than relative rates suffice. Moreover, the overuse of medicines often stems from the overuse of screening and diagnostic tests that are, themselves, of marginal if any value. A vicious cycle.

Ethicists and environmental activists have been urging practice of the “precautionary principle” – an inverse formulation of the outdated “what you don’t know can’t hurt you” maxim. In fact, the unknown has sharp teeth and can bite hard. And because the unknown, as the known, is a social construction, things can be built differently. And this reconstruction is perhaps urgent. And no more so than now. With private-public collaborations favoured by funding agencies, including the CIHR, and with pharmaceutical companies responsible for many, if not most, trials, there is definitely need to

rethink the entire system of drug testing especially. (And how, in Canada, no one seems to be fully charged with evaluating devices and screening tests...)

The more profits can be made for shareholders, the less vigilance there may be about getting drugs to the market. And Health Canada is, itself, complicit in this when it grants approval for marketing: most of these newer products are hugely expensive and add, at best, a few months, even only weeks, to pain-free high quality life. Why is the latter, HOW one lives, not given priority over the length of survival? What does a patient want? A few millimetres reduced in the size of a tumour? Or time for laughter and love with family and friends? And if one asks, it does seem that for older folks, too, quality does seem to get priority – with, perhaps, the increasing demand for physician-assisted death an expression of this?

Further complicating matters: researchers, even those university-based, have multiple conflicts of interest – and putting disclaimers into articles is only necessary, but not sufficient. As well, even patient groups demanding the newest and the latest treatments have major funding support from commercially-interested donors and so are financially implicated, even if indirectly. This all matters, since we will all pay for this when healthcare costs rise to cover the new pharma pills that will be marketed.

We all, of all ages and genders – and abilities, etc. – do not need all the screening, testing, medications, interventions we are recommended, if not coerced, to take. Rather, we do want those that are used to be truly effective for US who live real lives in a real world and not only for the ideal person often thought of as being a male, with a single health problem, who is of a certain size, colour, and age. Maybe there is one such prototype in each of our friendship circles, but likely most of those we know come with some “baggage.”

Randomized clinical trials must not become like airline inspectors measuring this baggage to ensure it fits their needs. We need researchers to stop thinking one-size-fits-all and to ensure they fit our needs by studying what matters to us, to all of us. To do otherwise is unethical.

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ISSN 1923-2799

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