The role of futility judgments in improperly limiting the scope of clinical research

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Abstract

In medical research, the gathering and presenting of data can be limited in accordance with the futility judgments of the researchers. In that case, research results falling below the threshold of what the researchers deem beneficial would not be reported in detail. As a result, the reported information would tend to be useful only to those who share the valuational assumptions of the researchers. Should this practice become entrenched, it would reduce public confidence in the medical establishment, aggravate factionalism within the research community, and unduly influence treatment decisions. I suggest alternative frameworks for measuring survival outcomes.

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The notion of medical futility has received a great deal of attention in the literature. Usually, the discussion centres around the question of attending physicians withholding treatments deemed by them to be futile (ie, deemed by them not to constitute a medical benefit to the patient). It seems to have gone unnoticed, however, that medical researchers are in a position to act on futility judgments when deciding whether certain data are worth recording and reporting. A researcher could reason that there is little advantage in using valuable time and space to report in detail treatment outcomes which do not benefit patients. It would then seem to make more sense to lump all non-beneficial outcomes into a single reporting category, and to focus instead on differentiating the various benefits, if any, likely to be afforded by a treatment. Whether any researchers have actually followed such a line of reasoning is difficult to say, but it can be said that some researchers in fact do not report in detail information about treatment outcomes which they deem to be without benefit to the patient. Lantos *et al*, studied the effectiveness of cardiopulmonary resuscitation (CPR) on low birthweight babies. The authors determined that none of the 38 babies receiving

CPR in the first 72 hours after birth survived to hospital discharge.¹ They judged that CPR was of no benefit to the subjects of the study, and concluded that CPR in infants of very low birthweight is "virtually futile".² Throughout the paper, Lantos *et al*, construe terms such as "success", "benefit", "futile", "effectiveness", "validated", and "proved" in terms of survival to hospital discharge. Even terms such as "survival" and "mortality" are employed by the authors merely as shorthand for "survival to hospital discharge" or "dying before discharge". The abstract says simply that "none of the babies who received CPR in the first three days of life survived".³ Lantos *et al* report virtually nothing of the treatment results that fell short of survival to hospital discharge. This omission makes sense given the parameters they demarcate for medical futility.

Rubinfeld *et al* seek to develop guidelines for the withdrawal of life-saving mechanical ventilation.⁴ The authors write: "It would be more clinically useful to define a subgroup of patients whose survival is so low that reasonable physicians and patients would agree that intensive care can no longer effectively fulfil the goals of transplantation".⁵ They state that life support should be withdrawn from such patients.⁶ Rubinfeld *et al* make clear that they regard survival short of hospital discharge as not beneficial to patients, and as unduly burdensome on family, caregivers and society.⁷ Alternative assessments are brushed aside as not rational, as limited by "arbitrary factors and cognitive biases".⁸ The authors accordingly define "surviving" patients as "those who were alive 30 days after extubation and who were discharged from the hospital".⁹ The only datum reported for survival short of "survival" is the total number of patients failing to "survive". The judgment by Rubinfeld *et al* that a life span short of hospital discharge is not worth living logically supports their evident judgment that information about the length of such survival is not worth reporting.

Several recent research reports make the futility judgment that outcomes short of "survival" do not benefit the patient.⁹⁻¹⁴ No information is given of

shorter survival intervals. As with Lantos *et al* and Rubenfeld *et al* such information would be *prima facie* pointless given the judgment that such results are of no medical benefit. It makes more sense to report only the total of such results, under a heading such as “failed to survive”.

The Utstein Consensus Conference recommends that responsible personnel record the following data: date and time of death in hospital, with exact time for patients who die within twenty-four hours; the Overall Performance Category and Cerebral Performance Category of the Glasgow-Pittsburgh Outcome Categories at time of discharge and at one year, with the best score the week before death recorded for those dying within one year, and the best outcome achieved during hospitalisation and in the year after the arrest.¹⁵⁻¹⁷ However, with respect to admitted patients dying in hospital, the conference recommends for *researchers* only that they “should tabulate the number of patients who die in the hospital, with special notation of patients who die within the first 24 hours of admission”.¹⁸ This would make sense if one regarded the more detailed information on survival short of discharge as not important enough to include in research reports.

I want to emphasise that none of the authors cited offers any justification for the choice of a measure of survival rates. My point here is that futility judgments potentially play an important role in the choice of treatment outcome measures since no one would choose to measure useless information. The choice of a treatment outcome measure is important since the measure filters the information to be reported. But, I will argue, i. it is wrong at present to limit the reporting of survival rates in accordance with the researcher’s futility judgments, and ii. an alternative method of reporting survival outcomes should be used.

The ability to limit the scope of research according to the researchers’ futility judgments gives medical researchers the ability to shape information in the image of their personal judgments about when life is worth living. Treatment results falling below the researcher’s minimum acceptable treatment outcome (MATO) can be lumped together and reported as a total under some heading equating to “failure to achieve meaningful results”. Patients with treatment survival goals falling below the measures of survivability used by researchers are denied the more specific information they would need to make an informed judgment, according to their own values, about whether to attempt the treatment in question. From the report, they could know only that in a certain number of cases

the treatment failed to achieve a given result. They could not know the extent, if any, to which it achieved lesser results they might deem acceptable.

One response might be that such patients are simply misguided in their choice of treatment goals, and that we are saving patients grief by refusing to give treatments that will not truly benefit them. This paper is not the place to try and settle the medical futility debate. It would seem, though, given the extremely personal nature of end-of-life decisions, that the burden of proof would lie on those who would allow health care professionals unilaterally to act in accordance with futility judgments. To my knowledge, *no* arguments have been offered to justify the practice of limiting the reporting of research results in accordance with futility judgments. Arguments have been made in favour of allowing attending physicians unilaterally to withdraw treatments judged to be futile, but even these arguments have been less than convincing to many authors.¹⁹⁻²⁷ Until a clearly adequate justification of the practice has been advanced, researchers should refrain from demarcating the limits of reported information in accordance with their own futility judgments.

Default position

The adoption of survival to hospital discharge as a MATO seems to have become a default position in the futility debate. “In the literature, in-hospital death seems to have become the standard account, for the data usually offered to support claims of imminent demise futility are data about survival to discharge”.²⁸ It is difficult to assess the extent to which futility judgments have influenced the reporting of information in recent research. This is because very few authors offer any justification for their selection of an outcome measure. What we know is that many authors, including some researchers, have argued explicitly for the futility of outcomes short of survival to discharge, and that at present much of the research literature uses survival to discharge as the primary measure of survivability, often the only measure.

Eisenberg *et al* in their 1990 review of 74 studies of survival rates, report that 51 of the 74 articles (69%) define “survival” as “discharged from the hospital”.²⁹ I conducted a search of MEDLINE using the search strings “survival rate + CPR”, “survival rate + burn”, and “survival rate + ventilation”. The searches using “survival rate + CPR” and “survival rate + burn” went back one year and generated eleven and fourteen citations respectively. The search using “survival rate + ventilation” returned many more entries, so I went

back only six months, generating eleven citations, for a total of thirty-six citations. Of the total citations, three did not have survival as a focus, one was untranslated from the Chinese, and four were not accessible. The twenty-eight remaining articles break down as follows:

- A. Seven explicitly define survival as survival to discharge.³⁰⁻³⁶ Five of these give no further survival data. Two note whether non-survivors were admitted alive after receiving CPR from emergency medical treatment (EMT) units; one of those also tracks survivors at one year after discharge.
- B. Seven did not explicitly define survival, but clearly are equating it with survival to discharge.^{9 10 37-41} Five of these give no further survival data. Two track survivors at one year after discharge.
- C. Seven studies simply offer no clear indication of the measurement used for survival.^{11-14 42-44}
- D. Six directly report a broad range of detailed data on the survival times of patients.⁴⁵⁻⁵⁰
- E. One study adopts a survival measure of 180 days, giving no additional information on survivability.⁵¹

Thus, of a total of twenty-eight studies, fourteen (50%) equate "survival" with "survival to discharge". That the authors in group B would use the crucial term "survival" without defining it, relying on context and the reader's background knowledge to make clear the assumed parameters of survival, is testimony to the widespread acceptance of survival to discharge as the proper measure of survival rates. Of the fourteen papers in groups A and B, thirteen (six from group A and seven from group B) give no information at all on treatment results less than survival to discharge. Of the total papers, only seven (one from group A and the six in group D; twenty-nine per cent of the total) give clear, systematic information about survivability short of discharge.

The above is not intended to constitute a statistically valid survey of the literature. Rather, it points out that survival to hospital discharge is a very commonly used outcome measure for survivability, often the sole measure. When the latter, survival to discharge filters information, intentionally or not, in the same way as would an explicit MATO. This motivates a discussion as to whether futility judgments can justify the practice of limiting the reporting of treatment outcomes in accordance with any particular survival measure, especially survival to discharge.

There are several reasons for thinking that futility judgments should not be used to limit the

reporting of research results. At the social level, research that accommodates only a narrow valuational attitude alienates all those members of society who do not share that valuational attitude. This will do nothing to instil confidence that the medical profession shares, or at least respects, the public's interests. Medical research, like the profession of medicine itself, is a social enterprise, dependent to some extent on the good will of the public. Whether from self interest, or because the researcher values social harmony and tolerance, the researcher should be willing to make room for a broad range of views concerning the value of life. Note that the practice of limiting the reporting of survivability to a single outcome measure such as survival to discharge also denies relevant information to those patients who would accept treatment only if it meant survival in terms much longer than the measure used by the researcher. (Only five papers of the twenty-eight cited above (18% of the total) discuss survival at one year.) Thus, the use by researchers of survival to discharge as the sole measure of survivability will deny patients with treatment goals on either side of that valuational point information relevant to their making informed treatment decisions consonant with their own values. This problem is a general one that applies to any single treatment outcome measure that might be chosen by a researcher. Whatever measure the researcher chooses, patients whose own MATOs fall above or below that measure can find themselves lacking information crucial to making informed treatment decisions.

Cultural warfare

The use of MATOs in reporting survival outcomes threatens further to import cultural warfare into the research arena. At the administrative level, ever-present limitations on funding force administrators to choose which researchers receive funding. Why would a responsible administrator of funds choose to "waste" money on researchers who use measures that do not track "meaningful outcomes", or, on the other hand, who set "unreasonably high standards" of outcomes? Administrators of funds will feel morally obligated to freeze out researchers whose studies exemplify the "wrong" values. The divisive effects of such exclusionism would not be helpful to the profession, but would be practically unavoidable once the research community got into the game of making narrow determinations of the value of life.

When the information needed for making practical ethical decisions is shaped according to certain categories and measurements there is a tendency uncritically to adopt those categories

and measurements. Regardless of whether researchers intend this result, by omitting information about the effects of treatment short of survival to hospital discharge, family members are steered away from considering the worth of treatments that could lengthen the patient's life short of survival to discharge. Some researchers might see this as a positive result, but whether such influence is desirable is, I would suggest, a matter to be publicly aired and debated before such a means of influence is used by the research community.

Physician decisions, and even hospital policies, concerning specific treatments will be impacted by the practice of using a single measure of survivability. Physicians and hospitals cannot in good faith offer treatments for which there is no evidence of effectiveness, and survival effects other than those measured by the researcher will not be reported. When the data have been filtered by the use of a MATO in accordance with a researcher's futility judgment, the question of treatment appropriateness will have been begged.

Two frameworks

How should data be reported? Lacking sound empirical data of the distribution of MATOs held by patients, I can give only sketches of two frameworks that seem appropriate in light of the considerations discussed in this paper. A good framework for recording treatment outcomes will be one that is feasible for researchers, does not unduly draw resources from other valuable projects, and provides information important to the consumers of the report. No precise, final answer is possible as to the optimum way to balance these legitimate, competing interests. A quick solution would be to make records of survival after initiation of treatment at hour one, day one, week one, month one, year one, and year five. While somewhat arbitrary, and grounded in conventional divisions of time, I believe that the above schedule would give most patients outcome information adequate to make treatment decisions in light of their personal values. This schedule would be modified when better information was available of the actual distribution of MATOs held by patients.

Better than such a schedule would be the use of a graph plotting all survival results, or a Kaplan-Meier curve showing the probabilities of survival. The latter is used by Steiner *et al* who present probabilities of survival in terms of days for up to 60 days after admission, and in terms of months for up to 12 months after admission.⁵² Such graphs seem to be a good way to provide accurate, dense, but understandable survivability information to patients. An added plus is that the provided

information seems dense enough largely to forgo the need for empirical research into the distribution of MATOs held by the patient population.

It may be objected that researchers cannot anticipate individual patient situations, and in fact should conduct their research without reference to possible patient idiosyncracies. This objection is misleading. I am not asking that research not be conducted in terms of statistical generalisations, nor am I asking that research be tailored for each individual patient. I am asking that researchers collect and report a broad range of data pertaining to survivability and not rely on a single outcome measure. It should be pointed out that even the level of reporting I have suggested may omit the survivability information needed by certain patients holding unusual MATOs. A patient holding a MATO of survival to ten years would require that treatment outcome studies last at least ten years in order to provide the desired information. However, the fact that not every logically possible MATO can be accommodated in practice is not a justification for adopting the other extreme of limiting the reporting of information to a single, discrete measure of survivability.

Note that there is no need to limit the freedom of researchers or journal editors to voice any manner of value judgment about the appropriateness of a treatment. For example, the editor of *Resuscitation* makes a comment at the end of one paper, voicing concern over the possible inappropriateness of a treatment for certain subgroups of patients.⁵³ The comment does not in any way obscure the reported data, and, however influential the comment may be, it does not impede the independent judgment of patients and other consumers of the report. Likewise, valuational statements by authors within the body of their own texts need not interfere with the reporting of data nor impede the decision making of patients. What is objectionable is for researchers to act on those value judgments by suppressing data important to independent decision making by patients and other consumers of the reported information.

In the interest of simplicity and brevity, I have not to this point discussed quality of life issues. For many patients, the quality of life associated with survival, and not just survival itself, will be an important factor in the decision of whether to accept treatment. "Quality of life" has manifold dimensions. Because of this, it admits of much greater variation among patients, and is a much more complex issue than simple survival. The Utstein Consensus Conference, cited above,¹⁵ sets a good minimum standard for the recording of performance outcomes. However, I recommend that researchers report this information in tandem

with a more adequate reporting of survivability results, so that the survival and performance outcomes for all patients are reported. This will give consumers of the report a better picture of the likely outcome of a given treatment option, and should help each patient to make an informed decision as to how best to face the future, however abbreviated that future may be.

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- 53 See reference 47: 231.

Omentum-to-Brain Transplants★

Beyond your simplistic jokes I can feel new blood bounce
into the cingulate, untangle the Alzheimer twos, and swish away the hibernation debris.
Lendrum's stain will fail as more
nuclei move to the center, reduce the umbras,
and return my social security numbers.
Glopy meals draw blood once aimed at the gut, but
now up. Whirl past the heart, the jaw, the ear, and
plunge through the dura to the thirsty bouton belt,
releasing Eleanor Roosevelt.
Each pulse attacks my old Wernicke's,
"Now where'd I put the car peas?"

★Goldsmith HS, *et al.* Regional cerebral blood flow after omental transposition. *Acta Neurochirurgica* 1990; **106**:45-52.

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Editor's note

Readers who wish to have a few additional clues to this poem should turn to page 319.