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# Important discussions

Samia Hurst

Can any limit be set to how much we will pay for a specific health care intervention? How much good should it do, in order to be worthwhile in any meaningful way? When does «expensive» become «too expensive»? What health care interventions do solidarity and fairness require us to cover collectively? On 23 November 2010, the Swiss Supreme Court gave a ruling on a case raising exactly such points.

First, the story: the patient in question is a 70-year-old woman, who was diagnosed three years earlier with late-onset Pompe's disease, the adult onset form of an orphan disease of muscular tissue which causes patients to lose muscular function, including the heart and respiratory musculature, with a lethal outcome [1]. Specific enzyme replacement therapy has been available for a few years, but the drug, Myozyme®, had not yet been approved for use in Switzerland at the time of diagnosis. This patient's doctors obtained approval for off-label use, and an agreement from the patient's insurer to cover the first six months. While on the drug, the patient's condition improved. The required dosage to obtain this effect was, however, greater than anticipated, as was the expense. After the first six months, the insurer denied continued coverage. The drug was discontinued, and in the time that followed the patient's symptoms worsened. The patient sued the insurer for coverage, and won in the first instance. The insurer appealed to the Swiss Supreme Court against the decision. The latter ruled that coverage in this case could be denied. The reasons were that off-label coverage requires that a «high therapeutic value» be demonstrated, which was not the case here. The Court further argued that even if a «high therapeutic value» had been present, coverage could still have been denied on the grounds of an insufficient cost-effectiveness ratio.

This was immediately hailed as a landmark decision, not least because it explicitly attempts to launch important and long overdue discussions regarding how to share out resources fairly in the health care system. Taken as a whole, this ruling is an excellent blueprint for just the sort of discussions the ruling calls for: a table of contents for future debate.

This is important not only to help discussions take place, but also to authorize them. Setting a limit, any limit, on health care coverage has been a bit of a taboo. But it is also truly inevitable. If the discussion does not take place, increasing pressures on health care costs are likely to simply follow the path of least resistance, and allocate resources away from the phases of our

lives, where we are weaker and more vulnerable [2, 3]. From an ethical angle, then, the question is not so much whether to limit, but how to do it justly and fairly, in a way which respects us all. This is also recognized as legitimate by the Court. Good. Let the discussion begin.

As it stands, the «Myozyme» ruling contains a number of very apt points. It also contains a number of debatable points. But these represent possible stands in very real controversies, and on issues, which ought to be debated. Many of these are taken up by various contributors to this issue. Overall, the discussion can be outlined as being about five main topics: benefits, costs, the acceptable relation between them, fairness in the allocation of resources, and just decision processes.

So first, what counts as a benefit, or as a meaningful benefit? How can we measure and quantify it? How do we know it's there? The «Myozyme» ruling requires a standard of evidence-based medicine which is welcome in principle, but for which some adaptation would have been justified in the case of an orphan disease. It also makes a distinction between life-extending treatment and treatments which do not extend life. This is a crucial point, which some commentators seem to have missed. Indeed, one of the standard critiques of the Quality-Adjusted Life Year (QALY) approach is that it does not sufficiently consider saving lives to be different from improving them. The ruling is also based on a careful definition of benefits as those effects which are not only statistically significant, but also clinically relevant. As Peter Suter points out, this is a crucial element which is not always easy to derive from the medical literature. Stéphanie Dagrón, however, is also correct: making this evaluation is anything but easy, and not clearly within the sole capacity of a court of law either. This, then, does remain an open question.

Christian Kind reminds us that the cost of the drug is never called into question. Several other contributors note that it is not by chance alone that a drug intended to treat an orphan disease is an expensive one. One way or the other, this aspect needs to be taken into account in discussing limits to health care coverage.

What sort of cost-effectiveness ratio is the «right» one? Valérie Junod and Jean-Blaise Wasserfallen explain why the ruling does not imply that the same threshold should be used in every case. Moreover, although a threshold of CHF 100 000.– per QALY is indeed broadly cited internationally, this may only be because everyone tends to cite each other on this otherwise very insecure point [4]. It may not be the «right» threshold

at all. Applying the same threshold in situations where there is, or isn't, an alternative may not be the right thing to do either.

So, what does fairness require when we distribute health care resources? Clearly, it requires that no *person* should be left aside. The ruling makes that very clear: if it were used primarily to deny care to patients who suffer from orphan diseases, this would be very problematic indeed. Fairness requires that everyone should be taken into equal consideration. But then what? Should everyone be given «the same»? And would that be: the same resources, the same chances, the same results? Should those who are worse off get more? How much more? Or perhaps we should set a common threshold for what everyone ought to get, and just let those who can afford it purchase care beyond this threshold? The «Myozyme» ruling takes an explicit stand on fairness: equality before the law requires that for the same impact of disease on quality of life, everyone should have the same resources when these resources have a similar effect. In philosophical terms, this is an egalitarian view; one of the main views applied in ethics to just such scenarios, but one which also raises problems. These predictably also apply here: if this – and only this – is what fairness means, then it is better for everyone to have less than for some to have more than others, even if no one ends up being actually deprived. Egalitarian views of fairness, however, are not the only ones. Nor is it entirely clear that a view of fairness based on a single principle is the right way to go [5–7]. The ruling underlines the importance of equity and grounds it solidly in Swiss law. This is crucial and welcome. But what it means in practice needs to be further examined. This is a major point of debate internationally, and if it became a more explicit one in Switzerland this would be an important contribution of this ruling.

All of these, and more, are difficult but important issues. How should we face them? Responding to the motion of Ignazio Cassis [8], the Federal Council declared that it would clarify the tasks which could be performed by a national health technology assessment

body. Several contributors to this issue call, in one way or another, for this sort of response as well. As long as discussions of prioritising continue to be so politically difficult, this may be the only way ahead. It will of course also remain crucial that such discussions take place both within and around the health care system. It is worth adding that this issue of Bioethica Forum had been targeted to focus on resource allocation long before this ruling was made. Once it took place, the occasion was too good to miss. We thank all the contributors who, in some cases at very short notice, wrote such a thoughtful collection of commentaries. We hope in this manner to help sustain discussions which our health care system will increasingly need in the years to come.

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