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### Report:

# Hidden and implicit economic normativity and their effects on healthcare and society

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November 2023 version The paper is "open for debate". If necessary, the current version will be

will be developed further. For this, please contact Dr. Romanens.

#### Purpose of this report

This report is the second in a series of reports, in which the VEMS assesses one instrument used in the evaluation of our healthcare system at a time. We aim to inform healthcare professionals, whose work at the bedside is affected by these tools. On the other hand, we address decision makers involved in the health care system on the meso and macro level, i.e., those in the institutes and institutions, as well as political authorities involved in legislative and executive politics. In each case, we ask a few selected individuals to comment on the report. We collect these comments in order to make them available to a broader public, if warranted. In any case, we make them available to the media, because our goal is to stimulate a social discourse, starting from a vantage that may not always be popular, but hopefully relevant.

Unlike insurers' cost-effectiveness proceedings (with potential punitive consequences), which we assessed in our first VEMS report, the VEMS report WZW, cost-effectiveness analyses, or CEAs, are not a directly operational tool. Rather, these analyses are introduced into discourses about the affordability of our health care system. Unfortunately, too often a single statement from the analysis is taken as a pithy headline to warn against exorbitant costs of allegedly unnecessary treatments. If one reads the whole analysis, the facts are quickly put into perspective. And, if one takes the trouble to revise these calculations, it often becomes apparent that they are characterized by a certain bias, and tend to present values in a way the authors would like to see them and have them seen, not necessarily objectively, as when based on clinical-medical evidence. Above all, the social and societal benefits are rarely sufficiently considered, if at all, e.g., the respective gains in quality of life of relatives, the added social value resulting through reintegration into the work process, et cetera. Consequently, we do not have actual cost-effectiveness analyses, which is what the calculations claim to be, but pure cost-utility analyses (CUA).

Although these do not always have a direct effect on medical decisions, they often influence them indirectly by provoking sentiments against certain treatments. This can lead to physicians bowing to social and political pressure, with the result that they prescribe the treatments in question more restrictively than a purely clinical-medical approach would demand of them. Physician networks can use such calculations to urge their physicians to adopt less medically appropriate treatment practices, professional societies can adapt their treatment recommendations, deletion lists can be drawn up, and regulatory decisions can be influenced at the meso and macro levels. The result can be that the important and correct clinical, scientific and ethical regulation of medicine is displaced by health economics, and economists ultimately restrict the range of medical decisions that clinically active physicians are allowed to make at the bedside.

This leads to a similar situation as we observe in the cost-effectiveness proceedings. The VEMS has issued a position paper on this in June 2019 and recently on the current situation VEMS report WZW mentioned above. For years, insurers have been conducting cost-effectiveness analyses, the unsuitability of which is well known, and which the Ethics Council of Public Statistics already described as an "abuse of statistics" in a statement in 2006. As a result, rationing-decisions are relocated from the macro level of the health care system, where they should be made systematically, if at all, to the bedside, and imposed

on individual physicians. The clinicians now must bear the moral burden of treatment decisions about which they can only make limited decisions. In the words of Schopenhauer, they can do what they want, but they can no longer want what they want.

What does it do to a medical professional to have to tell a senior citizen with colorectal cancer that it is not possible to treat him, because it is no longer worthwhile from a purely economic standpoint; to send him away untreated and leave him to a cruel death? Or one must delay treatment until the consequences of the illness are severe enough to produce a positive "cost-effectiveness ratio". How does such grotesquely cruel nonsense affect the shortage of medical professionals? What does it do to the patients, their families, relatives, and acquaintances who hear about it and have to live with it? And finally, what does this do to us as a society? It is quite possible that, in the coming years, we will be faced with a larger burden of disease. If we encounter it in this way, if we move on such thin moral ice as we are increasingly doing, then this could seriously disturb social peace and equality.

One will object: But we must draw the line somewhere. We can't treat everything, we have to weigh things up, and that requires numbers. That is true. But where has money ever been saved by miscalculating? Such theoretical short-range-savings-successes are Pyrrhic victories, and in the end, the expenses are often far higher. For example, spending on preventive medicine, the strongest medical instrument for cost reduction, is currently being reduced. Paradoxically, this generates systematically avoidable future treatment costs, based on cost-effectiveness analyses. It is important that we all become aware of this, because these costs affect us all – the monetary, as well as the health and social costs. In the following, we would like to show how the calculations are currently made and how – not only from our point of view, but based on established consensus – they should be made, in order to provide that measures taken to save money and other resources pay off for all of us, not just for the careers of the health administrators who implement them.

## QALY, the value of life and the hidden implicit normativity of economics

Content  $\rightarrow$ 

In this chapter, we show how health economics normatively influences medicine and distorts its cost-effectiveness – using the definition of certain numerical values and the implementation of formulas and models that obscure this influence.

In cost-effectiveness analyses (CEAs), the concept of quality-adjusted life years (QALY concept) is not mandatory, but (especially in Switzerland) commonly used. The basic idea is simple, and at first glance it is also impressive: In order to have a numerical value on the benefit side that can be compared with the calculated value on the cost side, a scale from 0 to 1 is used for the quality of life, where 0 means death and 1 means optimal quality of life. In practice, however, this has pitfalls. We will illustrate this with an example that we have already discussed elsewhere: the treatment with statins in primary prevention. Even if one disagrees with prescribing statins in primary prevention, the discussion concerning the calculation of financial and health consequences is exemplary of the necessity to calculate correctly, if economic aspects are to be considered at all.

Heart attacks and strokes cost Switzerland around 10 billion Swiss francs a year in terms of care and social costs. On the other hand, cholesterol-lowering statins, with daily costs of around 1 Fr. or less, are a comparatively inexpensive drug for preventing these conditions and subsequent costs. So, the prescription of statins where indicated has an extremely good cost-effectiveness ratio. However, the <u>statin</u> report of the <u>Swiss Medical Board</u> calculates a cost of 210,000 Fr. per QALY for the prescription of statins, a value that has not been reported anywhere in the international scientific discourse even close to this level. We will focus on the three points that show how normative intervention is taking place in this context, without going into all the errors made calculating costs and benefits.

The reason the cost-effectiveness of statins is not nearly as low in international scientific papers, is due to the fact, that the SMB report has not undergone the peer review process required in the scientific community. Instead, this process was bypassed and the report made available directly to the media, who have repeated the false results of this cost-effectiveness analysis so long that it has become a pseudotruth, which journalists should have questioned and exposed as fake news. The true cost-effectiveness of statins becomes apparent, if you do the math correctly, as shown in the article "Cost-effectiveness analysis of statins in primary care: results from the Arteris cohort study". This paper was written by members of the VEMS and co-authors and has undergone a proper peer review process, unlike the SMB statin report. The conflict presented here is not opinion against opinion, but intentional misinformation against science and the Hippocratic oath.

On the one hand, an incorrectly financialized endpoint, or one that is not included at all, can have a pronounced effect: in this case, the cost of a loss of life is stipulated to be 8,500 francs. Two questions now arise: Is it permissible in principle to financialize the value of life? And if so, what would be an appropriate amount? In the Swiss standard work "Methods for determining the benefit or value of medical services" from 2012, the value of life is discussed on page 47, but rejected for methodological reasons. The human capital approach, i.e., the value of a person financialized as the expected economic contribution until the end of life, is argued there to be outdated due to the described deficits and the lack of foundation of the human capital approach in microeconomic value theory, and is rarely used anymore. However, it would still be used in health economic evaluation studies to estimate the indirect (societal) costs of decisions for or against medical services.

On the other hand, when discussing the necessity of including the "statistical value" of life, the authors of the report remain vague and also omit a method defined by the WHO to solve the problem. We take this information from the report "The Value of Life" by Schleiniger and Blöchlinger published in 2006. According to the WHO, the value of one year of life is three times the gross domestic product (GDP) of a person. For the year 2021, the GDP per person was 84,055 Swiss Francs. The financial value of one year of life would therefore correspond to 252,165 Francs. For example, if a person at risk of death at the age of 50 is saved by a medical measure, he or she is left with a statistical probability of survival of about 32 years. The value of the life saved in this case is therefore 32 x 252,165 = 8,069,280 Swiss francs. The consideration of the VSL ("value of a statistical life") in the formulas of health economics probably has the greatest influence on the calculation of cost-effectiveness of medicine, as we will present later.

Note  $\rightarrow$ 

The decrease of the value of a statistical life with age demonstrates age discrimination inherent in the system, even if this value were defined correctly.

By arbitrarily defining the value of a life at one thirtieth of the international norm, the SMB not only diminishes the cost-effectiveness disproportionately, it also makes a normative statement – and does so without discussion or explanation: This is how much a human life is worth to us Swiss, period. Furthermore, the social costs of death, secondary illness, and absence from work, as well as the reduced quality of life of the relatives – actually the whole social system of the deceased – due to the event, were not even included. Again, we have the effect of artificially diminishing the calculated cost-effectiveness in this way. This again implies a normative statement: the social context is not important in Switzerland. Finally, the SMB also misinterprets/redefines the context of clinical medicine by calculating the costs per QALY over only 5 years instead of over at least 10 years, when the preventive effect really becomes apparent. This step is also normative in a sense, as it imposes an imbalance of power between medicine and economics just by redefining the time during which an effect is observed.

Using the SMB's assumptions about costs, we calculated the case-base according to the actual effects of statins stepwise as follows, running two models:

#### A) Model including QALY

- 1. 10 instead of 5 years of treatment and value of life = 8,500 Fr.: cost per QALY 210,279  $\rightarrow$  95,666
- 2. 10 instead of 5 years of treatment and value of life = 252,165 francs:  $\rightarrow 70,017$  Fr/QALY, with two years of life lost  $\rightarrow 43,473$  Fr/QALY
- 3. 20 years of treatment and value of life = 8,500 Fr:  $\rightarrow 38,359 \text{ Fr/QALY}$
- 4. Inclusion of QALY of the relatives: According to the SMB, 11 persons suffer cardiovascular events in 5 years, leading to about 33 affected relatives, who suffer a loss of QALY of 10% over 2.5 years. Thus, according to the SMB, the affected persons lose 9.5 QALY and the relatives 8.25 QALY→ 112,544 Fr/QALY
- 5. Inclusion of indirect social costs: according to the report the <u>indirect costs of non-communicable</u> <u>diseases</u>, indirect costs can be estimated by doubling treatment costs. In the base case of the SMB with treatment over 10 years, this results in→ 68,666 Fr/QALY

#### B) Model excluding QALY (Return on Investment (ROI)).

- 5 years of treatment, VSLY 252,165 Fr, cost of treatment 2,350,000 Fr for 1,000 persons→ ROI 174,172 Fr; for 1 million persons treated preventively with SMB risk for heart and brain stroke→ ROI 174.2 million Francs.
- 2. 10 years of treatment, VSLY 252,165 Fr, cost of treatment 4,700,000 Fr for 1,000 persons→ ROI 348,343 Fr; for one million persons treated preventively with SMB risk for heart and brain stroke→ ROI 348.3 million Francs.

The calculations can be reproduced using our **Excel spreadsheet on the Internet**.

Note  $\rightarrow$ 

Following a series of calculatory steps and setting normative values from an incomplete, purely economic perspective, can lead to a very cost-effective medical treatment being misrepresented as not being cost-effective at all.

What role, if any, can medical ethics still play in this setting? All in all, we can use the example of the <a href="Swiss Medical Board's statin report">Swiss Medical Board's statin report</a> as a good practical illustration of what the economist <a href="Peter Ulrich">Peter Ulrich</a> discussed theoretically when he wrote in an <a href="article in the "Zeitschrift für Wirtschafts- und Unternehmensethik" (Journal of Business and Corporate Ethics). We translate: "Where there is no normative input

justified in terms of its reasonable validity and bindingness, no normatively substantial output can result either. The squaring of the circle - and that means here: the methodical reduction of practical reason to purely economic rationality (efficiency) - cannot succeed here either, but can ultimately only be based on concealed implicit normativity. This is methodically generated by modeling economic subjects as if they were "homines oeconomici", who know no other motive and criterion of rational action than that of the respective private maximization of utility, success or advantage."

The ethics expert involved in the development of the SMB report did not only not criticize these ethically problematic points, but instead raised the question of whether physicians, who treat their patients preventively with statins at 210 000 Fr. per QALY, were acting ethically correctly, because of the costs incurred, but also because of the side effects, which were exaggerated. Consequently, the legal expert considered turning the legal mandate to provide health care on its head by asking whether medical treatment to prevent illness and loss of function constitutes justiciable behavior, as opposed to *non-treatment*. This twisting of ethical and legal relations under the hidden implicit normativity of economics has not only disrupted the prevention of cardiovascular diseases. It has also, and more fundamentally, contributed to steering the discourses of medical care for the elderly in a direction that certainly has features of a life-shortening debate. It may also have contributed to making a study protocol like that of the "Stream study" (see below) possible in the first place.

The situation: Although the European Society of Cardiology (ESC) clearly positions itself against discontinuing statin treatment in old age in its recommendation, the Stream study of the Bern Institute of Family Medicine motivates seniors to take this step, in order to see whether they subsequently suffer a heart attack or a stroke. The VEMS considers this procedure ethically problematic and the "Stream study" irresponsible. We have therefore filed a corresponding complaint with the Ethics Committee of the Canton of Bern on June 29, 2022. We have also submitted a report to swissmedic, because the patient information of the study contains false statements. However, we were not able to halt the study one way or the other. The study is supported by the Swiss National Science Foundation, so one might assume that everything is on the level. The VEMS is not opposed to the hypothesis, on the contrary. However, the hypothesis could be tested without unnecessary risk for study participants, by monitoring consenting seniors, who want to stop taking the medication anyway.

Note →

In the context of a health-economy that has a de facto ethical-normative effect on medicine via its operative instruments, the actual ethics of medicine as an independent discipline and as a reference system is undermined. QALY calculations have an impact beyond medicine and health care, and influence social questions regarding the human condition – questions that should be discussed openly and broadly within an enlightened democratic society. Such calculations, if uncritically waved through, are also capable of destroying gains made in years and decades of struggle for equality and against discrimination – and this under circumstances that do not permit social discourse at all. We are talking about the rights of people with disabilities, with mental illnesses, and addictions; but also, the rights of the LGBTQI+ community, in the possible context of gender reassignment surgery, which may one day be performed a little more often than people are willing to pay for. An «appropriately calculated» cost-effectiveness analysis could ensure that operations are no longer covered by health insurance. This much is certain: the weakest members of society always bear the greatest burden of shortsighted interventions. An open, modern, multicultural society cannot morally afford that questions of health and sickness are ostensibly publicly negotiated, but are ultimately decided parallel to these negotiations and definitively by an inaccessible implicit normativity of the economy.

We would like to illustrate this with another example, the SMB report on mammography screening from 2013. Here, the bias is particularly unpleasant, because it serves an age-old stereotype: that of the supposedly hysterical woman. To be sure, the SMB is generally critical of diagnoses, claiming that they led to unnecessary treatments. But while this skepticism is still comparatively moderate in the case of early detection of prostate cancer (PSA test) in men, the SMB seems to have taken a resolute stand against early detection of breast cancer in women. The SMB calculates here as follows:

#### Model A

The SMB calculates in its basic model (Model A) that quality of life, expressed in Quality adjusted life years (QALY), is reduced by screening. For every 10,000 women screened, the result is 129,647,175 QALY, compared with 129,648,600 QALY for 10,000 women without screening. Per woman, 810 Fr is spent on screening, which leads to a loss of -0.00014250 QALY. The cost per QALY is therefore 810 Fr /-0.00014250 QALY = -5 684 210.53 Swiss Francs. This means that 5.7 million francs are spent to harm the screened women. However, the SMB realized that this figure is absurd, and came up with the following solution:

#### Model B

Using a sensitivity analysis, the SMB now claims that the same 1,025 false positive mammograms, as in Model A, also reduce quality of life by 10% in Model B, but this now only lasts 2 months (Model B) instead of 6 months (Model A). This results in 129,681.34 QALY for the 10,000 women with screening and thus a gain in quality of life of 32.74 QALY or 0.00327417 QALY per woman with the result of 247,391.19 Fr. / QALY. With this result, the SMB goes public and destroys the positive medical effects of screening with its cost considerations.

#### **Model C:**

Model C is based on the very unfavorable model A, but now it is assumed that 1% of the 10,000 women, who do not receive mammography screening (because it is not free of cost, as part of a program, and because they could not afford to pay for it themselves (lower income, precarity)) suffer a loss in quality of life of 10% over 13 years, because they live in constant fear of breast cancer. As a result, 62,998.25 Fr per OALY would have to be spent.

Falsch positive (%)
Angst durch falsch positive (Monate)
Angst vor Krebs (%)

		QALY	MODELL	
	Your Model	Cost/QALY	SMB Model	Cost/QALY
1	10,25	247 391	10,25	247 391
	6			
1	1	62 998		

#### Value of life

The SMB calculates that screening 10,000 women will prevent 16 deaths due to breast cancer, and that each of these 16 women will lose an average of 18 years of life. This results in 18 x 16 = 288 years of life lost. The value of these lost life years in the calculations is stipulated to be 0 Swiss Francs! So, while the cost of quality of life is financialized (Francs per QALY), the value of life itself is not. First, this is not consistent and second, the SMB does not mention such financialization in the form of VSL (value of a statistical life) with good reason: mammography screening would otherwise be associated with a significant return on investment (ROI) for society. Mammography screening of 1,000,000 women would prevent 1,600 deaths at a cost of Fr 810,000,000 (810 million) over 6 years, resulting in a ROI of Fr 4,950,000,000 (4.95 billion) when the value of one year of life (VSLY) is defined as Fr 200,000 in accordance with the WHO (as shown above), and this ROI remains very high at Fr 2,772,277,102 (2.8 billion) even if the VSL were discounted by 6% per year.

Screening Kosten pro Frau
Screening von folgender Zahl Frauen
Anzahl Todesfälle
Wert eines verlorenen Lebensjahr
Anzahl verlorene Lebensjahre pro Frau
Kosten verlorener Lebensjahre
Kosten Screening
Return on Investment (ROI) über 18 Jahre
Diskontierungswert des VSL in %/Y, z.B. 6
Diskontierte Kosten verlorene Lebensjahre
Diskontierter ROI über 18 Jahre

VSLY MODELL (Wert des Lebens)				
Your Model	SMB Model			
810	810			
1 000 000	10 000			
1 600,0	16,00			
200 000	0			
18	18			
5 760 000 000	•			
810 000 000				
4 950 000 000				
6				
3 582 277 102				
2 772 277 102				

All calculations are available as Excel spreadsheets.

It seems unethical to financialize the value of a lost year of life. The QALY model of the SMB therefore works with a VSL of 0 Swiss Francs. But this is exactly why the costs of mammography screening appear to be unacceptable. If a lost year of life is effectively defined to be worthless, how can the saving of life be worth something? The assumptions underlying the calculations are exposed for what they are: purely

hypothetical and dangerously detached from societal values. After all, the VSLY includes not only the value of one year of a woman's life, but also the social value of that woman to family, work, and social environment. Thus, the SMB devalues the importance and value of women in society. Instead, it is virtually assumed that women tend to overreact to diagnoses, which supports the stereotype of the hysterical woman from past centuries, and is not suitable at all in approaching breast cancer prevention objectively.

The absurdity of men calculating women's feelings, speculating whether and how much the certainty of being healthy may affect her quality of life, also shows a fundamental problem inherent to QALYs: the limit of human empathy. This limit is lower for some, higher for others, but no empathy can be unlimited. These considerations therefore always have something speculative about them, because the actual quality of life experienced by the individual can only be guessed at, not determined with absolute certainty. It is also not a fixed quantity; humans are able to adjust to circumstances, even extremely adverse circumstances. On the other hand, it is difficult for us to anticipate how far we could adjust to presumed circumstances. It is even more difficult for us to estimate the quality of life of a person whose circumstances we, as outsiders, might find difficult or even not worth living.

Note  $\rightarrow$ 

Anyone who waves through operational health economic instruments – which can be inherently discriminatory on the basis of superficially pragmatic considerations – must always consider that this can also undermine their own ethical prerogatives.

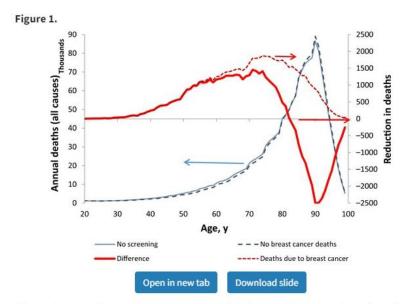
The quantification of such a subjective criterion as the quality of life creates a pseudo-objectivity that conceals the fact that this is accompanied by a computational objectification of the subjective experience of an individual, whose life value is now no longer inherently lived and experienced, respectively only as far as external attribution allows it. The consequence is systematic discrimination – even negation of the quality of life – of human beings with multiple illnesses, the aged, individuals with disabilities – in sum, of everyone whose life circumstances and feelings are less approachable for some calculators. For example, if someone cannot imagine the feelings associated with gender dysphoria, they will approach a costeffectiveness analysis of gender reassignment surgery accordingly, and this bias will have an impact on what models they choose, what factors they consider, what evidence they refer to, et cetera. We should by no means lose sight of this, and always approach such calculations with healthy skepticism, especially when they come to results that have not been "calculated" in this way anywhere before in international scientific discourse.

We will return to the example of mammography screening, because it illustrates something else: the underestimation of the complexity of medical interrelationships and the incorrect assessment of interdependencies by medical laypersons. The objection that mammography screening is not able to reduce overall

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mortality, serves as a good example of generating wrong answers with wrong questions. The US Preventive Taskforce states that mammography screening does not lead to a reduction in all-cause mortality. However, demonstrating a reduction in all-cause mortality is not the purpose of mammography screening studies, and consequently they were not designed to do so, as the abstract of one study shows: "Although mammography screening has been shown to reduce breast cancer-related mortality, some have suggested that evidence of effectiveness should be provided by lower all-cause mortality. Using a microsimulation model of breast cancer development, detection, and treatment, it is easy to show that this is an unrealistic expectation for studies of practical size and observational duration, even if the reduction in breast cancer mortality is substantial. Estimates of all-cause mortality depend not only on the effectiveness of the screening intervention but also on the alignment of the age distribution of the effect of screening on reducing deaths with that of the other major causes of death. The size of a randomized trial required to demonstrate a reduction in all-cause mortality therefore depends on the length and timing of the observation period and is usually at least 10 times larger than a trial designed to demonstrate a reduction in deaths from breast cancer. For breast cancer, which accounts for only a small proportion of total deaths, all-cause mortality is neither a practical nor a meaningful criterion for evaluating the effectiveness of screening."



All-cause deaths and breast cancer deaths vs age. Left axis: Annual deaths at each age from all causes for a cohort of 2.1 million women who (solid gray line) did not receive breast cancer screening (reference cohort) and (dashed gray line) one for which there are no deaths due to breast cancer. The curves appear to be nearly superimposed. Right axis, solid black line: The difference between the numbers of deaths in these cohorts, expanded for visibility. Positive values indicate fewer all-cause deaths in the cohort without breast cancer deaths. Also plotted (dashed black line) are the annual number of deaths from breast cancer in the reference cohort.

Moreover, the relative risk reduction of screening mammography on all-cause mortality is not 0% but 2% (link), which means: fewer women die overall, but this is not statistically significant, as previously mentioned, due to study-design/statistical power. Moreover, according to one <u>study</u>, after accounting for all variables, screening mammography remained associated with a lower risk of all-cause mortality, with a hazard ratio of 0.67 (95% CI, 0.60-0.74).

If women die due to other causes, this cannot be presented as the failure of the specific prevention program, but may be the consequence of the method used to analyze the outcome or the failure of prevention of other causes of death. Only the sum of all effective prevention options yields a correct calculation of the reduction in all-cause mortality. In the 2023 Guidelines, the U.S. Preventive Taskforce advocates additionally including women between 40-49 years of age (previously only after age 50) in mammography-screening. One reason for this is in fact a reduced all-cause mortality in this age group, as shown in a 2022 study. In 2012, the number of deaths due to breast cancer corresponded to 783,000 potential life years lost, and an average of 19 life years per death, even though breast cancer mortality rates have steadily declined since 1990.

Conclusion  $\rightarrow$ 

These examples and considerations demonstrate the need for a fundamental and broad examination of the tools of health economics. This is because CEAs specifically, and such tools in general, can distort the perceived cost-effectiveness of any *a priori* non-desirable treatment, to make it appear ineffective, though the opposite is true. This can lead to incorrect analyses, which can lead to faulty decisions, which in turn can lead to avoidable individual suffering and costs due to avoidable disease without even considering societal implications and costs.

## Are we riding a dead horse with the QALY concept in Switzerland?

#### Content $\rightarrow$

In this chapter, we show how the QALY concept was and is discussed in the Anglo-Saxon context, where it originated, how it is discussed in Switzerland, and what our institutes and institutions think about it.

The 2016 paper "Quantifying life: Understanding the history of Quality-Adjusted Life-Years (QALYs)" by Eleanor MacKillop and Sally Sheard does a very good job of working through the history of ideas behind the QALY concept, and considers numerous scholarly sources in weighing pros against cons. The text is well worth reading in any case, as we are well advised not to blindly repeat mistakes, that have already been made and recognized as such. The work shows that resistance to the QALY concept existed from the very beginning, especially in the medical community, and that it was recognized early on as in conflict with the ethical foundations of clinical medicine, where such calculations can function as a basis for or against treatment decisions.

The problem became known to a broader public through the <u>case of seven-year-old Coby Howard</u>, who died in 1987 in the state of Oregon in the USA because his bone marrow transplantation was not covered by Medicaid. The basis for this was a law that relied on inter-indication comparative effectiveness analyses that included QALYs and prioritized, i.e., rationed, accordingly. The idea of asking how much of the money gained by denying expensive to very expensive treatments could be used for other, less expensive treatments had convinced the voters. However, the prioritization lists were absurd and had to be corrected later. For example, therapy for thumb sucking was judged more cost-effective than treatment for fibrocystic inflammation and AIDS. Finally, the case of Coby Howard showed the public that these number-games could result in suffering and death, and so the experiment was stopped. A small, but not insignificant detail: the number of interventions of the treatments for which the money was supposedly saved did <u>not increase in the following years</u>. In other words, the money was not reallocated to the more «cost-effective» treatments.

Overall, the <u>debate in the USA</u> can be summarized as follows: QALYs are seen as an instrument to control rising drug costs, for example by comparing different drugs in the same patients (intra-indication comparisons). However, they are clearly rejected as a basis for or against treatments, or even as a basis for systematic discrimination of entire patient groups, even in the home of utilitarianism, due to ethical as well as social considerations. Ultimately, the hope of achieving substantial savings has given way to a certain disillusionment in the light of the facts of clinical reality.

#### Note $\rightarrow$

Due to negative experiences, a corresponding ethical awareness and the fact that the savings realized by applying QALYs in economical calculations and reasoning are not even substantial in the medium term, in addition to the risks of additional costs incurred by expensive follow-up treatments, the use of QALYs as a basis for or against treatment hardly finds any supporters today, even in the USA.

And what about us? As we have shown above, in the Swiss standard work "Methods for determining the benefit and value of medical services" from 2012, the QALY concept is critically assessed and many aspects that are obviously ethically problematic are rejected. So, no cause for concern? As we have also shown above, this does not change the fact that calculations continue to be made in a way that they should not, partly even by the same authors. So, we are lulling ourselves into a false sense of security: Depending on the client, the political and economic situation, etc., calculations will sometimes be made in one way, and sometimes in quite another, whatever suits the agenda. Sometimes the same authors choose thoroughly different bases for their calculations. This may be an ideal situation for politics (you never know which way the wind will blow), but medicine cannot work like this. And we cannot, and do not want to afford a dysfunctional medicine.

If basically any treatment can be presented as cost-effective or ineffective, depending on the need, sometimes for one lobby, sometimes for another patient group, then we do not have a situation of rational control of a health care system that is increasingly under cost pressure, but one of pure arbitrariness. This is grueling for patients, insurance-payers, physicians – for all of us. It destroys the faith in the people and institutions to whom we must be able to turn with confidence and conviction. The motivation to actively care for one's own health, by far the most effective cost-saving instrument in medicine, cannot be engendered in this way; on the contrary. What we would expect in this situation, would be a profound understanding and a clear stance of our institutes and institutions regarding CEAs, QALYs, and BIAs (budget impact analyses) – all these specific instruments, and on their role in managing our health care system in general.

#### Two examples:

The Swiss Academy of Medical Sciences (SAMS) supports the use of QALYs as one of several methods for evaluating the efficacy and effectiveness of health technologies and treatments. In its recommendations, the SAMS emphasizes that QALYs can be useful to make decisions about resource allocation in health care, if this method is applied ethically and in a methodologically appropriate manner.

However, the SAMS has also emphasized that QALYs should not be used as the sole basis for decision-making, but as a tool to support informed health care decisions. It is important to consider the use of QALYs in a broader ethical and societal context and to consider the impact on different groups of patients and society.

The SAMS has further recommended that the use of QALYs at the national level in Switzerland should be guided by a shared decision-making process between government authorities, patient organizations, professional societies, and other stakeholders to ensure that the use of QALYs is ethically and methodologically appropriate and considers the needs of patients and society.

Overall, therefore, it can be said that SAMS has a differentiated view regarding the QALY concept. What we miss here is that – in case of gross violations, as we have shown here, the SAMS should react and correct publicly, as well as issue warnings. But it does not do so. The misuse of statistics and mathematics is tacitly tolerated – as long as it serves the overriding goal of cost control?

The Federal Office of Public Health (FOPH) has not yet explicitly recommended or rejected the use of QALYs. However, the FOPH has emphasized that decisions about resource allocation in health care should be based on criteria such as medical necessity, clinical effectiveness, efficiency, and equity. The FOPH also emphasizes that it is important to consider the needs and interests of patients and society.

Overall, the relationship of Swiss health authorities to QALYs is mixed and there is no unified stance. However, the use of QALYs as a method for evaluating health technologies and treatments is accepted by some authorities and considered useful if this method is applied ethically and methodologically appropriately. However, again: There is no obligation to identify and correct gross violations against correct economical, scientific or clinical methods.

We could point out further examples here, such as the Conference of Health Directors GDK, which we have informed about manipulative CEAs in each case. These endanger the quality of care, but the health directors, who should guarantee quality of care, see no need for action. Our medical ethics institutions and institutes, have never, to our knowledge, expressed any criticism of the QALY concept, nor have our patient support organizations. Finally: What about the organizations of medicine themselves, the professional societies, the physician organizations, the FMH? They seem to be saying to themselves: That's just the way things are, the economy is now calling the tune.

More info at www.qualy.ch.

Conclusion  $\rightarrow$ 

While the QALY concept has been controversially discussed for some time, and in some cases clearly rejected in the USA and England, where it was largely developed, Switzerland continues to ride a horse that is more dead than alive, though the QALY concept is clearly not the hoped-for instrument for containing healthcare costs.

## When does a healthy skepticism regarding medicine change into a mania for supposed cost-effectiveness and utility?

No human being is free from bias. When you start to look at the cost-effectiveness of a particular medical treatment, you do so because you suspect it is likely to be used a little more often than makes sense. That is human and not wrong. However, one should remain honest in one's calculations, as in research, even if it becomes apparent that this assessment was perhaps not entirely correct. For example, one may expect that the current costs of treatment and medication (e.g., generic drugs) are implemented in calculating the costs, not old, incomparably higher costs. It would also be expected that the actual costs of treatments are considered, i.e., those that are actually carried out along the established treatment paths of clinical medical practice. In several reports that the Swiss Medical Board has introduced into the medical discourse in recent years, as we have shown, the costs have repeatedly been distorted to a considerable extent. We criticized this more than 6 years ago in an article on medinside.ch March 8, 2017, in addition to the distortions and incorrect calculations on the benefit side (efficacy), but little has happened since then.

Medical cost-effectiveness is still systematically underestimated by incorrect assumptions of health economics, as we have shown in the two reports of the SMB on statins and mammography screening above. The SMB also only considers the QALY of those with the disease, thus detaching them from their social context. However, the most important negative effect on calculated cost-effectiveness is the neglect of the value of life according to the WHO proposal (see above). Preventable deaths are likely to destroy billions of francs in "return on investment" (ROI) in our society over 5 or more years, according to the WHO model. Further destruction of cost-effectiveness results from so-called "budget impact analyses", where the influence of a medical measure on the expected amount of the insurance-premium burden is calculated. In this process, medical effects, e.g., prevention of heart attacks and strokes, are regularly offset against the costs over a period of 5 years (which is far too short for the treatment to take effect), resulting in poor cost-effectiveness and subsequent incorrect rationing of treatment. As we have seen above, the preventive effects are very cost-effective over longer periods of 10 to 20 years.

The simple example of a meniscus operation illustrates this clearly: freshly discharged from the hospital and during the first weeks with the operated knee, it still hurts, and one may wonder whether the operation was worth it. However, with a few weeks of physical therapy, resumption of regular exercise and sport, as well as habituation, the benefits become apparent. However, if patients who have undergone surgery are interviewed too early, the results on the benefit side are distorted. The same also applies to a number of preventive medical treatments, whose effect on the prevention of heart attacks or strokes, for example, shows an increase after an observation period of five to ten years, which is missed by a cost-effectiveness analysis that only observes this effect over a period of five years.

Incidentally, it is not only the VEMS that points to the miscalculated social benefit and gain in quality of life for the relatives. Rather, this is anchored in a basic paper of the Swiss Academies of Arts and Sciences, the paper "Methods for determining the benefit or value of medical services" published in

2012. On page 25, we read: "The authors of this report are of the opinion that this effect should be taken into account for medical services that significantly relieve the burden on relatives and/or caregivers. If, however, some of the same authors then do not necessarily always do this in their commissioned work for health insurance companies, then this remains for them to explain." In any case, none of their cost-cutting measures has yet done just this: saved money. On the contrary, the gigantic cost-control administrative apparatus devours more and more money and time, money that is not available to patients, and time that medical professionals could have with and for patients.

There are many more aspects to the topic, which we have presented on the website <a href="www.qaly.ch">www.qaly.ch</a>. In this report, our aim was to create a fundamental awareness of what is happening, and what it could do to us as a society. The mechanism of these instruments and, especially, the lack of transparency in their application, as well as the lack of knowledge regarding inherent risks in their use, have the ultimate effect that basically every treatment is open for debate, and every medical benefit can be converted to ineffectiveness. Those who have a lobby, a patient support group, can defend themselves; while those who do not, are more likely to suffer ill-health and handicaps. As stated, this always affects the weakest most. The fact that the Swiss population does not agree with this was clearly shown by the recent resistance to a reduction in funding for disabled children. It has also been shown in their attitude and behavior in the pandemic (see our papers "Covid19 and Utilitarianism" and "Covid-19 and Communication"). Problematic is that society and even clinical medicine cannot respond, if the mathematical errors that lead to discrimination against the weak and defenseless are not technically understood.

Fortunately, Switzerland has largely been able to develop into an open, tolerant society in recent years, a society that sees diversity as an opportunity, not as a danger. If, however, unseen and not understood in public discourse, a mathematical-economic machinery is now creating quite a different reality, then tolerance is only a beautiful pretense, if this machinery is not recognized and stopped.

It is not always pleasant to question figures, especially when they confirm one's own view; to recalculate them, to admit mistakes, at the risk of then being portrayed as a waster of money, voting for an unregulated medicine that no society can afford any longer. Overall, however, one will probably have to admit that the internal medical regulations, grown over centuries of constant professional dialogue on a scientific basis, do not function so badly compared to the hardly existing regulations of a neoliberal flat-rolling economy, whose systemic deficiencies are becoming increasingly apparent and can have devastating consequences.

Conclusion: We must not continue to leave the shaping of our social and living conditions to health economists without checks and balances. There must be a broad social discourse on how these economical computational instruments are to be used, and this is urgent and must be binding. With the steady integration of artificial intelligence into the administration of our healthcare system, we run the risk of being at the mercy of machines that will be incomprehensible and thus, virtually unstoppable. Once AI has learned that discrimination is "worthwhile," it will do so systematically and possibly not even detectably. What will this mean for decisions regarding expensive treatments, for decisions at the end of life? No one can imagine. So, we need to react now, and do what is necessary to fully understand these

instruments and especially the processes, the way they are used and work, in order to have a say in what it will mean in the future to be a human being and part of our society.