Where does WHO get its economic advice? Time to review and revive.

An open letter to Dr Tedros

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Dear Dr Tedros

Congratulations on your election. Many hopes are riding with you. In this open letter, I share some of my misgivings about the WHO of the past and the amateurishness of its economics. It may be that its economists have talked sense but have been overruled by those above. Whatever the truth of that, it matters a lot for WHO to get its economics right.

Aid – including aid for health – is under increasing scrutiny everywhere. Donors are increasingly needing to demonstrate its efficient deployment to their own taxpayers and, as funding dries up, many low and middle income counties (LMICs) are going to face even bigger financial and structural challenges in seeking to deliver goals like universal health coverage. Yet the WHO is in poor shape to help either side, givers or receivers. Its economics is, frankly, not up to it.

Why has WHO so consistently got its economics wrong? It's not (thank God) that it's fallen for the libertarian propaganda that some economists propagate in the name of social science; it's that amateurish economics seem constantly to have held sway in the hallowed halls of Geneva. Even from the very beginning (1948) the idée fixe of health as "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity" betrayed a stolen vision that plainly belonged to that other entity we commonly call "welfare" or "well-being", as well as claiming an absurdly inflated all-embracing scope for the then fledgling agency. This all-encompassing but unmanageable mission discourages focus and analysis.

The problem of amateurishness runs from the top to the bottom of WHO. If reported correctly, the assistant director general of health systems and innovation at WHO recently said in the context of valuing drugs "What's the value of life? This structure is good for luxury goods because you have a choice…if I'm sick with cancer, what's the choice? We think value-based pricing is not feasible for products that are indispensable." (http://raps.org/Regulatory-Focus/News/2017/05/12/27544/WHO-Officials-Offer-Opposition-to-Value-Based-Drug-Pricing/). Whose advice lay behind this sort of confused rhetoric? The value of life has little to do with the value of a medicine. True, some medicines offer the possibility of longer lives, and some of better health, and yet others of better health over a longer life, so the advice ought to be to discover the health effects of the *medicine* (the value of the medicine not the lives). More useful advice might have been: assess how much a health care system can afford to pay for the health effects of specific classes of new medicines. The WHO could also recommend a principle here: the monetary amount should reflect either how much additional healthcare expenditure the medicine will entail (everything else remaining the same) together with a judgment that there is no better way of spending that additional expenditure, or it should reflect the value of the health that would be lost if the necessary resource had to come from an unchanging rate of health expenditure and so withdrawn from other treatments. If this is likely to involve more health loss than the medicine in question is likely to create, then the (opportunity) cost is too high. Either approach involves a 'threshold' based on the consequences of a choice for people's health and an assessment of health opportunity costs, that is costs measured in terms of health (not money). More on this in a moment.

The Assistant DG cites “indispensable” cancer medicines as technologies that should not be valued. The choices confronting cancer patients and their physicians may be finite but they are also many. Few technologies, however, are “indispensable” as may be witnessed by the fact that most of the population of the world dispenses with them! Such woolly sloganizing characterizes much of WHO policy advice and militates against relevant research and purposeful policy design – policy designed, that is, to maximise the impact of a country’s chosen health budgets (plus any external assistance from aid donors) together with its extant infrastructure on its population’s health.

Why do people adopt daft concepts when sensible ones abound? Consider value-based pricing. Lower down in the organisation, a recent WHO report of an informal meeting of “experts” concerned *fair prices* for pharmaceuticals http://www.who.int/medicines/access/fair_pricing/ReportFairPricingForumIGMeeting.pdf?ua=1. One might have expected such a report to ask the basic question: what is the value of a medicine? One might also have expected an answer related to the kinds of therapeutic properties various medicines have - prevention, amelioration or cure, some more effective and some less, some more costly and some less - that is, their expected impact on health: for example their impact on the Quality-Adjusted Life-Years (QALYs) or the Disability-Adjusted Life-Years (DALYs) of those likely to be treated. That is the value of a medicine: the better health, or deterioration prevented, or longer life, or all three, that it enables. But the informal experts ask instead about the money value of health. Was this at the request of the assistant DG? Better not ask. But why convert health into a monetary value at all? After all, many countries go to considerable lengths to minimise the price of healthcare and to hide its true costs. Indeed, all insurance systems do this! And the reasons for doing so are not daft.

There is one particular public price, however, that all systems need and which needs to be got right if the public interest is to be served well. This is when one is choosing the services to be made available in an as-comprehensive-as-possible health care system that is available to all at low user cost or even entirely free of monetary payments. This is the sort of healthcare system that both I and the WHO are aiming for (well, anyway, I am).

A context like this will also suggest whose values ought to be brought into play in selecting suitable outcome measures, appraising the evidence on the relative impact of different interventions on people’s health and deciding whose health gain would NOT be given priority. Patients’? Well, not if they are deeply ignorant of the effects of a medicine. Doctors’? Well, not if they are bent on maxing out on "technology" or earning a living from dispensing as well as prescribing medicines, or never read systematic reviews of the research literature. Bureaucrats’? Well, not if they have hidden agendas or are in someone’s pocket or merely want a quiet life. Economists’? Well, not if they're the libertarian sort that have a mindless respect for the market and a no less mindless contempt for public decision making processes. Researchers’? Well, not if they selfishly fail to share research results or have conflicts of interest or other unacceptable biases. Politicians’? Well, not if they have been seriously misled by any of the foregoing. WHO’s? Ditto. The basic ideas are not all that complicated. On the basic question – what is the value? The answer is health gain. In what does that consist? Well, probably something like the QALY or the averted-DALY. Who decides? Well, maybe not any of the foregoing folks alone, even when they are the best of their kind, but how about a team on which the best of each of them is represented?

Let's call that team an “appraisal committee” that is charged with appraising the relative value of medicines ...

Hey, wait a minute, where have I seen this before? ....

I much prefer the QALY to the DALY. The DALY may be less statistically demanding than the QALY and it may be useful as a measure of disease burden, so long as disability is all one cares about. But the QALY is much more comprehensive and encompasses multiple human capacities. Why did WHO not care about the quality of life of disabled people? Why did WHO adopt for investment decisions a notion of health outcome that is so comprehensively at odds with its famous 1948 definition? The grounds for creating a new outcome measure instead of the QALY seem wholly absent, and in doing so WHO created two uncooperating and duplicative streams of outcomes research and application, with the high quality, relatively sensitive, QALY mainly being used for investment decisions in the rich countries and the low quality DALY in the poor. What a waste of scarce research talent! What a missed opportunity to create a family of universal and international outcome measures to suit the most common environments and population groups met in decisions about public insurance benefits packages. What a missed opportunity to grow the QALY itself into a comprehensive measure of the burden of disease. (The DALY is not even a very good measure of burden but to make it more comprehensive would merely make the DALY approximate to a negative version of the statistically demanding QALY).

So what about the one important monetized value I said one needs to seek? It is *the money value of a QALY*. And what is that money value? It is the *maximum public* (not private) willingness to pay for a QALY gained by adding a medicine to the benefits package, or it is the cost per QALY of the treatment most likely to be ousted if the money for the new treatment is to be found from existing resources. And what, if we ask our "committee", is that? It is, or ought to be, the *threshold* - the ratio of expected health gain to expected net cost gain that separates the procedures and interventions that are to be included in the benefits package from those (many of them, please note, of undoubted effectiveness) that are not to be included, given the healthcare expenditure commitment by the government (agency, etc.).

It would have been so much more instructive (and potentially useful) for WHO to have distinguished between the value of health and the price of healthcare. They could then have talked sense about the threshold. A well-judged threshold will ensure that procedures having a higher cost per QALY than the threshold are excluded, so a country will never include technologies that deliver additional health gain but only at the cost of greater health loss elsewhere. They could have set up the problem of healthcare pricing as a kind of game: there is always a *maximum* price the demander (whoever that is, collective or private) is willing to pay; it is always the case that their rate of demand rises (per time period) when/if price falls; and that there is always a *minimum* price manufacturers will accept to bring a product to market - and what they will bring per period will always rise as/if the price rises. The difference between these two prices, one demand side and the other supply side, at any planned or anticipated rate of output and use is a range in which one may negotiate. The link between the price of healthcare and the value of health gain is the threshold. Thus, if NICE or some similar agency elsewhere foolishly announces its maximum willingness to pay for healthcare well above a well-judged threshold it will certainly be transferring "surplus" to the manufacturers as well as actually reducing the health of the population by attracting procedures yielding fewer QALYs per dollar than those they drive out (or the QALYs of other candidate procedures that could have been included).

What have the "fair" prices sought by our informal experts to do with all this? Not a lot! The essential understanding you need concerns not what is "fair" but what (from a specific public perspective in a specific jurisdiction) the well-judged threshold is. The most important public price is this price of health – the threshold. There should be a WHO flag flying in Geneva with those very words on it. A very large flag.

Having messed that up, our informal group of experts began to dig still deeper holes. We are told, as they try to define a "fair" price for a medicine, that the demand for medicines is relatively inelastic (relative to what?). This is a gigantic red herring, of no value whatever in deciding what prices ought to be paid to drug manufacturers or paid by consumers. The price-elasticity of demand is a simple enough idea. It is simply the ratio of a percentage change in the rate of use of something divided by the corresponding percentage change in its price, over a small range of prices. Our informal experts (or their rapporteur) probably meant that the price-elasticity is less than unity (it's usually negative but the sign is commonly ignored). The reason for this low elasticity is (they say) the "nature of medical need". There is no explanation of what that nature is and it's hard to think what that nature could be. Do they seriously mean that if someone has pain and that this means they need a painkiller (this does necessarily follow; they may in practice need something entirely different) then the price-elasticity of demand for any one of dozens of available painkillers, all with different prices and different efficacies and different side-effects, is low? That seems to be what they say. But it is plainly wrong. In fact the opposite is true! The more substitute medicines etc. there are for a condition the *more* price elastic is the demand for any one of them.

Having confused one bit of elementary health economics they then move on to another by saying that because the elasticity is low manufacturers have market power. This too is exactly wrong. Manufacturers have market power because they are granted (for good reasons) limited forms of patent, giving them limited monopoly power. This does not mean that they can charge *any* price. But it *does* mean that they have to search for the price that maximises their profit – unlike a competitive producer who cannot depart far from the prevailing market price without losing its entire business (price-takers cf. price-searchers). Medicines typically have high developmental (R&D etc.) costs but low production costs. It's Economics 100 material that a profit-maximising monopolist will set price at a rate of production (so much per week, year, etc.) where marginal cost equals marginal revenue. If marginal cost is approximately equal to zero, then so is marginal revenue at a profit-maximising price. As a matter of arithmetic, this occurs only when the price-elasticity of demand is approximately *unity*! At any price above this (marginal cost now assumed positive) the profit-maximising firm moves into a price *elastic*, not inelastic, range of the demand for its product.

This still applies in a world of major collective buyers of pharmaceuticals, buyers like hospital chains or entire systems, like a ministry of health. Demanders will seek cost-effective products and a public service like a universal health coverage scheme will specifically be seeking cost-effective ways of making serious impact on the nation's health. The lower the price of healthcare, the more likely there are to be additional cost-effective uses for a product like a pharmaceutical. Uses that at higher prices were above the well-judged threshold will now fall below it and public demand accordingly rises.

Who cares? Well, we all ought to care. Getting prices like this (the threshold) important price wrong costs lives. For several years now the WHO's judgment, largely based again on bad economics, was that a threshold of 3x per capita gross domestic product represented an appropriate guide to the technologies for inclusion in publicly-subsidised benefits packages (i.e. none should be included without special reasons that have ratios greater than this threshold). This has led (and still leads) many countries to place products on their lists of "essential" medicines, and to include in their benefits packages, procedures that are far from locally cost-effective and that are simply unaffordable at local purchasing budgets. They are literally unaffordable in the hard-nosed sense that the budget is not big enough to pay for them. What happens is that a rag-bag of benefits emerges, one that comes nowhere near maximising the impact of healthcare spending on health, though of course some pockets may become better lined. Such a threshold, instead of showing

decision makers what health care to buy, deceives them and actively ensures that lives and quality of lives are lost as cost-ineffective treatments drive out cost-effective ones. What a way of immiserating the already poor!

You cannot judge the cost-effectiveness of any intervention save in a relative way. Cost-effectiveness is an inherently relativist idea. An intervention may be judged to be cost-effective relative to another in direct comparisons (when outcomes do not need to be monetized; the comparison is done in terms of QALYs or DALYs), or it may be judged cost-effective in relation to a well-judged threshold, which becomes a kind of context-dependent benchmark that all interventions may not exceed. Can WHO state what such a cost-effectiveness threshold is? No!

Why is this so? Because the threshold is context-dependent.

One of the most important characteristics of a well-judged threshold is that is cannot be specified numerically outside the context in which it is to be used – not even by the WHO. This is because it depends crucially on the budget set for healthcare (and therefore of that for all other public sectors, equally greedy for funding) and the jurisdiction's preferred public sector/private sector balance. It also depends on other factors, some of which affect the numerator (cost) and some the denominator (health gain). These include local demography; local epidemiology; local geography; local prices; local logistics (delivery platforms, transport, and similar structural matters); other local physical capacity; the number of cost-ineffective procedures in the local system; local clinical and managerial delivery capacity; local customs; local values; local trade and professional union behaviour; and local traditions. What WHO *can* do is to prescribe *ways of thinking* about what a well-judged threshold ought to be. This will be like prescribing a Reference Case: specifying the necessary conditions it must meet and making suggestions about factors, local and general, that may cause it to be raised or lowered. It does not entail specifying specific ratios, let alone one-size-fits-all ratios like pcGDP or 3x pcGDP.

Incidentally, here was a massive WHO missed opportunity. LMICs desperately need sound guidance and practical "how-to-do-its". Such guidance has come out in recent years to help them along the road to universal health coverage – an objective the WHO purports to support – in the form of a how-to-do-it manual of Health Technology Assessment (HTA). It's called a Reference Case: a recipe for HTA, which outlines core principles that should be considered and decided upon, such as the scope of costs and benefits. It would have been a natural vade mecum to come from the WHO. But who funded and published it? Not the public WHO but the private Gates Foundation. To its credit, the WHO has now embraced the idea of HTA as an important instrument if LMICs are to maximise the impact of their terribly limited resources on their populations' health. Yet it's not clear that the past WHO leadership truly understood either the technicalities or the ethics of HTA. The WHO's contribution to HTA has instead been to rebrand it as Health Intervention and Technology Assessment (HITA) – as if there were some possibility or doubt that the technologies in question are interventions, or that the term "technology" might not embrace as wide a range of interventions as the human imagination might come up with!

Dr Tedros – why not turn over a new leaf by developing a guide for LMICs on how to estimate their own thresholds? Make sure the economists (internal and external) are all competent and that the senior WHO hierarchy to whom they report understand what is being done and why it matters. Have them participate in the TORs so that they get a real sense of ownership.

Is all this so hard to understand? It's hardly rocket science. Why all this reinvention of the wheel? Why this unthoughtful adoption of bad policies that damage the health of people in poor countries?

Why this inability to detect the contradictory consequences of their policies for the aims they claim to espouse? Why advocate a principle that equates health with welfare and then promote a measure that equates health with disability averted? Why haven't WHO's economists understood the concept of opportunity cost and used it to promote efficient (and fair) healthcare spending? Why recommend thresholds that ensure that the unaffordable drives out the affordable? Why can't WHO offer practical models and frameworks, based on sound and ethical principles? Why does WHO dictate health-reducing threshold ratios rather than recommend context-sensitive ways of estimating them? Why doesn't WHO listen to sound messages from competent economists?

It must be time for the listening to start!