

In defense of a ‘thick’ formal equality principle in healthcare resource distribution

Lars Sandman

Given resource constraints in healthcare, demands justice and equity require the constant development of material principles for resource distribution. In many cases, such material principles are formulated as mid-level principles, well-adapted to handle healthcare distribution but suffering from aspects outside the healthcare context that affect their application. In healthcare, factors outside the healthcare system will sometimes affect patients’ equal opportunity to receive treatment and achieve health. Examples of such factors might include an individual’s economic means, the cost of drugs, geography, etc. This article explores whether the formal equality principle could help us address such problems. It is argued that the traditional (thin) formal equality principle can aid in priority setting, both as a heuristic tool to aid in consistency and also in handling under-determined cases. However, it appears to be too ‘thin’ to handle problems caused by factors outside the healthcare context. In the article, I explore a more robust version of the formal equality principle and argue that such a principle can be used to address such cases. However, even a more comprehensive formal equality principle will need to consider whether some other actors have a moral responsibility to address the problem or whether the issue could be solved more effectively by others. Furthermore, such a principle needs to consider whether the opportunity cost of achieving ‘thick’ formal equality is acceptable, given the material principles of distribution.

Introduction

Consider the following case:

Patient A is suffering from a debilitating common disease X, with a high impact on quality of life (QoL) and with shortened life expectancy. There is now a new pharmaceutical treatment available on the market that will cure X in Patient A. It will meet the accepted cost-effectiveness threshold, given the severity of X, and A is granted access to the treatment.

Patient B is suffering from a rare disease Y, with an identical impact in terms of QoL and life expectancy on Patient B as X has on Patient A. There is now a new pharmaceutical treatment available on the market that will cure Y in Patient B.

However, since the global prevalence of Y is very low, the price for this treatment has been set very high (to meet R&D costs and include a reasonable profit for the pharmaceutical company). Accordingly, this treatment cannot meet the cost-effectiveness threshold given the severity of Y, and Patient B is not granted access to the treatment.

These types of situations, which are becoming more and more common, given the increased development of ‘orphan’ drugs over the past few years, have raised the issue as to whether a higher cost-effectiveness threshold should be allowed to accompany orphan drugs that target rare diseases.¹ Many healthcare sectors are now accepting different thresholds to secure access to orphan drugs – either explicitly, like in Sweden and England (through NICE) – or implicitly.² However, the exact normative rationale for this is debated. In a previous article, I (together with Erik Gustavsson) have tentatively suggested that a potential normative rationale can reference formal equality.³ In short, A and B, in the aforementioned case, both suffer from diseases with a similar impact on their health, and there is treatment available that would cure them both, but they are granted differential access due to a factor (drugs being developed within a for-profit-market) that would seem to be of normative irrelevance for how we should distribute limited healthcare resources. This would seem to be a breach of formal equality, according to which equal cases (in terms of relevant factors) should be treated equally. An article by Juth is critical of introducing this interpretation of formal equity since he views it as too costly for the healthcare system and worries it would risk contributing to a more arbitrary system.⁴ Basically, he draws the conclusion that this implies that we would compensate for all irrelevant factors influencing whether equal patients end up with unequal treatment, the much feared ‘bottomless pit’ in priority setting. Furthermore, it is argued that formal equality is a normatively empty principle and cannot carry any real normative weight, and it is also argued that it is too vague in terms of how formal equality should be balanced against other normative principles in healthcare distribution. The aim of this article is to develop a more robust idea of how a formal equality principle can carry normative weight in healthcare distribution by developing what I will call a ‘thick’ formal equality principle.

Some background assumptions and conceptual clarifications

I will assume that we are dealing with healthcare distribution in a healthcare sector of a welfare system, where healthcare is funded by public resources that are distributed based on need. To simplify the analysis, I will assume that the needs-based approach is largely

¹ Quintiles IMS. *Pricing and market access outlook* (2017 edition). Online at https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwjE4ciXz-HiAhWPIIsKHTgADOsQFjAAegQIBBAC&url=https%3A%2F%2Fwww.iqvia.com%2F%2Fmedia%2Fquintilesims%2Fpdfs%2Fpricing-and-market-access-outlook-magazine-web.pdf&usq=AOvVaw2ONUf2jXI_LwfVkQXK5eOE (accessed 2023-03-30).

² SOU. *Läkemedel för djur, maskinell dos och sällsynta tillstånd—hantering och prissättning [Pharmaceuticals for animals, machine administered dosage and rare conditions—/management and pricing.]* (2014). Stockholm: Socialdepartementet. NICE. *NICE Highly Specialized Technology Guidance*. Retrieved from <https://www.elmmb.nhs.uk/elmmb-formulary/joint-medicines-formulary/appendix/nice-guidance/nice-highly-specialised-technology-guidance/> (accessed 2023-03-30).

³ Sandman, Lars and Gustavsson, Erik. The (ir)relevance of group size in health care priority setting - a reply to Juth. *Health Care Analysis*. Vol. 25:1. (2017), pp. 21-33.

⁴ Juth, Niklas. ‘For the Sake of Justice: Should We Prioritize Rare Diseases?’ *Health Care Analysis*. 25:1 (2017), pp. 1-20.

prioritarian.⁵ This implies that the worse off a patient is, the greater the moral value of improving the situation of this patient, and hence, the more resources we are willing to spend on this patient. These are approaches found in countries like Norway, the Netherlands, and Sweden, among others.⁶ For operational reasons, this is often expressed in terms of assessing the severity of the patient's condition and allowing that to set a cost-effectiveness threshold for how much we are willing to spend to improve the health of a patient at different severity levels. Now, we could have another distributional approach to, e.g., a largely egalitarian approach or some more complex form in which we combine different approaches. However, for the sake of simplifying the argument (and since we find this approach in several countries), I will assume a prioritarian approach.

I will also assume that this prioritarian approach is operationalized in terms of mid-level principles.⁷ This implies that they are adapted to handle distributional problems within the healthcare context; i.e., they are adapted to a specific context without taking a stand as to whether a prioritarian approach should characterize societal distribution at large. This is a more substantial assumption—in terms of being the reason we might need a thick formal equality principle—so allow me to expand upon this assumption. From a theoretical perspective, it might be argued that normative consistency requires us to apply the same distributional approach to whatever social goods we are considering. Michael Walzer and others have, on the other hand, suggested that different goods require different distributional approaches. This, in turn, has been criticized for being relativistic and too dependent on contingent historical facts.⁸ In this article, the assumption is not based on a definite stand in the theoretical discussion (even if I tend to side with Walzer's critics) but on the ambition of addressing a real practical problem in healthcare distribution in a normatively consistent way. As indicated above, we generally find specific distributional approaches to healthcare resources that we do not generally find in society; hence, the focus is on mid-level principles in this article. An advantage (but also a potential problem) of mid-level principles is that they are adapted to handle concrete and well-defined areas of moral controversy—in this case, distributive problems in healthcare. In this, they might more effectively guide action; the potential problem is that they do not concern themselves with what happens outside this well-defined area. Let me return to this in the analysis.

The following terms are central to this article: formal equality principles versus material distribution principles and 'thin' versus 'thick' formal equality. A principle of material distribution implies making claims about what characterizes whether a system that might be used to guide or assess whether a specific distribution is fair (or more or less fair). On the other hand, a principle of formal equality can only guide or assess whether two (or more) distributions fulfill requirements of equal cases being treated alike and not whether these two (or more) distributions are fair or not, per se. Hence, two distributions

⁵ Parfit, Derek. 'Equality or Priority?' In *The Ideal of Equality*, ed. Matthew Clayton and Andrew Williams, Basingstoke: Macmillan (2000) pp. 81-125.

⁶ Prop. 1996/97:60. *Prioriteringar inom hälso-och sjukvården [Priority setting in healthcare]*. Stockholm: Socialdepartementet. Stockholm. NOU. *Åpent og rettferdig-prioriteringer i helsetjenesten [Open and fair - priority setting in health care]*. Oslo (2014) Van de Wetering EJ, Stolk EA, Van Exel NJA, Brouwer WB. Balancing equity and efficiency in the Dutch basic benefits package using the principle of proportional shortfall. *The European Journal of Health Economics*, (2013). 14(1), pp.107–115.

⁷ Beauchamp, Tom L., and James F. Childress. *Principles of biomedical ethics*. 7 ed. New York: Oxford university press. 2013. p. 250–251.

⁸ Walzer, Michael. *Spheres of Justice: A Defense of Pluralism and Equality*. Oxford: Robertson. 1983. Tännsjö, Torbjörn. *Setting Health-care Priorities: What Ethical Theories Tell Us*. USA: Oxford University Press. 2019.

might fulfill formal equality requirements without fulfilling fair material distribution requirements. In saying that a formal equality principle is “thin,” I emphasize that it only contains these formal requirements. If the formal equality principle does incorporate aspects of materiality, i.e., it makes claims that will be relevant from a material perspective, I have chosen to call such a principle a “thick” formal equality principle. This might sound like a contradiction in terms. However, if my argument is successful, I will show that such a ‘thick’ formal equality principle still fulfills the role of a formal equality principle and that the materiality of this principle is still dependent on material principles of distribution, to which it functions as a corollary.

The formal equality principle

Beauchamp and Childress start their chapter on justice in healthcare by mentioning the formal principle of justice and attributing it to Aristotle: “Equals must be treated equally, and unequals must be treated unequally.” However, they claim that it “lack[s] all substance,”⁹ and both the relevant group of equals, and the relevant differences (as well as the irrelevant differences, one might add) need to be defined.

The formal principle of justice or equality, as it is also termed, has not received much attention in discussions of distributive justice in healthcare (more than being mentioned in passing) since the publication of *Principles of Biomedical Ethics* in 1979. In an article by Carr, formal justice is related to distributive justice in general. In analyzing the relationship between formal and material principles¹⁰ of justice, Carr argues that what he calls the “equal treatment principle” (henceforth the ‘formal equality principle’) is not a logically independent principle but simply the logical implication of applying (any) material principle of justice.¹¹ Hence, if a material principle of justice requires a certain line of action towards a specific individual, it follows from that very material principle that all other individuals relevantly equal to this individual should be treated equally. Carr even goes one step further than Beauchamp and Childress and labels the formal equality principle a “philosophical illusion.” Drawing on Feinberg’s discussion of comparative justice, he concludes that this also holds true when it comes to material principles of distributive justice.¹² MacKay claims that it only requires that people are treated equally in a formal sense, not taking characteristics into account that can influence whether equal opportunities can be taken advantage of.¹³ Basically, people should be given the exact same offer (in his case, to participate in research). To a large extent, I find this line of argument convincing; however, with an important caveat. In the article, Carr discusses cases when material principles of justice are under-determined but draws the conclusion that differences in interpretation and application for similar cases in such situations cannot be solved by reference to a formal equality principle. I will argue that it can, at least to some extent.

⁹ Beauchamp and Childress, *Principles of biomedical ethics*, p. 251.

¹⁰ Material principles are principles providing substantial guidance as to what should characterise just or fair distribution (if we focus on distributive justice), like achieving equal outcomes, or equal opportunity, or benefiting someone more the worse off they are, etc.

¹¹ Carr, C. L. The Concept of Formal Justice. *Philosophical Studies* 39:3. (1981), pp. 211–226.

¹² In the article, Carr primarily discuss other forms of justice (e.g., different legal or semi-legal cases). Feinberg, Joel. Noncomparative justice. *Philosophical Review* 83 (1974), pp. 297–338.

¹³ MacKay, D. "Fair subject selection in clinical research: formal equality of opportunity." *Journal of Medical Ethics* 42:10 (2016), pp. 672–677.

In Daniels and Sabin's discussion of accountability for reasonableness (A4R), we find a similar argument, with reference to the difficulty of agreeing on material principles and the moral uncertainty regarding how to interpret or balance different reasons for and against a certain course of action in individual situations.¹⁴ Daniels and Sabin seem to conclude that *not* following the formal equality principle, and treating equal cases alike, is tolerable—but the tolerability might depend on the type of healthcare system in which it occurs (i.e., a more or less centralized system). However, a sentence, written and read in passing, indicates that a formal equality principle might fulfill a more pragmatic role in: '...[demonstrating]...a lack of fair process and a kind of arbitrariness within an organisation.'¹⁵

Such a pragmatic use of the formal equality principle seems heuristically important and even *sine qua non*, especially given research on how psychological biases and underlying discriminatory attitudes might influence decision-making.¹⁶ My own experience working on priority decisions in healthcare showed the need to invoke such a heuristic tool every now and then to assess the consistency of and demonstrate a lack of unjustified biases in decision-making.

However, assume that such a heuristic application of the principle ends up concluding that no foul play occurred. Let us then assume there are no psychological biases involved, and we are applying a rational approach (with the agreement of what rationality requires) to the situation with full knowledge of what the moral principles require. Still, we might end up with different assessments in similar cases. Let us look at Daniels and Sabin's case of Harpo and Groucho.¹⁷ They both suffer from the same condition, a condition that is similar on all relevant accounts, and are the object of a decision as to whether to receive potentially life-saving treatment. Since these decisions are made in different contexts, the decision-makers, all following due process, come to different conclusions. For example, using the above-described prioritarian approach, different contexts might apply a different balance between severity and cost-effectiveness (to which there is no real principled answer).

Daniels and Sabin argue that this might be morally acceptable and that there might not be a complaint based on formal equality since we must accept moral uncertainty. Still, at this point, we should make a distinction between moral uncertainty, in terms of being genuinely uncertain which moral principles to apply to a situation despite moral conscientiousness, and the moral principles we are certain will be under-determined. MacAskill et al. have (in my opinion, convincingly) argued that there are rational norms to apply in order to resolve moral uncertainty; for example, maximizing expected choice-worthiness.¹⁸ Given that the cases of Harpo and Groucho are identical, save for the context in which the decision is made, it seems reasonable to accept that if these norms to resolve uncertainty give an answer in the case of Harpo, they should give the same answer in Groucho's case. If not, we will have to claim that there is a morally relevant difference between Harpo and Groucho, i.e., that the difference in context is morally relevant in some

¹⁴ Daniels, Norman, and James E. Sabin. *Setting limits fairly. Learning to share resources for health*. 2nd ed. Oxford: Oxford university press. 2008.

¹⁵ Daniels and Sabin, *Setting limits fairly. Learning to share resources for health*. p. 81.

¹⁶ Kahneman, D., J. L. Knetsch, and R. H. Thaler. Anomalies—The Endowment Effect, Loss Aversion and Status-Quo Bias. *Journal of Economic Perspectives* 5:1 (1991), pp. 193–206;

Wiss, J., D. Andersson, P. Slovic, D. Vastfjall, and G. Tinghog. The influence of identifiability and singularity in moral decision making. *Judgment and Decision Making* 10:5 (2015), pp. 492–502.

¹⁷ Daniels and Sabin, *Setting limits fairly. Learning to share resources for health*, p. 79–81.

¹⁸ MacAskill W, Bykvist K, Ord T. (2020) Moral Uncertainty. Oxford University Press, Oxford.

sense. If Harpo receives treatment and Groucho does not, Groucho will have a reasonable complaint based on formal equality. This complaint might, of course, imply that the process of decision-making in the two different contexts requires adjustment. In this case, the formal equality principle is still empty in the sense that it only reflects the requirements of rational decision-making in identical situations. However, imagine that the problem in the two contexts is instead that the applied principles are under-determined. We might, for example, be convinced that the aforementioned prioritarian approach – where we balance severity against cost-effectiveness to arrive at a decision – is the correct moral principle or approach. The prioritarian principle does not tell us exactly what an acceptable level of cost-effectiveness is given a certain severity; therefore, it is under-determined, given this balance. If, within the same healthcare sector or ‘moral’ jurisdiction, a decision is made to provide Harpo with treatment at a certain cost-effectiveness level, formal equality would provide us with a strong reason to accept the same cost-effectiveness level for Groucho. Obviously, since our principle is under-determined if a decision was made first for Groucho in a different context, they might have ended up with a different cost-effectiveness level, thereby driving the decision-makers to also accept this cost-effectiveness level for Harpo. Now, when deciding on Groucho’s case, it might be argued that given a different level of effectiveness in their healthcare system – e.g., a different level of marginal productivity – accepting the same level as for Harpo would have more serious consequences in terms of the opportunity cost of lost health.¹⁹ Accordingly, they need to establish a different level. Still, they would then still have strong reasons to be guided by the acceptable opportunity cost of providing Harpo with treatment and to apply the same level to Groucho – even if this implies accepting different cost-effectiveness thresholds. In effect, formal equality would still be a relevant driver of decision-making once the existence of an under-determined principle has been established.

In conclusion, I would argue that the formal equality principle (what I will call the ‘thin’ formal equality principle to distinguish it from the principle being discussed in the rest of the article) should play the following roles in situations of distributive justice (in healthcare):

- When material principles of justice (or a procedural approach) provide a fully determined answer to decisions regarding how resources should be distributed in individual cases, the formal equality principle is *normatively* redundant. The same goes for situations of moral uncertainty when norms for resolving uncertainty provide answers.
- However, in such situations, the formal equity principle can also fulfill an important heuristic role in exposing unjustified considerations being ‘smuggled’ into the decision.
- In situations when material principles of justice (or a procedural approach) are under-determined, the formal equality principle fulfills a normative role in providing a *prima facie* reason based on considerations of fairness to act in accordance with precedent.

¹⁹ Siverskog J. *Opportunity cost in healthcare priority setting*. Thesis. Linköping: Linköping university press. 2022.

When the Formal Equality Principle might be *too thin*

Let us return again to our introductory example:

Patient A is suffering from a debilitating common disease X, with a high impact on quality of life (QoL) and shortened life expectancy. There is now a new pharmaceutical treatment available on the market that will cure A from X. It will meet the accepted cost-effectiveness threshold, given the severity of X, and A is granted access to the treatment.

Patient B is identical to A in terms of suffering from a rare disease Y, which has the same impact on Patient B as X does on Patient A. There is now a new pharmaceutical treatment available on the market that will cure B from Y. However, since the global prevalence of Y is very low, the price for this treatment has been set very high (to meet R&D costs and include a reasonable profit for the pharmaceutical company). Hence, this treatment cannot meet the cost-effectiveness threshold, given the severity of Y, and Patient B is not granted access to the treatment.

Applying the normal 'thin' formal equality principle presented in the former paragraph does not seem to help us here. The patients are identical regarding relevant aspects like severity and patient benefit of treatment. The balance between severity and cost-effectiveness has been set before and therefore drives us to accept a similar level in these two cases. What differs between A and B is that the cost of treatment is much higher for B's treatment. We might then argue the following: if the level of cost is a relevant but given factor to how we should prioritize access to care, then A and B have different costs, the situations are not equal, and the formal equality principle has nothing to say or is not violated. Compare the following situation:

Patient C is identical to Patient A in terms of suffering from another common disease, Z, with the same impact on C as X has on A. There is now a new pharmaceutical treatment available on the market that will cure C from Z. However, since the price has been set very high due to high expectations of profit, inefficient production, etc. (or a combination of these factors), the treatment does not meet cost-effectiveness thresholds given the severity of Z, and C is not granted access.

In this case, it seems strange to claim that we should accept a higher cost-effectiveness threshold for accepting treatment for Z and thereby a higher opportunity cost for other patients within the healthcare system to satisfy stock owners, or to encourage further inefficiency in drug manufacturing, etc. These considerations, it might be argued, belong to a different distributional sphere and should have nothing to do with how we spend healthcare resources. However, let me qualify the last statement since it is far too simple.

First, talking about different distributional spheres here does not imply that we must accept Michael Walzer's idea about different spheres normatively requiring different distributional principles due to historical patterns, etc. It is simply an acknowledgment that if we have accepted pharmaceutical treatments developed on a for-profit market, this will have consequences for pricing, availability versus profitability, etc. The pharmaceutical industry will invest in treatments they think will be profitable and will expect a certain profit from developed treatments in order to remain in the market, etc. Society might impose restrictions or provide incentives to guide or steer the market, but even so, there will be market dynamics healthcare systems will have to relate to and adapt to. Furthermore, this specific industry might be part of a society, largely applying a

prioritarian approach to distribution by taxation and redistribution, i.e., applying the same distributional approach all over society.

Ideally, the level of cost-effectiveness accepted for introducing new treatments into the healthcare system will be a balance between the added value, the opportunity cost for patients already within the system, market considerations, etc. From a healthcare perspective, the question is: how much pressure can we apply to the price, thereby lowering the opportunity cost and still gaining access to valuable new treatments and stimulating the development of new valuable treatments?

In effect, once we have found acceptable cost-effectiveness thresholds for different severity levels, taking the above into account, we might argue that we need not bother with the market considerations of the pharmaceutical industry. If such a threshold can be generally met for new treatments by the industry, we have no (or very weak) reasons to make exceptions for those companies that cannot or will not meet them. Addressing these kinds of reasons would also signal the wrong sorts of incentives to the industry at the cost of the healthcare system.

So, why should we make exceptions for orphan drugs for rare conditions (if indeed we should), and how is this related to the formal equality principle?

Formal equality expanding

Consider the following example:

Patient D, a poor and homeless man with trouble finding the economic means to feed and support himself, suffers from condition H (but has no other health problems). H is not caused by the choices made by D. The doctor provides him with a prescription for treatment H(t) at the cost of 20€ to the patient. He does not collect the prescription and continues to suffer from H.

Patient E, a middle-class woman working as a teacher, suffers from condition H (but has no other health problems). H is not caused by the choices made by E. The doctor provides her with a prescription for treatment H(t) at a cost of 20€ to the patient. She collects the prescription, and her condition is cured.

To apply the 'thin' formal equality principle to this case would imply that the two patients are treated exactly the same in this situation—which they are. So, D could not complain with reference to the formal equality principle in this case. However, due to what happens outside the distributional decisions of the healthcare system, D is disadvantaged. We might argue, from a normative perspective, that this other distributional system should work differently and that people should not be so destitute not to afford to pay 20€ for medicine. However, in the above situation, the healthcare system will have to relate to the fact that some people are destitute the same way D is.

Now, we could argue that in the situation with D and E, we should not allow irrelevant factors to impact whether they receive treatment. For example, even if their respective genders are different between D and E, to allow that to make a difference (without being related to severity or capacity to benefit from treatment, etc.) would be a breach of the formal equality principle. Unless we think there is a morally relevant difference between doing and allowing in these cases (and I would argue we should not generally do so in healthcare), it is difficult to see why we should not take D's economic situation into account. For example, if D had a functional disability that would impose on his ability to take the medication, we would find it reasonable to make arrangements so he

would get it. If not, he could make a complaint based on the formal equality principle. In the above case with D and E, we could argue that under a somewhat 'thicker' formal equality principle, which does not allow irrelevant factors to impact equal treatment for equal cases, we should provide D with treatment H(t) free of charge (i.e., at the cost of the healthcare system).

If, generally, the formal equality principle claims that "equal cases should be treated equally," we need to provide an answer to when cases are equal and what follows from that in terms of equal treatment. A tentative answer to this, given the above example, is that this implies only distinguishing between cases based on normatively relevant features and only allowing such normatively relevant features to make a difference between cases.

In our first case between A and B, the fact that B belongs to a small patient population is not a normatively relevant difference and should not impact equal access to treatment, given that both patients are equal in normatively relevant aspects. In a similar vein for D and E, the fact that D is poor and cannot afford treatment is a normatively irrelevant difference (within healthcare) and should not impact equal access to treatment. However, accepting that we should provide D with treatment, free of cost, within the healthcare system would seem to imply that we should also provide B with treatment at a higher cost and then, accordingly, provide the same to C. In all these three cases, the reason they do not gain access to treatment under the existing approach are factors that fall outside of the healthcare context. This would have far-ranging consequences, implying that healthcare systems should compensate and thereby bear the opportunity cost of every irrelevant difference (associated with other distributional spheres) that might impact equal access to treatment (cf. Juth 2017 for this line of argument).

This line of reasoning indicates a potential difference between the thin and thick versions of formal equality, i.e., that the latter has a potential difference in opportunity cost between equal cases that are not associated with the former. Let us examine this in the next section.

The Opportunity Cost of Formal Equality

Every time we make a decision to use healthcare resources, there is an opportunity cost to this decision—we could have used these resources differently. Ignoring more practical differences between A and B or D and E (things like the time needed to make an assessment of the new drugs in the first case or the time needed to make a diagnosis in the second case), the potential opportunity cost for treating A is the same as for B (or for C), if we only apply the thin formal equality principle, and the same goes for D and E. In applying a thicker version of the formal equality principle, we are also accepting a higher opportunity cost for one of the patients in order not to allow irrelevant factors to impact equal (or equal access to) treatment. This difference in opportunity cost also indicates that the thick formal equality principle is far from thin or empty but that there is more 'distributional materiality' to this principle. This, in turn, indicates that applying the principle will impact the general distribution of resources in healthcare. The resources needed to live up to the thick formal equality principle, which need to be redistributed from other patients within the healthcare system. If the thick formal equality principle has more materiality than the original thin one, why not simply introduce a material principle doing the same job as a thick formal equality principle? Let me explore this in the next section.

Incorporate material principles to handle the effects of other distributional spheres

Regardless of in what way other spheres affect whether the distribution of healthcare resources is viewed as just or fair, it seems that some form of equal opportunity principle would be our best bet in terms of an added material principle.

In the discussion of general distributive theories, equality of opportunity for welfare has been advocated by, for example, Arneson.²⁰ Following Arneson, people should have equal opportunity to achieve equal outcomes of relevant benefits, but personal choice might then result in unequal outcomes. Later, this idea further developed in the discussion on luck-egalitarianism.²¹ A problem with this general idea, or set of ideas, is that they make the distribution, to some extent, dependent upon personal choice or responsibility – an idea that has been heavily criticized on several accounts.²² Now, we might imagine another idea about equal opportunity, without reference to personal choice, but rather an idea about equal opportunity of treatment.²³ In an article discussing and discarding different arguments for why rare diseases warrant special treatment in priority settings, Niklas Juth analyses such an idea by reacting to a preliminary argument I made.²⁴ Juth explores a number of different interpretations of the idea of equality of opportunity for treatment as a general and material principle of justice in healthcare: as access to all available treatments, as an equal probability to achieve health, as the luck-egalitarian version mentioned above, and as an equal probability for patient groups to gain access to treatment – and discards them all with convincing arguments.

Let us, therefore, try a more limited idea about equal opportunity, namely that patients fulfilling the same relevant criteria of our material justice approach to distribution should have equal opportunities to receive healthcare. If our prioritarian approach implies that the severity of the condition and the cost-effectiveness of treatment are relevant aspects to consider, and two patients score equal on these aspects, they should have equal opportunity to actually receive treatment. In the example with D and E, they do fulfill the same relevant criteria in terms of severity and cost-effectiveness (only looking at the cost for treatment) and hence should have equal opportunity to receive the prescribed treatment. In the case of A and B, they do not score equally on all aspects since the treatment differs in terms of cost-effectiveness due to a difference in cost. If we want this equal opportunity principle to be also applicable to the case with A and B (or A and C), we need to qualify it further. One way of doing so is to look at the underlying reasons why patients end up differently on the relevant aspects. Are there factors unrelated to the rationale for healthcare distribution that led to the difference?

Hence, we would need to formulate an equal opportunity principle for patients, scoring equal on relevant aspects, or when scoring unequal opportunities, this is the result of some morally irrelevant or problematic difference unrelated to the underlying rationale for distributing resources in healthcare that we then need to compensate for.

²⁰ Arneson, Richard J. Luck Egalitarianism: An Interpretation and Defense. *Philosophical Topics* 32 (2006), pp.1–20.

²¹ See for example Segall, Shlomi. *Health, Luck and Justice*. Princeton: Princeton University Press. 2010.

²² See for example Björk, J. *Just Responsibilities? On Responsibility for Health in Swedish Health Care Priority Setting*. Thesis. Karolinska institute. Stockholm. 2021.

²³ Juth, 'For the Sake of Justice: Should We Prioritize Rare Diseases?', pp. 1–20.

²⁴ Carlsson P, M. Hoffman, L-Å. Levin, L. Sandman, and J. Wiss . *Prioritering och finansiering av läkemedel för behandling av patienter med ovanliga sjukdomar. Rapport till Läkemedelsutredningen*. [Priority and financing of pharmaceutical for treatment of patients with rare diseases. A report to the Pharmaceutical inquiry.] Prioriteringscentrums rapportserie 2012:1

This would imply a fairly complex material principle to be added to our basic prioritarian approach (or whatever approach we apply). Such a material principle would obviously be related (to some extent) to underlying egalitarian theories, even if it is more restricted in scope. However, such a principle has no independent standing as a distributive principle since it requires that there are other material principles defining the relevant aspects that must be taken into account and whether they are fulfilled in the right way. So, this would imply that we add a material principle (with a less developed rationale) to material principles with a more developed rationale. At the same time, this material principle would have to have a similar function as a thick formal equality principle.

So, let us scale it down again, returning to the example with D and E. What we need in this example is a principle that would change things for D but not necessarily do so for E. E is doing just fine, picking up her prescription and paying her 20€. Expressed in other words, we need a principle that could help us handle situations when our mid-level principles, in this case, the prioritarian one, do not seem to give us a fully satisfying answer. As we said above, formal equality principles have been advocated as an aid to help us solve under-determined cases. Hence, it seems we need a formal equality principle of sorts, but which sort since we also concluded that the traditional thin formal equality principle did not do the job? A reason for this was that, in the example, nothing was under-determined from the perspective of the healthcare system.

In the choice between adding a material principle or an expanded or thicker formal equality principle, I would argue that we have reason to focus on the latter (even if both have a similar function). This is because:

- The thin formal equality principle is already an implicit part of any set of material principles.
- Expanding it somewhat further is in line with its suggested role in solving under-determined cases or working as a corollary.
- The expansion is related to the role it plays in treating equal cases equally but expands the relevant area in which this is applied (i.e., while also taking into account possible reasons affecting equality outside a strictly-defined healthcare context).

Towards a 'thick' formal equality principle

When dealing with mid-level principles, we need to distinguish between how they handle the context in which they are developed and how they handle aspects outside this context. Mid-level principles can provide fully determined answers within their specified context but will, for obvious reasons, generally give under-determined or no answers when considering aspects outside this context. In that sense, we can claim that the example with D and E is both fully determined and under-determined. Only considering aspects regulated by our mid-level material principles, there is no indeterminacy as to which answer it provides as to whether patients D and E should receive treatment—they have the same diagnosis, the same severity, would benefit from the same treatment, and this is equally cost-effective for them (only looking at treatment cost). However, when considering how aspects outside healthcare affect patient D's ability to benefit from treatment, these principles are under-determined. I am suggesting that a 'thick' formal equality principle could handle such borderline indeterminacy.

So, what characterizes a formal equality principle as distinguished from a material justice principle? As has been noted by several authors, even those who, in the end, refute the need for a formal equality principle, a formal principle is not a sufficient principle to solve problems of justice.²⁵ It can, at best, function as a corollary to material principles.

If we assume that our material mid-level principle for distributing healthcare resources is prioritarian, claiming that what should guide resource distribution is a balance between the severity of the patient's condition and cost-effectiveness, allowing a higher cost-per-effect for more severe conditions. Let us assume that our application of this prioritarian mid-level principle is fully determined for our healthcare system. Knowing the severity of a patient's condition, we will also know which level of cost-effectiveness is acceptable for treating this severity. This level has been set, taking into consideration things like the workings of the pharmaceutical market, the effectiveness of the system in producing health, etc. In order to avoid moral hazards and overuse of the system, we could introduce co-payments.

If, given this, we face situations like the ones including A, B, C, D, and E above, we need to consider whether this is a problem that should be solved within the healthcare system or in some other way. In line with this, we need to decide whether the opportunity cost for such a solution should be borne by the healthcare system or by some other actor in society. There are several factors that could impact whether the healthcare system or some other actor should be responsible for solving the problem: how large is the opportunity cost for the healthcare system (and for the other actor); which actor would be most effective in solving the problem; and how is moral responsibility attributed in solving the problem?

Moral responsibility

Given the normative basis for the healthcare system, if we have an equity and needs-based system, the healthcare system will have a moral responsibility to see to the healthcare needs of its patients in an equal and equitable way in line with these founding norms. It is not normally responsible for tending to the *economic* needs of citizens in the society in which it operates. Nor is it responsible for maintaining or stimulating a growing life-science sector (even if that is sometimes argued to be the case by the pharmaceutical industry). If there is a moral responsibility to do these things, they will rest with other actors in society – with social services, or with industry development programs, etc. In a market economy, one might argue that no one (except the company in relation to its shareholders) is responsible for maintaining and allowing the business of a single company to grow or flourish (there might still be general support systems not allowing entire business sectors to go under, support for unemployment, etc.). At the same time, from the perspective of the healthcare system, it might be argued that in order to tend to the healthcare needs of patients in an equitable way, the healthcare system needs to strike a balance between using resources as effectively as possible and stimulating continued development of new treatments for (at the very least) severe diseases. If the system would put pressure on the prices of new drugs to the extent that the pharmaceutical industry within a specific field would not survive or that the aforementioned pressure would lead to a reduction in innovation, this might not be in line with the healthcare system's overall moral responsibility to patients in terms of treating patients with equal needs in an equal way. On the other hand, accepting any and all prices from the pharmaceutical industry –

²⁵ Beauchamp and Childress. *Principles of biomedical ethics*; Carr. *The Concept of Formal Justice*.

as in the case of Patient C suffering from Z—would be taking that responsibility too far. Even if it would affect the survival of that single company, it is not generally necessary in order to have a thriving pharmaceutical industry within this area. Allowing higher prices in the case of patient C could, therefore, not motivate the increased opportunity cost for other patients within the system.

Effectively handling the problem

Another aspect of this is whether the healthcare system is the most effective agent when it comes to solving the problem of unequal access. Even if the opportunity cost for the healthcare system is negligible in providing D with treatment with no co-payment, social services might be better equipped to effectively solve D's economic problems instead of forcing the healthcare system to make a number of exceptions. This might also involve considerations of what is most effective in the long run. The healthcare system might set an example in the case of D that might lead to a less effective way of dealing with the problem than what a more specialized actor could manage.

In a similar vein, if the pharmaceutical industry needs different forms of incentives or stimulants to develop drugs for specific areas—e.g., rare diseases—this is probably more effectively handled by agents other than those in the healthcare system and by means other than having the healthcare system pay higher costs for drugs.

Opportunity cost

Even if, all things considered, the healthcare system does have a moral responsibility to address the problem and there is no other actor that could address it more effectively, the opportunity cost of doing so needs to be taken into account. As mentioned above, a thick formal equality principle will have an opportunity cost. In some cases, like in D, the opportunity cost is negligible and needs not to be considered (unless such a practice is more systematically implemented). The case with B and C is another matter. To allow for a higher cost-effectiveness threshold, in different healthcare sectors, we might see thresholds in the order of two-to-ten times as high as the threshold for a common drug, which will incur a substantial opportunity cost.²⁶ To take a real-life example:

A Swedish estimate when the drug Orkambi for cystic fibrosis was introduced concluded that introducing Orkambi gained 404 QALYs at the expense of 3457 QALYs in the system—or an 86 ratio given the marginal productivity level in Swedish healthcare (estimated to about 20,000 €/QALY). This is because Sweden allows a cost-effectiveness threshold for orphan drugs for highly severe rare conditions up to 200,000 €/QALY. For common highly severe conditions, Sweden allows up to 100,000 €/QALY—five times the marginal productivity level.

With a large number of orphan drugs coming on the market, this opportunity cost will be substantial. There is also a balance between the raised cost-effectiveness threshold and what is a necessary level from a market perspective, and what is possible given market considerations and access in other countries (given the global mobility of patients, etc.). With a prioritarian approach to healthcare distribution, we might argue that if the

²⁶ Siverskog, J., Henriksson, M., (2021), On the role of cost-effectiveness thresholds in healthcare priority setting, *International Journal of Technology Assessment in Health Care*, 37(1).

opportunity cost of a specific intervention risks access to treatment for patients (or patient groups) that are equally or more highly prioritized, then it is not motivated. Ideally, the opportunity cost should affect lower-prioritized patients or patient groups. However, that requires that the healthcare system has control over how resources are redistributed, which seldom seems to be the case. Such uncertainty, in terms of what the impact on the healthcare system will be, might need a second-order approach, in line with suggestions from MacAskill et al.²⁷ Consider the following example:

A healthcare system is considering whether to accept a higher cost-effectiveness threshold for orphan drugs. Two options are on the table. A threshold double the one for common drugs with equal severity, or a threshold that is three times as high. Given the extent that this would impact the healthcare budget, we have the following situation:

2x threshold: it is likely resources will be taken from treatments assigned a lower priority, given the size of the budget for these treatments and the potential for effectivization.

3x threshold: it is likely resources will be taken, at least in part, from equally highly prioritized treatments, given the size of the budget and the potential for effectivization.

Ideally, in both cases, there are resources available for lower prioritized treatments to be redistributed – but there is a political cost to this, and previous experience of how redistribution works, such a strategy does not seem likely.

Whether we go for the 2x threshold or the 3x threshold, it is theoretically possible to redistribute resources to pay for the opportunity cost from lower-prioritized patient groups. However, this is not how things are normally done, and it is also practically difficult due to system dynamics. To save resources on rationing, we can either stop paying for what we buy externally from providers – e.g., drugs from the pharmaceutical industry – or let go of the healthcare staff providing the rationed care. Given the ratio between the cost of drugs and staff, about 10% of the total budget in the former case and about 45% of the budget in the latter case (in the Swedish context), the fact the main part of the drug budget does not target low-prioritized patient groups (where cheap drugs and staff interventions are likely to be more common), the rationing of lower prioritized patient groups will need to affect staffing.²⁸

However, since healthcare staff distributes their time over both higher-prioritized and lower-prioritized patient groups, this will imply removing some of the tasks for staff. At the same time, work legislation will make it difficult to require that staff get a lower fraction of work time (with lower pay). In effect, ethically-required redistribution is difficult to achieve. Given this uncertainty about what exactly will happen in the system, it seems reasonable to adopt the 2x threshold before the 3x threshold, given that the higher likelihood of more equal access to orphan drugs in the latter case is bought at the expense of equally highly-prioritized patient groups.

²⁷ MacAskill et al. *Moral Uncertainty*.

²⁸ SKR. *Ekonomirapporten* [The Economy Report]. Stockholm:SKR, 2022.

A tentative suggestion for a thick formal equality principle

Based on the above reasoning, we might then formulate a suggestion for a thick formal equality principle.

A thick formal equality principle applies when two of the following criteria hold true:

1. When two (or more) patients are equal in all relevant aspects given our material principle(s) of justice within the healthcare system but differ based on irrelevant factors outside the healthcare context, OR
2. When the only difference between two (or more) patients regarding relevant aspects within our system depends on irrelevant aspects falling outside the healthcare context, AND
3. this will affect these patients differently in terms of access to treatment.

The thick formal equality principle then provides a reason to even out such differences, dependent upon the following:

To what extent the healthcare system has a stronger moral obligation than an alternative actor to correct the situation?

To what extent some alternative actor can correct the situation more effectively than the healthcare system?

To what extent the increased opportunity cost for correcting the situation can be motivated, given the material principles of justice in the healthcare system?

Let me illustrate how this principle could be applied to a different case.

Patient F, who lives a ten-minute walk away from the hospital, has a risk of developing condition Z. If she, in fact, does develop Z, she needs the advanced treatment T within 1 hour, or she will die.

Patient G, living alone in the wilderness, is on a 2-hour flight by helicopter from the hospital and has a risk of developing condition Z. If he, in fact, does develop Z, he needs the advanced treatment T within 1 hour, or he will die.

Unless we do something, patients F and G— who are similar on all accounts following our material principle, in our case, a prioritarian principle— will be treated differently in this case. What would our thick formal equality principle say about this case?

Both patients have the same disease, with the same risk of developing a severe condition where they would benefit equally from treatment, and this treatment would be equally cost-effective, given the actual cost of treatment to the healthcare system. Hence they are equal, given the relevant aspects of our prioritarian approach. Still, they will have different access to treatment due to the geographical distance to the hospital from their respective homes. Geography is not a relevant factor to consider following our material principle. Hence, the entrance criteria 1 and 3 for applying the thick formal equality principle apply. Let us then look at the other three criteria.

Is there any other actor that is responsible for addressing the problem in this case? Other actors in society are obviously responsible for how public transport is organized and made available, but even so, it seems to extend beyond their responsibility (but also the possibility) to offer transport for patient G on a systematic basis that would overcome the

required distance. Neither is it likely that such a solution would be a more effective solution than what could be offered within the healthcare system. One might argue that G has the moral responsibility to move closer to the hospital instead of expecting the healthcare system to compensate for his choice to live in the wilderness at an increased opportunity cost for other patients. At the same time, this would lead us into a more general discussion as to what extent we should expect patients to make certain choices in order to reduce the chance that their healthcare needs will be contingent on luck.²⁹ Hence, to what extent we could argue that G has a certain degree of moral responsibility for solving the problem depends on to what extent we accept this to be generally within our healthcare system; in other words, whether such considerations are part of our material principles. Let us assume they are not.

Hence, in this case, a preliminary assessment is that the healthcare system has the major moral responsibility to try to solve the problem and will do it more effectively than any other actor. However, imagine that this could be done in different ways. We could set up this treatment at the nearest primary care facility (about 50 minutes away from G) and employ staff to provide the treatment. This, in turn, could be done in different ways. We could train the staff at the primary care facility to provide the treatment (which would require renewed training to keep up competence, but at the same time imply less skillful management due to the lack of actual provision), or we could have a circulation scheme for trained hospital staff, where they spend every tenth week at the primary care facility instead of at the hospital. Since this involves highly specialized staff, they might not be skilled at doing much else other than waiting for when G needs the treatment. Looking at these two different options, there is a greater opportunity cost to the latter, while the former will imply a somewhat reduced probability of successful treatment in case G needs it. To assess whether any of the options are reasonable, it should also be considered how the redistribution of resources to enable these options would take place.

Still, we might make the assessment that the former option strikes a reasonable balance between cost-effectiveness and opportunity cost. Hence, treatment is set up with training for existing staff at the primary care facility.

Summary and practical implications

In this article, I have argued that we need a thicker formal equality principle to complement material mid-level principles for healthcare distribution. Such a thicker formal equality principle is supposed to handle fairness problems arising from factors outside the context of healthcare affecting equal opportunity to benefit from treatment within the healthcare system. However, being a *prima facie* principle, the opportunity cost and displacement of other patients in the healthcare system need to be taken into account when applying such a principle. Moreover, if the fairness problems are better solved somewhere else in society, we might have reason to do so from the perspective of efficacy.

Let me return to the question of why this is important and the role such a principle might play in practical priority setting within healthcare. The distribution of scarce resources in healthcare is one of the most ethically challenging tasks of decision-makers, where decisions (regardless of on what grounds they are made) will have winners and losers among the population. It has been observed that one essential basis for making such decisions that can be accepted as legitimate is that the reasons for making them are robust

²⁹ Björk J, *Just Responsibilities? On Responsibility for Health in Swedish Health Care Priority Setting*.

and consistent.³⁰ For this reason, several healthcare jurisdictions have decided to develop normative frameworks or principles to guide priority setting and enable consistent reasoning when making hard decisions. These are developed for ‘internal’ use within the healthcare system and do not regulate the distribution of resources outside of the healthcare system. At the same time, aspects outside the healthcare system will sometimes have an impact on the extent to which patients can access healthcare interventions. In such cases, our principles or frameworks for the material distribution of healthcare resources are silent or will give counter-intuitive results (as indicated by the examples in this article). Avoiding ad-hoc solutions and continuing to rely on robust and consistent decisions requires a principled approach. Here we seem to have two possible choices: to add another material principle that is supposed to guide these borderline cases or to develop the formal principles we are already using within the existing system. That is, either implicitly or explicitly, our material principles or frameworks are also complemented by formal equality principles to make sure we do not allow irrelevant considerations to affect our decisions. In this article, I have argued that developed and ‘thicker’ formal equality principles might work better than yet another material principle and may imply less of a change to the principles we are already applying within our systems. In the Swedish case, we have already used such a formal equality principle to change how we make decisions pertaining to orphan drugs, testing the practical relevance of such a principle as a complement to our existing material distribution principles. The more robust formulation of such a principle, as developed in this article, might hopefully offer better support in other cases when deciding to what extent we should take distribution patterns and aspects outside of healthcare into account when making priority decisions within the healthcare system.

Lars Sandman, National Centre for Priorities in Health,
Department of Health, Medicine and Caring Sciences, Linköping University,
lars.sandman@liu.se

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³⁰ Daniels and Sabin. *Setting limits fairly. Learning to share resources for health*.

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