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Should relational effects be considered in health care priority setting?

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Abstract

It is uncontroversial to claim that the extent to which health care interventions benefit patients is a relevant consideration for health care priority setting. However, when effects accrue to the individual patient, effects of a more indirect kind may accrue to other individuals as well, such as the patient's children, friends, or partner. If, and if so how, such relational effects should be considered relevant in priority setting is contentious. In this paper, we illustrate this question by using diseasemodifying drugs for Alzheimer's disease as a case in point. The ethical analysis begins by sketching the so-called prima facie case for ascribing moral weight to relational effects and then moves on to consider a number of objections to it. We argue that, whereas one set of objections may be dismissed, there is another set of arguments that poses more serious challenges for including relational effects in priority setting.

KEYWORDS indirect effects, need-based health care, priority setting, significant others

1 | INTRODUCTION

While it seems difficult to reach a consensus on which principles should guide health care priority setting, some considerations are less controversial than others. Health care systems with guidelines for priority setting normally ascribe importance to treatments having the potential to benefit *patients*.¹ However, when effects accrue to an

¹See, for example, Hofmann, B. (2013). Priority setting in health care: Trends and models from Scandinavian experiences. Medicine, Health Care and Philosophy, 16(3), 349-356; Ottersen, T., Forde, R., Kakad, M., Kjellevold, A., Melberg, H. O., Moen, A., Ringard, A., &

individual patient, effects of a more indirect kind may accrue to other individuals as well, such as the patient's children, friends, or partner. These effects accrue to these other individuals as a consequence of treating the patient and are often dependent on the relationship between the patient and the other individual.² If, and if so how and

Norheim, O.-F. (2016). A new proposal for priority setting in Norway: Open and fair. Health Policy, 120(3), 246-251; Sabik, L. M., & Lie, R. K. (2008). Priority setting in health care: Lessons from the experiences of eight countries. International Journal for Equity in Health, 7, 4. https://doi.org/10.1186/1475-9276-7-4; Beauchamp, T. L., & Childress, J. F. (2018). Principles of biomedical ethics (7th ed.). Oxford University Press.

²In this paper we refer to these other beneficiaries as significant others.

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why, such *relational* effects should be considered is more controversial both in guidelines for priority setting,³ and in the literature on priority setting ethics.⁴ In this paper we explore the ethical relevance of relational effects for priority setting in the context of a need-based system using disease-modifying drugs for Alzheimer's disease (AD) as a case study.

The paper unfolds as follows. In Section 2, we give some background to AD and disease-modifying drugs for AD. In Section 3, relational effects are characterized in relation to so-called indirect effects. In Section 4, we outline the context in which the discussion unfolds. In Section 5, we present, what we will refer to as the *prima facie* argument for taking indirect and therefore also relational effects into account. In Section 6, we discuss a counterargument based on formal equality, showing how this argument fails. In Section 7, we present a more compelling counterargument based on need-based health care. In Section 8, we present some further difficulties in implementing considerations of relational effects into the health care system. In the final section, we conclude.

2 | AD AND NOVEL DRUG CANDIDATES

To illustrate the following discussion, we use disease-modifying drugs for AD as a case. Early stages of AD are normally referred to as Mild Cognitive Impairment, which involves memory problems or other cognitive disorders but does not affect the patient's ability in terms of Activities of Daily Living (ADL). In later phases, the patient often experiences memory impairment, visual-spatial impairment, and impaired language with an effect on the patient's ability to ADL. Consequently, AD can profoundly affect the patient's significant others, often exemplified by spouses having to carry a heavy care burden. This effect is a crucial aspect of AD research as well as clinical treatment and care.⁵

In January 2023, the Food and Drug Administration (FDA) approved the second potentially disease-modifying drug targeting

AD via the Accelerated Approval pathway⁶ and more candidates are underway. Although the documented effect of the approved drug on the clinical presentation of AD is scarce, to say the least, more effective disease-modifying drugs are likely to be underway within the foreseeable future. The aim of these drugs is to slow the course of the disease, for example by postponing the onset of AD or by slowing down the rate at which AD develops. Accordingly, more effective treatments for AD that would make a significant difference for the patient, also have the potential to impact greatly on the lives of significant others. When such AD drugs are approved and introduced in health care systems, the question discussed in this paper becomes real: should these relational effects be considered when prioritizing these drugs?

Note that this issue is present for other kinds of measures than pharmaceutical treatment that potentially could improve the situation for AD patients, for instance, improved palliative care. Perhaps such measures could turn out to be more cost-effective than pharmaceutical treatments, which would then be an argument to prioritize these measures. The question of whether relational benefits should be included in priority-setting decisions is present regardless of what specific intervention we are considering.

3 | RELATIONAL VERSUS INDIRECT EFFECTS-SOME PRELIMINARIES

In the literature on medical ethics, benefits that accrue to someone else than the patient, as a consequence of treating the patient, are often referred to as *indirect benefits* or more generally *indirect effects.*⁷ These indirect effects are often exemplified by effects that accrue to children when their parents are given priority or more general socio-economic benefits of giving priority to people of working age.⁸

In this paper, we focus on what we refer to as *relational effects* which is one instance of indirect effects. Relational effects accrue to someone else than the patient, as a consequence of treating the patient, and depend on the relation the patient has to the other individual. While some more systemic indirect effects, for example, wider economic effects for society, are already integrated into present guidelines for cost-effectiveness analyses, relational effects are more controversial in this regard.⁹ Relational effects also seem to be of special relevance for treatments targeting AD and of more general importance for priority-setting ethics.

⁹See, for example, Pennington & Wong, op. cit. note 3.

³Ministry of Health and Social Affairs (Socialdepartementet). (1995). Priorities in Health Care –Ethics, economy, implementation. Final report from the Swedish parliamentary priorities commission (Swedish Government Official Reports, SOU 1995:5). Fritzes; NICE. (2013). Guide to the methods of technology appraisal; Pennington, B., & Wong, R. (2019). Modeling carer health-related quality of life in NICE technology appraisals and highly specialized technologies. University of Sheffield; Official Norwegian Reports. (2014:12). Åpent og rettferdig–prioriteringer I helsetjenesten [Open and fair–Priority setting in the health service]. Departementenes sikkerhets-og serviceorganisasjon.

⁴Brock, D. W. (2003). Separate spheres and indirect benefits. *Cost Effectiveness and Resource Allocation*, 1(1), 1–12; Lippert-Rasmussen, K., & S. Lauridsen. (2010). Justice and the allocation of health care resources: Should indirect, non-health effects count? *Medicine, Health Care and Philosophy*, 13, 237–246; Du Toit, J., & Millum, J. (2016). Are indirect benefits relevant to health care allocation decisions? *Journal of Medicine and Philosophy*, 41(5), 540–557.

⁵Wimo, A., & Gauthier, S. (2018). Global estimates of informal care. Alzheimer's Disease International & Karolinska Institutet; Wittenberg, E., & Prosser, L. A. (2013). Disutility of illness for caregivers and families: A systematic review of the literature. *Pharmacoeconomics*, 31(6), 489–500; Jakobsen, M., Poulsen, P. B., Reiche, T., Nissen, N. P., & Gundgaard, J. (2011). Costs of informal care for people suffering from dementia: Evidence from a Danish survey. *Dementia and Geriatric Cognitive Disorders Extra*, 1(1), 418–428.

⁶FDA. (2023). FDA grants accelerated approval for Alzheimer's disease treatment. https:// www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-

alzheimers-disease-treatment. For a broader ethical discussion about these kinds of drugs see Gustavsson, E., Raaschou, P., Lärfars, G., Sandman, L., & Juth, N. (2021). Novel drug candidates targeting Alzheimer's disease–Ethical challenges with identifying the relevant patient population. *Journal of Medical Ethics*, 47(9), 608–614.

⁷Brock, op. cit. note 4; Lippert-Rasmussen & Lauridsen, op. cit. note 4; Du Toit & Millum, op. cit. note 4.

⁸Lippert-Rasmussen & Lauridsen, op. cit. note 4.

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To what extent a given person is affected in terms of relational effects is an empirical question and will, in principle, be measurable. Relational effects can, of course, be both benefits and burdens.

Whether or not these relational effects *should* be taken into account in decisions about priority setting is a subsequent normative question and will be discussed below.

4 | RELATIONAL EFFECTS AND HEALTHCARE PRIORITY SETTING

To place the question about relational effects into context we discuss it presupposing a needs-based framework for healthcare priority setting.¹⁰ Traditionally, in the context of priority setting, there have been primarily two ways in which one might understand a needsbased framework. Either it has been interpreted as saying that resources should be distributed with regard to (a) how badly off a patient is or. (b) a patient's capacity to benefit from treatment.¹¹ As some of us have argued elsewhere,¹² and as has been suggested by other scholars,¹³ we believe that a plausible interpretation of a needs-based distribution is constituted by both how badly off a person is and the extent to which that person can benefit from treatment. However, depending on how one interprets principles of need more specifically, such principles will ascribe weight to these components to different degrees and for different moral reasons. When we discuss the moral importance of relational effects in the following, we do so under the assumption that both these components constitute relevant criteria for priority setting in a needs-based system.

In the following sections, we will move on to the normative discussion and first discuss one argument in favor of ascribing weight to relational effects, and second, discuss arguments against taking such considerations into account.

5 | A PRIMA FACIE CASE FOR RELATIONAL EFFECTS

The most straightforward argument for considering relational effects in a priority setting is what we will refer to as the *prima facie* case for relational effects. According to this argument, all valuable effects should be taken into account and no difference should be made between direct and indirect effects.¹⁴ For example, consider Lippert-Rasmussen and Lauridsen who argue that since

> ... such benefits or harms are real benefits or harms, and in other contexts—e.g. when allocating resources to the health sector and other sectors of society—we take our decisions to be legitimately guided by them; so unless there are special reasons why they are irrelevant to health-resource allocations they should be deemed relevant in this context as well.¹⁵

Suppose that there is a scale of health-related quality of life from 0 to 1 (where 0 represents *death* and 1 *full health*). Suppose also that studies suggest that while novel drug candidates increase patients' health-related quality of life from 0.4 to 0.8, significant others are raised from 0.6 to 0.9. If the prima facie argument is valid, the relevant health improvement is 0.7, if not, the improvement is 0.4.

The argument for ascribing weight to relational effects is related to the intuition that it is inconsistent to disregard relevant effects that an intervention might have without having a good reason for that. Therefore, it is argued, the burden of proof belongs to people who argue that relational effects should be considered *irrelevant* for priority setting. This is obviously a compelling argument, and we need strong counterarguments to refute this *prima facie* claim.

6 | FORMAL EQUALITY

A potential counterargument is that taking relational effects into account would imply that identical patients, with respect to other criteria relevant to priority setting, would be treated differently since their close relationships will affect how their condition-treatment pair is prioritized.

Patients and patient groups with relevant relations would have relational effects accruing to their significant other added to the "total" effect and cost-effectiveness calculus. Therefore, these patients would generally receive higher priority and, consequently, those without relevant relations would generally receive lower priority, all else being equal. This seems to violate a principle of formal equality according to which equal cases should be treated equally, and morally irrelevant factors should not be considered. However, this argument seems to beg the question, since this is precisely the issue at hand: whether relational effects are irrelevant factors or not. To see this, consider a situation where there is a patient and a significant other who is equally negatively affected (direct and indirect) by different conditions, and where treatment would reduce the negative impact of these conditions equally for both parties. It could be seen as a violation of formal equality to treat them differently.

¹⁰Bognar, G., & Hirose, I. (2022). The ethics of health care rationing (2nd ed.). Routledge. ¹¹See, for example, Cookson, R., & Dolan, P. (2000). Principles of justice in health care rationing. *Journal of Medical Ethics*, 26(5), 323–329; see also Hope, T., Østerdal, L. P., & Hasman, A. (2010). An inquiry into the principles of needs-based allocation of health care. *Bioethics*, 24, 470–480.

¹²Juth, N. (2015). Challenges for principles of need in health care. Health Care Analysis, 23, 73–87; Gustavsson, E. (2018). Characterising needs in health care priority setting [Doctoral dissertation, Linköping University].

¹³Crisp, R. (2002). Treatment according to need: Justice and the British National Health Service. In R. Rhodes (Ed.), *Medicine and social justice: Essays on the distribution of health care* (pp. 134–143). Oxford University Press.

¹⁴Brock, op. cit. note 4; Lippert-Rasmussen & Lauridsen, op. cit. note 4; Du Toit & Millum, op. cit. note 4.

¹⁵Lippert-Rasmussen & Lauridsen, op. cit. note 4. p. 241.

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It may still seem to be something unjust that individual *patients* that are alike in relevant respects (e.g., the same severity, and the same capacity to benefit) are treated differently, depending on whether they have close relations to others or not. For example, suppose that there are two individuals, Jack and Jill, that are both diagnosed with AD in the final phase of the disease. Both are also equally badly off in terms of clinical symptoms such as memory impairment, visual-spatial impairment, and impaired language. Jack has a son and a daughter with whom he seems to have very close relations, whereas Jill lacks significant others that could be benefited from Jill getting better. It may still seem overly harsh, even unjust, against Jill to down-prioritize her on that ground.

A potential way to handle this kind of objection is to relate relational effects to conditions on a group level rather than to individual patients, that is, identify condition-treatment pairs more likely to result in relational effects since they do affect close relationships to a greater degree. In accordance with the focus on a group level, individual patients would not be treated unequally (due to the lack of close relationships) as Jill is in the aforementioned case, but condition-treatment pairs would rather be ranked on a systemic level.

Given that patients have such a condition (normally with great relational impact), everybody in the patient population is treated equally with regard to relational effects regardless of their individual relationships. Accordingly, while the condition-treatment pair (i.e., group) AD combined with a disease-modifying drug would be prioritized differently from other patient groups with significantly less relational effects, individual patients within the AD group will not.

Is moving the question from an individual to a group level a less serious problem from an equality perspective? Different condition-treatment pairs are already treated differently due to differences in severity, effect, and evidence of this effect of existing treatment, the cost-effectiveness of existing treatments, and so forth. To the extent making these differences is accepted, it is because these aspects are considered ethically relevant. Similarly, here, to the extent we find that relational effects are ethically warranted, a difference in priority based on such effects would *not* be unjust.

7 | A NEEDS-BASED HEALTH CARE

Even if it is an open question whether introducing relational effects will conflict with requirements of formal equality, a more serious problem is that it might conflict with a need-based healthcare system, more specifically, considerations of the severity of the disease. The crucial implication of severity in the subsequent discussion is that the more severe a condition is, the higher the cost that can be accepted for health improvements. Below we discuss these higher costs in terms of conditions having different thresholds for cost-effectiveness depending on the severity of the disease. Consider the following situation:

> Two patient groups A and B have a condition that places them on 0.2 (again on a scale from 0 to 1). There is a treatment that could bring both groups up

to a level of 0.8. Suppose that for the severity levels that A and B exemplify (0.2), cost-effectiveness ratios below 100 000€/health improvement are accepted. The treatments for A and B both have a costeffectiveness ratio of 120 000 €/health improvement. The difference between A and B is that while A has a condition with a relational severity for significant others placing them at 0.8, B has no such relational effects. Considering the relational effects for the significant others of A will result in treatment for A making the cost-effectiveness threshold, since the significant others also have their severity reduced to 0. B, however, would not.

This case shows that if A is provided with treatment and B is not, we have allowed the lower severity of the significant others of A to be treated as on par with the higher severity of A. In other words, by adding the relational effect we are allowing the significant others of A (with lower severity) to be prioritized over B (with higher severity), by piggybacking on the severity of A. This seems to violate the rationale for taking the severity of the disease into account, according to which there are stronger reasons to prioritize more severe conditions over less severe conditions, all else being equal.

One way to handle this would be to distinguish between the severity and capacity to benefit A on the one hand, and the severity and capacity to benefit the significant others of A, on the other. Consider a modified case:

Suppose that we can distinguish between the benefit for the patients and the significant others of treating A. The patient group gets 0.6 units of effect, the significant other gets 0.2 units of effect. Given the cost-effectiveness threshold of 100 000 ϵ /health improvement for the severity of A, and adding that the cost-effectiveness threshold of the severity of the significant others is 25 000 ϵ /health improvement this implies that the total acceptable cost of treatment for A (together with the significant others of A) is 650 000 ϵ . For B the highest acceptable cost is 600 000 ϵ .

This suggests that even treating the direct and indirect impact of A's condition separately in terms of severity, capacity to benefit, and the acceptable cost-effectiveness thresholds for these levels of severity we would still accept higher costs for treating A than treating B.

Now, since the budget is fixed, to introduce treatment for A we need to ration treatment for some other patient groups (note that we cannot ration treatment for significant others independently of rationing treatment for patients). Hence, by introducing relational effects as a relevant consideration, we are likely to allow lowerprioritized groups to disadvantage higher-prioritized groups. Moreover, when we are considering treatment where the cost is dependent on the pricing of a for-profit actor (like a pharmaceutical 672

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company), they might adjust pricing after what they get and therefore set the price higher if relational effects are taken into account.

Consider next the reversed situation, where a patient group is suffering from a condition with moderate severity for the patient group itself, but with a much greater impact on the significant others leading to high severity for them. While it may be difficult to find such a condition with such relational effects on a group level we assume this case for the sake of argument. If we would prioritize this patient group according to their need in terms of severity, that might disadvantage the significant others, that is, a group with a greater need. If significant others are affected this way, the health care system has a reason to treat them as patients in their own right and provide treatment or support to the extent available in line with their need. However, let us assume that such direct treatment or support is not available, and the only way to reduce the severity of the significant others is to treat the patient. To tend to the needs of the significant others, we will then have to give a higher priority to the patients. Once again, this will imply a breach of our need-based approach to health care-this time allowing a patient group to piggyback on the severity of the significant others.

In conclusion, there is tension between accepting considerations of relational effects and a needs-based approach to priority setting.

8 | IMPLEMENTING RELATIONAL EFFECTS IN PRIORITY DECISIONS

Even if the advocates of the *prima facie* argument are not convinced by the more principled arguments from need, there might still be adverse effects of implementing considerations of relational effects in actual priority setting. In this section, we consider such side effects.

There is a high degree of complexity and subjectivity in priority decisions (e.g., in the assessment of severity, patient benefit, and in cost-effectiveness). To introduce further factors risks making the decision more complex and, perhaps, increase the risk of arbitrariness. A recent overview exploring the health economics literature on relational effects discusses a number of methodologically unresolved issues.¹⁶ For example, the opportunity cost of introducing an intervention will change, and as a result, cost-effectiveness thresholds would have to change, with unclear systemic effects. But it also raises questions about how these effects should be measured. For instance, should they be part of the health economical modeling and internal to the incremental cost-effectiveness ration or introduced into the decision through a multicriteria model?

A particularly challenging area is treatments with an effect on the life-length of the patient, since prolonging the life of a patient may also prolong the negative impact on the significant others (i.e., result in a, balance, relational burden). In line with this, it is generally recommended not to allow relational effects to be considered in such situations.¹⁷ From an ethical point of view, it is a counterintuitive effect of the methodological approaches that the prolonged survival of a loved one only result in increased relational burdens.

Furthermore, a sound system of priority setting should not be vulnerable to various kinds of corruption that bring further arbitrariness into the system.¹⁸ Such corruption also risks undermining the public legitimacy of any system. In a situation where there are a number of unresolved methodological issues, strong patient groups, or strong financial interest might be both better at lobbying for taking relational effects into account but also in conducting the necessary studies to show relational effects. This might be true in particular when it comes to new drugs, with a strong pharmaceutical industry as a sponsor. The development of new psycho-therapeutic approaches might have less financial support to show relational effects. Hence on a systemic level, even if we in theory would have good reasons to introduce relational effects (which we find doubtful), we might get unwanted inequalities between different treatment modalities. Since different treatment modalities are more or less common or dominating in relation to different conditions, this will also affect conditions unequally. This is not only a theoretical concern: other kinds of priority considerations have been shown to have these effects. For instance, the United Network for Organ Sharing (UNOS) point system in the United States, used the sickest-first as one of their bases for allocating organs. Some centers deliberately represented their patients as especially badly off to get them ahead in the system.¹⁹ Of course, these tendencies can be, at least partly, countered by robust systems with strict procedures and control mechanisms, but this comes with a cost.

9 | CONCLUSION

In this paper we have explored if, and if so how and why, relational effects should be considered relevant for priority setting. In order to illustrate this question, we have related it to AD and disease-modifying drugs targeting AD. We then sketched, what we have referred to as, the *prima facie* case in favor of ascribing weight to relational effects only to move on to consider a number of objections to it. While arguments from formal equality against relational effects are begging the question, we find that there is a tension between introducing relational effects and a needs-based approach to priority setting. Moreover, given the complexities of the methodological issues, introducing relational effects comes with a greater arbitrariness in health care systems and a greater risk of potential corruption or bias from strong pressure groups.

¹⁶Heintz, E., Degerlund Maldi, K., Sharma, A., Simarmata, B., & Davidson, T. (2022). Externa effekter hos n\u00e4rst\u00e5enden vid beslut om subvention av l\u00e4kemedel [External effects on significant others in decisions on pharmaceutical reimbursements]. Karolinska Institutet; see also Pennington & Wong, op. cit. note 3.

¹⁷Heintz, E., et al. op. cit. note 16.

¹⁸Persad, G., Wertheimer, A., & Emanuel, E. J. (2009). Principles for allocation of scarce medical interventions. *The Lancet*, 373(9661), 423–431.

¹⁹Murphy TF. (2004). Gaming the transplant system. The American Journal of Bioethics, 4, W28; Zink, S., Wertlieb, S., Catalano, J., & Marwin, V. (2005). Examining the potential exploitation of UNOS policies. The American Journal of Bioethics, 5, 6.

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The purpose of introducing relational effects would be to provide a more reasonable distribution of resources. However, given that taking such effects into account introduces additional room for arbitrariness in the system, the introduction of relational effects seems to counteract the initial purpose. Hence, based on these considerations, we conclude that relational effects should not be considered in the type of priority decisions we have discussed in this article.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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