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EDITORIAL

Future unrelated medical costs need to be considered in cost effectiveness analysis

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Abstract
New medical technologies that prolong life result in additional health care use in life years gained. Some of these costs in life years gained are considered to be related to the intervention while other costs are considered unrelated. Here, we argue that ignoring these so-called future medical costs in cost effectiveness analysis is contrary to common sense, results in lost health and fails to inform decision makers for whom cost effectiveness is supposed to serve.

Background

Health services in most of the developed world are under increasing strain as populations age: this is no less true for being a cliché [1, 2]. An important driver of growing health care expenditures is the introduction of new medical technology (often targeted at the elderly) [3]. Although some medical technology has made important contributions to improvements in population health, not all new technologies result in health gains at 'acceptable' prices. Cost effectiveness analysis (CEA) aims to inform decision makers at what price new technologies yield health gains.

The most notable and systematic use of CEA is in England, where the National Institute for Health and Clinical Excellence (NICE) has been established to assess whether new technologies within health care yield sufficient value for money to allow routine use within the English National Health Service (NHS). Consequently, NICE guidance with respect to the use of health care technologies, not only their methodological guidance on how to assess health care technologies have been highly influential in England, but also serve as role model for other countries wishing to use CEA results in decision making. When developing guidance, cost effectiveness is considered explicitly by NICE in the so-called assessment phase in which evidence on cost and effects is gathered, and subsequently in the appraisal phase in which there is a deliberation upon the gathered evidence [4]. An intervention is deemed cost effective by NICE if 'its health benefits are greater than the opportunity costs of programmes displaced to fund the new technology, in the context of a fixed NHS budget. In other words, the general consequences for the wider group of patients in the NHS are considered alongside the effects for those patients who may directly benefit from the technology' [4]. In this article we question whether the current guidelines for health technology assessment used by NICE are appropriately given in this definition of cost effectiveness. The point we want to take issue with, in particular, is the handling of "unrelated future medical costs" in cost effectiveness analysis. These are now explicitly excluded from these analyses in current guidelines, but, as we will argue, they should be included to support better decisions [5].

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Future costs and cost-effectiveness analysis

Medical interventions that increase life expectancy of patients may create additional consumption of medical goods and services in so-called 'added life years'. Added years are those years that would not have been lived without the intervention. A part of this medical consumption in added years is directly related to the intervention. In case of a successful heart transplantation, costs of visiting the cardiologist in life years gained are considered related. These costs are typically included in economic analyses. Other costs in added years are not directly related to the intervention and are termed costs of 'unrelated medical care'. This would for instance be the case for costs resulting in dementia care in added life years after the same heart transplantation. These costs are typically excluded from economic analyses. However, given the increased survival of older patients and a high concentration of spending in the elderly, it is likely that life-prolonging technologies create a lot of 'unrelated' health care use in life years gained. A recent study suggested that a substantial part of the rise in emergency admissions to hospitals can be explained by improved survival of patients from previous admissions and, therefore, creation of a new set of frail patients, who would in previous years have died [6].

Whether we should worry about unrelated costs in added life years in cost effectiveness analysis when we decide on a life-prolonging technology is currently much debated [7, 8]. To better understand the relevance of unrelated medical costs when deciding on health care interventions, we invite readers to consider the story in Box 1 where we present a stylized example relevant for individual decision making. If you, the reader, had to give advice to the family about this difficult choice, would you ignore the dialysis costs in informing their decision about chemotherapy on the grounds that they are "unrelated"?

Box 1: Unrelated costs and individual decision making

A 62-year-old member of a family in a poor country without healthcare coverage has kidney failure and requires dialysis, imposing a significant, but bearable recurrent financial burden on her family. She then additionally receives an unrelated cancer diagnosis with a terminal prognosis. The family can borrow money for chemotherapy—their decision is whether to do so. The financial costs of servicing the loan would be bearable in the absence of the dialysis costs, but together with the dialysis costs the family will be wiped out financially, the children will have to leave school and start work, the parents will have to work two jobs and can give up any hope of retirement, and even then they might be bankrupted and have to abandon the dialysis anyway. The situation is tragic, but a choice has to be made.

While the example in Box 1 may highlight the salience of these costs, some authors have argued in favour of excluding future unrelated costs. Their main points are that these costs can be safely ignored as they are not material to decision making, and including these costs would only complicate decision making and pose empirical challenges when one needs to estimate such costs [9, 10]. Other arguments against inclusion are that these costs relate to specific treatments that should be evaluated separately [10, 11]. However, research has called into question these arguments, and develops a theory which shows that including costs of unrelated diseases would increase population health in the long run [12]. Furthermore, empirical problems in estimating such costs can largely be solved as there is ample research on the impact of ageing on healthcare use.

It may seem counterintuitive that including more costs in an economic evaluation, thereby pushing the incremental cost-effectiveness ratio (the ICER) upwards, ultimately results in more health. However, key to understanding this logic is that including future unrelated costs leads to different choices that on balance result in more health benefits [12]. Intuitively, including the costs of unrelated medical care makes sense as they also contribute to the health gains which are implicitly included in practice [5]. By neglecting unrelated future costs, life-prolonging technologies appear to be more cost-effective than they truly are. Therefore, underestimating the costs of life-prolonging health technologies might result in erroneously adopting life-prolonging technology at the expense of interventions that yield more health per pound spent. Ultimately, future unrelated costs are real and will affect the budget left for other care. Given that NHS budgets are fixed, opportunity costs of implementing new technologies consist of QALYs foregone due to disinvestment in technologies for unidentified patients [13]. Ignoring future unrelated medical costs result in an underestimate of QALY losses of unidentified patients in the future.

Guidelines

Whether unrelated costs are taken into account in economic evaluations in practice crucially depends on guidelines for economic evaluations. To ensure that economic evaluations are performed in a sound way, aligning with the goals and

constraints of the NHS, they should be conducted by adhering to guidelines such as those developed by NICE [4]. With respect to the inclusion of future costs, current NICE guidelines for technology assessment advise that "Costs related to the condition of interest and incurred in additional years of life gained as a result of treatment should be included in the reference-case analysis. Costs that are considered to be unrelated to the condition or technology of interest should be excluded". The Dutch Health Care Institute had identical advice regarding unrelated medical care as NICE, but recently recognized the inconsistency of ignoring these real costs and decided to change these guidelines to encourage inclusion of all future medical costs [14]. Note that the Dutch are not the first to recommend inclusion of these costs as Swedish guidelines for cost-effectiveness analyses have always recommended inclusion. Furthermore, recently updated guidance from the US panel on cost effectiveness also recommends inclusion of future unrelated medical costs [15]. As a consequence of current NICE guidance, costs of dementia treatment in life years gained would be ignored in an economic evaluation of cancer treatment. The consequence is that the health losses as a result of disinvestment in older technologies might be greater than the health gains of investing in newer technologies resulting in balanced health losses.

Recent research has shown that the value for money as measured by the incremental cost-effectiveness ratio (ICER[1]) is an important determinant whether a technology will be recommended by NICE [16]. On average, an increase of the ICER of £1000 decreases the odds of being adopted by about 7% [16]. Including future unrelated costs can have a big impact on the incremental cost-effectiveness ratio (ICER). Although the numerical impact may differ from intervention to intervention, in general, the impact of unrelated medical care will be bigger for life-saving interventions targeted at elderly and frail people. While for interventions that do not extend life, the ICER would be unaffected, including future unrelated medical costs which could increase the ICER by thousands of pounds for interventions that extend life considerably, but where life years gained are spent in poor health. Therefore, a change in NICE guidance could have a substantial impact on decisions. Box 2 gives an example which illustrates the impact of future unrelated costs for decisions reached by NICE.

Box 2: Future unrelated medical costs and the cost effectiveness of transcatheter aortic valve implantation (TAVI)

Transcatheter aortic valve implantation (TAVI) is a recently developed technology that prolongs life for patients with severe aortic stenosis and coexisting conditions which are not candidates for surgical replacement of the aortic valve [17]. Recently, an economic evaluation of TAVI was produced using NICE guidance which led to a base case ICER estimate of 16,100 lb per QALY and a health gain per patient of 1.56 QALYs [18]. In line with NICE guidelines, costs of reoperation were included, but future unrelated costs in life years gained, such as costs of treating dementia, were excluded. In case of TAVI, eligible patients are old (> 75), face a high mortality risk and generally have multiple co-morbidities [18]. Health care consumption for other diseases besides heart disease in additional life years of this group of patients can, therefore, expected to be relevant. If we were to include future unrelated costs, the ICER would increase from £16,100 to £ 23,500 per QALY gained [12]. With a threshold of £20,000, inclusion or exclusion of future unrelated medical costs could mean the difference between adopting and rejecting a technology. However, if TAVI would be adopted based on the ICER of £16,100, this would result in health losses if the technology that is displaced has a cost effectiveness of £20,000 per QALY gained. More specifically, as the total costs for the TAVI procedure for one patient (including future unrelated medical costs) are about £37,000—one could have gotten 1.85 QALY (37,000/20,000) rather than the 1.56 produced by the TAVI technology. As there are about 2000 patients eligible for TAVI in England, this would result in a health loss of almost 700 QALYs.

Ethical considerations

Could the analysis which we present above have ethically undesirable implications? It is possible to construct examples where including unrelated future costs in analysis can produce conclusions which are hard to swallow—for example when considering life-extending interventions in institutionalised and/or chronically ill patients (see Box 3).

Box 3: Future costs and ethical issues

Life-extending treatments in patients with chronic kidney disease (CKD) on dialysis are examples of treatments in which the inclusion or exclusion of future unrelated

[1] A central element of an economic evaluation is an incremental cost effectiveness ratio (ICER) which indicates how much has to be paid for an additional QALY by adopting a new intervention relative to some relevant comparator (e.g. current care). In the UK, the ICER is a ratio that is derived by dividing the additional costs falling, roughly speaking, on the NHS and also the Personal Social Services (PSS) budget by the additional population health gains measured in terms of quality adjusted life years (QALYs).

medical costs can have a very large impact on the ICER [19]. For such patient groups, future unrelated medical costs include the costs of dialysis in life years gained. These costs of dialysis are typically extremely high, and dialysis may in fact be considered cost-ineffective if judged against conventional thresholds. However, without ongoing dialysis, patients with end-stage renal disease face certain death. As the ICER of dialysis is already very high, the inclusion of dialysis costs in CEAs of interventions that extend the lives of dialysis patients, will lead to a situation in which even the most effective life-extending intervention will turn out to be cost-ineffective. For instance, statin treatment which is very cost-effective in some patient groups, may be deemed to be cost-ineffective in CKD patients on dialysis. It is clear that this raises questions regarding the ethical implications of including costs in gained life years which will have to be dealt with in priority setting in health care. In response to this, some authors have actually argued that including the costs of dialysis when evaluating statins would be 'unethical' and, therefore, plead for ignoring these costs in life years gained [19]. However, as statin treatment in this patient group increases the need for dialysis, ignoring these costs implies ignoring real (and potentially large) opportunity costs in terms of health forgone within the health care sector.

We share the moral intuition that denying access to life-extending treatments to dialysis patients specifically, is ethically challenging. One prominent reason for this is that patients with chronic kidney disease are already, through their illness, disadvantaged relative to the general population and so might deserve exceptional consideration. Another reason is that denying a treatment for a specific minority subpopulation, when that treatment is available to everyone else, might be socially divisive and contrary to the concept of universal coverage.

One might argue that denying any individual a therapy that offers them benefits because of costs is ethically troubling. Yet this is the reality of opportunity costs in the context of budget constraints. The concept of opportunity cost is not only an economic concept but also an ethical one, as the opportunity costs consist of health losses in other patients. Pretending such costs do not exist, does not seem to us to be ethically acceptable.

Conclusion

The upcoming pressures on the healthcare system from our ageing population will be intense. It is more important than ever that decisions about resource allocation are made in a spirit of stewardship, informed by robust common sense. We argue that current technical guidance on unrelated future costs in many countries does not meet this standard, and NICE should set an example and follow the Dutch change in guidelines, and recommend inclusion of future unrelated medical costs in health technology assessments. For some patient groups, including future unrelated medical costs may imply a huge increase in the ICER for life-prolonging technologies and thereby trigger difficult ethical debates. However, NICE stresses that decisions should be made in a way which is procedurally fair, which allows for such arguments to be raised and deliberated upon when appraising the evidence [20]. The task of the analyst in these situations is to provide decision makers with a full picture of the relevant consequences for the healthcare budget now and in the future. Expert advisers—whether to a family or to a nation—have the responsibility to present *all* relevant information to whom society has seen fit to entrust with decision-making responsibility.

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