

Combining health and outcomes beyond health in complex evaluations of complex interventions: Suggestions for economic evaluation

Running title: Economic evaluation of complex interventions [see full title above]

John Wildman^a and Josephine M. Wildman^b

^a Newcastle University Business School, Newcastle University, 5 Barrack Road, Newcastle upon Tyne, NE1 4SE, UK email: john.wildman@ncl.ac.uk, phone: 0191 208 1640

^b Institute of Health and Society, Newcastle University, James Spence Building, Royal Victoria Infirmary, Newcastle upon Tyne, NE1 4LP, UK

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Abstract

In the pages of this journal there has been considerable discussion regarding the development of tools for valuing the multiple attributes that arise from complex interventions with benefits beyond health. However, unlike the rigorous underpinnings of cost-utility analysis, much of this work has been taking place in fragmented research communities and without theoretical underpinnings, leading to a call for better and more comprehensive frameworks. We discuss the challenges faced by economic evaluation using as our example a ‘social prescribing’ intervention, a novel health intervention based on the social model of health. We suggest, a mixed-methods approach to uncover important attributes and then combine tools from health economics and economics to provide measures of benefit in a common money numeraire. This approach provides the theoretical underpinnings necessary for deliberate, transparent and structured decision-making processes. It also enables the correct allocation of costs within complex payment systems. We suggest that, due to the complexities of RCTs, interventions should be introduced in a way that allows the application of causal analysis for evaluation. In the short-term, such evaluations may be challenging and expensive. However, as has happened with health economics evaluation and the QALY, when a common sets of attributes is agreed upon the expense will fall and these methods can become embedded in interventions with diffuse outcomes.

Highlights:

- The literature has called for comprehensive frameworks that can accommodate multiple attributes. This paper considers the challenges of applying economic evaluation to complex interventions using the example of a novel health intervention based on the social model of health.
- It has been suggested that multi-criteria decision analysis and value frameworks lack theoretical underpinnings. We combine tools from health economics and economics, with theoretical underpinnings, in order to value health and outcomes or attributes beyond health in a common numeraire.
- We suggest that important attributes should be identified through mixed-methods approaches and valued at the population level.

Concise summary

We suggest a method for combining health and non-health attributes into a common numeraire in an economic evaluation and the implications for such a method.

Introduction

Nearly 40 years since the initial development of the Quality Adjusted Life Year (QALY) [1], methods for the evaluation of healthcare interventions are well-developed [2]. However, as Garrison et al [3:pg.212] have observed in these pages, although health gains and the resulting cost offsets are “core value drivers of health care interventions”, it is increasingly clear that other features of healthcare have value. Because an estimated 70% of health outcomes are determined by social factors [4], there is increasing interest, and investment, in complex interventions that seek also to address the wider social determinants of health. Complex interventions are defined as those comprising a number of essential elements and ‘active ingredients’ [5]. For example, with some complex interventions the process itself is of benefit to the recipients [6]. Other interventions realise individually-determined (self-defined) benefits. Yet others have multiple benefits with no one outcome having primacy over others. Diffuse outcomes and wide implications [6] mean that current evaluation methods are not easily applied to complex interventions.

In response to the challenge of evaluating interventions with outcomes beyond health, much space has been devoted in the pages of this journal to the discussion of methods of valuing multiple attributes within a health-care intervention, grouped under the heading of ‘multi-criteria decision analysis’ (MCDA) [7-11]. Multi-criteria approaches allow the quantification of additional attributes alongside the primary criteria (usually health) in a cost-effectiveness analysis (CEA) [12] and are gaining currency as a way of addressing the limitations in current health technology assessment (HTA) systems [8, 10, 13, 14]. Devlin and Sussex [15:pg.4] define MCDA in broad terms as “a set of methods and approaches to aid decision-making, where decisions are based on more than one criterion, which make explicit the impact of the decision on all the criteria applied and the relative importance attached to

them”. There is increasing interest, too, in ‘value assessment frameworks’, described by Briggs [12] as essentially a form of MCDA (however, others suggest that MCDA is a component of value frameworks [9]). Developed in the US, value frameworks attempt to value health-care spending in a multi-payer system [7, 9]. Even in single-payer systems such as the UK’s National Health Service (NHS) there are often numerous decision-makers [16]. Indeed, it could be argued that the UK health-care funding system increasingly resembles a multi-payer system, which although initially funded through general taxation comprises multiple organisations with no single perspective. The added complexity introduced by multi-payer systems is encountered by evaluators in the UK with payment-for-performance/payment for results mechanisms used to fund interventions that seek to tackle complex social problems [17]. The most recent variant of payment for performance funding for health care is the ‘social impact bond’ (SIB). This model sees public-sector commissioners partnering with third-sector social investors or private sector for-profit investors with the aim of shifting the financial risks of funding complex interventions away from the public sector [17].

Phelps and Madhavan [10:pg.251] have argued, in this journal, that we “need better, comprehensive frameworks to assess the value of health that can accommodate different values and incorporate multiple attributes”. Much of the development of multi-attribute approaches has been taking place in fragmented research communities [14]. Briggs [12:pg.1505] suggests that, while the development of multi-criteria approaches has been taking place outside of health economics, economic techniques have much to offer (he proposes that cost-benefit analysis (CBA) represents the “original MCDA”). We believe that the current tools of (health) economic evaluation can be applied to tackle the complexities of evaluating complex interventions. In this paper, we address the evaluation challenges posed

by complex interventions and suggest how methods with theoretical underpinnings can be used to accommodate a range of outcomes. We explore these issues using the example of ‘social prescribing’, a complex intervention actively promoted in the UK as a solution to the problems of funding the increasing costs of caring for patients with long-term health conditions (LCTs) and tackling the social determinants of health [18, 19]. Similar interventions that attempt to address social causes of ill-health are also becoming more prevalent in the US [20, 21]. Despite the enthusiasm for social prescribing interventions, largely due to the evaluation challenges posed by their complexity, there is currently no robust evidence for their effectiveness or value for money [22, 23]. We begin by describing ‘social prescribing’.

‘Social prescribing’ interventions

Social prescribing in the UK takes place within the NHS, a tax funded comprehensive health care service free at the point of use. Social prescribing has been embedded in primary care services that act as gatekeepers for secondary care. Social, rather than health, problems place considerable burdens on primary care, with 20 percent of patients consulting their general practitioner (GP) for primarily social problems [24]. Based on the social model of health [25], ‘social prescribing’ interventions aim to reduce service pressures by allowing primary-care practitioners to refer patients to non-clinical services in the community and voluntary sectors [26]. Many social prescribing interventions employ a ‘link worker’ (alternative titles include ‘health trainer’ and ‘community navigator’ [26]). The rationale behind the ‘link-worker’ role is that without support navigating and accessing community services can be extremely challenging for patients [27]. Social prescribing is an exemplar complex intervention (as defined by Byford and Sefton [28]): it targets patients with complex health and social problems that are chronic in nature, impact on multiple areas of a person’s life (and,

potentially, of their family's life), and impose significant societal costs; it is characterised by a high degree of user involvement; it has multiple, individually-tailored components; its recipients are heterogeneous; it has multiple complex goals and multiple complex outcomes (targeting physical health, but also social problems such as debt, housing and welfare entitlements and more abstract 'wellbeing' outcomes); it has multi-agency involvement; and the mechanisms through which outcomes are achieved are uncertain.

The Challenges of Evaluating Complex Interventions

The outcomes of complex interventions include a range of attributes (including health) that are diverse and potentially of value to stakeholders, society and/or the individual. These attributes, as in our social prescribing example, often, in the language of Sen [29], contribute to all the possible functions for a person. Here we suggest how multiple non-health attributes and health can be combined in an economic evaluation. We then highlight the challenges posed by multiple perspectives and the attribution of costs before suggesting how, in the face of these challenges, attributes should be selected.

Combining health and non-health attributes

Garrison et al [3:pg.215] assert that it *should* be possible to incorporate into economic evaluations a range of valuable attributes "by adding their valuations to those of the 'core' elements of value". They go on to observe that evaluators must choose whether to use patient or population valuations before converting them into a common numeraire. We suggest that the current tools of (health economic) evaluation can be applied in combination to allow both health and further attributes to be combined into a single outcome, measured in a common numeraire, preferably, we argue, money. Using a money numeraire would maintain consistency, reduce the cognitive burden placed on decision-makers and provide insights into

allocative efficiency (where the marginal benefit of one extra unit of spending is equal across programmes). Further, valuing all attributes in monetary terms allows stakeholders to converge on a negotiated decision by creating a 'market' of prices [10].

Monetary values could be assigned to both health and non-health attributes using Discrete Choice Experiments (DCEs) [14, 30]. Briggs [12] argues that DCEs are a form of multi-criteria analysis based, as they are, on attributes and levels of attributes that are important to an individual's utility function. Sacrifice and opportunity costs are key concepts in an economic evaluation (and can be lacking in some forms of multi-criteria analysis [12]). A major strength of DCEs is that they elicit preferences across alternatives using a range of scenarios, allowing attributes to be traded-off and allowing decision-makers to observe the weights applied to different attributes by the population. Furthermore, if a CBA approach is taken, health can be included as an attribute in its own right, allowing individuals to trade-off all attributes.

Alternatively, if an evaluator wishes to retain an extra-welfarist focus and consider health separately, DCE and CUA approaches can be combined to find a common numeraire. Health gains could be valued using QALYs that can be converted into a monetary numeraire through the use of thresholds applied by bodies such as the UK National Institute for Health and Care Excellence (NICE), or from the willingness to pay for a QALY [6, 31]. This approach, however, would not allow individuals to trade-off health against other potentially desirable attributes.

Alternatively, the common numeraire could be health. This could be achieved by converting the monetary valuations of the attributes into QALYs, again via the use of a threshold. Unlike

combining attributes and health using a monetary numeraire that is focused on the demand side (opportunity costs in terms of foregone consumption), this latter approach provides a QALY total for the intervention. Subsequently, a supply-side threshold could then be applied to the whole intervention, representing the opportunity costs in terms of health forgone if the intervention is funded. We return to a consideration of supply-side issues below.

Challenges to the extra-welfarist perspective posed by moving beyond health as a primary outcome mean that it may be preferable to return to welfarism's focus on individual preferences, or, at the very least, extend the extra-welfarist perspective. It is to this debate we now turn with a consideration of whose perspective should be incorporated into an evaluation.

Whose perspective?

Combining health and other attributes, as described above, raises a number of normative challenges for economics evaluations in terms of the perspective of an evaluation: Should the extra-welfarist decision maker approach of CUA be maintained over the welfarist approach of CBA? How should costs be accounted for? And how should attributes be selected and valued?

When combining health and non-health attributes it may be possible to extend the extra-welfarist notion of functionings and capabilities [29] beyond health. The decision maker philosophy of Sugden and Williams [32] allows the incorporation of a wider range of stakeholders who could select the important attributes of treatment to be the relevant arguments in the objective function (that is, what is to be maximised). Including key

attributes beyond health in the objective function would counter the criticism that extra-welfarism places too much focus on health [33, 34].

However, as interventions have become more complex in terms of outcome, they have also become more complex in terms of delivery. Figure 1 demonstrates the range of stakeholder perspectives in our social prescribing example. The social prescribing SIB we describe here links primary care providers and commissioners, a social investor, an intermediary (a ‘special purpose vehicle’ (SPV)) whose role is to contract service providers, receive investments and make outcomes payments), service provider organisations, services users and voluntary and community sector organisations (who provide the activities to which service users are referred by link workers) (see Figure 2). In this model the social investor provides capital (via the SPV) for service provider organisations to deliver the intervention to the population in need (the service users). The Commissioner (in this case the Clinical Commissioning Group), who is funded from the NHS budget, repays the social investor if pre-determined outcomes are achieved – such as a reduction in secondary care costs.

[Figure 1 about here]

[Figure 2 about here]

Social prescribing programmes pose a further challenge for evaluators in that they are locally-based, with different structures being applied to different areas to reflect the local needs, the diverse populations and the existence (or not) of a voluntary sector. Stakeholders in one community may chose different attributes compared with other stakeholders in other communities. In a centralised system such as the UK NHS, it may become impossible, even at a practical level, to extend the decision maker approach to accommodate wider attributes.

It may, however, be more possible in fragmented systems where local economics evaluation are possible.

So from whose perspective should values be decided? With outcomes beyond health, externalities and altruism affecting the monetary valuations of the attributes we suggest moving away from the extra-welfarist perspective to the classic welfare economics approach of individual preferences. By using individual preferences it is possible to obtain a population average valuation of the benefits of treatment and so apply a societal perspective to the analysis as used by evaluators in the areas of transport and environment [35]. Moreover, for complex interventions aimed at producing change in a range of areas, the societal level is the only perspective that can take account of a range of possible externalities. If health interventions are affecting, for example, welfare payments, debt management, planning and organisation, then these factors will need to be accounted for in the benefits and costs because there will be spill-overs from the intervention to the wider public and private sectors.

Whose costs?

Complex interventions in multi-payer (complex funding) systems may lead to unintended consequences if the costs savings/cost burdens follow simplified outcomes targets, whose only real advantage is that they are measureable. This risks having outcome targets that do not reflect the range of benefits or take account of where the costs savings/increased costs may actually occur. Supply-side issues are particularly difficult to resolve when there are outcomes beyond health to consider. Once attributes beyond health are introduced as part of the benefits to be valued then different sectors (funders) have incentives to cost-shift and free ride on other each other. To illustrate, if one important outcome is 'social care', in a multi-payer system should payment fall on the health sector or the social care sector? Where do the

opportunity costs lie? For example, if a social prescribing intervention is funded by the NHS in the UK, how much health are we willing to sacrifice to reduce the probability of the loss of independence?

Within the health sector there have been efforts to estimate health opportunity costs [36]; there are no such values for other sectors. For example, there are no values of the opportunity cost estimate for social care. As noted above, if the full cost of an intervention comes from the health funder it may be possible to consider the health opportunity costs of a programme overall, However, as not all benefits are health, should health systems be paying the full cost?

Returning to our example above, in the UK especially, we would expect the marginal cost of providing social care to be lower than the marginal cost for health care and we would expect the marginal benefits to be higher. Therefore, assessing the opportunity costs across the two sectors would be difficult and may highlight a need to re-allocate resources across sectors.

Garrison et al [3] suggest that including valued attributes beyond health gains in fixed-budget systems (such as the UK) is likely to result in changes in relative values (opportunity costs) potentially resulting in reduced willingness to pay for health gains at the margin because other elements of value are preferred.

The method we suggest, combining the valuation of attributes with QALYs, allows for the attribution of cost based on the demand side valuations from the DCE/CUA methods. With the use of a common monetary numeraire it is possible to have transparent attribution of programme costs that will limit cost-shifting. Costs should occur proportionally to the valuations of the benefits. For example, if 50% of the valued benefits from a social

prescribing intervention stem from the process of interaction with the link worker, then 50% of the costs should be targeted here.

However, while the attribution of costs is helpful it still does not inform us with regard to supply side opportunity costs. What is required is a different way to think about funding. Complex interventions may need to be matched by different funding structures to account for these opportunity cost issues. An example would be a greater use of integrated budgets, so that, over time, it would become possible to understand the impact of new interventions in terms of overall opportunity costs.

Which, and whose, attributes?

A central evaluation challenge lies in the actual process of identifying the key attributes that should be valued as part of an intervention's benefits. There are a number of means by which intervention attributes are identified, including existing priority-setting frameworks or decision-makers' criteria [15]. Complex interventions are aimed at improving a range of outcomes (or attributes). Examples applicable to social prescribing interventions include return to work, improvements in subjective wellbeing, reductions in health inequalities, and aspects of delivery of health care ('process') [15]. Social prescribing interventions are also likely to generate externalities; for example, strengthened communities.

We argued above that it would be possible for stakeholders to determine which attributes should be part of the objective function. However, such an approach is not without its difficulties. Figure 1 illustrates how different attributes may be of particular relevance to different stakeholders. Improvements in health are valuable, in and of themselves, from most stakeholder perspectives. From the perspectives of providers, payers and planners, health

improvements are valuable in leading to a reduction in health-care utilisation and, hence, reduced costs. Improvements in dimensions of wellbeing are likely to be valued from the perspective of a wider societal good. From certain stakeholder perspectives (payers, primary care producers and planner), wellbeing improvements are also likely to be particularly valued as leading to a reduction in primary and secondary health-care use.

However, the attributes valued most highly by stakeholders are often the monitored ‘core’ outcomes used to judge an intervention’s success [37]. Already, in practice, deciding on core outcomes that properly reflect the whole range of potentially valuable attributes is extremely challenging [26, 38]. Relevant outcomes are frequently over-simplified. Indeed, research with service provider organisations delivering the SIB-funded social prescribing intervention suggests that existing outcome measures fail to capture the complex nature of the intervention and its range of patient and societal benefits [39].

While there is a high degree of convergence between valued attributes across the range of stakeholders, the ‘process’ attribute is likely to be valued only by patients. This is important. If the patient’s perspective is not included in the process of attribute identification, then this attribute would be absent from the evaluation. There are a number of models of social prescribing, ranging from the ‘light’ (simply ‘signposting’ patients to sources of community support) to the ‘holistic’ (intensive support over a period of months or years from a well-networked community link worker trained in behaviour change and motivational techniques) [40]. In previous studies, the presence of a link worker is consistently identified by social prescribing participants as playing a central role in their engagement with an intervention and in improvements in their wellbeing [41, 42]. If this important attribute is omitted, then an intervention’s costs might falsely outweigh its identified benefits. The key implication of this

is that attributes need to be identified and valued at the population level, using representative samples from the population, as health states currently are.

In terms of selecting the attributes included in any economic evaluation we suggest that mixed-methods approaches combining quantitative and qualitative methods - such as Q-methodology [43] - are likely to be most effective choosing the key attributes to be valued. A major advantage of this approach lies in its ability to combine individual preferences and stakeholder perspectives within the attribute choice process. Such an approach would help to identify a core set of attributes that could be applied to all economic evaluations.

Discussion

In this paper we have tackled the challenges encountered in the evaluation of complex interventions, with a particular focus on social prescribing interventions. A limitation of multi-criteria approaches is that they are being developed without recourse to theory and with the implementation of ad hoc assumptions [9, 12]. This risks the funding of programmes that should not be funded and not funding those that should. What we propose here tackles the issues of theoretical underpinnings. DCEs and attributes have a strong theoretical grounding in the work of Lancaster [44], where individuals purchase goods on the basis of the attributes that they provide. This allows the framework to be rooted in welfarism, where individuals seek to maximise utility.

However, the question arises: why not simply use Cost Benefit Analysis (CBA)? There are two reasons: firstly, CBA aggregates a whole programme, so we can obtain a benefit value overall but we cannot see how benefits are related to individual attributes. By first disaggregating and then valuing attributes we are able to identify what is valued and how

trade-offs may occur. Secondly, CBA gives no primacy to health. If evaluators are uncomfortable with the welfarist approach our recommendations allow health to be valued separately, and still in a QALY framework if necessary, incorporating and extending the extra-welfarist dimension that currently exists in health economic evaluation.

A major strength of multi-attribute approaches is that they make trade-offs explicit and transparent and bypass some sources of cognitive bias that influence decision-making [10]. Health technology assessments do consider other criteria alongside cost-effectiveness in decision-making processes. For example, decision-making by NICE in the UK accounts for factors beyond increases in length and quality of life, including severity, proximity to end of life, stakeholder perspectives, disadvantaged populations and children [45]. However, it is not clear the extent to which this list is exhaustive, the weights given to the criteria, and whether the criteria are multiplicative or additive [15]. Sculpher [16] stresses that decisions on what is valuable are not for analysts to make; this is the role of decision-makers. Evaluations generate evidence that reflects decision-makers objectives and constraints. Allowing stakeholders to weight attributes according to value may lead to widely differing outcomes; however, this can be taken into account by decision makers in a way that is transparent [13]. The approach suggested here would increase the extent to which decision-making processes are deliberate and structured [16]. Furthermore, by combining values of many attributes there may be changes in the relative values of the opportunity costs incurred across sectors resulting in a socially acceptable diversion of health-care spending towards social spending, or the greater use of integrated budgets.

Finally, consideration needs to be given to the implementation of interventions. With the low power/low recruitment problems associated with RCTs, new interventions require thoughtful

planning to allow the application of causal inference to large datasets. Such approaches may be natural experiments exploiting geographical and/or temporal differences, or discontinuity designs that allow for the comparison of exogenously determined ‘treatment’ and ‘control’ groups [46].

Conclusion

Complex interventions with multiple outcomes require new methods of evaluation [6]. These evaluation methods, tied to benefit measurement from causal inference, mean moving away from the traditional model of health economic evaluation alongside a clinical trial. Proper evaluation of complex interventions will be expensive and will require extensive data collection [47]. However, putting the task into the ‘too difficult and too expensive’ box risks funding interventions that are not cost-effective (or failing to fund those that are). Identifying key attributes of social prescribing will take time. A ‘clean slate’ approach [15:pg.48] is needed through which we seek, using the tools suggested here, to identify a relevant set of attributes for complex interventions and to establish values for those attributes. However, once identified a generic instrument could be developed much-reducing the costs of future evaluations.

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Figure 1: Social Prescribing stakeholders' perspectives and valued outcomes/attributes

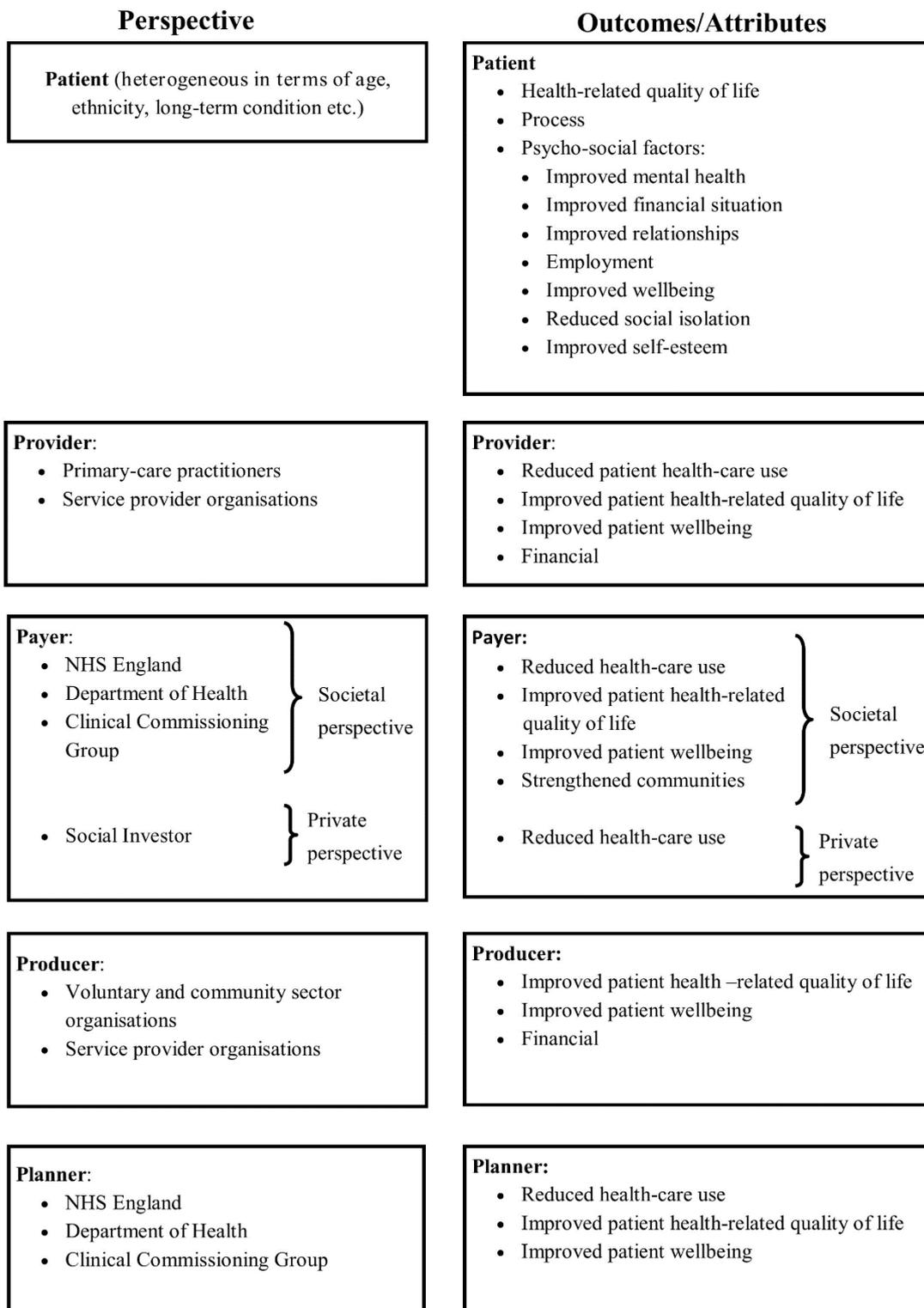


Figure 2 Social Prescribing Social Impact Bond Structure

