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Title: Resource Modelling: the missing piece of the HTA jigsaw?

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Abstract:

Within health technology assessment (HTA), cost-effectiveness analysis and budget impact analyses have been broadly accepted as important components of decision making. However, whilst they address efficiency and affordability, the issue of implementation and feasibility has been largely ignored. HTA commonly takes place within a deliberative framework that captures issues of implementation and feasibility in a qualitative manner. We argue that only through a formal, quantitative assessment of resource constraints can these issues be fully addressed. This paper argues the need for resource modelling to be considered explicitly in health technology assessment (HTA). First, economic evaluation and budget impact models are described along with their limitations in evaluating feasibility. Next, resource modelling is defined and its usefulness is described along with examples of resource modelling from the literature. Then, the important issues that need to be considered when undertaking resource modelling are described before setting out recommendations for the use of resource modelling in HTA.

Key Points for Decision Makers

- Economic analyses typically ignore the short term constraints (e.g. beds, availability of CT scanners, nurses, etc) which might lead to low levels of uptake.
- A quantitative assessment of technology diffusion, its related resource requirements and capacity constraints is required for uptake to be formally considered by decision makers
- Resource modelling is especially useful if there are significant changes in the amount or type of resources needed within the pathway by implementing the new technology
- Modelling techniques exist that can capture these resource implications and these analyses can be performed at a national level or at an organisational level

1. Introduction

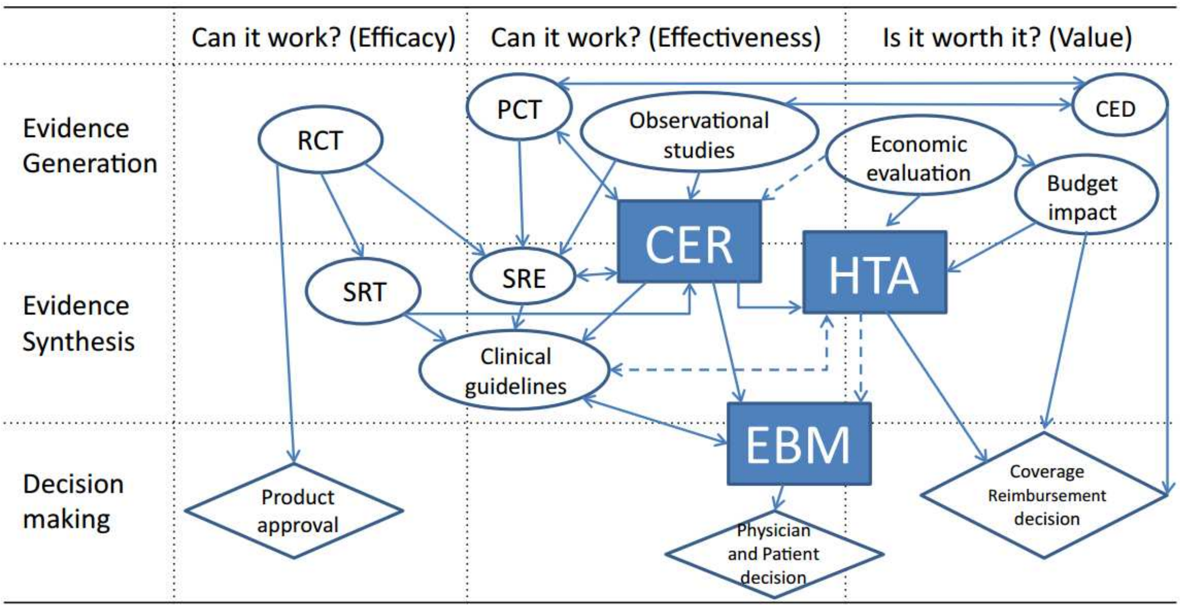
Health technology assessment and reimbursement (HTA&R) bodies are proliferating across the globe [1;2]. Whilst the health care systems that the HTA&R bodies relate to are extremely varied, the methods by which the value of new health interventions are assessed are somewhat more uniform [2]. Comparative effectiveness research (CER) and evidence based medicine (EBM) are the cornerstones of HTA. The role of economic evaluation is slightly more varied, with it generally being part of the process and the favoured method being cost-effectiveness analysis (CEA), with or without the use of quality adjusted life years (QALYs). How this information is used to generate a reimbursement decision is perhaps the most varied part of the process as the standard methods come face to face with the socio-political complexity of the health care system.

Whilst the CEA framework has become more widely recognised, the extent to which resource contraints within the health care system will impact on the implementation of HTA recommendations has been largely ignored. Expected implementation, described at a point of time, may not be feasible if the necessary resources can not be made available. Excellent evidence can be generated showing effectiveness and value for money, that generates a positive recommendation, but this does not guarantee that the technology will be used in clinical practice [3-5]. Even with mandatory guidance, such as that produced by the National Institute for Health and Care Excellence (NICE) in England and Wales, the implementation of positive guidance remains disappointingly low in some circumstances [6]. Figure 1 shows how evidence generation, synthesis and decision making can be seen as forming a matrix with issues of efficacy, effectiveness and value, with the different activities that feed into HTA positioned within this matrix [7]. This represents the standard framework that is commonly applied. However, this framework largely ignores implementation.

Most economic evaluations regularly assume that all physical resources (e.g. beds, doctors, nurses, CT scanners, etc) required by the new technology are immediately available and consumed, regardless of actual supply constraints (or likely demand). The ISPOR-SMDM modelling good practice guidelines state that despite the availability of methods to simulate these resource constraints, modellers typically ignore the actual short-term resource constraints [8]. Ignoring these constraints may result in negative consequences ranging from low levels of uptake through to infeasibility (i.e. the technology not being implemented). Implementation should form a fourth row in the matrix, with feasibility exercises feeding into the HTA, economic evaluation, budget impact analyses and reimbursement decisions.

The aim of this paper is to emphasise the need for 'resource modelling' to be considered as an explicit set of analyses that could feed into the HTA process. In Section 2 of this paper we describe economic evaluation and budget impact models, which are the two economic analyses that currently feed into HTA. This will highlight their purposes, their methods and their limitations in informing issues of feasibility and implementation. In Section 3 we define and introduce resource modelling before giving examples from the literature in Section 4. In Section 5, we highlight some important issues that need to be considered when undertaking resource modelling before setting out recommendations for the use of resource modelling in HTA&R processes in Section 6.

Figure 1: HTA and related processes



Source: Luce et al. [7]. RCTrandomized controlled trial, CER comparative effectiveness research, PCT pragmatic clinical trial, HTA health technology assessment, SRT systematic review of trials, EBM evidence-based medicine, SRE systematic review of evidence, CED coverage with evidence development. Solid lines indicate clear relationships, and dotted lines indicate disputed relationships. Diamonds represent decision processes, and circles and ovals represent all other evidence activities, except for the rectangles, which are reserved for EBM, HTA and CER

2. Economic evaluation and budget impact modelling

Within HTA, one of the most prominent forms of analysis is economic evaluation. This assessment of the costs and effects of all relevant comparators is central to the issue of value as it is the only form of analysis that can generate legitimate conclusions relating to efficiency [9]. Such analyses most commonly require the development of a mathematical model to synthesise relevant evidence from a range of sources in order to predict costs and health consequences associated with each decision alternative. Economic analysis is commonly referred as an aid to decision making, thereby recognising that other important considerations which are not captured in the economic evaluation inevitably impinge upon the decision making process. Examples of these other considerations may include ethical, legal and social implications (e.g. equity, patient convenience, innovation, etc).

However, in order that a sensible decision is made, there must be an assessment of feasibility alongside the assessment of cost-effectiveness. One possible representation of how assessments of feasibility are incorporated in economic evaluation is given in Table 1. The simplest form of CEA – which we term a naïve analysis (Column 2) - does not consider feasibility at all within the analysis; all comparators are appraised, then after the decision is made, feasibility issues are identified via aggregate data during the attempted implementation of the guidance. This can lead to lower than anticipated uptake, or the need further investment to assist implementation. A simple improvement to this is to assess feasibility when scoping the CEA through a deliberative/consultative process (Column 3). This will hopefully remove those treatment options that are not thought feasible from the analysis, but from that point onwards, the CEA and its implementation proceed as with the naïve approach. As a result, the same are possible, but perhaps, less likely to happen. A further improvement is made by adding a quantitative assessment of resource constraints at the aggregate level (which we more fully define later as resource modelling) to the previous deliberative approach (Column 4). This again, is expected to reduce the likelihood of recommending an infeasible option. In the extreme, it is possible in theory, to incorporate all national and local level constraints into a cost-effectiveness model and identify an optimal solution (Column 5). Such an optimisation approach will be extremely complex and data hungry, but is the only approach that ensures that constraints and cost-effectiveness are considered simultaneously.

. Undoubtedly, only the most naïve assessments will ignore an assessment of feasibility within the preliminary assessment of issues undertaken by the decision maker. This 'scoping stage' identifiesthe relevant patient population, the intervention, its comparators and its outcomes. However, not all scoping exercises will address broader issues of ethics, equity and barriers to implementation. Likewise, some assessment of barriers to implementation is present within most decisions, for example NICE TA guidelines identify constraints on local implementation as a possible issue to be raised within its appraisals [10]. However, such concerns tend to be considered subjectively within a deliberative process rather than via a formal quantitative analysis (Table 1).

In the absence of any formal assessment of the resource requirements for a technology to be implemented, it is possible that shortages of some resources are possible in the short run. Possible negative consequences of not identifying these resource shortages within the CEA include zero uptake, slow uptake and a technology being deemed not cost-effective once the additional costs required to increase uptake have been included in the CEA (Table 1). Whilst a rigorous scoping exercise could reduce the probability and severity of each of these negative consequences, they cannot be ruled out in advance of the CEA (which generates the estimates of future resource use contingent on the effectiveness of the comparator technologies).

Table 1: The assessment of feasibility and implementation within CEA

	'Naïve' CEA	CEA with deliberative examination of feasibility and implementation	CEA with resource modelling at an aggregate (national) level	CEA with resource modelling using individual organisational constraints
Within scoping	All comparators	All relevant and feasible comparators	All relevant and feasible comparators	All relevant and feasible comparators
Within the analysis	No assessment of feasibility and implementation	Subjective assessment of feasibility and implementation	Quantified assessment of feasibility and implementation issues (i.e. resource	Operational research to optimise implementation within single

		issues.	modelling).	organisation constraints.
After the decision	Informal assessment of feasibility during implementation at the multi-organisation level	Informal assessment of feasibility during implementation at the multi-organisation level	Formal assessment of feasibility and implementation at the single organisation level	-
Possible negative consequences	Chosen technology is unfeasible. Chosen technology is not cost-effective due to high implementation costs. Slow uptake due to resource shortages.	Chosen technology is unfeasible. Chosen technology is not cost-effective due to high costs of implementation. Slow uptake due to resource shortages.	Chosen technology is unfeasible in some organisations. Chosen technology is not cost-effective due to high costs of implementation in some organisations. Slow uptake due to resource shortages in some organisations.	Optimal technology may vary between organisations, depending on the nature of their constraints.

Alongside cost effectiveness models, budget impact models are also an aid to decision making. However, their principal purpose is to assess affordability rather than efficiency. The general aim of budget impact models is to estimate the financial consequences of an implementation profile across different organisations [11]. This may in itself highlight potential barriers to implementation, for example, due to shifts in income and costs between different organisations. Also, whilst reimbursement decisions may ask for evidence-based estimates of current and projected treatment rates, they are not typically the result of a formal analysis based on issues of capacity and constraints, but instead they are generated informally through a separate deliberative process with key opinion leaders.

Consequently, a budget impact analysis (BIA) may show cost changes that are considered affordable through either growth in budgets or disinvestments, but a technology could still be infeasible to implement if the relevant capacity requirements cannot be realised in the short-run. The identification of these capacity constraints and incorporation of these into the CEA scope and the BIA implementation profile is possible, yet such analysis is rarely undertaken. We argue that such issues should be considered as an explicit analysis; resource modelling.

3. What is resource modelling?

In this section, first we define “resource” and provide a classification of the different types of resources. We then argue why cost-effectiveness models and budget impact models, which are the two economic analyses that currently feed into HTA, do not adequately deal with the issue of implementation and feasibility. We then define and introduce resource modelling, which can be used to formally assess the issues of feasibility and implementation.

3.1 Resources types

Each episode of care requires a set of physical resources [12],[13] and the episode of care can range from a procedure (for example screening or diagnosis), a visit (for example outpatient, inpatient), all services related to a health condition (for example diabetes or heart failure) or all services related to a health outcome (myocardial infarction, deep-vein thrombosis, etc). The resources required can be broadly classified into two categories: a) single-use and b) re-usable (or multi-use) resources [14].

Single-use resources are items that can only be used once, like pharmaceuticals, assays for diagnostic tests and some equipment such as syringes, plasters, masks, etc. Re-usable resources, on the other hand, are those which are occupied for a given time period, but can be redeployed. Examples of re-usable resources include staff (e.g. general practitioners, doctors, nurses, consultants, laboratory technicians, and administrative personnel) and equipment (e.g. hospital beds, ICU, surgery theatre, ambulances, MRI scanners). It should be noted that some of the re-usable resources can be reused right away (e.g. hospital staff, x-ray machines, etc) but there might be a time delay before redeployment for others (e.g. re-using surgical theatres, redeploying mattresses after sterilisation, etc). It should be noted that even for resources that can be used right away, other constraints may exist that need to be considered (e.g. working hours for hospital staff i.e. day/night shifts, skill mix i.e. staff are deployable only for specific care/administration).

3.2 Resource modelling

For feasibility to be assessed, the time profile of uptake is required alongside an assessment of constraints. We therefore define resource modelling as *the quantitative assessment of technology diffusion curves, their related resource requirements and their capacity constraints*. Understanding whether capacity constraints can meet the resource demand is important in determining whether projected uptake is feasible. For depleting resources, it is important to understand whether there is enough capacity for the entire target population and if not, either deem the technology as infeasible or plan to have contingency plans in place (e.g. by placing additional orders) to address these shortages. For occupied resources, it is important to understand the fluctuation in the resource availability to estimate whether there is enough capacity to meet the rate of demand (e.g. arrival rate of patients) and their time of occupancy (e.g. length of stay in hospitalisation).

Economic evaluation only assesses resource requirements. BIA goes one step further by assessing the impact of diffusion; however, this tends to focus solely on budgets (not resources) and does not assess capacity constraints. The estimation of types and quantities of resources required for alternative technologies is integral to economic evaluation and BIA. These resource estimates are then valued using prices to generate costs, which in turn are summed into categories and summed further to produce a total estimated cost of adopting a given technology or service. Whilst the reporting of resource requirements is seen as good practice [9;15], it is not universally undertaken, especially in HTA reports where reporting standards are more varied than CEA in academic journals. Also, whilst some agencies aim to capture implementation issues and evidence-based estimates of current and projected treatment rates, these are not brought together in a formal analysis. By undertaking resource modelling in addition to the standard deliberative economic evaluation (columns 3 and 4 in Table 1), feasibility would be directly (and formally) assessed in the decision making process.

As highlighted in Table 1, there are two types of resource modelling within HTA depending on whether the constraints considered are aggregate (national) constraints or individual organisation constraints. If the HTA&R decision is made at the multi-organisation level, then the overall capacity constraints may hide considerable variation in organisation level constraints. Therefore, whilst the system may have sufficient capacity to provide for all patient treatments, individual providers may find it infeasible (assuming that costless patient transfers are not possible). In order to obviate possible failures of this kind, separate resource modelling activities may need to be undertaken in each individual provider organisation. This could be done through a series of organisational level analyses of the resource requirements and constraints of the national guidance. This could then be aggregated to produce a national assessment of feasibility of selected implementation levels at points in time. Alternatively, by parameterising the capacity constraints of the individual organisation into a national model, an optimal health maximising solution could be derived mathematically. It should be noted, however, that this optimal solution could result in different technologies being the most cost-effective in different organisations; different constraints can lead to different optimal solutions. We will highlight examples of both these types of resource modelling studies in Section 4.

4. Resource modelling examples

This section provides examples of studies that have performed resource modelling. Rather than presenting an exhaustive list of studies, the emphasis is on providing an overview of the different approaches that have been used for resource modelling. We have defined resource modelling as the entire process of quantifying technology diffusion, its related resource requirements and any capacity constraints, and few studies have undertaken all of the constituent parts. Whilst this will limit the ability to assess feasibility and implementation, the examples provided here show that the components parts of resource modelling are themselves feasible and useful.

The examples provided in this section are split into two parts. The first part provides examples of resource modelling that were performed at an aggregate (national) level alongside traditional economic evaluation methods such as CEA or BIA. The second part provides examples of resource modelling studies that were performed at an individual organisation level.

4.1 Examples of resource modelling at an aggregate (national) level

This section provides examples of studies that conducted resource modelling alongside economic evaluation at an aggregate (national) level. In particular, these studies reported the number of physical resources required for the intervention as well as a discussion around the resource constraints and the feasibility of the technology.

Sharp et al [16] have estimated annual health service resource requirements for population-based colorectal cancer screening programme in Ireland. They have developed a Markov model to estimate the costs and benefits and used intermediate outcomes predicted by this model to estimate the resources for the first ten years following screening implementation. The methodology used is similar to budget impact analysis and estimates the screening-related resources required (e.g. screening tests, diagnostic tests, etc.) and resources linked with health outcomes experienced (e.g. adenomas, bowel perforations). These estimates are summed for the ten years following screening implementation for the cohort, incorporating changes in patient demographics over time and lower cancer prevalence in later screening rounds. Their results suggested that whilst faecal immunochemical test (FIT)-based screening for everyone would be most effective, the heavy resource requirements might render it infeasible and a staggered age-based roll-out of FIT-based screening was deemed a better option within their current capacity constraints. The authors report that this screening approach has been implemented in Ireland, albeit in a slightly different patient population to that which they assessed.

Marshall et al [17] have developed a model to determine resource use implications, along with the associated costs and health benefits, of implementing the strategies reported in the guidelines for the prevention of cardiovascular disease in primary care. Resource implications were modelled as total nurse time assuming that all clinical tasks are carried out by practice nurses and looked at three scenarios assuming that the primary care team allocates one, two, or three clinics a month to the prevention of cardiovascular disease. Their analysis suggested that the resource implications of following the guidelines are substantial for relatively modest benefits and that the efficiency can be greatly enhanced by using alternative pathways.

Dixon et al [18] examined the resource consequences and costs of different strategies for reducing UK NHS reliance on allogeneic blood (2005). Their evaluation examined the impact of four different methods for reducing allogeneic blood use; better pre-operative assessment, preoperative autologous donation, intra-operative cell salvage and postoperative cell salvage. Whilst incremental costs were small, or even negative in some situations due to reductions in length of stay related to a reduction in adverse events, the feasibility of some of the proposals were called into question. In particular, capacity constraints within hospitals were identified as important; some analyses showed the need for 17,000 additional outpatient clinics and 460,000 autologous donation sessions. Whilst potentially affordable when multiplying these numbers up with unit costs, the capacity was simply not there.

Each of these examples have explored resource requirements explicitly and have been able to draw conclusions about the feasibility of implementation, however, only the study by Sharp has addressed all the components of resource modelling that we have set out; description of diffusion (or the roll-out of the programme with respect to time), description of the resource requirements and the identification of capacity constraints. Despite the shortcomings in the other studies, the value to decision makers of the analyses has clearly been enhanced by the explicit consideration of resources and constraints. However, these national level studies do not provide information about the feasibility in a given individual organisation, yet as highlighted in Table 1 that is the level at which constraints operate. A national evaluation of a new technology would need to model a few representative organisations (e.g. small, medium and large size hospitals, due to the expected differences in outcomes between these hospitals) or each individual organisation in the extreme scenario. Otherwise, these national constraints would imply that resources can be moved across the system instantaneously and without cost. Whilst it may be possible to adjust parameters of the model to reflect different settings in certain cases, bespoke resource modelling activities may need to be undertaken for the individual provider organisation and examples of such studies are provided in the next section.

4.2 Examples of resource modelling at individual organisational level

These studies are typically found in the field of healthcare operational research (OR), with discrete event simulation (DES) and system dynamics (SD) the most commonly used OR techniques for resource modelling. SD is a cohort modelling approach utilising *stocks* (collection of resources e.g. hospital staff, scanners, beds, etc) that can accumulate or deplete over time based on *flows,* rate of change in *stock* (measured per unit of time e.g. hospital staff per day, scanners per hour, beds per minute, etc). DES, on the other hand, is an individual level modelling approach using *entities, attributes, events* and *resources. Entities* are individual objects (e.g. patients) with *attributes* (e.g. age, gender, etc) that experience a sequence of *events* (e.g. hospitalisation, myocardial infarction, etc). *Resources* are objects (e.g. doctors, beds, etc) that provide services to *entities* and can result in time delays due to queuing (e.g., if a health resource is not available at a given time).

Both DES and SD methods can provide estimates of resource use and availability over time, which are useful in understanding the capacity issues to ascertain the feasibility of a given service setting. SD methods model the behaviour of complex systems at a cohort level and are typically used at a strategic level as they provide a high level overview of the system. DES models, on the other hand, usually tend to be detailed operational models of the system as they use individual entities and provide detailed outputs such as waiting time, resource availability, etc over time. In particular, DES models allow explicit incorporation of resource constraints (which may result in delays if the resources are not available). It should be noted that both these techniques are being increasingly used for health technology assessment [19-21].

Brailsford et al [22] used SD for a whole-system review of emergency and on-demand health care in Nottingham, England in order to simulate patient flows and to identify system bottle-necks for resources. They used a stock-flow modelling approach, where stocks represented accumulations of patients (e.g, waiting to see a GP, waiting for treatment in A&E, or occupying a bed in an acute admission ward) and the flows were the admission, transfer, treatment and discharge rates. The contents of each stock were updated at regular intervals (time step of 0.1 days) by solving a set of differential equations representing the inflows and outflows from that stock. The outputs included the throughput and the occupancy rates of each of the wards and hospital departments. The authors concluded that the system is currently operating dangerously close to capacity and if the demand were to increase, the hospitals are unlikely to reach elective admission targets -thus recommended increasing the care options available in the community to alleviate these problems.

Similarly, Taylor et al [23] have also modelled the feedback effects of reconfiguring cardiac catheterisation services in the U.K using SD and identified measures that need to be put in place to balance supply and demand. Stein et al [14] have used SD to develop a resource modelling tool that can support public health officials in understanding and preparing for surges in resource demand during influenza pandemics. Hirsch et al [24] also used SD modelling to plan programs for the prevention and treatment of cardiovascular disease in El-Paso County in the US to make the best use of its limited resources. Similarly, Homer et al [25] also used SD modelling for resource planning of care for diabetes and heart failure in the Whatcom county of Washington State in the US.

DES has also been used for informing the planning of a wide range of services, either the setup of a new service or to inform service reconfiguration, by capturing system effects such as overall resource utilisation [26]. For example, queuing theory and simulation modelling techniques were also applied to model the bed and ICU use for hospital planning [27-30]. Similarly, DES has also been used to plan renal services in a health district level as well as national level [31;32], to plan NHS walk-in centres and Accident and Emergency departments in the UK [27]. More recently, DES techniques have also been used as a vehicle for cost-effectiveness modelling to include an explicit incorporation of resource use and service impacts [33].

Jahn et al [34] showed in a case example for cost effectiveness of drug-eluting stents that neglected limited capacities can cause wrong results. They developed a DES model where resources capacities and dynamic waiting lines were explicitly modelled. .. Cost-effectiveness, utilization, waiting time, and budgetary impact of alternative treatment scenarios were analyzed under the assumption of limited and unlimited resource capacities. In the analyses, the new drug-eluting stents led to less reocclusions and therefore less repeated stentings than the comparator. As a consequence, stenting resources were set free and became available for other patients, which resulted in lower waiting times and increased health benefits. In summary, some treatment scenarios that were cost effective in the unlimited analysis became dominated when the number of stent placements per day was limited. By quantifying the constraints and incorporating them mathematically within the appraisal, these studies are, in principle, able to make the issue of feasibility redundant; the solution is optimal given the constraints. Only when some constraints are not included, will an additional assessment of feasibility be needed.

5. Issues to consider

As seen in Section 4, resource modelling can be performed using a number of different approaches. However, there are several issues that need to be considered when choosing the appropriate resource modelling methodology and these will be presented in this section. The first question is whether resource modelling is necessary i.e. when it should be used. If so, the next question is about the choice of methodology. A related question is whether a standard exercise is enough for the whole jurisdiction or whether bespoke evaluations need to be performed for different local settings in the jurisdiction. Finally, the choice of data is also linked to the type of methodology chosen for resource modelling with certain sources of data more appropriate for certain decision problems.

5.1 Is it always necessary?

It should be noted that resource modelling might not always be necessary. For example, if the new technology is a drug B replacing the current technology drug A, with identical administration methods and the same effectiveness profile, it could be argued that there is no need for resource modelling as there are no additional resource use implications in using the new technology. However, even small increases in the amount or type of resource can have profound implications for uptake and broader system dynamics if resources are severely constrained. We can only be completely certain whether constraints are relevant, and resource modelling necessary, once the resource modelling is complete (even if assuming certainty in data and model structure). Consequently, identifying when resource modelling is required, and at what level, includes an element of subjectivity. However, we feel that five circumstances can be specified that increase the likelihood of resource modelling being of greater value.

Firstly, when a new technology might result in need for significant additional resources compared to current situation. All other things being equal, large changes in resource use will move a system closer to a constraint.

Typically, this is relevant for acquiring new equipment or facilities, performing new (or additional) procedures such as screening tests, surgery, etc or significant restructuring of the current pathways.

Secondly, when the new technology is reliant on occupied resources. Changes to the availability of occupied resources tend to be more difficult to produce than the procurement of additional depleting resources. Such changes will typically require factor substitution either within the target patient group or elsewhere in the system to free up the necessary occupied resources. Alternatively, increased availability of staff resources can sometimes be achieved through overtime payments, which will feedback into changes in the cost-effectiveness of the new technology.

Thirdly, when the occupied resources related to the new technology are specialised. In such circumstances, the degree of substitution between the specialised and other factors of production is extremely limited. For example, clinical assessment of a patient with neuropathic pain may be feasible, but multi-disciplinary pain team assessment may not be feasible. Another example of this is when services are provided at specialist centres, such as regional referral centres.

Fourthly, and most obviously, when specific resources are known to be in short supply. In such circumstances, it does not take much of a change for the constraints to impact on implementation.

Fifth, when the new technology has a positive effect on already existing queues (e.g. a faster medical device, less repeated interventions). New technologies that require fewer resources can lead to a decrease in waiting time of other patients and this can have a substantial impact on cost-effectiveness. Whether this positive effect will become apparent to its full extend depends on the framework of the model (e.g. considered patient population, time horizon etc).

Thus, the choice of whether resource modelling is useful depends upon the amount and type of additional resources and the relevance of the constraints to the changes in scale.

5.2 Is it generalisable?

There are a number of factors that make the results of a resource modelling study difficult to be generalisable to other settings/jurisdictions. This issue of transferability is not limited to resource modelling and has been identified as a significant barrier in HTA [35-39]. The applicability of resource modelling results to a given setting depends on the degree of variation between the settings in terms of diffusion, resource use and their associated constraints.

The resource use and the constraints for the same service might vary across different jurisdictions and even different organisations in the same jurisdiction, which could lead to different results in different settings. For example, in a study by Thokala et al [40], the resource use depended on how the discharge decision is made after a diagnostic test. In some settings, the doctor is available on demand to make the decision about discharging the patient as soon as a diagnostic test result is available where as in other settings the patients have to wait till the doctor ward rounds (which are either once or twice per day). This has an impact on the resource use and thus, the results from one setting may not be applicable to another setting. Similarly, the amount of resource use depends on the number of patients passing through the system and these may vary across setting and over time (diffusion dynamics). The rate of resource use may not have a linear relationship with the number of patients and thus there may be a need to model different scenarios.

Dynamic factors in user skill over time might also make the estimation of resource modelling particularly challenging (and difficult to generalise). This relates to the change in aptitude of the hospital staff, and even patients, in performing a task (e.g. an MRI scan, a surgery, etc) over time, which can vary at different rates across settings [41]. Moreover, there might even be baseline differences in user skill between different personnel which results in a dynamic element to resource use (e.g. due to complications following laparoscopic surgery) that depends on the user's current position on a hypothetical learning curve. The impact of these issues on resource use has been recognised [42;43] and may need to be considered when performing resource modelling.

5.3 Should it be at an individual organisational level?

The question of the level of detail required relates to whether the resource modelling should be at the aggregate/national level or whether it should be at a local organisation level. In its simplest form, resource modelling can be done alongside an economic evaluation or BIA at national level. This can be achieved by using intermediate outputs of the model to estimate the resource requirements (e.g. number of surgeries required per year from approval). Once all the relevant resource requirements have been estimated, it would be useful to have them in the form of a tabulated list of resources for decision makers to understand the feasibility at the national level. Whilst this exercise can provide an estimate of the overall resources required, it does not provide insight into the capacity constraint issues i.e. it cannot inform when or if the resource requirements exceed the capacity constraints of the individual organisations.

Therefore, we suggest the following approach: First, one should identify the main physical resources that are required for the implementation of the new technology and interdependencies need to be assigned (e.g. a bundle of resources that are required at the same time). Second, the resources should be classified depending on potential scarcity on national, regional, individual organization level (and potential interchangeability). Third, depending on the required perspective of analysis (societal, health care insurer, etc) and the level of potential scarcities the level of the analysis and the modelling approach should be determined.

There are two broad methods to deal with the local level variations a) to build flexible user-friendly models at the national level which can be adapted to local circumstances [44] or b) develop bespoke models for the organisation under consideration. Developing flexible models at the national level is a significant undertaking and it still might not cover all the different service settings [36;38]. Bespoke modelling at the local level, also increasingly being referred as 'hospital based HTA' [45-48], requires health economics expertise in the local organisation which may not be readily available. The advantage of bespoke modelling is that local level data can be used which provides confidence that the results obtained are relevant to the organisation under consideration [49]. Indeed, the impact of hospital based HTA in promoting effective use of budgets has been acknowledged [45;46].

Recently, so called hybrid modelling approaches have been applied. They allow for modelling specific parts of the health care system at different levels (e.g. individual patient level analysis applying discrete event simulation in combination with a system dynamics approach that facilitates the whole systems [50-52].Whilst in theory, a national decision maker could commission work to look at constraints and implementation in all provider organisations, except in the most centralised health care systems, this would move them into operational issues over which they have not control or authority. As such, we see a national decision maker only making recommendations over the need for national analyses, and in light of these, recommending further organisational level analyses be undertaken by the individual organisations themselves. It should be noted, however, that separate to this process, individual organisations may still undertake their own resource modelling, as many do already.

5.4 What data is needed?

Resource modelling will increase the data requirements for analysts and decision makers. A cursory examination of the proposed definition of resource modelling – the quantitative assessment of technology diffusion curves, their related resource requirements and their capacity constraints – highlights the need for data on diffusion and constraints, in addition to resource data. These two additional components can be quite complex as they require time-varying estimates over the decision making time horizon.

However, a commitment to undertake resource modelling could impose additional data requirements on the cost-effectiveness analysis on which it is based, as resource measurement needs to align to the relevant constraints, not to convenient unit costs (or prices). So, for example, a national unit cost may be readily available for a hospital clinic attendance, but this unit of resource (the clinic attendance) is actually comprised of several more specific resources such as doctor time, nurse time, clerical time, space and diagnostic services. Knowing whether there is a constraint on clinic attendances is difficult to assess unless each component is considered, and as such, estimates of how much of each are required need to be collected. From a technical point, it should be noted that for example, in DES models a bundle of resources that are required for a specific service can be defined. Hence, even if only one of these resources is not available then the service is delayed until all resources of the bundle are available i.e. interdependencies between resources can be modelled (e.g. a hospital can have a large capacity of beds, but without staff the patient cannot be treated). Furthermore, for resources with multiple uses (e.g. MRI scanners), the resource use not related to the modeled intervention may also need to be taken into account. In addition, availability of resources need to be defined upfront such as working hours of staff or availability during the day, maintenance periods or the probability of a failure of a medical device.

As a consequence of this, unit costs from national tariffs may need to be replaced, or supplemented, by detailed costings. Where patient billing systems are already in place, this may be quite straightforward. However, in many instances, it may require the development of micro-costing studies. In most situations, this level of detail on resource use may not be available (and will certainly differ between settings), the lack of the data is a challenge for resource modelling. However, accurate resource-use measurement has been identified as a challenge within an economic evaluation [53] and methodologies are under development to methods to improve the precision and accuracy of resource-use estimates [54;55].

6. Conclusions

HTA uses several tools to assist decision makers make recommendations about use of new technologies. Two economic tools – cost-effectiveness analysis and budget impact analysis – are widely used to assess efficiency and affordability. Issues of implementation and feasibility are typically captured qualitatively within the decision making process. However, only a formal, quantitative assessment of diffusion, resource use and resource constraints can fully address issues of feasibility. Analyses that do not consider these issues run the risk of recommending technologies that cannot be delivered within the expected time-frame, or which require higher than expected costs to ensure delivery thereby reducing the cost-effectiveness of the recommendation.

Resource modelling, defined as the quantitative assessment of technology diffusion curves, their related resource requirements and their capacity constraints, should be considered when undertaking a HTA. The value of resource modelling should be assessed within the context of the decision making process and the nature of the constraints as identified within the project scoping. Simple or rapid processes may preclude formal resource modelling. Alternatively, a small set of depleting constraints may be readily replenished through a coordinated procurement process informed by resource modelling, instead of piecemeal requests to suppliers from a myriad of health care organisations reacting to national guidance.

The results of resource modelling should be used to inform decisions as to the feasibility of different options/technologies. Those options/technologies that are considered unfeasible should be removed from the incremental analysis within the CEA. The diffusion curve generated for the resource modelling, and the associated implementation costs, should be used within any associated BIA.

Whilst national level resource modelling exercises offer many advantages when assessing the implementation and feasibility, the accurate quantification of constraints is only practicable at the organisational level. Further research should examine the potential use of operational research techniques in the assessments of cost-effectiveness and feasibility.

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