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Paper: Anderson, P., Webb, P. & Groves, S. (2017). Prioritisation of specialist health care services; not NICE, not each be done. <i>Health Policy, 121</i> (9), 978-985. http://dx.doi.org/10.1016/j.healthpol.2017.06.007	sy but i

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Title

Prioritisation of Specialist Health Care Services; Not NICE, Not Easy But it Can Be Done

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Acknowledgements

The authors acknowledge the contribution of Dr Geoffrey Carroll who was at the time of the development and delivery of the prioritisation panels, the Medical Director of Welsh Health Specialised Services Committee. His wisdom and guiding hand in the process was ever present and much appreciated.

Research highlights

• Implementing robust prioritisation methods with limited resources can be accomplished.

• Complex decisions supported by limited evidence require an adaptive approach to be

successful.

- Simple methods to facilitate multi-criteria decision analysis can be implemented
- Group decision support using technical aids improves the decision process.
- Implementation of decisions based on recommendations remains a challenge.

Abstract 250

The challenges of delivering healthcare within budget constraints are ever present. Highly specialised technologies (HSTs) with relatively high costs of provision inevitably contribute to NHS cost pressures. In 2012 he Welsh Health Specialised Services Committee (WHSSC) developed prioritisation methods to determine which HSTs recommendations for use in Wales. Methods adapted as the process continued but was always evidence based and supported by a prioritisation panel of stakeholders. Methods changed from discreet choice to the Portsmouth Score Card, a simple multi-criteria decision analysis (MCDA) method. This was latterly augmented by group decision support techniques MCDA makes explicit the impact on a decision of relevant criteria and their relative importance: a strength of the method. The prioritisation panel had an intense workload and reviewed on average eight HST condition treatment pairs in each panel meeting, covering 133 HSTs over the 3 years reviewed. Available evidence, information and value judgements were used to make decisions. Importantly, the WHSSC framework identifies investment, disinvestment and recommendations transparently. The 'real-world' need for timely decisions was met, in the absence of NICE guidance on HSTs (which initiated in 2013, covering only covers drugs). Using these methods robust and timely prioritisation recommendation for HSTs were accomplished, without extensive resources such as available to NICE. In mid-2015 the prioritisation process was benchmarked against the EVIDEM framework, identifying areas for improvement and areas of best practice. This revealed a need for greater public and patient engagement. Some implementation issues for decisions based on panel recommendations were still to be resolved.

Research highlights

- Implementing robust prioritisation methods with limited resources can be accomplished.
- Complex decisions supported by limited evidence require an adaptive approach to be successful.
- Simple methods to facilitate multi-criteria decision analysis can be implemented
- Group decision support using technical aids improves the decision process.
- Implementation of decisions based on recommendations remains a challenge.

Keywords

Prioritisation, resource allocation, disinvestment, highly specialised technologies, MCDA

BACKGROUND

Highly specialised medical technologies (HSTs) are revolutionising the management and treatment of patients in the United Kingdom and elsewhere. In the UK HSTs are provided in relatively few hospitals with catchment populations of more than one million people and are services that are currently nationally commissioned (e.g. heart and lung transplantation). In general, these services can be relatively expensive to provide and some may be described as high cost/low volume services (1). Conditions in this category usually affect fewer than 500 people across England and Wales, or involve services where fewer than 500 highly specialised procedures are undertaken each year (1). There are 143 specialised services defined in the NHS England Manual of Prescribed Specialised Services (2) of which 75 HSTs were commissioned in Wales in 2014(3). HSTs are usually at the cutting edge of clinical research and include innovative areas such as regenerative medicine proton beam therapy and the management of rare diseases with ultra-orphan status.(1). HSTs are driving up costs of health care (4, 5). HSTs/specialised procedures account for approximately 10% of the total NHS budget and cost about £11.8 billion per annum(6) and the rate of increase in spend is expected to be substantial, not only driven by changing population demographics buy the pace of innovation in medical technologies. For example, stem cell research and regenerative medicine are thriving areas of research with breakthrough discoveries and advances in the field having accelerated translation of stem cell biology into therapies. (7).

Health care budgets in the UK and elsewhere are under strain and the challenges of delivering healthcare within budget constraints are not going away (8) (9). Between 2009/10 and 2012/13 Wales was the only UK country where health spending was cut in real terms by 4.3% (10). This means that priorities for health care provision have to be identified and decisions made about how much will be provided and to whom. These challenges are not new as suggested by Ham "*Priority*"

setting is not amenable to once and for all solutions and the issues involved must be kept under continuous review". (11)

An important issue for NHS decision makers and the people of Wales (and elsewhere) to consider more explicitly, when addressing the demand for increased spending on HSTs, is the opportunity cost the NHS faces when any health benefits associated with HSTs is offset against the health benefits that may be forgone elsewhere in the NHS when funding is allocated to HSTs.

A report from the Bevan Commission published in 2013, based on prior research and engagement with the Welsh NHS was in response to the need for the NHS in Wales to address the pressures on health care and make changes, sets out the key issues and actions needed to address the resource issues while also improving the health of the population of Wales(12). One of the recommendations from this report was that:

"We should only spend money on things that work, focusing upon a smaller number of areas with greater impact and outcomes(12)"

and that Prudent Healthcare is defined as:

"By Prudent Healthcare we mean healthcare which is conceived, managed and delivered in a cautious and wise way characterised by forethought, vigilance and careful budgeting which achieves tangible benefits and quality outcomes for patients." (12)

The 'Prudent Healthcare' initiative arising from these recommendations commenced in Wales in 2014 (13). The initiative was not intended solely as a means of delivering service reductions to address budget pressures, but also as a means to improve patient care and outcomes. 'Prudent healthcare' was designed to be a way of reshaping the NHS in Wales. Prudent Healthcare is "Healthcare that fits the needs and circumstances of patients and actively avoids wasteful care that is not to the patient's benefit." (12, 13) The four principles for Prudent Healthcare established by The Bevan Commission are:

- Achieve health and wellbeing with the public, patients and professionals as equal partners through co-production;
- Care for those with the greatest health need first, making the most effective use of all skills and resources;
- 3. Do only what is needed, no more, no less; and do no harm;
- Reduce inappropriate variation using evidence-based practices consistently and transparently.

In the context of this emerging initiative, embracing robust priority setting and resource allocation was critical. However, priority-setting is by no means a clear-cut 'science', in part because it involves values as well as evidence. People who are responsible for resources whether they be financial or time related, have to make prioritisation decisions. They have to allocate new resources, either reallocate existing resources, which may have been subject to a reduction from previous levels or even, disinvest. In addition to evidence informing decisions, judgement is required, which requires both technical skills to appraise the strength of evidence, and ethical insights. The ethical consideration is very important; funding an intervention whether or not it is considered to be of high priority, means funding for something else will not be occur. Prioritisation decisions therefore are technical, ethical and social, in that all patients, communities and population groups will be affected to some degree.

Daniels and Sabin suggest that people involved in prioritisation decisions may fear they will be held to account for the harm that might result from making healthcare resource allocation decisions and/or be faced with public and political pressure. Daniels and Sabin, in their proposals for good decision making, have emphasised, what they will be held to account for is the *reasonableness* of their decisions as defined below (14, 15):

"Accountability for reasonableness is the idea that the reasons or rationales for important limitsetting decisions should be publicly available. In addition, these reasons must be ones that 'fairminded' people can agree are relevant to pursuing appropriate patient care under necessary resource constraints. This is our central thesis, and it needs some explanation. By 'fair-minded', we do not simply mean our friends or people who just happen to agree with us. We mean people who in principle seek to cooperate with others on terms they can justify to each other. Indeed, fair-minded people accept rules of the game – or sometimes seek rule changes – that promote the game's essential skills and the excitement their use produces." (14, 15)

The accountability for reasonableness framework consists of four conditions: relevance, publicity, appeals/opportunity for revision, and regulation or enforcement (14,15). Relevance means that decision makers should provide a reasonable explanation of how they seek to meet the varied healthcare needs of a defined population within available resources. Publicity requires that decisions are and the rationales for priority-setting decisions be made publically accessible and open to scrutiny. The appeals/revision condition requires a mechanism that provides stakeholders with an opportunity to challenge and revise decisions.

THE WELSH CONTEXT

The setting for this research is Wales, one of the four UK countries. Wales has a tax funded health care system where, unlike England, there is no purchaser-provider split, services being provided by seven local Health Boards (LHBs) and two NHS trusts, from a unified budget with commissioning existing as a function rather than as explicit commissioning organisations as in England.

The Welsh Health Specialised Services Committee (WHSSC) is a committee representing the trusts and LHBs in Wales. The LHBs are responsible for meeting the health needs of their resident population and delegate the responsibility for commissioning a range of specialised and tertiary services to WHSSC. In 2011 WHSSC estimated an increase in demand for specialised services, simply based on the changing demographics of the Welsh population, of between 3% and 5% over the subsequent ten years pushing demand and costs of HSTs up further (3). Thus in the emerging context of Prudent Healthcare, emerging innovations and demand pressures on healthcare in Wales,

developing and implementing robust methods for resource allocation and prioritisation were critical for the future of the Welsh NHS. Yet more challenging in this context for WHSSC, was making decisions about HSTs, given the interventions and patient populations, which are relatively small, robust evidence being often sparse and the costs of the intervention threatening budgets or even being unaffordable.

In this context, WHSSC developed an evidence evaluation and prioritisation framework, to support decisions about funding and recommending HSTs in Wales. The frame work was to be evidence based, transparent and robust, and when published in 2014 (13), in line with Prudent Healthcare principles. However there was no additional budget to undertake this initiative so this framework and process was developed and delivered within existing resources and with the support of a university based health economist.

The methods for HST prioritisation were intended by WHSSC to meet the following objectives;

- To understand the epidemiology and health needs related to the HSTs;
- To consider evidence for clinical and cost effectiveness;
- To develop transparent methods and reporting;
- To pilot the methods on a range of specialised and non-specialised services to examine whether the method can be applied to the range of funding requests received for consideration by WHSSC;
- To confirm the preferred prioritisation method in order to make comparisons between the specialised (and other) services in a report to the Joint Committee of WHSSC;
- To identify key areas of the process that would need to be further developed, including methods, techniques for evaluation and impact assessment.

To meet their commitment to these objectives, between 2012-13 WHSSC developed an initial trial prioritisation process for HSTs. The methods used by WHSSC were intended to be adaptive – the prioritisation project team had a commitment to learn from the process and take account the

feedback from panel members as they reviewed evidence and made their deliberations. The methods were reviewed as each round (4-6 consecutive meetings) of prioritisation was undertaken and then reviewed and reflected upon and refinement of methods made. This paper reports on the experience of the process and outcomes; how the process and method evolved and changed in the light of experience, issues of implementation and finally reports the outcomes of prioritisation recommendations.

THE PROCESS

In early 2013, WHSSC convened the first Prioritisation Panel with a timelines to ensure, ideally, that the recommendations and subsequent Joint Committee decisions linked to both the LHBs and Trusts upcoming Annual Plans and the development of subsequent three year plans. These timelines meant that the meetings had to make clear recommendations after each round.

The Prioritisation Panel as initially convened represented a wide range of experts and stakeholders (including public health, LHBs, academic partners, health economists, patient representatives, citizens, specialised services, commissioners, clinicians). A scoping exercise was undertaken with WHSSC staff and Clinical Effectiveness and Evaluation Groups in Wales to horizon scan HSTs for use in Wales based on the following critera:

- High cost individual care;
- New HST, or services;
- Growth in existing services that exceeded an incremental cost of £50,000 or where material resources would need to be incrementally allocated;
- Areas identified as requiring evidence review because of uncertainty about evidence or ability to benefit;
- Implementation of new standards requiring resources.

Some of the HSTs were in current use whilst others were under consideration for use in Wales. The two categories provided different challenges for the Prioritisation Panel given that a negative decision for an HST in current use would require disinvestment. Needs assessment and evidence evaluation were undertaken in conjunction with the Evidence team at WHSSC and Observatory function in Public Health Wales (PHW), and included (as far as the data available allowed) a detailed assessment of epidemiology, literature searches and equality impact assessments, using previously agreed and validated methods through PHW. For example: the epidemiology data was that which was routinely provided by PHW, readily available in Wales and/or to be found in the literature, and estimated for Wales. The literature searching was comprehensive and searches used best practice methods, but were not systematic reviews in the technical sense (that would have reduced the amount of information available to the Prioritisation Panel) and the assessment of evidence used GRADE methods¹.

Adhering to the principles of 'Accountability for Reasonableness' (14, 15) was considered, by consensus, to be the appropriate framework for deliberation of prioritisation recommendations and Joint Committee decisions.

In the first phase of methods development for the prioritisation process, Condition-HST pairs were created for the interventions meeting the criteria, evidence reviews were then undertaken, these paying attention to the current treatments/management strategies for patients without the HST under consideration and evidence of effectiveness and cost effectiveness (where available).

Discreet choice methods were then used to rank order and apply a cut off point for commissioning or not. Attributes relevant to the work programme for HSTs were assigned levels, consistent with the approached described by Mangham and colleagues(16). Defining the attributes required a good understanding of the target audience's perspective and experience and was based on pilot data previously developed by WHSSC staff based on an expert panel of health care physicians, health care

¹ http://www.gradeworkinggroup.org/

managers, public health and patient groups. Policy concerns also helped shape the choice of attributes. The discussions were facilitated by the Medical Director and an independent consultant in Public Health and were tape recorded, transcribed, translated and supplemented by detailed written notes. Once the attributes were established, attribute levels were assigned. Typically these levels reflected the range of situations that respondents might expect to experience. Ensuring the levels were realistic and meaningful increased the precision of parameter estimates.

Whilst all the HST condition treatment pairs were reviewed by the Prioritisation Panels were supported by an evidence review; some meetings had clinical representation at the meeting (all meetings invited an appropriate clinician, though not all had a positive response to the invitation). Detailed discussion of the intervention and querying the data were regular features of the meetings. In 2014/15 a change to the process moved from discreet choice methods to MCDA based methods using the Portsmouth Scorecard (17) which was felt to better support the prioritisation task and reduce complexity (the panel found the discreet choice methods taxing and time consuming). The benefit of using the Portsmouth Scorecard was that it enabled explicit weighting of key criteria for panel decisions. The list of criteria were developed, in light of the panel meetings and decisions made, from the original longer list used for the discreet choice exercises. The Prioritisation Panel developed the relative criteria weightings in a meeting dedicated to this task. The final version of the Portsmouth Scorecard had five criteria each of which were weighted with the specific context of resource allocation and prioritisation of HSTs in mind (Box 1). Selecting, defining and weighting the criteria went through a number of iterations before the five criteria were agreed. The final criteria and weights are shown in Box 1. The differing HSTs were scored against the criteria with a resulting continuum of priority weights being complied (Figure 1 shows an example) at the end of the rounds of meetings.

In the last rounds of prioritisation panel meetings in mid to late 2015, group decision support methods were integrated into the process to assist the members and improve the use of time in

meetings. Group decision support methods were supported by an expert in the methods, who joined the team, facilitated decision-making at various stages during the meetings and enabled the prioritisation process. This method employed a voting system using TurningPoint™ software and a set of wireless handsets to enable parallel, simultaneous and anonymous individual inputs, generating a group outcome that can be accessed and displayed in various ways at the meeting or later(18). Research into specific features of this form of group decision support has reported gains in meeting efficiency (19), improved levels of participation and a reduction in potentially negative influences from dominant members of the group (20) and thus seemed a beneficial approach to facilitate the panel recommendations.

The refinement of the process and use of the Portsmouth Scorecard in the later panel meetings allowed criteria to be weighted and feedback suggested that this supported more confident decisions.

Through the process the Prioritisation Panel was required to make judgements: scientific value judgements about interpreting the quality and significance of the evidence available and social value judgements. These judgements were made under the principles of accountability for reasonableness (14) as initially agreed at the start of the process plus agreement by the panel to have respect for autonomy, non-maleficence, beneficence and distributive justice.

Despite the constraints experienced, decisions on investment and disinvestment were made, a prioritisation and commissioning list, recommendations were created and specific HSTs identified for commissioning, non-adoption and decommissioning at the end of the last panel meeting in 2015.

The use of the Portsmouth Scorecard and availability of scores representing an overall 'health value' of an HST to be created (in the absence of cost effectiveness data) and relative value to be identified. Creating a bubble diagram enabled graphical representation of the overall scores for differing HSTs which was very useful to support the panel members' final recommendations. Figure 2 is an example of a bubble diagram used in the later meetings. With the knowledge of the prior scoring for

meeting rounds (an example is shown in Figure 1) using group decision support methods, the panel could make a final decision made as to whether the condition treatment pair should be funded by NHS Wales. Examples of this final voting are shown in Figure 3. Examples of this final voting are shown in Figure 4 which illustrate different panel votes for three HSTs. HST1 had a split vote, which led to some discussion but the 'no' was sufficiently strong to carry the recommendation of 'no funding'. HST2 had two indications - the difference between the votes was driven by the original scores in the ranking and the burden and severity of the health problem. The stronger yes in the paediatric intervention was because in children the problem is more severe and life threatening.

OUTCOMES OF THE PRIORITISATION PROCESS

The disease areas, types of technology, and number of condition treatment pairs and results of panel decisions are summarised in Table 1. Throughout the whole prioritisation programme, through in the various phases, 133 condition treatment pairs were evaluated. Of those, the majority were in the cancer area. These were not all drugs but HSTs such as genetic testing and HSTs for unresectable cancers. Other HSTs evaluated ranged from trans-aortic valve implantation for severe symptomatic aortic stenosis in high-risk patients, to left ventricular assist devices as a bridge to transplant and other indications, to ultra-orphan drugs to LVA microsurgery for lymphoedema.

Most deliberations resulted in a decision and recommendation - only 3% (n=4) were 'undecided'.

The 'undecideds' arose in the period before 2104 where discreet choice methods were used. Of the 'not recommended' decisions 15% (n=10) were reversed for a variety of reasons, including political imperatives, funding for equipment and infrastructure provided assuming a 'yes' would been the recommendation ahead of the decision, which in the event being a 'no'.

Of the recommendations made at the time of writing, 50% had not moved to implementation — which was out of the Prioritisation Panel hands. Panel members found this somewhat frustrating. Reasons for non-implementation, apart from the most recent decisions which had not had time to progress, included; the resource required (e.g. staff, equipment, estate) to implement not (yet)

being available and organisational challenges created about movement of services and resources across LHBs to consolidate or centralise the provision of service. One recommendation not to fund was overturned at government level.

ISSUES OF IMPLEMENTATION ENCOUNTERED

An early learning from the prioritisation process was that, if there were multiple indications or populations, for which an HST was an option, a split into each indication/population was needed and each specific indication should be considered separately. This 'unpicking' resulted in 58 separate decisions being made under the 'cancer' category (table X).

The desire for rapid evidence assessment and policy development conflicted with the desire for policy based on robust evidence and subject to appropriate clinical consultation, which was not always available. Timeliness of decisions was key, as there is an imperative to make appropriate arrangements for policy to be developed at the time without compromising quality. This meant that the prioritisation process was 'pragmatic' and making a recommendation was essential. The discreet choice methods did not always enable clear recommendations where the Portsmouth Score card did.

Overall, the common experience for the Prioritisation Panel was the lack of evidence and or variability of evidence, supporting the condition treatment pairs to guide confident decision making. Extended appraisal and modelling to fill in evidence gaps (as undertaken by NICE in technology appriasals) was just not possible

The practical limitations for the administration of the panel were recruiting and retaining representative stakeholders to the prioritisation panel and getting people to keep up attendance, as, with busy working lives, taking a day out for the meetings on a regular basis was difficult. Enabling and sustaining patient and public participation was a continual challenge. The setting and discussion can be quite daunting for most 'lay' participants. The absence of regular and committed

representation of was not for want of the project team at WHSSC trying to engage with the representative bodies. In mid-2015 the prioritisation process was benchmarked against the EVIDEM framework (21) which, as a comprehensive evidence based framework created by a multi country and a multidisciplinary initiative that was accessible appeared to be a good standard by which to judge the WHSSC process. Whilst the process was robust and best practice was adhered to, an important area for improvement was public and patient involvement being the major area of concern.

REFLECTIONS ON THE PROCESS

The process of making resource allocation decisions is complex, with many factors listed by EVIDEM (22) that need to be taken into account. The decisions that WHSSC were faced with in their priority setting exercises are perhaps more challenging than most given relatively scarce data, the decisions about funding HSTs having significant budget and human impact and potential public interest and media challenges.

HSTs approved for funding by WHSSC have significant opportunity cost; that is the financial and NHS resources consumed by providing these HSTs mean that other interventions are not available to other NHS patients. Claxton and colleagues (23) illustrate this concept in their paper, estimating the impact of providing new interventions which impose additional costs on the NHS. The authors emphasise that the resources required to deliver these interventions must be found by disinvesting from other interventions and services elsewhere. This displacement will inevitably result in health decrements for other individuals. Whilst the WHSSC prioritisation framework identifies both potential investment (high scores) and recommendations not to fund (any more) that are clear and transparent, the process does not always suggest what service or interventions have to be reduced to make funds available for the HST as often the alternatives for the HST patients are best supportive care or palliative care.

The WHSSC process does not completely meet the accountability for reasonableness framework (14,15). The conditions of relevance, publicity, appeals/opportunity for revision are adhered to, but regulation/enforcement still prove challenging for the reasons previously mentioned.

Reflecting on the process described here, it is some way away from the rigorous HST appraisal process undertaken by NICE for drugs (24) but the criteria used for decision making align well with the EVIDEM framework which was the chosen benchmark. Using the Portsmouth Scorecard, a simple MCDA method, which makes explicit the impact on the decision of all the criteria applied and the relative importance attached to them, plus group decision support, improved the process and allowed the panel to review and progress around eight condition treatment pairs in one six hour panel meeting. In the 'real world' of the LHBs, with a need for timely decisions and, in the absence the NICE guidance, we have demonstrated that robust and timely prioritisation decisions in the challenging area of HSTs can be accomplished.

The processes developed over time by WHSSC adhered to good practice, as described by the EVIDEM framework and accountability for reasonableness. However the true test of the process and the Prioritisation Panel recommendations will be for WHSSC to undertake a review of the Joint Committee decisions, subsequent to the recommendations from the panel to assess consistency and also see how LHBs overcome implementation challenges faced in 'real life'.

NEXT STEPS FOR PROCESS?

There is an organisational commitment at WHSSC to continued improvement of the process when it restarts in 2016/17. Discussions with panel members about potential improvements at the end of the 2015 process, suggested that further developments and additional benefits could be gained by extending the WHSSC framework; perhaps by providing programme budget at LHB level for an HST, or similar contextual information, as recommended by the Bevan Commission(12) when final recommendations are being made, might be a worthwhile extension. This proposal was made because in cases where a single HST comes up for funding it may be strongly supported if it is

presented as a single simple option, either to fund or not: the stakeholders may demand that the innovation is funded, irrespective of the general financial climate. If however, the proposal is set in the context of other bids for funds for the same of the population group, then there may be a different perspective. Presentation of options in this way highlights the fact that the opportunity cost of funding needs to be thought about. The assessment of the most efficient way of producing a health benefit for the smallest relative input will enable a discussion of the opportunity cost of alternative budget allocations both during and after the event. In particular, decision makers in the Health Boards (through the Joint Management Committee) can test the impact of the relative opportunity cost of financing alternatives, by exploring what interventions would have to be given up if that alternative were to be funded. This concept is one the essential elements of the Prudent Healthcare approach.

Table 1: Prioritisation decisions made over the course of the programme

Disease area	Assessments	%	Recommended	%	Not	%	Undecided	%	Change	% no
— —	Assessments	total	to be commissioned	total	recommended to be commissioned	total	Ondecided	total	from No to Yes	to yes
Cardiovascular	24	18%	16	12%	8	6%	0	0%	0	0%
Cancer	58	44%	20	15%	34	26%	4	3%	3	5%
Genetics	8	6%	8	6%	0	0%	0	0%	0	0%
Immunology	3	2%	2	2%	1	1%	0	0%	1	2%
Mental health	3	2%	3	2%	0	0%	0	0%	0	0%
Neurological sciences	9	7%	3	2%	6	5%	0	0%	1	2%
Plastics and Burns	8	6%	3	2%	5	4%	0	0%	2	3%
Renal	4	3%	3	2%	1	1%	0	0%	1	2%
Rare diseases	13	10%	6	5%	7	5%	0	0%	2	3%
Regenerative medicine	3	2%	0	0%	3	2%	0	0%	0	0%
Total	133	100%	64	48%	65	49%	4	3%	10	15%

Figure 1: Ordering of total Portsmouth Scorecard scores from 2015 prioritisation supported by TurningPointTM Technology

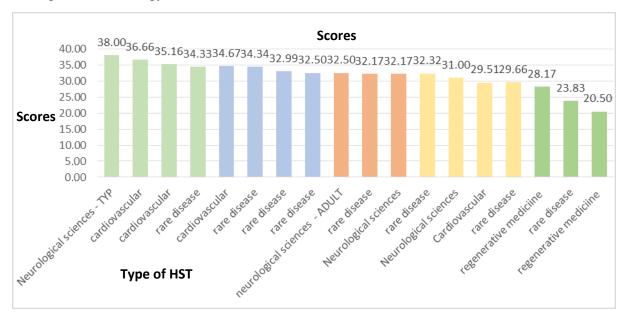


Figure 2: Bubble Chart Showing Health 'Value', Numbers of Patients, and Costs per annum(£s)

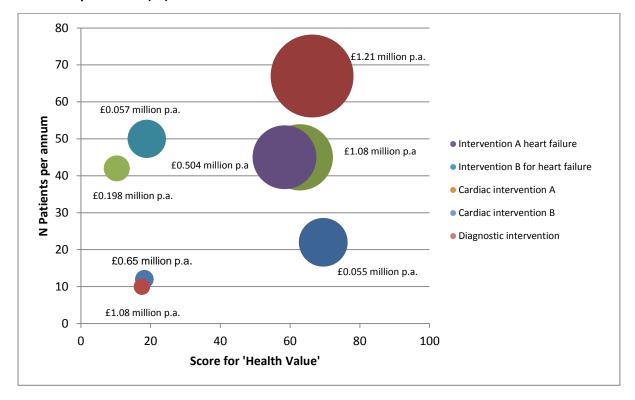
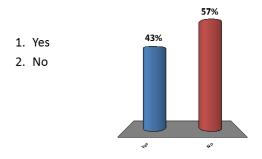


Figure 3: Examples of voting outputs

HST 1: surgical intervention Is this an intervention that we can support? 1. Yes 2. No

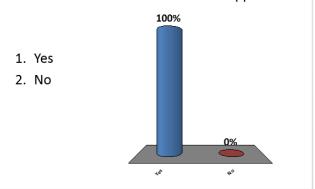
HST 2: non invasive non drug adult intervention

Is this an intervention that we can support?



HST 2: non invasive non drug paediatric intervention

Is this an intervention that we can support?



Box 1: Criteria for prioritisation of the HSTs at the final panel meeting

Criterion	Relative criterion weight (average weight from panel
	members)
Burden of Disease	25
Magnitude of effect	23
Grade of Evidence	17
Economic assessment	23
Prevention of future illness	12

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Appendix: Box 2: The EVIDEM PRINCIPLES AND FRAMEWORK(22)

The EVIDEM framework is designed to evaluate interventions and facilitate their prioritization using a comprehensive set of decision criteria organized into pragmatic tools. Each criterion can be justified by at least one of the ethical positions underlying healthcare decision making:

- Deontology: imperative to help, beneficence, non-maleficence (predominantly at the patient level)
- Utilitarianism: greatest good for the greatest number (predominantly at the population level)
- Distributive justice & fairness: prioritize those who are worse off
- Value ethics and practical wisdom
- The framework includes criteria rooted in these ethical positions which are often conflicting, thus
 allowing the tackling of ethical dilemmas that healthcare decision makers are facing.
- Decision criteria included in the EVIDEM framework were defined to explicitly reflect the complex
 process underlying the appraisal/prioritization of healthcare interventions. This process includes
 normative (i.e., what should we do?) and feasibility (what can be done?) considerations that are made
 explicit by the criteria and design of the framework.
- Universal criteria

The framework assumes that highest rank (or priority) should be given to healthcare interventions:

- For severe disease
- For common disease
- For disease with many unmet needs
- Either conferring major risk reduction or major alleviation of suffering; this design allows to consider
 both preventive and therapeutic interventions, without giving a priori priority to either one
- Conferring major improvement in efficacy/effectiveness over standard of care
- Conferring major improvement in safety & tolerability over standard of care
- Conferring major improvement of patient-reported outcomes/patient-perceived health over standard of care
- That result in savings in treatment expenditures as well as other medical and non-medical expenditures

- For which there is sufficient data, that is fully reported and valid and relevant
- Recommended in consensus guidelines by experts
- Cost-effectiveness is a composite of some elements of other criteria and does not comply with the non-redundancy design requirement of MCDA. It may be included in the framework since many decision making processes currently rely on this composite measure, but it should ultimately be replaced by the criteria with which it overlaps.

Other contextual criteria which are incorporated into the EVIDEM framework are:

- Opportunity costs and affordability: the actual or anticipated financial impact of an intervention and
 the available budget need to be aligned using budgeting tools; considerations of opportunity costs
 and silo budgeting should be part of this financial exercise
- System capacity and appropriate use of intervention: a number of aspects may need to be considered under this umbrella (e.g., skill requirements, organizational requirements);
- Political, historical and cultural context: a number of aspects need to be considered under this umbrella (e.g., cultural acceptability, precedence, current political priorities, impact on healthcare research;
 - Deontology: imperative to help, beneficence, non-maleficence (predominantly at the patient level)
 - Utilitarianism: greatest good for the greatest number (predominantly at the population level)
 - o Distributive justice & fairness: prioritize those who are worse off