

# GRASPING THE NETTLE AND ENDURING THE PAIN: HEALTHCARE PRIORITY SETTING AND DISINVESTMENT IN THE CONTEXT OF PRUDENT HEALTHCARE

Philippa Allen MSc

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## ABSTRACT

Since the financial crisis of 2008 economic pressures mean that healthcare budgets were and still are substantially constrained. The NHS in Wales has had to face the reality of rationing healthcare. Implementation of fair and equitable rationing is a challenge, however. This is a situation where the economic concepts of scarcity, opportunity cost and the margin can support effective prioritisation and resource reallocation decisions. In this context, the aim of this research was to develop pragmatic prioritisation and resource reallocation frameworks for the Welsh Health Specialised Services Committee (WHSSC) who commission highly specialised technologies for Wales and commissioning boards in Abertawe Bro Morgannwg University Health Board (ABMUHB). The prioritisation and resource reallocation methods for WHSSC were developed over a series of prioritisation meetings resulting in a framework based on multi-criteria decision analysis methods. In ABMUHB, programme budgeting marginal analysis (PBMA) was the approach used and two pilot PBMAs run in different service areas. Disinvestment and 'doing less' to invest in more beneficial activities within budget were accomplished in one pilot project; the other project managed resource reallocation but revealed issues in achieving service standards. Both pilots enabled development of a PBMA Framework for ABMUHB. Group decision support methods were an important feature of implementation of decision making in all three projects. The research conducted for this thesis has shown it has been possible to develop and deliver robust, evidence based, effective and practical frameworks based on economic concepts for prioritisation, disinvestment and resource reallocation. Both organisations have taken 'ownership' of the frameworks and will make them a 'way of working' for the future rather than an academic exercise. A key learning of the research was that pragmatism must prevail if prioritisation and resource reallocation methods are to gain traction and become embedded in commissioning.

296 words

## DECLARATIONS AND STATEMENTS

**Supervisor/Department:** Prof. Ceri Phillips and Prof. Deborah Fitzsimmons College of Human and Health Sciences, Swansea University.

**Funding body:** National Institute for Social Care and Health Research Social Care (now Health and Care Research Wales) Studentship Award

Qualification/Degree obtained: Doctor of Philosophy

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## DEDICATION

This thesis is dedicated to the memory of my beloved 'little brother' Bill Allen (b. 4<sup>th</sup> January 1963 d. 10th September 2014).

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## LIST OF ABBREVIATIONS

ABMUHB	Abertawe Bro Morgannwg University Health Board
EVIDEM	<b>E</b> vidence and <b>V</b> alues <b>I</b> mpact on <b>D</b> ecision <b>M</b> aking
HB	Health Board
HTA	Health Technology Assessment
IMTP	Intermediate Term Management Plan
GMS	General Medical Services
NICE	National Institute for Health and Care Excellence
NHS	National Health Service
nvAF	Non-valvular atrial fibrillation
PAR	Participatory Action Research
PBMA	Programme Budgeting Marginal Analysis
PROMS	Patient Reported Outcome Measures
QALY	Quality Adjusted Life Year
WHSSC	Welsh Health Specialised Services Committee
UK	United Kingdom

# CHAPTER 1: INTRODUCTION TO THESIS

# 1 INTRODUCTION

## 1.1 CHAPTER SUMMARY

This chapter outlines the aims and objectives of this thesis. It sets out the rationale for the research, the context for the research and the 'how and why' of formulating the approach undertaken. In addition it summarises the content and structure of the thesis and each of chapters so that the reader can navigate the thesis. Chapters two, three, four and five are intended to be standalone elements so there is some, inevitable, repetition of information.

### 1.1.1 RATIONALE FOR THESIS

In classical economics, acknowledging scarcity - the fact that resources are limited - is fundamental to the discipline. The existence of scarcity requires the efficient allocation of resources and theoretically drives innovation to work around limitations.

Acknowledging scarcity and being able to manage the wants and needs for healthcare within budget by the United Kingdom (UK) government, the devolved governments and the NHS health care providers has always been necessary but now it is more than ever is a brutal reality. Since the financial crisis of 2008 economic pressures mean that budgets have been reduced and still are substantially constrained. Thus the NHS in Wales and NHS elsewhere across the UK have to face the fact that rationing healthcare is a reality. Recognising this reality is one thing but moving to implementation of fair and equitable rationing is quite another.

Many have commented on the need to understand how to prioritise and Williams and colleagues in their analysis of health and social care commissioning in England argue that an integrated priority setting approach in this situation is essential; (1)

*"...population level priority setting which seeks to target resources where need and capacity to benefit are greatest might be a helpful tool for commissioners " "...arguably it is the commissioner's responsibility to ensure that resources are distributed fairly and efficiently across patient and service user populations". (1) p4*

In a 2008 BMJ Editorial Godlee (2) identified several questions to address in order to move forward in health care rationing;

*"Should clinicians take the lead...can we hold decision makers to account for the "reasonableness" of their decisions?...or should we look forward to economic frameworks (systematically stopping things that don't work and spending money on things that do)? ...Some combination of all three approaches is likely to be the answer".(2) p903*

McGuire and Raikou found that the ageing population and the adoption of relatively costly, new health technologies are factors that put pressure on health care budgets (3). Being able to innovate and improve healthcare within a fixed budget in reality means managing scarcity. Allocating resources and priority setting for health care services has to accommodate the notion of rationing and resource reallocation.

Given the current economic and political climate there is an argument for the Welsh Government and health and social care commissioners in Wales to be more explicit about 'rationing' and 'disinvestment' in health care interventions and help it become more acceptable to disinvest in interventions and services that deliver little or no benefit to the Welsh population in order to reinvest in interventions that deliver better value.

The Welsh Government published two important documents laying out policy developments for healthcare in Wales, aiming to reshape the NHS and healthcare in Wales, of which Prudent Healthcare is the most recent.

The first is 'Setting the Direction: Primary and Community Services Strategic Delivery Programme' published in 2010 (Welsh Government, 2009). This is a White Paper aimed at assisting the Health Boards (HBs) in the development and delivery of improved primary and community based services. The goals are to improve efficiency and redesign services to achieve improved outcomes for the citizen. The second is 'Together for Health: A 5-year vision for the NHS in Wales', was published in 2011(4) following the reorganisation of the NHS Wales structures, where the aim to create a world class health care service in Wales was the stated aim – whilst acknowledging some of the problems the NHS faced, which included limited funding.

The 'Prudent Healthcare' initiative was initiated in Wales in 2014. Professor Drakeford – the Welsh Minister for Health and Social Care at the time - defined Prudent Healthcare as:

*"Healthcare that fits the needs and circumstances of patients and actively avoids wasteful care that is not to the patient's benefit."* (5)

Prudent Health Care aims to deliver three objectives: (5)

- Minimising avoidable harm.
- Delivering the best-evidenced treatment and services to the most appropriate level, based on individual need.

- Promoting ‘co-production’ of health and shared responsibility for delivering health care.

Given the current economic and political climate and the drive for ‘Prudent Healthcare’ by the Welsh Government, HBS in Wales needed (and still need) to establish and grow robust and transparent approaches to priority setting, resource allocation and disinvestment to address the healthcare needs of patients within available budgets. Prudent Healthcare is about embracing the need to restrict services to the populations who will benefit the most and embrace disinvestment for interventions and services that deliver little or no benefit to the Welsh population is a reality of our times. To create a sustainable way forward the commissioners and budget holders ideally should understand that it is acceptable – indeed the right thing to do - to disinvest in interventions and services that deliver little or no benefit to the Welsh population and spend budget prudently, commissioning services that optimise the benefits to patients and meets the goals and values of the NHS and LHBs – this is the intent of Prudent Healthcare. Public understanding of and participation in decisions related to prioritisation, reorganization and disinvestment of health care resources as well as co-production is also important for Prudent Healthcare.

### *1.1.2 ECONOMIC THINKING*

In classical economics, the fact that resources are limited while desires are unlimited is fundamental to the discipline. The existence of scarcity requires the efficient allocation of resources and drives innovation to work around limitations. Economic methods and their use in healthcare have been in use in the UK for some time. Economic evaluation has perhaps, been the mainstay of the appraisal of costs and benefits in health care and is- perhaps been most developed-as a technical discipline and as a decision tool, in the hands of the National Institute of Health and Care Excellence (NICE). Health technology assessment (HTA) and the clinical guideline development process have embraced economic evaluation and the use of cost effectiveness analysis with the quality adjusted life year (QALY) as the primary outcome measure of evaluation. The health economic methods deployed in HTA and the products of HTA are unarguably excellent and have contributed to better evidence based health care in the UK. HTA, however, gives an ‘answer’ to specific questions but does not enable understanding of opportunity cost, changes at the margin or what interventions or services might have to be displaced to enable funding that implementing recommendations of HTA might precipitate.

There are other economics based frameworks (within which information from economic evaluation and HTA has an important place, as part of the evidence base) that also take account of the need to solve a multi-faceted prioritisation problem. It is to these methods that this research has turned to find workable solutions for Welsh Government and health and social care providers and commissioners to support the challenges of prioritisation and resource allocation to enable decisions about best use of limited NHS resources. In addition these methods and the underlying theory can help participants understand prioritisation methods and be more comfortable with and explicit about 'rationing' and 'disinvestment' when making decisions about allocating health care resources.

In summary: this research is all about operationalising economic theory and related tools to enable (difficult) resource allocation decisions to be made with confidence and in a way that the citizens of Wales and NHS users and employees can accept are robust, reasonable, transparent and operational. This thesis reports research that is about 'making things happen' rather than achieving methodological perfection in both research methods and the outputs, whilst committed to robust and rigorous theoretical underpinnings of published methodology – in this case Programme Budgeting Marginal Analysis (PBMA) and multi-criteria decision analysis. Evidence based and theoretically sound methods have no worth if the methods are not adopted and used. This research is intended to identify, adapt and provide frameworks that are user friendly, practical and operational for robust prioritisation, disinvestment and resource reallocation in a HB and for specialist services in Wales. On this basis I set out to address the problem of using methods as well as having the right methods and on this basis this thesis was developed.

### *1.1.3 ENSURING IMPACT OF THIS RESEARCH*

This thesis is also based on the premise that a successful research process goes beyond delivering 'results' and 'suggestions for further research'. It is about understanding the context and how the research 'works' and how to make the 'intervention' - be it a prioritisation and resource allocation process or a new medical technology – fit in with that context and the NHS system. It is no use having a perfect tool if no one wants to use it or if it is too complicated to understand or implement. This perspective and understanding has been developed from my own professional and personal experience in working across the research process and with health services in Europe. This has included many years listening to and responding to stakeholders in health and social care about what matters most in delivering relevant and important evidence which can

make a purposeful and meaningful difference to decision making. Learning from the process, making an impact and enabling change based on the research is what I wanted to accomplish. Thus, capturing the process of my research within this thesis was as important in reporting the findings gained from this in-depth investigation to tackling real-world issues in health care decision making.

The research did not go smoothly all the time and some elements of the research worked well and others did not – that is as I expected. These have been reported with candour in order to provide lessons for other researchers and other on future endeavours within this field.

During the journey of doing this PhD research I met many people who contributed to the work – different perspectives, perceptions and team participation were needed to derive creative solutions to the problems identified. Various people enriched my understanding of what it means to work in and for the NHS in Wales and impressed me with their dedication to the principle of an NHS that seeks to serves its population. The research would not have happened without them. And we all got there.

New ways of working to enable prioritisation, resource reallocation and disinvestment have been implemented – seeds of change have been planted. This thesis attempts to capture the aim, methods, process and the outcomes achieved.

Thus the initial aim of the research, which forms the basis of this thesis, was to find a setting where I could test a prioritisation, resource reallocation and disinvestment framework - based on economic principles - that would be usable in routine management and decision making about health care for the population of Wales, in the context of static or diminishing budgets.

Once the setting was found, after understanding the context and aspirations of the setting and the people involved, I then developed and refined the aims and objectives of the research and wrote a proposal. In effect my overall ‘research question’ related to addressing the title of this thesis; could a community of health care decision makers grasp the ‘*nettle*’ of making resource reallocation decisions which would involve stopping or reducing provision of a service or intervention and enduring the pain – i.e. the ‘flak’ that comes after making a potentially unpopular decision. My particular interest for this thesis was in the making of disinvestment decisions which are notoriously difficult to make in the health care setting.



## 1.2 CONDUCT OF RESEARCH FOR THESIS

### 1.2.1 LITERATURE REVIEW

As with all research I started (in 2010-2011) with a literature review to understand what had been done before in the field of prioritization and resource allocation and what approaches were successful and less successful. This was instrumental in refining the focus and scope and for the research aim to be developed and addressed within the thesis, taking into account the time constraints and resources available. The findings of the literature review are presented in this chapter.

At the time of finalising this thesis (Autumn 2016) I revisited the literature to see how the research and practitioner community had moved the methods along and how the outcomes of my research compared with others.

### 1.2.2 EXECUTING THE RESEARCH

It took some while to find partners and the settings for my research – there were many who were interested, but only a very brave few were able to convince their organisations to take a risk, pilot methods and develop the framework. In addition, between 2011 and 2013 I had a hip replacement, a knee replacement and three revisions of my knee replacement, which rather slowed things down. To the people who stuck with me and facilitated the research I am everlastingly grateful.

The thesis has a Welsh context, but the story it tells and the outcomes of the research are designed to be applicable and useful to other tax-funded health care systems rooted in the principles of solidarity.

## 1.3 AIMS OF THE RESEARCH

This research is intended to develop ethical, equitable, systematic frameworks and to support HBs, the Welsh Health Specialist Services Committee (WHSSC) and ultimately the NHS in Wales to promote and enable rational healthcare priority setting and resource reallocation as an integrated part of (prudent) health care policy making.

The research was then pursued through the establishment and implementation of three projects;

1. Redeveloping and delivering a framework for prioritisation of HSTs in Wales;
2. Developing and delivering two Programme Budget Marginal Analysis (PBMA) pilot projects; one in unplanned care and the other in planned care;

3. Developing a PBMA framework that would be operational in ABMUHB as part of commissioning programmes.

Alongside the projects I undertook interviews with project participants and collected my experiences and observations by keeping notes as the projects progressed based on participative action research methods as advocated by Peacock and colleagues (6, 7) (see section 1.10 for more information). The purpose of these activities was fundamentally to enable my understanding of NHS processes and what would work, and what would not, when it came to devising the frameworks for prioritisation and resource reallocation. I was also able to draw on these interviews to inform my interpretation of the findings and develop the discussion sections in this thesis.

#### 1.4 FUNDING SOURCE

The PhD research was funded by Health and Care Research Wales (formerly National Institute for Health and Social Care Research).

#### 1.5 THESIS STRUCTURE

Some considerable, careful and deliberate thought went into the presentation of this thesis in order to capture the coherency and flow between the projects to address the aim of the thesis, rather than present a conventional thesis structure (e.g. Introduction, Methods, Results and Discussion) which would be a rather piecemeal presentation of three quite distinct projects with different outcomes. Thus this thesis is presented as a series of three projects described in three separate chapters, which allows the context, journey and the outcome of each project to stand alone. The research processes and outcomes of the three projects are drawn together in a discussion of the findings and consideration of what this thesis has added to the body of knowledge in this area. The thesis is therefore presented as six chapters;

- The first chapter is this introductory chapter which includes a review of the pertinent literature and a summary of the relevant economic concepts underpinning the research. These set the context for the PhD research and enabled development of the programme of work;
- The second chapter addresses the development of a prioritisation framework for WHSSC as a case study;
- The third and fourth chapters present the development and delivery of two pilot PBMA as case studies;

- The fifth chapter presents the PBMA framework developed in light of the two pilot projects, to enable PBMA to become as 'a way of working' for ABMUHB;
- The final, sixth chapter reflects on the research, providing discussion and conclusions and its original contribution to knowledge in this field.

## 1.6 LEARNING FROM THE LITERATURE

A literature search was devised to search both the CINHALL and Web of Knowledge Data bases (those available to me via the University information services at the time). The individual search terms for separate searches used were 'disinvest\*', 'programme budget or PBMA', 'ration\*' and 'priority setting'. Given the large number of hits (<10,000) from the latter two searches they were restricted with the term 'health care'.

The literature search was extended though grey literature searching on the web, sourcing cited papers and from recommendations via personal communications. This was a non-systematic pragmatic review which attempted to find everything pertinent to the aims of the research.

The resulting abstracts or full documents were reviewed and assessed for relevance to the topic of this research and the full papers and reports that appeared pertinent relevant fully reviewed and reported in this paper.

Formal literature searching using the key word 'disinvest\*' returned only 11 relevant papers from 149 hits. However using key words 'ration\*', 'priority setting', and 'programme budget\*' returned 11/58, 9/775, 9/58 and 16/26 papers, respectively which addressed relevant content. As my reading of this content continued citations were used for 'pearl growing' the literature and grey literature I accessed. A flow diagram illustrating the literature search and review is provided in Appendix 1.

Below is the summary of the literature and how it informs the research reported here.

### 1.6.1 PRIORITY SETTING, RATIONING AND DISINVESTMENT

Godlee (2) suggests that the terms priority setting, rationing and are interchangeable whilst Klein (8) distinguishes between the terms in the following way:

*"Priority setting describes decisions between the competing claims of different services, different patient groups or different elements of care. Rationing, in turn, describes the effect of those decisions on individual patients, that is the extent to which patients receive less than the best possible treatment as a result".*

This thesis uses the term rationing to imply some denial of health care services.

Pearson and Littlejohns define disinvestment as “...an explicit process of taking resources from one service in order to use them for other purposes that are believed to be of better value. Therefore disinvestment is closely linked to efforts to set priorities and allocate resources wisely. But because disinvestment focuses on removing or limiting current services, rather than just allocating new resources, it represents a particularly useful tool to consider in a flat or reduced overall health care spending“. (9)p160.

Elshaug and colleagues use a more ‘brutal’ definition (10) ;

*“...disinvestment ....relates to the processes of (partially or completely) withdrawing health resources from any existing health care practices, procedures, technologies or pharmaceuticals that are deemed to deliver little or no health gain for their cost, and are thus not efficient health resource allocations“. (10) p2*

The latter definition of disinvestment is used in this thesis as it suggests that, unlike Pearson and Littlejohn’s (11) definition, disinvestment can also mean that resources may not be re-invested; a current or future budget may be reduced in comparison to a prior budget, and thus resources not available to be re-invested.

In the UK, the establishment, in England and Wales, of the National Institute for Health and Care Excellence (NICE) in 1999 may not have been seen as an explicit attempt to institute rationing, but could be said to have an efficiency agenda, given NICE’ s stated aims at the time

*“NICE provides guidance, sets quality standards and manages a national database to improve people’s health and prevent and treat ill health”*

*“NICE makes recommendations to the NHS, local authorities and other organisations in the public, private, voluntary and community sectors on:*

- *How to improve people’s health and prevent illness and disease;*
- *Using NICE guidance may ....help cut costs while at the same time maintaining and even improving services“. (12)*

NICE technology appraisal and guideline development processes are central to NICE’s work. However the methods used by NICE do not consider the health gains forgone by reallocating resources from existing programmes to fund new programmes, do not recognise the constraints of the existing NHS budget explicitly (13) and no explicit recommendations are made to make disinvestments in other treatments to fund the new, recommended intervention. A nod in that direction is, however made via the NICE ‘Do Not Do’ programme.(14)

Hughes and Ferner (15) suggest that NICE could pay more attention to identification and appraisal of medicines for disinvestment and that generic substitution for branded

medicines where substitution would bring no health decrement is an obvious candidate area for disinvestment. However this approach seems not to have progressed.

In 2008, an edition of the BMJ contained invited editorials from three contributors with perspectives on moving forward with rationing (16) (17) (18). In the first editorial Norheim, a clinician based in Norway, does not address rationing explicitly in his contribution, but suggests principles of fair priority setting for clinicians.(16) These were:

- Impartial consideration of patient characteristics, except where clinical outcomes are affected (e.g. co-morbidities);
- severity of disease and expected outcome of treatment, based on evidence distributing health fairly across patient groups (16).

Norheim also suggests:

*“...that fair minded clinicians should not always fight for more resources for their patients if this leads to lower priority for other patient groups with stronger claims. Narrow minded clinical autonomy and professional interest can hamper fair priority setting” (16).p903*

The second editorial was from Daniels and Sabin, who have written extensively on Accountability for Reasonableness - an approach to ensure that health care resource allocation and decision making for priority setting and rationing is good and robust. Accountability for reasonableness requires users to *“...give weight to transparency, getting buy-in from relevant stakeholders and revising decisions in light of new evidence and arguments” (18).*

The third was from Donaldson and colleagues (17) emphasise the need to;

*“...wake up and tackle rationing through explicit recognition and management of scarcity” (17).*

Donaldson and colleagues state that the management of scarcity requires that first, waste is eliminated and beyond that, relative value i.e. disinvesting from interventions providing little benefit to fund those of greater benefit is the next step. They also highlight, as others have done, that assessment agencies that use methods grounded in health technology assessment (e.g. NICE) *“...never deal with the trade-offs implied by their recommendations...they often fail to recognise that even interventions with a low incremental cost per QALY still require extra resources”*. The way forward, Donaldson

and colleagues conclude is to use programme budgeting and marginal analysis (PBMA) framework jointly with Accountability for Reasonableness (described in more detail in section 7.5) and developing these robust processes (following national leads) for local decision making.

Goold and Baum (19), commenting on the three 2008 editorials in the BMJ described above (16) (17) (18) remark that democratic deliberation and public participation contribute to the legitimacy of health spending priorities and that these ideas received scant mention. They conclude that “...*economic tools...contribute greatly to evaluate to what extent those tools, and which methods of public deliberation, improve the accountability and legitimacy of health spending decisions*”.

### **1.6.1.1 Disinvestment Policy and Practice**

The literature that specifically addresses disinvestment in its own right, not subsumed into rationing and priority setting activities, suggests ways in which disinvestment decisions could be implemented. The main features of these are summarised below.

Elshaug and colleagues introduce the emerging Australian disinvestment initiatives in a paper outlining the challenges to disinvestment in the Australian policy processes (10). The critical issues that Elshaug and colleagues present are that, despite the advances made in the clinical and economic evaluation of new technologies, the Australian system has a legacy of health care interventions currently in use that have not been subject to such stringent evaluation (a situation similar to that in many other jurisdictions) (10).

Elshaug and colleagues suggest that clinical guideline development and implementation in Australia – as elsewhere – go some way towards eliminating ineffective interventions, interventions that deliver little value and obsolete interventions but they are not the solution to implementing a programme of disinvestment that will drive resource release and more effective and economic use of health care resources.

In setting out the challenges to disinvestment in the Australian policy processes Elshaug and colleagues identify the contributing elements (10).

1. Lack of dedicated resources by key stakeholders to build and support disinvestment policy mechanisms;

2. Lack of reliable administrative mechanisms to identify and prioritise technologies and/or practices with relative uncertainty as to their clinical or cost effectiveness;
3. Political, clinical and social challenges to removing and established technology (including challenges to limiting coverage to specific patients, institutions or providers);
4. Lack of published studies that clearly demonstrate that existing technologies/practices provide little or no benefit;
5. Inadequate resources to support a research agenda to advance disinvestment methods.

These elements seem to be applicable and generalisable to other jurisdictions. Some other important points that Elshaug (10) makes are also specifically generalisable to the UK and Welsh setting;

*“In Australia the incentive pendulum supports diffusion and not retraction or disinvestment...”*

*“For existing technologies there are complexities that beset those that are new or emerging. These relate to their entrenched status...”*

*Resistance to change due to established clinical training and practice paradigms;*

*Multiple clinical, consumer and political interests;*

*Clinical and consumer influence and preferences, and supplier induced demand;*

*...social systems work hard to resist change...”(10)p3*

Elshaug and colleagues conclude their paper (10) by emphasising the need to address the policy challenge of disinvestment, to achieve good quality of care and sustainable resource allocation, and this depends less on the availability of resources than on the political will to support work in this area.

Elshaug and colleagues also investigated Australian policy makers’ perspectives and their views on disinvestment. In this research ten Australian policy stakeholders were canvassed to assess their perspectives on the nature of disinvestment (20). The respondents identified challenges (below) that much in line with Elshaug and colleagues’ prior paper (10) and suggest that PBMA has potential utility as a disinvestment framework given its consideration of opportunity costs (PBMA and opportunity costs are discussed in section 1.6.3). However they suggest that disinvestment is not without its challenges as follows:

- Resource challenges; most notably if the ideal of undertaking evaluations of identified interventions were to be implemented as a parallel process to new ones.
- Political challenges; the challenge lying in balancing clinical autonomy and patient choice;
- Methodological challenges; that embrace not only the clinical, patient safety, economic evidence but also social ethical and political analyses to address how disinvestment in ineffective practices need to be addressed and then implemented. (20).

In 2009, Elshaug, and colleagues published a paper 'for debate' suggesting criteria for determining candidate interventions or practices to disinvest from (21). These are listed below;

- Geographic or provider variation;
- Temporal variations;
- Technology developments;
- Lack of evidence of effectiveness;
- Disease burden (low or high);
- Variation in care;
- Futility;
- New Evidence;
- Public interest;
- Nomination;
- Consultation;
- Leakage;
- Conflict with guidelines.

Other researchers have looked at the problem of disinvestment from differing perspectives, addressing specific topics. Karnon and colleagues (22) use economic modelling and value of information analysis to demonstrate how from a range of candidate technology(s) candidates for disinvestments can be identified freeing up resource for the new technology in the treatment pathway. Interestingly and usefully Karnon and colleagues (22) also address the issue of transferability of resources related to a disinvestment decision and suggest that a type of 'friction cost' methods could be used to estimate productivity loss. But they also mention important issues – potential loss of morale and impact on work ethic and loyalty that might be impacted



by a disinvestment programme. The process described is however resource intensive and takes time to develop and deliver.

In 2006 NICE published a draft project plan for introduction of a new disinvestment programme both for treatments and public health programmes (23) This was followed by further commentary of how NICE could guide disinvestment efforts, published in 2007 by Pearson and Littlejohns (9). The suggestions focused on three main areas;

1. Use appraisals to identify current technologies that are ineffective or less effective than established alternatives;
2. Use guidelines explicitly to reduce inappropriate use of expensive procedures ;
3. Expand the range of clinical guidelines to include evidence based strategies to improve the coordination of health care services.

Pearson and Littlejohns suggest two ways forward for NICE - enacting a disinvestment programme or incorporating the processes above into existing programmes (9). It is notable that the second and third proposed areas are the ones that had 'legs' and the first has not materialised. NICE's approach to supporting disinvestment in England and Wales has been firstly to emphasise how money can be saved and quality preserved or improved by following published NICE guidance(23). Perhaps most important of all in terms of formal disinvestment is the NICE 'Do Not Do' database (14). The 'Do Not Do' recommendations are based on interventions identified as part of the clinical guidance programme where, as part of the guideline development programme of work and review of the evidence, the independent advisory bodies frequently identify NHS clinical practices that they recommend should not be used routinely or in fact discontinued completely

In Australia Elshaug and colleagues' work described above has driven and supported important regional and national initiatives. A report for the New South Wales Treasury from the Centre for Health Economics Research and Evaluation (CHERE) usefully summarises these Australian initiatives (24). Activity focused specifically on disinvestment seems to have started in 2007, when the Victorian Department of Human Services and the Victorian Policy Advisory Committee on the Clinical Practice and Technology initiated a disinvestment initiative by Southern Health – 'the SHARE project (Sustainability in Healthcare by Allocating Resources Effectively). The initiative started with a systematic literature review to identify existing models and a second phase involved formulation of a project framework. This resulted in a national workshop on disinvestment (25) in 2009 which brought together individuals with an

interest in disinvestment. This resulted in agreement that a national framework should be developed for identification and prioritisation of disinvestment activities. Other key issues that were highlighted underlined the importance of evidence in decision making – the role of national level HTA being crucial to this; the need for all involved in decision making - clinicians, managers, policy makers, funders and consumers of health care - to work together; the need to change attitudes and building understanding before attempting disinvestment – stakeholder engagement and ‘buy-in’ being essential and finally the importance of funding research for disinvestment activities was agreed.

The ASTUTE Health (Assessing Service and Technology Use to Enhance Health) study (26) was a three year project running from 2009 to 2011 funded by the Adelaide Health Technology Assessment. The goal of the study was to design, implement and evaluate a model to identify the social, ethical, political, economic and epidemiological factors that perpetuate the use of ineffective health care practices and to test if practices can be disinvested.

The CHERE report (24) evaluated PBMA as a framework within which to manage disinvestment and concludes that, while it seems an appropriate approach, there are pitfalls, not least of which are the resource intensiveness of the process and considerable commitment required of clinicians and managers. The report notes that there is a disincentive for disinvestment if health professionals lose the resources freed by disinvestment.

Spain is another setting where interest in disinvestment has grown. In 2007 an initiative led by the Galician HTA agency published the report ‘Identification, prioritisation and assessment of obsolete health technologies: A methodological guideline’ (27). The methodological guide proposes a standardised process and ways in which potentially obsolete health technologies could be identified, priorities described and assessed for disinvestment. The main output of the initiative is a web application – the PriTec tool – built based on 3 domains, (population end users, risk-benefit and costs, organisation and other implications). Clinicians, managers and end users developed the weights. Another useful output from the project is an assessment document structure.

In addition to this project another research group in Spain was devoted to develop a guideline for the process to evaluate the potential for disinvestment in certain health technologies that “...fail to achieve the objectives(s) for which they were originally

*funded*" (28). The researchers used a nominal group technique to determine the relevant aspects of disinvestment decision making and went on, through a number of iterations to finalise the 'GuNFT guideline' with supporting software to facilitate implementation. As the time of publication the authors say that guideline and software have not been tested in 'real life'.

#### 1.6.2 USE OF ECONOMICS IN PRIORITY SETTING AND RESOURCE ALLOCATION

Economic concepts and theory underpin the health economist's approach to prioritisation and resource allocation. These are scarcity, Pareto optimality, opportunity cost and the margin and are described below.

The notion of **scarcity** is the underpinning economic concept for priority setting and resource allocation.

Vilfredo Pareto, Italian engineer and economist, used the concept of **Pareto optimality** in his studies of economic efficiency and income distribution. This important notion is a (hypothetical) situation where the allocation of resources (in this case health care resources) cannot be improved: i.e. it would be impossible to make any one individual better off without making at least one individual worse off. Kaldor and Hicks (in the 1930s) extended the notion of Pareto optimality and separately proposed potential compensation test to "expand" policy uses of Pareto optimality. (29, 30) The additional concepts they introduced suggested that exchanges could be made in which persons made better off can hypothetically compensate losers and still be better off; these are called 'Kaldor and Hicks improving' i.e. a situation is Kaldor and Hicks efficient if all improving exchanges of compensation have been made. Kaldor and Hicks improvement is obtained if the amount gainers are willing to pay losers (i.e. willingness to pay) as 'compensating variation' is large enough to compensate losers for implementation of program. Kaldor and Hicks improvements are also gained if the amount losers are willing to pay gainers (willingness to accept) the 'equivalent variation' is large enough to compensate gainers for withholding implementation of program if the amount gainers are willing to pay losers is large enough to compensate losers for implementation of program. A re-allocation is a Kaldor-Hicks improvement if those that are made better off could hypothetically compensate those that are made worse off and lead to a Pareto-improving outcome. The compensation does not actually have to occur.

Whilst these are somewhat theoretical notions they are the foundation for optimising allocation of resources where there is scarcity.

Given limited budgets, thus finite resources, trade-offs must be made between health care interventions and the resources associated with the interventions or services. By allocating resources to one service or intervention, they are not available to be used elsewhere – this is the notion of **opportunity cost**. The benefits of an alternative service or intervention are foregone due to resources being allocated elsewhere.

When changing how much of a service or an intervention is provided decisions have to be made at the '**margin**'. The 'margin' in this context is a specific economic concept and the cost of producing one more unit of a defined output (e.g. health), is the marginal cost. The cost of adding or subtracting one additional unit of output is the incremental cost.

Normative health economics is focused on the economic evaluation of interventions, mainly clinical or organisational, to aid decision makers in allocating health care resources. Economic evaluation of health care stems initially from the 'welfarist' views following the basic principles that individuals are the best judges of their own welfare (utility or well-being) and that, if one individual can be made better off without another being made worse off, there is a global improvement in welfare – until Pareto optimality is attained. The welfarist view is thus that of an individualistic standpoint and relevant social choices can only be made by the individuals who will be impacted by those choices (31). The objective of welfare economics is to create decision rules that allows ranking of states of a wide range of arrangements and activities based on specific outcomes, such as individual utility (welfare or well-being). Economic evaluation based on these principles has been the mainstay of appraisal of costs and benefits in health care and is perhaps been most developed, as a technical discipline and as a decision tool, because of NICE, as part of the clinical guideline development process and within the multi-technology appraisal process. However welfare economics does not consider the distribution of utility across individuals, and thus supposes (Pareto) optimality only on one dimension.

Extra-welfarism takes a different approach to and differs from welfarism in a number of ways: it considers a variety of outcomes beyond utility; sources of valuation are extended beyond just the affected individual; the weighting of outcomes is not necessarily preference-based and finally interpersonal comparisons of wellbeing are permitted on a range of dimensions (32). Extra-welfarism rejects exclusive focus on

individual utility and takes a wider view that includes outcomes such as happiness, social interaction and pain.

However neither approach really delivers a comprehensive economic theory that is totally relevant to explaining the 'real world' of NHS prioritisation decisions where many important factors and values have to be considered.

### *1.6.3 PROGRAMME BUDGETING AND MARGINAL ANALYSIS*

Peacock and colleagues review of the use of economic approaches for priority setting (33) and demonstrate how using economics contributes to setting pragmatic and ethical priorities in health care. Written in a time of investment in the UK NHS, none the less the review emphasises the fact that resource management is essential as demand always outstrips supply. The economic approach proposed as the solution to resource management is programme budgeting marginal analysis (PBMA). This is a framework that accommodates economic analysis, multi stakeholder inputs, values, needs and perspectives within one framework – balancing health services within a total budget and optimising use of resources. The two economic concepts - opportunity cost and marginal analysis – are at the heart of the framework. As stated previously opportunity costs are those benefits forgone when investment is made in an intervention or service. A disinvestment decision - a forgone opportunity - releases resources that can, if budgets allow, be re-invested. In order to make a rational (or even a reasonable) decision the (opportunity) costs and benefits of various healthcare activities need to be examined at the margin. That is the benefit gained from an extra resource unit, or lost from having one unit less in a programme or treatment pathway are identified and reallocated until the ratios of marginal benefit to marginal cost are equal – maximising patient benefit. For example, the opportunity cost of funding one more hip replacement could be, within a joint replacement programme, a reduction in physiotherapy based rehabilitation services, or across services, reduction in oncology services.

In their writing Peacock and colleagues also acknowledge that managers and clinicians will face other challenges than balancing budgets and managing resources; there are organisational objectives to be met, understanding organisational context, readiness, getting an advisory panel together and ensuring implementation (7). One of the greatest challenges to a PBMA process is acknowledged - that of finding the strong management, leadership and clinical champions to drive implementation of the process

and outcomes. Peacock and colleagues propose seven steps for priority setting using PBMA, outlined in the list in

Box 1:1 below (7).

**Box 1:1 Stages in priority setting using programme budgeting and marginal analysis  
Taken from Peacock 2006 (7)**

1. Determine the aim and scope of the priority setting exercise: will the analysis examine changes in services within a given programme or between programmes?
2. Compile a programme budget: The resources and costs of programmes combined with activity information;
3. Form a marginal analysis advisory panel: The panel should include key stakeholders (managers, clinicians, consumers, etc.) in the priority setting process;
4. Determine locally relevant decision making criteria: The advisory panel determines local priorities (maximising benefits, improving access and equity, reducing waiting times, etc.) with reference to national, regional, and local objectives;
5. Identify where services could grow and where resources could be released through improved efficiency or scaling back or stopping some services: The panel uses the programme budget along with information on decision making objectives, evidence on benefits from service, changes in local healthcare needs, and policy guidance to highlight options for investment and disinvestment;
6. Evaluate investments and disinvestments: Evaluate the costs and benefits for each option and make recommendations for change;
7. Validate results and reallocate resources: Re-examine and validate evidence and judgments used in the process and re-allocate resources according to cost-benefit ratios and other decision making criteria.

Peacock and colleagues (7) also pay attention to ethical considerations in relation to the PBMA process. This topic is covered in more detail later in this chapter. However Peacock and colleagues suggest that Daniel's and Sabin concept of Accountability for Reasonableness could be integrated into the design of the priority setting process. However they suggest that using this process does not bypass the need to engage with economic principles for resource management decisions.(7) Accountability for Reasonableness is described in more detail in section 1.6.5 of this chapter.

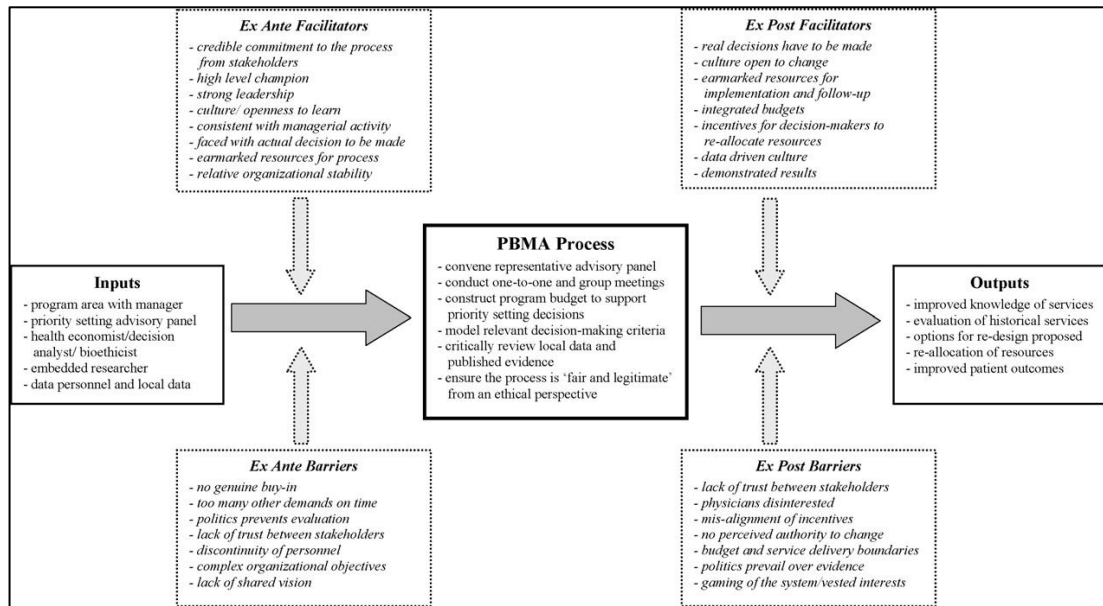
Some researchers have built further on PBMA methods. In 2009 Wilson and colleagues (34) reviewed this approach and a number of other, published approaches to score

costs and benefits - some relatively simple and some less so - in a PBMA framework, with a particular focus on suitability for local level decision making. They suggest possible solutions to the problem of attempting to the ranking/scoring exercise required to produce a weighted benefit score for prioritising services and interventions under scrutiny on a scale of 0-10. Importantly Wilson and colleagues emphasise that there will always be problems with any approach that attempts to undertake this and that;

*“...the formulae cannot provide the answer. They do however provide a valuable starting point and framework for discussion ...”*(34)

In a 2009 review paper Peacock and colleagues (6) bring together the PBMA literature on the ‘latest state of the art’, describing an interdisciplinary framework for PBMA based on ‘real-world’ experience. In order to aid potential users of PBMA they also reviewed the barriers to implementation of PBMA. The authors suggest the techniques of multi-criteria decision analysis (MCDA), participatory action research (PAR) and Accountability for Reasonableness are all integrated into the framework; the benefits of each respectively, being that whilst maintaining adherence to economic principles. MCDA helps to quantify attributes of services that matter to the public and decision makers, within the context of decision making, PAR captures data from the perspective of those individuals who would have to implement new processes and Accountability for Reasonableness’ in order to be sure the process constantly holds ethical conditions in mind. (6) Figure 1:1 below illustrates the empirical model of PBMA used in health care priority setting and is taken from Peacock and colleagues paper. (6)

**Figure 1:1 An empirical model of the PBMA priority setting process (from Peacock 2009)(6)**



### 1.6.3.1 Multi Criteria Decision Analysis

Complex decisions with many factors that need to be taken into account – decisions such as those taken in a PBMA – can be deconstructed to identify what criteria are important and their relative importance in a transparent and consistent way. This is the essence of the MCDA process. Stakeholders in this process use all available information and value judgements to make decisions about resource allocation. This approach can be used within the priority setting frameworks of PBMA or as a standalone framework. The process makes explicit the impact on the decision of all the criteria applied and the relative importance attached to them.

A recent review of the use of MCDA in health care decision making (35) describes how MCDA has been used in similar settings to the Welsh NHS and describes the range of approaches to characterising and weighting criteria for use in an MCDA process. A monograph 'Incorporating Multiple Criteria in HTA' produced by the Office of Health Economics (36) summarises the use and potential use of MCDA in HTA. Both of these sources are in line with the approaches suggested by Mitton, Donaldson and Peacock in their papers (summarised above) describing the use of MCDA in PBMA.

The PBMA framework assumes that when using MCDA, higher rank/weightings/priority that should be given to some criteria when thinking of investment and then the criteria/weights can be 'reversed' for the disinvestment process (37).



### 1.6.3.2 Criteria for decision making

Based on work undertaken by others and summarised by the EVIDEM initiative which, as a comprehensive evidence based framework created by a multi country and a multidisciplinary initiative (37, 38) the EVIDEM framework is a suitable benchmark for establishing criteria for decision making in this context, it is likely that there are two levels of criteria for decision making that needed to be agreed when using MDCA and PBMA:

Contextual criteria

- **Utility** - Goals and Values of ABMU/Prudent Health Care/Welsh NHS considering (mis)alignment of intervention with the mission and scope of the ABMU/Prudent Health Care/Welsh NHS and policy imperatives
- **Fairness** - Population priorities and access of ABMU/Prudent Health Care/Welsh NHS : considering alignment of intervention with priorities
- **Efficiency** - Opportunity costs and affordability considering actual financial impact of intervention and need to disinvest other services (opportunity cost)
- **System capacity and requirements:** considering requirements to implement intervention (e.g., skills, organisation) and capacity to ensure proper use
- **Pressures/barriers from stakeholders:** acknowledging these aspects to address them and ensure that the decision is aligned with mission and scope
- **Political and historical context:** considering overall context (e.g., cultural acceptability, precedence)

Another criterion may also be important depending on context: **Environmental impact** of the intervention. This means considering whether the potential environmental impact related to the intervention under scrutiny will affect the decision.

There are other criteria which are more 'detailed' and may be more specific to the certain contexts and decisions.

This comprehensive list of criteria is mostly taken these from the EVIDEM framework, referred to as normative universal criteria, but also from other frequently used criteria from the PBMA and MCDA literature(37, 39). EVIDEM calls these.

- Severity of disease;
- Burden of disease;

- Whether a common disease;
- Disease with many unmet needs;
- Increases accessibility/balances geographic distribution;
- Addresses health inequalities;
- Ability to effect timely implementation;
- Recommended in guidelines by experts/on the NICE do not do list (or other stop doing/low value lists);
- 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/perceived health over standard of care;
- Strength and quality of evidence of achievable health outcomes;
- Either prevention of ill health or conferring major risk reduction or major alleviation of suffering; NB this allows consideration of both preventive and alleviating interventions, without giving a priori priority to either one;
- That results in savings in treatment expenditures as well as other medical and non-medical expenditures;
- Other economic impact:
  - Is cost-effective (established by falling below lowest NICE threshold?)
  - Affordable/Reasonable cost per patient/acceptable budget impact

Achieving consistency for the core criteria is important for the MDCA and PBMA described in chapters two, three and four.

#### *1.6.4 PBMA AND DISINVESTMENT*

Goodwin and Frew (40) report on the implementation of a PBMA exercise applied within NHS Plymouth, an English PCT responsible for commissioning services for a population of approximately 270,000. The process produced clear strategic and operational priorities for 2010/11, providing staff with focus and structure, and delivered a substantial planned reduction in hospital activity levels. NHS Plymouth adhered to the PBMA process, although concerns were raised about the evidence for some priorities, decibel rationing, and a lack of robust challenge at priority-setting meetings. Participants expressed satisfaction with the process and highlighted several external benefits, particularly in terms of cultural change, and felt the process should encompass the whole local health and social care community. This evaluation indicates that the prioritisation method was effective in producing priorities for NHS Plymouth

and that PBMA provides an appropriate method for allocating resources at a local level. However it is notable that Goodwin and Frew suggest that in order for PBMA to identify savings, cultural and structural barriers to disinvestment must be addressed.

Donaldson and colleagues present a commentary on 'rational disinvestment' in a paper published in 2010, no doubt as a reaction to the cuts to healthcare resulting from the financial crisis(41). Importantly Donaldson and colleagues refer to the current budget pressure in the UK NHS, the scale of the cuts that are needed and the reality of the possibility that genuine disinvestments - in the form of stopping some services for some people - might be required. In addition, this "*genuine disinvestment*", the authors suggest will inflict harm. To minimise this harm, they propose, 'rational disinvestment' is the logical way forward. That is using the principles of opportunity cost and marginal analysis within a PBMA framework; taking resources away from one part of the clinical pathway to give it to another to achieve the same benefit for less cost. The authors provide an example; the Canadian province of Calgary, facing a financial deficit in 2002-2003, used the 'rational disinvestment' approach and successfully eliminated the deficit but also was able to introduce new spending initiatives. In a 'debate' paper Mortimer proposes re-focussing and re-orientating PBMA towards disinvestment (42). Mortimer suggests that the 'disinvestment PBMA' model is a distillation of PBMA to minimise barriers to disinvestment is and is differentiated by four features;

- "Hard budget constraint with budgetary pressure;
- *Programme budgets with broad scope but specific investment proposals linked to disinvestment proposals with similar input requirements;*
- *Advisory working groups that include equal representation of sectional interests plus additional members with responsibility for advocating in favour of disinvestment;*
- *Shift lists populated and developed prior to wish lists and investment proposals within a relatively narrow budget area."*(43)

However, Mortimer recognises that the challenges to PBMA implementation remain and the risks that(43);

*"...political considerations will dominate disinvestment policy..."* (43)

but calls for urgent application of mechanisms for disinvestment and a trial of this re-orientated PBMA.(43)

Cooper and Starkey, in a BMJ editorial, bring their understanding of organisations and psychology to the topic of disinvestment in health care (44). Acknowledging all of the ways in which disinvestment can be promoted:

*“...better evidence based clinical decision making, better alignment of health services between primary and secondary care providers, better integration of the health system with the social care system and community care; new technology, a culture of collaboration rather than competition; a better managed system of skill development; changes in working practice; the empowerment of patients; reduction in administrative costs; and greater dialogue to promote knowledge and understanding so that policy options can be better discussed and agreed between relevant stakeholders” (44) p605;*

Cooper and Starkey explain why (based on social and psychological research) disinvestment is likely to meet resistance;(44)

*“Sociologists emphasise the contested problem of managerial control and how institutions tend to change only when a major shift in the nature of control occurs and a new management model is generally accepted. Psychologists emphasise resistance to change as a cognitive and emotional response at the individual and group level. We cling to what we know. Indeed, it seems natural to resist change, and it would be unexpected if major change was enthusiastically embraced. Studies of resistance to change imply that for change to happen managers need to be skilled in aligning individuals, groups, and stakeholders in terms of promoting more ways of framing contentious matters and they must tackle the problems of irrational thought processes. In the complex environment of health care, managing change requires skilful management at several levels, including leadership, culture (organisational and local), teams, and technology. In public sector change generally, we need to do better at engaging the front line in policy making”.(44) p605*

#### 1.6.5 ETHICAL ASPECTS

Many of authors and practitioners of priority setting, most particularly driven by the sensitive issues of rationing or disinvestment, have stated that the economic approach, whilst a vital component of the exercises, must be tempered by pragmatism and ethics. The approach to dealing with ethical issues most frequently encountered in this review of the literature is that of Daniels and Sabin (18). In their book ‘Setting Limits Fairly; learning to share resources for health’ (45) Daniels and Sabin set out to develop an approach which would enhance control over limit setting in health care and enable public deliberation that is so central to a democracy - i.e. Accountability for Reasonableness. Accountability for Reasonableness is based on certain conditions;

- **Regulated** (voluntary or public) to be sure that the conditions are met;
- **Transparency/Publicity:** decisions regarding both direct and indirect limits to care and their rationales must be publicly accessible;
- **Relevance:** decisions must be supported by reasonable principled, evidence based rationales of how the organisation has tried to accomplish the provision of value for money health care;
- **Revision and appeals:** there must be mechanisms for challenge and change, revising decisions in light of new evidence and arguments.

In the BMJ editorial mentioned earlier (18) Daniels and Sabin, give examples of three jurisdictions that have attempted to implement Accountability for Reasonableness - these are summarised here; NICE in the UK, by establishing a citizens' council (public stakeholder involvement on issues of social value); Mexico as an example of a jurisdiction that is exploring ways of involving clinical, economic, ethical and social inputs with full disclosure of the rationale behind decisions; and Oregon, who following the programme of rationing in the 1990's is involved in a new health reform effort. It has included a wide range of stakeholders in the working groups and is placing its documents on a public web site. They explicitly state that they are using Accountability for Reasonableness (described in more detail in section 1.6.5) to review the reform process and propose a framework of values for the legislative proposals. Daniels and Sabin concludes that *"The next step is to assess whether and how it (Accountability for Reasonableness) adds value to the policy making process". (18)*

Gibson and colleagues (46) evaluated a PBMA exercise (undertaken in 2001-2002) in the Canadian province of Calgary using Accountability for Reasonableness as a process benchmark. PBMA was adopted as a framework for priority setting because it was perceived to be fairer than previous approaches. A number of 'opportunities for improvement' to the PBMA process were identified - some perhaps relating more to the Calgary context, but are useful to know and understand in order to ensure PBMA meets ethical standards. The opportunities for improvement reported were:

- *"Relevance:*
  - *Engage stakeholders in the development of priority-setting criteria;*
  - *Include strategic considerations among decision criteria*
  - *Identify 'givens' explicitly and upfront*
  - *Collect data related to decision criteria*

- *Allow more time for deliberation and discussion*
  
- *Publicity:*
  - *Develop a formal communication plan to engage internal and external stakeholders;*
  - *Publicise the decision and its rationale.*
  
- *Revision and appeals:*
  - *Provide formal mechanisms to review decisions and to resolve disputes as the health care environment changes or as new data emerges.*
  
- *Enforcement:*
  - *Ensure strong executive leadership to enforce conformity with fair priority setting;*
  - *Develop explicit mechanisms to respond to 'gaming' behaviour".(46)p36*

Peacock and colleagues (7) suggest that the conditions of Accountability for Reasonableness could be incorporated into the resource management process and could be either be addressed by interviewing stakeholders after results have been implemented or be an integral part of the design of the priority setting process, so that ethical evaluation is conducted alongside economic appraisal.

A 2005 publication by Newdick (47) 'Accountability for Rationing' evaluates the rationale for decision making and resource allocation used in the UK, by NICE, using QALYs with the Accountability for Reasonableness approach in the context of an English Primary Care Trust (PCT) which were the health care organisations that existed prior to Clinical Commissioning Groups (CCGs) which exist in England now . Newdick describes PCT's priorities committee's ethical framework which is concerned with; evidence of clinical effectiveness (with an emphasis on outcomes that are important to patients), cost of treatment (related to benefit), the need for treatment, the needs of the community (influenced by decisions made by NICE, the UK Department of Health) and national standards (such as NICE guidance). Estimates of cost per QALY gained are reported to be important to the committee. Newdick examines the tensions created by NICE mandating implementation of NICE guidance without providing supportive advice on which disinvestment should be made to enable resources to be diverted to fund adoption, and the strains placed on availability of treatment for technologies that have not had NICE approved technologies. This publication is over 10 years old and still this

problem has not been resolved by NICE or other bodies. Claxton and colleagues more recently illustrate this concept in a paper, estimating the impact of providing new interventions which impose additional costs on the NHS(48). 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 and incurs an opportunity cost.

#### **1.6.5.1 Public and Patient Involvement**

Newdick points out that PCTs and hospitals have a statutory duty to involve the public in decision making, and do so in many and various ways, but that no clear guidance exists to state what that should be – Newdick comments that “*the NHS has much to learn about how to involve the public*”.(47) In 2009 and 2010 Owen-Smith, Coast and Donovan reported their research into the information needs of patients and health professionals and understanding of rationing when making and communicating rationing and NICE decisions. (49-51). Owen-Smith and colleagues used qualitative methods - structured interviews with two groups - patients and health care professionals. The research also explores how feasible and appropriate it is to make health care rationing decisions openly at the level of consultation between health professional and patient. The research findings suggest that both groups understood the need for rationing and had preferences for explicit discussion at the consultation, although the reality emerging from the interviews is that these discussions can be distressing for all and stressful for the health care professional. Reported reactions to rationing by the patients ranged from a sense of entitlement to NHS care, an understanding of the issues but a basic personal ‘want’ for treatment for themselves whatever the cost, and distress at being denied treatment because of ‘rationing’. (49-51).

In 2009 Mitton, Smith, Peacock, Evoy and Abelson reported the results of a scoping review of public involvement in health care priority setting, focused on empirical studies of public engagement – within and outwith health care. The purpose of the research was to determine the gaps in the existing literature (52). The main findings are that there are approaches in development that they deem promising but it is challenging to determine which of the approaches, old or new are ‘the best’ as the types of study, context etc. make comparison difficult. Two findings are evident; there is a lack of practical guidance on integrating public input with any other form of evidence and evaluation of outcome of the specific involvement of public in the study outcomes.

Unfortunately Mitton and colleagues' review (52) was inconclusive as to methods for both soliciting public involvement and on methods that optimised outcomes. Mullen and Spurgeon somewhat embrace this issue in their book 'Priority Setting and the Public'(53) and suggest:

*"...ultimately, which method, or combination of methods, is most appropriate in any given circumstance will depend on the objectives or purpose of the exercise".(53)*

Gallego and colleagues (54) report research (not picked up by the Mitton and colleagues review, above (52)) which gathered the views of the Australian general public (n=200) about access to High Cost Medicines. In response to the questionnaires the participants overwhelmingly wanted health care resources to be distributed *"for the greatest benefit for the greatest number of people"*. However, over half of the respondents did not want to be involved directly in decision making whilst 38% did.

#### **1.6.5.2 PBMA Implementation Issues and Challenges**

Whilst Peacock and colleagues cite use of PBMA in decision making in health care in *"...over 70 priority setting exercises in countries such as Australia, Canada, New Zealand and the UK..."* (33). The literature describing such exercises within the recent past is few, and limited in the UK. A PBMA exercise reported by Cohen is older but relevant and useful to review to draw lessons from; undertaken in the Mid Glamorgan region in Wales in 1995 (55). Cohen's PBMA exercise was successful in as far as the prioritisation process, but the reallocation of resources between programmes in a single 'health gain' area was not reported in the paper, and never happened (Cohen 2011 personal communication), due to the difficulty of the process taking a long time and stopped by a reorganisation of the health authority before the process was completed; a telling example of the need to drive a programme forward within a relatively tight time frame given the changes being experienced in the UK health care system at the time of writing.

Dionne and colleagues report a PBMA analysis successfully undertaken in the Vancouver Island Health Authority (VIHA) between 2006-2007(56). The researchers focus more on the process and procedure of implementing PBMA rather than the outcome. Stakeholder interviews were a crucial element of the research to get input to the PBMA implementation about the desired features of a priority setting process. A first round of PBMA implementation was executed followed by a second round of stakeholder interviews. These interviews revealed a number of significant problems



with implementation - for example, lack of clarity of decision-making criteria, senior executives circumvented staff determined priorities and poor communication about decisions particularly about project re-prioritisation.

A second round of PBMA implementation – learning from the first round experiences, was undertaken. New complaints about; “...*the impossibility of coming up with disinvestment options*” arose in this round. The researchers noted the conflicts that arose when ‘must-do’s’ are part of the PBMA process. Interestingly earlier criticisms about communication diminished somewhat. (56)

The researchers also report the continued ‘buy in’ to PBMA by the VIHA as PBMA continues to be an advisory process to resource allocation and the CEO’s commitment to the ‘added value’ of the process; (56)

*“...transparent and defensible decision making...clinician engagement and partnership and evidence driven decisions”*. (56)

Clearly, driving a programme of priority setting using PBMA, that is determined to embrace disinvestment, faces substantial challenges on a number of different fronts. But in anticipation of accomplishing a completed programme, how will the contributors to the programme know they have been successful? How would a programme be measured in terms of outcomes? The local flow of finances would tell their own story but that is only part of the picture. This question was somewhat addressed by Sibbald and colleagues, who in 2009 and 2010 reported a conceptual framework for development of an evaluative framework for priority setting and then their pilot study of the framework in a Canadian hospital setting. (57, 58) In this programme of research Sibbald and colleagues developed - from three empirical studies drawing on the experience of Canadian health service decision makers, Canadian public, patients and policy makers - ten elements that specify both qualitative and quantitative dimensions of priority setting and relate to both processes and outcome components The pilot study resulted in the detail of the conceptual framework being refined but the basic framework held good (see below in

Box 1:2). (57, 58)

**Box 1:2 Refined Elements of conceptual framework taken from Sibbald et al (57, 58)**

	Elements conceptual framework
Process	1. Stakeholder engagement
	2. Use of explicit process
	3. Clear and transparent information management
	4. Consideration of values and context
	5. Revision or Appeals Mechanism
Outcomes	6. Improved Stakeholder Understanding
	7. Shifted Priorities/Reallocation of Resources
	8. Improved Decision making Quality
	9. Stakeholder Acceptance and satisfaction
	10. Positive Externalities

The ten elements are inter-connected and inter-dependent, are not weighted with some relatively more important than others, nor are they based in any moral, ethical or economic theory. Rather they are based on the input of the participants – decision makers who were motivated to improve policy making because they are involved in doing it. Sibbald and colleagues describe the “*value-relevance*” of their study was based in participants’ values – normative reasoning – not from data analysis. “*The participants provided their input on what ‘should be’*”. (57, 58) These ‘elements’ seem very much in keeping with Accountability for Reasonableness(45).

Criteria for successful PBMA were also described by Tsourapas and Frew based on a literature review which looked at different definitions of success and how PBMA reported in the literature (59).

*“PBMA was successful in 52% of cases when success was defined in terms of the participants gaining a better understanding of the area under interest; in 65% of cases when success was defined as ‘implementation of all or some of the advisory panel’s recommendations’; in 48% of the studies when success was defined in terms of disinvesting or resource reallocation; and in 22% when success was defined in terms of adopting the framework for future use”.* (59).

**1.7 THE CHALLENGE FOR WALES**

As the economic climate in the UK has become more constrained not only have the comfortable years of investment in the NHS by the prior UK governments come to a close, with the 2008 financial crisis, but in Wales budget reductions as well as efficiency savings are being implemented. The health care system in Wales has been under pressure for some years, budgets falling rather than staying the same or increasing. Between 2009/10 and 2012/13 Wales was the only UK country where health spending was cut in real terms by 4.3% (60).

A report from the Bevan Commission published in 2013, in response to the need for the NHS in Wales to address the pressures on health care in Wales 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(61). 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 ....(61)”*

Thus the ‘Prudent Healthcare’ initiative, which was outlined earlier in this chapter, was initiated in 2014 (5). The initiative should not be considered solely as a means of delivering service reductions to address budget pressures, but also as a means to improve patient care and outcomes.

This is a climate in which disinvestment and service reduction has to be faced. Robinson, and colleagues(62) present the issues facing the English NHS in the then new context where GP consortia act as commissioning bodies -CCGs - but their representation of the issues and challenges are very relevant for Wales. The authors suggest that;

*“Substitution and disinvestment (of less costly services) present considerable challenges;*

- *The need to establish agreement over the criteria by which decisions will be taken;*
- *The need to develop a thorough understanding of the full range of current services and areas of investment and their performance against these criteria;*
- *The need to manage and negotiate the political hazards and fall out associated with the removal/withdrawal of services;*
- *The difficulty of implementing substitution and disinvestment in complex systems. The challenges posed by reduced overall budgets also have implications for national bodies such as NICE, which will need to devote greater attention to the disinvestment evidence base that has hitherto been the case”.p145*

Robinson and colleagues exhort those likely to face the necessity of making disinvestment decisions - citing Williams and colleagues; (63)

*"...to engage the public over the fundamental aims of health care by which the disinvestment decisions will be judged. To secure legitimacy for these endeavours the must also develop stronger relationships with their authorising environment - government, citizens and the media - so that the "bitter pill" of disinvestment becomes more easily swallowed" (63).p4*

Robinson and colleagues conclude that *"...in order to release funds tough choices will have to be made and there will inevitably be losers as a result" and that "...it is unlikely (that) the challenge of resource scarcity can be met by GP commissioners alone. Rather that nettle will have to be grasped by government, interest groups and wider civic society if reasonable disinvestment is to be achieved"*.

## 1.8 IMPLEMENTING THE RESEARCH

Taking the wealth of research reported here, learning from it and determining a workable framework for implementation was the intent of this review of the literature. Looking at the challenges that the community of health care decision makers in NHS Wales faces having robust methods based in sound economic theory is all well and good, but in the imperfect world of poor data, practical and political pressures, the need to address health inequalities and work with citizen and health care values seem impossible to establish fully within these theories.

The proposed framework and implementation is based on the following 'Guiding Principles' which were derived from the learning I took from the literature review. The outline for a pilot study of the frameworks as originally conceived at the initiation of this research is outlined below. The research plan was for this to be a starting place and then develop in the light of experience and feedback from participants to end up with a framework that is 'owned' by the organisation and people in the organisation.

The guiding principles used for this research were:

- The methods to be based on the notion of scarcity, principles of opportunity cost, use of marginal analysis, under the conditions of 'accountability for reasonableness'(45) and includes public involvement;
- Take account of both good practice in priority setting and resource allocation, PBMA and Accountability for Reasonableness but at the least burdensome level of quality;

- Not resource intensive for the HB or researcher(s) but meets minimum criteria for quality but a workable, small scale but robust approach;
- A scalable approach to allow implementation of framework(s) developed in the research but never the less be affordable and quick enough to achieve results within necessary timeframes;
- Project champion within HB to drive process to be identified;
- Findings publishable in peer review publications – in order to disseminate results of process and outcome to the research community and other HBs;
- Scaling and weighting of interventions and their value will take account of best practice and state of the art but must be operational and pragmatic;
- Utilises the Tsourapis and Frew (59) criteria for success.

Based on the findings from the literature evaluated here, the key steps (not necessarily sequential) identified for a priority setting framework that can accommodate disinvestment processes within the Welsh NHS/HBs were thought to be;

1. Stakeholder Engagement and Explicit Process
  - Convene working group and hold meeting
  - Identify candidate interventions/services/programmes and agree which are to be piloted informed by e.g. NICE 'do not do's' , the 'Elshaug criteria', nominated interventions, other exemplar PBMA programmes that can be focussed on disinvestment;
  - Convene advisory group with a remit of setting up building blocks of the framework which should include representatives of stakeholders ;
  - Public involvement (using existing HB public involvement process)
2. Information Management
  - For candidate intervention(s) assemble HB data (financial and health outcomes);
  - Undertake marginal analysis;
  - Validate results.
3. Consideration of Values and Context
  - Determine priority setting criteria (and agree what - if any - proportion of resource release will be re-invested);
  - Weighting exercise.
4. Execution of process
  - Evaluation and agreement of disinvestments and any re-investment.

5. Revision and Appeal
  - Validate/Improve decisions;
  - Address disagreements.
6. Implementation of decisions
7. Outcome review

## 1.9 RESEARCH BACKGROUND

There were two main settings, for the research reported in this thesis, both requiring different approaches for prioritisation, but differing in the context and the prioritisation needs. The first setting was in an NHS organisation which services all of Wales and the second a HB covering the Swansea area. The two settings are described below.

### 1.9.1 *WELSH HEALTH SPECIALISED SERVICE COMMITTEE*

The first setting was in a Welsh NHS organisation called Welsh Health Specialised Service Committee (WHSSC). This organisation has the responsibility for commissioning highly specialised technologies (HSTs) These technologies 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 (64). 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. There are around 143 specialised services (NHS England, 2013) of which there were 75 HSTs commissioned in Wales in 2014 (WHSSC, 2016). 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.(64). HSTs are driving up costs of health care (65, 66). HSTs/specialised procedures account for approximately 10% of the total NHS budget and cost about £11.8 billion per annum(67) and the rate of increase in spend is expected to be substantial. For example, stem cell research and regenerative medicine are thriving with breakthrough discoveries and advances in the field having accelerated translation of stem cell biology into therapies. (68).

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.

The situation in WHSSC lent itself to using MCDA rather than PBMA as the HSTs are so diverse and WHSSC is somewhat semidetached from the HBs and the programme budgets. As I will discuss in chapter 2, the chapter that describes this project, this was in the end perhaps not the optimal decisions. However we selected this as the main methodological approach because 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 either have to allocate new resources, 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 occur. Prioritisation decisions in the WHSSC setting are technical, ethical and social, in that all patients, communities and population groups will be affected to some degree.

### *1.9.2 ABERTAWE BRO MORGANNWG UNIVERSITY HEALTH BOARD*

The other setting for the research was Abertawe Bro Morgannwg University Health Board (ABMUHB) where I ran two projects.

In 2014 the HB undertook a Strategic Commissioning Development Programme as part of strategic changes in the health board. The programme included creation of Commissioning Boards which were to have a role in:

- Identifying opportunities for re-allocating existing resources within the system to deliver best value (where value is defined as quality, experience, and outcome) and the principles of Prudent Healthcare;
- Propose new models of care and service configurations with partners which shift care up-stream preventing future demand rather than managing existing demand and



- Delivering a highly engaged approach which involves citizens and the public as well as clinicians in decisions to change or remove services and pathways in the system.

The ABMUHB senior management felt that the situation for both services deserved scrutiny and knew the services desired change but had no further funding to allocate to the anticoagulation services or MSK. Thus undertaking a prioritisation/resource reallocation exercise was discussed with the ABMUHB senior management and commissioning development lead. The main theme discussed was that there was a requirement to make some disinvestment of a low value/no value element of the services and reinvestment into high value aspects of the services.

Pilot projects were desired to enable a 'bespoke' resource reallocation method to be developed for wider use, if successful, within ABMUHB.

Programme Budgeting Marginal Analysis (PBMA) seemed an appropriate approach to support the ABMUHB Commissioning Boards in fulfilling the commitment to Prudent Healthcare and budget constraints. The PBMA framework provides a structure which incorporates the values and goals of the health board and yet is a robust evidence based process which provides an explicit and transparent framework.

The overriding intent of this research was to adapt the PBMA methods to be pragmatic, practical and useable in the long terms within the ABMUHB setting rather than a one of academic exercise, and to utilise appropriate action research methods as advised by Peacock (6, 7) to enable project team and stakeholders act as participants in the process of the PBMA pilot and also inform the final framework.

### *1.9.3 SELECTION OF TOPICS FOR ABMUHB PBMA PILOTS*

Having reviewed the literature for approaches to topic selection a 'methodology' was devised by me to enable the ABMUHB stakeholders to scan the services covered by the commissioning boards and select candidates. The criteria for the identification and selection process are described below.

- The candidate programmes/services for review should be discrete programmes or services and part of an identifiable budget area where financial and outcome and activity data are available. These could be:
  - an area where it is self-evident that there is a need for some 'shuffling' of investment/saving/areas of service likely to be de prioritised;

- areas where ABMUHB is an outlier in terms of costs and outcomes compared with other health boards in Wales;
- an area that is NOT politically sensitive or 'owned' by a person who would be hard to bring on board so that implementation stood a reasonable chance;
- an area where the clinical and health care professionals are easier to work with and would 'get' what the process is trying to achieve – i.e. should be an area where key stakeholders are likely to be engaged and support the process;
- an area where secondary care to primary care shifts could aid in service delivery and meet prudent health care agenda;
- an area where access is complicated or less than timely perhaps where there are some out of health board referrals that could be re thought and that could be reversed;
- an area where there is some really good evidence for outcomes (maybe even a patient reported outcomes (PROMS) data collection area) for ABMUHB
- an area where low value interventions/NICE do not do's/interventions of low value/ are still in use;
- where a re-organisation of resources could be scalable;
- where there could be some reorganisation of the staffing so that non-medical staff can step into some roles thus freeing up valuable (expensive) clinical time;
- an area where PBMA has been executed elsewhere so that we can learn and grow from the experience;
- an area where disinvestment/resource release can realistically be achieved as a proof of concept.

These criteria were utilised and inspired review of the areas below, as candidates for pilot projects:

1. Musculoskeletal: the osteoarthritis/physio/joint replacement services; a need to work out how to determine 'population needs' for joint replacement and criteria for eligibility balanced with some low value/NICE do not do's in this area; possibilities are to work through service provision to reduce 'need' by intervening earlier to avoid joint replacement but helping patients to understand that this is what a good service looks like.

2. Gastroenterology/oncology: There are newer less invasive interventions for upper GI cancers/Barrett's oesophagus/GORD – these newer interventions can reduce need for surgery
3. Elderly and polypharmacy: inappropriate polypharmacy in the elderly is a frequent cause of admissions and audits at Morrision Hospital evidence the high level of admissions in the elderly associated with polypharmacy.
4. Heart failure: a growing problem and apparently there is scope to re think re profiling echocardiogram services utilising other health professionals rather than cardiologists.
5. Diabetes: there have been prior successful PBMA's in this area (the Bedford PBMA)
6. Obesity: services for children.
7. Anticoagulation services: varied services across the locality and a requirement to improve services to meet NICE clinical guidelines
8. Pain services: many NICE do not do's in this area and a lot of 'need' for these services.
9. Continence services: population growing and unmet need - continence clinics can deliver savings (allegedly) if efficient and engaged in GP education and with lots of do not do's and there is a considerable unmet need according to research.
10. Children and Adult Mental Health Services.
11. Where PBMA's have been undertaken in this area before.

Topics 1 and 7 were thought to be the best pilot areas, falling under the responsibility of two commissioning boards. The two PBMA pilots are described in Chapters three and four.

#### 1.10 PARTICIPATORY ACTION RESEARCH

This thesis has further been influenced by the work of Patten and colleagues who propose use of Participatory Action Research (PAR) in priority setting (69) and Mitton and colleagues who propose using PAR in PBMA (6). Mitton lays out the rationale as follows:

*“Enacting change in the prioritisation process may involve the staged introduction and development of PBMA. Several recent PBMA studies have shown that formal and informal training (through researcher-led and/or researcher-decision maker co-led workshops) can be used to raise decision-maker and stakeholder understanding of the proposed change, introduce economic concepts and principles, the PBMA framework, and examples of practical applications of PBMA .....*

*...Recent studies have also focussed on developing prioritisation processes iteratively and interactively (with decision-makers, stakeholders and researchers) and refining them by repeated exercises, adapting elements of PBMA to suit the local context. Reflections on the change should be elicited prior to refining the process. In-depth one-to-one interviews/surveys and focus groups can be used to review and verify the changes decided upon, and gather reflections and suggestions for refinement of the new process. Furthermore, analysis of observational data collected throughout the implementation of the process can be used to examine specific challenges encountered during framework implementation and the prospects for its longer term sustainability in the organization. Finally, it is often desirable to collect and analyze reflections on the PAR process itself, and its outcomes. In this context, the intent of PAR is to foster change towards more systematic, evidence-based priority setting processes within health care organizations. It does this by trying to recognize the complexity of PBMA from the decision-maker's perspective which can best be achieved by embedding researchers within the organization. What we are suggesting here is that PAR may be used as a vehicle to effectively translate economic knowledge and principles into practice by working closely with managers to demonstrate that such principles are entirely consistent with good practice in decision-making." (6)(p 131)*

This paper and these thoughts influenced my approach to the role I played, in addition to being a known PhD researcher, in the projects and as a team member.

#### 1.11 RECENT DEVELOPMENTS IN PRIORITY SETTING AND RESOURCE ALLOCATION

The literature review described above was completed in 2011, but during the time lag between discussing the initial proposals with WHSSC and ABMUHB and completing the main projects in early 2016 other people were undertaking research in this area. Clearly it was important to keep in touch with the literature in the area during the active research period, which I did. However the research I undertook was initiated in light of that initial literature and nothing emerged in the literature subsequently that would have made me change what I did. However, more recently pertinent literature emerged from the Canadian researchers, particularly Mitton and colleagues cited earlier in the literature summary, Gavin Mooney (before his death in 2012) from Australia and researchers from Bristol University. Much of this research related to use of qualitative methods to investigate stakeholders and decision makers' feedback on the PBMA processes and explore what constitutes high performance in priority setting and resource allocation. This literature is summarised below.

Mooney and colleagues authored a report on priority-setting methods which included a section on best practice(70). These publications form a useful body of work that supplement enable evaluation the performance of the projects beyond the 'Tsourapis criteria' (59) and refine the frameworks that have emerged.

The report from Mooney et al (70) is redolent of common sense. One point in the chapter on best practice is reassuring about the pragmatic approach I wanted to take.

*“As is the case in so many fields it is argued here that getting the principles or the ideas right is what matters; data can be less precise and still be OK. Thus it is better to have a good approach and poor data than a poor approach and good data”*

*“Some system of rationing is inevitable and it is better that it be rational and explicit than irrational and implicit. Without an acceptance of the need for priority setting, any recommendations from any priority setting approach may well be ignored. This is a way to try to use resources in health care to maximise the benefits sought, to pursue fairness and to acknowledge explicitly the trade-off between these two”(70).p 15*

Box 1:3 is a summary of the key criteria Mooney and colleagues suggest relate to best practice and priority setting.

**Box 1:3 Criteria for best practice priority setting from Mooney and Colleagues (70)**

- 1) *Any reasoned priority setting system must have at its core recognition of such scarcity and some way of dealing with it. It cannot be assumed away; it has to be addressed. This involves the economic concept of opportunity cost – the idea that when a resource or set of resources is committed to the provision of one service, it cannot be used in the provision of another. Opportunity cost, strictly defined, is the benefit foregone in the best alternative use of resources.*
- 2) *If scarcity and in turn of choice is not accepted by the key players in the relevant services, then attempting to get the recommendations from any priority setting system implemented is all too likely to fail.*
- 3) *A third point is that priority setting is about change and trying to determine whether some redeployment of resources can result in greater benefits. It is about altering the balance of resources within some fixed budget to squeeze more benefit out of them; or if more resources become available establishing where the extra resources will do most good; or if there is a fall in the monies available where cuts can be made to do least harm. This means that priorities are to be established in terms of opportunity cost and 'the margin', where the margin relates to change.*
- 4) *A fourth point is that any reasoned priority setting system must be based on some set of principles (or values) or be seeking to support the attainment of some objective or set of objectives. This means that there needs to be acknowledgement that the organisation involved is:  
  
(a) objectives focused; b) based on some set of principles (or what has been called a constitution); or (c) some combination of these two. In turn these objectives and principles need to be made explicit.*

Jan (71) in his overview also emphasises Gavin Mooney's approach to 'proceduralism' i.e. the importance of understanding the utility of process as well as outcome - Jan suggests that:

*"At a macro level, he developed a framework in which the social objective of equity was defined by procedural justice in which communitarian values were used as the basis for judging how resources should be allocated across the health system. Finally, he applied the notion of procedural justice to further our understanding of the political economy of resource allocation; highlighting how fairness in decision making processes can overcome the sometimes intractable zero-sum resource allocation problem".(71)*

In Jan's summary he suggests that programme budgeting marginal analysis (PBMA) was thought by Mooney as the least bad option (my words) for supporting prioritisation and health care resource allocation. PBMA also takes account of the need to solve a multi-faceted prioritisation problem – supported by Accountability for Reasonableness and community based values about which Mooney felt were vital. In the 2012 report Mooney strongly advocates PBMA as a '*recommended approach*'. (70)

In Canada probably the most experienced practitioners of PBMA (Mitton and colleagues) published a paper evaluating the role of PBMA in 'Times of Austerity' (72). The review emphasises that even in Canada where there has been a strong culture of priority setting the update is still challenging. The authors suggest that that in many contexts "*incentives are mis-aligned between physicians as drivers of service use and health regions seeking to constrain costs*". Mitton and colleagues also looked at evaluation of priority setting approaches in terms of success and described elements of high performance based on qualitative work undertaken in Canada as shown in Box 1:4, reproduced from this paper summarising the elements of high performance. These elements were very important for me to keep in mind as the projects were initiated and became active.

## 1.12 CONCLUSION

The scene setting research, the initial conceptualisation of workable priority setting frameworks and the search and identification of partners has been summarised here. This was just the start – and it took a while. In mid-2014 the research was ready to move into an active phase. The next three chapters, two, three and four, describe each project and chapter five presents the PBMA based priority setting and resource



allocation framework devised for ABMUHB to use as part of their commissioning programme.

**Box 1:4: Summary of elements of high performance from Mitton et al 2014(72)**

Table 3 Summary of elements of high performance			
Structure	Processes	Attitudes/behaviours	Outcomes
SMT has the ability and authority to move financial resources within and across silos	<p>PSRA at the organization-wide level is based on economic and ethical principles and involves:</p> <ul style="list-style-type: none"> <li>• Well-defined, weighted criteria which reflect the organization's values and strategic priorities</li> <li>• Use of a scoring tool to operationalize criteria in ranking individual proposals</li> <li>• Mechanisms for incorporating best available evidence</li> <li>• A decision review mechanism</li> </ul>	<p>Fit of priority setting decisions with social and community values is sought:</p> <ul style="list-style-type: none"> <li>• Public participation and input is valued; it is integrated into decisions in meaningful ways.</li> <li>• Consideration is given to how decisions align with external partners and the larger health system.</li> </ul>	Actual reallocation of financial resources is achieved
<p>Mechanisms are established for engagement of staff (clinical and non-clinical) in PSRA decisions, with particular though not exclusive attention to physicians</p> <ul style="list-style-type: none"> <li>• May include the use of incentives to encourage participation</li> </ul>	SMT ensures effective communication (both internally and externally) around its priority setting and resource allocation—leading to transparency	SMT displays strong leadership for PSRA—SMT is aware of and manages the external environment and other constraining factors, and is willing to take and stand behind tough decisions.	Resource allocation decisions are justified in light of the organization's established and agreed upon core values.
<i>SMT</i> senior management team, <i>PSRA</i> priority setting and resource allocation			

### 1.13 ETHICAL CONDUCT AND REVIEW

The research was approved by Swansea University College of Human and Health Science and College of Medicine Ethics Committee (see Appendix 2 for approval communications) in accordance with the data protection act and Swansea University procedures for research governance and ethics

(<http://www.swansea.ac.uk/research/researchintegrity/researchgovernance/> and <http://www.swansea.ac.uk/research/researchintegrity/researchethics/>)

I undertook interviews as part of the research. All interviewees were assured anonymity and the electronic files of the transcripts were anonymised and stored electronically on an encrypted computer and subsequently deleted. Paper copies of interview participant consent forms were stored in a locked filing cabinet in a lockable room.

## CHAPTER 2: PRIORITISATION OF HIGHLY SPECIALISED TECHNOLOGIES FOR HEALTH CARE SERVICES IN WALES

## 2 PRIORITISATION OF HIGHLY SPECIALISED TECHNOLOGIES FOR HEALTH CARE SERVICES IN WALES

### 2.1 CHAPTER SUMMARY

This chapter is about prioritisation of health care technologies in a notoriously challenging area – that of commissioning highly specialised technologies (HSTs). The setting for the project described here is the Welsh Health Specialised Services Committee (WHSSC) where those responsible for making recommendations about which HSTs should be recommended for use in NHS Wales are located. The team responsible for prioritisation used complex methods for prioritising and informing WHSSC commissioning recommendations with some success but also recognised that improvements were possible.

The project leads were open to my involvement in revising and simplifying the process and responded positively to my suggestion of utilising multi-criteria decision analysis (MCDA) methods. I was also able to introduce group decision support methods to facilitate scoring and voting, using an expert in the field to facilitate sessions. Through the time my research progressed, process redevelopment was achieved and prioritisation and funding recommendations were made, but in many cases implementation did not occur. WHSSC had several changes of leadership during the period of this research and there were differences of opinion about the processes being developed for prioritisation of HSTs, particularly about the transparency and use of explicit criteria.

As is often the case when undertaking research it is not just about the development and delivery of the methods as about people and politics and managing processes. Nevertheless in the ‘real world’ of NHS Wales, with a need for timely decisions and in the absence of guidance from the National Institute for Care and Health Excellence (NICE), robust and timely prioritisation recommendations for commissioning HSTs were accomplished. The challenge for WHSSC remains for the Joint Committee of the Health Boards (HBs) to make decisions based on the recommendations and then getting them implemented.

### 2.2 INTRODUCTION TO CHAPTER

Prioritisation and resource reallocation is the focus of this thesis. This second chapter focusses on the former, prioritisation, and devising rigorous methods based on best practice to enable the prioritisation panel responsible for making recommendations for

commissioning HSTs to do that, but in a way that is robust, pragmatic and relatively 'painless'.

This chapter reports on the experience of the process and outcomes of redeveloping a prioritisation process for WHSSC. It reports on how the process evolved in the light of experience, issues of implementation and finally the outcomes of recommendations and decisions.

### 2.3 BACKGROUND

HSTs are revolutionising the management and treatment of patients in the United Kingdom and elsewhere. In the United Kingdom (UK) HSTs are provided in relatively few hospitals with catchment populations of more than one million people and commissioned nationally (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 (64). 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. There are around 143 specialised services (73) of which there are 75 HSTs commissioned in Wales in 2014(74). 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.(64). HSTs are driving up costs of health care (65, 66).

HSTs/specialised procedures account for approximately 10% of the total NHS budget and cost about £11.8 billion per annum(67) and the rate of increase in spend is growing. For example, stem cell research and regenerative medicine are thriving with breakthrough discoveries and advances in the field having accelerated translation of stem cell biology into therapies. (68).

Health care budgets in the UK and elsewhere are under strain and the challenges of delivering healthcare within budget constraints are not going away (75) (76). Between 2009/10 and 2012/13 Wales was the only UK country where health spending was cut in real terms by 4.3% (60). 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*". (77)

A report from the Bevan Commission published in 2013, 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(61). 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 ....(61)”*

The ‘Prudent Healthcare’ initiative commenced in Wales in 2014 (5). The initiative was not initiated 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.”* (5, 61) 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;
- Do only what is needed, no more, no less; and do no harm;
- Reduce inappropriate variation using evidence-based practices consistently and transparently.

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.

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 either have to allocate new resources, 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 occur. Prioritisation decisions therefore are technical, ethical and social, in that all patients, communities and population groups will be affected to some degree.

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 but, as 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 (78, 79):

*“Accountability for reasonableness is the idea that the reasons or rationales for important limit-setting decisions should be publicly available. In addition, these reasons must be ones that ‘fair-minded’ 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.” (78, 79)*

The Accountability for Reasonableness framework (described in more detail in Chapter 1 section 1.6.5) 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 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.

### 2.3.1 THE WELSH CONTEXT FOR HSTS

The setting for this chapter is that of specialised commissioning in Wales. As Wales has a tax funded health care system but, unlike England, there is no purchaser-provider split. Services are provided by HBs from a unified budget with commissioning generally existing as a function rather than as explicit commissioning organisations as in England. However one area where commissioning is more explicit is with the WHSSC which was formed in 2011. This is an organisation representing the seven HBs in Wales. WHSSC reports into a Joint Committee comprising senior management from the seven HBs. The HBs 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.



HST evaluations for medicines are undertaken by NICE and recommendations on the use of new and existing highly specialised medicines within the NHS in England are adopted in Wales. However the NICE HST programme only considers drugs for very rare conditions leaving many HSTs unevaluated.

In 2011 WHSSC estimated an increase in demand of between 3% and 5% for HSTs, based on the changing demographics of the Welsh population, over the subsequent ten years (74). The budget for commissioning HSTs is fixed each year. Thus in the context of Prudent Healthcare and demand pressures on healthcare in Wales, developing and implementing robust methods for resource allocation and prioritisation were critical for the Welsh NHS. Never more challenging in this context, then, for WHSSC, was making decisions about HSTs where the nature of the interventions and patient populations, which are relatively small, means that robust evidence is often sparse and the costs of the intervention can threaten budgets or even be unaffordable.

In this context WHSSC developed an evidence evaluation and initial prioritisation framework, to support decisions about funding and recommending HSTs in Wales are evidence based, transparent and robust, adhering to Prudent Healthcare principles. However there was only budget to fund evidence reviews so in the main the frameworks and process were developed and delivered by the two project leads and from 2013 my support as a university based health economist undertaking PhD research.

The methods for HST prioritisation in WHSSC aimed to meet the following objectives in order to support robust prioritisation decisions.

- 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, in 2012-13 WHSSC developed and initiated a prioritisation process for HSTs. The methods used by WHSSC were deliberately adaptive – the commitment from the prioritisation project team was to learn from the process and listen carefully to 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 meetings were undertaken and then reviewed and reflected upon, and necessary changes in methods made.

## 2.4 METHODS AND PROCESS

In early 2013, WHSSC convened the first Prioritisation Panel with a timeline to ensure, ideally, that the recommendations and subsequent Joint Committee decisions linked to the Annual Plans and development of Intermediate Term Management Plans (IMTPs) in subsequent years. These timelines meant that the meetings had to make clear recommendations after each round.

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 criteria:

- 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 (the majority) were under consideration for use in Wales. The two categories provided different challenges for the Prioritisation Panel given that a negative decision for an existing HST 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 methods<sup>1</sup>.

#### *2.4.1 COMPOSITION OF THE PRIORITISATION PANEL*

The Prioritisation Panel convened represented a wide range of experts and stakeholders (including public health, HBs, academic partners, health economists, patient representatives, citizens, specialised services, commissioners, clinicians). A typical meeting would have representation from the experts and stakeholders, but not always the same individuals came to every meeting and the people did change over time. Reassuringly however a number of people remained committed and attended reliably. In 2015 the voting was restricted to fewer members at the request of the then chief executive officer of WHSSC. Box 2:1 below lists the composition of the panel with the 2015 split into voting and advisory members shown.

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<sup>1</sup> <http://www.gradeworkinggroup.org/>

**Box 2:1 Panel Composition**

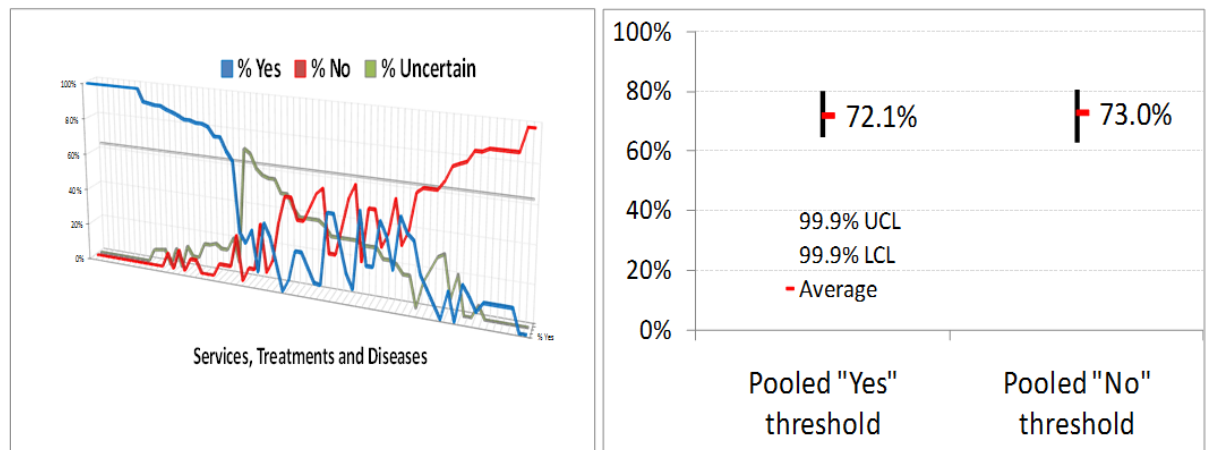
Prioritisation Panel Membership
Medical Director/Deputy Medical Director – Chair of panel
Public Health Professional
Nursing Professional
Medical Professional
Therapies Professional
Lay Member
Health Professional Forum Representative
Stakeholder Reference Group Representative
Prioritisation Panel Attendees in an Advisory Capacity after 2015
Clinical Advisors (Clinical Directors as per topics)
Service Improvement Advisor
Health Service Planning Advisor
Health Economics Advisor
Finance Advisor
Equality Advisor
Ethical Advisor

Adhering to the principles of Accountability for Reasonableness (78, 79) (described in more detail in Chapter 1 section 1.6.5) was important to support prioritisation recommendations and Joint Committee decisions.

In the first phase of methods development for the prioritisation process, in the horizon scanning process pairing of the specific condition and the HST treatment were made - Condition-HST pairs - were created for the interventions meeting the horizon scanning 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). Discrete choice methods were then used to rank order and apply a cut off point for commissioning or not. Whilst all the HSTs 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, before decisions in light of the evidence were made. Figure 2:1 is an illustration of the types of output that were created from the discrete choice methods.

**Figure 2:1 An example of the discrete choice outputs generated from the early panel meetings.**



In 2014/15 a change to the process, led by the author in partnership with the highly engaged project team, saw a move from discrete choice methods to an multi-criteria decision analysis (MCDA) based method using the Portsmouth Scorecard framework (80) which was felt to better support the prioritisation task, reduce complexity (the panel found the discrete choice methods taxing and time consuming) and arrive at a clearer more confident recommendations. Using the discrete choice methods, a number of condition-HST pairs resulted in 'uncertain' situations which did not lead to a recommendation one way or another. The benefit of using the Portsmouth Scorecard approach was that it enabled explicit weighting of key criteria for panel decisions. The list of criteria for the MCDA was changed, in light of the panel meetings and decisions made, from the original longer list used for the discrete choice exercises.

At the same time the Joint Committee reviewed the lists of HSTs that had been through horizon scanning and were under scrutiny. They came up with a new scheme of assessment for prioritisation after horizon scanning (categorising the HSTs as red [no

funding] amber [uncertain for funding] green [funded]) and asked the prioritisation project team to review the HSTs categorised as amber. This was very timely and allowed a proposal for prioritisation (which was approved) using MDCA as the core methodology. The full proposal and the terms of reference for the panel convened for this process are provided in Appendix 3 and the proposal for the MDCA methods to be supported by group decision support methods is provided in Appendix 4. The terms of reference for the panel convened for this process are provided in Appendix 5. The methodology as the agenda for panel meeting where MDCA was introduced is provided in Box 2:2.

**Box 2:2: Prioritisation Panel meeting agenda 24<sup>th</sup> April 2015**

AGENDA PRIORITISATION PANEL 24<sup>th</sup> April 2015

Morning session

Item	Lead
1. Background in context to the WHSSC IMTP	Project Lead 1
2. Criteria for decision making	Pippa Anderson
3. Panel discussion	All
4. Deciding weightings	All
5. Potential for 'virtual voting'	All
6. Training and CPD	All
7. Prioritisation Programme Overview	Project Lead 2

Afternoon session

- |   |                |
|---|----------------|
| 1. Applying MCDA to Evidence Evaluations  | Pippa Anderson |
| 2. HSTs for review  | All            |
| <ul style="list-style-type: none"><li>• Pipeline embolisation for giant aneurysms</li><li>• Radiofrequency ablation (RFA) and EMR for</li><li>• High Grade Dysplasia in Barrett's Oesophagus</li><li>• Stereotactic radiotherapy for cerebral metastases</li><li>• Stereotactic radiotherapy for the management of AVM and CCM</li><li>• Stereotactic radiotherapy for acoustic neuromas</li><li>• Bariatric surgery for the management of morbid obesity</li><li>• Surgical valve replacement for the management of severe symptomatic aortic stenosis</li><li>• CABG for the management of stable angina</li><li>• Angioplasty for the management of stable angina</li><li>• Angioplasty for the management of STEMI</li><li>• TAVI in high risk patients turned down for surgery</li><li>• TAVI in high risk patients as a substitution for surgery</li><li>• ECP in T-cell lymphoma</li><li>• ECP in GVHD</li></ul> |                |

#### 2.4.2 OPERATIONALISING THE MCDA BASED METHODS

The final version of the WHSSC Portsmouth Scorecard had five criteria each of which were weighted with the specific context of resource allocation and prioritisation of HSTs in mind. The Prioritisation Panel developed the relative weightings for the decision criteria in a meeting dedicated to this task. Selecting, defining and weighting the criteria went through a number of iterations before the five criteria were agreed.

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 guided by accountability for reasonableness and respect for autonomy, non-maleficence, beneficence and distributive justice. The panel meetings allowed discussion of areas of judgement.

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. However the Prioritisation Panel had to make complex decisions, which necessarily took time. After moving to the Portsmouth Scorecard approach the scoring was done around the table and scores revealed, any extremes discussed and to a certain extent some had to justify scores. Occasionally these were modified. Whilst not overtly causing dissonance or problems there was some discomfort in the public nature of the scoring. To aid the decision making process, to give more rigour and ease of use decision support approaches to facilitate decision-making at various stages during the process were introduced. In the last rounds of prioritisation panel meetings in mid to late 2015, these methods were integrated into the process to assist the members with the decisions and improve the use of time in meetings. Group decision support methods were supported by an expert in the methods who joined the team, used to facilitate decision-making at various stages during the meetings and the prioritisation process. The group decision support process used TurningPoint™ technology<sup>2</sup> to support voting. This is a voting system that employs 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(81). Research into specific features of this form of group decision support has reported gains in meeting efficiency (82),

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<sup>2</sup> <http://www.turningtechnologies.co.uk>.



improved levels of participation and a reduction in potentially negative influences from dominant members of the group (83).

The author took notes through the meetings and from discussions with the project leads and latterly with the group decision support facilitator. All parties understood that the general thrust of discussions to inform process development might be included in final reporting at the end of the process. At the end of 2015 the author interviewed the two project leads, just prior to their leaving WHSSC, to review the whole history of the process of the prioritisation project and to capture their reflections on the process. Ethical approval covered these detailed interviews. This information has primarily informed the discussion and supplements the reflections of the author.

## 2.5 RESULTS: OUTCOMES OF PRIORITISATION PROCESS

Despite the constraints experienced, some recommendations were made and specific HSTs identified for commissioning, non-adoption and decommissioning in the majority of panel meetings. Additionally the panel members agreed criteria for the prioritisation process and when the methods moved to use of MCDA relative weights for the criteria were agreed without problems. The final criteria and weights are shown in .

Table 2:1.

**Table 2:1 Criteria weights generated in 2015 for prioritisation of the HSTs**

<b>Weights</b>					
<b>Panel Member</b>	Burden of Disease	Magnitude of Effect	Grade of Evidence	Economic assessment	Prevention of Future Illness
<b>1</b>	25	25	20	20	10
<b>2</b>	30	20	15	20	15
<b>3</b>	25	25	15	20	15
<b>4</b>	20	25	15	25	15
<b>5</b>	20	25	20	20	15
<b>6</b>	30	15	15	30	10
<b>Mean</b>	25	23	17	23	13
<b>Percentage</b>	125%	113%	83%	113%	67%

The differing HSTs were individually scored against the criteria and then weighted scores calculated for each HST with a continuum of priority weights being compiled (Table 2:2 and Figure 2:2 at the end of the rounds of meetings. The TurningPoint™ raw score and mean scores for each intervention are shown, as they were displayed at the

meeting, in Figure 2:3a TurningPoint™ outputs for interventions 1-3 of the 2015  
Prioritisation Panel (raw scores and mean scores)Figure 2:3a-g.

**Table 2:2 MS Excel outputs for the nineteen interventions reviewed by the 2015 Prioritisation Panel using group decision support**

	Interventions	Burden of Disease	BODW	Magnitude of Benefit	MOBW	Grade of Evidence	GOEW	Economic Assessment	EAW	Prevention of Future Illness	POFW	Total Mean Weighted Score	%	Total Mean Score	% W
9	PROTON - CHILD	9.17	11.46	8.00	9.00	7.00	5.83	7.17	5.98	7.33	4.89	37.16	74%	37.16	74%
10	PROTON - TYP	9.17	11.46	8.00	9.00	6.83	5.69	6.83	5.69	7.17	4.78	36.63	73%	36.63	73%
2	VAD - BTR	9.00	11.25	7.50	8.44	6.83	5.69	6.00	5.00	7.33	4.89	35.27	71%	35.27	71%
1	VAD - BTT	9.33	11.66	7.50	8.44	6.67	5.56	5.83	4.86	5.83	3.89	34.40	69%	34.40	69%
18	IVACAFOR NONG551D	9.00	11.25	8.50	9.56	6.00	5.00	5.00	4.17	5.83	3.89	33.87	68%	33.87	68%
4	VAD - CentriMAG	9.00	11.25	6.83	7.68	6.50	5.42	6.17	5.14	6.17	4.11	33.61	67%	33.61	67%
17	SUSOCTOCOG	8.00	10.00	7.83	8.81	6.17	5.14	5.67	4.73	6.67	4.45	33.12	66%	33.12	66%
12	ELOSULFASE ALFA	9.50	11.88	7.33	8.25	5.33	4.44	5.33	4.44	5.50	3.67	32.67	65%	32.67	65%
13	TRANSLANA	9.50	11.88	7.17	8.07	5.50	4.58	5.33	4.44	5.00	3.33	32.30	65%	32.30	65%
11	PROTON - ADULT	8.67	10.84	7.17	8.07	5.33	4.44	5.83	4.86	5.50	3.67	31.87	64%	31.87	64%
14	ASFOTASE ALFA	8.67	10.84	7.00	7.88	5.17	4.31	5.00	4.17	6.33	4.22	31.41	63%	31.41	63%
7	NERVE STIM - OCC	8.50	10.63	6.50	7.31	5.17	4.31	6.00	5.00	6.00	4.00	31.25	62%	31.25	62%
16	SAPROPTERIN	7.83	9.79	6.83	7.68	5.83	4.86	5.83	4.86	6.00	4.00	31.19	62%	31.19	62%
8	NERVE STIM - GANG	8.50	10.63	6.33	7.12	4.67	3.89	5.83	4.86	5.67	3.78	30.28	61%	30.28	61%
3	VAD - DT	9.17	11.46	6.17	6.94	5.33	4.44	4.67	3.89	4.17	2.78	29.52	59%	29.52	59%
15	SEBELIPASE ALFA	8.83	11.04	6.50	7.31	4.83	4.03	4.17	3.48	5.33	3.55	29.40	59%	29.40	59%
6	PANCREAT & ISLET	7.50	9.38	5.50	6.19	5.17	4.31	4.50	3.75	5.50	3.67	27.29	55%	27.29	55%
19	MALIGNANT MELANOMA	8.83	11.04	3.50	3.94	5.50	4.58	3.50	2.92	2.50	1.67	24.14	48%	24.14	48%
5	HAND TRANSPLANT	5.50	6.88	5.17	5.82	3.67	3.06	2.33	1.94	3.83	2.55	20.24	40%	20.24	40%

**BODW=BURDEN OF DISEASE WEIGHTED SCORE MOBW=MAGNITUDE OF BENEFIT WEIGHTED SCORE GOEW=GRADE OF EVIDENCE WEIGHTED SCORE  
EAW=ECONOMIC ASSESSMNET WEIGHTED SCORE**

**Figure 2:2 Ordering of total scores from 2015 Prioritisation Panel sessions where decisions were supported by group decision support**

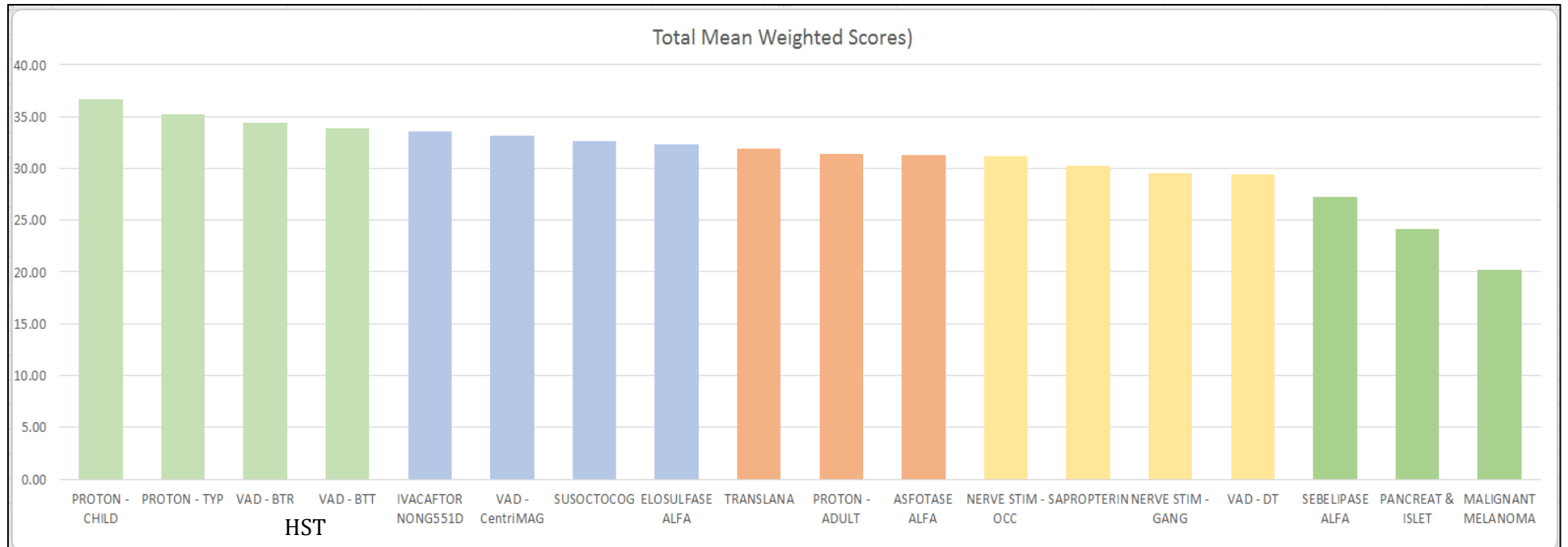


Figure 2:3a TurningPoint™ outputs for interventions 1-3 of the 2015 Prioritisation Panel (raw scores and mean scores)



Figure 2.3b: TurningPoint™ outputs for interventions 4-6 of the 2015 Prioritisation Panel (raw scores and mean scores)

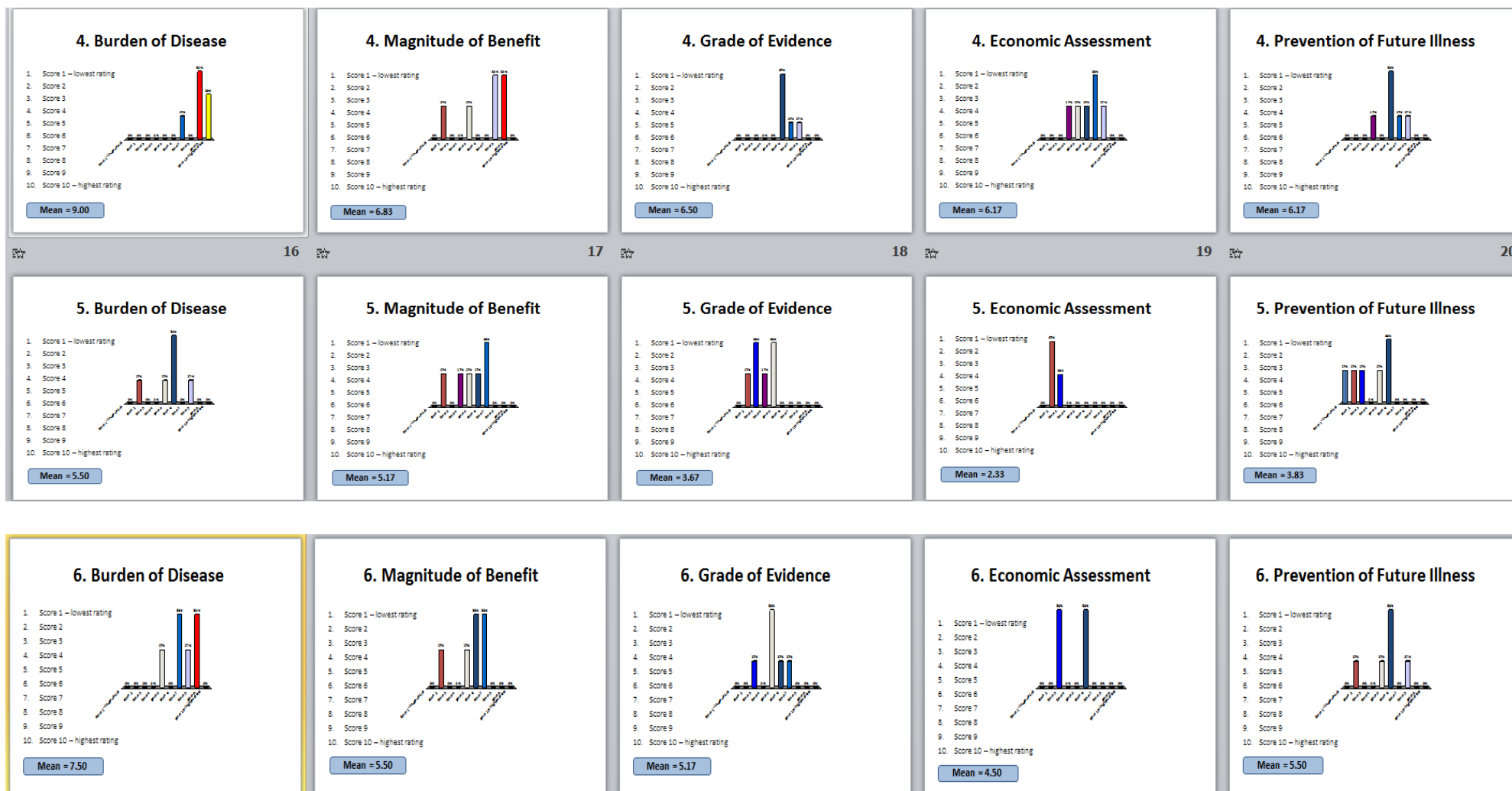


Figure 2.3c: TurningPoint™ outputs for interventions 7-9 of the 2015 Prioritisation Panel (raw scores and mean scores)

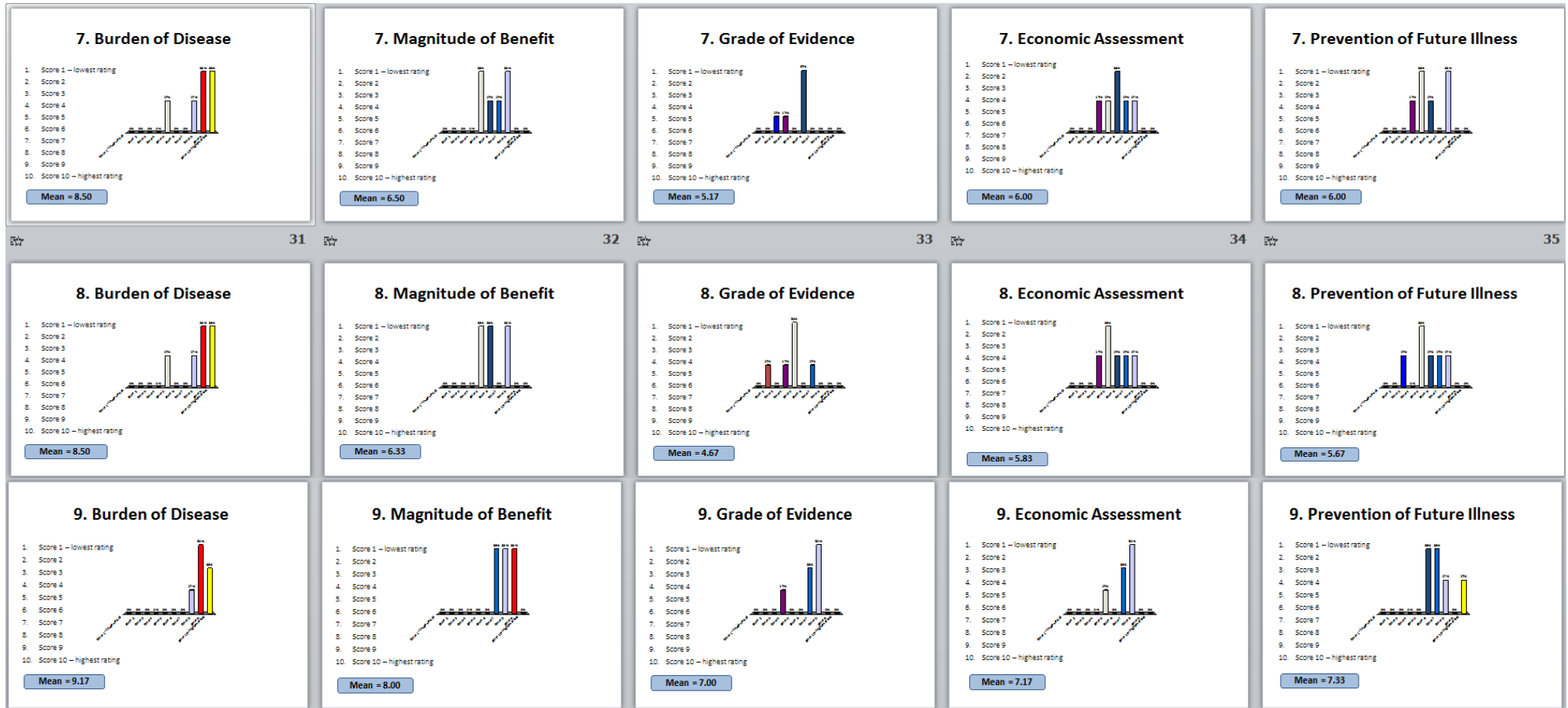


Figure 2.3d: TurningPoint™ outputs for interventions 10-12 of the 2015 Prioritisation Panel (raw scores and mean scores)

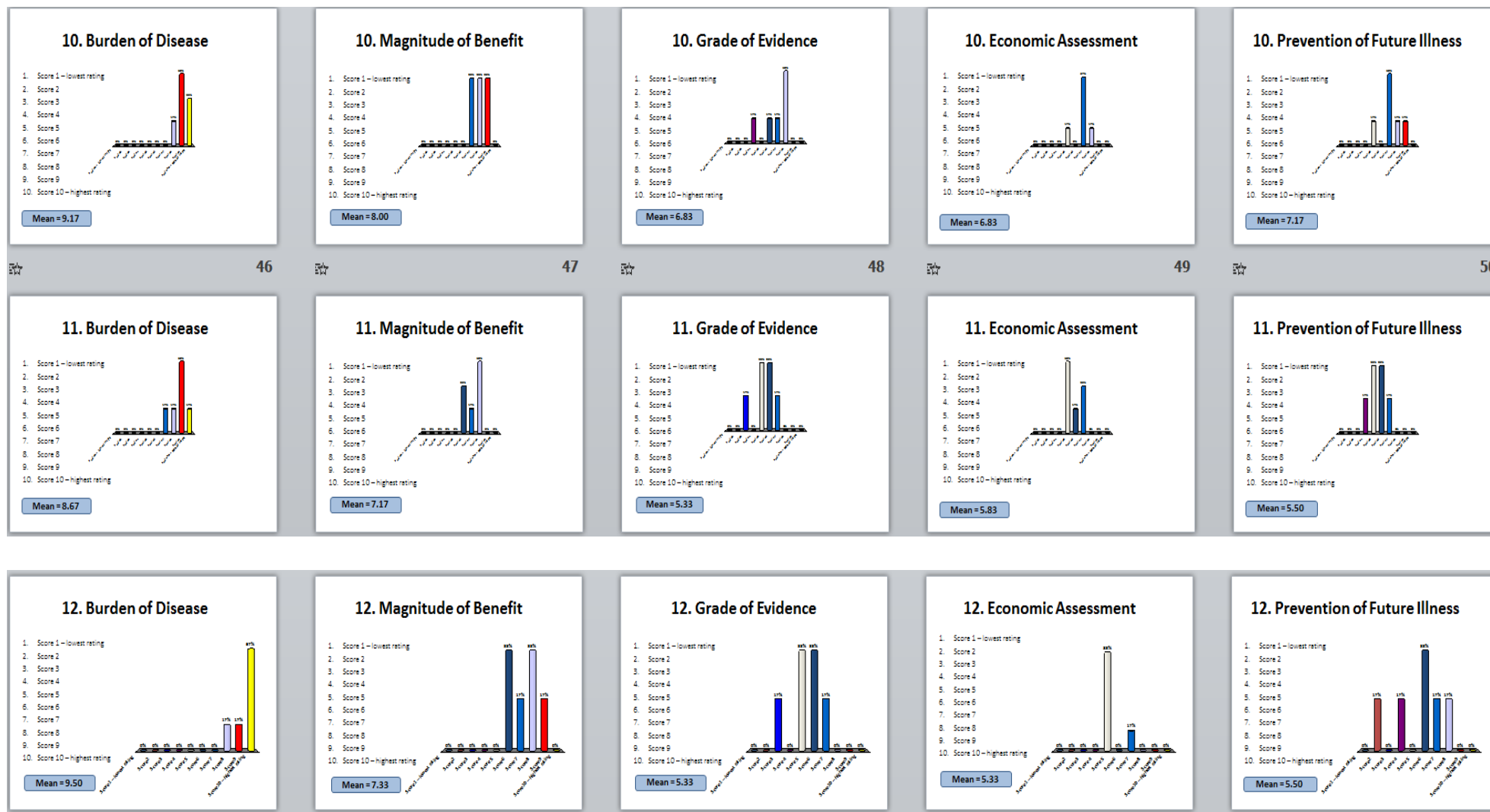




Figure 2.3e: TurningPoint™ outputs for interventions 13-15 of the 2015 Prioritisation Panel (raw scores and mean scores)

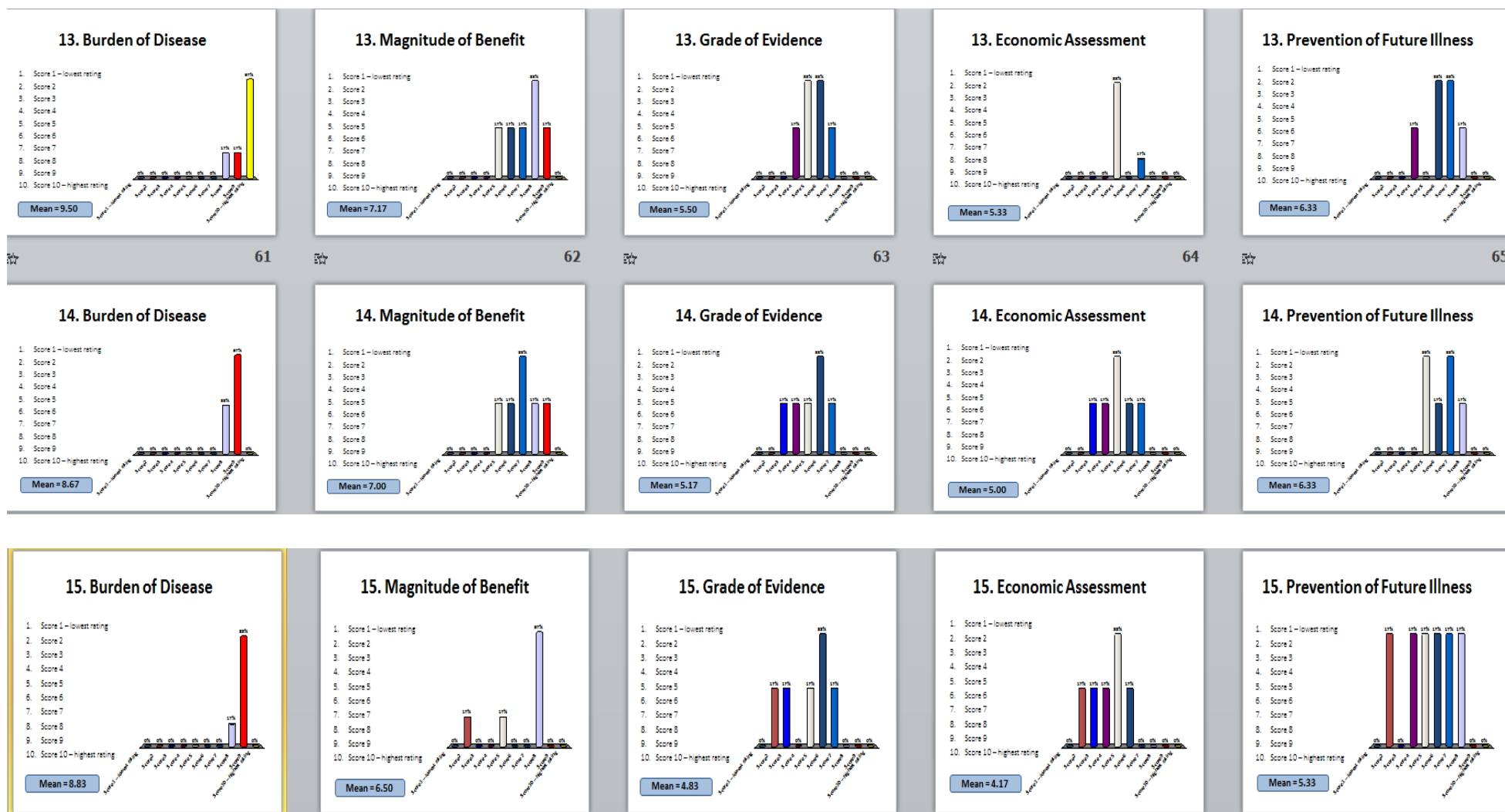


Figure 2.3f: TurningPoint™ outputs for interventions 16-18 of the 2015 Prioritisation Panel (raw scores and mean scores)

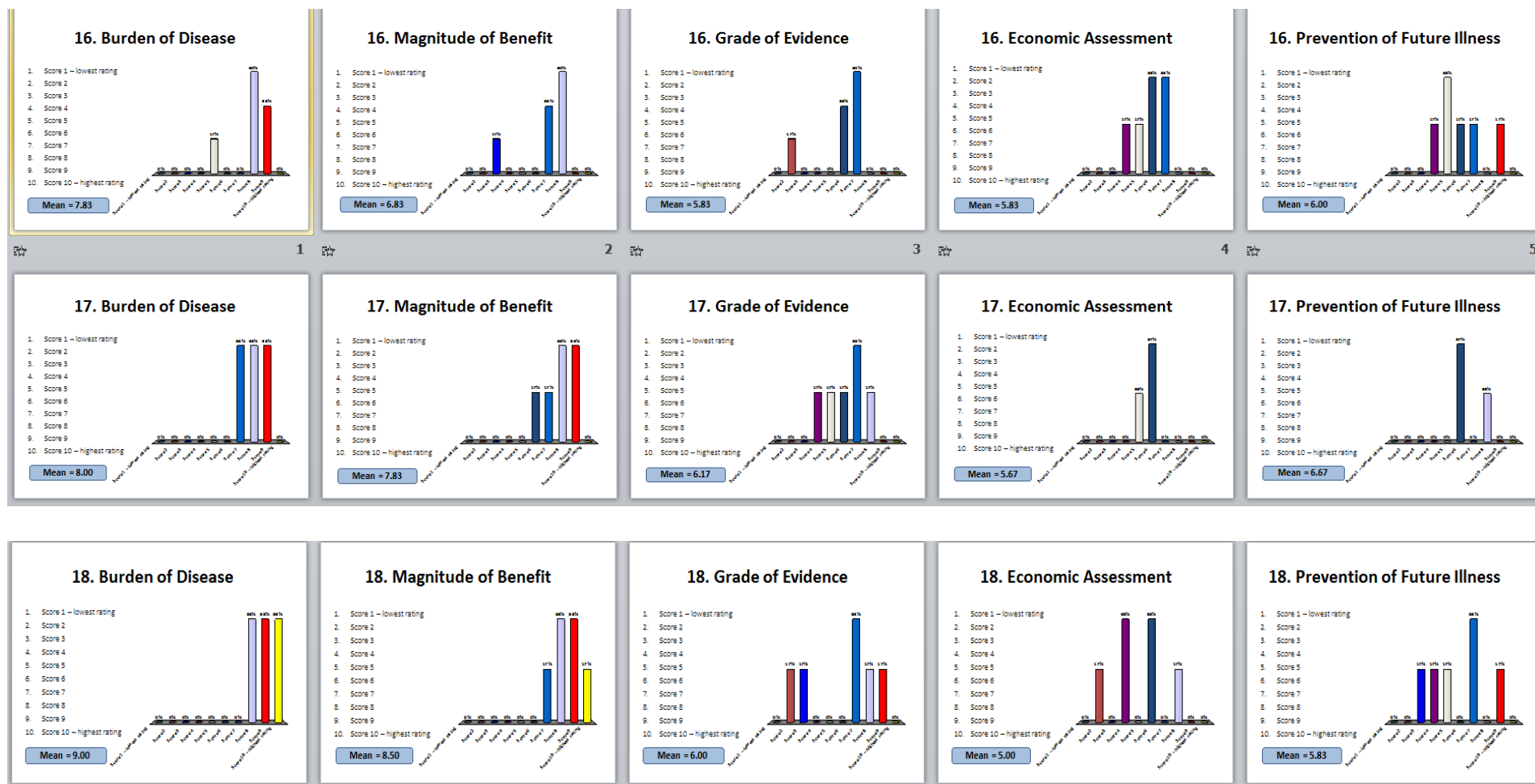
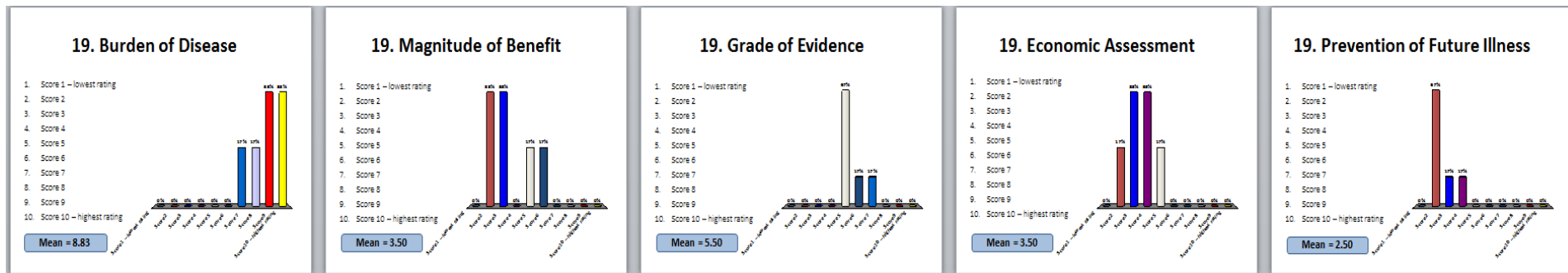
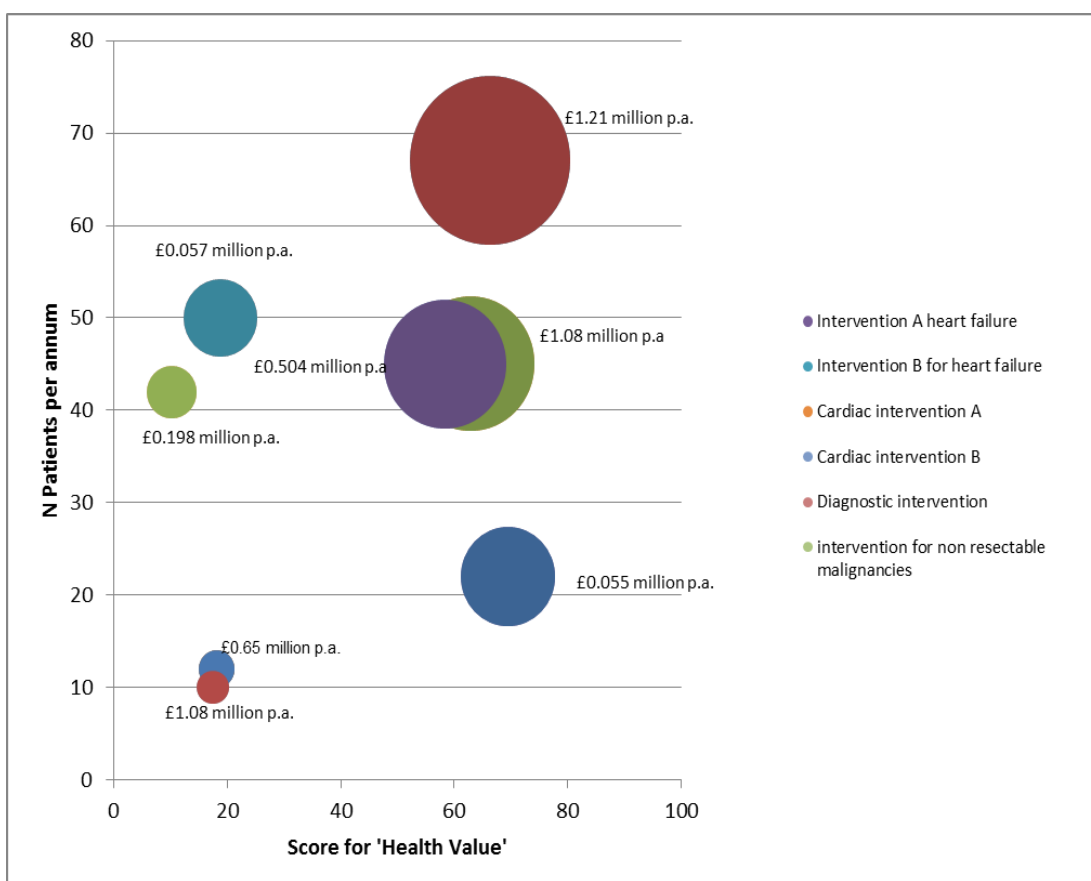


Figure 2.3g: TurningPoint™ outputs for intervention 19 of the 2015 Prioritisation Panel (raw scores and mean scores)



Very, very few of the HSTs evaluated were supported by good quality evidence and published studies with health economic evidence to support the evidence of value of the HST. The availability of weighted scores representing an overall 'health value' score of a specific HST to be created – in the absence of cost effectiveness data this allowed a form of relative value to be identified using the expected cost of the HST. The bubble diagram enabled graphical representation of the overall scores for differing HSTs and budget which was very useful to support the panel members' final recommendations of whether the HST should be available in Wales. Figure 2:4 is an example of a bubble diagram used in meetings. The scores used to generate the bubble diagram are provided in Table 2:3

**Figure 2:4: Bubble Chart Showing Health 'Value', Numbers of Patients, and Costs per annum (£s)**



**Table 2:3 Data used to create the Bubble diagram shown in Figure 2.4.**

<b>Intervention</b>	<b>Health Value</b>	<b>N of prevalent patients</b>	<b>Value * N</b>
<b>Intervention A heart failure</b>	69.5	22	1529
<b>Intervention B for heart failure</b>	66.3	67	4442.1
<b>Cardiac intervention A</b>	62.8	45	2826
<b>Cardiac intervention B</b>	58.4	45	2628
<b>Diagnostic intervention</b>	18.9	50	945
<b>intervention for non resectable malignancies</b>	18.2	12	218.4
<b>Rare disease drug</b>	17.5	10	175
<b>surgical intervention</b>	10.3	42	432.6

With the knowledge of the prior, relative scoring for the HSTs (as shown in Table 2:2) towards the end of the series of panel meetings where we had started using group decision support, it became apparent that the panel could also utilise group decision support methods to enable decisions made as to whether the HSTs under consideration should be funded or not by NHS Wales and give a 'yes/no' recommendation, in addition to supporting the weighting of criteria and scoring the interventions.

The PowerPoint outputs from this new round of 'final voting' are shown in Figure 2:5. Votes were not always clear cut and interestingly there was one case where the vote for adults differed from votes for younger patients. This was proton beam therapy: the use of proton beam therapy for adults had a split vote, with 'no' being the majority vote. This led to some discussion at the meeting but the 'no' was agreed sufficiently strong to carry the recommendation of 'no funding'. The use of proton beam therapy for paediatric, teenager and young adults was a 100% yes vote. The difference between the votes appeared to be driven by the original scores in the ranking and the burden and severity of the health problem. The stronger yes in the paediatric, teenager and young adults intervention was because in the younger population the problem is more severe and life threatening. The voting for ventricular assist devices (VADs) illustrates the difference (yes) for VADS that are a transition intervention to enable a patient to get through to a 'solution' for their problem, whereas a VAD as destination therapy (no) is relatively free of long term evidence and a risky intervention.

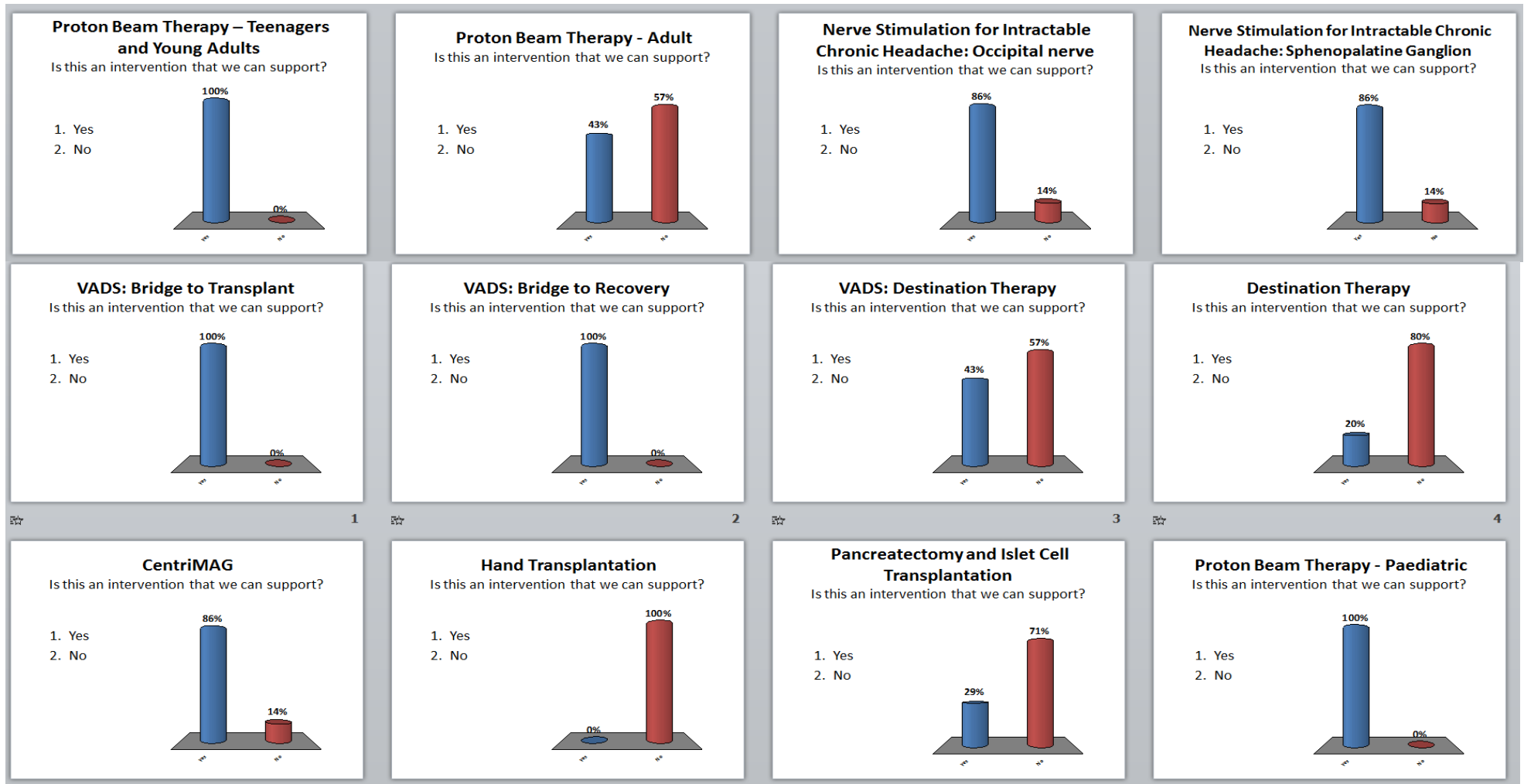
The disease areas, types of technology, and number of condition treatment pairs and results of panel decisions for the whole prioritisation programme are summarised in

Table 2:4. Throughout the whole prioritisation programme, in all the phases of development, 133 condition treatment pairs were evaluated (see Table 2:5). Of those the majority were in the cancer area. However these were not all drugs but HSTs such as genetic testing and HSTs for un-resectable cancers. Other HSTs evaluated ranged from trans-aortic valve implantation for severe symptomatic aortic stenosis in high-risk patients, to VADs as a bridge to transplant and other indications, to ultra-orphan drugs to LVA microsurgery for lymphoedema.

Most of the deliberations summarised in Table 2:4 resulted in a decision and recommendation - only 3% (n=4) were 'undecided'. The undecideds arose in the period where discrete choice methods were used. Of the 'not recommended' decisions 15% (n=10) were reversed for a variety of reasons, including political imperatives, which will be discussed further in section 2.6.2.3, funding for equipment and infrastructure provided assuming a 'yes' ahead of the decision being a 'no'. As indicated Cancer HSTs were the most frequently assessed HSTs and the most frequently not recommended and all the 'undecideds' were cancer HSTs. They formed half of the recommendations actually implemented. Of the recommendations made at the time of preparing these tables (January 2015), 50% of the recommendations had not moved to implementation. The interviews with the project leads speculate (with insight) for some of the process reasons for this.

The individual Condition-HST pairs and the weighted scores that the Prioritisation Panel assigned are shown in Table 2:4. Prioritisation decisions made over the course of the full prioritisation programme (133 condition- HST pairs) (reported in descending order of overall score). The weighted scores above 50 tended to have high scores on two or more of the burden of disease, magnitude of benefit or grade of evidence. The only two HSTs that had reasonable quality health economic evidence were two genetic tests - BRAF 600 in malignant melanoma and the KRAS/NRAF in malignant colorectal cancer. The HST at the bottom of the list with the lowest score (9.7) by a considerable margin was lymphovenous anastomosis (LVA) microsurgery for primary and secondary lymphoedema. The next lowest score was 19.7. This HST was already available in Wales but provided under exceptional circumstances. The evidence review for this HST as provided to the panel is provided as Appendix 6. The pertinent sections are provided in Box 2:3 below.

Figure 2:5 Voting outputs for final recommendations



**Table 2:4 Prioritisation decisions made over the course of the full prioritisation programme (133 condition- HST pairs)**

<b>Disease area</b>	<b>N of Assessments</b>	<b>% total</b>	<b>N Rec'ded</b>	<b>% total</b>	<b>N not Rec'ded</b>	<b>% total</b>	<b>N pre MCDA Undecided</b>	<b>% total</b>	<b>Change from No to Yes</b>	<b>% no to yes</b>	<b>N Rec'dations Implemented</b>	<b>% Rec'dations implemented</b>
<b>Cardiovascular</b>	24	18	16	12	8	6	0	0	0	0	16	12
<b>Cancer</b>	58	44	20	15	34	26	4	3	3	5	26	20
<b>Genetics</b>	8	6	8	6	0	0	0	0	0	0	8	6
<b>Immunology</b>	3	2	2	2	1	1	0	0	1	2	1	1
<b>Mental health</b>	3	2	3	2	0	0	0	0	0	0	0	0
<b>Neurological sciences</b>	9	7	3	2	6	5	0	0	1	2	3	2
<b>Plastics &amp; Burns</b>	8	6	3	2	5	4	0	0	2	3	3	2
<b>Renal</b>	4	3	3	2	1	1	0	0	1	2	0	0
<b>Rare diseases</b>	13	10	6	5	7	5	0	0	2	3	7	5
<b>Regenerative medicine</b>	3	2	0	0	3	2	0	0	0	0	0	0
<b>Total</b>	<b>133</b>	<b>100</b>	<b>64</b>	<b>48</b>	<b>65</b>	<b>49</b>	<b>4</b>	<b>3</b>	<b>10</b>	<b>15</b>	<b>64</b>	<b>50</b>

Rec'ded = recommended



### Box 2:3 Key Evidence for LVA Microsurgery

#### Background

Lymphoedema is a chronic disease caused by impairment of the lymphatic transport capacity, resulting in oedema, excess of tissue proteins, and in latter stages, inflammation and irreversible changes such as fibrosis and excess of adipose tissue. Lymph transport impairment and clinical signs of lymphoedema can be acquired (secondary) or congenital (primary). Treatment of lymphoedema is challenging. Therapeutic approaches consist of both non-operative and operative methods. The overwhelming majority of patients can effectively be treated by non-operative means such as complex decongestive therapy (CDT) in combination with manual lymphatic drainage, bandaging, physical exercises, skin care and elastic stockings. In the long lasting maintenance phase, therapeutic elastic stockings are mandatory. The goal of all non-operative treatment modalities is to reduce capillary filtration, improve drainage of interstitial fluid and macromolecules, and therefore reduce swelling, inflammation, recurrence of erysipelas, and improve quality of life. Operative treatment is only indicated in a few cases as a last resort. Many reconstructive techniques have been described, such as lymphovenous anastomosis (LVA), lymphovenous-lymphatic (LVL) transplant (especially in the presence of venous hypertension), and forms of lymph vessel transplantation. LVA has been the most frequently used type of operation.

#### Outcomes Summary

The evidence is based on one meta-analysis (Basta MN et al (2014) based on 27 case series studies in 1,619 patients and 22 case series studies of LVA microsurgery in 945 patients (range 2 – 446 patients). Patient had secondary and primary lymphoedema in upper and lower extremity locations. 21 of the case series were retrospective data. No randomised controlled evidence was found, although one small study (Morotti M et al (2013) had a historical control matched to an LVA cohort.

The meta-analysis by Basta MN et al (2014) included 24 studies offering level IV evidence (GRADE very poor) and three studies offering level III evidence (GRADE poor) in 1,619 patients with upper and lower limb lymphoedema. Lymphovenous shunt procedures were performed in 22 of the studies and lymph node transplantation was performed in 5 of the studies. Excess circumference was reduced by  $48.8 \pm 6.0$  percent, and absolute circumference was reduced by  $3.31 \pm 0.73$  cm. Studies reporting change in volume demonstrated reduction in excess volume by  $56.6 \pm 9.1$  percent, and absolute volume was reduced by  $23.6 \pm 2.1$  percent. The incidence of no improvement in lymphoedema postoperatively was 11.8 percent, and 91.2 percent of patients reported subjective improvement. Approximately 64.8 percent of patients discontinued compression garments at follow-up. Complications included operative-site infection (4.7 percent), lymphorrhea (7.7 percent), re-exploration for flap congestion (2.7 percent), and additional procedures (22.6 percent). Notably, secondary outcomes appear promising. Specifically, the incidence of no postoperative quantifiable improvement in lymphoedema was 11.8 percent, suggesting that 89.2% of patients derived benefit from surgery. In an attempt to translate this benefit into a clinically relevant parameter, the ability to discontinue conservative therapy was investigated and found to be 65 percent across all studies reporting this outcome. Moreover, lymph node transplantation was superior to lymphovenous shunt, affording a 20 percent greater chance of discontinuing conservative treatment. Complication rates were relatively low throughout, and major complications such as operative re-exploration had an incidence of less than 3 percent and a concomitant flap salvage rate of 100 percent. It appears, in general, that these procedures are safe for most patients. Overall, microsurgical interventions for peripheral lymphoedema appear to provide consistent quantitative improvements postoperatively and have a relatively wide safety margin. These quantitative improvements have clinical relevance, as a substantial number of patients are able to discontinue conservative therapy. Lymphatic tissue transplantation may provide better outcomes compared with lymphovenous shunt; however, well-designed head-to-head comparisons are still needed to evaluate this more definitively. Of the studies included, only three were level III evidence and the remainder were level IV. As such, interpretation of the findings of this review mandates evaluation of the evidence in light of the methodologic flaws inherent in the studies included. There was significant heterogeneity in patient selection, surgical approach, anatomical location, lymphoedema severity and outcome measures used to demonstrate clinical effectiveness. The overall GRADE of evidence was very poor.

**Table 2:5 Condition and HST intervention Portsmouth Scorecard scores for all the 2015 Prioritisation Panels; weighted score in rank order**

HST	Burden of illness	Weighted score	Magnitude of Benefit	Weighted score	Grade of Evidence	Weighted score	Economic Assessment	Weighted score	Prevention of Future Illness/harm	Weighted score	Overall Score	Weighted Overall Score
<b>CRT-P for the management of heart failure</b>	15.0	13.0	16.0	20.7	14.5	13.7	11.0	11.4	14.0	12.6	70.5	71.3
<b>Bariatric surgery for morbid obesity</b>	10.4	9.0	14.4	18.6	14.9	14.1	12.6	13.1	13.4	12.1	65.7	66.8
<b>CRT-D for the management of heart failure</b>	15.0	13.0	16.0	20.7	14.5	13.7	6.8	7.0	14.0	12.6	66.3	66.9
<b>ICDs - Primary Prevention sudden cardiac death</b>	11.5	9.9	15.5	20.0	16.0	15.1	5.8	6.0	15.5	14.0	64.3	65.0
<b>KRAS and NRAS testing in mCRC</b>	8.5	7.3	15.0	19.4	13.8	13.0	14.5	15.0	5.5	5.0	57.3	59.7
<b>ICDs- Secondary Prevention arrhythmias post infarct</b>	12.0	10.4	11.7	15.1	12.5	11.8	6.7	6.9	15.5	14.0	58.4	58.2
<b>BRAF 600 in Malignant Melanoma</b>	5.3	4.5	12.8	16.5	15.0	14.2	16.8	17.4	4.5	4.1	54.3	56.6
<b>MSI Testing in stage II CRC</b>	5.3	4.5	9.3	11.9	14.8	13.9	13.8	14.3	6.8	6.1	49.8	50.7
<b>Surgical AVR for SSAS</b>	9.6	8.3	12.0	15.5	10.3	9.7	7.6	7.9	8.6	7.7	48.1	49.1

<b>HST</b>	<b>Burden of illness</b>	<b>Weighted score</b>	<b>Magnitude of Benefit</b>	<b>Weighted score</b>	<b>Grade of Evidence</b>	<b>Weighted score</b>	<b>Economic Assessment</b>	<b>Weighted score</b>	<b>Prevention of Future Illness/harm</b>	<b>Weighted score</b>	<b>Overall Score</b>	<b>Weighted Overall Score</b>
<b>TAVI for SSAS in surgically inoperable patients</b>	8.3	7.2	13.6	17.6	10.7	10.1	9.0	9.3	4.7	4.2	46.3	48.4
<b>Oncotype DX in early breast cancer</b>	7.0	6.0	11.0	14.2	14.3	13.5	6.5	6.7	7.5	6.8	46.3	47.2
<b>RFA and EMR of high grade dysplasia in Barrett's Oesophagus</b>	6.9	6.0	10.5	13.6	6.2	5.9	11.3	11.7	7.7	6.9	42.6	44.0
<b>1p36/19q13, MGMT IDH1 and IDH2 in glioblastoma</b>	6.4	5.5	10.2	13.2	5.0	4.7	7.0	7.3	5.6	5.0	34.2	35.7
<b>SBRT NSCLC (unresectable)</b>	5.3	4.6	8.0	10.3	6.9	6.5	8.0	8.3	3.9	3.5	32.1	33.2
<b>HIPEC and CRS for the treatment of peritoneal malignancies</b>	4.2	3.6	10.3	13.2	6.3	5.9	3.4	3.5	6.0	5.4	30.1	31.7
<b>Eculizumab in aHUS</b>	3.3	2.8	7.6	9.8	3.1	3.0	0.8	0.8	6.3	5.6	21.0	22.0
<b>TAVI for SSAS in high risk patients as a substitution for surgical AVR</b>	4.3	3.7	5.0	6.5	5.6	5.3	3.7	3.8	3.3	3.0	21.9	22.3
<b>Pipeline</b>	3.7	3.2	6.2	8.0	3.7	3.5	3.5	3.6	3.5	3.2	20.6	21.5

<b>HST</b>	<b>Burden of illness</b>	<b>Weighted score</b>	<b>Magnitude of Benefit</b>	<b>Weighted score</b>	<b>Grade of Evidence</b>	<b>Weighted score</b>	<b>Economic Assessment</b>	<b>Weighted score</b>	<b>Prevention of Future Illness/harm</b>	<b>Weighted score</b>	<b>Overall Score</b>	<b>Weighted Overall Score</b>
<b>embolisation</b>												
<b>SRT Cerebral Metastases</b>	4.4	3.8	5.3	6.8	3.7	3.5	5.0	5.2	1.6	1.4	20.0	20.8
<b>68-Ga DOTA peptides for the detection of NETs</b>	4.5	3.9	5.0	6.5	2.0	1.9	2.0	2.1	5.4	4.9	18.9	19.2
<b>LVA microsurgery for lymphoedema</b>	3.0	2.6	1.0	1.3	1.0	0.9	0.4	0.4	4.9	4.4	10.3	9.7

### 2.5.1 BENCHMARKING THE WHSSC PRIORITISATION PROCESS

The project was being developed and delivered against a background of change. There were five chief executive officers (CEOs) during the whole timeline of the prioritisation project (2012 – 2015) and three CEOs in the period that the author was collaborating with the team. One CEO challenged the process continuously – speculatively – because it attempted to be evidenced based, transparent and explicit and adhere to all of the conditions of Accountability for Reasonableness and this approach did not fit with his individual approach to prioritisation.

A potential solution to these challenges at WHSSC was developed. In order to build confidence with the Joint Committee and the sceptics in WHSSC the prioritisation process was benchmarked against accepted best practice for prioritisation. This would provide the Joint Committee and the WHSSC CEO with the evidence of performance against an external standard. Thus in mid-2015 the prioritisation process was benchmarked against the EVIDEM framework (39) which, as a comprehensive evidence based framework created by a multi country and a multidisciplinary initiative that was accessible and was considered to be a good standard by which to judge the WHSSC process. The EVIDEM framework is described fully in chapter 1 section 7.3.2. The full report of the assessment is provided as Appendix 7.

Table 2:6 lists the EVIDEM criteria and compares the WHSSC criteria, process and activities with those of EVIDEM. In summary the key findings were:

- The processes developed by WHSSC adhere to good practice, Accountability for Reasonableness and are transparent and robust;
- The evidence reviews were undertaken with the highest level of accepted good practice and are to be commended;
- The challenges of evaluating interventions with limited evidence have been understood and dealt with appropriately;
- The area where the process could improve is in bringing in a higher level of patient and public engagement to the process.

The findings from the benchmarking exercise suggested that whilst the process was robust and best practice was being adhered to; one important area for improvement was the level of public and patient involvement and was the only major area of concern. This review focused on the prioritization process and not the execution of the panel

decisions (ratification and implementation of recommendations or rejection). Review of the management decisions, subsequent recommendations and implementation related to the prioritization panel recommendations were not reviewed.

**Table 2:6 WHSSC Prioritisation benchmark check list and comments**

PRIORITISATION ATTRIBUTE	WHSSC PRIORITISATION PHASE 1: 2012-14	WHSSC PRIORITISATION PHASE 2: 2014/15: PORTSMOUTH SCORE CARD	COMMENTS
Process			
Considered all aspects of decision	No	Yes	Phase I was based primarily on the consideration of clinical and cost effectiveness with limited consideration of burden of disease and/or equity. Phase II aligned to criteria the Portsmouth Score Card and MCDA approach. Patient and public preferences have not to date been included in the Prioritisation approach by WHSSC: this would need to be developed in the future
Supported consistent deliberative process	Yes	Yes	Both Phase I and Phase II used the Delphi technique to embed a deliberative process. Phase II allowed for relative prioritisation to be considered
Sharing decisions transparently	Yes	Yes	Decisions/results were conveyed and shared through the Governance process of WHSSC to the Management Group and Joint Committee of WHSSC
Universal criteria considered by decision makers			
For severe disease	Yes	Yes	Disease severity quantitatively assessed using available epidemiological data including calculation of Patient Years of Life Lost and mortality to incidence ratios (where available based on Welsh data derived from PHW Observatory)
For common disease	Yes	Yes	Common conditions are not normally the subject of specialised services and therefore relative comparison about the relationship between common and rare conditions resource allocation was not considered. There are equity issues that may need to be discussed as part of the development of this process

PRIORITISATION ATTRIBUTE	WHSSC PRIORITISATION PHASE 1: 2012-14	WHSSC PRIORITISATION PHASE 2: 2014/15: PORTSMOUTH SCORE CARD	COMMENTS
For disease with many unmet needs	Yes	Yes	'Unmet' needs were difficult to clarify – a description and definition of unmet need were included as part of the technical document and guidance provided to Prioritisation Panel members
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	No	Yes	The scope of Phase II and change of methods allowed broader comparisons to be made with other interventional procedures and programmes of care
Conferring major improvement in efficacy/effectiveness over standard of care	Yes	Yes	Included in the assessment of the magnitude of clinical benefit criteria and the avoidance of future harms adopted more specifically in Phase II in particular
Conferring major improvement in safety & tolerability over standard of care	Yes	Yes	Included in the assessment of the magnitude of clinical benefit criteria and the avoidance of future harms in the MCDA approach adopted in Phase II in particular



PRIORITISATION ATTRIBUTE	WHSSC PRIORITISATION PHASE 1: 2012-14	WHSSC PRIORITISATION PHASE 2: 2014/15: PORTSMOUTH SCORE CARD	COMMENTS
Conferring major improvement of patient-reported outcomes/patient-perceived health over standard of care	Yes	Yes	Explicit in the criteria for Phase II as part of the MCDA approach. Sometimes difficult to quantify in specialised services as 'standard of care' often does not have either UK or International consensus
That result in savings in treatment expenditures as well as other medical and non-medical expenditures	Yes	Yes	A broad perspective on costs was adopted in Phase II as part of overall economic assessment. Evidence on non-medical expenditure was limited by the scope adopted in key research papers used to assess economic benefit in the literature as part of the evidence synthesis
For which there is sufficient data, that is fully reported and valid and relevant	Yes	Yes	Levels and Grading of evidence was considered technically in both Phase I and Phase II. Phase II adopted the Cochrane Collaboration GRADE system of evidence as international best practice
Recommended in consensus guidelines by experts	No	Yes	Clinical guidelines were accepted as evidence in Phase II
Cost effectiveness	Yes	Yes	Specific criteria in Phase II under Economic Assessment. This scope was broadened to 'economic impact' due to the paucity of data for formal cost-effectiveness for specialised services/interventions
Weighting applied to criteria (Yes/No)?			
Contextual criteria			

PRIORITISATION ATTRIBUTE	WHSSC PRIORITISATION PHASE 1: 2012- 14	WHSSC PRIORITISATION PHASE 2: 2014/15: PORTSMOUTH SCORE CARD	COMMENTS
Opportunity costs and affordability:	No	Yes	Weighting exercise was undertaken by Panel members for Phase II
System capacity and appropriate use of intervention	No	No	Not addressed as seen to be a Commissioning issue relating to subsequent Clinical Access Policy development and service specification post decision
Political, historical and cultural context	No	No	May be useful context but not thought to be useful as part of the technical methods assessment for prioritization

## 2.6 DISCUSSION

### 2.6.1 *ISSUES ENCOUNTERED*

An early lesson learned 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.

The desire for rapid evidence assessment and policy development conflicted with the desire for policy to be 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 discrete 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 supporting the condition HST pairs to guide confident decision making. Extended appraisal and modelling to fill in evidence gaps (as undertaken by NICE HST assessment for medicines) was just not possible so the panel had to become more confident and comfortable with low quality evidence.

The practical limitations for the administration of the panel by the project leaders 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. This issue was discussed with the Community Health Councils and it was agreed that perhaps other avenues should be explored, such as undertaking surveys with the objective of establishing public and patient preferences and values related to funding HSTs.

### 2.6.2 *REFLECTIONS ON THE PROCESS AND OUTCOMES*

The process of making resource allocation decisions is complex, with many factors listed by EVIDEM (37) 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.

### **2.6.2.1 Opportunity cost of HSTs**

One area of concern for some panel members, the project leaders and the author was that the HSTs that are approved for funding by WHSSC have significant opportunity cost, within the WHSSC budget and for NHS Wales; 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 (48) 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) are in principle 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. There are arguments and some evidence reported by Linley and colleagues that HSTs may not be a special case for exceptional funding.(84)

### **2.6.2.2 Accountability for Reasonableness**

The WHSSC process does not completely meet the Accountability for Reasonableness framework described in the introduction (14,15). The condition of relevance is met, publicity is met when the Joint Committee decisions are made and communicated to the HBs, but not when the recommendations are 'stuck' in the process with WHSSC and not moved to implementation; appeals/opportunity for revision are as yet untested, but regulation/enforcement at HB still prove challenging for the reasons that are discussed below.

### **2.6.2.3 Acting on Recommendations and Implementing Decisions**

Decisions were made and presented to Joint Committee but driving through to implementation 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 HBs to consolidate or centralise the provision of service.

There were also challenges within the structure of WHSSC, where the explicit evidence based prioritisation process was not taken seriously by individuals in the organisation who had the ability to 'sit on' decisions. Further the progression of recommendations through the Joint Committee was subject to erratic delays, and the project leaders felt that there was an issue of certain people within the organisation or on the Joint Committee putting obstacles in the path of getting recommendations accepted by the Joint Committee. Individuals in WHSSC had the ability to stop papers and decisions being made at Joint Committee by blocking papers going through internal governance processes within WHSSC. This allowed people internally to WHSSC if they do not agree with the recommendations to stop anyone in the Joint Committee or externally ever seeing the recommendations and the results of recommendations. In the main, one of the project leaders felt that the majority of the blocks came in from a very few people; there was the fierce opposition displayed by at least one of the other Executives who was not a supporter of the process and came into conflict with the two project leaders at this point. One of the project leaders theorised that the people who were the blockers for adopting this particular prioritisation method were:

*"...far more interested in their personal exercise of individual power than actually coming up with the right thing and disseminating it into a clear way to, chief execs making resource allocation decisions".*

The author was interested in why the Joint Committee was not creating a pull for papers on all of panel recommendations to be submitted in a timely fashion after each round of the panel meetings. The project lead thought that the Joint Committee would be inundated with a series of things that they have to read and which they have to sift through to be able to get to the 'meat' and thus can fail to recognise that material is not coming through:

*"...they're never going to see what they don't know..."*

*"And when they ask a particular question about the process not delivering something, they get told a particular thing by the people presenting the information to them at the Joint Committee, about the state or readiness or otherwise of what's being delivered..."*

*"...unfortunately for us, the Joint Committee at best only meets once a quarter, so if you can avoid having those discussions four times, you've gained twelve months of not implementing something".*

The other project lead expanded on the reasons he thought recommendations were being slowed or blocked in the system;

*“... if you look at an organogram of the organisation, there are twenty plus planners and twenty plus finance people, and then there’s (name of other project lead) and me and my deputy. So you have a kind of, the dominant,...finance complex, which feels severely challenged if we do a huge amount of in-depth evidence based analysis because it conflicts with their incredibly superficial and light touch on planning, which is kind of, which is focused on organisational risk, on ... it’s a really critical issue that their perception is not about patient benefit, it’s very much about minimising the risks and exposure of the organisation”.*

*“it’s also incompetence in terms of not commissioning fully and effectively”.*

Aside from internal WHSSC politics there were external politics to contend with. One recommendation not to fund was overturned at Welsh Government level. This was one aspect of the prioritisation process that was not foreseen and was the case of lymphovenous anastomosis microsurgery for primary and secondary lymphoedema. The last row of Table 2:2 shows that this intervention was the lowest ranked of all HSTs reviewed by the prioritisation panel in 2015. The evidence review is provided as Appendix 6 to this chapter and summarised in Box 2:3 in this chapter. The recommendation of the panel members was that this HST was not recommended for use in NHS Wales as the evidence was weak and the benefits doubtful. My notes were clear that this was an easy and uncontentious decision. The recommendation was passed to the Joint Committee who agreed that the intervention would not be commissioned in Wales. However, via a process that is not clear, the Minister for Health and Social Care in Wales overturned the decision to insist that the HST should be made available. The politics behind the decision were - speculatively - fuelled by a politically high profile All Wales Lymphoedema service. However speculation as to motivations aside the outcome of this decision is that a risky, poorly studied, relatively expensive HST was available to people with lymphoedema in Wales and of course there will be an opportunity cost of this decision and health benefits will be lost by other patients.

### *2.6.3 NEXT STEPS FOR PRIORITISATION PROCESS*

There was nearly a year’s break in the prioritisation process at the end of 2015 as one of the project leads was on a rolling renewable three month contract through 2015 and did not get his contract renewed and thus officially retired in December 2015. The other project lead simultaneously found a secondment elsewhere in the Welsh NHS and also left at the end of December 2015. There was therefore a hiatus in the process until September 2016 when the vacant posts were filled and the process could re-start, in December 2016. Thus the prioritisation process recommenced – the first meeting being 5<sup>th</sup> December 2016 (which was attended by the author who continues as a health

economics advisor). There also an organisational commitment at WHSSC under the auspices of a new managing director to continued improvement of the process as it restarts in 2016/17.

Whether the discussions with panel members about potential improvements at the end of the 2015 process and the suggested developments will proceed as planned is not known. However it is useful to summarise here the discussions the project leads, myself and the panel members had about potential improvements to the process and the issues of opportunity costs.

There were suggestions that additional benefits from the prioritisation process could be gained by extending the WHSSC framework by providing programme budget information at HB level, or similar contextual information. This would potentially bring the framework into a programme budgeting marginal analysis process, as recommended by the Bevan Commission(61) when final recommendations are being made. This is because in cases where a single HST is approved for funding out of the WHSSC budget, it may be strongly supported, irrespective of the general financial climate and calls upon budget in the HB. If however, the proposal is set in the context of other bids for funds for the same service or patient 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 HBs (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 in line with the Prudent Healthcare approach.

## 2.7 CONCLUSIONS

Reflecting on the process described here, it is some way away from the rigorous HST appraisal process undertaken by NICE for drugs (85) 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, making 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. The

processes developed over time by WHSSC adhered to good practice, in line with the EVIDEM framework. However the true test of the process and the Prioritisation Panel recommendations will be for WHSSC to overcome the internal political challenges with progressing recommendations through the Joint Committee. Hopefully the changes at WHSSC will support this.

With time WHSSC can continue to review Prioritisation Panel recommendations compared with Joint Committee decisions to assess consistency and also see how HBs overcome implementation challenges faced in 'real life'.



CHAPTER 3: PROGRAMME BUDGETING  
MARGINAL ANALYSIS FOR ABERTAWE BRO  
MORGANNWG UNIVERSITY HEALTH  
BOARD: A PILOT IN ANTICOAGULATION  
SERVICES FOR ATRIAL FIBRILLATION

### 3 PROGRAMME BUDGETING MARGINAL ANALYSIS FOR ABERTAWE BRO MORGANNWG UNIVERSITY HEALTH BOARD: A PILOT IN ANTICOAGULATION SERVICES FOR ATRIAL FIBRILLATION

#### 3.1 CHAPTER SUMMARY

This chapter covers the pilot programme budgeting marginal analysis (PBMA) undertaken in the Abertawe Bro Morgannwg University Health Board (ABMUHB) for anticoagulation services for Atrial Fibrillation (AF). The chapter outlines the approach taken with respect to the identification, adaptation and implementation of the PBMA and within that to identify the most effective prioritisation and resource reallocation processes, from the initial concept discussions and scoping specifically for the for anticoagulation services for AF and Unplanned Care Commissioning Board (UCCB) in ABMUHB.

The chapter charts the processes and progress made through the PBMA. This PBMA pilot differs from the pilot PBMA described in Chapter four as, whilst some opportunity for resource reallocation was identified, there were no significant disinvestments. Potential health gains though the likely reduction of stroke rate and resource release because of improvements to the service and some low cost activities proposed to improve services overall were identified. However it was clear that the services being provided in many cases did not adhere to best practice and that a wider view of the services was needed. In the last stages of the PBMA the Welsh Government gave ABMUHB £500,000 to invest in improving the anticoagulation services allowing the PBMA project team an opportunity to prioritise and proposed how best to invest these funds.

#### 3.2 INTRODUCTION

The ABMUHB senior management felt that the situation for anticoagulation services for people with AF deserved scrutiny and knew the services desired change but had no further funding to allocate to the anticoagulation services. Similarly to the situation described for musculoskeletal (MSK) services in chapter four, undertaking a prioritisation/resource reallocation exercise was proposed to be a way of creating the improvements needed for the service within the existing budget. As with the MSK pilot described in chapter four I proposed programme budgeting marginal analysis (PBMA) as the appropriate approach to enable the prioritisation and resource reallocation exercise.

### 3.2.1 ATRIAL FIBRILLATION AND STROKE

Non Valvular Atrial Fibrillation (nvAF) is a common condition occurring in people without significant aortic or mitral valve disease. nvAF occurs when abnormal electrical impulses suddenly start firing in the atria of the heart. These impulses override the heart's natural pacemaker, which can no longer control the rhythm of the heart. This results in a very irregular pulse rate. nvAF affects 1 in 200 people and the prevalence doubles every decade of life (86, 87); 4% for people over 65 and 8% prevalence in people over 75s(87). As the aging population increases so the burden of nvAF on NHS services increases. nvAF is associated with a fivefold increase in stroke risk.(87) nvAF treatment normally includes a rate-control treatment (beta-blocker, rate-limiting calcium channel blocker, or digoxin) and possibly referral for rhythm-control treatment (cardioversion), if the person has nvAF with a reversible cause(86).

### 3.2.2 ANTICOAGULATION AND ORAL ANTICOAGULANTS

Because having nvAF increases the risk of stroke and thromboembolism anticoagulants are used in people with nvAF (whatever the cause) to reduce that risk. After an assessment for stroke risk for the individual with nvAF using the CHA<sub>2</sub>DS<sub>2</sub>VASc assessment tool, the risks and benefits of anticoagulation are assessed, and treatment is started if required. Because of the increase in clotting time the HAS-BLED assessment tool is used to assess the risk of a major bleed and to identify and manage modifiable risk factors for bleeding (such as uncontrolled hypertension, harmful alcohol consumption).

There are oral medications that act on blood clotting rates. Warfarin, which has been used for many decades as an anticoagulant, is a coumarin derivative that acts by inhibiting vitamin K dependent clotting factors (II, VII, IX, X) as well as the anticoagulant proteins C and S. Warfarin had been used for decades to treat and prevent venous thromboembolism. Apixaban, dabigatran, and rivaroxaban are novel oral anticoagulants (NOACs) with a novel mode of action: Apixaban and rivaroxaban are direct inhibitors of factor Xa which prevents thrombin generation and thrombus development. Dabigatran is a reversible inhibitor of free thrombin, fibrin-bound thrombin, and thrombin-induced platelet aggregation. Apixaban, dabigatran, and rivaroxaban are recommended by the National Institute for Health and Care Excellence (NICE) as: *an option for preventing stroke and systemic embolism within its licensed authorization, and an option for the prevention of venous thromboembolism in adults after elective hip or knee replacement surgery.* (86)

In addition, rivaroxaban has been recommended by NICE as: *an option for the treatment of pulmonary embolism (PE) and deep vein thrombosis (DVT) and prevention of recurrent DVT and PE in adults after diagnosis of acute DVT.* (88) The aim of anticoagulation is to decrease the blood's tendency to clot, but not stop it clotting completely. The international normalised ratio (INR) is a measure of how long it takes blood to clot. The longer it takes blood to clot, the higher the INR. The most common complication of warfarin therapy is bleeding, which occurs in 6 to 39 percent of recipients annually. The incidence of bleeding is directly related to the intensity of anticoagulation. (86) With the reductions in anticoagulation intensity that have evolved over the past 20 years, the incidence of hemorrhagic complications has decreased dramatically. In patients receiving warfarin therapy, the median annual rate of major bleeding ranges from 0.9 to 2.7 percent and the median annual rate of fatal bleeding ranges from 0.07 to 0.7 percent. The incidence of complications varies within the ranges, depending on the clinical indication and the intensity of anticoagulation. Intracranial hemorrhage accounts for approximately 2 percent of the reported hemorrhagic complications of warfarin therapy and is associated with a mortality rate of 10 to 68 percent. (89)

Unlike warfarin, apixaban, dabigatran, and rivaroxaban do not require regular INR monitoring. However, regular follow up and monitoring is still required to assess compliance and check for any adverse effect (e.g. bleeding) and for the presence of thromboembolic events. The most common adverse effect of anticoagulants is bleeding; however, there is currently no antidote to administer in the event of a bleeding event for the NOACs, as there is for warfarin. Harrington and colleagues investigated the relative cost effectiveness of the NOACs compared with warfarin. (90) The authors found that there was a probability of between 44% and 15% of the NOACs being cost effective (i.e. more effect for more cost) at a threshold of USD 50,000 the main drivers influencing the relative costs and effects are the age adjusted stroke rate and cost of NOAC.

While it may appear intuitively desirable to treat all patients with NOACs there are many reasons why warfarin should remain first line for the majority of patients:

- INR measurement acts as a useful indicator of compliance with therapy and is a valuable predictor of increased bleeding risk;
- Coagulation effects are not monitored with NOACs therefore compliance cannot be assessed;
- There is no available antidote to NOACs which is in contrast to warfarin;

- Two of the three NOACs are still subject to a black triangle<sup>3</sup> and therefore subject to intense monitoring and surveillance for safety reasons;
- NOACs are not suitable for patients with moderate to severe renal impairment.

Anticoagulation ameliorates the stroke risk for a person with nvAF by approximately 70%. (91) Regular measurement of INR for people on warfarin is used to determine the dose of warfarin a person needs to take. Over time the person aims to keep their INR in the correct range of (2.0 – 3.0) the risk of stroke for patients on oral anticoagulants is significantly reduced if the INR time in range (TTR) is maintained above 64%. (92) Evidence also suggests that as TTR increases above this level to above 70% there is increasing stroke risk reduction. (92)

The established evidence base has made anticoagulation the cornerstone of nvAF management and is clearly recommended by all national and international guidelines.

There is evidence from recent randomised controlled trials that NOACs are superior to warfarin or non-inferior (with less bleeding) (90). There is some debate as to whether a high quality warfarin service with a high TTR would be as effective as NOACs in delivering these possible benefits in stroke reduction (but at an increased risk of bleeding) (93).

The findings of research into the implementation of cost effective new technologies from the Policy Research Unit in Evidence Evaluation of Health and Social Care Interventions (94) indicates that the value of implementation of NOACs appears highest when targeting efforts to increase utilisation in patients with average to poor warfarin control. Most importantly they suggest that greater (absolute) value to the NHS would potentially be achieved with higher uptake of anticoagulation more generally (i.e. NOACs and warfarin) given the high proportion of patients with nvAF who are currently receiving no treatment or anticoagulation. The authors estimate that switching 5% of patients potentially eligible for anticoagulation but currently on no treatment or on antiplatelet therapy (aspirin) to warfarin would generate an additional

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<sup>3</sup> When medicines come onto the market, we may have relatively limited information about their safety from clinical trials. These trials generally involve only relatively small numbers of patients who take the medicine for a relatively short time and will identify only the more common adverse effects of treatment. Only when large numbers of patients have taken a medicine are rare or long latency adverse effects identified. Therefore, effective surveillance after marketing is essential for the identification of rare adverse effects, and to ensure that appropriate action is taken. <https://www.gov.uk/drug-safety-update/the-black-triangle-scheme>

7,550 QALYs (£151,004,965) across England and Wales and 30 QALYs (£606,866) in an average CCG population(94) (which might approximate to the ABMU population).

### 3.2.3 NATIONAL GUIDANCE

#### 3.2.3.1 NICE

NICE Guidance (CG180 Atrial fibrillation: the management of atrial fibrillation)(86) states that the use of anticoagulants - warfarin or novel oral anticoagulants (NOACs) - is recommended for all patients with nvAF except those at the very lowest risk of stroke. Aspirin as an alternative to anticoagulation is no longer recommended for the management of stroke risk reduction in nvAF.

NICE Quality Standard 93: nvAF and associated measures recommends (88):

- *Statement 1: Adults with non-valvular atrial fibrillation and a CHA<sub>2</sub>DS<sub>2</sub>-VASc stroke risk score of 2 or above are offered anticoagulation.*
- *Statement 2: Adults with atrial fibrillation are not prescribed aspirin as monotherapy for stroke prevention.*
- *Statement 3: Adults with atrial fibrillation who are prescribed anticoagulation discuss the options with their healthcare professional at least once a year.*
- *Statement 4: Adults with atrial fibrillation taking a vitamin K antagonist who have poor anticoagulation control have their anticoagulation reassessed.*
- *Statement 5: Adults with atrial fibrillation whose treatment fails to control their symptoms are referred for specialised management within 4 weeks.*
- *Statement 6 (developmental): Adults with atrial fibrillation on long-term vitamin K antagonist therapy are supported to self-manage with a coagulometer.*

#### 3.2.3.2 AWMSG

At the time of undertaking the pilot project reported here the All Wales Medicines Strategy Group was revising their 2014 guidance on the role of oral anticoagulants (OACs). This was published in 2016.(95) The updated guidance is provided in Appendix 8 and is in line with the NICE guidance cited here.

### 3.2.4 WELSH GOVERNMENT CONTEXT

An action plan was announced by Welsh Government in 2012, to reduce the number of strokes and stroke related deaths in Wales and includes emphasis on the need to improve detection and treatment of nvAF. (96) In Wales in 2010 data suggests that there were 11,000 stroke events, including 6,000 new strokes per year, 25% of strokes occurred in people who are under the age of 65 and up to 30% of people who have a stroke died within one month.(96)

### 3.2.5 ABMUHB CONTEXT

Currently in AMBUHB approximately 2% of the population (just fewer than 10,000 patients) are actively monitored on warfarin, either in primary or acute care. SSNAP (Sentinel Stroke National Audit Programme) data suggests that annually in ABMU 112 patients are admitted having had a stroke that have known nvAF and are undertreated (either no treatment or an antiplatelet agent)(97).

ABMUHB currently operates a number of different nvAF anticoagulation service models across the three localities (Swansea, Bridgend and Neath Port Talbot (NPT)). All patients will either be initiated on warfarin as an inpatient, by their GP or by an INR/anticoagulation clinic. The monitoring, dosing and prescribing from then on is in the main determined by a patients' locality of residence, although there are some anomalies. Patients receive varying approaches to their care in varied in relation to;

- Point of care testing or venous blood testing,
- frequency of face to face counselling,
- separation of prescribing and monitoring and
- Location of service (GP, community based in 'one stop' clinics, hospital based) and in staff engaged in delivering the service (e.g.GP, pharmacist, nurse).

A National Enhanced Service exists for warfarin monitoring; this is in place in all practices in Bridgend Locality and in some practices in NPT Locality but is not available in Swansea Locality. The budget for National Enhanced Services is a ring-fenced budget within general medical services (GMS).

### **3.2.5.1 Bridgend locality**

This locality operates a primary care based model where the majority of patients are monitored, dosed and prescribed warfarin by their GP with point of care testing (POCT).

### **3.2.5.2 Neath Port Talbot Locality**

More than half of NPT patients are monitored and dosed by an acute care anticoagulation clinic using POCT and the prescribing undertaken by GPs. The remaining patients are monitored, dosed and prescribed by their GP (approximately 700 patients on the national enhanced service) or picked up by the Swansea service (approximately 500). Neath Port Talbot hospital pharmacy run a POCT anticoagulation clinic for 1794 patients. Swansea Locality

### **3.2.5.3 Swansea locality**

The Swansea service monitors approximately 3535 patients who have venous blood samples taken by the hospital phlebotomy service and a range of locations and dose changes are made by the anticoagulation nurses and communicated, primarily, by post. Prescribing is again undertaken by the GPs. A small proportion (<10%) of Swansea patients are monitored by the Clydach INR Clinic which is a one stop clinic where patients are monitored, dosed and prescribed warfarin by non-medical prescribers (both pharmacists and nurses). Each patient is seen face to face by staff at the clinic.

### **3.2.5.4 Anticoagulation Service standards**

The services were benchmarked against NICE CG 180(86) and National Patient Safety Agency (NPSA) Guidance(98); these which indicate that services using POCT are preferable to services using laboratory based venous testing and providing nurses, pharmacists and biomedical scientists with adequate training to ensure they have the necessary work competences to undertake their duties safely can help deliver inpatient and ambulatory care more safely. More intensive patient counselling improves reviewing patients face to face and by phone. The purpose of these standards is to optimise patient outcomes. Failing to achieve standards implies that patient outcomes are not as good as they can be and ultimately results in increased adverse events and strokes.

ABMUHB internal prescribing data suggests that prescribing of the NOACS is rising within the health board, but not necessarily in line with NICE or AWMSG guidance.



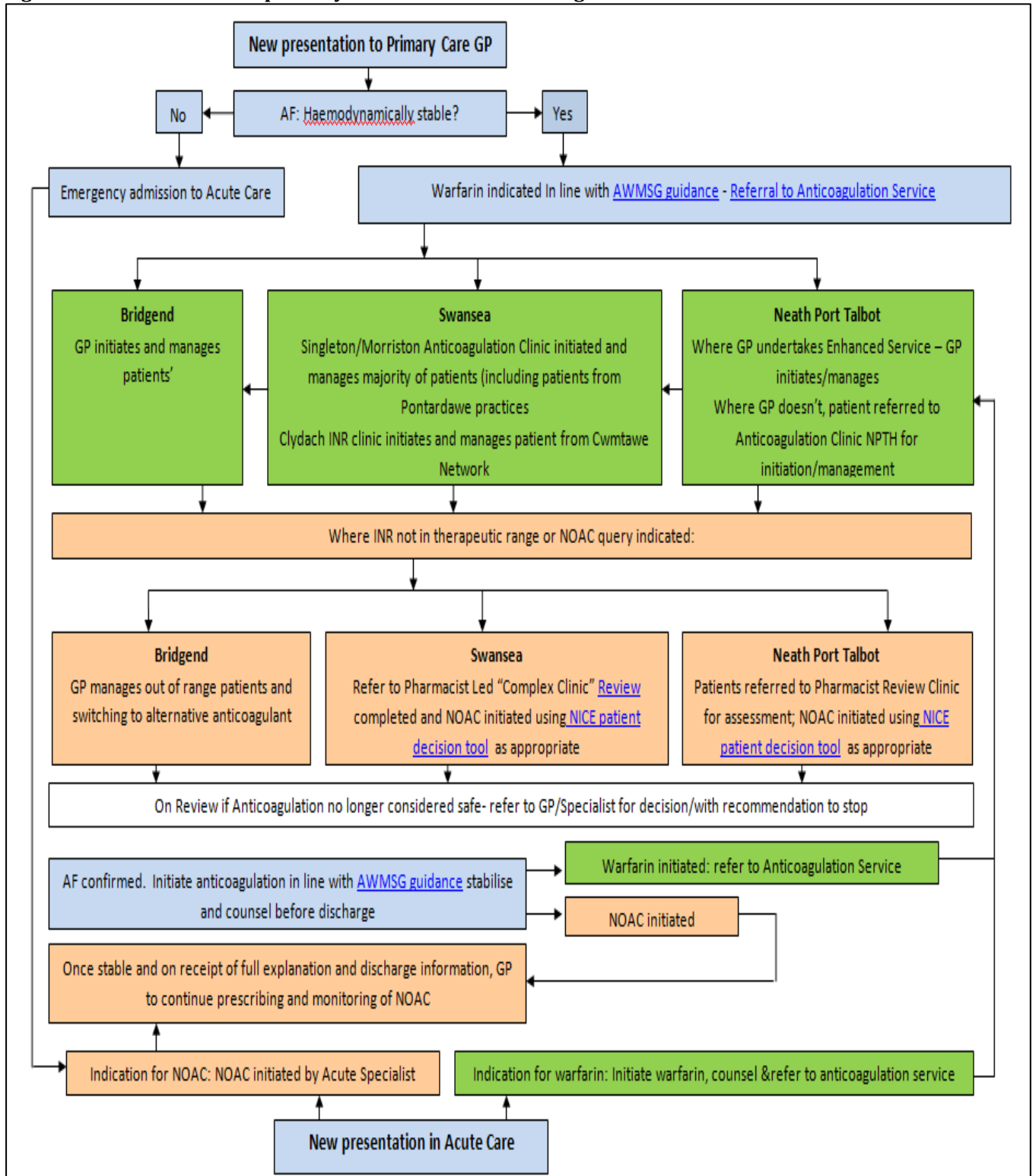
Concerns about anticoagulation service standards, which may be the reason for a shift to inappropriate NOAC prescribing had also been flagged up to the health board. There will always be patients unsuitable for warfarin that will need to be prescribed a NOAC. However to prescribe in line with guidelines, patients must be assessed on an individual basis and an informed evidence based decision made by the patient and a clinician that is familiar with the treatment options. To accomplish this it is necessary to ensure all patients have access to appropriate assessment and counselling before commencing any anticoagulation therapy. Some patients will be identified as not suitable for warfarin at this point whilst others may be commenced on warfarin but identified as unsuitable further down the line through monitoring. It was a concern to the health board that this best practice was not being achieved within ABMUHB as a whole.

Table 3:1 gives an over view of the numbers of patients and costs of the ABMUHB services and Figure 3:1 illustrates the flow of patients through the service.

**Table 3:1 Overview of current anticoagulation services in ABMUHB 2012 - 2015**

	2012				2015 Current Resourced Capacity			
	Swansea	NPT	Bridgend	Total	Swansea	NPT	Bridgend	Total
Activity								
Warfarin	3,935	2,494	2,786	9,215	5,335	3,164	3,886	12,385
NOACs	200	40	60	300	258	76	163	497
Untreated known nvAF Patients	1,600	760	1,240	3,600	200	90	140	430
Anticoagulation Costs	£000	£000	£000	£000	£000	£000	£000	£000
Infrastructure	344	254	395	993	496	389	578	1,463
Warfarin	163	103	115	381	220	131	161	512
NOACs	158	32	47	237	204	59	129	393
Total	664	388	558	1,610	921	579	868	2,367
Outcomes								
Strokes	150	85	113	348	99	60	73	232
Bleeds	38	24	27	89	46	29	34	110

**Figure 3:1 ABMUHB Patient pathway for nvAF related anticoagulation**



### 3.3 METHODS

This section describes the methods used to deliver the pilot PBMA.

#### 3.3.1 PROJECT TEAM AND PROCESS MANAGEMENT

The project team established for the pilot was jointly led by two clinicians - one from primary care (a GP with a special interest in Cardiology) and one from tertiary care (a consultant Cardiologist) plus a project manager from the service delivery team, a representative from the commissioning development programme, a health economist (the author), a representative from ABMUHB finance, a specialist in group decision support and a project administrator. The team was joined half way through by an ABMUHB specialist in healthcare intelligence. *Ad hoc* contributions were solicited from Pharmacists and a Stroke consultant,

The initial goal was for the PBMA to be completed within six months. Project team meetings were booked at regular intervals and these were punctuated by stakeholder group meetings. The planned time table also allowed the project team access to public meetings facilitated by ABMU which would allow engagement with public and patients. A service user survey was planned into the timetable and also a survey of general practitioners.

The progress and recommendations for change arising from the PBMA were targeted at meetings of the UCCB and ultimately at the completion of the process the Intermediate Term management Plan which would commit the services to action in line with recommendations and to be accountable for delivering the agreed changes.

Through the PBMA journey a series of interviews were undertaken with stakeholders and project team members in order to get feedback on the process and enable framework development to ensure PBMA could fit into the way in which prioritisation and resource re allocation develops in ABMUHB and be integrated into its commissioning process.

#### 3.3.2 STAKEHOLDER GROUP

In order to get input and priorities for the community affected by anticoagulation services generally and nvAF in particular, the project team contacted a wide range of people and invited them to an initial meeting to explain the remit and purpose of the PBMA and invite them to regular meetings thereafter, to report back and get further input. The stakeholder group comprised all of the key representatives of the services, patient representatives and other vital informants. The list of stakeholders is provided in Box 3:1 below.

**Box 3:1 The stakeholders for the nvAF PBMA**

Name	Role
James Barry	Co-Chair
Ravindra Midha	Co-Chair
Pippa Anderson	Health Economist
Patricia Jones	Commissioning Development Support Manager
Charlie Mackenzie	Finance
Katie Mitchell	Planning & Performance Lead/IPMM
Tersa Humphreys	DGM , Regional Services
Phillipa Thompson	SLN, Regional Services
David Murphy	Assistant DOTHS
Duncan Davies	Anticoagulation Pharmacy
Sean Young	Clinical Director primary care, Bridgend
Jayne Morgan	Anticoagulation CNS
Rebecca Jones	Anticoagulation CNS
Navjot Kalra	Prudent Healthcare Intelligence Manager
Ashrok Rayani	GP & LMC Representative
Kerry Broadhead	Head of Commissioning Development
Les Hammond	ADGM, Cancer Services
Darren Griffiths	Assistant Director of Strategy
John Terry	Pharmacy, Neath
David Mackerras	ABM CHC
Sue Evans	ABM CHC
Manju Krishnan	Stroke Physician
Judith Vincent	Clinical Director of IPMM
Harish Bhat	Consultant in Medicine & Elderly Care
Tom Yapp	Consultant Gastroenterologist
Andrea Croft	Anticoagulation ANP
Paul S Davies	Head of Nursing, Regional Services
Christian Heathcote-Elliott	Public Health Representative
Andrew Muir	GP
Chris Hudson	Consultant Physician & C.D.
Diparup Mukhopadhyay	Consultant Physician – Stroke Medicine
Jan Worthing	Locality Director – Swansea
Mark Ramsey	Consultant Cardiologist

Name	Role
Saad Al-Ismaïl	Consultant Haematologist
Tal Anjum	Consultant Stroke Physician
Rhodri Davies	Strategic Planning & Commissioning Manager
Lauren Jones	Strategic Planning & Commissioning Support Manager
Chris Johns	C.D primary Care
Firdaus Adenwalla	Consultant Physician
Karl Murray	Deputy Director, POWH
Kirstie Truman	GP
Martyn Richards	Consultant Cardiologist
Daniel Harris	Lead Clinical Pharmacist
Nimish Shah	LMC
Mushtaq Wani	Consultant Physician – Stroke Medicine
Vanessa Morton	Prescribing Adviser
Fiona Hughes	Swansea Locality – Integrated Medicine
Andrew Muir	GP
Hilary Dover	Director Primary and Community Services

The wider stakeholder group was consulted at key stages of the PBMA process to allow findings from research and options for change in the services to be discussed and developed with stakeholder input. The areas of scrutiny and sources of information initially identified by the project team were validated and developed. Relative priorities for changes in the anticoagulation services were defined, redefined and prioritised using the TurningPoint® voting system by the stakeholder group, during the PBMA process. TurningPoint™ technology<sup>4</sup> to support voting. This is a voting system that employs 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(81). Research into specific features of this form of group decision support has reported gains in meeting efficiency (82), improved levels of participation and a reduction in potentially negative influences from dominant members of the group (83).

### 3.3.2.1 Patient and Public Input

An ABMUHB Changing for the Better (C4B) public engagement event held on 7<sup>th</sup> May 2015<sup>5</sup> serendipitously allowed the project team to engage with the widest possible group of stakeholders and work with the C4B team, using the TurningPoint® voting system to get input on priorities for health services overall, based on 10 commissioning criteria that related to ABMUHB values: '*caring for each other*' through improving experience, '*working together*' through involving patients and staff and '*always improving*' through seeking out and using evidence of best practice. The ABMUHB criteria for the PBMA (underpinned by the ABMUHB values) are listed and characterised in Table 3:2 below.

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<sup>4</sup> <http://www.turningtechnologies.co.uk>.

<sup>5</sup> <http://www.wales.nhs.uk/sitesplus/863/news/23672>

**Table 3:2 ABMUHB Commissioning Criteria**

<b>Criteria</b>	<b>Description</b>
<b>Fairness</b>	Demonstrates that different clinical conditions, treatment and patient groups are considered equally and without preference e.g. equal consideration to Cancer and Diabetes patients or older people and working age adults
<b>Inequalities</b>	Demonstrates that inequalities in access to healthcare and the potential to achieve positive health outcomes between different groups within ABMU is addressed, in particular for our most deprived communities e.g. targeting services within deprived communities
<b>Evidence of clinical effectiveness</b>	Demonstrates that the proposal is based on evidence that the treatment or intervention is considered to be clinically effective by trust worthy professional bodies
<b>Value for money/cost effectiveness</b>	Demonstrates that the outcomes and improvements that will be delivered are equal to the cost of the investment, delivering good value for money and evidence of being cost-effective
<b>Strategic fit</b>	Demonstrates the proposal has a strong fit and alignment with current national and local strategies, policies and priorities
<b>Disease burden</b>	Demonstrates delivery of benefits and outcomes which positively affect a significant proportion of our local population so as to create a meaningful impact on the burden of disease we experience
<b>Outcomes</b>	Demonstrates delivery of demonstrable improved health outcomes, including preventing ill health, reducing risk to health and alleviating suffering
<b>Patient experience</b>	Demonstrates that available evidence on the impact of any changes on patient experience or satisfaction have been taken into account and that improving patient experience can be demonstrated as an outcome
<b>Standards of care</b>	Demonstrates delivery of relevant quality standards or other markers of high quality healthcare, and addresses unacceptable variation in quality of care across ABMU
<b>Reducing Harm</b>	Demonstrates that the intervention will not cause harm and/or will reduce harm currently experienced and/or will cease/reduce delivery of interventions that deliver no impact (approx 20%)



The participants in the C4B event rank ordered the criteria in order of importance for PBMA decisions making; Figure 3:2 shows the ordering of criteria. The first three criteria that participants thought were the most important for making decisions in a PBMA were:

1. Health Outcomes;
2. Patient Experience;
3. Evidence of Clinical Effectiveness.

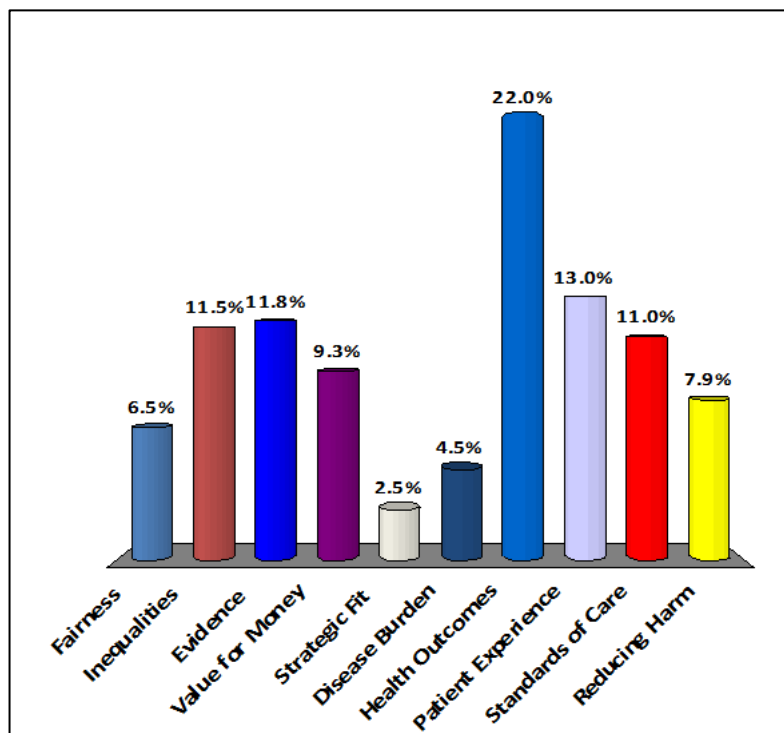
**The same exercise was run again with the nvAF PBMA stakeholders with some interesting differences (see**

Figure 3:3).

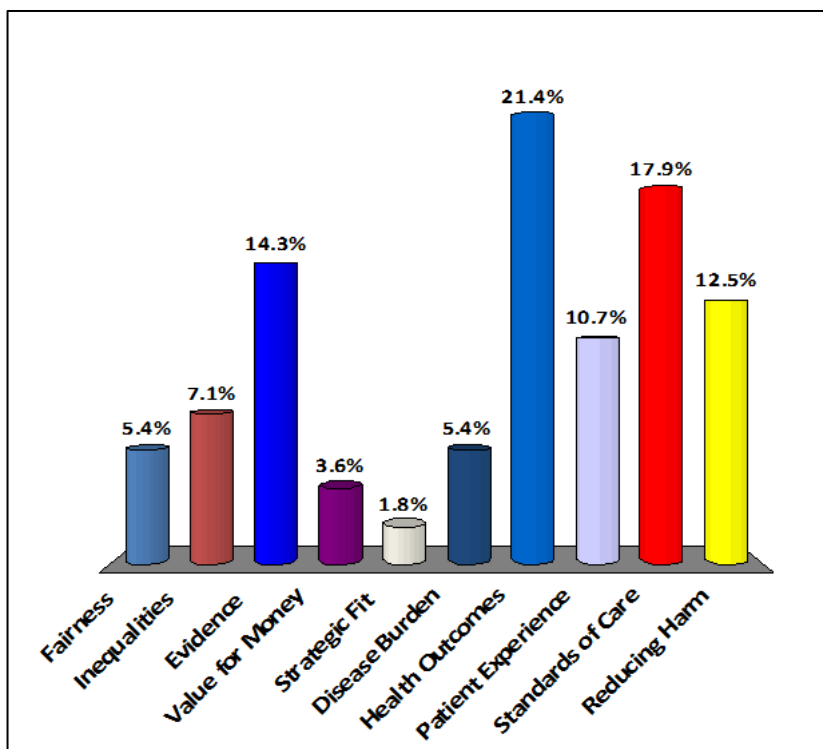
1. Health Outcomes
2. Standards of Care
3. Reducing Harm.

These shifts in priorities and effectively the weights that should be applied to decisions were not surprising given the therapy area and the concerns about care that were known and emerging.

**Figure 3:2 C4B participants rank ordering of commissioning criteria**



**Figure 3:3 nvAF Stakeholders rank ordering of commissioning criteria**



### 3.3.3 SCOPING

After some considerable discussion the scope of the PBMA was narrowed down to one area; anticoagulation for the management of nvAF; anticoagulation for other reasons were not included. Although there are clearly close relationships between these services for nvAF and other coagulation management problems, these were also excluded. The UCCB Board specifically wanted to pilot PBMA to enable decisions to be made about resource reallocation in anticoagulation services in the health board. The PBMA pilot candidates were required to identify and agree resources related to low value interventions which could be disinvested in to enable re-investment of that resource into higher value interventions and better ways of working. The PBMA scope agreed with the UCCB was *'anticoagulation for people with nvAF'*.

The timelines, progress and recommendations for change arising from the PBMA were targeted at meetings of the UCCB and ultimately at the completion of the process, needed to be timed to have recommendations accepted as part of the Intermediate Term Management Plan (IMTP) which would commit the services to action in line with recommendations and to make the service delivery teams accountable for delivering the agreed changes.

### 3.3.4 DATA TO INFORM THE PBMA

The sources of population statistics, prescribing and service utilisation data were available from ABMUHB internal sources at varying levels of accuracy and detail. The overwhelming gap in data were primary care data which were available in the health board as all the routine health data is held within a secure anonymised linked data bank. However the data are difficult to access without considerable administrative processes, which would not inform the PBMA within the desired timeline and required funding (a budget for the PBMA pilot was not available to the project team) to extract and analyse the data. Audit data from the anticoagulation services was available, but patchy and provided in differing formats (paper and electronic in community and secondary care).

The 2007 National Patient Safety Alert NPSA Alert (98) included an audit tool for NHS organisations. Some of the audit questions relate the wider management of anticoagulation in an acute setting whilst some specifically relate to the anticoagulation services. Swansea, Clydach and NPT Anticoagulation Services completed audits and these data were obtained to inform the PBMA.

Audit+ data based on electronic general practitioner (GP) records was unavailable to the team to describe the services provided by GPs.

#### 3.3.4.1 NICE Guideline and Costing Tool

As part of the NICE clinical guideline CG180(86) NICE provides an MS Excel based costing model (Costing Tool ref) which we adapted with available ABMUHB data and Public Health Wales/ Stats Wales population data and predictions. The tools and resources supporting the NICE CG180 was also examined in detail to allow us to consider the ABMUHB situation in context with the guidance(99). The Oxford Vascular Study (OXVASC) data was also helpful in estimating and validating the incidence of nvAF related stroke rates.(91)

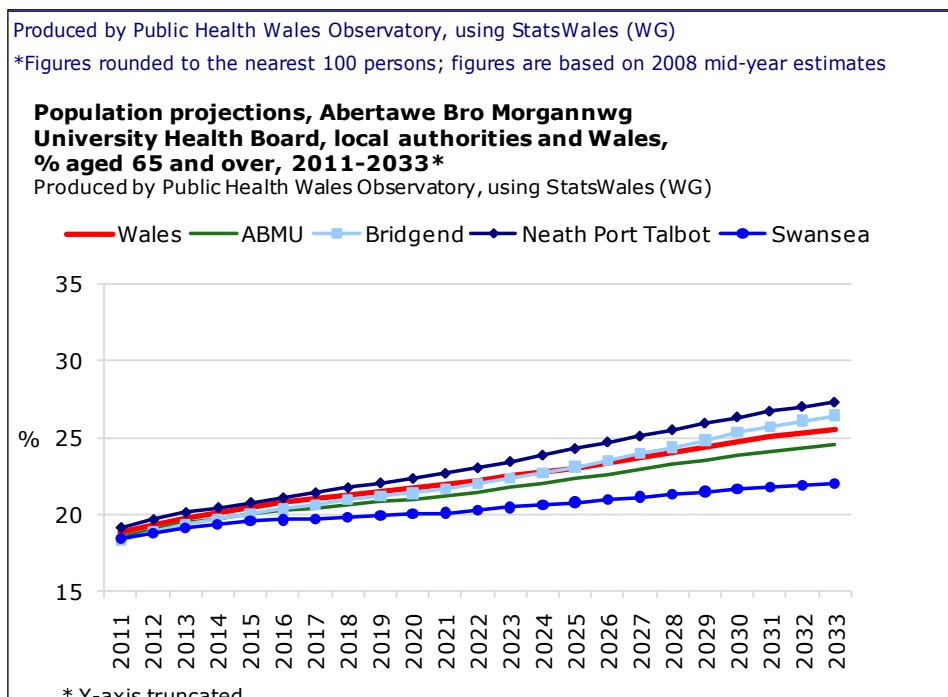
One of the resources available alongside the NICE CG180 was a costing model (99). This enabled estimates of the impact of the aging ABMUHB population, estimates of nvAF prevalence and stroke rates, increasing use of NOACs and the hypothetical 'savings' related to reduction in INR monitoring requirements offset against the cost of the NOACs. These estimates informed and validated the more detailed costing

developed in collaboration with the finance project team member, using ABMUHB finance data.

### 3.3.5 ABMUHB POPULATION DATA

Using population predictions from Stats Wales (100) and the published data from the OXVASC study (91) we estimated that ABMUHB will see a likely increase in the nvAF population of the order of 12% in the next 5 years. The increase is driven by the increasing elderly (i.e. over 65) population. Figure 3:4 below illustrates the population dynamics in each locality.

**Figure 3:4 ABMUHB population projections 2011 to 2033(100)**



The estimated increase includes patients with nvAF who are identified and known to the service, some of whom will not be treated through their own choice or because they are contraindicated. There are still many people who have nvAF but are not aware of it (but are none the less at risk of stroke). Improving nvAF detection was outside the scope of the PBMA but is important. However it is likely that in the future the proportion of unknown' nvAF will diminish and the known increase as detection rates of nvAF will improve given the 'push' from NICE guidance. This needed to be factored in to the estimates we made.

### 3.3.6 NICE COSTING MODEL

NICE describe the process they used to prepare a costing model to provide a cost impact analysis.(99) This process is reproduced below from page 11.

*“We use a structured approach for costing clinical guidelines; We have to make assumptions in the costing model. These are tested for reasonableness with members of the Guideline Development Group (GDG) and key clinical practitioners in the NHS.*

*Local users can assess local cost impact, using the costing template as a starting point, and update assumptions to reflect local circumstances.....*

*We worked with the GDG and other professionals to identify the recommendations that would have the most significant resource-impact*

*Costing work has focused on these recommendations.”(99)*

In so far as was possible I adapted the NICE costing model (99) to accommodate use of the ABMUHB data and Stats Wales predictions for demographic changes in age. The model was password protected which did not allow structural changes to accommodate the specific information needs of the PBMA and the ‘real world’ of the health board. Despite a number of requests to NICE I was not able to persuade them that it would be helpful to have an unprotected version of the model, as a result of which my adaptations and additional calculations to inform the PBMA proved time consuming and frustrating.

The Stats Wales data on population predictions for ABMUHB(100) was not provided in a format suitable for the NICE model inputs so the PHW date was grouped and sorted to conform with the NICE model (Appendix 9 Table 1a-e). The costing model base population has options for the distribution of males and females by age quintiles to be input to the spreadsheet. However, the model appears to be driven *only* by the population over the age of 18 years suggesting some links within the model are non-functional; so that I had to create a number of ‘work arounds’ to be able to generate age and sex specific outputs.

The inability to access primary care data within the health board at a patient level meant it was impossible to assess the validity of the NICE model within ABMUHB. However a review of admitted stroke patient care data in 2015 suggests broad consistency in the actual number of strokes experienced within the nvAF populations within Swansea and NPT populations(101). Fewer strokes appear to be reported for the Bridgend population but this may be explained by issues of coding consistency (101). However it should be noted that the Bridgend locality run a primary care based

anticoagulation service using local enhanced service levels 3/4 contracts <sup>6</sup> which is not the case in the other two localities.

### 3.3.7 ABMUHB ACTIVITY AND FINANCIAL DATA

The project team member from ABMUHB finance team used the data available within the health board(101) to work up a picture of activity and costs of anticoagulation services and acute patient care in ABMUHB. This was compared with the predictions I generated from the NICE costing model purposely to assess the financial consequences of changing the anticoagulation services within ABMUHB; the analyses were intended to identify the additional funding required to expand anticoagulation services and to assess to what extent funding can be released from budgets elsewhere in ABMUHB as a result of a consequent reduction in the incidence of strokes among those diagnosed with nvAF.

The sources of information incorporate detail from:

- The 2014 review of ABMUHB Anticoagulation services;(101)
- ABMUHB admitted patient care costed minimum data set April 2013 to September 2014.(101)

The PBMA process was informed by all these data on population, morbidity and current prescribing levels presented and compiled from Table 3:1 and in

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<sup>6</sup> Local enhanced services (LEs) – schemes agreed by health boards in response to local needs and priorities, sometimes adopting national service specifications.

Table 3:3 below. Prior to April 2015 it was estimated that 3170 patients with a diagnosis of nvAF were not receiving appropriate anticoagulation treatment in line with NICE CG180(86).

**Table 3:3 ABMUHB 2014 nvAF population profiles(101)**

	ABMUHB		Swansea		NPT		Bridgend	
<b>Population</b>	544,300		252,100		137,800		154,400	
<b>% with nvAF<sup>1</sup></b>	10,300	1.9%	4,400	1.7%	2,700	2.0%	3,200	2.1%
<b>Being prescribed</b>								
<b>Warfarin<sup>2</sup></b>	6,400	62.1%	2,600	59.1%	1,900	70.4%	1,900	59.4%
<b>Aspirin</b>	-		-		-		-	
<b>Dabigatran etexilate<sup>3</sup></b>	100	1.0%	67	1.5%	13	0.5%	20	0.6%
<b>Rivaroxaban<sup>3</sup></b>	100	1.0%	67	1.5%	13	0.5%	20	0.6%
<b>Apixaban<sup>3</sup></b>	100	1.0%	66	1.5%	14	0.5%	20	0.6%
<b>No Treatment</b>	3,600	35.0%	1,600	36.4%	760	28.1%	1,240	38.8%
<b>Contraindicated for treatment<sup>4</sup></b>	430		200		90		140	
<b>Undertreated Population</b>	3,170		1,400		670		1,100	

**Notes:** 1. Assumes 95% of patients on AF register have diagnosis of AF, 2. Data on warfarin patients with nvAF only available from Swansea – NPT and Bridgend figures extrapolated based on Swansea percentage Warfarin patients with nvAF. 3. NOAC information derived from CASPA – maybe overstated as not all may be nvAF – assumes equal split between drugs. 4. Based on NICE assumption of patients unsuitable for anticoagulation.



The cost of the current infrastructure associated with the current anticoagulation service was determined and summarised in Table 3:4 below.

**Table 3:4 Anticoagulation services costs estimated for 2015(101)**

<b>Current Service Costs</b>	ABMUH B Overall	Swanse a	Clydach	Neath Port Talbot	Bridgend
<b>Number of patients treated</b>	9,215	3,935	400	2,494	2,786
<b>Infrastructure (£)</b>	948,394	299,587	64,000	253,570	395,237
<b>Cost of warfarin (£)</b>	381,000	146,000	17,000	103,000	115,000
<b>Total per patient costs (£)</b>	144	108	202	143	183

Budgetary responsibility for these services is spread across a number of localities and directorates reflecting the different models of care currently operated. The models of care are summarised above in sections 3.5.1, 3.5.2 and 3.5.3. Some financial details of these costs – for instance the cost of phlebotomy in Swansea were not able to be quantified, so the Swansea cost is artificially low.

### **3.3.7.1 Use of Data to Inform the PBMA and Decision Process**

The project team pulled together audit data for the anticoagulation services, ABMUHB and the Stats Wales population data, worked on building up the financial picture for 2015 and 5 years ahead. Scenarios were created to inform the project team; these were based on the NICE costing model(99) looking at different rates of NOAC adoption and reduction in the untreated nvAF populations over time. Together and separately all these data were used to create future scenarios to understand the impact of the aging population, exploration of the impact in the change of stroke rates and the balance of prescribing NOACs and differing models of provision of anticoagulation services. These were iterated through the regular project meetings building up the best picture of the finances related to these scenarios, and how outcomes of different models of delivering anticoagulation services might impact finances.

As the health economist for the PBMA my efforts were directed at exploring data, identifying the pertinent literature, clinical and economic, creating analyses and making recommendations based on all of these sources including the NICE costing model. The project team member from ABMHB finance prepared financial analyses focussed on the activity data within the ABMUHB systems. Regular meetings between me and the finance team member allowed review of discrepancies between the estimates from the different sources to be resolved or 'lived with'. What was very clear was that the NICE model incorporated cost offsets from reduction in strokes which were potentially not realisable in the 'real world' of the LHB and from the different sectors of the patient pathway relating to stroke and anticoagulation and the project team had to consider the offsets in abstract terms and as probably only 'theoretically releasable'.

Outputs developed to inform the project team are presented and described below. These are options looking at how cost offsets from both or either reduction in anticoagulation services as NOACs use increases and warfarin decreases and/or reduction in strokes. The financial data is presented first and the outputs from the NICE costing model after. None of the options explored generated a cost neutral situation, because of the relative proportion of untreated patients who needed to be treated, the relatively high cost of NOACs compared with warfarin and the reduction in stroke rate not being large enough to offset against increased costs.

#### *SCENARIOS*

The consequences of expanding the service to the currently undertreated population were calculated initially assuming each locality expands its current service model. (Option 1, see

Table 3:5). The financial impact of this option and the other options has been calculated on a unit cost basis as follows:

- Swansea – Hybrid of Clydach and Swansea secondary care based model unit costs.
- NPT - Unit cost based on NPT Hospital based service.
- Bridgend – Extension of Enhanced services assuming level 4 payments.

A second option of treating all additional patients through prescription of NOAC was considered (Option 2), illustrated in Table 3:6, below.

**Table 3:5 Option 1 each locality expands its current service model**

	<b>Situation at May 2015</b>				<b>Option 1 : expansion of existing model</b>			
<b>Anticoagulation</b>	Swansea	NPT	Bridgend	Total	Swansea	NPT	Bridgend	Total
<b>Total N on Warfarin</b>	3,935	2,494	2,786	9,215	5,335	3,164	3,886	12,385
<b>GP Model</b>		700	2,786	3,486	-	700	3,886	4,586
<b>NPT Model</b>		1,794		1,794	-	2,464	-	2,464
<b>Clydach Model</b>	400			400	400	-	-	400
<b>Swansea Model</b>	3,535			3,535	4,935	-	-	4,935
<b>Total N NOAC</b>	200	40	60	300	200	40	60	300
<b>Total N anticoagulated</b>	4,135	2,534	2,846	9,515	5,535	3,204	3,946	12,685
<b>Total Costs (£)</b>	661,168	388,234	557,754	1,607,156	828,511	481,060	765,247	2,074,818
<b>Incremental costs for Infrastructure (£)</b>					109,495	65,142	162,041	336,678
<b>Incremental costs for Drugs (£)</b>					57,848	27,684	45,452	130,984
<b>Total Incremental Cost (£)</b>					167,343	92,826	207,493	467,662

**Table 3:6: Option 2: New patients treated with NOACs**

<b>Cost of Extending Treatment</b>	ABM	Swansea	NPT	Bridgend	NOAC
<b>Untreated Patients</b>	3,170	1,400	670	1,100	3,170
<b>Existing Service Models</b>					
<b>Infrastructure</b>					
<b>Unit Cost (£)</b>		76	97	147	
<b>Total Infrastructure Costs (£)</b>	333,770	106,587	65,142	162,041	Not applicable
<b>Warfarin (£)</b>	130,984	57,848	27,684	45,452	
<b>NOACS (£)</b>					
<b>Dabigatran etexilate</b>					847,218
<b>Rivaroxaban</b>					809,935
<b>Apixaban</b>					847,126
<b>Total Expansion Cost (£)</b>	464,755	164,435	92,826	207,493	2,504,279

The financial impact of treating the nvAF population on a single ABMUHB wide basis with one of the service models applied in other localities was estimated; referred to here as a 'board wide' service. These are presented in Table 3:7 below.

**Table 3:7 Options 4-7: Single Service Health Board Wide Options**

<b>Currently treated N= 9,215</b>				
<b>Untreated N= 3,170</b>				
<b>Total N=12,385</b>				
	<b>Infrastructure (£)</b>	<b>Drugs (£)</b>	<b>Total (£)</b>	<b>Net Impact (£)</b>
<b>Current</b>	948,394	380,764	1,329,158	
<b>Clydach Model (Option 3)</b>	1,985,071	511,748	2,496,819	1,167,661
<b>Swansea Model (Option 4)</b>	824,994	511,748	1,336,743	7,585
<b>NPT Model (Option 5)</b>	1,204,151	511,748	1,715,900	386,742
<b>Bridgend Model (Option 6)</b>	1,824,434	511,748	2,336,183	1,007,025
<b>All NOAC Model (Option 7)</b>		9,784,066	9,784,066	8,454,909

A review of ABMUHB admitted patient care for the period April 2013 to September 2014 was undertaken(101). All patient episodes with a primary diagnosis indicating a stroke (Coded I61, I 63, I64) were identified and those patients suffering from nvAF identified from the presence of ICD10 Diagnosis code I48 in the subsidiary diagnoses. Patients were classified to Locality based on GP registration. The number of stroke patients identified are summarised in

**Table 3:8 Actual stroke events in ABMUHB 18 months April 2013 – September 2014**

Stroke Events	April 2013 to September 2014					
		N Patients	Annualised n of patients	Rate per 1000 Pop'n	NICE Model annual Stroke rate Estimates	Difference
<b>Without nvAF</b>	Bridgend	300	200	1.30		
	NPT	238	159	1.15		
	Swansea	374	249	0.99		
<b>ABMUHB Total</b>		912	608	1.12		
<b>With nvAF</b>	Bridgend	112	75	0.48	113	51%
	NPT	110	73	0.53	85	15%
	Swansea	201	134	0.53	150	12%
<b>ABMUHB Total</b>		423	282	0.52	348	

The numbers of strokes for patients with nvAF per 1000 population are similar across the localities. The ABMUHB numbers were less than those predicted by the NICE model but the difference is most marked in Bridgend. There are a number of potential explanations for this:

- Coding of secondary diagnoses not as complete in Bridgend – ‘Non AF’ strokes per population higher in Bridgend;
- The data on the number of patients on currently on warfarin in Bridgend may be an underestimate;
- Some flow of Bridgend stroke patients outside of ABMUHB to Cardiff and Vale Health Board;

The breakdown of activity by primary care network shows lower numbers of stroke in the East and North of the locality, which is not unexpected given demographics of the residents. (Table 3:9 below).

**Table 3:9 Bridgend locality Stroke rate per 1000 population**

	Stroke rate per 1000 population	
	Without AF	With nvAF
<b>Bridgend East Network</b>	1.16	0.41
<b>Bridgend North Network</b>	1.21	0.43
<b>Bridgend West Network</b>	1.70	0.70

The NICE costing template works on the assumption that the financial impact of a stroke in the first year is £12,228 and applies this rate to the avoided strokes number to offset the cost of expanding the treatment. This is based on a study undertaken in 2003 (102) and the values inflated to 2014 costs (the year the NICE guidance was published). The average ABMUHB 'nvAF Stroke' patient is estimated to be £9,409 with an average length of stay of 31.7 days. The difference between this figure and the NICE assumption may be explained by:

- A slightly shorter stay than the study used by NICE;
- Patient Level Costing is still reliant on a number of crude apportionments for a number of cost drivers where patient level data is unavailable – most importantly in this context 'Therapies';
- The calculated cost only represents the cost of Admitted Patient Care and does not reflect ongoing rehabilitation delivered in community and primary care settings. The NICE model cost is a 1 year cost.

The patient level costs identified are fully absorbed and in order to determine whether resources can be released if the stroke rate reduces and re invested in the anticoagulation services it was necessary to understand which elements of this cost can be released to do that. Thus the costs associated with avoided activity identified were classified as:

- **Cash Releasing Savings** – for instance drugs and other consumables.
- **Direct Cost Offsets** - Costs associated with capacity that in theory are released but in practice are likely to be required to meet other pressures for which alternative funding streams may be available – for instance bed capacity required to meet unscheduled care pressures.
- **Opportunity Cost Savings** – Costs associated with capacity that in theory are released but in practice is likely to be required to meet other pressures for which no explicit funding streams are available.

The costs associated with nvAF Stroke patients were classified according to these categories and summarised in



**Table 3:10 Classification of ABMUHB stroke patient costs**

<b>Cost Category</b>	<b>Cost / Patient (£)</b>	<b>Cash Release (£)</b>	<b>Direct Offset (£)</b>	<b>Opportunity Cost (£)</b>
<b>Drugs / Consumables</b>	266	266		
<b>Critical Care</b>	150			150
<b>Imaging</b>	101			101
<b>Pathology</b>	90			90
<b>Therapies</b>	404			404
<b>Pharmacy</b>	106			106
<b>Wards</b>	4,191		4,191	
<b>Medical/Specialist Nursing</b>	1,593			1,593
<b>Other Clinical</b>	23			23
<b>Overheads/Other Support</b>	2,485			2,485
<b>Total</b>	9,409	266	4,191	4,952
<b>NICE cost model assumption</b>	12,228			
<b>Unidentified Opportunity Cost</b>	2,819			2,819
<b>Total Opportunity Cost</b>				7,771

It was assumed that within the Intermediate Term Management Plan (IMTP) there will be provision for the funding of additional capacity to address the growth in unscheduled care. If it can be agreed that this requirement can be mitigated by the reduction in capacity required to care for stroke patients then potentially unscheduled care funding may be redirected within the context of the PBMA to fund the expansion of anticoagulation to the untreated population.

Clearly there are significantly higher costs associated with the incidence of a stroke than the acute care costs presented here and the one year costs cited in the NICE CG180, reflecting ongoing complications and the wider costs to society impacting for instance on Social Services and Social Security. However, whilst it is important to recognise the wider benefits of reducing the incidence of strokes, the perspective for

this PBMA was relatively short term (12 – 24 months) in order for the health board to be able to locate and reallocate resources within the anticoagulation services that are the focus of this PBMA. It would be impossible to quantify any longer term/further savings accruing directly to the health economy which could be redirected towards anticoagulation services. On this basis the savings and/or cost avoidance associated with different models of care have been quantified for option 1 or 2 and are presented in Table 3:11 below.

**Table 3:11 Savings and/or cost avoidance relating to increase in anticoagulation for those not currently treated.**

	<b>Option 1: Warfarin (£)</b>	<b>Option 2: NOACs (£)</b>
<b>Strokes Avoided</b>	118	190
<b>Cash Releasing Savings</b>	31,353	50,423
<b>Potential Direct Offset</b>	494,688	795,560
<b>Opportunity Cost</b>	917,214	1,475,069

The NICE Costing Template includes an assessment of differential risk of major bleeds associated with the alternative treatment regimes. The cost of these incidents has been assumed as £1173 and the impact forecast on that basis and used to estimate costs illustrated in Table 3:12.

**Table 3:12: Cost of serious adverse events (bleeding) from anticoagulation**

<b>Number of people treated under each option</b>	<b>Option 1 Warfarin</b>	<b>Option 2 NOAC</b>
<b>Baseline</b>	89	89
<b>Proposed Treatment expansion</b>	107	103
<b>Additional serious adverse events</b>	18	14
<b>Additional Cost (£)</b>	21,455	16,442

Activity and cost assumptions were not been validated but given the relative immateriality of the cost the project team agreed to treat these as a notional cost.

A preliminary assessment of the net funding requirements for all the different options was prepared based on the assumptions set out above. These are summarised in Table 3:13. None of these options have attempted to assess the cost of service reconfiguration and implementation where that would be required. The options

explored all illustrate the challenges of releasing funding - that is 'real' cash that can be picked up from one budget and placed in another to fund change. The two most expensive options are 'Clydach' as the board wide single model and 'NOAC single model'. It is notable that the 'Clydach' model is the 'gold standard' service which meets best practice and guidelines standards for the smallest promotion of patients in ABMUHB, and at a high price. The 'NOAC single model' option switches all eligible patients to NOACs (compared with 'NOAC expansion' which is where the status quo for existing patients is 'business as usual' and the required reduction of the proportion of the 'untreated' population is accomplished by treating with NOACs).

The other options are more acceptable in terms of budget impact, but all services (with the exception of Clydach) have issues that need to be addressed to be confident that they meet required service standards. The most attractive option is 'Swansea' i.e. to expand the existing services but this service is the most unacceptable from a variety of standpoints, including the numerous risks inherent in this system due to separation of the testing and prescribing, and chain of communications. It is also the service where there is most uncertainty around the costs.

The 'locality specific' expansion does not address the service improvements needed - it is 'more of the same' but the 'same' is not good enough, but it is probably the easiest to accomplish logistically. Neither this nor the 'NOAC single model' would incur notable service change costs.

The NPT model is an attractive option as it is close to best practice standard and is relatively efficient in terms of staffing. Some of these options are purely hypothetical - rolling out a Bridgend model across the health board would not be acceptable to all GPs, as not all GPs would be prepared to take on an enhanced service but the exercise helps focus the project team and the stakeholders on the possible, the aspirational and the impossible and ways of viewing the budget.

**Table 3:13 Cost of alternative options for anticoagulation for untreated people**

	<b>Option 1</b>	<b>Option 2</b>	<b>Option 3</b>	<b>Option 4</b>	<b>Option 5</b>	<b>Option 6</b>	<b>Option 7</b>
<b>Type of coverage</b>	Expand Coverage	Expand Coverage	Single Model	Single Model	Single Model	Single Model	Single Model
<b>Strategy</b>	Locality Specific	NOAC	Clydach	Swansea	NPT	Bridgend	NOAC
<b>Funding Required (£)</b>	464,755	2,504,279	1,167,661	7,585	386,742	1,007,025	8,454,909
<b>Funding Available (£)</b>							
<b>Cash Releasing (£)</b>	(31,353)	(50,423)	(31,353)	(31,353)	(31,353)	(31,353)	(50,423)
<b>Potential Direct Offset * (£)</b>	(494,688)	(795,560)	(494,688)	(494,688)	(494,688)	(494,688)	(795,560)
<b>Total Potential Funding Releasable (£)</b>	(526,041)	(845,982)	(526,041)	(526,041)	(526,041)	(526,041)	(845,982)
<b>Net Funding Required (£)</b>	(61,287)	1,658,296	641,620	(518,456)	(139,299)	480,984	7,608,926
<b>Opportunity Cost Saving (£)</b>	(917,214)	(1,475,069)	(917,214)	(917,214)	(917,214)	(917,214)	(1,475,069)
<b>Notional Cost (£)</b>	21,455	16,442	21,455	21,455	21,455	21,455	16,442
<b>Notional Net Impact (£)</b>	(957,046)	199,668	(254,139)	(1,414,216)	(1,035,059)	(414,776)	6,150,298

\*Will be dependent on availability of funding within the IMTP which can be redirected.

I used the NICE costing model to explore some 'real life' scenarios independent of the service models to explore how the separate and combined impacts of the reduction of the untreated population and relative uptake of NOACs and warfarin affected costs (with a background increase of an increasingly ageing population). The NICE model was only able to assess cost offsets in cash terms, rather than the potential for resource release; the challenges to realising this in practice have been explained above.

The author ran versions of the model for 2015 to 2020, each run changing the population by year in line with Stats Wales population predictions(100), sorted into age quintiles to fit the NICE model. The model was then adapted to concentrate specifically on the population aged 65 years of age and over as this seemed more pertinent to the information useful to the PBMA scope.

The NICE costing model allows some ABMUHB local data (either directly or via workarounds) to be entered for some variables that influence stroke rate and costs (e.g. prevalence of nvAF). These data were input to generate base case outputs. These were then varied using differing rates of NOAC use (using assumptions informed by current prescribing data and use elsewhere), warfarin use, reduction of aspirin use for anticoagulation to zero in line with NICE recommendations and proportion of people untreated (which would include the small proportion of those contraindicated for treatment, remaining untreated).

This enabled aggregation of data to summarise estimates of overall budget changes (albeit hypothetical), adverse event rates (bleeds related to treatment) and stroke rates from 2015 to 2020. The base case for 2015 was populated with the information agreed at prior meetings, and informed assumptions made to create the scenarios.

The cost of stroke for one year was assumed to be £9,500 based on the data held by the health board based on its own costing system. As mentioned previously this value is solely secondary care costs and very much underestimates the cost of care for people with stroke. We know saving a stroke will reduce many more costs than just acute care, let alone the impact on unscheduled care and last but not least to human beings. However given the constraints of the NICE model and the need to re allocate 'releasable' resources and cash a one year perspective seemed acceptable. It was assumed that this cost would remain about the same over the 5 years we are considering, given advances in management would perhaps reduce stay in acute hospitals which would balance out increase in costs.

The cost of anticoagulation used in the base case was the ABMUHB average of £144 per patient. This was increased to the higher rate for Bridgend (£183 per patient) in sensitivity analysis

All the other cost inputs remained as provided by NICE given the uncertainty surrounding the local data and model inflexibility. The prices for pharmaceuticals are as list price used in the NICE costing model given no alternative information about any discounts that may have been negotiated locally.

The model was then run with assumptions about growth of and relative proportions for NOAC use, warfarin use and assumed a gradual reduction in the untreated population, changes in the relative proportions of warfarin to NOAC to aspirin use etc.. The first set of analyses looked at how population change – all else held equal – would affect nvAF related stroke rates. These are summarised in Table 3:14, below.

**Table 3:14 Predicted budget changes driven by population change alone 2015-2020.**

<b>Year</b>	<b>% Rx NOAC</b>	<b>dabigatran</b>	<b>rivaroxaban</b>	<b>apixaban</b>	<b>aspirin</b>	<b>% untreated &amp; not contraindicated</b>	<b>% warfarin treated nvAF population</b>	<b>2015 budget</b>	<b>future budget impact</b>	<b>change in budget</b>	<b>% change budget</b>
<b>2015</b>	2%	1%	1%	0%	4%	29%	67.00	£4,790,345			
<b>2016</b>	2%	1%	1%	0%	4%	29%	67.00	£4,790,345	£5,061,725	£271,379	6%
<b>2017</b>	2%	1%	1%	0%	4%	29%	67.00	£4,790,345	£5,084,392	£294,046	6%
<b>2018</b>	2%	1%	1%	0%	4%	29%	67.00	£4,790,345	£5,106,145	£315,799	7%
<b>2019</b>	2%	1%	1%	0%	4%	29%	67.00	£4,790,345	£5,128,273	£337,927	7%
<b>2020</b>	2%	1%	1%	0%	4%	29%	67.00	£4,790,345	£5,149,325	£358,979	7%

**Table 3:15 Comparison between NICE estimates and ABMUHB estimates for base year**

	<b>Unit cost £</b>	<b>N pop'n</b>	<b>Total cost £</b>	<b>Unit cost £</b>	<b>N pop'n</b>	<b>Total cost £</b>
	NICE data			ABMUHB data		
<b>Total population selected</b>		526,997			526,997	
<b>Prevalence nvAF in people &gt;18 yrs.</b>		8,432			10,540	
<b>Current practice</b>						
<b>Cost of drugs and monitoring</b>						
<b>People receiving warfarin</b>	41	2,894	119,568	41	6,640	274,358
<b>Monitoring for people receiving warfarin</b>	242	2,894	698,948	144	6,640	956,138
<b>People receiving aspirin</b>	32	1,896	60,801	32	402	12,905
<b>People receiving dabigatran etexilate</b>	802	399	320,017	802	7	5,915
<b>People receiving rivaroxaban</b>	767	399	305,936	767	12	8,886
<b>People receiving apixaban</b>	802	399	319,985	802	0	169
<b>People receiving no treatment</b>	0	2,445	0	0	3,478	0
<b>Costs of adverse events</b>						
<b>Strokes cost in 1st year of having stroke</b>	12,228	310	3,789,185	9,500	361	3,426,382
<b>Major bleeds</b>	1,173	63	74,243	1,173	90	105,592
<b>Estimated costs of current practice</b>			£5,688,684			£4,790,346



Table 3:15 shows how the changing rates of uptake of anticoagulation initially reduces estimates of overall offset costs (by reducing stroke rate) but after the NOAC uptake increases above 12%, the cost of NOACs increases the overall budget (that is anticoagulation services and treatment costs and unscheduled care costs for stroke). The changes assumed for 2017 show the biggest estimated change in stroke rate, whilst budget reductions compared with 2015, the base year, are evident.

Internal data also suggested that prescribing of the NOACs was rising within ABMUHB(101). A forecast that preceded the PBMA suggested that if NOAC prescribing rises to 20% or anticoagulants overall this will equate to £1.4 m additional cost to the health board over 5 years from an April 2015 baseline unless there were cost offsets that could be directly realised and set against the prescribing budgets.

**Table 3:16 Estimated stroke rate by year related to AF population uptake assumptions**

<b>Year</b>	<b>NOAC total Rate<sup>7</sup></b>	<b>aspirin</b>	<b>% not contraindicated &amp; untreated</b>	<b>% managed with warfarin</b>	<b>2015 estimated expenditure</b>	<b>Future estimated expenditure</b>	<b>change in budget</b>	<b>% change budget</b>
<b>2015</b>	2%	4%	29%	67%	£4,790,345			
<b>2016</b>	5%	2%	29%	63%	£4,790,345	£4,750,998	-£39,347	-1%
<b>2017</b>	12%	1%	24%	63%	£4,790,345	£4,570,781	-£219,564	-5%
<b>2018</b>	15%	1%	20%	64%	£4,790,345	£5,464,054	£673,708	14%
<b>2019</b>	20%	0%	15%	65%	£4,790,345	£5,683,075	£892,729	19%
<b>2020</b>	20%	0%	10%	70%	£4,790,345	£5,619,379	£829,033	17%

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<sup>7</sup> relative proportions of NOACs available remaining the same

**Table 3:17 Stroke rates predicted by year based on Table 3:16 Estimated stroke rate by year related to AF population uptake assumptions**

**anticoagulation rate and type assumptions**

<b>Year</b>	<b>N stroke</b>	<b>Year on year reduction in stroke</b>	<b>N major bleeds</b>	<b>Relative increase in bleeds year on year</b>
<b>2015</b>	361		90	
<b>2016</b>	348	4%	94	4%
<b>2017</b>	302	13%	101	7%
<b>2018</b>	297	2%	101	0%
<b>2019</b>	273	8%	105	4%
<b>2020</b>	254	7%	108	3%

**Table 3:18 Sensitivity analysis of costs of anticoagulation using the 'Bridgend rate' for cost of anticoagulation service**

	<b>Service cost (£) in Bridgend (£183 per person per year)</b>	<b>Change in service costs (£)</b>	<b>% change</b>
<b>2015</b>			
<b>2016</b>	5,031,763	-290,225	-6%
<b>2017</b>	4,902,039	-419,949	-9%
<b>2018</b>	5,730,621	408,633	7%
<b>2019</b>	5,954,984	632,996	11%
<b>2020</b>	5,913,406	591,418	11%

**In pulling all of the scenarios, activity data, stroke and bleed outcomes and the cost data together for the project team they were able to make a reasonably confident prediction of what 2020 might look like for services. These 'best estimates' for past present and likely future are summarised in Table 3:16**  
**Table 3:16 Estimated stroke rate by year related to AF population uptake assumptions**

Table 3:17, Table 3:18 and Table 3:19.

**Table 3:19 Predictions for anticoagulation uptake in ABMUHB in 2020**

	Current Resourced Capacity				Capacity in 2020			
	Swansea	NPT	Bridgend	Total	Swansea	NPT	Bridgend	Total
Anticoagulation Activity	Number of people treated							
Warfarin	5,335	3,164	3,886	12,385	5,129	2,955	3,705	11,790
NOACs	258	76	163	497	999	613	740	2,351
Untreated 'Known' nvAF Patients	200	90	140	430	200	90	140	430
Anticoagulation Costs	Costs in £000							
Infrastructure	496	389	578	1,463	492	382	551	1,425
Warfarin	220	131	161	512	212	122	153	487
NOACs	204	59	129	393	781	479	579	1,840
Total	921	579	868	2,367	1,485	983	1,283	3,752
Outcomes								
N Strokes	99	60	73	232	106	64	78	248
N Bleeds	46	29	34	110	52	32	39	123

While the absolute amount of the budget and the ability to release cash and resources from unscheduled care into the anticoagulation services may be contentious, overall the finances are driven by the same uncontentious drivers – cost of stroke, cost of anticoagulation (including warfarin) and cost of NOACs. The analyses seem to indicate that theoretical savings from reduced strokes and controlled spending on anticoagulation services seen in the first two years will be overwhelmed in the last three years by increasing costs of NOACs, where the benefits of not needing anticoagulation services for these agents is no longer offset by the higher price for the treatment, rather than being driven by the rate of nvAF in an increasingly ageing population. However if use of NOACs can be targeted at the people who might benefit the most as suggested by Sculpher and colleagues (94) and the budget held below the threshold amount without causing harm and ensuring those managed with warfarin are not disadvantaged or put at higher risk the budget could theoretically ‘fund’ service change and continued to be run as ‘neutral’ if the unscheduled care and anticoagulation services budgets could be transferred in this way.

#### 3.3.8 PATIENT PERSPECTIVE

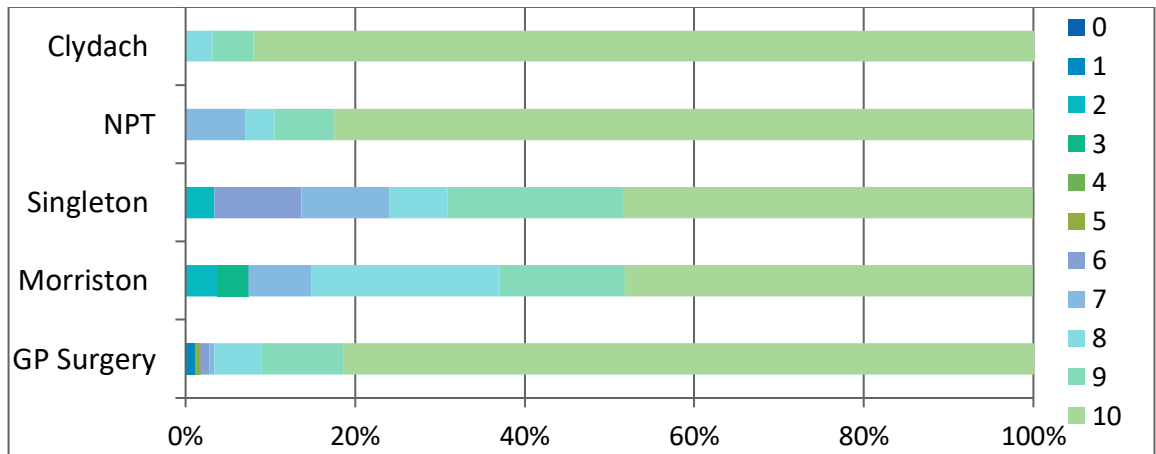
A patient engagement exercise and survey was undertaken by a project team member to inform the PBMA. This took the form of a postal survey in which patients were asked to complete a questionnaire on their experience of using ABMUHB anticoagulation services. From the whole population of service users 364 (35%) questionnaires were completed and returned and there was a representative response from all services. Overall service users were happy with anticoagulation services. Figure 3:5 illustrates the response to the question ‘*How would you rate your overall experience of the service you receive currently? (0= bad 10=excellent)*’

The service users biggest concerns related to; waiting times, parking, the availability of information and being able to contact someone in the service when they needed advice about changes in their condition or its management.

The survey was not undertaken by me but the results collected by the project team member are available in Appendix 10.



Figure 3:5 Patient survey: response to question about experience of anticoagulation services overall



### 3.3.9 GP STAKEHOLDER PERSPECTIVE

It was vital that GPs were represented and as a body informed the PBMA and whilst there was GP participation in the PBMA in both the stakeholder group and the project team, an additional survey was undertaken by a project team member to get views of the ABMUHB GPs. The GPs were asked to complete a questionnaire giving their views on nvAF management and anticoagulation services (full survey results are provided in Appendix 11). There was a good response: 39 returns from 73 practices - from all three localities providing a representative sample of GPs. It was not always clear from the survey response whether they represented individual GP, from within the practice, views or whether the response was a group response from a practice representing the views of the whole practice. Nevertheless the responses were very informative. Responses identified the following key issues;

- Serious concerns about current separation of prescribing of warfarin and INR monitoring in most services. The responses highlighted a significant clinical risk if GPs were to withdraw prescribing services, because of these concerns and this matter had also been highlighted by Local Medical Committee and General Practice Committee Wales' letter to ABMUHB in early 2015.
- GPs don't feel that they have adequate support to diagnose nvAF;
- There is limited access to specialist services for management of complex/out of range patients (i.e. onward referral from existing 'warfarin services');
- Some GPs have a lack of confidence in the service provided by the Health Board which isn't always reflective of other audit outcomes;

- Lack of clarity about switching to alternative anticoagulants to warfarin, pathways and monitoring requirements;
- Poor communication between GP/anticoagulant Services/acute care clinicians;
- Capacity concerns within current anticoagulation Services to allow them to undertake full service/see patients in a timely way.

Generally the tenor of the responses reflected the stakeholders and project team members assessment of situation. The response to the survey question about the confidence the GPs had in anticoagulation services Table 3:20 reflects the overall tone of the GP responses

**Table 3:20 GP Survey responses to ‘confidence in service’ questions**

<b>How confident are you that your current service:</b>	<b>Swansea</b>	<b>Bridgend</b>	<b>NPT</b>
Is responsive to changes in patients’ medication? (Scale 0-10)	5.5	8.3	6.7
Identifies patients who are not in therapeutic range?	25% confident	89% confident	36% confident
Responds successfully when it identifies patients not in therapeutic range?	38% confident	89% confident	64% confident
Do you know the current reported time in therapeutic range (TTR) of the service your patients use?	31% yes	89% yes	55% yes

### 3.3.10 WHAT DOES GOOD LOOK LIKE?

The ideal service the PBMA stakeholders desired, benchmarked against current practice is illustrated in Table 3:21 below.

**Table 3:21 The Existing anticoagulation services benchmarked against key criteria**

	Neath Port Talbot		Bridgend	Swansea	
	Pharmacy Model	Enhanced Service	Enhanced Service	Clydach	Singleton Morryston
Community based	x	√	√	√	x
Face to face	√	√	√	√	x
Offering both warfarin & NOAC	√	√	√		x
No prescribing & dosing separation	x	√	√	√	x

Based on the summary above and the feedback received from patients and GPs the project team identified gaps in provision across all services and all localities; the Singleton/Morryston Service met none of the criteria.

During the PBMA process the stakeholder groups were asked about the criteria which were most important to guide decision making and relative priorities under which decisions for change in services should be made.

The stakeholder group reflected on the 'Changing for the Better' meeting (see section 3.3.2.1) held on the 7<sup>th</sup> May 2015 where stake holders felt that the top 4 priorities should be these were:

1. Health Outcomes,
2. Standards of Care,
3. Evidence and
4. Reduced Harms

As a next stage, the stakeholders in the nvAF PBMA came together in a meeting and using group decision support methods supported by a facilitator and the TurningPoint software the stakeholders were asked for guidance and priorities for the specific characteristics of the service which were important to them. The questions and answers are summarised below in Box 3:2.

Box 3:2 stakeholders preferences for anticoagulation service configuration

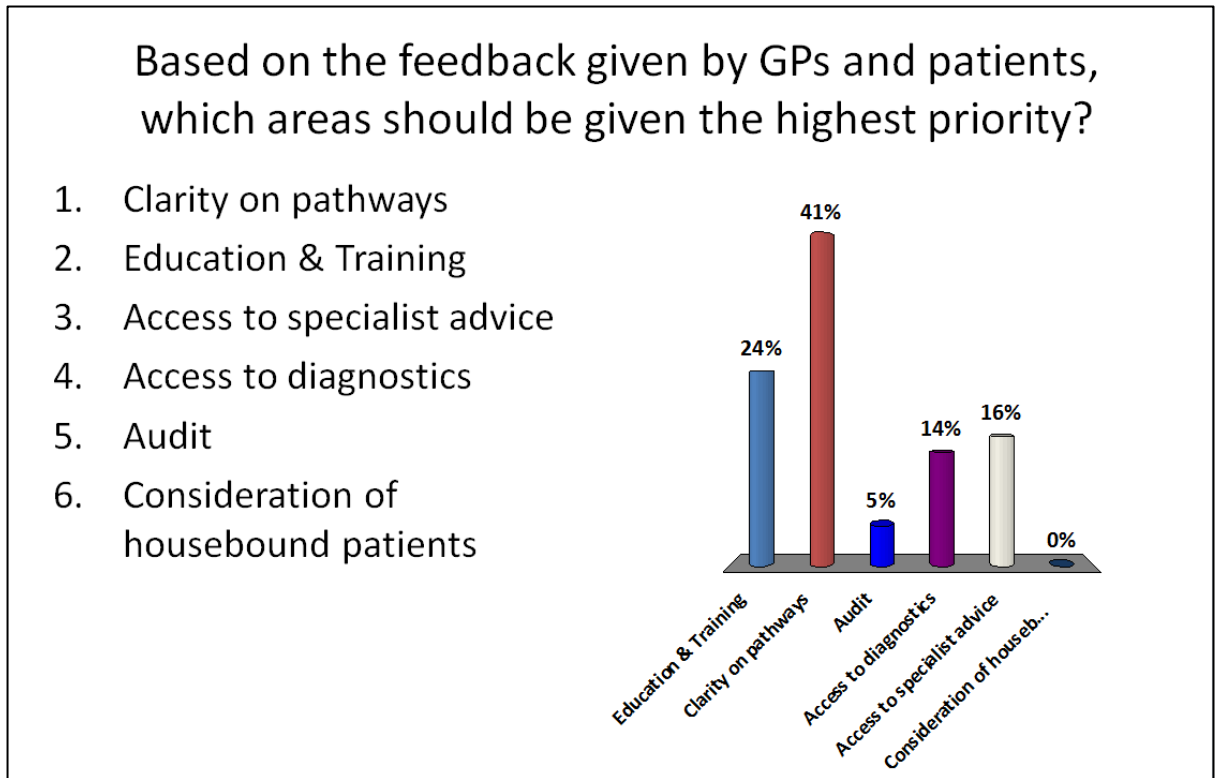
• What agent should be prescribed?	
○ Warfarin only	20%
○ NOAC only	0%
○ Both	80%
• Where should nvAF counselling/prescribing be done	
○ In a hospital based clinic ?	11%
○ In a community based clinic ?	89%
• Does specialist care mandate it be a hospital review?	
○ Yes	15%
○ No	85%
• Should the person prescribing the anticoagulant be responsible for dosing?	
○ Yes	75%
○ No	25%
• How should the patient be notified about dosing?	
○ Face to face	95%

An open ended question was also asked of the stakeholders about what the ideal service would be. The stakeholders agreed that it should be:

- Community based;
- Face to face;
- Offering both warfarin & NOAC;
- No separation between prescribing & dosing;
- Prioritising the attributes of the service in line with the most important of the ABMUHB criteria as previously established.

Having received these views the stakeholders were then asked to prioritise further based on the GP and patient survey results. The relative priorities are presented in Figure 3:6 below.

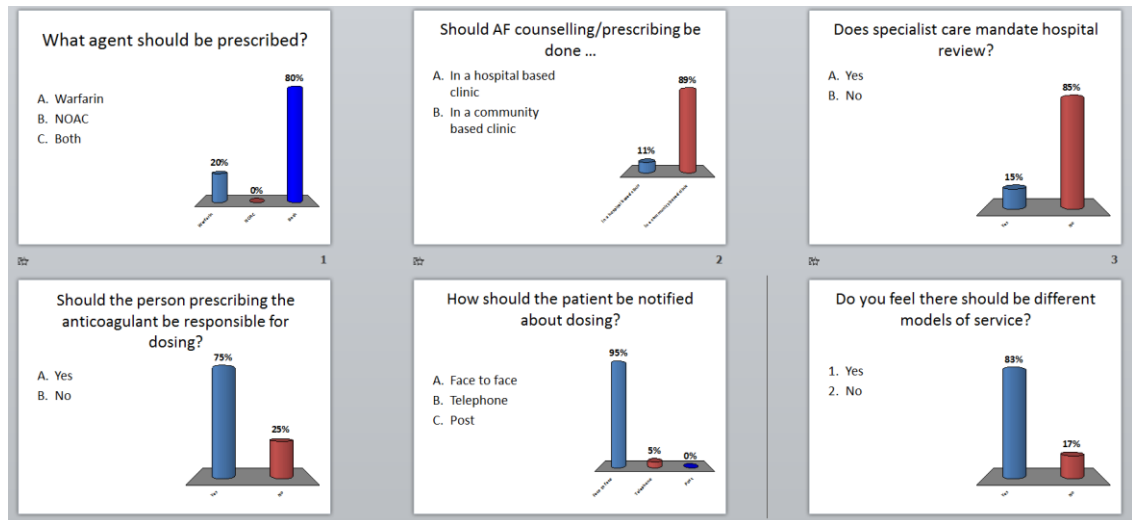
**Figure 3:6 Stakeholders responses to service characteristics and priorities questions**



Clarity on pathways, patient education and training were the two highest priorities followed by access to specialist advice and access to diagnostics.

Further clarification to determine the important characteristics of the anticoagulation services for people with nvAF were explored using group decision support to understand what was important and what was not. The TurningPoint™ outputs are shown in Figure 3:7

**Figure 3:7 Stakeholders views on important anticoagulation service characteristics**



All of this information and the relative priorities guided the development of the options that the team researched and issues that needed further investigation. The totality of stakeholder input is summarised below:

- **Patients' biggest concerns** related to access; waiting times, parking, the availability of information & being able to contact someone in the service
- GPs concerns related to:
  - They don't feel that they have adequate support to diagnose AF;
  - There is limited access to specialist services available for management of complex/out of range patients (onward referral from existing 'warfarin services');
  - Some GPs have a lack of confidence in the service provided by the Health Board which isn't always reflective of other audit outcomes;

At the final stakeholder meeting, when asked to determine the final criteria under which priorities for reallocating resources within the existing budget should be made, stakeholders' top priorities chosen from a list of options were:

1. Improving communication between GPs/Anticoagulation Services
2. Clarifying pathways;

and equal 3rd were;

3. Explore options for improving data collection and re-establish Thromboprophylaxis & Anticoagulation Committee

The other criteria which were lesser priorities were:

5. Standardise audit criteria & merchandise for collecting & reviewing audit results,
6. Improving communication between Acute Care/Services,
7. Explore education & training opportunities, leaflets/e-learning,

These priorities enabled the project team to pull together the recommendations for change to present to the stake holders for prioritisation and thence to the UCCB.

In the ideal world the UCCB decisions should have been made comparing the proposals from the PBMA project team with other proposals in front of them, using MCDA and a simple method for prioritisation such as the Portsmouth Score card(103). However the established processes of the health board did not allow for this and the only mechanism for enabling decision making under the 'PBMA ethos' was to prepare a business case proposal for resource reallocation within budget in the ABMUHB template form and use that opportunity to communicate the criteria and rank ordered preferences of the stakeholder groups as the process evolved. At the time the PBMA exercise was being completed the Welsh Government, independent of the PBMA, made a one-time only budget supplement of £500,000 to ABMU to assist meeting the requirements of NICE CG80 guideline and management of nvAF. The template format did allow a good opportunity to describe the recommendations for change within budget and the options to consider for utilising the 'one off' budget increase provided by the Welsh Government.

### *3.3.11 RECOMMENDATIONS FOR RESOURCE REALLOCATION*

The project team proposed a number of options for the UCCB to consider within budget, all ratified by stakeholders. These were all opportunities available to improve on current practice and reduce stroke rate or address the responsibilities of the health board that were not being optimised. The project team presented the stakeholders with no cost/low cost options for service improvements where the increased quality of the service would reduce stroke rate and where the modest costs of these activities would be offset by plausible cash release/resource reallocation within the timeline of the IMPT.

At the time the PBMA exercise was being completed the Welsh Government, independent of the PBMA, made a one-time only budget supplement of £500,000 to

ABMU to assist meeting the requirements of NICE CG80 guideline and management of nvAF.

In terms of activities that could be accomplished within the reallocation of the budget there were some very low cost activities that were strongly recommended. Indeed one of the priorities proposed was the no cost activity of re-establishing, supporting and better empowering the Thromboprophylaxis & Anticoagulation Committee to drive through improvements and changes. Existing services have some capacity to initiate the identified activities related to improved communication as support was available from central ABMUHB services such as Learning and Development Team, Medical Illustration and the Information Team to engage staff and patients and improve standards. These were to be designed to accomplish:

- Clarity on pathways
- Clarify responsibility for aspects of anticoagulation identified in NPSA Alert
- Introduce standardised audit criteria for anticoagulation services and wider Health Board
- Development of Health Board wide patient/GP leaflets etc.
- Communication exercise with GP colleagues and acute care clinicians to clarify:
  - Anticoagulation service processes
  - Referral criteria
  - Need to communicate regarding adverse events

The project team proposed that ABMUHB and UCCB should consider and agree what audit information they require from GP practices who deliver the Enhanced Services and put mechanisms in place to collect and review this data on a regular basis (and consider using Audit+ data) and explore options for renegotiation of Enhanced Service in recognition of additional pressures on primary care. It also should reflect need for training and auditing as per the National Patient Safety Agency recommendations (98) and the need for annual review of treatment.

In the NPT service, pending decisions about investment in decision support software, there should be better data capture using software available to all at no extra cost rather than paper in order to facilitate mandatory audit and reporting requirements.

In Swansea in the Clydach service, resource release to facilitate increased patient throughput and potentially release capacity was possible by letting 'no dose change' patients leave the clinic without a face to face meeting with clinic staff. In Swansea, The



secondary care based service faced the most problems and the team felt they had the opportunity to substitute postal communications which are deceptively costly with telephone/face to face reviews which would be budget neutral.

However as the PBMA fact finding progressed it was clear that the resource required to implement the range of higher value interventions required to significantly improve quality and reduce risk would exceed the budget currently available, even if all the 'releasable resource' from strokes avoided were available to invest in the anticoagulation services immediately .

Thus given the knowledge gained through the PBMA an additional proposal was made to the UCCB to optimise the budget and suggested ways in which current service models could be improved with this extra resource.

An identified priority was to ensure access is available to specialist services. This service could be incorporated into revised service models but will be driven by recruiting people with the appropriate skills to undertake this function. Approximate costs for the specialist service were estimated at £34,000. There was consideration of the support that the current GPwSi service provided to GPs at the point of referral and whether this service needs to be expanded or whether a specialist service could provide some of the additional support needed.

Investment in a Health Board wide decision support tool to support the management of patients on warfarin was also recommended; this would facilitate:

- Targeting out of range patients for more intensive review and consideration of alternative treatment/stopping treatment;
- The availability of audit data which would be used for benchmarking/service improvement;
- The ability to provide data to other healthcare professionals; regular reporting to GP practices on their patients;
- Opportunities for further integration with other Health Board/GP systems to further improve communication/patient management/patient safety.

In the proposal to UCCB the project team presented Three 'Models of Care' as options for service improvement which could be funded by the £500,000 Welsh Government grant for service improvement. These are illustrated in Figure 3:8, Figure 3:9, Figure 3:10 and Figure 3:11 below. Further detail on the options is provided in the detailed proposals for change as presented to the UCCB in Box 3:3.

**Figure 3:8 Service Improvement Investment Model 1**

<h2>Model 1</h2>	
<ul style="list-style-type: none"> <li>• Replicate NPTH Pharmacy Model for Swansea patients (including Clydach)</li> <li>• Continue use of DAWN dosing software</li> <li>• Consideration of locations (likely multiple locations needed)</li> <li>• Cost £602,000 – £656,000 (depending on band of staff)</li> </ul>	
Benefits	Risks
Face to face reviews	There will still be a separation of dosing and prescribing
Point of care testing	May not be community based (should be considered when identifying locations – likely trade off between economies of scale <u>vs</u> community)
Depending on the experience of nurses/pharmacists running the service it may be possible to include specialist managed/switching as part of service	

**Figure 3:9 Service Improvement Investment Option 2**

<h2>Model 2</h2>	
<ul style="list-style-type: none"> <li>• Increase available nursing resource within Swansea service :                             <ul style="list-style-type: none"> <li>– all patients to be telephone dosed</li> <li>– all new patients to have face to face 1 month follow up appointment</li> <li>– all patients to have a face to face annual review</li> <li>– out of range patients to have face to face reviews</li> </ul> </li> <li>• Cost assumes Clydach service would continue for Cwmtawe patients as this model does not move completely to best practice</li> <li>• Cost £613,000 (includes resource for Education &amp; Training) £536,000 (without E&amp;T resource)</li> </ul>	
Benefits	Risks
Will increase face to face appointments for out of range patients	Not point of care testing
<ul style="list-style-type: none"> <li>▪ Evidence suggests this would increase TTR</li> </ul>	Patients won't be seen face to face after every INR test
Small scale change	Not community based

**Figure 3:10 Service Improvement Investment Option 3a**

<h2>Model 3a</h2>	
<ul style="list-style-type: none"> <li>• Roll out Clydach service across Swansea</li> <li>• Consideration of locations (likely multiple locations needed)</li> <li>• Cost £689,000</li> </ul>	
Benefits	Risks
Point of care testing	Would require a number of non-medical prescribers (could consider one/two per network rather than all)
Face to face appointments	
No separation of monitoring and prescribing	Need to consider availability of appropriate facilities
Community/cluster based	May not benefit from economies of scale – should consider this as part of service redesign

**Figure 3:11 Service Improvement Investment Option 3b**

<h2>Model 3b</h2>	
<ul style="list-style-type: none"> <li>• Roll out Clydach service across Swansea but adapt model to allow more patients to be seen in each clinic session</li> <li>• Consideration of locations (likely multiple locations needed)</li> <li>• Cost £538,000</li> </ul>	
Benefits	Risks
Point of care testing	Would require a number of non-medical prescribers (could consider one/two per network rather than all)
Face to face appointments	
No separation of monitoring and prescribing	Need to consider availability of appropriate facilities; may be more difficult if needing to run concurrent clinics
Community/cluster based	

Model 3b was the preferred option voted for by the stakeholders as the option to propose to UCCB to utilise the Welsh Government additional funding.

The project team also proposed that to optimise nvAF related stroke prevention within existing resource a large scale review of the whole stroke pathway, recognising “upstream” efficiency savings realised by stroke prevention.

Identification of nvAF and management of nvAF other than by anticoagulation, though important, was not within the scope of this proposal. Clearly this was important and assumptions about the reduction in the 'unknown untreated population' were made in the various scenarios created. The project team recognised that more work was required to support GPs to identify and identify and manage nvAF in primary care and flagged this up to the UCCB.

The PBMA also recognised some aspects of the service that may not be efficient use of resources but were appropriate use. There was extensive discussion amongst the stakeholder group about consideration of patients with other indications receiving anticoagulation and their requirement for monitoring. It was agreed that, in the main, particularly in Swansea where much of the service provision was based in Singleton and Morriston Hospitals, it is not realistic or possible to separate services for patients with nvAF from those services for patients with other indications who may be better served by a secondary care based service – a critical mass of patients is required to make this service sustainable and this needs to be considered in any future service redesign.

Specific service consideration for housebound patients and patient self- monitoring were not fully addressed by the PBMA and have not been included. However, these areas were flagged to UCCB as important areas and investigation of how these patients should be best managed should be built into any service redesign.

The details of all the service reconfiguration options open to the UCCB to determine which to take forward and integrate into the IMTP were presented in November 2015 and are provided as provided to the UCCB in below in Box 3:3.

**Box 3:3 Proposals for change as presented to UCCB from nvAF PBMA project team**

The recommendations in this proposal contribute to improving quality of care and reducing potential harm for AF patients in relation to the following areas:

- patient information
- patient access
- anticoagulation management for AF patients
- staff education and awareness
- quality and management of audit data to inform risk management

The combined impact of the recommendations will assist with reducing the risk of stroke, however they will not address some of the core issues associated with best practice in the management of AF patients in this respect.

The proposal aims to make recommendations to improve the prevention of stroke in people with probable Atrial Fibrillation (AF) in relation to referral and initiation of anticoagulation for AF. It also recognises the need for more work to be done around diagnosis and management of AF in primary care. There are a number of recommendations presented in section A of table 1a below. These are considered possible by the project team to be delivered within existing resource and will contribute to reducing risk and improving quality of care for patients. Recommendations in section B of table 1a relate to the temporary suspension of commitment of funding recently secured by the ABMU Primary & Community Delivery Unit from Welsh Government for £538k so as further improvements in quality and efficiency can be generated from this resource.

Recommendations in section C of table 1a would require additional investment to deliver.

Table 1a proposed recommendations to reduce risk and improve quality of care for AF patients

SECTION A within existing resource recommendations	
Recommendation	Specific Actions
1.Patient Information Improve patient information communication to patients, primary care and acute care colleagues.	Development of Health Board wide Atrial Fibrillation patient care information leaflet to enhance existing standardised anticoagulation information. ( <a href="http://patient.info/health/preventing-stroke-when-you-have-atrial-fibrillation">http://patient.info/health/preventing-stroke-when-you-have-atrial-fibrillation</a> ) Improved information for clinical colleagues on current services; referral information, shared audit data, information on adverse events etc.

<p>2.Clinical Training Strengthen Education &amp; training for clinical staff</p>	<p>Review current training provision across Health Board around anticoagulation (post registration training) to ensure standardisation and clarity on responsibility for this provision.</p> <p>Create departmental staff registers to capture staff requiring training and track compliance and ensure this is monitored by the appropriate committee.</p> <p>Consider alternative, more effective ways of delivering training, e.g. Health Board wider e-learning programme</p> <p>Review training requirements and competencies in Primary Care</p>
<p>3.Governance Improve responsibility within the Health Board for the wider management of anticoagulation</p>	<p>ABMU Medical Director to re-establish Thromboprophylaxis &amp; Anticoagulation Committee or allocate specific responsibility to an appropriate committee</p> <p>It needs to be extant that any service providing anticoagulation care needs to comply with all relevant aspects of NPSA and this would need to come under the oversight of the relevant committee</p> <p>Confirm responsibility for aspects of anticoagulation identified in NPSA Alert e.g. if Thromboprophylaxis &amp; Anticoagulation Committee be re-established should this have overall responsibility for inpatient/outpatient services.</p>
<p>4.Audit Improvements to audit programme for the management of anticoagulation and anticoagulation services</p>	<p>Review whether data required to complete NPSA audit is available and where it is not put steps in place to extract the necessary information, e.g. incidence of adverse events.</p> <p>Confirm whether NPSA audit tool captures all necessary audit data or whether additional audit data is required</p> <p>Medical Director to nominate a responsible Committee. (recommendation 3, action a)</p>
<p>SECTION B within recently allocated new resource recommendations</p>	
<p>Recommendation</p>	<p>Specific Actions</p>
<p>5. Findings from the AF project team work be applied to further improve on the quality and efficiency gains generated from this resource.</p>	<p>Unscheduled Care Commissioning Board request that the Primary &amp; Community Care Delivery Unit present a revised approach to Unscheduled Care Commissioning Board for recommendation/approval.</p>
<p>SECTION C requires additional resource recommendations</p>	
<p>Recommendation</p>	<p>Specific Actions</p>

<p>6. Procurement of a Health Board wide decision support tool to support the management of patients on Warfarin</p>	<p>To be considered within Stoke pathway redesign work of the unscheduled care board.</p> <p>All work and analysis from the AF project to be shared with the stroke redesign team.</p> <p>Consider interim measure of an in house data capture (e.g. excel, access database)</p>
<p>7. To commission further work to identify and the management of AF (outside of anticoagulation) to reduce the health impact and financial burden to the health economy</p>	<p>The case for change issues within this proposal and data gathered by the AF project team be utilised by the UCCB stroke redesign team to further improve stroke prevention for AF patients.</p>
<p>8. Improved access to services for patient queries.</p>	<p>Introduce/improve telephone helpdesk to improve access.</p>
<p>9. Leveraging the data from the SAIL database</p>	<p>Based on the facts presented in the document earlier and from an intelligence point of view as a Health Board we would need to track the patients with AF who end up having stroke. This would enable us to understand the population needs from a commissioning point of view. It will also help us develop a baseline to monitor and evaluate the services going forward.</p> <p>The flow needs to be understood from a primary and secondary care perspective and leveraging SAIL to be able to map out this information would be crucial.</p> <p>The next step would be to map the outcomes on a patient level (link with audit information) which is an aspiration from an intelligence point of view.</p>

Table 2a within resource recommendation benefits

SECTION A recommendations within resource	
Recommendation	Benefits
1.Patient Information Improve patient information communication to patients, primary care and acute care colleagues.	<ul style="list-style-type: none"> <li>• Increase confidence in services provided</li> <li>• Improve patient experience</li> <li>• Improved patient condition awareness and management through information/education.</li> </ul>
2.Clinical Training Strengthen Education & training for clinical staff and documentation. Identify requirement and identify current compliance	<ul style="list-style-type: none"> <li>• Improved quality of care</li> <li>• Improved patient experience</li> <li>• Shared learning particularly from adverse events</li> <li>• Standardisation of training and transferable skills across the Health Board</li> <li>• Efficiencies resulting from better understanding of process</li> </ul>
3. Governance Improve responsibility within the Health Board for the wider management of anticoagulation	<ul style="list-style-type: none"> <li>• Health Board will have improved oversight and assurance of the management of oral anticoagulation</li> <li>• Less adverse events as a result of non adherence to process as audit loop being completed</li> <li>• Efficiencies resulting from improved understanding of process</li> <li>• Improve patient experience</li> </ul>
4.Audit Improvements to audit programme for the management of anticoagulation and anticoagulation services	<ul style="list-style-type: none"> <li>• Ability to benchmark services</li> <li>• Shared learning between services</li> <li>• Improved assurances for Health Board</li> <li>• Reduction in risk and adverse events</li> </ul>

SECTION B within recently allocated new resource recommendation benefits

Recommendation 5.

Based audit results and feedback received from stakeholders, patients and GPs, the project team has identified gaps in provision across all services and all localities and the recommendations in section A seek to address some of these. Section B focuses on the current Singleton/ Morryston Service Model. Audit results and feedback indicate



that this service would benefit from a full service redesign to implement best practice and improve experience for patients. The Project Team proposes that findings from the AF PBMA be applied when investing the new resource.

Model 3B is a revised version of the current Clydach model. The Clydach model involved POCT, on a network basis, where patients are reviewed face to face after each INR test by non-medical prescriber who also provide the warfarin prescriptions. The main revision to the model is to provide and to also implement a slightly different clinic set up which would see improved patient flow and increased throughput of patients using the same resource (e.g. introducing a fast track system, whereby patients who are in range do not have a face to face appointment every time or having 2 people dosing at any one time to reduce the bottle necks associated with one person dosing).

Consideration could also be given to utilising a number of non-medical prescribers on a rotation with staff unable to prescribe still able to monitor and dose patients. This should increase efficiency and could result in more capacity for the same resource currently in place in the Clydach model.

It is proposed that this model should be applied to patients currently receiving the 'Swansea' secondary care service (which is the service currently deemed least compliant with best practice/priorities of stakeholder group); it would see the following changes, benefits and risks:

Benefits of the model	Risks of the model
Point of care testing	Would require a number of non-medical prescribers (could consider one/two per network rather than all)
Face to face appointments	
No separation of monitoring and prescribing	Need to consider availability of appropriate facilities; may be more difficult if needing to run concurrent clinics
Community/cluster based	

Given the volume of patients currently utilising the Swansea service, as well as the geographical area, consideration should be given to the delivery of clinics over multiple sites; further engagement work should be undertaken to identify appropriate locations.

The cost of delivering this model has been provisionally quantified as £538,000 – the

funding made available by Welsh Government is £544,000.

The cost of the current service in Swansea has been quantified as £495,000. The current baseline will need to be reviewed to determine:

- Elements of the current service will be directly transferable to the new model.
- Those costs (for instance postage) that can be released as savings.
- Residual resources that are either still required or can be redirected to support other priorities.

It is important to recognise that elements of the resource to support AF anticoagulation are required to support anticoagulation for other reasons and probably the haematology department generally. Some examples of support requirements:

- Nursing study days/induction
- Medical students training
- Student Nurse education
- Junior doctor training
- Ward based support and training
- Ward audits
- GLORIA AF global study
- Producing Information for the wards – Morriston, Singleton and Gorseinon

SECTION C requires additional resource recommendation benefits

Recommendation 6.

Procurement of a Health Board wide decision support tool to support the management of patients on warfarin (e.g. extension of DAWN software currently used in Swansea)

This would enable;

- Targeting out of range patients for more intensive review and consideration of alternative treatment/stopping treatment
- The availability of audit data which would be used for benchmarking/service improvement
- The ability to provide data to other healthcare professionals; regular reporting to GP practices on their patients
- DAWN software is in place in Swansea currently and it would be possible to extend

this licence for other areas: Indicative costs for DAWN software; £1,800 per additional 500 patients, £1,200 per additional user licence, 20% maintenance costs). Consideration should be given to other suitable software.

- Opportunities for further integration with other Health Board/GP systems to further improve communication/patient management/patient safety

Recommendation 7.

Identification, treatment and management of AF be further improved to reduce the health impact and financial burden by reducing strokes.

Recommendation	Benefits
Redesign Swansea anticoagulation service to provide community based POCT service (similar to current Clydach model)	Point of care testing (evidence suggests superior to laboratory testing and also better patient experience)
	Face to face appointments (intense counselling improves time in range)
	No separation of monitoring and prescribing reduces risk of error, reduces separation
	Community/cluster based (patient centred)
Health Board wide decision support software (e.g DAWN, INR*,RAT)	<ul style="list-style-type: none"> <li>• Improved assurances for the Health Board</li> <li>• Improve access to information</li> <li>• Shared learning</li> <li>• Ability to benchmark services</li> </ul>

After consideration of the proposals the UCCB decided to take the proposed option to optimise nvAF related stroke prevention within existing resource and also take the findings overall into a large scale review of the whole stroke pathway, recognising “upstream” efficiency savings realised by stroke prevention, but felt that the findings of the PBMA more valuable if integrated into a larger initiative related to the stroke

pathway (albeit that this would delay implementation of the recommendations of the PBMA).

### 3.4 DISCUSSION

Reflecting on the process and informing an 'ABMU specific' PBMA was another objective of the service. The experience of the process was invaluable and informs the framework proposed in Chapter 5. The interviews undertaken by the author and informal interactions and experience of the process noted by the author informs this framework and the discussion in this chapter. The main learning from the process are summarised below.

#### 3.4.1 RESOURCE RE ALLOCATION

The scope of the PBMA was to reallocate resources, within budget, from low value to high value within the anticoagulation services to ensure that ABMUHB met the NICE CG 180 (86) standards. The project was one of the pilots for testing and modifying PBMA to be a framework for resource reallocation for ABMUHB to adopt for the future.

The PBMA exercise was initiated in a climate of constraint and an appreciation that the majority of the anticoagulation services were not meeting best practice standards. Recommendations were made to the UCCB with this in mind, but it was clear that the recommendations made within budget were not going to raise standards to the extent needed, although the 'tweaks' that could be made with budgets could make a difference. However as the PBMA project came to a closed it transpired that not only had the additional £500,000 been allocated by Welsh Government but in an astonishing by pass of the PBMA project the money had been allocated without consultation with the PBMA project team and decisions taken on how to allocated the resource (more staff rather than the options recommended by the project team). The project team asked for the spending to be halted and the UCCB review the recommendations of the PBMA not only for 'within resource' options but also recommendations as to optimise the spending of the £500,000.

In terms of providing the UCCB with recommendations the project team were able to make recommendations for change that could be accommodated within existing budget. However whilst these changes had value and impact the stroke rate, they are not the substantial changes that the team identified the anticoagulation service needs to accomplish the goal of meeting the standards of the NICE guideline CG 180. The one off £500,000 budget supplement from the Welsh Government allowed the project team

make recommendations that exceed the existing budget but are within expanded budget.

However as things turned out, poor communications between the persons responsible for administration of the extra budget and the project team and commissioning lead, meant that the opportunity to spend this money in line with the PBMA principles had been lost. Clearly any commitment to PBMA in the future means that this situation has to be avoided.

#### *TIME AND RESOURCES*

The PBMA project team did not have 'protected time' to drive the project forward. The health economist (author) was available to the team to support the process with literature review, evidence collection and analysis as there was a vested interest in seeing the project through to completion. The time of the group decision support expert and the use of the TurningPoint software and handsets were also provided by Swansea University *pro bono*. However the time I provided (of the order of 20% FTE) as a health economist was effectively provided *pro bono*. ABMUHB does not have a health economist nor is there an official arrangement with the University to support the health board with health economics expertise; which for future projects is a considerable concern.

Group decision support expertise enabled the prioritising and voting to be a collegiate and positive process and whilst the technology could be purchased by ABMUHB, outside of the University the decision support expertise is not available.

The commissioning lead, administrator and finance team member did have a remit from the health board to support and complete the pilot but the service based staff and GP did not have protected time and whilst the commitment to the project was evident the time from the 'day job' was clearly not available and all the work was being squeezed in. The GP took annual leave to be able to participate. The project team had no budget to facilitate, buy out their time (pertinent for a GP) or expedite the process. This clearly is not sustainable for an effective process. Indeed not giving a high profile pilot project a budget is tantamount to setting it up for failure.

#### *SCOPE*

With hindsight the project team agreed that the scope was too narrow and, as it turned out, releasing resources from within the services to reduce the low value care and increase high value were not enough to achieve the needs of the service. Shifting resources from acute care, very much under pressure, into the anticoagulation services

was something of a theoretical construct with releasable resource restricted in the main to prescriptions. The scope was necessarily and rightly restricted to people with AF, however, there were issues with this especially in the Swansea locality as the services is partially provided in the tertiary hospitals which have to support people with other clinical reasons for anticoagulation and also has to provide for inpatient services. Disinvesting from these services, however compelling a reason for people with AF and even if to reinvest elsewhere in the patient pathway, had the potential to impact these other patients' services as the service requires a critical mass to be maintained within the secondary care service.

#### *PACE*

The project team were able to drive the PBMA process forward to completion but found it hard to move at the pace originally envisaged. However the team managed to make their target meetings and prepare the necessary documents for the commissioning board meetings, albeit on a schedule later than envisaged. The process, from start to finish took 12 months rather than the ambitious six month schedule envisaged at the start of the project. A suggestion from one interviewee was that the stakeholder meetings should be booked right at the beginning of the PBMA process and locked in people's diaries as fixing up meetings to suit the majority slowed the pace down. Project team meetings were more regular but on the same basis could be planned ahead on a bi weekly basis.

#### *STAKEHOLDERS*

As the PBMA moved forward calling the stakeholder group together for feedback and engagement proved increasingly challenging as pressures of work and inevitable dwindling interest as time went by. As with the project team the stakeholders did not have 'protected time' to dedicate to the PBMA meetings so only the most committed to the process and the outcome stayed through the project to the end. Multiple stakeholders included primary care independent contractors. The late Dr Sean Young, representing the GP community as chair of the Local Medical Committee and ABMU Primary Care lead was a valued participant and the author wants to make a special mention that he attended meetings whilst on sick leave and his insights at the meeting, in interview and his overall contribution to the PBMA were all highly valued. Had Dr Young not been on sick leave we would not have been able to get such a valuable contribution.

It should be noted that attendance at stakeholder meetings was limited and whilst every effort was made to engage with stakeholders who were unable to attend in

person, decisions made by this group may not be reflective of all stakeholders and further consultation may be needed for the stroke pathway review.

The patient survey was useful and highlighted the things that mattered to patients on a very practical level. However whilst the project team felt that the results from the survey were positive overall, it was probably the case that very few patients had experienced alternative services and so the contrasts between Clydach patients who were getting 'gold standard' treatment and people who had experience of other services would not know that things could be different or better, and they may not be aware of the risks that were prevalent throughout the system. Had this knowledge been available to them, then we may have received different responses.

#### *DATA*

ABMUHB is fortunate in having skilled staff with excellent understanding of the in house finance and activity data - strength of the PBMA. We also had the NICE costing model to assist in estimating impact of changes in anticoagulation services but it is a crude tool; whilst evidence based and gives plausible estimates it lacks the ability to utilise the detailed data available through ABMU systems and do more detailed and situation specific analyses. The results of the analyses had to be treated with caution and be just be taken as indications of the direction and potential magnitude of change for delivering reduction in stroke rates through anticoagulation for people with nvAF, and the impact of not changing the present situation, rather than evidence of savings and reinvestment opportunities that can be directly realised . With hindsight and had budget been available an economic model should and could have been started from scratch using the same data we had to better effect. The point at which this became evident, after frustrating lack of communication from NICE and ultimately lack of willingness to make a non-password protected model or model password available meant that there was no time to do that.

Sophisticated electronic patient data is wide ranging and is theoretically available in Wales. However none of the data were available to the PBMA. Primary care data - entered into Audit+ in GP surgeries to enable reporting for various service requirements was not available to the PBMA. In effect the data belongs to the practices and the project team would have to make specific negotiations and arrangements via NHS Wales informatics and specific practices to use the data.

Wales has a tremendous resource in the Secure Anonymised Information Linkage (SAIL) data bank (<http://www.saildatabank.com/>) which hosts all of the ABMUHB

primary and secondary care data. This at the time of the PBMA SAIL was being exploited by a company called WePredict (<http://www.wepredict.co.uk/>) who use sophisticated multivariate analytical techniques and interactive visual outputs to inform health board projects. Frustratingly the SAIL database with its data governance and charges for use was not an option to inform the PBMA with the data and insights that would have been most useful. WePredict were using SAIL and ABMU data sets and delivering analyses for an ABMUHB diabetes project that would also have informed our PBMA but again the governance around the data use and lack of budget to set up a separate set of informative analyses for the PBMA made that resource unavailable to the PBMA.

Having data resources that were clearly useful and unavailable to the project was frustrating and highlighted the need for ABMUHB to have in house access to these data resources and 'dashboards' for ABMUHB analytical staff to work efficiently without obstacle to deliver best quality data to a PBMA. Towards the end of the PBMA ABMUHB appointed a senior staff member to lead the development of a health intelligence function and she had good understanding of the issues the project team experienced and knew how to take the issues forward and find solutions.

#### *MCDA AND DECISION MAKING*

Using the C4B event gave the team a great opportunity to get the list of criteria prioritised for both PBMA pilots. Using group decision support methods supported by an expert in the field and the TurningPoint™ enabled the priorities and preferences to be honed from a more general list of criteria that applied to any service down to a series of very specific preferences based on experience and knowledge to shape recommendations. However the use of MCDA fell at the final hurdle as the final decision on recommendations was taken by UCCB in the board meeting in the normal way. However it was clear in the proposal documentation that the process had been shaped by a series of discussions and recommendations prioritised and criteria that were evidence based and balanced by stakeholder input. Adopting the Portsmouth score card approach at the end of the PBMA process as initially envisaged, before making recommendations to the UCCB might have been appropriate, but for the fact that there was so little that could be done to reallocate resources within the existing budget that there was no benefit in doing this.

#### *RESOURCE REALLOCATION AND DISINVESTMENT*

Unfortunately this PBMA did not accomplish explicit resource reallocation and a major level at the point at which this chapter was prepared. The reasons are understandable



with all the benefits of hindsight. The scope, on reflection, was too narrow, the service underfunded by a considerable amount so very limited opportunities existed to disinvest in any substantial element of the service to release funds, and releasing and redistributing monies from 'bed days saved' in acute care from the strokes avoided, was not easily accomplished for many reasons, but not least because the acute services are so over stretched that the bed days released would be required for other acute conditions. The PBMA for perfectly sensible and practical reasons - not least lack of access to primary care data - could not evaluate the impact of service revision and potential disinvestment and resource reallocation in primary care.

#### *WAS THE PBMA A SUCCESS?*

The best way of assessing this PBMA in terms of its success as a process for enabling resource reallocation and prioritisation overall is to check back on Tsourapis and Frew's literature review of successful PBMA (59).

- *PBMA was successful in 52% of cases when success was defined in terms of the participants gaining a better understanding of the area under interest; this criterion was met – the scoping, data analysis and fact finding was successful and an insightful.*
- *In 65% of cases when success was defined as 'implementation of all or some of the advisory panel's recommendations'; this criterion was met as the UCCB implemented the recommendation to fold the PBMA findings into a review of the stroke pathway.*
- *In 48% of the studies when success was defined in terms of disinvesting or resource reallocation; uncertain - at the present time it is not known whether the disinvestment and resource reallocation recommended was implemented (due to the stroke path way review is still ongoing).*
- *In 22% when success was defined in terms of adopting the framework for future use". This criterion was met as the PBMA framework is being adopted for future use.*

In their paper Tsourapis and Frew also noted factors associated with success, which were:

- Availability of data;
- High level support;
- Size and composition of advisory panel (include clinicians and not too large);
- Implementation friendly' local structure.

The experience of this pilot endorses this message – all of these factors were important and influential. Without high level support from the chief executive office is it doubtful that the PBMA would have got going and/or have competed.

Robinson and colleagues (62), in a paper presenting the issues facing the English NHS – at the time when CCGs, began acting as commissioning bodies - made a clear representation of the issues and challenges which are also are very relevant for Wales. The authors suggest that; *“Substitution and disinvestment (of less costly services) present considerable challenges (62);*

- *The need to establish agreement over the criteria by which decisions will be taken;*
- *The need to develop a thorough understanding of the full range of current services and areas of investment and their performance against these criteria;*
- *The need to manage and negotiate the political hazards and fall out associated with the removal/withdrawal of services;*
- *The difficulty of implementing substitution and disinvestment in complex systems. The challenges posed by reduced overall budgets also have implications for national bodies such as NICE, which will need to devote greater attention to the disinvestment evidence base that has hitherto been the case”. (62)p145*

These points are pertinent to the experience of the nvAF PBMA. The agreement of criteria was relatively easy because the values of ABMUHB and commissioning criteria were clear and transparent. The second was accomplished successfully apart from the activity in primary care to add to what the GPs told us. Political hazards and fall out would be related to decommissioning/reducing secondary care anticoagulation services in secondary care in Swansea, even though these were the least well performing services when audit data were reviewed. Most particularly the last point – the anticoagulation services are complex in of themselves but in the context of unplanned care and the influence of anticoagulation on stroke rates was in fact a very complex system.

### 3.5 CONCLUSIONS

The PBMA pilot for anticoagulation in nvAF described here, was successful in terms of a number of ‘success criteria’ and along with the MSK pilot has informed the development of a PBMA framework for ABMUHB, provided in Chapter five. This is to be a living process, learning each time it is applied and will be adopted as ‘a way of working’ and refined - based on the learning from the pilots – and further tested in a PBMA exercise in the diabetes area.

CHAPTER 4: PROGRAMME BUDGETING  
MARGINAL ANALYSIS IN ABERTAWE BRO  
MORGANNWG UNIVERSITY HEALTH  
BOARD: A PILOT IN MUSCULOSKELETAL  
SERVICES

## 4 PROGRAMME BUDGETING MARGINAL ANALYSIS IN ABERTAWE BRO MORGANNWG UNIVERSITY HEALTH BOARD: A PILOT IN MUSCULOSKELETAL SERVICES

### 4.1 CHAPTER SUMMARY

This chapter describes the pilot programme budgeting marginal analysis (PBMA) that I developed and was undertaken in the Abertawe Bro Morgannwg University Health Board (ABMUHB) for the musculoskeletal services (MSK).

This chapter and the next chapter move the methods that we used for prioritisation in chapter two forward and allowed me to consider the relative priority of the interventions in the context of a programme of ABMUHB services and consider opportunity cost and the margin - the economic concepts underpinning PBMA. Two simple economic concepts - opportunity cost and marginal analysis - are at the heart of the PBMA framework which provides a structure which incorporates the values and goals of the HB and yet is a robust evidence based process which provides an explicit and transparent framework.

The chapter also describes the approach taken with respect to the identification, adaptation and implementation of the PBMA. It identifies the activities that I undertook to inform what might be the most effective prioritisation and resource reallocation processes for ABMUHB. It describes the initial concept discussions and scoping to the final outcomes for prioritisation, disinvestment and resource reallocation specifically for the MSK programme and Planned Care Commissioning Board (PCCB) in ABMUHB.

Similarly to the prioritisation project described in Chapters two and three I undertook interviews through the course of the development and delivery of the PBMA and noted my observations and ideas.

This PBMA pilot differs from the pilot PBMA described in Chapter three as the opportunity for resource reallocation and disinvestment was identified and these were agreed and implementation ratified and moved to action.

### 4.2 INTRODUCTION

ABMUHB are reintroducing commissioning by establishing six commissioning boards. The purpose of these boards is to deliver improved quality, experience and outcomes

for the population based on need, evidence and prioritisation of resource. As part of the process of establishing commissioning the ABMUHB senior management felt that the MSK services deserved scrutiny, were candidates for change and knew the management team for MSK desired change and wanted to improve the services. However the health board (HB) had no further funding to allocate to MSK. Thus I discussed undertaking a prioritisation/resource reallocation exercise with the ABMUHB senior management and commissioning development lead and set up pilot projects. The main outcome of our discussion was that there was potential to make some disinvestment of a low value/no value element of MSK services and make savings and/or reinvestment into high value aspects of the services. PBMA methods appeared to be solution to the aims of the ABMUHB stakeholders and was agreed to be the appropriate approach to achieving the prioritisation and resource reallocation aims of the HB and the MSK services.

I also proposed to ABMUHB commissioning lead that I would use the pilot projects to enable a 'bespoke' resource reallocation method based on the process and outcomes of the PBMA pilots, to be developed for wider use within the HB in the commissioning process, if the two pilots were successful. My aim was to adapt PBMA methods to be usable within the ABMUHB setting and utilise appropriate aspects of participatory action research (PAR) methods as suggested by Patten, Mitton and colleagues (6, 69) (described in chapter 1 section 1.10) to enable project team and stakeholders act as participants in the process of the PBMA pilot and enable me to develop the final framework. I thus implemented the advice of Mitton and colleagues in their paper advocating the use of interdisciplinary methods when implementing PBMA. (6)

*"Recent studies have also focussed on developing prioritisation processes iteratively and interactively (with decision-makers, stakeholders and researchers) and refining them by repeated exercises, **adapting elements of PBMA to suit the local context. Reflections on the change should be elicited prior to refining the process. In-depth one-to-one inter-views/surveys and focus groups can be used to review and verify the changes decided upon, and gather reflections and suggestions for refinement of the new process.** Furthermore, analysis of observational data collected throughout the implementation of the process can be used to **examine specific challenges encountered during framework implementation and the prospects for its longer term sustainability in the organization.**"(6)*

My research concentrated on the items in bold in the above quote from Mitton and colleagues recommendations. Alongside the projects I undertook interviews with project participants and collected my experiences and observations by keeping notes as the projects progressed based on participative action research methods as advocated by Peacock and colleagues. (6, 7)

Having reviewed the literature for approaches to topic selection I devised a topic selection methodology combining these to enable the commissioning development lead in ABMUHB to scan the services covered by the commissioning boards and select potential PBMA candidates. The criteria for the identification and selection process for this PBMA are described in chapter x section XX.

#### 4.3 MUSCULOSKELETAL SERVICES INTRODUCTION

##### 4.3.1 *OSTEOARTHRITIS*

Osteoarthritis is the most common type of arthritis. Joint wear and tear can result in damage to the joint and the symptoms of osteoarthritis can develop. These symptoms include pain, stiffness and problems moving the joint. Sometimes the joint swells and becomes inflamed. According to Arthritis Research UK symptoms can vary greatly from person to person or between affected joints. (104) Pain and other symptoms can often flare up and settle back down again. The level of pain does not always reflect the condition of the joint. Osteoarthritis is most common in the hips, knees, hands and feet, but other joints can also be affected. It is not unusual to have osteoarthritis in more than one joint. Some people also experience swelling, tenderness and a grating or crackling sound when moving the affected joints. The severity of osteoarthritis symptoms can vary greatly from person to person, and between different affected joints. For some people, the symptoms can be mild and may come and go. Other people can experience more continuous and severe problems which make it difficult to carry out everyday activities.

Arthritis Research UK (104) suggests that factors associated with having osteoarthritis are:

- age –risk of developing the condition increases with age;
- family history – osteoarthritis may run in families, although studies haven't identified a single gene responsible;
- obesity – being obese puts excess strain on joints, particularly those that bear weight, such as knees and hips.

There are drug and non-drug treatments for osteoarthritis and ultimately some people are offered joint replacement surgery to alleviate symptoms and restore mobility.

#### 4.3.2 NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE GUIDELINES

In February 2014 the National Institute for Health and Care Excellence (NICE) published Clinical Guideline CG177 (CG177) on the care and management of arthritis (105), including osteoarthritis. The guideline states six key priorities for implementation. These are:

1. Diagnosis
2. Holistic approach to osteoarthritis assessment and management
3. Education and self-management
4. Non-pharmacological management
5. Referral for consideration of joint surgery
6. Follow-up and review

The underlying ethos and advice in the guidelines are very much in line with the principles of prudent healthcare and also highlight area where a PBMA may be usefully deployed to promote a shift from low value to high value care in line with the NICE guideline on joint replacement surgery

Box 4:2 taken from NICE CG177(105) summarises the advice on exercise and losing weight plus joint replacement surgery.

Box 4:1 summarises the NICE advice on exercise, weight loss and joint pain.

**Box 4:1 NICE CG177 Summary Advice on Exercise and Weight Loss (105)**

### Exercise

Exercise has been shown to help people with osteoarthritis – this includes helping to reduce pain. Your GP should explain more about this to you. Exercise should include muscle strengthening as well as aerobic exercise (that is, moderate exercise that increases your heart rate – for example, swimming, cycling or brisk walking). The type of exercise that is best for you will depend on things like any other health problems you have, how much pain you are in, and what is available in your local area.

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### Losing weight

Being overweight can make your joint pain worse. If you are overweight or obese, you should be given advice and support to lose weight.



#### Box 4:2 NICE Summary Advice on Joint Replacement(105)

Most people with osteoarthritis do not need joint surgery. But if you have tried a number of treatments and you still have a lot of joint pain and stiffness, then you and your healthcare professional may decide that referral to a surgeon is the best option for you.

The most common type of surgery is joint replacement surgery, where a damaged joint is replaced by an artificial one – for example, a knee or hip replacement.

You and your healthcare professional should discuss possible referral for joint surgery before your symptoms and pain become so bad that you find it hard to carry out your day-to-day activities.

Surgery may be an option regardless of your age, whether you are male or female, whether or not you are overweight or smoke, or if you have other health problems as well as osteoarthritis.

If you are thinking about having surgery, your GP or another healthcare professional should give you information about the following:

- the benefits and risks of surgery, and what might happen if you decide not to have surgery
- how long recovery is likely to take, and what you will need to do to help your recovery (for example, exercising the joint)
- if you have joint replacement surgery, the ways in which an artificial joint might affect you
- how care is organised in your local area, including where surgery will take place and support after surgery.

You should not be referred for a procedure in which your knee joint is washed out (known as 'lavage and debridement'), unless you have had a problem with your knee 'locking' on a number of occasions.

#### 4.3.3 DISINVESTMENT AND NICE 'DO NOT DO' RECOMMENDATIONS

The purpose of the PBMA pilots were, given fixed budgets and a need to improve and develop services, to identify interventions of little or no value and reduce or disinvest in these and utilise the resources freed to commission more of the high value services or invest in new services that would deliver high value benefits.

Pearson and Littlejohns define disinvestment as “...an explicit process of taking resources from one service in order to use them for other purposes that are believed to be of better value. Therefore disinvestment is closely linked to efforts to set priorities and allocate resources wisely. But because disinvestment focuses on removing or limiting current services, rather than just allocating new resources, it represents a particularly useful tool to consider in a flat or reduced overall health care spending“. (9)p160.

Elshaug and colleagues use a more 'brutal' definition (10) ;

“...disinvestment ...relates to the processes of (partially or completely) withdrawing health resources from any existing health care practices, procedures, technologies or pharmaceuticals that are deemed to deliver little or no health gain for their cost, and are thus not efficient health resource allocations”.p2(10)

I use this latter definition of investment as it suggests that, unlike Pearson and Littlejohn's definition, disinvestment can also mean that resources may not be re-invested; a current or future budget may be reduced in comparison to a prior budget, and thus resources not available to be re-invested.

Australia has led the charge in engaging in explicit disinvestment initiatives; Elshaug and colleagues introduce these in a paper outlining the challenges to disinvestment in the Australian policy processes (10). Clinical guideline development and implementation in Australia – as elsewhere – go some way towards eliminating ineffective interventions, interventions that deliver little value and obsolete interventions but they are not the solution to implementing a programme of disinvestment that will drive resource release and more effective and economic use of health care resources.

In setting out the challenges to disinvestment in Australian policy processes Elshaug et al (10) identify the contributing elements (below). There is no reason to believe these are not applicable and generalisable to Wales.

1. Lack of dedicated resources by key stakeholders to build and support disinvestment policy mechanisms;
2. Lack of reliable administrative mechanisms to identify and prioritise technologies and/or practices with relative uncertainty as to their clinical or cost effectiveness;
3. Political, clinical and social challenges to removing and established technology (including challenges to limiting coverage to specific patients, institutions or providers);
4. Lack of published studies that clearly demonstrate that existing technologies/practices provide little or no benefit;
5. Inadequate resources to support a research agenda to advance disinvestment methods.(10).

In 2009 Elshaug and colleagues published a paper 'for debate' suggesting criteria for determining candidate interventions or practices to disinvest from (21). These are summarised below;

- Geographic or provider variation;
- Temporal variations;
- Technology developments;

- Lack of evidence of effectiveness;
- Disease burden (low or high);
- Variation in care;
- Futility;
- New Evidence;
- Public interest;
- Nomination;
- Consultation;
- Leakage;
- Conflict with guidelines.

In the UK, we have not been so brave, despite increasing pressures on health care budgets. The establishment, in England and Wales, of NICE in 1999 may not have been seen as an explicit attempt to institute rationing, but could be said to have an efficiency agenda, given NICE's stated aims:

*"The National Institute for Health and Clinical Excellence (NICE) provides guidance, sets quality standards and manages a national database to improve people's health and prevent and treat ill health"*

*"NICE makes recommendations to the NHS, local authorities and other organisations in the public, private, voluntary and community sectors on:*

- *How to improve people's health and prevent illness and disease.*
- *Using NICE guidance may ....help cut costs while at the same time maintaining and even improving services". (12)*

NICE technology appraisal and guideline development processes are central to NICE's work. However the methods used by NICE do not consider the health gains for forgone by reallocating resources from existing programmes to fund new programmes, do not recognise the constraints of the existing NHS budget explicitly (13) and no explicit recommendations are made to make disinvestments in other treatments to fund the new, recommended intervention. However a valuable nod in that direction is via the NICE 'Do Not Do' programme (106). As part of the guideline development process NICE are able to identify interventions that do not provide benefit or may even do harm for patients. Associated with each guideline are evidence based 'do not do' statements. One of these, the last bullet in

Box 4:2 is:

*Do not refer for arthroscopic lavage and debridement as part of treatment for osteoarthritis, unless the person has knee osteoarthritis with a clear history of mechanical locking (as opposed to morning joint stiffness, 'giving way' or X-ray evidence of loose bodies).(14)*

#### 4.3.4 NATIONAL JOINT REGISTRY AND GET IT RIGHT FIRST TIME

At a UK level an important audit is undertaken by the National Joint Registry (NJR) for England, Wales, Northern Ireland and the Isle of Man.(107) The registry collects information on joint replacement surgery and monitors the performance of joint replacement implants. It was set up in 2002 by the Department of Health and Welsh Government, Northern Ireland joined in 2013 and the Isle of Man in July 2015. A wide range of implants can be used in the joint replacement operations. The registry helps to monitor the performance of these implants and the effectiveness of different types of surgery, improving clinical standards and benefiting patients, clinicians and the orthopaedic sector as a whole. The NJR currently collects data on all hip, knee, ankle, elbow and shoulder joint replacements across the NHS and independent healthcare sector. Most pertinent to this proposal is the registry data collection on hip and knee replacement. The NJR goals are to:

- Monitor in real time the outcomes achieved by brand of prosthesis, hospital and surgeon, and highlight where these fall below an expected performance in order to allow prompt investigation and to support follow-up action;
- Inform patients, clinicians, providers and commissioners of healthcare, regulators and implant suppliers of the outcomes achieved in joint replacement surgery;
- Evidence variations in outcome achieved across surgical practice in order to inform best practice;
- Enhance patient awareness of joint replacement outcomes to better inform patient choice and patients' quality of experience through engagement with patients and patient organisations;
- Support evidence-based purchasing of joint replacement implants for healthcare providers to support quality and cost effectiveness.
- Support suppliers in the routine post-market surveillance of implants and provide information to clinicians, patients, hospital management and the regulatory authorities.

Another UK national audit has been led the British Orthopaedic Association (BOA), the body that represents the professional interests of orthopaedic surgeons across the UK,

has published a report reviewing current practices and outcomes of NHS hospitals providing orthopaedic surgery in England, to identify and quantify variation in clinical outcomes, processes, patient experience, patient pathways, network arrangements, financial impacts and waiting times. The report 'Getting It Right First Time (GIRFT)' (107, 108) reports on the current situation in elective orthopaedics in England and suggests ways in which extensive savings and improvements could be made in elective orthopaedics by hospitals to ensure continuing high quality care and access for patients within the financial constraints of the NHS. NHS England funded the GIRFT pilot as a national professional pilot across England. The project was hosted on behalf of the BOA, at the Royal National Orthopaedic Hospital (RNOH) in Stanmore. The GIRFT team, led by Tim Briggs during his year as BOA President, developed a programme for reviewing the total pathway of adult elective orthopaedics and spinal activity and considering all efficiencies including clinically unsupported variations of practice in terms of device and procedure selection, price benchmarking, infection rates, quality outcomes and litigation costs. Tim Briggs visited the ABMUHB orthopaedic team in 2015 to discuss GIRFT, learnings from which, after his visit were taken on board.

#### 4.4 WELSH GOVERNMENT CONTEXT

In 2015 the Welsh Government initiated a national planned care programme in order to support health boards improve patient experience by sharing good practice and creating sustainable pathways of care. Planned care services refer to health care such as surgery which is scheduled in advance. Scheduled or planned care includes booking outpatient consultations and treatments as well as diagnostic tests (109). The goals of the programme are stated to be (109):

- reduction in referral to treatment waiting times through actively managing capacity and demand;
- reduction in the number of patient to consultant visits by supporting GPs to manage people in the community;
- reduction in the variability of practices across NHS services in Wales by identifying and sharing areas of good practice, captured in the programme implementation plans.

Within the planned care programme there are four clinically led specialty boards to share good practice and identify variation across services of which one is Orthopaedics. In the plan, published in 2015 a number of action points were developed: (109, 110)

- **Action 1** Health boards will put in place systems to collecting patient reported outcomes measures (PROMS) for major joint surgery.
- **Action 2** Health boards will put in place systems to measure and report “capacity and demand” according to an agreed set of national (all Wales) parameters for each pathway.
- **Action 3** National Orthopaedics Board to review and where necessary expand the list of do not do’s to health boards and review responses from Medical Director or Chief Executive Officer.
- **Action 4** Health boards will undertake a waiting list “validation” to remove patients on the waiting list who don’t require an outpatient appointment or who don’t need treatment.
- **Action 5** Health boards will measure and report the number of follow up appointments per patient after hip and knee replacement.
- **Action 6** Health boards will establish community based services for patients suffering with “non specific” lower back pain.
- **Action 7** Health boards will measure and report the numbers of carpal tunnel procedures on a rolling 6 monthly basis.
- **Action 8** Health boards to put in place systems to provide a 4 week out patient service for patients with knee trauma and significant immobility.
- **Action 9** National Orthopaedics Board to review urgent categories in elective Orthopaedics to determine “exceptionality” to the urgent category policy.
- **Action 10** Each health board will establish an interface collaborative (OIC) in accordance with national terms of reference with a view to monitoring patient flow and delivery of the National Orthopaedics Implementation Plan.
- **Action 11** Health boards will establish “structures” in community settings to activate patients and provide decision support mechanisms.
- **Action 12** Health boards will establish measures of patient activation and decision support scores.
- **Action 13** Health boards will put in place systems to record, report and manage the knee quality bundle.
- **Action 14** Health boards will establish mechanisms to estimate cost of knee replacement pathway according to a standard national methodology.
- **Action 15** The planned care programme team will work with health boards to consider whether central procurement for certain items such as evidence based prostheses.

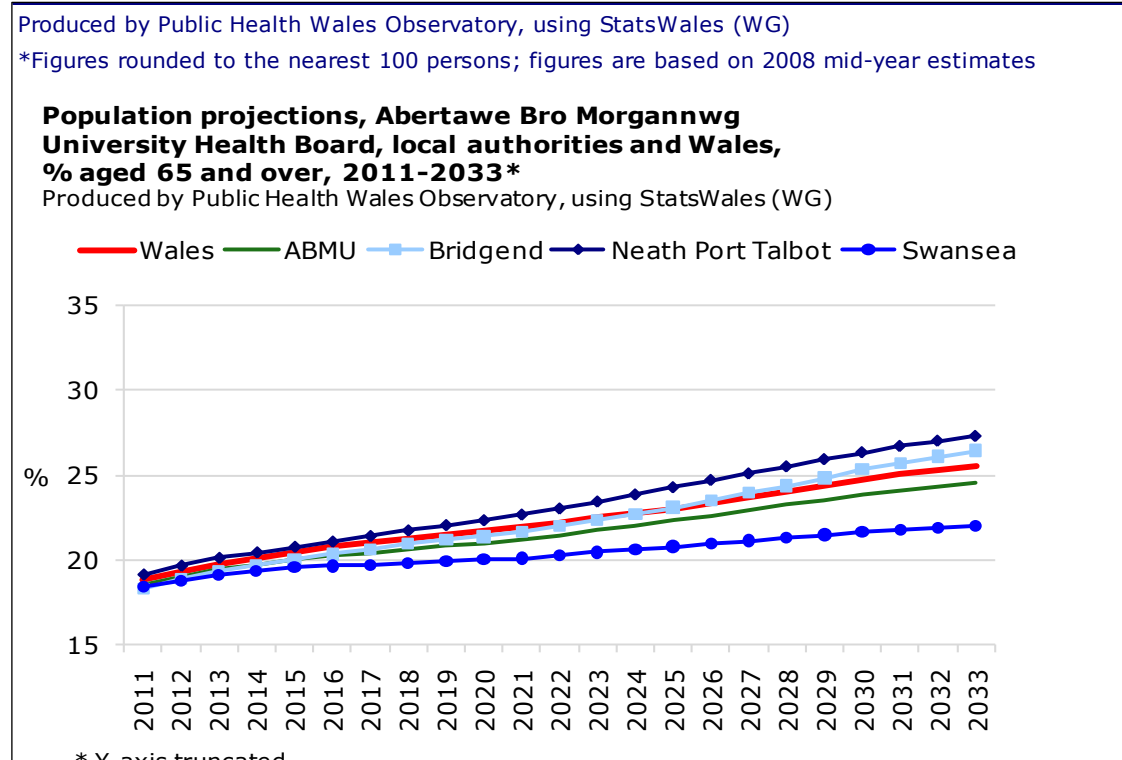
#### 4.5 ABMUHB CONTEXT

ABMUHB resident population was estimated at 520,710 in the 2013 population estimates, around 17% of the total population in Wales. (100)The population is projected to increase by 42,350 people (8.1%) between 2013 and 2036 (Figure 4:1). The biggest increases are projected in the older age bands with the over 85 population predicted to more than double by 2036 (see Figure 4:2). (100) An ageing population is likely to result in a significant increase in the demand for health and social care services. An increasing overall population may mean an increase in the demand and need for health care, putting pressure on already limited resources.

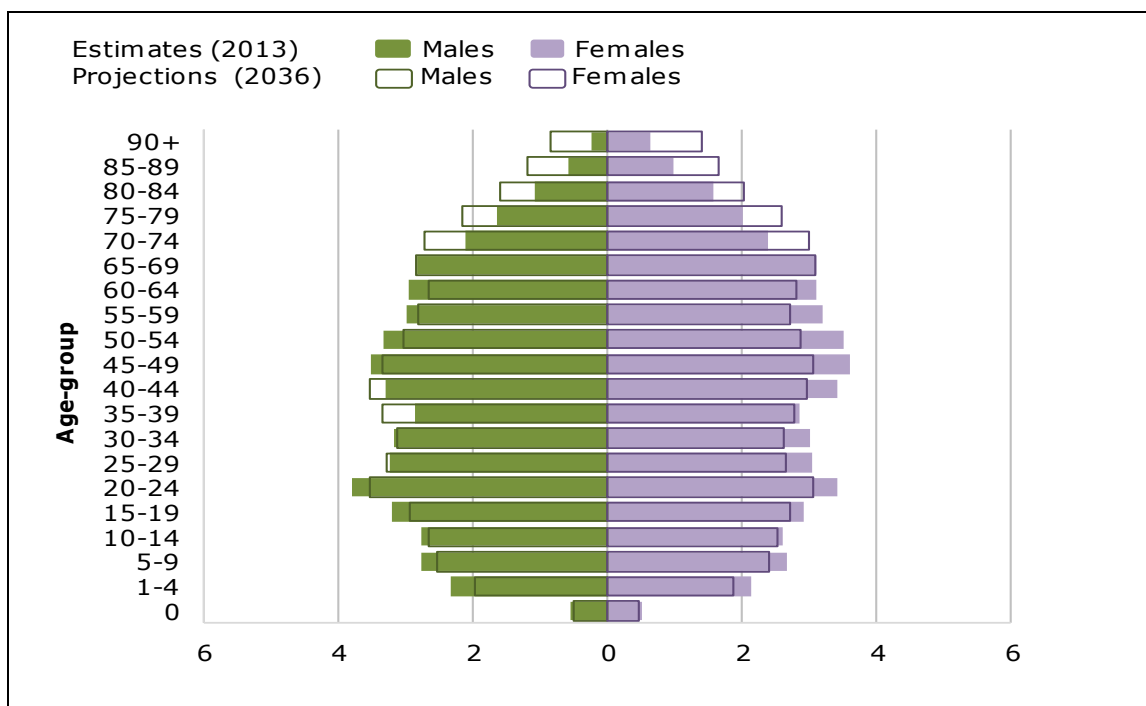
ABMUHB Strategic Needs Assessment produced in 2015 identified the key areas where ABMUHB needed to prioritise action, in order to improve health for the population throughout. (111) The needs assessment linked with the orthopaedic work streams are:

- To reduce health inequalities
- To tackle obesity – a major risk factor in contribution to muscular skeletal disorders

**Figure 4:1 ABMUHB population projections 2011 to 2033(100)**



**Figure 4:2 Percentage of ABM University Health Board population by age-group, estimates (2013) and projections (2036) (100)**



Source: Public Health Wales Observatory Data (112)

ABMUHB has a smaller black and minority ethnic (BME) population of 3.9% than that across Wales of 4.3%. The majority of the BME population reside in Swansea (6.0%) and lowest in Neath Port Talbot (1.9%), with Bridgend's BME population at 2.2%.(100)

Health inequalities have increased over the last ten years with the life expectancy gap between the least and most deprived areas across ABMUHB increasing from 9.1 to 10.4 years for men, and 6.6 to 7.3 years for women. Healthy life expectancy varies by over 20 years for men and 16 years for women between ABMUHB's best and worst areas.(100) In ABMUHB area 88 of the 323 areas are ranked in the most deprived 20% areas nationally.(100)

In the last decade across the UK levels of overweight and obesity have continued to rise. Figure 4:3 shows that nearly 6 out of 10 adults aged 16+ are overweight or obese

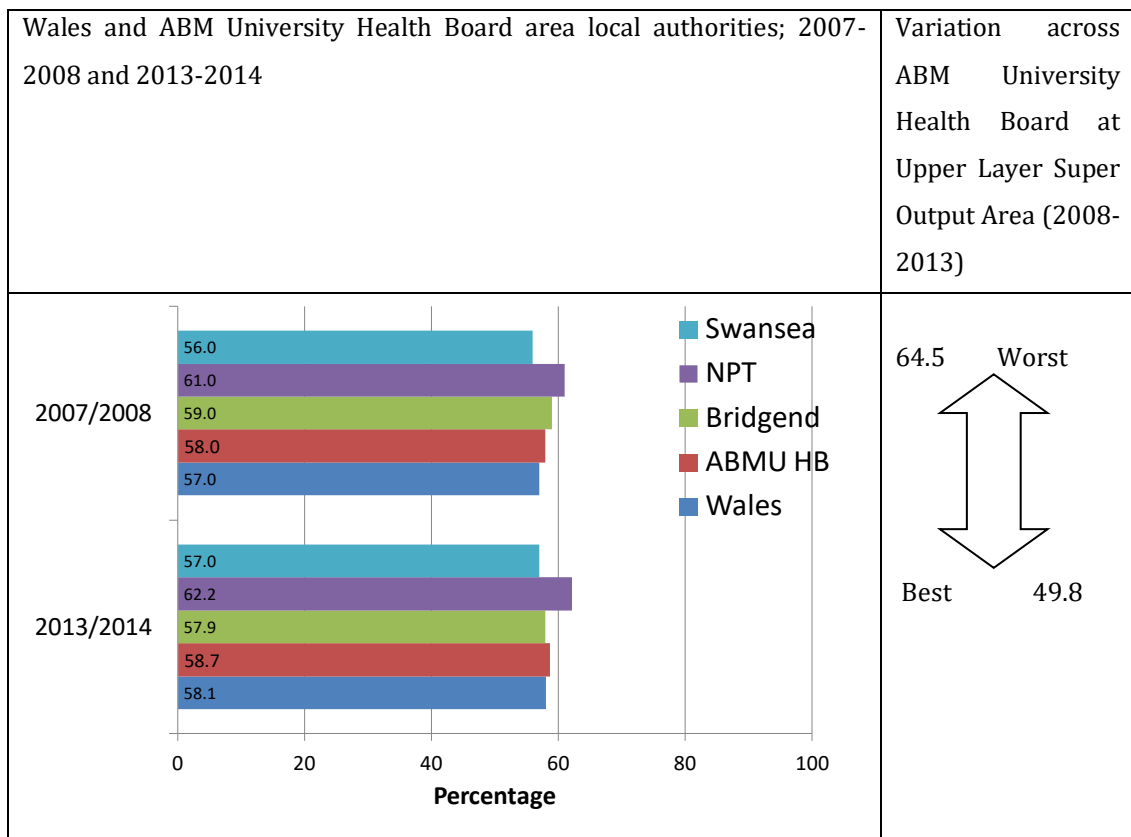


in ABMUHB area. This is in line with the Welsh average. Neath Port Talbot has the highest percentage of the population who are overweight or obese (62.2%). (100)

There is a social gradient to overweight and obesity. Within ABMUHB the data for 2008-2013 show there is a 15 percentage point difference between the best and worst areas (Figure 4:3).(100)

Adult physical activity levels have remained low in Wales and in ABMUHB area only 1 in 3 adults take 30 minutes of moderate physical activity on at least five days per week.(113)

**Figure 4:3 Age-standardised percentage of overweight and obese aged 16 and over, all persons(100, 113)**



Source: Welsh Health Survey, Welsh Government (113)

In January 2015, in ABMUHB there were 835 patients waiting for orthopaedic follow up appointments, over target. The referral to treatment statistics for orthopaedics in January 2015 were: 715 patients who have waited more than 36 weeks, 206 of these patients waiting for over a year. Patients waiting for outpatient appointments for hip and knee consultations averaged at 18 weeks for knees and 16 weeks for hips. The longest wait for both however was over 29 weeks. During the month of January at Morriston Hospital, Swansea (one of the two tertiary hospitals in ABMUHB) 48

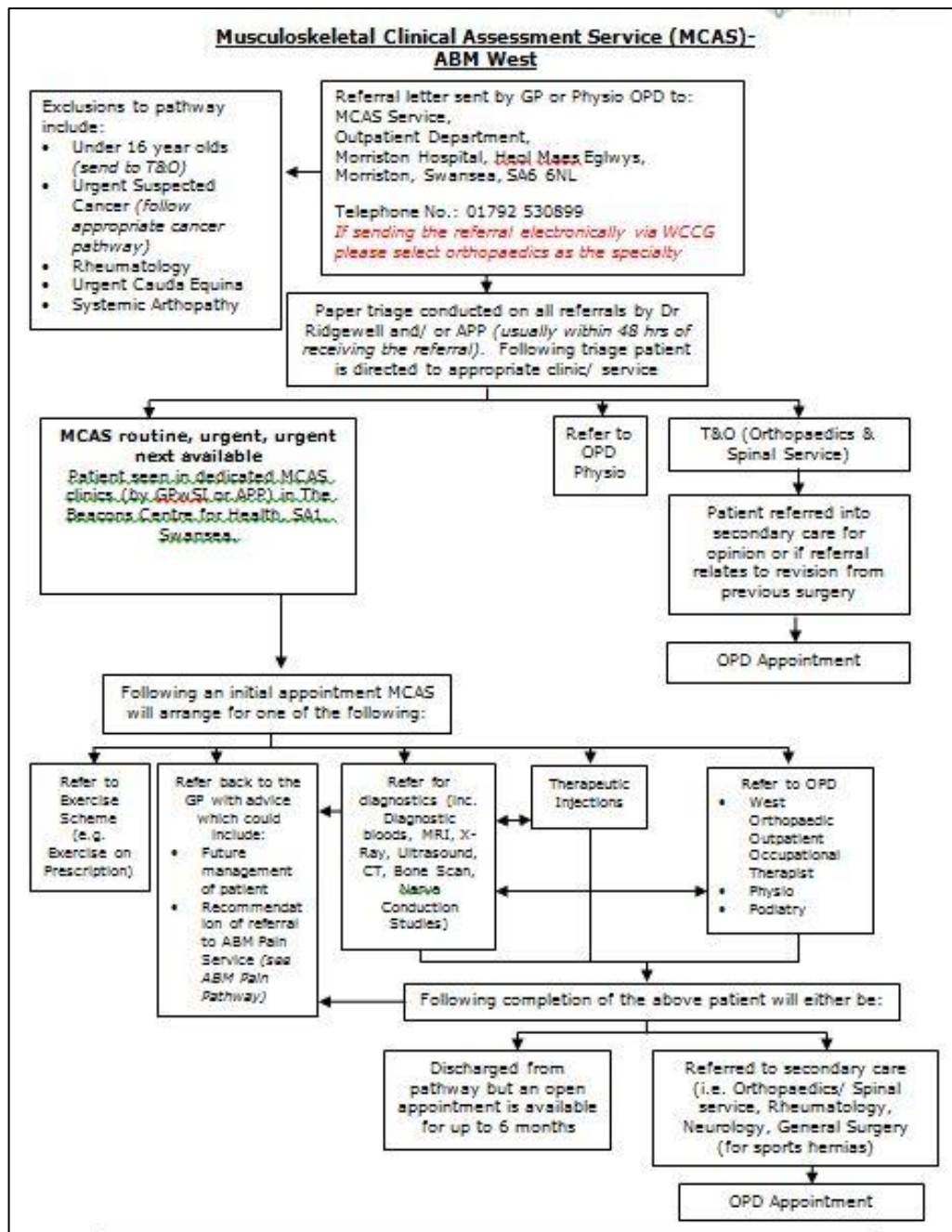
orthopaedic operations were cancelled with 7 of these due to the lack of available beds. In Singleton Hospital (the other tertiary hospital in ABMUHB) the number was 12 with 11 of these due to bed availability.(101)

#### *4.5.1 MUSCULOSKELETAL CLINICAL ASSESSMENT SERVICE*

In the west of ABMUHB there is a Musculoskeletal Clinical Assessment Service (MCAS). The MCAS is the main point of contact for all referrals from GPs and other health professionals across ABMUHB which require a specialist musculoskeletal assessment. The service is based in the centre of Swansea to enable easy access for patients, rather than having to go out of town to the hospitals.

The MCAS service comprises Advanced Physiotherapy Practitioners and GPs with specialist interest in the assessment and management of musculoskeletal conditions. The team individually assess all referrals and make sure the needs of the patient are at the centre of their care pathway. Due to the team working across primary and secondary care, they have been able to ensure the correct professional is involved in the ongoing care of the patient. This reduces unnecessary referrals and enables patients to be seen more quickly. The flow of patients is illustrated in Figure 4:4 below. Since the establishment of the service in 2012 the levels of joint replacement surgery have stabilised compared with the rest of Wales (personal communication) but nevertheless the waiting list for surgery is several orders of magnitude higher than people in England would experience.

Figure 4:4 Patient flow through MCAS service



#### 4.5.2 OBESITY AND EXERCISE REFERRAL SCHEMES

A UK study reporting in 2001 suggested that that if all overweight and obese people lost 5kg of weight or brought their BMI into the recommended range, approximately 25% of all knee replacement operations could be avoided (114) The risk of needing surgery was almost 3 times higher if the BMI was over 35 compared with a BMI of 22. (115)

The ABMUHB health needs assessment showed that 59% of the adult population in ABMUHB (approximately 252,000 adults) were estimated to be overweight or obese and 24% of the population estimated to be obese (approximately 103,000 people). (116) The needs assessment states that the Health Board with its partners should develop and implement a community-wide, multi-agency approach to address obesity prevention and management. (116) Specific recommendations are:

- Activities should be included in Intermediate Term Management Plan (IMTP) and broader regeneration and environmental strategies and
- Community based weight management services which follow best practice, should be accessible across the ABMUHB area.

Obese people have a much higher risk of potentially deadly complications following surgery Research by de Guia and colleagues (115) suggests that obese patients had a significantly higher risk of postoperative complications. In addition, the study showed morbidly obese patients (patients more than 100 pounds over their ideal weight) were nearly twice as likely to die as a result of complications following non-cardiac surgery. Bamgbade reports postoperative complications among 6,773 surgical patients treated between 2001 and 2005. Of the patients who experienced complications, about one-third were obese and nearly 15% were morbidly obese. (117) The results showed obese patients had much higher rates of postoperative complications than non-obese patients, such as:

- 5 times higher rate of heart attack;
- times higher rate of peripheral nerve injury;
- 1.7 times higher rate of wound infection;
- 1.5 times higher rate of urinary tract infection.(117)

In CG177 NICE guidance for treatment of people with osteoarthritis and are obese recommends that for this risk group the service should (105):

- Offer advice on the following core treatments to all people with clinical osteoarthritis:
  - Access to appropriate information.
  - Activity and exercise
  - Offer Interventions to achieve weight loss if the person is overweight or obese

- Agree individualised self-management strategies with the person with osteoarthritis. Ensure that positive behavioural changes, such as exercise, weight loss, use of suitable footwear and pacing, are appropriately targeted.
- Advise people with osteoarthritis to exercise as a core treatment, irrespective of age, co-morbidity, pain severity or disability. Exercise should include local muscle strengthening and general aerobic fitness<sup>8</sup>. Exercise has been found to be beneficial but the clinician needs to make a judgement in each case on how to effectively ensure participation. This will depend upon the person's individual needs, circumstances and self-motivation, and the availability of local facilities).

NICE CG 177 (105) suggests that primary care organisations and local authorities should recommend to patients, or consider endorsing, self-help, commercial and community weight management programmes only if they follow best practice by:(105)

- Helping people assess their weight and decide on a realistic health target weight (people should usually aim to lose 5-10% of their original weight) aiming for a maximum weekly weight loss of 0.5kg-1kg ;
- Focusing on long-term lifestyle changes rather than a short term, quick fix approach
- Being multi-component, addressing both diet and activity, and offering a variety of approaches;
- Using a balanced, healthy eating approach;
- Recommending regular physical activity (particularly activities that can be part of daily life, such as brisk walking and gardening) and offering practical, safe advice about being more active;
- Including some behaviour change techniques, such as keeping a diary and advice on how to cope with “lapses” and “high-risk” situations ;
- Recommending and/or providing ongoing support.(105)

Another of the Welsh National Orthopaedic Board summary of actions for all orthopaedic centres to deliver for orthopaedic patients, pertinent to obesity is Action 11: report the number of patients who smoke or who have a BMI>35, the proportion that complete either a stop smoking or weight reduction programme prior to elective

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<sup>8</sup> It was not specified whether exercise should be provided by the NHS or whether the healthcare professional should provide advice and encouragement to the person to obtain and carry out the intervention themselves.

surgery and the proportion who successfully stop smoking or achieve their weight reduction target.(109)

NICE clinical guidance for management of obesity states (118):

- Primary care organisations and local authorities should recommend to patients, or consider endorsing, self-help, commercial and community weight management programmes only if they follow best practice by:-
- Helping people assess their weight and decide on a realistic health target weight (people should usually aim to lose 5-10% of their original weight);
- Aiming for a maximum weekly weight loss of 0.5kg-1kg;
- Focusing on long-term lifestyle changes rather than a short term, quick fix approach;
- Being multi-component, addressing both diet and activity, and offering a variety of approaches;
- Using a balanced, healthy eating approach;
- Recommending regular physical activity (particularly activities that can be part of daily life, such as brisk walking and gardening) and offering practical, safe advice about being more active;
- Including some behaviour change techniques, such as keeping a diary and advice on how to cope with “lapses” and “high-risk” situations ;
- Recommending and/or providing ongoing support.(118)

#### 4.5.3 *THE WELSH NATIONAL EXERCISE REFERRAL SCHEME*

The National Exercise Referral Scheme (NERS) is a Welsh Government funded scheme which was developed to standardise exercise referral opportunities across all Local Authorities and Local Health Boards in Wales. (119) The scheme targets people who have a chronic disease or are at risk of developing chronic disease. The scheme operates in all 22 local authorities, running for 16 consecutive weeks and consists of 2 fully supervised group-based sessions each week. Each session lasts for approximately one-hour and costs between £1.50 and £2.00 depending on local authority. The sessions are usually run in Leisure or Community centres but there are some outdoor opportunities available in most areas.

#### 4.5.4 *ESCAPE PAIN PROGRAMME*

The ESCAPE Pain programme developed by Professor Mike Hurley(120) has a good evidence base to base investment in and implementation of a rehabilitation programme

for people with hip and knee osteoarthritis. The programme integrates simple self-management and coping strategies with an exercise regimen and can signpost to ongoing support individualised to participants.

The ESCAPE-pain programme (121) has been studied in the research setting and is supported by a good evidence base. It is very much based on co-production in a supportive environment. Demonstrable benefits for patients over the age of 50 with knee pain for longer than 5 years have been shown in randomised controlled trials and short and longer term improvements in outcomes compared with usual care (120, 122). ESCAPE pain rehabilitated participants had better functioning than participants continuing usual primary care (3.33 difference in WOMAC-func score; 95% confidence interval 5.88, 0.78;  $p=0.01$ ) (Hurley 2007). Similar improvements in outcomes were seen in a study of people with chronic hip pain receiving the ESCAPE pain programme (123) The programme has been demonstrated to be cost effective compared with usual care (124). Evidence suggests that patients undergoing the ESCAPE-pain programme have lower overall healthcare costs than those undergoing normal outpatient physiotherapy, taking use of accident and emergency services, secondary care and medication into account. Similarly over a period of 30 months post-intervention, patients undergoing ESCAPE-pain incur lower healthcare costs than those managed by analgesia in primary care, taking the cost of the programme into account (122).

#### *4.5.5 CWM TAF PILOT*

In 2013 Cwm Taf University Health Board set up a pilot project of a community based joint care programme pilot. The model developed consisted of an exercise professional led (rather than physiotherapy led), dietetic and exercise intervention targeting obese patients with knee Osteoarthritis. The evaluation of the pilot followed a cohort of 18 patients through a 16 week dietary and exercise intervention. Feedback was obtained via a combination of group feedback, individual questionnaires and informal semi structured interviews. (125)

This programme provided an innovative, evidence based approach which as well as addressing strategic priorities and guidance, did achieve the anticipated patient outcomes for many and was highly valued by patients. The evaluation showed that there are clear benefits shown in the data related to pain scores, function and quality of life for patients completing this programme. Limitations related to the small sample size due to cohort size need to be considered, but are consistent with other findings reported in the literature. (125)

The scale of this pilot was too small to have any noticeable effect on local orthopaedic resource. Given the evidence in the literature particularly that relating to the ESCAPE-pain programme it is reasonable to assume that, if scaled up, this approach could be successful in reducing both the numbers of joint replacements and post-operative complication rates.

#### *4.5.6 JOINT REPLACEMENT SURGERY*

With an increasingly older population and rates of obesity climbing the current pressure on ABMUHB orthopaedic services is only going to get greater. Joint replacements are relatively expensive surgeries, albeit delivering good value for money and incremental cost per quality adjusted life year (QALY) values fall well below the NICE threshold of what is considered good value for money(105). NICE guideline CG177 (105) suggests factors that should be born in mind when selecting the joint prosthesis for joint replacement, based on the national joint registry data and the literature abounds with research that suggests that length of stay can be shortened. This evidence has been turned into initiatives in the orthopaedic services in ABMUHB with some success and initiatives to improve patient care, saving resources and money and improving throughput is still a challenge. As suggested by Winemaker in 2015 it is also the case that joint replacement surgery patients vary as do the types of surgery and prostheses so care needs to be taken when imposing 'rules' about who gets what when(126). At the time of initiating the PBMA there were two areas where pressures on the system had yet to be explored more fully in order to assess whether savings and resources could be released. These areas were rationalising procurement of joint prostheses and post-operative follow up schedules.

### **4.6 METHODS**

#### *4.6.1 INTRODUCING PBMA*

As the likely participants in the MSK PBMA had not been exposed to economics based methods of prioritisation and resource reallocation two meetings with stakeholders and project team members were held at which I presented the underlying concepts, the evidence and use underpinning PBMA and how we planned to tackle the PBMA process . Throughout the process I did short 'reprise' presentations, summarised how we were progressing through the PBMA steps and addressed one additional topic such as accountability for reasonableness, or multi criteria decision analysis (MCDA) to keep participants engaged in the process and feeding back in to the process.



#### *4.6.2 PROJECT TEAM AND PROCESS MANAGEMENT*

The project team established for the MSK pilot was jointly led by the general manager of MSK services and the clinical director of MSK services – and orthopaedic surgeon, a project manager from the MSK service delivery team, a public health consultant, a representative from the commissioning development programme, a health economist (the author), a representative from ABMUHB finance, and a project administrator.

The initial goal was for the PBMA to be completed within six months, but had to be extended to 18 months. Project team meetings were booked at regular intervals and these were punctuated by stakeholder group meetings. The planned time table also allowed the project team access to public meetings facilitated by ABMU which would allow engagement with public and patients.

The progress and recommendations for change arising from the PBMA were targeted at meetings of the planned care board and ultimately at the completion of the process the Intermediate Term Management Plan which would commit the services to action in line with recommendations and to be accountable for delivering the agreed changes.

Through the PBMA journey a series of interviews were undertaken with stakeholders and project team members in order to get feedback on the process and potential improvements to ensure the PBMA process was able to integrate into the ABMU commissioning process.

#### *4.6.3 STAKEHOLDER GROUP*

In order to get input and priorities for the community affected MSK services the project team contacted a wide range of people and invited them to initial meetings to explain the remit and purpose of the PBMA and invited them to regular meetings thereafter, to report back and get further input. The stakeholder group comprised all of the key representatives of the services, patient representatives and other vital informants. The list of stakeholders is in Box 4:3 below

#### Box 4:3 PBMA Stakeholders

*STAKEHOLDER GROUP REPRESENTATIVES*

Dougie Russell – Unit Medical Director, Singleton Hospital

Mike Bond – GM for CSS and Orthopaedics/Spines

Kerry Broadhead – Head of Commissioning

Pippa Anderson – Health Economist (Swansea University)

Patricia Jones – Commissioning Support Manager

Vikki Gibbs – Service Improvement Manager

Rachael Powell – Strategic Planning Manager

Ceri Gimblett – GM for Surgery & Orthopaedics (PoW)

Carol Rees – Service Manager Orthopaedics (PoW)

David Robinson – Clinical Lead for Orthopaedics (PoW)

Charlie Mackenzie – Finance

Christian Heathcote-Elliott – Public Health Wales

David Mackerras – Community Health Council

Sue Evans – Community Health Council Ian Harris – GP

Jeanette Munn – Planning Officer City & County of Swansea

Sandy Mather – Patient representative

Carol Ross – Patient representative

Susan Learmonth – OT Lead

Sharon Maggs – Physiotherapy Lead

Tyrone Lewis – Patient representative

The stakeholder group was consulted at key stages of the PBMA process to allow findings from research and options for change in the services to be discussed and developed with stakeholder input. The areas of scrutiny and sources of information initially identified by the project team were confirmed.

#### **4.6.3.1 Patient and Public Input**

An ABMUHB Changing for the Better (C4B) public engagement event held on 7<sup>th</sup> May 2015<sup>9</sup> serendipitously allowed the project team to engage with the widest possible group of stakeholders and work with the C4B team, using the TurningPoint® voting system to get input on priorities for health services overall, based on 10 commissioning criteria that related to ABMUHB values: *'caring for each other'* through improving experience, *'working together'* through involving patients and staff and *'always improving'* through seeking out and using evidence of best practice. The ABMUHB criteria for the PBMA (underpinned by the ABMUHB values) are listed and characterised in Table 4:1 below:

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<sup>9</sup> <http://www.wales.nhs.uk/sitesplus/863/news/23672>

**Table 4:1 ABMUHB Commissioning Criteria**

<b>Criteria</b>	<b>Description</b>
<b>Fairness</b>	Demonstrates that different clinical conditions, treatment and patient groups are considered equally and without preference e.g. equal consideration to Cancer and Diabetes patients or older people and working age adults
<b>Inequalities</b>	Demonstrates that inequalities in access to healthcare and the potential to achieve positive health outcomes between different groups within ABMU is addressed, in particular for our most deprived communities e.g. targeting services within deprived communities
<b>Evidence of clinical effectiveness</b>	Demonstrates that the proposal is based on evidence that the treatment or intervention is considered to be clinically effective by trust worthy professional bodies
<b>Value for money/cost effectiveness</b>	Demonstrates that the outcomes and improvements that will be delivered are equal to the cost of the investment, delivering good value for money and evidence of being cost-effective
<b>Strategic fit</b>	Demonstrates the proposal has a strong fit and alignment with current national and local strategies, policies and priorities
<b>Disease burden</b>	Demonstrates delivery of benefits and outcomes which positively affect a significant proportion of our local population so as to create a meaningful impact on the burden of disease we experience
<b>Outcomes</b>	Demonstrates delivery of demonstrable improved health outcomes, including preventing ill health, reducing risk to health and alleviating suffering
<b>Patient experience</b>	Demonstrates that available evidence on the impact of any changes on patient experience or satisfaction have been taken into account and that improving patient experience can be demonstrated as an outcome
<b>Standards of care</b>	Demonstrates delivery of relevant quality standards or other markers of high quality healthcare, and addresses unacceptable variation in quality of care across ABMU
<b>Reducing Harm</b>	Demonstrates that the intervention will not cause harm and/or will reduce harm currently experienced and/or will cease/reduce delivery of interventions that deliver no impact (approx 20%)

The participants in the C4B event rank ordered the criteria and the top three criteria under which the PBMA decisions should be made were voted to be:

- 1) Health Outcomes**
- 2) Patient Experience and**
- 3) Evidence**

Two representatives from the Community Health Council<sup>10</sup> to represent patients were part of the stakeholder group and participated in the PBMA process all the way through to the end. Four patient representatives were invited to the Stakeholder events to review the ideas for review and investment. Meeting papers were also shared amongst the third sector and comments and feedback solicited. In addition to presenting the PBMA at the C4B event on the 7<sup>th</sup> May 2015, where stakeholders and patient representatives attended the Service Improvement Manager also met with the patient representatives separately to hold more intimate conversations with patients to ascertain their individual thoughts/views on the proposal. Patient representatives continued to be involved in the PBMA stakeholder meetings, with information being shared via the third sector. The MSK service made a commitment that the outcome of the PBMA - implementation of disinvestment and re-investment proposals –would be monitored throughout to ascertain how the patients feel about the change and new services.

#### *4.6.4 SCOPING AND COLLATION OF DATA*

The scope of the PBMA was agreed to be the entire MSK pathway encompassing therapies such as physiotherapy, occupational therapy, MCAS, community, primary and secondary care services. The PBMA pilot candidates were required to identify and agree resources related to low value interventions which could be disinvested in to enable re-investment of that resource into higher value interventions and better ways of working.

The timelines, progress and recommendations for change arising from the PBMA were targeted at meetings of the PCCB and ultimately at the completion of the process, needed to be timed to have recommendations accepted as part of the IMTP which

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<sup>10</sup> Abertawe Bro Morgannwg Community Health Council is a statutory organisation, the independent voice representing the public's interest in the NHS in the County Boroughs of Bridgend, Neath/Port Talbot and city of Swansea.  
<http://www.wales.nhs.uk/sitesplus/902/home>

would commit the services to action in line with recommendations and to make the service delivery teams accountable for delivering the agreed changes.

At the time the PBMA started MSK services were managed across the entire patient pathway by one team. The project team and commissioning leads felt this was a great opportunity to examine the entire pathway and look at how possible it would be to disinvest from secondary care activity and invest earlier in the patient pathway (left shift) to delay or avert patients conditions deteriorating and reduce patients attendance in secondary care. Many ideas were explored by the stakeholder groups at initial meetings and subsequently formal proposals for investment were invited, after disinvestment/resource release candidates were identified and quantified. The proposals included:

#### *RESOURCE RELEASING*

1. Examining NICE 'do not do' recommendations in MSK;
2. Clear referral guidelines for people with OA for GPs;
3. Better joint prosthesis procurement 'deals' across the whole of ABMUHB;
4. Risk based arthroplasty post-operative follow up programmes rather than the current 'standard' programme.

#### *INVESTMENT*

1. PROMS data collection tools;
2. Investment in MCAS services enabling people with osteoarthritis to improve their joint related health and wellbeing.

### 4.7 INFORMING THE PBMA: DATA AND INFORMATION

#### 4.7.1 ABMUHB DATA

The sources of population statistics, prescribing and service utilisation data were available at varying levels of accuracy and detail. The overwhelming gap in data were primary care data which were available in the health board as all the routine health data is held within a secure anonymised linked data bank (SAIL) at Swansea University. Whilst the MCAS and physiotherapy data or example is sent to SAIL for upload and linking it is not a 'given' that the health board automatically has access to the linked data and would have to make a formal research request to be able to analyse the data, and provide funding to have a SQL analyst extract the data. However the data is difficult to access without considerable administrative processes, and would not have

informed the PBMA within the desired timeline and required funding (not available to the project team) to extract and analyse the data.

Audit+ data based on electronic GP records was unavailable to the team to describe the services provided by general practitioners (GPs).

#### **4.7.1.1 NICE 'Do Not Do' Recommendations**

The main NICE 'do not do' recommendation that was relevant to the PBMA, and resonated with the project team and stakeholders was:

*Do not refer for arthroscopic lavage and debridement as part of treatment for osteoarthritis, unless the person has knee osteoarthritis with a clear history of mechanical locking (as opposed to morning joint stiffness, 'giving way' or X-ray evidence of loose bodies)(14).*

The Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) undertakes similar work to NICE and produces 'prioritisation support' summaries. One of these is 'Arthroscopic Surgery is Ineffective in Knee Osteoarthritis and Results in High Costs'(127). The authors emphasise that arthroscopic surgery in knee osteoarthritis has no effect on pain, function and quality of life, and also involves risks. The risks identified (based on a registry study of over 14,000 participants) include deep vein thrombosis, surgical complications, infections, cardiovascular events and death within 3 months. It is also reported as a high cost procedure, consuming considerable resources (SEK 33 million - approx. GBP3 million - in 2012) and a procedure that is disproportionately given to more men than women and people with higher education. The SBU recommend more cost effective treatments for knee osteoarthritis, the one with the highest recommendation being long term regular supervised strength and functional training.

The total fully absorbed cost<sup>11</sup> of undertaking Knee arthroscopy across the Health Board was quantified in 2013/14 as £1.1m. The service has been benchmarked against the Albatross Patient Cost Benchmarking Peer Group<sup>12</sup>.

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<sup>11</sup> A fully absorbed cost is one that has taken account of every element contributing to producing the item.

<sup>12</sup> Albatross is a Welsh data system containing secondary care activity data by ICD 10 code. The peer group is the appropriate benchmark service(s) in Wales.

The cost per case in ABMUHB is broadly comparable to the Albatross Peer Group and is consistent with the Albatross peer group. The ABMUHB procedure time in theatre is significantly shorter than the peer group average (see Table 4:2). The total capacity under review for this intervention is:

- 686 Bed Days per annum
- 148 Half Day Theatre Sessions per annum
- 148 Half Day Anaesthetic Sessions per annum
- 148 half Day Surgeon Sessions per annum

**Table 4:2 ABMUHB knee arthroscopy compared with Albatross Peer Group**

	<b>ABMUHB Average</b>	<b>Albatross Peer Group</b>
<i>Cost £</i>	1,702	1,640
<i>Length of Stay (days)</i>	1.1	1.1
<i>Theatre Time (minutes)</i>	51	59

The orthopaedic surgeons in the stakeholder group suggested that there may be merit in investigating the ABMUHB knee arthroscopies to ascertain whether there were any 'do not do' knee arthroscopies in the health board and whether there was an opportunity to release resource.

A pilot study was conducted within the orthopaedic service within ABMUHB to try to obtain data to understand the clinical reasons and decision making in the run up to knee arthroscopy cases from electronic records without the need to review the paper notes. A batch of ten records was reviewed but it quickly became apparent that the data necessary to form a reasoned judgement as to the appropriateness or otherwise of the decision making process were not easily available from the electronic record alone. This process was therefore abandoned in favour of a paper exercise, reviewing patient notes.

A random sample of 103 sets of patient notes drawn from all surgeons undertaking knee arthroscopy in ABMUHB on patients who had received a knee arthroscopy were obtained in batches and analysed by Mr Andrew Davies an orthopaedic surgeon at Morriston Hospital. Throughout this process it was understood that there is more than one 'correct' way to manage patients conditions and that there are appropriate variations in clinical practice. This was not a process to examine surgical technique in



theatre or outcomes thereafter. This was very much an attempt to study the decision making process that led to the decision to proceed to knee arthroscopy, if that was a decision that was appropriate or one that would have been classified as a NICE 'do not do'. In understanding how the intervention came to be performed, the goal was to try to establish how that decision making process could be improved and/or costs of undertaking a potentially inappropriate intervention be reduced. The process was also not intended to target individuals, rather practice in general. Results were therefore anonymised to avoid the identification of individual surgeons. Each set of notes was examined to determine:

- Patient age.
- Initial presenting complaint and referral source.
- Who was the patient first seen by and their grade?
- What was the working diagnosis after the outpatient consultation?
- Was an MRI performed?
- Who listed patient for arthroscopy?
- Was the working diagnosis confirmed at arthroscopy?
- What was the management plan thereafter?
- A judgement was then made regarding the decision making process for each case and categorised as either '*no concern*', '*questionable*' in the opinion of the reviewer or '*hard to justify*'.

Of the 103 sets of notes studied in detail, five were found not to contain enough relevant data to make a sound judgement regarding the appropriateness or otherwise of the decision making process leading to the operation, thus 98 cases notes therefore formed the data set. These patients had been operated by a total of 10 different surgeons, of whom six had performed a total of ten cases between them. The remaining four surgeons had performed 7, 16, 25 and 39 cases respectively. The outcomes of the review are summarised in

**Table 4:3 Knee arthroscopy: outcomes of case note review**

<b>Consultant</b>	<b>No Concern</b>	<b>Questionable</b>	<b>Hard to Justify</b>
1	7	0	0
2	17	5	3
3	1	0	0
4	8	2	6
5	25	6	8
6	3	0	0
7	3	0	1
8	1	0	0
9	0	1	0
10	0	1	0

Of the 98 case notes studies, 65 cases raised no concerns, 15 were questionable in the reviewer's opinion and 18 were '*hard to justify*'. Within the '*hard to justify*' category, two patients had had two arthroscopies and one had had five, bringing the total number of procedures that fell outside of a reasonable decision making process, to 24 from the 98 case notes studied.

Three surgeons, numbers 2, 4 and 5 (see

Table 4:3) stood out as having apparently disproportionate numbers of *questionable* and *hard to justify* decision making processes.

Surgeon 2 had performed 25 cases of which 8 (33%) were deemed *questionable* or *hard to justify*. Surgeon 4 had performed 16 cases of which 8 (50%) were deemed *questionable* or *hard to justify*. Surgeon 5 had performed 39 cases of which 14 (36%) were deemed *questionable* or *hard to justify*. If the *questionable* cases were included, then the justification for 39 (40%) of the cases studied was not obvious.

If it is accepted, as noted above, that there are legitimate variations in practice and the *questionable* cases could justifiably be categorised as ‘no concern’ by other reviewers, then 24 (25%) of the cases could be considered as potentially inappropriate and a target for service rationalisation and cost re-distribution.

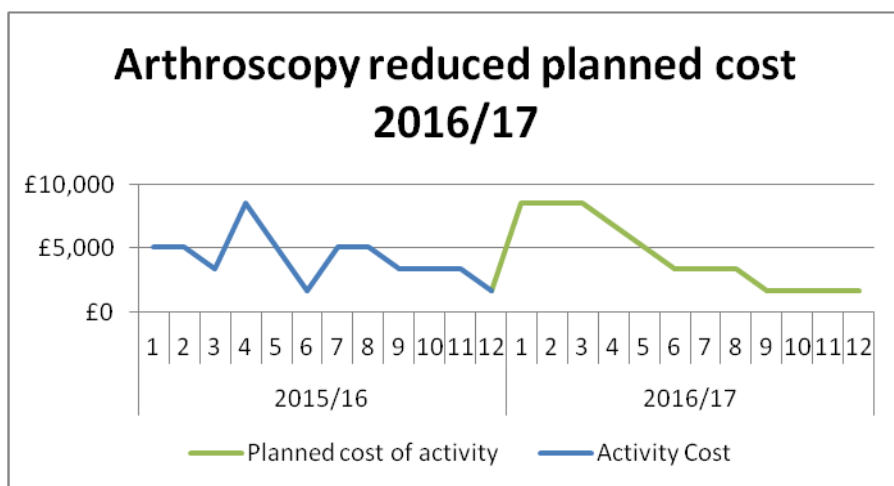
As a result it was thought reasonable for orthopaedic service in ABMUHB, to reduce the 25% of arthroscopies that the audit deemed inappropriate (according to the NICE ‘do not do’ criteria) within the next 12 months and thus, if achieved across the whole Health Board, the resources presented in Table 4:4. This is also illustrated in

Figure 4:5.

**Table 4:4 Estimated resource release from reduction of ‘do not do’ knee arthroscopy**

<b>Resource type</b>	<b>Unit of resource</b>	<b>£</b>
<b>Consumable Cost</b>		24,000
<b>Theatre Staff</b>	44 Half Day Sessions pa	20,000
<b>Surgeon Time</b>	44 Half Day Sessions pa	12,000
<b>Anaesthetic Time</b>	44 Half Day Sessions pa	12,000
<b>Total</b>		68,000

**Figure 4:5 Arthroscopy reduced planned cost 2016/17**



In order to understand the reasons why the ‘do not do’s had occurred and in order to prevent the inappropriate practice continuing the orthopaedic surgeon who undertook the review tried to unravel the underlying reasons as to why such surgeries had gone ahead. These observations are summarised below.

Detailed study of the cases deemed *hard to justify* revealed a complex and varied set of problems however a few themes did emerge. Several cases were in patient groups identified by NICE guidance as being older and with established osteoarthritis. Such patients may actually request a ‘washout’ as they may have experienced subjective benefit previously, however such practice is actively discouraged. This is a clear case of guidance not being followed and could be relatively easy to change.

In some cases, initial sensible management plans taken by consultant general orthopaedic surgeons to manage pain and avoid surgery were overturned at follow up either by non-consultant grade surgeons or by sub-specialist knee surgeons. These patients were typically younger, more active and presenting with longstanding knee pain with no obvious surgical target. These procedures seemed rather speculative and based around the premise that ‘something should be done’ often despite previous failed arthroscopy.

Some patients appeared to be in recurring cycles of arthroscopic washout, non-operative management for a few years and then re-referral from primary care for recurrent symptoms. Such patients were often young and active with degenerate knees for whom a knee replacement would be inappropriate due to their high activity levels but who found their pain hard to cope with. Sadly we do not have all the answers for such patients but repeated arthroscopy for osteoarthritis is known to be misguided.

The evaluation of the representative sample of knee arthroscopy procedures from across ABMUHB was informative and gave good indications regarding the appropriateness, or otherwise, of the decision making process that lead up to the decision to proceed to arthroscopy in each case. The majority of the cases that raised concerns were performed by a small number of higher volume arthroscopic knee surgeons. The bulk of these cases were not in the traditional categories covered by NICE guidance and several were under the care of specialist knee surgeons.

#### **4.7.1.2 Clear Referral Guidelines for People with Osteoarthritis**

At the stakeholder group meetings there was vigorous discussion between all of the clinical participants: the GP representative in the stakeholder group suggested that GPs were not clear about thresholds for referral for people with pain and/or mobility limitations and OA. The problem was felt to be minimal by the orthopaedic surgeons and further complicated by the ABMUHB population around Swansea having access to MCAS, which has as part of its remit, to provide that 'sifting' of patients before they saw an orthopaedic surgeon. In addition a major research initiative - the development of the ACHE tool<sup>13</sup> - led by the Oxford Musculoskeletal Biomedical Research Unit, funded by the National Institute for Health Research (NIHR) initiative, seemed to address the very issue articulated by the GP. Professor David Beard was invited to a stakeholder meeting to make everyone aware of the research, and the progress it was making. Although the research would not be complete within the timeline of the PBMA, it was unanimously agreed that a perceived problem would be solved and the topic was taken off the list.

#### **4.7.1.3 Joint Prosthesis Procurement**

The current proposal focuses on making savings in respect of the procurement of prosthesis. The total spend in this area has been quantified as £1.925m per annum. The two hospitals providing arthroplasty surgery procure separately and the general manager understood from suppliers that if the two hospitals procured as a single purchasing unit discounts would be greater. Whilst investigating the utilisation of prostheses it was clear that there was an inability to routinely match prosthesis spend to patient, which prevents any direct benchmarking to other organisations. It is possible however to undertake high level comparison within the Health Board. For

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<sup>13</sup> <https://www.oxford.msk.bru.nihr.ac.uk/clinical-trials/current-trials-and-studies/ache-tool>

instance relative spend on knee prostheses may be compared between Swansea and Bridgend Services illustrated in Table 4:5.

**Table 4:5 Cost of knee prostheses in ABMUHB in 2014**

	<b>Swansea</b>	<b>Bridgend</b>
<b>Total Cost (£)</b>	591,613	476,110
<b>Activity (number of cases)</b>	325	302
<b>Average Cost Per Case (£)</b>	1,820	1,577

Whilst some caution would need to be exercised around relative case mix complexity for arthroplasty surgery potential savings could be made by standardising purchasing practice within ABMUHB increasing discounts and 'basket deals' with manufacturers. Total savings for the orthopaedic service in ABMUHB for knee and hip procedures were anticipated to be of the order of £231k. This equates to a reduction of 12% of procurement costs for prostheses across orthopaedic services in the 2016/17 financial year. Patient and service benefits from standardisation were identified as well as the cash saving:

- Increased number of utilisation of a specific kit will reduce error rate and allow familiarisation for surgeon and theatre staff;
  - Simplicity;
  - Eradicating the need for loan kit and rep attendance in theatre;
  - Efficiencies in theatre;
- Standardise process for support services i.e. HSDU;

Estimates of overall source and application of cash release from procurement rationalisation are summarised in Table 4:6 below:

**Table 4:6 Procurement rationalisation: anticipated cash release**

	<b>Potential</b>	<b>Budget</b>	<b>Agreed</b>
<b>Resource Released</b>			
<b>Procurement West</b>	131,000	Morrison	131,000
<b>Procurement East</b>	100,000	POW	To be agreed
<b>Total Release</b>	343,000		131,000

At the time of making the case for savings for the West of ABMUHB were clear and were removed from the annual prostheses budget from the 1<sup>st</sup> April 2016 and held centrally within finance until the reinvestment proposal was fully designed.

#### 4.7.1.4 Arthroplasty Post-Operative Follow Up

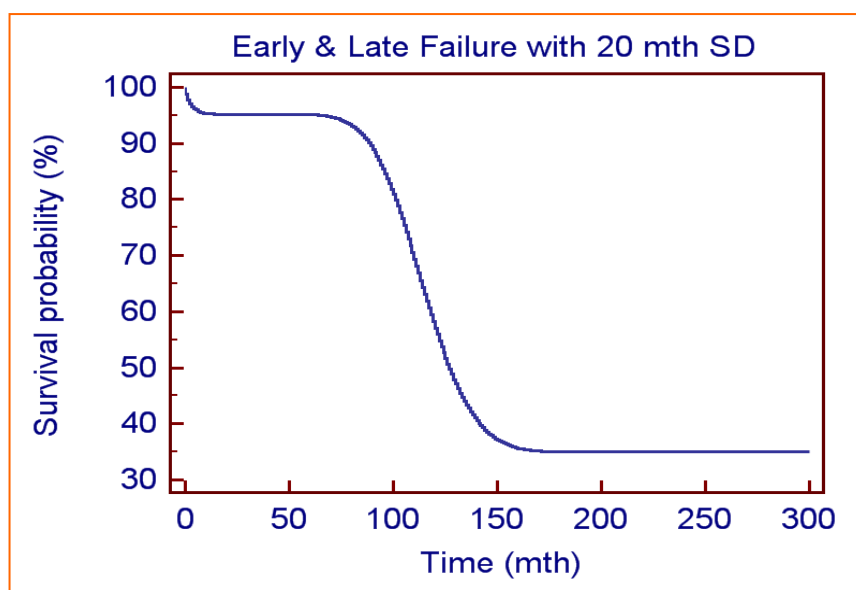
There were a variety of clinicians consulted in the stakeholder events, of which these were orthopaedic surgeons, GPs, the Clinical Lead for MCAS and therapists. The clinical view at the time was that there was a need to address the long waits for orthopaedic appointments, balanced with the understanding that there is also the need to financially deliver on targets. There was consistent support from clinicians that addressing the capacity issues and enhancing patient experience and outcomes was important.

Once someone has had joint replacement surgery there is a well-established follow up programme, typically six weeks after the surgery and then at a year and five years post-surgery for a prosthesis with a good track record. However, since both people differ and prostheses differ so one follow up programme may not be right for all.

In addition there are considerable pressures on the service to ensure that the post-operative follow ups are booked and patients seen on time. The number of follow ups not booked (FUNB) is a measure that is tracked by the service as a measure of effectiveness. In 2015/16 there had been a reduction of the arthroplasty FUNB lists in the west of ABMUHB already, simply through the orthopaedic secretaries validating the lists. This currently equates to approximately 68% or 1750 arthroplasty patients.

Research utilising mathematical modelling of risk based timing for follow up appointments was being undertaken by Mr David Woodnutt – an orthopaedic surgeon at Morriston Hospital. Analyses available at the time suggested that risk profiling the patient, type of arthroplasty and the prosthesis used would result in an appropriate follow up schedule that would result in a tailored programme rather than the habitual programme. The National Joint Registry (NJR) is a rich resource of complications, prosthesis survival and failure data which can be sub set by region and variables affecting risk such as age and prosthesis type. In this follow up model the patient could be seen at the times when risks are higher and problems are most likely to occur (Figure 4:6) and earlier in the follow up programme the follow up should be consultant led and later in the programme when ‘wear and tear’ are the more likely reasons for loosening and failure, other health professionals rather than a consultant engage with patients in the follow up appointment.

Figure 4:6 Illustration of survival probability of joint prosthesis (taken from Mr Woodnutt’s data).



The analyses undertaken by Mr Woodnutt (personal communications) suggested that a considerable number of patients would not need the frequency of follow ups currently booked if the risk based approach was followed. In addition the patient should feel connected and have the ability to come back into the system if they are experiencing problems. Contact with the patient could be maintained in the intervals between visits by postal survey asking key questions to detect any problems with the joint. Crude estimates suggested that approximately 66% of consultant follow ups could be avoided for patients without complications. Taking into account the impact of alternative arrangements, such as virtual review and nurse led clinics and the continued need to continue to follow up a proportion of patients, it was estimated that the equivalent of two weekly clinics could be saved with resource releasable potentially for other clinics (Table 4:7).

**Table 4:7 Implementation of a risk based arthroplasty follow up programme estimated releasable resource**

Consultant Sessions	£24,000
OPD / Medical Records Staffing	£20,000
Total	£44,000

In July this year, the Welsh National Orthopaedic Board issued a summary of actions for all orthopaedic centres to deliver for orthopaedic patients in Wales (109). Within the implementation plan are action points that are pertinent to the PBMA:



**Number 4:** undertake a waiting list “validation” to remove patients on the waiting list who don’t require an outpatient appointment or who don’t need treatment.

**Number 5:** measure and report the number of follow-up appointments per patient after hip and knee replacement as well as adherence to the new policy on long-term follow-up for major joint surgery directed by the Welsh Orthopaedic Board.

**Number 9:** determine criteria for the urgent category in elective orthopaedics and health boards to put in place systems to provide a maximum 6 week outpatient service.(109)

The National Orthopaedic Board for Wales was also investigating follow up intervals and at the time of the PBMA, were considering emulating the model NHS England were contemplating – again a reduced schedule but still ‘one size fits all’. It was clear that these differences in approach needed resolving, as although both might release resource short term and long term an inappropriate schedule may result in higher resource use as avoidable problems occur. Further work in collaboration with Mr Dave Woodnutt and the National Orthopaedic Board was required to establish evidence based set of criteria for optimal follow up intervals and identify how the resource currently supporting this activity can be released, redirected or saved, as the MSK services could not undertake anything different from a decision made by the National Orthopaedic Board.

This resource release proposal focused specifically on follow up of joint replacements. The total number of patient consultant follow ups being generated is estimated at 4,094 per annum (based on an average of 3 follow ups per patient). It was not possible to accurately cost this specific patient cohort from routinely available information and it would appear that there is significant difference in practice throughout ABMUHB. An indicative cost might be derived by applying the fully absorbed cost – £110 per attendance – to the activity level to arrive at an estimated £450,000. Whilst specific benchmarking data for this patient cohort was not available it was possible to benchmark the ‘overall new follow up’ rates in trauma and orthopaedics against the CHKS (Caspé Healthcare Knowledge Systems) peer group, summarised in Table 4:8 below.

**Table 4:8 Benchmarking of ABMUHB hospital follow ups**

Specialty	Sum of new	Sum of all	All to new follow	CHKS Peer
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	<b>follow ups</b>	<b>follow ups</b>	<b>up Ratio</b>	<b>Group Ratio</b>
<b>Morrison Hospital</b>	13,341	28,015	2.10	1.70
<b>Princess of Wales</b>	13,574	23,538	1.73	1.70

Whilst some caution around case-mix issues is required, it would appear that (particularly within the Morrison service) there is variation against the peer group average.

There are a variety of different clinic templates and staffing profiles currently used to accommodate this activity which have the potential to be re defined. However more immediate resource release could be obtained by more formally implementing the already successful use of the secretarial staff within orthopaedics to validate lists for discrepancies and duplications.

#### *4.7.2 OPTIONS FOR DISINVESTMENT OR RESOURCE RELEASE*

From the potential candidate areas for disinvestment, change and/or reduction the PBMA process identified three areas where the implementation of the changes could be made: joint prosthesis procurement, review and validation of arthroplasty post-operative follow up and reduction in knee arthroscopy, due to fewer 'do not do' cases. Table 4:9, shows the initial estimates that guided the decision.

**Table 4:9 Options for disinvestment or resource release**

	<b>Potential cash or resource release (£)</b>	<b>Formally agreed release (£) August 2016</b>
<b>Resource Location</b>		
<b>Procurement West</b>	131,000	131,000
<b>Procurement East</b>	100,000	
<b>Arthroscopy West</b>	24,000	24,000
<b>Arthroscopy East</b>	44,000	
<b>FUNB</b>	44,000	
<b>Total Release</b>	343,000	131,000

The more immediately releasable resources were located in the west of ABMUHB at Morriston Hospital – a function of the location, in the west, of the management of the MSK services and the more active engagement of the Morriston orthopaedic team in the PBMA stakeholder group.

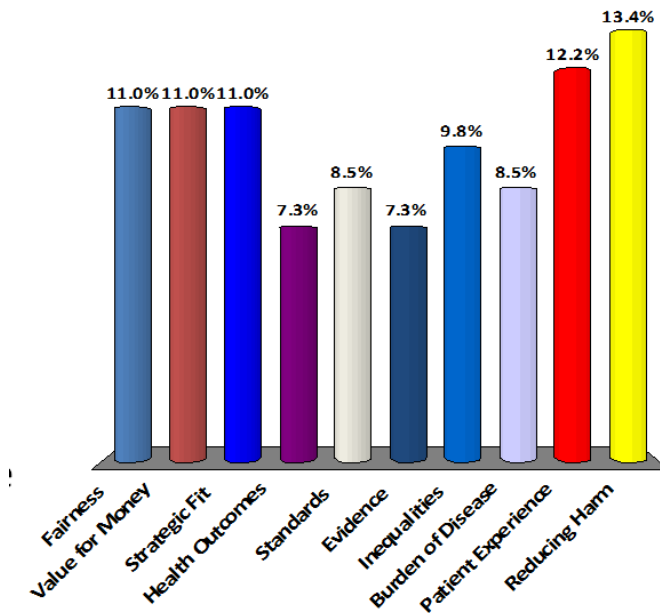
#### *4.7.3 DECISION MAKING*

During the PBMA process the stakeholder groups were asked about the criteria which were most important to guide decision making and relative priorities under which decisions for change in services should be made. The stakeholder group reflected on the ‘Changing for the Better’ meeting held on the 7<sup>th</sup> May 2015 where stake holders felt that the top 4 criteria to influence decisions should be:

1. Health Outcomes
2. Standards of Care
3. Evidence and
4. Reduced Harms

The full list of criteria and the rank ordering at the meeting are shown in Figure 4:7 below.

**Figure 4:7 Changing for the Better Meeting 7th May 2015: Decision making Criteria and relative Priorities**



When the discussion came around to re-investment all the stakeholders were encouraged to make a case for a reinvestment for something they felt would be useful. A *pro forma* to complete was provided (available in Appendix 12) and the proposers encouraged to return this, completed with their ideas. The *pro forma* were then available to the project team as a 'pre read'. The proposers were then invited to a meeting of all the stakeholders to introduce the case and provide the evidence around it. At this time it was evident that the overwhelming desire was to introduce an exercise/lifestyle service within the MCAS framework that would help people with weight problems, their osteoarthritis and pain. I made a proposal to emulate the ESCAPE-pain programme given it was evidence based and had long term outcomes and economic evaluation to support the programme. (120) Another proposer wanted to invest in a specialist running machine to use with the morbidly obese to help them get going with exercise and focus on a lifestyle plan with this particular sub group and others wanted to reintroduce a holistic service for weight and lifestyle management which had run in the past. In effect all proposers wanted to introduce much the same intervention with much the same aims.

The ACHE tool <sup>14</sup> when completed would solve other problems and aid in future resource release and service planning and the MSK service planned to introduce

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<sup>14</sup> <https://www.ndorms.ox.ac.uk/clinical-trials/current-trials-and-studies/ache>

software to collect PROMS data. Thus it seemed to all stakeholders overwhelmingly obvious where the investment should be made, without the need to go through an MCDA process to prioritise. It was clear all would work together to devise an exercise and lifestyle programme based on ESCAPE-pain to fit in with available budget/resource release. The ESCAPE-pain publications had all the information needed to devise and cost up a service and the project team were able to consult with both Professor Hurley and those who had established a ESCAPE-pain service at Southmead Hospital Bristol.

Within the stakeholders' discussions at the meetings there was no detectable opposition to any of the programmes for resource reallocation and there was unanimous agreement that the programmes should go ahead as the budget released by the disinvestments/reductions was sufficient. The project team felt that there was no need to have any voting or relative prioritisation.

Somewhat more problematic would be the generation of the resource release, moving from the 'paper' estimations to the reality. The two hospitals that provide arthroplasty surgery in ABMUHB (Princess of Wales Hospital in the East and Morriston Hospital in the West) were not used to purchasing together as one service and whilst the theory was acceptable to the service the author could sense some reluctance in one hospital to cede the purchasing power to a central decision maker. The other challenges facing the project team and the recommendations they made to the PCCB related to ongoing activity and policy making at National level which potentially could help or hinder decision making and implementation. The Welsh National Orthopaedic Board was evaluating joint prostheses for use in Wales as was (and continues to) the Wales National Medical Consumables and Devices Strategy Group. The Welsh National Orthopaedic Board was also making determinations about follow up intervals after arthroplasty surgery which could help or hinder a risk based approach. This drove a decision to do something much more simple (though already seen to be effective) by having the secretarial staff undertake a thorough review of patient notes and post operative follow up bookings status to triage and reduce the post operative 'follow ups not booked' (FUNB). The reality of the FUNB and the 'purge' would mean that resource release from the outpatient clinics would not be seen for some time as the service caught up and got back on track. This however had a benefit in that the national decision making may have completed and the discussions about risk based follow up at national level when the FUNB was back on track. In summary it is clear that no service ever runs in isolation locally or nationally and these issues may not be atypical.

In the ideal world the PCCB decisions about the resource reallocation and disinvestment should have been confirmed at the PCCB, using MCDA and a simple method for prioritisation such as the Portsmouth Score card (ref), comparing the proposals of the MSK PBMA team with other proposals. However the established processes of the HB did not allow for this and the only mechanism for enabling decision making under the 'PBMA ethos' was to prepare a business case proposal in the ABMUMHB template form and use that opportunity to communicate the criteria and rank ordered preferences of the stakeholder groups as the process evolved, the rationale for the proposals and recommendations. The template format for submissions to the PCCB did allow a good opportunity to describe the recommendations for change within budget.

#### *4.7.4 RECOMMENDATIONS FOR RESOURCE REALLOCATION AND DISINVESTMENT*

As described above the project team invited suggestions for reinvestment from the stakeholder group. These ranged around one theme – trying to avert the need for joint replacement by earlier intervention with diet exercise and lifestyle advice and practical support. After consultation with stakeholder groups these ideas very heavily informed by the ESCAPE-pain programme (120) but focussed on a patient population who are obese, rather than just those with knee pain and osteoarthritis were folded into one main programme which was to be developed with the MCAS service as the 'host' and costed out. This is described below.

The programme devised was to be an evidenced based effective intervention for obese patients with knee osteoarthritis. An effective referral pathways was also to be established with the referring health professional as they have a vital role in promoting the benefits to the patient of weight loss and exercise and endorsing the programme as a 'treatment' option. The main features of the programme were to be (in addition to being in line with NICE guidance):

- Community venues preferable to hospital settings for patients. Issues such as accessibility and transport must be considered.
- Delivery led via exercise referral schemes a viable option, but adequate staff training and support to be funded to take on the new challenges of this type of programme irrespective;
- Effective pain management a fundamental component of care to enable the participation in the scheme is vital for this patient group.
- Roll out of this programme addressing:

- Awareness training for referring GPs;
- Links to pain management source;
- Use of special interest GPs who support orthopaedics;
- Links to pharmacy;
- Ensure exercise professionals are aware of all potential community based exit routes for patients as this is a vital aspect of embedding lifestyle change;
- Leisure services need to consider the need for more low impact exercise routes for these patients to progress on to;
- Consider evening/weekend options;
- Addressing literacy levels when continuing to develop delivery mechanisms;
- For the patients requiring more specialised dietary or pain management the option of 'fast track' route to services available;
- Effective methods of feedback to referrers an important part of programme particularly for those patients who still may require evaluation for joint replacement surgery.

In addition further discussion with the national working group rolling out 'Foodwise' programme<sup>15</sup> needed to be undertaken to ensure feedback is incorporated into the revised pack at the time of writing.

The resource release available from the 'certain' sources was estimated to be more than adequate to fund the service meeting the requirements above for a 12 month pilot, starting January 2017 (

Table 4:10).

Table 4:11 a-c shows in more detail how the individual sources of resource release and related funding was to be released transferred from one part of the patient pathway to another.

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<sup>15</sup> 'Foodwise for Life' is written by Public Health Dietitians in Wales (PHDiW) and is an eight week structured weight management programme which focuses on long term weight loss. The programme is delivered by a range of community based staff in settings such as leisure centres, community halls and schools.  
<http://www.cardiffandvaleuhb.wales.nhs.uk/foodwise-for-life>

It was anticipated that at the time of implementation PROMS data collection methodology and supporting software would be in place to enable patient outcomes to be effectively captured and enable evaluation at the end of the pilot period.

**Table 4:10 Initial estimates for resource release and investment required for new service**

	<b>Potential cash or resource release (£)</b>	<b>Formally agreed release (£) August 2016</b>
<b>Resource Released</b>		
<b>Procurement West</b>	131,000	131,000
<b>Procurement East</b>	100,000	
<b>Arthroscopy West</b>	24,000	24,000
<b>Arthroscopy East</b>	44,000	
<b>FUNB</b>	44,000	
<b>Total Release</b>	343,000	131,000
<b>Reinvestment</b>		
<b>MCAS expansion</b>		107,316

**Table 4:11a Detailed financial impact statement for PBMA: Overall**

<b>Items</b>	<b>Year 1 (£)</b>	<b>Year 2 (£)</b>	<b>Year 3 + (£)</b>
<b>Additional Investment Required</b>			
<b>Direct Pay</b>	22,389	85,373	85,373
<b>Direct Non Pay</b>	8,200	12,800	12,800
<b>Capacity</b>	0	0	0
<b>External Provider</b>	13,000	26,000	26,000
<b>Total Cost</b>	43,589	124,173	124,173
<b>External Funding</b>	0	0	0
<b>Disinvestment</b>			
<b>Direct Pay</b>	0	0	0
<b>Direct Non Pay</b>	127,500	255,000	255,000
<b>Capacity</b>	33,069	66,137	66,137
<b>External Provider</b>	0	0	0
<b>Total Disinvestment</b>	160,569	321,137	321,137
<b>Net Impact</b>	(116,980)	(196,965)	(196,965)





**Table 4.12 b: Detailed Activity and Financial Assumptions: Investment estimates**

<b>Investment</b>						
<b>Additional Activity Generated</b>			<b>Year 1</b>	<b>Year 2</b>	<b>Year 3+</b>	
<b>Description</b>	<b>Point of Delivery</b>	<b>Currency</b>				
<b>MCAS Assessment</b>	Community	Attendance	72	288	288	
<b>MCAS Follow Up</b>	Community	Attendance	72	288	288	
<b>Physio Assessment</b>	Community	Attendance	72	288	288	
<b>Physio Follow Up</b>	Community	Attendance	72	288	288	
<b>Dietetics Assessment</b>	Community	Attendance	72	288	288	
<b>Dietetics Follow Up</b>	Community	Attendance	72	288	288	
<b>Physio</b>	Community	Group Session	33	132	132	
<b>MCAS Follow Up</b>	Community	Group Session	13	52	52	

**Table 4.12 c: Detailed Activity and Financial Assumptions: Investment estimates**

Additional Investment Required			Year 1	Year 2	Year 3+	Budget source
<b>Direct Pay Costs</b>			PC&C= Primary Care and Community			
Description	Grade	WTE	£	£	£	
MCAS	8a	0.38	6,274	20,913	20,913	PC&C
Dietetics	Band 7	0.54	6,201	24,805	24,805	PC&C
Physiotherapy	Band 6	0.72	6,929	27,715	27,715	PC&C
Podiatry	Podiatry	0.04	428	1,711	1,711	PC&C
Dietetics Assistant	Band 4	0.12	767	3,069	3,069	PC&C
Weight Loss Coordinator	Band 2	0.36	1,790	7,160	7,160	PC&C
<b>Total Direct Pay</b>			22,389	85,373	85,373	
<b>Direct Non Pay Costs</b>						
Description			£	£	£	
Accommodation			2,500	10,000	10,000	PC&C
Consumables			700	2,800	2,800	PC&C
Set Up Costs			5,000			PC&C
<b>Total Direct Non Pay</b>			8,200	12,800	12,800	
<b>Additional Capacity Required</b>						
External Providers Description			£	£	£	
University Sports Science SLA			13,000	26,000	26,000	PC&C
<b>Total External Providers</b>			13,000	26,000	26,000	

**Table 4.12d : Resource Release and Disinvestment**

<b>Disinvestment</b>				
<b>Activity Avoided</b>	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	
<b>Direct Non Pay Savings</b>				
<b>Description</b>	<b>£</b>	<b>£</b>	<b>£</b>	
<b>Prostheses Procurement</b>	65,500	131,000	131,000	Morrison
<b>Prostheses Procurement</b>	50,000	100,000	100,000	Princess of Wales
<b>Arthroscopy Non Pay</b>	4,420	8,839	8,839	Morrison
<b>Arthroscopy Non Pay</b>	7,581	15,161	15,161	Princess of Wales
<b>Total Direct Non Pay</b>	127,500	255,000	255,000	
	0	0	0	
<b>GA Theatre Sessions (PA)</b>	21	42	42	27 POW / 15 Morrison
<b>OP Sessions</b>	21	42	42	Morrison
<b>Anaesthetic Sessions</b>	21	42	42	27 POW / 15 Morrison
<b>Consultant Sessions</b>	42	84	84	27 POW / 57 Morrison
<b>Capacity Cost</b>	<b>£</b>	<b>£</b>	<b>£</b>	
	33,069	66,137	66,137	28k POW / 38k Morrison

#### 4.8 DISCUSSION

Reflecting on the process and informing development of an ‘ABMUHB specific’ PBMA framework was another objective of the pilot PBMA. The ‘PAR’ approach to experiencing the PBMA pilot process was invaluable and informs the framework proposed in Chapter 5. The interviews that I undertook alongside the progress of the PBMA pilot and informal interactions, discussions at meetings and experience of the process I noted informed the development of the framework. The main learnings from the process are summarised below.

##### *TIME AND RESOURCES*

The PBMA project team did not have ‘protected time’ to drive the project forward. As the health economist undertaking PhD research I was available to the team to support the process with literature review, evidence collection and analysis as there was a vested interest in seeing the project through to completion. However this time (of the order of 20% FTE) of the health economist was effectively provided *pro bono*. The time

of the group decision support expert and the use of the TurningPoint software and handsets was also provided by Swansea University *pro bono*. ABMUHB does not have a health economist nor is there an official arrangement with the University to support the health board with health economics expertise; which for future projects is a considerable concern. Group decision support expertise enabled the prioritising and voting to be a collegiate and positive process and whilst the technology could be purchased by ABMUHB, outside of the University the decision support expertise is not available.

The commissioning lead, administrator and finance team member did have a remit from the health board to support and complete the pilot but the service based staff. In the middle of the PBMA two major events occurred – winter and reorganisation.

Winter is recognised as a pressured time for all health services as events such as influenza outbreaks and snow and ice lead to people being hospitalised. These pressures occupied a huge amount of the service improvement managers time and prevented her contribution to driving the PBMA forward.

Reorganisation within the health board led to considerable impact on the PBMA. At the start of the PBMA MSK was one complete service run by the general manager and the clinical director. The patient pathway from primary, community and secondary care for the whole health board was run in this one service. The service also included rheumatology as well as the surgical services within the secondary care setting. Thus transferring money and resources from acute care to primary care was feasible and culturally more acceptable than if the money had to be transferred from one service's budget to another. This was the perfect setting for a PBMA. Halfway through the PBMA the service was split in to primary and secondary care and also surgical and medical care was split apart within the acute sector. This also had implications for the general manager of the service as he had to apply for a new job, which initially was close enough to the PBMA scope to enable him to be engaged but finally meant that he moved to another health board. The clinical director also changed jobs and became the clinical director of another hospital. This had implications not only for the PBMA recommendations being implemented but it also slowed down progress considerably.

The factors that helped the PBMA make progress was the project administrator who kept all engaged and the commissioning development lead who kept up pressure on the team to deliver

#### *SCOPE*

As mentioned above the PBMA started in the best possible context to evaluate the whole patient pathway and vire money from one area to the other. This allowed the scope to be very wide and indeed look at a whole programme budget. If the PBMA were to start in the current service configuration then the scope may well have been smaller and the outcomes quite different.

#### *PACE*

The project team were able to drive the PBMA process forward to completion but found it hard to move at the pace originally envisaged – hence the extension to the timeline. However the team managed to make their target meetings and get to the stage of making the re-investment decisions and starting to prepare the necessary documents for the PCCB meetings, albeit on a schedule later than envisaged. The reorganisation of the MSK service structures and winter pressures initially slowed things down and then the development of the ‘reinvestment’ programme was quite slow as the negotiations for this had to occur within the primary care services, where the MCAS service sat in the ‘new world’ rather than in the old ‘complete pathway’ MSK services. The process, from start to finish took 18 months rather than the ambitious six month schedule envisaged at the start of the project.

The reorganisation also made it difficult to undertake the interviews planned to the extent originally planned (during the PBMA and after completion) as there was considerable reduction in the project team after the end of the PBMA.

#### *STAKEHOLDERS*

As the PBMA moved forward calling the stakeholder group together for feedback and engagement proved increasingly challenging as pressures of work and because of slow progress inevitable dwindling interest as time went by. As with the project team the stakeholders did not have ‘protected time’ to dedicate to the PBMA meetings so only the most committed to the process and the outcome stayed through the project to the end. Multiple stakeholders included primary care independent contractors who had their own challenges with service delivery and priorities in their primary care practices.

#### *DATA*

ABMUHB is fortunate in having skilled staff with excellent understanding of the in house finance and activity data - a strength of the PBMA. Sophisticated electronic patient data is wide ranging and is theoretically available in Wales. However none of

the data were available to the PBMA. Primary care data - entered into Audit+ in GP surgeries to enable reporting for various service requirements was not available to the PBMA. In effect the data belongs to the practices and the project team would have to make specific negotiations and arrangements via NHS Wales informatics and specific practices to use the data.

Wales has a tremendous resource in the Secure Anonymised Information Linkage (SAIL) data bank (<http://www.saildatabank.com/>) which hosts all of the ABMU primary and secondary care data. This at the time of the PBMA SAIL was being exploited by a company called WePredict who use sophisticated multivariate analytical techniques and interactive visual outputs to inform a health board project.

Frustratingly the SAIL database with its data governance and charges for use was not an option to inform the PBMA with the data and insights that would have been most useful. WePredict were using SAIL and ABMU data sets and delivering analyses for a ABMUHB diabetes project that would also have informed our PBMA (the data being used included exactly the type of patients that the 'reinvestment' service wanted to target) but again the governance around the data use and lack of budget to set up a separate set of informative analyses for the PBMA made that resource unavailable to the PBMA. Additionally the therapy services and MCAS were providing data to SAIL but were unable to access these data lined to other important patient information and have these data analysed to inform the PBMA. Having data resources unavailable to the project was frustrating and highlighted the need for ABMUHB to have in house access to these data resources and 'dashboards' for ABMUHB analytical staff to work efficiently without obstacle to deliver best quality data to a PBMA. Towards the end of the PBMA ABMUHB appointed a senior staff member to lead the development of a health intelligence function and whilst she had good understanding of the issues the project team experienced and knew how to take the issues forward and find solutions, she did not have the time to add the MSK PBMA to her portfolio of work and remained focused only on the anticoagulation services for nvAF PBMA.

Outcomes of the exercise and lifestyle programme would be monitored through a PROMS data collection as it would be a de novo programme. Understanding if there were patient benefits or dis-benefits from the reduction in 'do not do', change in follow up patterns for joint replacement or consolidation of prosthesis procurement are much harder to establish without the commitment and support of the data providers in Wales.

#### *MCDA AND DECISION MAKING*

Using the C4B event gave the team a great opportunity to get the ABMUHB commissioning criteria prioritised for the conditions under which decisions would be made for both PBMA pilots. However the MSK PBMA ended up with a list of disinvestment/resource release options which no one disagreed with and all could be implemented to some degree immediately and could be pursued over time to give additional benefits. Undertaking a MCDA process at this stage did not add value. Equally with a diminishing list of options for reinvestment and complete buy in of all stakeholders to the reinvestment programme that remained, using MCDA methods to decide on this was superfluous. In an ideal world the PCCB might have been making choices between programmes and use an MCDA/Portsmouth Score Card approach to choosing between making savings over all by evaluating the proposed reinvestment option compared with other options open to them and reinvesting in other planned care activities that delivered the most value.

It was clear in the proposal documentation that the process had been shaped by a series of discussions and recommendations prioritised and criteria that were evidence based and balanced by stakeholder input.

#### *RESOURCE REALLOCATION AND DISINVESTMENT*

The PBMA was successful in identifying disinvestment/resource reduction candidates and on the face of it there were ways of implementing the programme. It was clear, during discussions with the orthopaedic surgeons that limiting clinical freedom to have free choice of the prosthesis they wanted for a patient was an issue, especially when the proposed initiative came from one hospital rather than both.

Immediate solutions to the 'do not do' knee arthroscopies probably did not exist according to the orthopaedic surgeon lead on the project team but he felt that savings of resource was feasible, but with giving a set of clear referral criteria for arthroscopy, continuing education of orthopaedic surgeons, individual reflection on practice and regular audit including repetition of the current study in future to determine whether the proportion of cases that are hard to justify, falls over time,

#### 4.9 CONCLUSIONS

The PBMA pilot for the MSK area described here, along with the anticoagulation in AF pilot has informed the development of a PBMA framework (reported in Chapter 5) for ABMUHB which will be adopted as 'a way of working' and refined - based on the



learning from the pilots – and to be further tested in a PBMA exercise in the diabetes area.

The best way of assessing this PBMA in terms of its success as a process for enabling resource reallocation and prioritisation overall is to check back on Tsourapis and Frew's literature review of successful PBMA (59).

- *PBMA was successful in 52% of cases when success was defined in terms of the participants gaining a better understanding of the area under interest; this criterion was met – the scoping, data analysis and fact finding was successful and an insightful process. The evaluation of the NICE 'do not do's' was particularly useful.*
- *In 65% of cases when success was defined as 'implementation of all or some of the advisory panel's recommendations'; this criterion was met as the PCCB implemented the recommendation to put the one year pilot project recommended in place*
- *In 48% of the studies when success was defined in terms of disinvesting or resource reallocation; the disinvestment and resource reallocation programmes were accepted. At this stage it is too early to tell how far implementation has gone .*
- *In 22% when success was defined in terms of adopting the framework for future use". This criterion was met as the PBMA framework is being adopted for future use.*

In their paper Tsourapis and Frew also noted factors associated with success, which were(59):

- Availability of data;
- High level support;
- Size and composition of advisory panel (include clinicians and not too large);
- Implementation friendly' local structure.

The experience of this pilot endorses this message – all of these factors were important and influential. Without high level support from the chief executive office is it doubtful that the PBMA would have got going and/or have competed.

Robinson and colleagues (62), in a paper presenting the issues facing the English NHS – at the time when CCGs, began acting as commissioning bodies - made a clear representation of the issues and challenges which are also are very relevant for Wales.

The authors suggest that; *“Substitution and disinvestment (of less costly services) present considerable challenges;*

- The need to establish agreement over the criteria by which decisions will be taken;
- The need to develop a thorough understanding of the full range of current services and areas of investment and their performance against these criteria;
- The need to manage and negotiate the political hazards and fall out associated with the removal/withdrawal of services;
- The difficulty of implementing substitution and disinvestment in complex systems. The challenges posed by reduced overall budgets also have implications for national bodies such as NICE, which will need to devote greater attention to the disinvestment evidence base that has hitherto been the case”.(62)p145

These points are pertinent to the experience of the MSK PBMA. The agreement of criteria was relatively easy because the values of ABMUHB and commissioning criteria were clear and transparent. The second was accomplished successfully apart from the activity in primary care to add to what the GPs told us. As regards the third it was clear that procurement and reducing the ‘do not do’s would have to be handled with kid gloves as political hazards and fall out were evident risks. Most particularly the last point applied after the service reorganisation was implemented – what had been a unified service with a continuous and contiguous patient pathway was broken up and the patient pathway was split under more than one service.

CHAPTER 5: THE ABERTAWE BRO  
MORGANNWG UNIVERSITY HEALTH  
BOARD PROGRAMME BUDGETING  
MARGINAL ANALYSIS FRAMEWORK

## 5 THE ABERTAWE BRO MORGANNWG UNIVERSITY HEALTH BOARD PROGRAMME BUDGETING MARGINAL ANALYSIS FRAMEWORK

### 5.1 CHAPTER SUMMARY

This chapter describes the 'bespoke' PBMA framework that was developed on the basis of the two PBMA pilots reported in Chapters three and four, talking with participants, with people who had experienced PBMA before and an analysis of the literature.

The collaboration with Abertawe Bro Morgannwg University Health Board (ABMUHB) was based on the promise that I would develop a prioritisation and resource reallocation process that would work for them, based on the 'journey' through the process and relating that to experiences described or published elsewhere. The intention was to come up with a way of enabling the HB and service managers to literally pick up the document and supporting slide set and know what the goals of the PBMA should be and how to go about setting up and driving through the process. This chapter describes the 'modified' PBMA that I developed based on a combination of best practice key steps blended with pragmatism to get the best fit for ABMUHB, the Welsh context and resources available to the LHB and is effectively a tool-kit and written with an HB audience in mind.

### 5.2 INTRODUCTION

As many practitioners will attest undertaking a prioritisation or resource reallocation process in health care is challenging; in the face of these complex decisions all too often organisations do what they think is best or the way things have always been done and rely on political and/or historical resource allocation processes. (72) ABMUHB thought that things could be done better and after discussion and accepting my proposal it enabled the two pilot PBMA that formed the basis of the research reported in Chapters three and four of this thesis to take place from the development of the idea in 2012 through to 2016 when the final outputs were agreed by the planned care and unplanned care commissioning boards.

The PBMA framework was developed based on the knowledge gained in the literature review reported in chapter one. This was in the main the literature on priority setting, resource reallocation, disinvestment and PBMA. I also developed the initial ideas for what the framework might look like based on a series of informal interviews

undertaken with experienced practitioners of these methods in Canada, the UK and Australia<sup>16</sup>. As the pilot project progressed, based on the recommendations of Mitton and colleagues paper on use of interdisciplinary methods in priority setting, (6) I utilised participatory action research (PAR) methods. However I employed this approach not as an embedded researcher, as they suggest, as I was employed by the University all through the period of my research and had a separate job responsibilities there. However I was fully integrated and accepted as a team member and project participant. As suggested by Patten, Mitton and colleagues, (6, 69) in this capacity, I acted as both as a participant - providing specific expertise in health economic and priority setting methods – and as an observer researching the process. I also had informal and formal discussions with the project team and stakeholders and also held a round of specific formal interviews with project team members and stakeholders as the PBMA progressed.

It was clear that the process of delivering recommendations and informing resource reallocation decisions had to be a relatively ‘non-technical process’. Not because the ABMUHB team were ‘non-technical’ – far from it. However the PBMA we envisaged was and should *not* be an academic exercise, leaning heavily on ‘experts from the University’ to deliver the PBMA. It was intended instead to be a ABMUHB ‘way of working’ and thus some of the more complex and refined elements of PBMA could be downplayed if they did not seem vital for the effective delivery of the PBMA or too resource intensive to be delivered in a timely manner and support a sustainable process.

### 5.3 WHY A RESOURCE REALLOCATION FRAMEWORK WAS NEEDED

As described in chapter one, the National Health Services (NHS) in Wales face considerable financial challenges on all parts of the system and the continuing drive to get value from every penny of public money spent on healthcare creates tension with the rise in demand. Need and demand, coupled with an increasingly aging population plus constrained financial resources, has made delivering healthcare in the current model increasingly difficult. The 2015 Welsh Health Survey results (128) indicate the present and future health problems that are prevalent in Wales:

- 51% of adults reported currently being treated for an illness
- 59% of adults were classified as overweight or obese, including 24% obese.

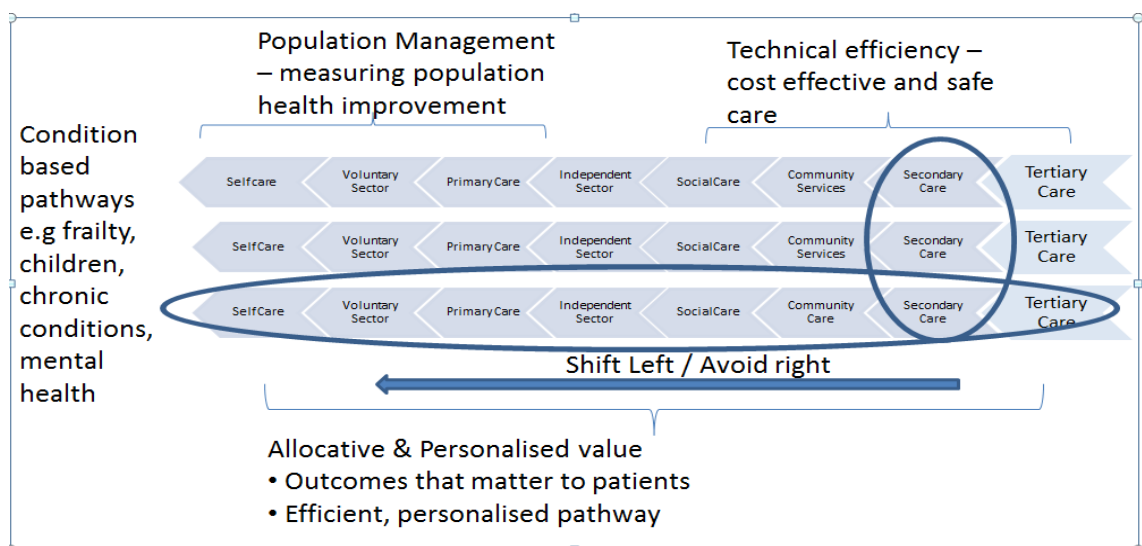
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<sup>16</sup> Cam Donaldson, Danny Ruta, Elizabeth Godwin, Emma Frew, Angela Bate

- 20% of adults currently being treated for high blood pressure,
- 14% for a respiratory illness,
- 12% for arthritis,
- 13% for a mental illness,
- 8% for a heart condition and
- 7% for diabetes.
- 33% of adults reported that their day-to-day activities were limited because of a health problem/disability, including 15% who were limited a lot.
- 19% of adults reported fair or poor general health.

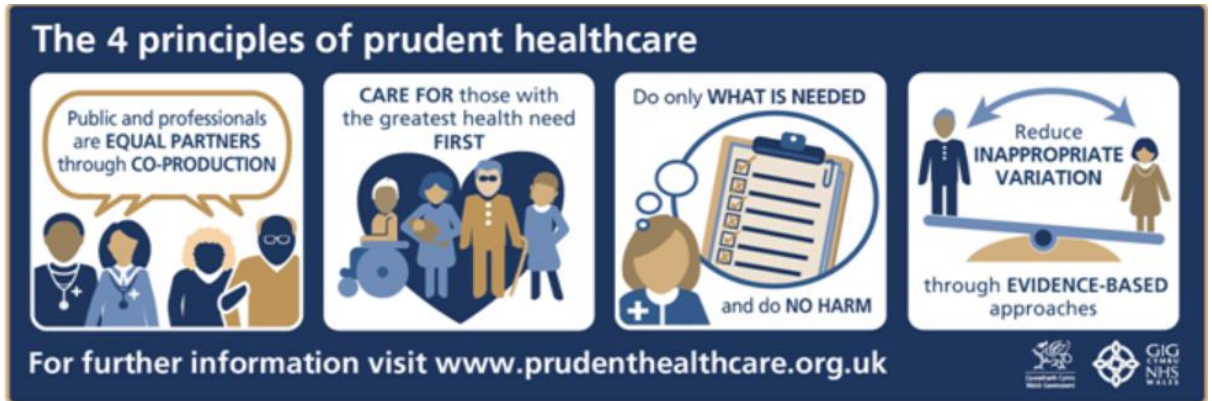
The goals of ABMUHB, in line with Prudent Healthcare (129), are to accomplish a ‘shift left’ to help people avoid hospital admissions and enable co-production as illustrated in Figure 5:1 below.

**Figure 5:1 The drive to ‘Shift Left’**



In ABMUHB steps were taken to address these challenges leading to the establishment of six commissioning boards in early 2015, informed by a Joint Strategic Needs Assessment (JSNA) in September 2015 (111). The objectives of the JSNA was to gain understanding the health issues in the region and inform plans to improve the health of the ABMUHB population. Not only are these drivers important but there was and is also a need to provide sustainable health care services. Given the current economic and political climate and the principles of ‘Prudent Healthcare’ that (61) (Figure 5:2) identified by the Welsh Government and in the context of limited budgets this inevitably means that not all needs will be met and priorities will have to be set for reallocating limited resources.

**Figure 5:2 The Principles of Prudent Health Care (taken from Making Prudent Healthcare Happen: (129))**



The purpose of commissioning in ABMUHB is to balance the competing objectives of meeting population health needs and improve population health outcomes specifying, on the basis of evidence, what services healthcare providers are able to deliver for their local communities, within available budgets.

To support these commissioning objectives ABMUHB needed to establish and implement robust and transparent approaches to priority setting, resource allocation and disinvestment that fit the values and priorities for the organisation and the needs of its and residents, within available budgets.

#### 5.4 HOW ECONOMICS AND PBMA HELP PRIORITISATION DECISIONS

As explained in Chapter 1 the Commissioning Boards wish to allocate resources towards services in a way that optimises health benefits and redirect resources by stopping or reducing provision of interventions and services that deliver little or no benefit to the ABMUHB population.

Economic evaluation has been the mainstay of appraisal of costs and benefits in health care in the United Kingdom. It has perhaps been most developed, as a technical discipline and as a decision tool, in the hands of the National Institute of Health and Care Excellence (NICE), as part of the clinical guideline development process and within the single and multi-technology appraisal processes. Whilst acknowledging the importance of the guidance of NICE, there are issues created by NICE's technology appraisals and implementation often means that an HB has to invest in technologies and services that are more effective, but cost more than the technologies or services they replace or supplement. This means that following NICE guidance is not always the 'the answer' to balancing the books in an HB.

Economists have developed methods to support decision making in such situations and times of constraints such as programme budgeting and marginal analysis (PBMA). This is an economics based framework within which information from economic evaluation has a place, as part of the evidence base, but it also takes account of the need to solve a multi-faceted prioritisation problem. PBMA is a framework that accommodates economic analysis, multi stakeholder inputs, values, needs and perspectives within one framework – balancing health services within a total budget and optimising use of resources. The two economic concepts - opportunity cost and marginal analysis – are at the heart of the framework. Opportunity costs are those health benefits forgone when investment is made in an intervention or service. A disinvestment or service reduction decision releases resources that can, if budgets allow, be fully or partially re-invested.

In order to make a rational (or even a reasonable) decision the opportunity costs and benefits of various healthcare activities need to be examined at the margin. That is the benefit gained from an extra resource unit, or lost from having one unit less in a programme or treatment pathway are identified and then reallocated until the ratios of marginal benefit to marginal cost are equal – maximising patient benefit. For example, the opportunity cost of funding one more hip replacement could be, within a joint replacement programme, a reduction in physiotherapy based rehabilitation services, or across services, reduction in oncology services.

A report from the Bevan Commission (130) suggests PBMA as a rational approach for prioritisation that sits comfortably with the notion of prudent health care. The PBMA approach supports the remit of Commissioning Boards as the approach provides a structure which is able to incorporate the values and goals of the health board and yet is a robust evidence based process in an explicit and transparent framework, supported by a moral and ethical guide: Accountability for Reasonableness,(45) and seeks to ensure that the priority setting process is fair and legitimate. The process is explicit in terms of acknowledging a fixed (programme or sub programme) budget and can enable a fully informed process for optimising the use of resources whilst determining which services can be deprioritized and potentially disinvested in so as to be able to fund and deliver higher priority services to the ABMUHB population.

PBMA has a long history of established use in Canada where it is now established as a prioritisation approach. More recently PBMA has been used in a number of countries and settings, including in Wales - (Public Health Wales in 2011(131) and Betsi



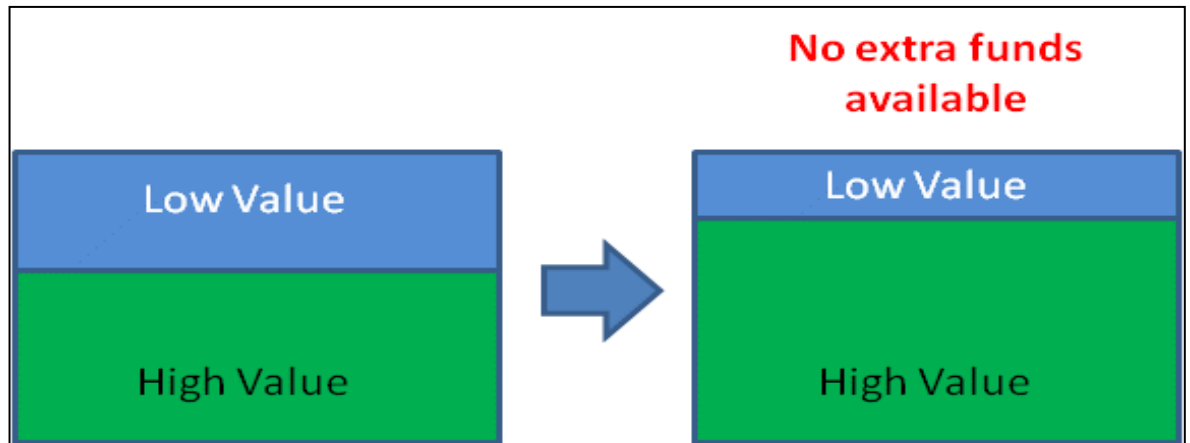
Cadwallader HB in 2013) and in England where PBMA has been used by PCTs for example a review of diabetes (Hull and Bedford), CAMHS (Newcastle), and mental health (Norfolk)(132-134). Goodwin and Frew (40) report on the implementation of a PBMA exercise across acute services within Plymouth. Each exercise was predicated on the assumption that any additional investment would require the identification within the budget of a corresponding resource releasing disinvestment.

This PBMA framework and the guidelines for use are not intended to be an overly prescriptive guide and all PBMA's undertaken by ABMUHB should be planned pragmatically with the context and scope in mind. However the main principles and key steps described here should be adhered to for all PBMA's to ensure that ABMUHB has a consistent transparent, ethical and robust approach.

### 5.5 THE PURPOSE OF PBMA

The overarching aim of PBMA is to get the best value (in terms of outcomes and patient experience) from each programme as a whole for a specific amount of money (Figure 5:3).

**Figure 5:3 Optimising value through resource reallocation**



PBMA takes stakeholders and clinicians through a fully informed process for determining services that could be de-prioritized and potentially disinvested so as to be able to fund and deliver services they consider to be of higher priority. The PBMA framework is systematic, rational, evidence based, transparent and objective framework and engages all stakeholders in the process and decision making.

Clinical judgement, equity, ABMUHB priorities, national targets and principles of prudent health care can all be integrated into the framework.

The process driven by the PBMA framework enables identification of existing costs, patient outcomes and the opportunity to explore alternative - better value - uses of those resources. In order to make a rational (or even a reasonable) decision the (opportunity) costs and benefits of various healthcare activities need to be examined in the context of a programme of care and a budget envelope (programme budget) and changes at the margin (marginal analysis). That is the benefit gained from an extra resource unit, or lost from having one unit less in a programme or treatment pathway is identified and reallocated until the ratios of marginal benefit to marginal cost are equal – maximising patient benefit. For example the opportunity cost of funding one more hip replacement could be, within a joint replacement programme, a reduction in physiotherapy based rehabilitation services, or across services, reduction in oncology services.

The ABMUHB PBMA should be undertaken using the principles of ***Accountability for Reasonableness***(135) described below:

1. **Regulated** (voluntary or public) to be sure that the conditions are met;
2. **Transparency/Publicity**: decisions regarding both direct and indirect limits to care and their rationales must be publicly accessible;
3. **Relevance**: decisions must be supported by reasonable principled, evidence based rationales of how the organisation has tried to accomplish the provision of value for money health care
4. **Revision and appeals**: there must be mechanisms for challenge and change, revising decisions in light of new evidence and arguments

## 5.6 OUTPUTS FROM PBMA

The outputs from the PBMA are presented in the form of progress reports and final recommendations to the Commissioning Boards and it will be these boards who endorse recommendations. These recommendations are likely to encompass doing less or even disinvesting in some services or technologies. These are hard decisions and need to be made on robust evidence, agreed criteria and transparent processes. Robinson and colleagues (62) present the issues facing the English commissioning bodies but their representation of the issues and challenges are very relevant for Wales and should be borne in mind. The authors suggest that;

*“Substitution and disinvestment (of less costly services) present considerable challenges;*

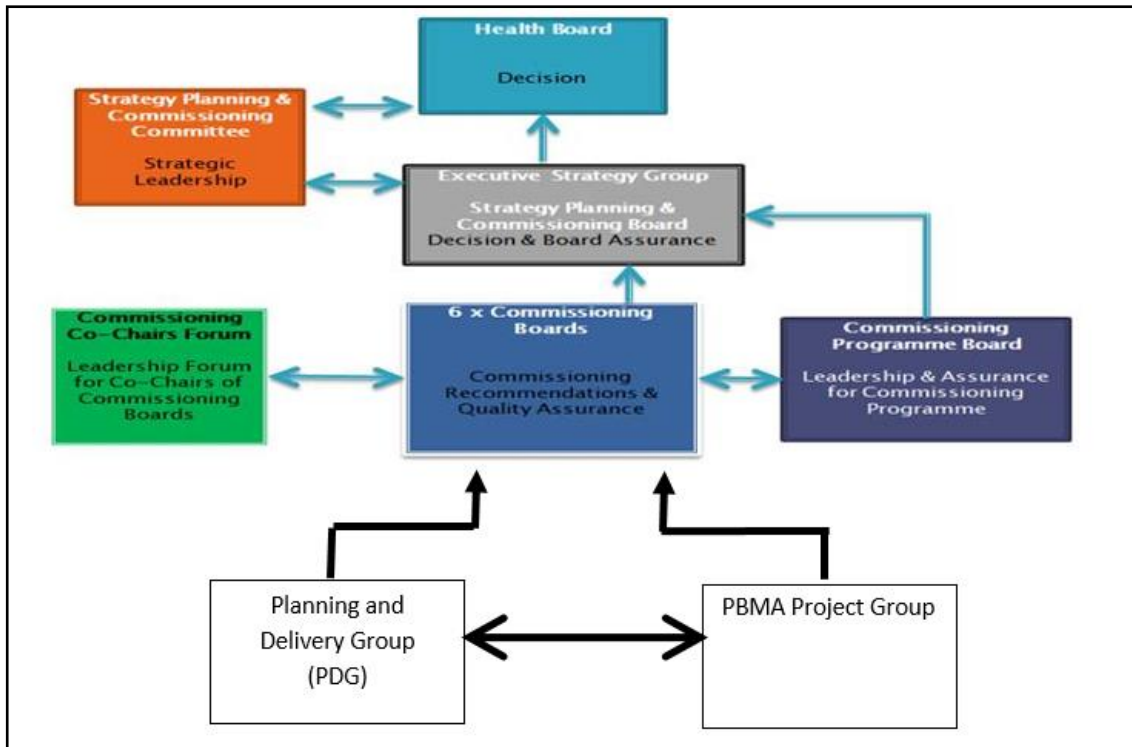
- *The need to establish agreement over the criteria by which decisions will be taken;*

- *The need to develop a thorough understanding of the full range of current services and areas of investment and their performance against these criteria;*
- *The need to manage and negotiate the political hazards and fall out associated with the removal/withdrawal of services;*
- *The difficulty of implementing substitution and disinvestment in complex systems. The challenges posed by reduced overall budgets also have implications for national bodies such as NICE, which will need to devote greater attention to the disinvestment evidence base that has hitherto been the case".p145*

At the end of the PBMA process the commissioning lead supported by the project team will write a proposal based on the PBMA recommendations. Implementation and support for submission to the relevant commissioning board. Figure 5:4 represents the commissioning structure which supports the PBMA process. The initial and interim outputs from the PBMA process are (at least) progress reports etc. to the relevant commissioning board, supporting presentations. The final outcome of the PBMA will be the recommendations within the proposal output endorsed by the Commissioning Board and incorporation of approved proposal into the IMTP as mandatory for implementation (which may require implementation plans to be developed with the service delivery teams).

Figure 5:4 shows how the PBMA project team and the commissioning boards should interact based on the experiences of this PBMA pilot.

**Figure 5:4 ABMUHB commissioning and PBMA project team relationships and structure**



## 5.7 IMPLEMENTING A PBMA IN ABMUHB

Because PBMA methods need to be robust, fit for purpose and not overly complex, the guiding principles used to help devise the ABMUHB PBMA approach were:

- Methods that have been used (and reported) before;
- Relative simplicity of the process;
- Use of decision support methods to support prioritisation and decision making;
- Transparency of decision making (e.g. no black box software);
- Criteria for decision making specific to ABMUHB values and commissioning criteria
- Implementation friendly.

Implementation of the PBMA framework is step wise process; some steps can overlap somewhat but it is essentially a linear process. In theory a PBMA can take between 4 and 6 months depending on the experience of the team, extent of the programme or sub programme under scrutiny and the extent of the information and evidence available. In practice experience suggests 12 months may be needed to allow for evidence collation, and each step to be completed, working in with the commissioning cycle and reporting into Commissioning Board meetings.

The PBMA timeline should take account of planning cycles, decision making meetings and take advantage of specific events which engage with patients and public in order to inform criteria development and relative priorities to enable decision making. The project plan should also take account of pressure points for different teams through the annual cycles and service pressures at different times of the year.

#### *5.7.1 RESOURCES REQUIRED FROM ABMUHB FOR PBMA*

Experience from other PBMA's undertaken elsewhere, described in detail in chapter one and summarised in section 4 above and the two pilots undertaken within ABMUHB suggest that as a process it requires robust leadership and the project team needs to have the following individuals, at a minimum:

- Project manager who is accountable for delivering the PBMA outputs supported by an administrator;
- Representative from finance with sufficient time and seniority to understand the context of the PBMA, utilise the finance data to establish the programme budgets, sub budgets and create reports and forecasts to inform the project team and stakeholder consultations;
- Clinical representation; primary and secondary care;
- Nursing, Allied Health Professionals (who depends on the nature of the PBMA topic)
- Pharmacist(s) depending on topic this could be a pharmacist in the community and/or secondary care and/or prescribing advisors as relevant
- Service manager(s)/service delivery team member;
- information specialists with skills in;
  - rapid evidence review
  - routine data analysis
  - business intelligence
- Health Economist;
- Representatives of patients and the local community;
- Decision support (voting technology and professional expertise);

This is a long list and has to be balanced with the need to have an agile and effective project team. The above list describes a 'core' team but the service area under consideration will inevitably create specific needs for additional individuals to be identified for the team who can contribute their expertise at different times.

The project lead should ensure that the staff time to deliver the PBMA outputs is ring fenced from 'day job' and the supporting resources e.g. any support and data required from sources/staff outside of ABMUHB is defined and agreed up front so that the outputs are not compromised (e.g. support from Public Health Wales, data intelligence and evidence identification and health economics support (currently provided from Swansea University). Each PBMA will have specific demands on time but as a general rule, based on the experience of the two ABM UHB pilots the PBMA will occupy each of these team members at 0.1 to 0.2 FTE per week on average for the duration of the PBMA.

The PBMA also requires the support and participation for a representative group of all stakeholders involved in delivering and receiving the health care services under consideration, community health councils and ideally representatives of the general public. Setting up stakeholder groups and interactions can be PBMA and topic specific but must be addressed.

#### *5.7.2 SELECTING THE PROGRAMME OR SERVICE FOR A PBMA*

The candidate programmes/services for review should be discrete programmes or services and have an identifiable budget area where financial and outcome and activity data are available. These could be a programme or sub programme of services:

- Where it is self-evident that there is a need for some 'shuffling' of investment/saving/areas of service likely to be de prioritised;
- Where ABMUHB is an outlier in terms of costs and outcomes compared with other HBs in Wales;
- That is not politically sensitive or 'owned' by a person who would be hard to bring on board so that implementation stood a reasonable chance;
- Where the key stakeholders are likely to be engaged and support the process;
- where secondary care to primary care shifts could aid in service delivery and meet prudent health care agenda;
- Where access is complicated or less than timely perhaps where there are some out of health board referrals that could be re thought and that could be reversed;
- Where there is some really good evidence for outcomes (maybe even a patient reported outcomes (PROMS) data collection area) for ABMUHB
- Where low value interventions/NICE do not do's/interventions of low value interventions are still in use;

- Where a re-organisation of resources could be scalable;
- Where there could be some reorganisation of the staffing so that non-medical staff can step into some roles thus freeing up valuable (expensive) clinical time;
- Where PBMA has been executed elsewhere so that we can learn and grow from the experience;
- Where disinvestment/resource release can realistically be achieved.

### 5.7.3 *MAKING DECISIONS WITHIN THE PBMA PROCESS*

Sometimes the decisions that are made in the context of priority setting and resource reallocation are obvious and not too difficult to make. This is not always the case. Priority-setting is not always easy; in part because it involves values as well as evidence. People engaging in the PBMA process have to make priority decisions. They either have to allocate new resources, reallocate existing resources, which may have been subject to a reduction from previous levels or disinvest. In addition to evidence, judgement is required, which requires both technical skills to appraise the strength of evidence, and ethical insights. The ethical consideration is very important; funding something whether or not it is considered to be of high priority, means something else will not be funded. Priority decisions therefore are technical, ethical and social, in that patients, communities and population groups will be affected to some degree.

These complex decisions with many factors that need to be taken into account – decisions such as PBMA stakeholders and ultimately Commissioning Boards may be faced with when undertaking resource reallocation – can be deconstructed to identify what criteria are important and their relative importance in a transparent and consistent way. The criteria can then be used to inform and support decisions about which services to prioritise and deprioritise.

There are ways to support decision making processes and one well established and theoretically robust method called multi-criteria decision analysis (MCDA) can be used in PBMA to help make decisions where they are complex and multifaceted. Participants in this process use all available information and value judgements to make decisions about resource allocation. The process makes explicit the impact on the decision of all the criteria applied and the relative importance attached to them.

A recent review of the use of MCDA in health care decision making (35) and a monograph 'Incorporating Multiple Criteria in HTA' produced by the Office of Health Economics (36) plus the EVIDEM framework all informed the development of the



MCDA processes that can be used in the ABMUHB PBMA Framework. The approach being used for MCDA in the ABMUHB PBMA is a scoring system, like the Portsmouth Score card(80), rather than a complex process, requiring software support for example the socio-technical allocation of resources - STAR - approach(136).

The EVIDEM (**E**vidence and **V**alue: **I**mpact on **D**ecision-**M**aking) Collaboration(38) is an independent non-profit organization run by an international Board of Directors to promote public health by developing efficient multi criteria decision making (MCDA) based solutions to healthcare decision making and priority setting<sup>i</sup>. The Collaboration has developed a pragmatic decision making and priority setting framework in order to:

- Consider all aspects of decision;
- Support consistent deliberative process;
- Share decisions transparently;
- Rank and prioritize interventions based on their contextual value.

The EVIDEM framework (137) represents best practice for prioritization in health care decision making and has clear definitions of important criteria for developing prioritisation frameworks. This is the framework for decision making that the ABMUHB PBMA will use.

The PBMA framework assumes that higher rank/weightings/priority that should be given to some of these criteria when thinking of investment and then the criteria/weights can be 'reversed' for the disinvestment process. Based on work undertaken by others and summarised by the EVIDEM initiative(37, 39) It is likely that there are two levels of criteria for decision making that needed to be agreed;

#### **5.7.3.1 Contextual criteria**

- **Utility** - Goals and Values of ABMUHB/Prudent Health Care/Welsh NHS considering (mis)alignment of intervention with the mission and scope of the ABMU/Prudent Health Care/Welsh NHS and policy imperatives
- **Fairness** - Population priorities and access of ABMUHB/Prudent Health Care/Welsh NHS : considering alignment of intervention with priorities
- **Efficiency** - Opportunity costs and affordability considering actual financial impact of intervention and need to disinvest other services (opportunity cost)
- **System capacity and requirements:** considering requirements to implement intervention (e.g., skills, organisation) and capacity to ensure proper use

- **Pressures/barriers from stakeholders:** acknowledging these aspects to address them and ensure that the decision is aligned with mission and scope
- **Political and historical context:** considering overall context (e.g., cultural acceptability, precedence).

Another criterion is also important: **Environmental impact** of the intervention considering whether the potential environmental impact related to the intervention under scrutiny will affect the decision. There are other criteria which are more 'detailed' and more specific to the ABMUHB context. These criteria, below, are mostly taken from the EVIDEM framework, but also from other frequently used criteria from the PBMA and MCDA literature cited above (138, 139) - EVIDEM call these normative<sup>17</sup> universal criteria.

- Severity of disease
- Burden of disease
  - whether a common disease
  - disease with many unmet needs
- Increases accessibility/balances geographic distribution
- Addresses health inequalities
- Ability to effect timely implementation
- Recommended in guidelines by experts/on the NICE do not do list (or other stop doing/low value lists)
- 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/perceived health over standard of care
- Strength and quality of evidence of achievable health outcomes
- Either prevention of ill health or conferring major risk reduction or major alleviation of suffering; NB this allows consideration of both preventive and alleviating interventions, without giving a priori priority to either one
- That results in savings in treatment expenditures as well as other medical and non-medical expenditures,
- Other economic impact:
  - Is cost-effective (established by falling below lowest NICE threshold?)

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<sup>17</sup> I.e. a value judgement

- Affordable/Reasonable cost per patient/acceptable budget impact.

### **5.7.3.2 ABMUHB Criteria to Support Decision Making**

The MCDA process begins when the stakeholder group agrees the overarching criteria for the decision making and the list of candidate reduce/disinvest service/interventions agreed for appraisal and all the epidemiology, clinical, economic, health outcomes and financial data (that are available) are summarised to enable the project team, stakeholders and Commissioning Boards to see what outcomes may be sacrificed and what pot of money has been created to redistribute. Some 'rules' on reductions and redistribution should be decided prior to the MCDA rather than after to enable unbiased decisions. These could simply be split as follows:

1. % put towards savings (to help meet any savings target)
2. % returned to the sacrificial part(ies) to spend on a 'project' in their own investment list (the 'Danny Ruta'<sup>18</sup> method)
3. Balance goes for re-investment

MCDA is utilised only for disinvestments and investment decisions.

As well as using best practice and recognised criteria for making recommendations and decisions in the PBMA process it is important to use relevant and local values and criteria for ABMUHB. ABMUHB values are shown in Box 5:1 and the ABMUHB commissioning criteria are laid out in

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<sup>18</sup> Advice received from Dr Danny Ruta based on his PBMA experience

Table 5:1, below.

**Box 5:1 ABMUHB values**

*Caring for each other* through improving experience, *working together* through involving patients and staff and *always improving* through seeking out and using evidence of best practice.

**Table 5:1 ABMUHB Commissioning Criteria**

<b>Criteria</b>	<b>Description</b>
<b>Fairness</b>	Demonstrates that different clinical conditions, treatment and patient groups are considered equally and without preference e.g. equal consideration to Cancer and Diabetes patients or older people and working age adults
<b>Inequalities</b>	Demonstrates that inequalities in access to healthcare and the potential to achieve positive health outcomes between different groups within ABMUHB is addressed, in particular for our most deprived communities e.g. targeting services within deprived communities
<b>Evidence of clinical effectiveness</b>	Demonstrates that the proposal is based on evidence that the treatment or intervention is considered to be clinically effective by trust worthy professional bodies
<b>Value for money/cost effectiveness</b>	Demonstrates that the outcomes and improvements that will be delivered are equal to the cost of the investment, delivering good value for money and evidence of being cost-effective
<b>Strategic fit</b>	Demonstrates the proposal has a strong fit and alignment with current national and local strategies, policies and priorities
<b>Disease burden</b>	Demonstrates delivery of benefits and outcomes which positively affect a significant proportion of our local population so as to create a meaningful impact on the burden of disease we experience
<b>Outcomes</b>	Demonstrates delivery of demonstrable improved health outcomes, including preventing ill health, reducing risk to health and alleviating suffering
<b>Patient experience</b>	Demonstrates that available evidence on the impact of any changes on patient experience or satisfaction have been taken into account and that improving patient experience can be demonstrated as an outcome
<b>Standards of care</b>	Demonstrates delivery of relevant quality standards or other markers of high quality healthcare, and addresses unacceptable variation in quality of care across ABMUHB
<b>Reducing Harm</b>	Demonstrates that the intervention will not cause harm and/or will reduce harm currently experienced and/or will cease/reduce delivery of interventions that deliver no impact (approx. 20%)

To aid the decision making process, to give more rigour and ease of use we are able to use decision support methods and technology to facilitate decision-making at various stages during the process. The TurningPoint™ technology<sup>19</sup> is a voting system that employs voting software, and a set of wireless handsets which exports results to MS Excel and MS PowerPoint This approach enables parallel, usually simultaneous and anonymous individual inputs, generating a group outcome that can be accessed and displayed in various ways at the meeting or later(81). Research into specific features of this form of group decision support has reported gains in meeting efficiency (82), improved levels of participation and a reduction in potentially negative influences from dominant members of the group (83).

Having defined the overarching criteria which should be related to ABMUHB values, the PBMA criteria are used, as follows, to drive the decision making processes:

1. Undertake a process of weighting criteria relative to each other;
2. Rank criteria or scoring from 1-10 or 1-100 within criteria;
3. Calculating weighted scores within criteria (check plausibility, consistency and agreement);
4. Combine overall weighted scores;
5. Check that this all is reasonable, discuss, and agree.

The TurningPoint® technology supports and facilitates these steps.

To finalise the criteria, make decisions about what to reduce or not provide and before re investing or realigning with available budget and then agree process is no small task for the PBMA process, but critically important. Achieving consistency and alignment with ABMUHB values for the core criteria is important to make sure that decisions are 'reasonable' and 'transparent'.

#### *5.7.4 PBMA PROJECT PLANNING*

Experience in the ABMUHB pilot projects suggests that the project timetable should be laid out in advance with types of meeting, key meeting dates and required participants in meetings established, so that availability can be assured. A similar approach should be taken for the Stakeholder group and any other consultation exercises. A sample timeline is provided in Table 5:2 below.

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<sup>19</sup> <http://www.turningtechnologies.co.uk>

**Table 5:2 The ABMUHB PBMA implementation steps and pragmatic timeline**

<b>ABMUHB PBMA Main Steps</b>	<b>12 month PBMA (months to completion)</b>
<b>ORGANISATIONAL READINESS</b>	
Pre-set up phase: <ul style="list-style-type: none"> <li>• Pre-work to assess the knowledge and training required by stakeholders and others who will be engaged in or support the PBMA process. This could include scoping the service area/programme, assessing local evidence, data availability and usability ensuring resources (people, time, knowledge, health board and service resources) to engage in the process and to follow through the whole process are available.</li> <li>• Discussions with senior leadership to engage support for the PBMA and take guidance on any sensitivities or issues.</li> </ul>	T= -6
<b>Informative meeting:</b> <ul style="list-style-type: none"> <li>• <b>Hold a meeting of an extended group of all potentially interested parties, stakeholders and project team members to explain what PBMA is, how it is intended to benefit the stakeholders and ABMUHB and what the process is.</b></li> <li>• <b>Establish who the interested participants are and how they can contribute and invite to join the process.</b></li> </ul>	T=-4
<b>SET UP</b>	T=0
<b>1. Finalise service area/programme for PBMA and required timeline for intermediate and final outputs</b>	T=0
<b>2. Appoint chair and project team, ABMUHB project lead and project team members</b>	T=0
<b>3. Refine aim and scope of PBMA</b>	T=1
<b>4. Identify and recruit any additional skill or knowledge areas required for project team and invite to join PBMA. Identify any senior support required.</b>	T=1
<b>5. Identify and recruit all stakeholder group and recruit participants</b>	T=1
<b>6. Set up timelines to achieve target milestones to fit with stakeholders, commissioning cycle, key 'Changing for the Better' patient events and any other ABMUHB and public events where engagement with patients, public and stakeholders can be accomplished and ensure timelines fit around finance team commitments and financial cycles.</b>	T=1
<b>7. Communicate widely to relevant parties in particular the PBMA project, timelines, key meetings, the what and how and when outputs can be expected</b>	T=1
<b>IMPLEMENTATION</b>	
<b>8. Compile programme budget for services under evaluation</b>	T=3
<b>9. Establish evidence for outcomes of existing services/interventions under consideration and all other pertinent evidence such as effective clinical governance</b>	T=3
<b>10. Determine relevant PBMA decision criteria (in line with ABMUHB values) with stakeholders using group decision support methods to achieve consensus, rank ordering and weights</b>	T=4
<b>11. Communicate outcome of 8, 9 and 10 above</b>	T=4
<b>12. Identify OPTIONS for resource release/service growth with substantiating evidence and present to stakeholders for</b>	T=5

ABMUHB PBMA Main Steps	12 month PBMA (months to completion)
<b>feedback in agreeing relative priorities (with group decision support available to assist discussion)</b>	
13. Establish evidence for outcomes of ALTERNATIVE services/interventions under consideration and all other pertinent evidence such as effective clinical governance	T=7
14. Share evidence summaries and financial data, resource used or likely released for all services/intervention under scrutiny in the most useful and appropriate way for the stakeholder group (e.g. evidence booklets, presentations, key papers, NICE/AWMSG guidance)	T=9
15. Identify options for options to use released resource, capacity or finance and ability to move resource or funds across services areas. With supporting evidence present to stakeholders for feedback. Use decision support tools and methods to assist in agreeing relative priorities according to the pre agreed criteria. Evaluate investments and disinvestments, the resource reallocation/costs and health outcomes impacts of change plus implementations costs and benefits.	T=10
16. When priorities for 15 agreed develop proposal for review with appropriate stakeholder groups to validate outcomes of 13.	T=10
<b>DELIVERY</b>	
17. Submit validated proposal with evidence to commissioning board for ratification and consequent inclusion in IMPT	T=11
18. Implementation plan developed by service delivery team based on IMPT and reviewed and signed off by commissioning board with referenced to PBMA project team	T=12
<b>REVIEW</b>	
19. In 12-24 months post IMPT issue review service/intervention changes to understand how far expected costs and benefits are being realised and if not why not and what remedies are required (at what cost)	T=24/36



## 5.8 MAKING SURE THE PBMA IS SUCCESSFUL

Considerable time and effort goes into working through the PBMA process and the decisions and implementation of a PBMA are intended to benefit the ABMUHB population. It is worth thinking about what factors are key to the successful implementation of a PBMA. Usefully these factors are summarised in a literature review by Tsourapas and colleagues. (59) Key factors for success from this review are:

- Availability of data;
- High level support;
- Size and composition of advisory panel (include clinicians and not too large);
- Implementation friendly' local structure.

It is worth bearing in mind that the most important factor related to success is implementation (a decision is no good without execution) and accomplishing the task of making the reduction or disinvestment and the subsequent reallocation.

Learning from the PBMA Pilots it is important to understand how easy or difficult it is to transfer funds and/or resources across service areas and settings.

## 5.9 CONCLUSION

The PBMA process described here is based on the key elements of best practice as evidenced in the literature, informal discussions with people who have had experience of implementing PBMA and most relevant for the framework proposed here, working hard to understand what was needed for ABMUHB and what was possible (and impossible) to achieve. The original framework devised then tested and adapted through the experience of undertaking two pilot projects within ABMUHB.. The final version as described here was characterised using careful reflection of observations of the process of the pilot projects and the experiences of the participants, collected through formal interview and informal discussions. The combination of these inputs has served to create this 'pragmatic and prudent' PBMA for ABMUHB.

With each PBMA the participants and the health board will learn more and thus this framework is not set in stone – rather it will be an evolving process where what the participating teams do each time is fit for purpose, and builds on PBMA experience - but is always robust, fair and in line with the principles of Accountability for Reasonableness.

# CHAPTER 6: DISCUSSION AND CONCLUSIONS

## 6 DISCUSSION AND CONCLUSIONS

### 6.1 CHAPTER SUMMARY

This chapter revisits the aims of the thesis, bringing together an overall summary and discussion of findings from chapters two, three and four with specific focus on evaluating the success or otherwise of the three projects. It will then provide a critical reflection of these findings within the context of previous research in order to demonstrate what the thesis adds as an original contribution. The impact of the research will be outlined, including further research questions to be addressed. It is a 'bringing together' of the three projects and the framework developed for ABMUHB. Finally I propose further research and conclusions that can be drawn from this research overall.

### 6.2 AIM OF RESEARCH

This aim of this thesis was to develop ethical, equitable, systematic frameworks and associated methods to support HBs and Welsh Health Specialist Services Committee (WHSSC) and ultimately the NHS in Wales to promote and enable rational healthcare priority setting in the context of Prudent Healthcare. The research programme was intended to deliver frameworks for implementation beyond the completion of the PhD research.

The research was then pursued through the development and implementation of three projects;

4. Redeveloping and delivering a framework for prioritisation of HSTs in Wales;
5. Developing and delivering two Programme Budget Marginal Analysis (PBMA) pilot projects; one in unplanned care and the other in planned care;
6. Developing a PBMA framework that is operational in ABMUHB as part of commissioning programmes.

### 6.3 SUMMARY OF FINDINGS

This thesis reports on the methods, processes and outputs of the three separate research projects and how I provided the NHS organisations, with which I collaborated, two evidence based and methodologically robust frameworks for prioritisation. I provided ways of working with those frameworks - summarised below - to support ongoing priority setting and resource allocation within the NHS organisations:

1. For WHSSC : an MCDA based approach to prioritisation based on the Portsmouth Scorecard approach and group decision support methods (using TurningPoint™ software and an experienced facilitator) to facilitate the process;
2. For ABMUHB: a PBMA framework (see chapter 5) supported by group decision support methods (using TurningPoint™ software and an experienced facilitator) to ease the process.

The three projects themselves provided outputs and prioritisation and resource allocation decisions.

### 6.3.1 WHSSC

In the case of WHSSC, using the Portsmouth Scorecard, a simple MCDA method plus group decision support, was used for prioritisation. This approach makes explicit the impact of all the criteria applied on the decision and the relative importance attached to them. The project delivered recommendations for the Joint Committee, improved the process for the Prioritisation Panel and allowed the panel to review and progress around eight condition treatment pairs in one six hour panel meeting. These processes developed over the time I collaborated with WHSSC and adhered to good practice, as described by the EVIDEM framework. However the true test of the process and the Prioritisation Panel recommendations will be for WHSSC to overcome the internal political challenges to implement recommendations through the Joint Committee.

Hopefully the changes in senior management after the turbulent times towards the end of my project with WHSSC will support more timely decisions at the Joint Committee. Ultimately with the accumulation of more decisions from the Joint Committee , based on the Prioritisation Panel recommendations, WHSSC can undertake a review of the decisions, compared to the recommendations from the panel to assess consistency

This first output was a success in that the framework was usable; the disappointing element was that only 50% of the recommendations based using the methods were implemented. However, this is broadly in line with the published literature on implementation of prioritisation decisions covered in chapter one. Until these implementation barriers are overcome the framework is not making a substantial difference to patients in Wales. The stark reality of how personalities and politics affects decision making and delivery of health care is reported in the literature (70, 140) (40) and discussed in this chapter, but the reality of these during this project was

nevertheless surprising to me given the opportunity cost impact of HSTs, the impact on the NHS budget and on individuals where the evidence supporting positive outcome is poor.

### 6.3.2 ABMUHB

The PBMA pilot projects for the MSK services and the planned care commissioning board and anticoagulation in AF pilot have informed the development of a PBMA framework for ABMUHB which will be adopted as 'a way of working' and refined from the published literature on PBMA based on the learning from the pilots – and further tested in a PBMA exercise in the diabetes area.

The best way of assessing these pilot PBMA's in terms of their success as a process for enabling resource reallocation and prioritisation overall is to reflect back on Tsourapis and Frew's literature review of what defines a successful PBMA (59). Tsourapis and Frew's definitions are in italics and the status of the pilot PBMA's in comparison in normal text.

- *PBMA was successful in 52% of cases when success was defined in terms of the participants gaining a better understanding of the area under interest; this criterion was met – the scoping, data analysis and fact finding was successful and an insightful process.*
- *In 65% of cases when success was defined as 'implementation of all or some of the advisory panel's recommendations'; this criterion was met as the PCCB implemented the recommendation to put the one year pilot project recommended in place and the UCCB brought the findings of the PBMA into the redesign of the stroke pathway.*
- *In 48% of the studies when success was defined in terms of disinvesting or resource reallocation; the disinvestment and resource reallocation programmes were accepted.* At this stage it is too early to tell how far implementation has gone but the decisions were made that might enable implementation to be accomplished.
- *In 22% when success was defined in terms of adopting the framework for future use".* This criterion was met as the PBMA framework is being adopted for future use.

In their paper Tsourapis and Frew also noted factors associated with success, which were:

- Availability of data;
- High level support;
- Size and composition of advisory panel (include clinicians and not too large);
- 'Implementation friendly' local structure.

The experience of the pilot PBMA projects endorses these criteria – all of these factors were important and influential. Without high level support from the chief executive officer of ABMUHB is it doubtful that the PBMA pilots would have got going and/or have been completed. The advisory panel was comprehensive and inclusive of all relevant stakeholders and initially well attended. The local structure initially was very implementation friendly as it covered the entire patient pathway, but by the end of the project it was less so as the pathway was split across different sectors.

I also draw on the findings of Angell and colleagues who have recently (2016) published an insightful paper on implementing priority setting frameworks.(140) The researchers undertook a targeted survey of 18 leading researchers in the field of priority setting and resource allocation, exploring their experience of implementation and evaluation of these exercises. It is salutary to review their overall findings.

*“Approximately one third of respondents knew of situations where recommendations of priority-setting exercises had been implemented, one third knew that recommendations had not been implemented and the final third responded that they did not know whether recommendations had been adopted. The lack of evidence linking the implementation of priority-setting recommendations to equity and efficiency outcomes was highlighted by all respondents. Features identified as facilitating successful implementation of priority-setting recommendations included having a climate ready to accept priority-setting, good leadership or a ‘champion’ for the priority-setting process and having a health economist to guide the process. Successful disinvestment was very uncommon in the experience of the researchers surveyed. Recommendations emerging from Program Budgeting and Marginal Analysis exercises appeared to be more widely implemented than those coming from alternative processes. Identifying if the process was repeated following the initial process was suggested as a means to measure success”.(140)*

The use of PBMA and the framework have been adopted by the commissioning teams in ABMUHB and a PBMA is being initiated in the Diabetes area. The strategy lead for the area is responsible for ‘owning’ the process and the MSK PBMA is considered to be an example of good practice in the delivery of Prudent Healthcare by the Welsh Government. The lead is The Head of Commissioning Development in ABMUHB and is driving the use of framework as a ‘way of working’ in ABMUHB. Thus the output from the PBMA pilots can also be considered to be successful by a number of descriptions of success.

The journey we all undertook to deliver these outputs was as vital as actually getting there. Understanding how the HB works, how the staff and the project team members in their various roles interacted and what motivated them to engage in the process was important for the success of the prioritisation and resource allocation projects. Being able to create a PBMA based framework that was a meaningful and useful roadmap for teams in the HB to use and 'own' PBMA as a process required the understanding that I gained over time.

Understanding the language of the health board and the problems associated with explicitly speaking of 'disinvestment' was an early learning point for me. Resource reallocation as a term rather than disinvestment was the only way I could communicate the act of doing less or stopping an intervention or service of low or no value that people felt comfortable with.

#### 6.4 DISCUSSION OF FINDINGS

This research was intended to research and develop ethical, equitable, systematic frameworks and associated methods to support HBs and Welsh Health Specialist Services Committee (WHSSC) and ultimately the NHS in Wales to promote and enable rational healthcare priority setting and resource reallocation as an integrated part of (prudent) health care policy making.

Reflecting on the three projects, it seems reasonable to conclude that using the simple economic concepts of scarcity, opportunity cost and the margin to enable prioritisation and resource reallocation (including a disinvestment decision) and using multi-criteria decision analysis (MDCA) and group decision support helped to facilitate the process and the outcome. But it is necessary but not sufficient to have good tools and robust theory. The tools can solve problems but do the people who have the responsibility and want the problems solved and actually deliver the solution? For the teams I worked with the answer is yes; for the leaders of one of the organisations - WHSSC - the answer was probably no, in the case of ABMUHB a cautious 'sit on the fence' strategy was employed and then when the pilots looked set for success a yes and authoritative support for PBMA.

In each of Chapters three, four and five I have discussed in detail the research in the context of each project and the outputs. Here I draw together the threads from each project together and discuss the common themes in relation to the aim of this research.

##### 6.4.1 *SHOULD PRIORITY SETTING AND RESOURCE ALLOCATION BE DIFFERENT FOR HSTS?*

NICE evaluates HSTs that are medicines separately from the 'normal' assessment and appraisal processes and employs a special HST process. There are criteria for accepting higher incremental cost-effectiveness ratios for these HST medicines over conventional therapies that do not go through this process and the threshold for acceptance is higher, much higher. Box 6:1 contains a quote from a press release from NICE in October 2016 which makes it clear that a higher threshold than the 'commonly accepted' threshold of £20,000 - £30,000 per QALY gained could be exceeded for HSTs(141).

**Box 6:1 The potential 'acceptable' incremental cost per QALY for HSTs taken from NICE website October 2016 (141)**

NICE and NHS England are also consulting on a proposal to introduce a cost effectiveness level of £100,000 per QALY for NICE's Highly Specialised Technologies (HST) programme.

The programme, which looks at treatments for very rare diseases that are commissioned nationally by NHS England, currently does not have a cost effectiveness level.

The proposed level is five times the usual cost effectiveness level used by NICE. Drugs that exceed the level will still be considered for funding by NHS England when prioritised alongside other drugs and treatments for rare conditions.

In 2012 Linley and Hughes published their study exploring societal preferences for HST drugs and drugs eligible for the Cancer Drug Fund in England as it stood at the time(84). The authors conducted a choice-based experiment with 4118 UK adults via web-based surveys. Preferences were determined by asking respondents to allocate fixed funds between different patient and disease types reflecting nine specific prioritisation criteria. Respondents supported using the criteria of "*severe diseases, address unmet needs, are innovative*" provided the drugs offered substantial health benefits, and had wider societal benefits but did not support criteria of "*the end-of-life premium or the prioritisation of children or disadvantaged populations*" nor did they support the special funding status that prevails even now for treatments of rare diseases, nor the for the cancer drug fund. Linley and Hughes suggest that "*policies introduced on the basis of perceived—and not actual—societal values may lead to inappropriate resource allocation decisions with the potential for significant population health and economic consequences*".(84)

Bearing this survey in mind – the findings of which do not seem to have been superseded – the case for integrating the WHSSC and Joint Committee recommendations and decisions into a PBMA process at national level with the HBs seem to be an important next step as there seems no case for making HSTs a special case for being funded disproportionately(84). As mentioned in chapter 2, Claxton and



colleagues (48) draw attention to the opportunity cost of funding interventions with high costs can be higher than the interventions they displace.

However the established 'separation' of decisions for HSTs from 'the rest' seems established in the teeth of the evidence that this does not reflect the public view. I have proposed that the prioritisation process undertaken by WHSSC might be a first step in a chain of prioritisation activities that culminates in a PBMA in the National programmes of care that encompasses the management of people with conditions for which HSTs are an option. However I recognise that this may be politically indigestible. Whilst I propose that the prioritisation process undertaken by WHSSC might be a first step in a chain of prioritisation activities that culminates in a PBMA in the National programmes of care that encompass the management of people with conditions for which HSTs are an option. This may be politically indigestible.

#### 6.4.2 POLITICS AND PERSONALITIES

The situation in WHSSC was highly charged, with the high commitment of the project leaders for the prioritisation of HSTs - having over 60 years of health service experience between them - clashing with the fierce opposition displayed by at least one of the other Executives. Angell and colleagues (140) in their paper comment on the politics and factors hindering priority setting and its implementation – the emphasis in bold is mine:

*A number of respondents noted that when a priority-setting process has sought to take resources away from an area and to do so explicitly and transparently, this 'disinvestment' process often floundered. These decisions, as one observer put it, 'are much easier when they are obscured and shrouded rather than open and transparent.' This interesting relationship between the importance of prominent leadership and the transparency of the process was also highlighted by Mitton: **'In one case, one CEO backed away from implementation because despite there being support from senior managers he wanted a less transparent process . . . because he didn't want anything pinned on him.'** Mooney reported on a similar situation which arose in an Area Health Service in New South Wales (Australia) where the CEO, having had the Area Health Service staff complete a PBMA exercise and with solid recommendations, called in NSW Health who then ignored the study recommendations and cut X% across the board. **The CEO did not want to be seen in the local community to be responsible for the cuts.** Mooney adds that there may be an optimal distance between cuts and making decisions about cuts—and it is 'not up close.'*

It seems that humans when in positions of health service 'power' exhibit common behaviours that have been reported in other health care systems such as Canada and Australia.

In ABMUHB, I, together with the Head of Commissioning development 'sold' the concept of PBMA to the chief executive officer of ABMUHB. The theory and methods were definitely viewed with positive intent and a letter of support for the pilots was issued to those who were being asked to participate, but it remained for the PBMA pilots to deliver useful outputs before commitment to the framework became firmer at senior level. This seems quite reasonable. But this is the classic 'which comes first – the chicken or the egg?' situation. Do you need the leadership support first to make the prioritisation framework successful or can it be successful in a vacuum? Once again Mooney and colleagues have something useful to say on this topic in their review of priority setting;(70)

*"Introducing a new explicit priority setting system can be threatening to certain parties within the system and there needs to be recognition of this. The adage that information is power is true here and making priority setting explicit can threaten to usurp the power of existing decision makers. This is no easy matter to handle but it is here that first class leadership is needed to try to gain the necessary 'buy in' from those parties who otherwise might feel threatened.*

All three of the projects that form part of this thesis had clinicians leading the prioritisation process – this was established in WHSSC not only because the one of the project leaders was a clinician, but also because of his extensive experience in public health and exposure to various priority setting initiatives. All the advice I received in the scoping phase of preparing the proposals for the ABMUHB pilots directed me to proposing clinical leadership for the PBMA's. This was also noted in Mooney and colleagues in their report on priority setting methods(70):

*"Finally there needs to be leadership in implementing any priority setting system – champions for efficiency and equity... One is within the clinician community itself. That body is much more likely to listen to one of its own"(p 17)(70)*

#### 6.4.3 THE MERITS OF PBMA

**Revisiting Mooney and colleagues' papers on priority setting methods to inform prioritisation decisions (70, 140) suggest that, at whatever level in the health care system it may occur, the PBMA approach meets the essential and desirable criteria. The proposed key criteria and methods for priority setting frameworks are shown in**

Table 6:1(70).The authors derived their recommendations from the review of the literature they did for the Sax Institute report on priority setting.(70) The assessment made by the authors shows how well PBMA meets the criteria. Given the similarity between the health care systems we can substitute UK or Wales for New South Wales in Australia (the setting under consideration by the authors) without any loss of validity of the criteria. In this assessment PBMA 'ticks all the boxes'.

**Table 6:1 Essential and highly desirable criteria by approach taken from Mooney et al(70)**

Approach							
Criteria		PBMA	QALY league tables	Needs assessment/ cost of illness/burden of disease	Target setting	Core Services	Generalised cost-effectiveness
Essential	Opportunity cost	✓	✓?				✓
	The margin	✓	✓				✓
	Acceptable principles/objectives	✓	✓?	✓?	✓?	✓?	
	Understandable to clinicians	✓	✓	✓	✓	✓	
Highly desirable	Explicit/transparent	✓	✓	✓?	✓?	✓	
	Evidence based	✓	✓	✓		✓?	✓
	Local NSW evidence	✓					
	Local NSW values	✓					
	Efficiency	✓	✓?				✓
	Equity	✓	✓?	?		✓	
	Non-health service costs included	✓		?			
	Whose values re principles, benefits, etc.	✓	✓?				✓
	How and by whom equity is defined	✓	✓?				
	Relative weight of efficiency vs. Equity and who weights	✓					

**Legend:** The criterion applies ✓ ? The criterion might or can apply [Blank] The criterion does not apply NSW=New South Wales

#### 6.4.4.1 group decision support

One of the developments for practice of prioritisation and resource allocation that this research introduced was using group decision support. I was fortunate in having a colleague who is an experienced practitioner who led me to read further about the topic, which then enabled me to see how these methods could support the decision making processes in the projects reported here. I realised that this was the 'make all the difference' element to include into my methods for the rounds of discussion and decision making, facilitating the MDCA elements of the projects.

In an environment where contentious issues exist, as it did in all three projects, using group decision support to enable the process by providing a focus for discussions, encouraging the development of consensus, and providing a more comfortable environment for those who are reluctant, or unable, to express their opinion publicly was a great step forward. To aid the decision making process, to give more rigour and ease of use we are able to use decision support methods and technology to facilitate decision-making at various stages during the process. TurningPoint™ technology<sup>20</sup> is a voting system that employs voting software, and a set of wireless handsets which exports results to MS Excel and MS PowerPoint. This approach enables parallel, usually simultaneous and anonymous individual inputs, generating a group outcome that can be accessed and displayed in various ways at the meeting or later (81). Research into specific features of this form of group decision support has reported gains in meeting efficiency (82), improved levels of participation and a reduction in potentially negative influences from dominant members of the group (83). Bringing 'voting' technology into the small group environment to smaller, organisational groups, showing that individuals may be more involved in the interactions, and may contribute to the development of consensus. The process overcomes some of the problems concerning participant involvement in two ways:

1. Allows participants to provide anonymous judgements via the group decision support, avoiding 'primacy effects', and providing a more comfortable environment for expressing individual choices, both 'popular' and 'unpopular'.
2. Displays the degree of support for minority selections. In this way, participants supporting a minority position may find that they are not alone in their

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<sup>20</sup> <http://www.turningtechnologies.co.uk>

judgement, which could enable them to feel more comfortable in providing minority arguments in conversation.

My observation was that all were engaged in the process because they had the opportunity to make a vote and listened carefully to presentations and discussions. It is speculative but maybe the act of pressing the voting button and seeing the results in real time was the hook that brought people into the decision making process and the anonymity engaged them in making their contribution more effectively.

#### **6.4.4.2 The role of the health economist**

My role as a health economist in all the projects was as a researcher, initiating methods development (MDCA and PBMA) and related discussions, observing the process and feeding back iteratively on how far the methodological requirements were being adhered to and making pragmatic adaptations to facilitate progress; being an 'information expert' who could, because of expertise and experience, and affiliation with the University, quickly access the pertinent health economics literature, guidelines and other resources that related to health economic methods and research to inform the progress of the projects as went along; as analyst who could adapt and turn around results from the NICE costing model for the anticoagulation and AF PBMA and as a participant in group discussions and decision making. Taking advice from those people I spoke to, in the UK, who had undertaken PBMA projects themselves, the health economist should definitely NOT lead the PBMA project as it sends the wrong messages to the stakeholders and the PBMA would preferably have clinical leadership in order to give it best chance of success. Mooney and colleagues concur and suggest that the involvement of health economist as a resource and to ensure the 'economic way of thinking' is vital for the success of a PBMA: (70)

*"..... having a health economist 'embedded' in the system; or at least 'to hand' is important in implementation." (p17)(70)*

Whilst WHSSC and ABMUHB were cognisant of my using the projects for PhD research there are no HBs or trusts in Wales that have a health economist on the staff to collaborate with me to give the project support (or provide support in the future). Given these projects have come to an end the organisations have done nothing to acquire or contract health economics expertise. This is a less than ideal situation – even when the frameworks have been adopted and supported - as such activities require health economics expertise and support such a passive reaction does not bode

well. Maybe getting the framework and support 'for free' devalues the 'currency' and perceived value of health economics

#### **6.4.4.3 Resourcing PBMA with information**

As the literature on PBMA frequently observes it is challenging to inform a PBMA with good (local) data. This certainly was the case with the two pilot PBMA reported in chapters three and four. Ever the pragmatist Mooney suggests that;

*"... a set of inadequate data and poor measuring supporting the right thinking is more likely to get us to an approximation of where it is desirable to be than will better data and better measuring techniques where the thinking is wrong" (p15)(70).*

We were able to access excellent financial data for the secondary care elements of our PBMA interventions. This was vital for the success of the PBMA and might not have been so useful had it not been for an experienced and skilled user of the financial data systems who enthusiastically embraced the PBMA approach.

It was impossible to get primary care data. This is all the more frustrating because primary care data is generated by GPs in ABMUHB and held in the Secure Anonymised Information Linkage (SAIL) databank in Swansea University<sup>21</sup>. Although the databank takes data from the HBs and in the ABMUHB area, from primary care no arrangements were (nor are) in place to enable the health board to access and analyse these data. It is available to research but for a fee and there is a requirement for a SQL programmer to access the data and as no extracts are 'allowed' the researcher has to work within a gateway which is prone to crashes (in my experience). Tables from analyses of the data are not allowed to leave the gateway unless they are cleared by a governance panel. This can take several days to be accomplished. And even if the HBs should be able to find or fund a SQL programmer, refine a research protocol, get a suitably qualified statistician to deliver the analyses and find the fee, the extended governance arrangements (despite the data being anonymised) means that a quick turnaround to answer a PBMA or prioritisation question relating to a disease or intervention cannot be delivered in a useful time frame.

This issue aside ABMUHB has invested in the need for capitalising on the use of routine data they have ownership of outside of SAIL and user friendly analytics to assist in providing health intelligence for PBMA and other activities.

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<sup>21</sup> <http://www.saildatabank.com/>

A paper evaluating tools supporting health system transformation (including PBMA) by Willis et al (142) raises the crucial need for technology-enabled knowledge management and translation. The authors use two exemplar initiatives that unfortunately show how ABMUHB (and other organisations in Wales) are missing the opportunity (or rather how Swansea University and the Welsh Government are) to harness the SAIL data to support health care prioritisation and decision making. According to the authors *“The Australian e-Health Research Centre are investing in smart methods for using health data linkage technologies... to permit more universal use of secondary data”* and *“the CAPTURE project in Canada provides real world pan Canadian data for informing chronic care programmes ...”*(142)

These initiatives could be the exemplars for Wales and enable priority setting and resource allocation to be better informed with local data – something strongly advocated by Mooney and colleagues(70).

#### **6.4.4.4 Leadership, Relationships and Trust**

Cornelissen and colleagues mention, almost in passing, in the PBMA they undertook, that one participant mentioned building trust was important;(143)

*“Participants stated that Year-1 should in part be about building trust with each other and the process: I am not sure once you are in the process there really is room for discussion about trust and power and control. You can acknowledge that yes those are issues, but. . .you can’t pull out or not participate authentically because of issues around trust, power or control. You had better speak up and then let it go. (Year-1 Participant #7)”* (p271) (143)

For me as the health economist I felt it vital that I build trust with the three teams with which I worked, but additionally the teams had to trusts each other. My experience was that we had three project teams that functioned well and had considerable trust in each other and adopted the same approach to my involvement. I tried hard to build trust and ensure that my involvement was not as an ‘academic’ using them for an academic exercise, rather the process was about ‘them’ and their service’ and I was there to help and guide and be a resource, but it was not ‘my’ project.

Many of the NHS staff knew each other prior to the project team forming and it was abundantly clear that the co-chairs of the two PBMA's trusted each other implicitly. Even when the reorganisation of the health board meant that the co-chairs (clinical director and the general manager of the MSK services) both moved into different jobs, they continued to work together to drive the MSK proposals for the PCCB though to conclusion.



The importance of trust was extended in the discussion from Angell and colleagues' paper bringing together insights from researchers in this field (my use of bold)(140);

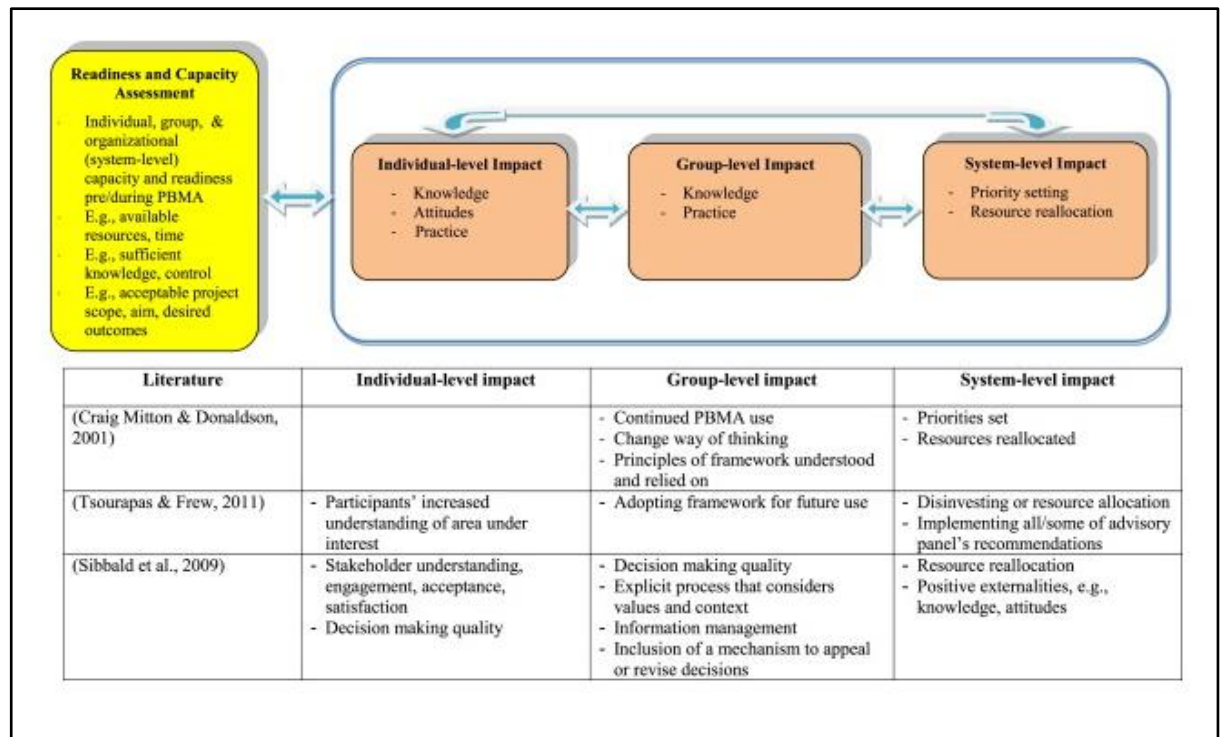
*"The importance of organisational-level factors to priority-setting processes were highlighted by many respondents. Donaldson, for example, argued that the keys to success were 'leadership, organisational ready-ness and simply having good project management skills and support in place.' Peacock emphasised the importance of strong leadership in getting recommendations implemented, **together with a culture open to change and buy-in from the bottom up**. At a broader level, many respondents highlighted the importance of garnering support for the priority-setting process across the system. Mitton emphasised that 'implementation is tied to political backing, which speaks to the need for up-front work on buy in, acceptance of criteria and lots of engagement activity"(p1391)(140)*

Both of the PBMA pilots had the 'culture open to change' in the team and buy in for the whole team. Smith and colleagues recently published a paper describing how proposal for change for the priority setting and resource allocation processes, in a hospital in Canada, introducing PBMA were viewed by the senior leadership involved(144). The authors interviewed twenty six individuals. One of the pertinent findings for this discussion is a mention from interviewees that the PBMA process:

*"...provided a way for people to have a voice"... "it was a good way to getting frontline staff engagement and involvement". (144)(p27)*

Another, earlier, Canadian study also used qualitative methods to assess impact. Cornelissen and colleagues suggest that participants connect with PBMA in different ways and looked at individual level, group level and system level impacts using different commentators' definitions of impact (see Figure 6:1 taken from the paper below).

**Figure 6:1 Levels of impact from implementing PBMA (from Cornelissen et al) (145)**



Some of the group level impacts represented by Figure 6:1 are in accord with my experience in the projects, especially that of the project team and stakeholders engaged in the pilot PBMA. At a group level and at individual level (in the terms illustrated in Figure 6:1) the process changed their way of thinking. The PBMA based framework considered values and context which seemed consistent with the team's respect and trust for each other, and their knowledge and practice.

## 6.5 STRENGTHS AND LIMITATIONS

The strengths of the research are that the two approaches - MDCA and PBMA - enabled the organisations in which the research was implemented to accomplish explicit prioritisation resource reallocation decisions and disinvestment recommendations. The participants were comfortable with the decision processes and in both cases a workable framework was developed for taking the prioritisation and resource allocation methods into new phases of prioritisation work streams.

There were some limitations to the research. In the case of the PBMA pilots that informed the framework for ABMUHB certain compromises were made in the PBMA steps and methods, particularly in terms of a detailed and explicit MDCA exercise within the PBMA. However this was accomplished for WHSSC.

Certainly some elements of MDCA were applied as ABMUHB values and decision making criteria and their relative importance were discussed. The value and criteria were part of the mix as the decisions for resource reallocation, disinvestment and reduction were made (especially for the anticoagulation in AF PBMA). In some senses the decisions to be made were so obvious and uncontentious that including an extra process of scoring and ranking seemed superfluous. Rounds of decisions were made with the criteria for decision making (unweighted but presented in rank order of preference were in the fore front of the stakeholders minds, evidenced by the discussions at the time. In the case of the MSK PBMA the choices were so clear and obvious – pushing through an MCDA process would have added nothing but irritation. Personal communication with a Dr Mark Lim<sup>22</sup> who had led a PBMA in Bedfordshire PCT had exactly the same experience on one of his PBMA's. The problem of 'not enough budget to even deliver safe services to enough people' hindered an MDCA exercise in the anticoagulation in AF PBMA and the news about the extra funding from Welsh Government came rather at the last minute so again pragmatic recommendations – the obvious ones within budget – were made without using MCDA.

A paper by Cornelissen and colleagues(143) in Canada (a team that has considerable experience in using PBMA) validates the pragmatic 'let it go' decisions I made about using MCDA at these pilot PBMA's .

*“Rather than focusing on implementing the full PBMA approach, focusing on adaptation or adoption of those stages that decision makers are ready for may be the better approach. Attention to individual PBMA stages, and clarifying the purpose, use and benefits of each stage independent of the others, enables users to adopt those stages that resonate for them. Our findings suggest that this adaptability be built into PBMA implementation, along with a focus on clarity (and the issues encompassed by the term clarity in this study) through targeted education and communication, and the addition of an organizational readiness and capacity assessment stage. Assisting decision makers in this way, rather than focusing on implementing an ideal PBMA model in its entirety, have more influence on evolving priority setting practice in the real world”(p8)(143)*

With regard to the lack of implementation of a full MCDA process, another limitation in this vein was that for all three projects the PBMA/prioritisation teams delivered recommendations based on these methods but were not the final decision makers. The UCCB and PCCB did not use tools to prioritise the recommendations made in extensive business case documents based on the PBMA's, compared with other proposals made to them. The recommendations the teams made were accepted and became part of the

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<sup>22</sup> One of my PBMA 'experienced informants' with whom I spoke when setting up the programme of research

IMTP – which should then drive implementation - but that decision making process was not transparent.

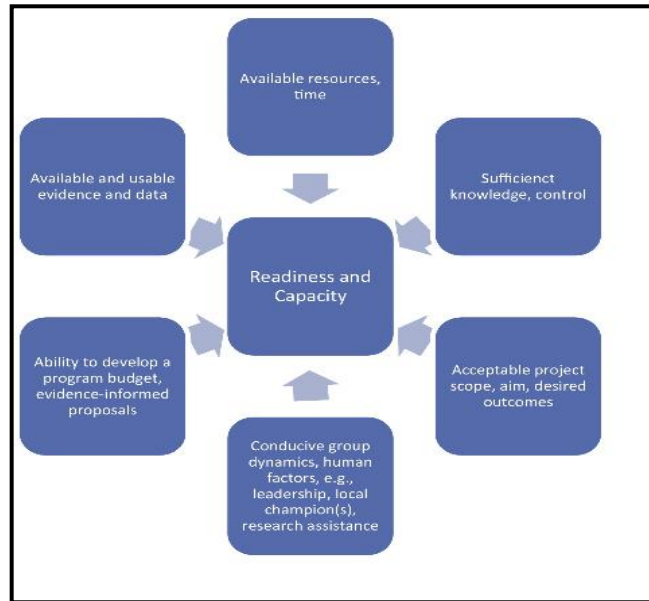
## 6.6 IMPLICATIONS AND LEARNING FOR FUTURE PRIORITISATION INITIATIVES

The findings of previous authors looking at factors associated with success for prioritisation are validated further by the findings of the research reported here. A paper from Cornelissen and colleagues reporting on a PBMA exercise that failed, and exploring the reasons why it failed, make a suggestion that resonates with the experiences reported here (albeit the two PBMA's reported here were successful); (143)

*“... Coaching PBMA implementation in a broader change management strategy may facilitate its acceptance...., Thus, the addition of a pre-PBMA assessment phase to determine (and then prepare) system and decision maker readiness to adopt PBMA seems prudent....this stage can include assessing the knowledge and training required by decision makers to participate effectively in PBMA, assessing local evidence/data availability and usability (e.g., to develop the programme budget), and ensuring resources (in particular, decision maker time, knowledge and power to follow through) are available. Necessary human factors include multi-level leadership, local champion(s), research assistance, conducive group dynamics, and participant capacity.” (p7)(143)*

Cornelissen and colleagues bring together their evaluation of success and failure into a visual representation of the ‘capacity and readiness factors’ they feel are important for a health service organisation in a diagram (Figure 6:2 below) that they propose, had they been in place, might have driven the PBMA through to success rather than being terminated early. Working on these factors with WHSSC may have changed the outcomes - or perhaps not – but for future PBMA's engaging in some more robust pre-work on ‘organisational readiness’ may improve the process and speed it up. It may also set the stage better for investing the time and effort in developing the MDCA elements of the PBMA.

**Figure 6:2 Individual group and organisational capacity and readiness assessment taken from Cornelissen et al (143)**



Mitton and colleagues, in a paper reviewing approaches to priority setting (72), comment on elements of high performance in priority setting that healthcare organisations can benchmark themselves against and provide a summary, as reproduced in Table 6:2 below. This provides a good check list against which future prioritisation and resource reallocation initiatives could be evaluated and inspire proactive action to optimise the setting and contextual conditions before starting. It prompts thought about and where possible motivations and incentives – and at the worst, understand what project leads might be up against.

**Table 6:2 Summary of elements of high performance (taken from Mitton et al)(72)**

Table 3 Summary of elements of high performance			
Structure	Processes	Attitudes/behaviours	Outcomes
SMT has the ability and authority to move financial resources within and across silos	PSRA at the organization-wide level is based on economic and ethical principles and involves: <ul style="list-style-type: none"> <li>• Well-defined, weighted criteria which reflect the organization's values and strategic priorities</li> <li>• Use of a scoring tool to operationalize criteria in ranking individual proposals</li> <li>• Mechanisms for incorporating best available evidence</li> <li>• A decision review mechanism</li> </ul>	Fit of priority setting decisions with social and community values is sought: <ul style="list-style-type: none"> <li>• Public participation and input is valued; it is integrated into decisions in meaningful ways.</li> <li>• Consideration is given to how decisions align with external partners and the larger health system.</li> </ul>	Actual reallocation of financial resources is achieved
Mechanisms are established for engagement of staff (clinical and non-clinical) in PSRA decisions, with particular though not exclusive attention to physicians <ul style="list-style-type: none"> <li>• May include the use of incentives to encourage participation</li> </ul>	SMT ensures effective communication (both internally and externally) around its priority setting and resource allocation—leading to transparency	SMT displays strong leadership for PSRA—SMT is aware of and manages the external environment and other constraining factors, and is willing to take and stand behind tough decisions.	Resource allocation decisions are justified in light of the organization's established and agreed upon core values.

*SMT senior management team, PSRA priority setting and resource allocation*

## 6.7 CONTRIBUTION AND IMPACT OF RESEARCH

This research adds to the exiting body of work on prioritisation and resource allocation in several ways. The research delivered a prioritisation framework based on simple workable MDCA methods for HSTs - all HSTs not just drugs - in Wales. This was prior to a wider (and better resourced) NHS England initiative for specialised commissioning that is currently being developed (146) and as such is unique in the UK.

The two PBMA pilot projects were unique in that the adaptation of the PBMA process allowed the ABMUHB team to take 'ownership' and make it a 'way of working' for the future and not an academic exercise. Disinvestment and 'doing less' to invest in more beneficial activities within the programme budget were accomplished in the MSK pilot project and a PBMA framework that is owned and 'lives' within ABMUHB. The MSK PBMA has been chosen as an exemplar of Prudent Healthcare by the Welsh Government.

The PBMA framework will be tested and adapted further in a PBMA in the diabetes area in 2016/17.

Ultimately what this research and use of PBMA adds is that it is not just an academic project advancing the practice of PBMA but it is also a very practical project grounded in the values of ABMUHB and Prudent Healthcare that should be a driver for change and improvements in delivery of healthcare and health gain for the population of ABMUHB and Wales. It also brought a new way of thinking to ABMUHB.

## 6.8 GENERALISABILITY OF RESEARCH

All three of the projects reported here are set in Wales and the frameworks developed are specific to the setting in Wales. Nevertheless it is clear from the literature that the health problems in Wales, the budget challenges and the challenges faced in the 'journey' of undertaking prioritisation and resource (re) allocation decisions is not unique to Wales. The politics, the people, the research outcomes – the decisions and the frameworks - could be applied to similar contexts where the allocation of scarce resources has to be made.

## 6.9 IMPLICATIONS FOR FURTHER RESEARCH

Based on the findings reported here, further research arising from this work might usefully focus on:

- Streamlining methods and shrinking timelines for PBMA;
- Devising ways of better engaging the public (as they are also the tax payers) in
  - Increasing understanding of rationing and that no rationing is unrealistic;
  - the need for priority setting and resource reallocation activities;
- Investigating the attitudes of health professionals, health care commissioners, managers and the public attitudes to priority setting and resource allocation in health care and their understanding the economic concepts of scarcity, opportunity cost and the margin;
- Revisiting the challenges of implementation of recommendations and decisions not only from the health economists' perspective but also from the perspective of behavioural economics and implementation science, using methods from those disciplines to enable progress.

However there is one simple overarching recommendation – that more PBMA should be undertaken, evaluated using quantitative and qualitative methods, benchmarked against best practice, analysed and reported so that eventually the practice of PBMA becomes better embedded in health services.

#### 6.10 IMPLICATIONS FOR HEALTH ECONOMICS AND COMMISSIONING

PBMA has been a 'text book' methodology in health economics for many years. Passionate practitioners - at least those publishing papers - are generally health economists. The tendency over the years has been to introduce methodological refinements to PBMA - increasing their complexity and restricting the ability of health economists to advise on and support ~~deliver~~ effective implementation of PBMA.

MCDA has also been a tool for decades, but the most recent UK incarnation of MCDA has been in a very sophisticated way – the STAR project (136136). The STAR approach requires an expert in decision conferencing to facilitate meetings and a series of meetings is required to generate data inputs for a computer model, which yields 'the answer'. As with the very technical PBMA the 'expert' is needed to make the prioritisation and resource (re)allocation exercise possible.

The aim of this research was to ensure the economic theory and concepts were at the heart of the projects but to keep the expert input in the background in a supportive manner and enable the participants to understand and buy in to the 'economics' and make the execution their own 'way of working'. Looking back over the time spent

undertaking this research it was important that my contribution was credible and based on experience. I was open with my collaborators that my experience of prioritisation exercise was negligible, but that I understood and had experienced the consequences of not undertaking such prioritisation exercises. My age and experience as a health economist was probably an influencing factor in giving my collaborators confidence that I could lead them through the journey to success and that I had the academic resources to ensure that what we did had credibility.

There may be a case for using exemplar projects to keep PBMA in the health economics 'tool kit,' but there may also be a case for health economists to do 'missionary work' to educate and enable commissioners, clinicians and other health professionals in the utility of MCDA and PBMA, keeping methods simple and effective and not keep the execution of the methods in the health economics camp. Educating health care professionals in the principles of health economics is becoming more common – now is the time perhaps, because of the considerable resource constraints in health care, to make PBMA as a term as commonly used and understood as Health Technology Assessment or 'cost effectiveness analysis'.

## 6.11 CONCLUSIONS

In conclusion, harking back to the title of this thesis: Nettles can be grasped, it is possible for those involved in health care prioritisation and resource (re)allocation to hang on, despite the pain and harvest good things from the nettle patch - plus make something good and nutritious – nettle soup - out of the process. However it is evident that occasionally within the Welsh NHS people don't like nettle soup, however good it is for them.

Finally the research conducted as part of this thesis has shown it has been possible to develop and deliver robust, evidence based, effective practical frameworks based on economic concepts for prioritisation, resource (reallocation and disinvestment. A key learning of the research was that pragmatism must prevail if prioritisation and resource reallocation methods are to gain traction and become embedded in commissioning in ABMUHB and elsewhere.



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# APPENDICES

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