

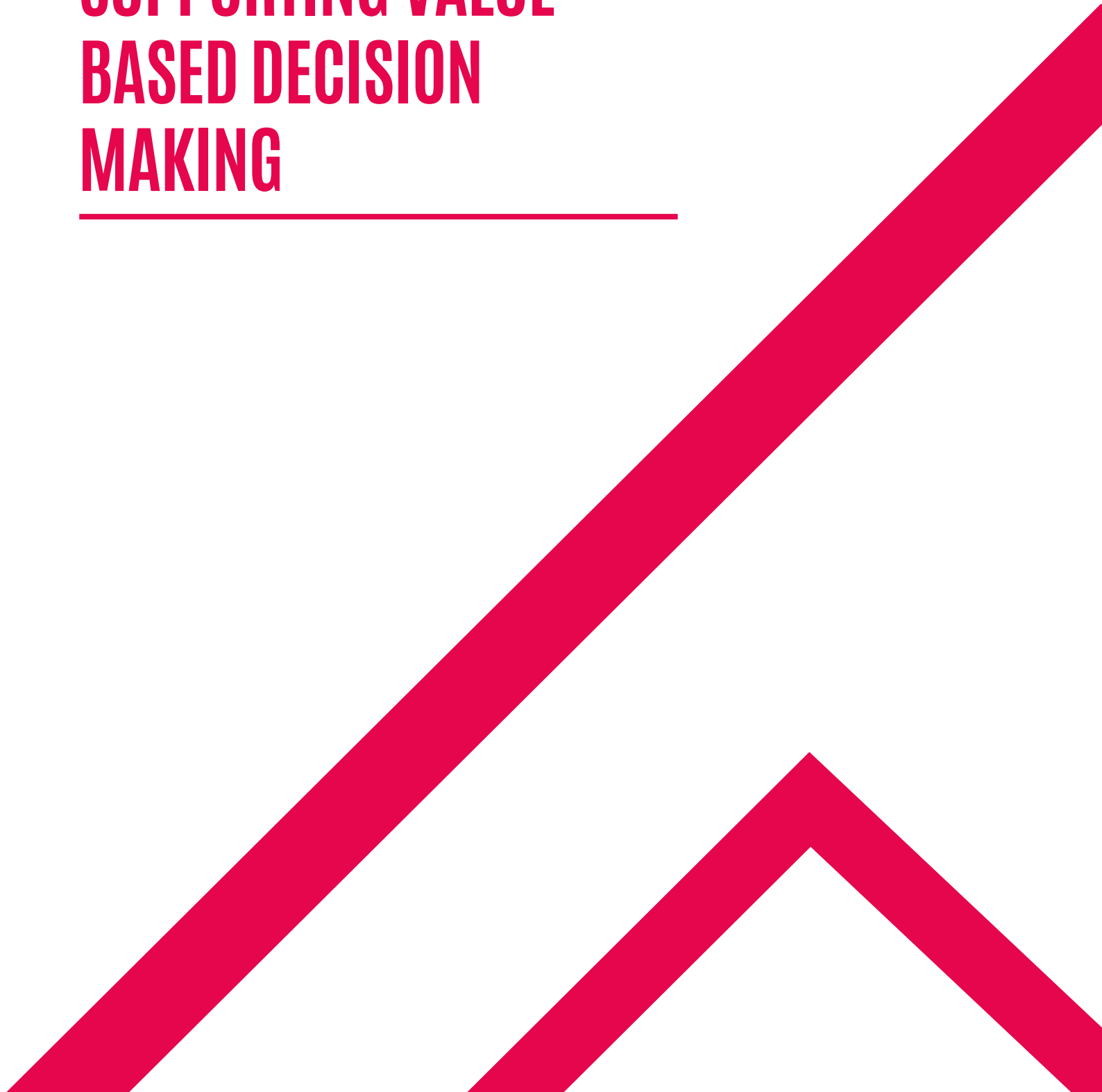
# ABHI

VALUE AND ACCESS

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## SUPPORTING VALUE- BASED DECISION MAKING

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# INTRODUCTION

**The COVID-19 crisis has demonstrated the critical role HealthTech plays in the protection and treatment of our citizens. Never before has the value, rather than the price of technology, been so well appreciated, and the outcomes achieved by using technology to deliver care been so highly prized. In that context we review how value is, and might be, considered in NHS procurement.**

The Carter Review (2016) on productivity and performance in English hospitals<sup>1</sup> revealed the fragmented nature of hospital procurement which led to wide variation and inconsistencies in clinical care. It made the case that the NHS could achieve better cost efficiencies in its purchasing of goods and services. Following the report, the Procurement Transformation Programme (PTP) was implemented and began to consolidate the supply chain process by centralising the sourcing, supply and delivery of healthcare products and services through NHS Supply Chain (NHS SC).

This has brought about much change in the procurement landscape over the last six years and has streamlined many disparate and outdated processes. It has proven that it can deliver cost-savings to the NHS and has resulted in more joined-up working with manufacturers and service providers.

Over the last two years, it has been pivotal in ensuring continuity of supply of medicines and medical devices during the Brexit transition period and COVID-19 pandemic.

Whilst there is much to commend in its success, there have been issues with the way in which the management and administrative functions of NHS SC have grown over this period and the wide range of bodies, working groups and pilots formed to support NHS SC. Questions remain over the openness and transparency of some of these bodies and how they work with other suppliers such as social enterprises and private sector contractors.

At the level of product and service procurement, the Category Towers were formed by NHS SC to ensure cost efficiencies in the bulk purchasing and distribution of items considered commoditised such as surgical gloves and theatre gowns (although COVID-19 has demonstrated that considering items used in critical clinical settings as commodities and not valuing them is risky) and hospital services such as cleaning and catering. A far greater challenge has been in the procurement of highly personalised medical devices which require a complex set of clinical and benchmark criteria to enable procurement decision-making.

# VALUE-BASED HEALTHCARE

Value-based healthcare (VBH) models found in the US such as the patient-centred medical home (PCMH) and accountable care organisations (ACO) evolved from the desire to have in place a more equitable, evidence-based, quality focused system of health provision<sup>2</sup>. The purported benefits for the healthcare system include; better outcomes for patients, higher patient satisfaction for hospital providers, stronger cost control and risk management for payers and, in the case of suppliers, the ability to align prices with outcomes. Rather than a fee for service system, it incentivises clinicians and providers to look for improved outcomes so that patients live healthier lives whilst also managing the incidence of chronic disease. The end goals are to enable better health in populations and reduce healthcare spending. It has also been suggested that the value approach, in the case of prescription drugs, also allows for innovation and wider access to personalised healthcare<sup>3</sup>.

There have been several other initiatives in the US arising from the Affordable Care Act to support VBH such as Payment-for-Performance (P4P) and the Hospital Value Based Purchasing Program. Both looked to incentivise high quality care by using a complex set of performance indicators including process measures, mortality rates and patient experience.

Findings and opinion on the success of value-based purchasing has been mixed<sup>4,5</sup> with studies showing little improvement in patient outcomes and populations primarily because the principles pertaining to value (and the structures needed to support it) were either not there or misconceived. Quality measures were used to target clinical conditions and episodes of care and did not include the measures that clinicians and patients would have deemed important to their care. Instead, it has been suggested that care should be specifically tailored to patient subgroups, each with its own unique set of metrics, so that better targeting can occur. Despite its shortcomings, commentators have suggested that policies to enable VBH and value-based purchasing should not be scrapped but should instead be refreshed, bearing in mind the lessons learned.

The UK has had the advantage of the experience from the US but whilst VBH makes good policy sense in a system that is based largely on health insurance and Medicaid/Medicare, how will it translate into a single-payer, publicly-funded system such as the NHS?

# VALUE-BASED HEALTHCARE IN THE UK

Gray<sup>6</sup> has noted the work of the Academy of Royal Medical Colleges and BMJ in reducing unnecessary interventions, preventing overdiagnoses and the over-medicalisation of healthcare. Whilst valuable in helping to make the health system run more efficiently and reducing costs, these activities require the health system to look at provision at the population level.

In this context, the value of healthcare needs to be seen from two perspectives:

1. **Allocative**, where the desire is to allocate resources accordingly to different groups within the population to minimise health variation, and
2. **Clinical**, where clinical decision-making is central to ensuring that the right services and treatments find their way to the right patient so that care is optimised.

Taking Gray's thesis a step further, VBH makes good sense from the community perspective as it allows the patient to self-manage their condition whilst helping them to maintain their independence. For these reasons, mental health and emotional wellbeing and other quality of life measures are important considerations in value-based healthcare.

This shift in focus towards a VBH model complements the NHS RightCare ethos and the Getting It Right First Time (GIRFT) workstreams that place value at the centre of care provision with the intention to reduce unwarranted variation in local populations.

In fact, the RightCare model prescribes 'personalised value' in addition to the two perspectives described above<sup>7</sup>. This approach relates to the value that each patient deems important to them in their care and their desired outcomes. Arguably, innovation occurs when the NHS works in partnership with patients (through patient groups, voluntary organisations and charities) and industry, to improve clinical and quality outcomes and patient experience so that medium to longer term solutions are developed to the benefit of the patient, payers and the healthcare system.

At the core of RightCare is availability of evidence and data to recommend a care pathway, presided over by strong clinical leadership. It is therefore key that any procurement activity taps into such clinically-led intelligence on different ways of working and of product or service use. One of the past criticisms has been that NHS SC with its various Category Tower clinical working groups and the Clinical and Product Assurance (CaPA) unit have often worked in silos. The focus was on delivering value at the level of cost, based on measures such as product features that did not take into consideration quality of life impacts and patient choice. In essence, despite the nod towards VBH, health variation continued to exist due to the stringent following of the standards and commissioning advice set by these groups. It would be useful for commissioning bodies and those setting procurement guidelines to pay heed to the personal value described above to ensure that patient views and needs are met.

# THE NHS LONG TERM PLAN, FURTHER INTEGRATION AND VALUE-BASED PROCUREMENT

The NHS Five Year Forward View<sup>8</sup> and the Sustainability and Transformation Plans (STPs) borrowed heavily from the ACO model of care. The key principles of partnership and collaboration between healthcare providers have evolved into the latest iteration<sup>9</sup> of the NHS Long Term Plan<sup>10</sup>. Alongside the DHSC's White Paper<sup>11</sup> which seeks to enable better planning, coordination and delivery of services through the Integrated Care Systems (ICSs), the NHS is in a good place to ensure that the system works as it treats and cares for an ageing population suffering from complex lifestyle diseases. The big question is if these broad policy objectives align with the value-based approach to procurement.

MedTech Europe, the umbrella body for European medical device manufacturers, adopts a more pragmatic approach in its concept of value-based procurement (VBP) which examines the holistic value that medical technologies bring to patients<sup>12</sup>. Closely tied to VBP is the idea of the 'smart procurement' of medical devices and MedTech Europe have published their principles<sup>13</sup> which contain recommendations for stakeholder engagement, quality and good practice in procurement.

Given the complexities of EU public procurement legislation and its implementation across the 27 Member States, MedTech Europe started the Most Economically Advantageous Tender (MEAT) Value-Based Procurement initiative<sup>14</sup>.

In addition to the elements found in US-based models are imperatives around sustainability, social/environmental and public health responsibilities. One of the more progressive aspects of the MEAT process is the suggestion that clinical outcome and value criteria are embedded in pathways alongside costs. These measures are then included in tenders published by healthcare providers to optimise VBP in the delivery of patient care. In theory, patients (through patient groups) will work with local contracting authorities so that their concerns and needs are reflected in tenders. This is the truly innovative aspect of the MedTech Europe approach since the patient voice is reflected in the treatments and services provided.

The current UK Green Paper on public procurement<sup>15</sup> has adapted the MEAT concept to the Most Advantageous Tender (MAT) recognising that there are different ways in which to evaluate economic benefit in procurement and that the cheapest product or service does not equate to better outcomes.

According to the MAT model, contracting authorities will need to consider the wider consequences of their procurement decisions, including social value. This supports the DHSC's aspirations to enable more integration of healthcare with social services through closer collaboration between the NHS and its suppliers. More importantly, evaluation undertaken needs to incorporate the views of the clinicians prescribing medical devices and the patients using them.

# NHS PROCUREMENT FRAMEWORKS AND THEIR IMPACT ON PATIENTS

However, NHS procurement frameworks agreements have in the past been focused solely on price with the cheapest costs/bids being put on the list. For instance, in the case of medical devices, there have been several initiatives developed by contracting authorities including threshold and reference pricing, mini competitions and electronic reverse auctions (e-auctions) which have in fact stifled competition and innovation. These approaches turn the NHS-supplier relationship into a purely transactional one and, more importantly, result in the adversarial nature of procurement marked by distrust and a lack of transparency between procurement and commissioning managers and manufacturers.

In the first instance, threshold pricing is a blunt instrument where suppliers are given a price point that the buyer accepts. Medical devices are seen as commodities offering little differentiation and there is no room for discussion about individual product benefits. In the second instance, reference pricing is used to as a tool for deciding on the cost of a product when it is listed. The reasons why medical device prices are different across the world do not get factored into price negotiations. Instead, lower price points from other economies are used as a crude comparator. This has the effect of pricing a manufacturer out of the market. Apart from resulting in the use of lower quality medical devices in the NHS, in the medium to longer term, such procurement procedures can lead to the UK being regarded as a low-innovation country. This results in innovations not being launched in the UK and is leading to research being carried out outside of the UK as the standard of care comparator is not the treatment offered in the UK.

This is all counter to the Government's objective to make the UK a global leader in the life sciences.

Furthermore, procurement practice that is motivated by price alone is detrimental to care and treatment provision. Clinicians and patients have been excluded from the contracting process and from the perspective of the manufacturer, it may result in secondary, informal deals like discounts and rebates being made between suppliers and distributors. Manufacturers will exit the market once it is no longer profitable to offer their products and services and this will impact on the smaller, home-grown businesses that will find it hard to compete in the market.

Similarly, Clinical Commissioning Groups have in the past been under pressure to look for cost savings resulting in the switching of products and services which were not always in the best interest of the patient or health system. This further fragments service provision in the NHS, causing the so-called 'postcode lottery' and introduces inequalities into the system. As much as the Integrated Care Systems are meant to put an end to this, if procurement is based primarily on price considerations, it may in fact have the opposite effect.

# NHS SUPPLY CHAIN AND VALUE-BASED PROCUREMENT

NHS SC, through Supply Chain Coordination Ltd (SCCL), started to examine embedding VBP into its procurement model in 2019 as a means to enable better purchasing and sustainability. The main purpose of VBP is to demonstrate whole-life costs through savings generated across the patient pathway, rather than savings achieved each time care is provided<sup>16</sup>. This means that rather than looking rigidly at cost and price, other indicators such as the reduction in the length of hospital stay and/or numbers of readmissions over a period of time from the use of a product or service, will be used as indicators in VBP.

This approach to examining financial benefit to the health system 'above a reduction in purchase price'<sup>17</sup> is welcomed by medical device manufacturers. In this context, it should be noted that tools like e-auctions, which were introduced as a means to adjust pricing in stagnant markets, do not always deliver ongoing longer-term cost efficiencies. Indeed, the experience of e-auctions for medical device suppliers has been poor since it is a rough mechanism that is entirely price driven, often below market value, just so manufacturers can go on a procurement framework. The startling contrast is that e-auctions have reduced the value of products in the UK to such an extent that the same innovative products can sometimes fetch a higher price in third world countries. Examples of this include PPE, safety cannula and infusion pumps. This is resulting in choices being made by manufacturers not to make products available to the UK with the unintended consequence of disadvantaging UK patients. This cannot be seen as a 'win' for this procurement practice.

In product areas such as chronic care serving patients in the community, e-auctions as a means of procuring products for the NHS, are fundamentally discriminatory and have the effect of limiting the market to a few low-cost suppliers.

In this context, the quality of service and other metrics never outscore financial considerations, including patient choice. Value is stripped away from the price of the product/service and the manufacturer has to make up the loss in revenue in other parts of the healthcare system. Where revenue cannot be secured, manufacturers have exited the market and the net result is that these products will not be manufactured in the UK market due to the uncompetitive nature of bidding. In the longer term, not only has this resulted in restricted patient access to high quality and innovative products, thus going against the standard of care found in other countries, it also meant that some manufacturers could not offer their full product range in the UK.

There is much to recommend the development of VBP as a method of procurement for the NHS. It signals a shift in the traditional payer-supplier relationship since payers will need to look at longer-term benefits based on patient outcomes as opposed to shorter term cost savings which have often been shown to be a false economy due to the unintended consequences. Similarly, manufacturers must rethink their way of working beyond that of selling to payers. Proposals to the NHS must include the tangible and value-added benefits of product use and all products claims must be supported by robust evidence, thereby representing a change in the way research, audit and reporting are conducted in medical devices. This impetus to generate good quality evidence on unmet need, patient experience and quality of life is in line with the current NICE reviews into health technology appraisal topic selection, methods and processes and the preference for HealthTech Connect as the channel to introduce new promising technologies into the market. It would be good to see managed access schemes, like those found in pharmaceuticals, make their way into medical devices with a role for VBP in the commissioning of new technologies.

# THE NEXT STEPS FOR VALUE-BASED PROCUREMENT?

In their report<sup>18</sup> on the VBP pilots published in February this year, the VBP project team at NHS SC made some probing observations. Their most critical assessment is that commitment is needed from trust finance teams, at the executive level, to get buy-in for VBP programmes. We are told that payers and commissioners tend to focus on short term gains and are risk adverse. The lack of understanding of the purpose and objectives of VBP mean that operationally, the focus will be on lowering prices and reducing costs. There is therefore the need to work with procurement managers so they understand the principles and implementation of VBP and how savings will be seen in other areas along the patient pathway.

In cases where senior executives were engaged in the concept of VBP, they were more willing to unlock the resources and cooperation needed to make it a success but more fundamentally, they were crucial to giving due recognition to the system and service improvements from these VBP projects. The report also noted that deliverables are needed from suppliers on the forecasted outcomes and promised efficiencies to incentivise the NHS to adopt VBP solutions. To this end, the project team have created a VBP assurance framework to help the NHS and suppliers. It is hoped that as the NHS transitions into integrated care systems, the benefits of VBP can be maximised when delivered at scale through the ICSs.

In order for VBP to work, partnership working within the ICS, executive teams and suppliers is essential with all involved having common, shared goals. However, this is not always possible because of conflicting interests as described above. Perhaps the most telling depiction of the NHS-supplier divide can be found in the paragraph on the different interpretations of value in procurement:

*"From the initial call for pilot projects, it became evident that there was a misalignment between the medical device industry and the NHS interpretation of value. Suppliers by the nature of the markets in which they operate, are highly adept at engaging with clinicians and understand the features and clinical benefits of their products. However, due to their lack of insight to the NHS finance regime, gaps existed in relation to how the operational benefits contained in the supplier's proposal, would deliver tangible and measurable financial, system and patient benefits."*

We are reminded by the VBP project group that the lack of understanding in medical device manufacturers of the way finances flow in the NHS means that they are unable to make the case of how the use of their products and services, developed with clinical input and patient experience, results in innovation, quality and improvement for the NHS. There is also the need to demonstrate to NHS procurement managers how supplier input in healthcare provision has the further advantage of freeing up administrative time so that clinicians can focus on patient care.

The conclusion of the VBP project team is that in order to lift the internal blocks to VBP, we are at a crossroads with regards to the way the concept and practice of VBP is embraced by integrated care systems in the NHS Long Term Plan. Cooperation within the health ecosystem, between the NHS and suppliers is very much needed and the one way for that to happen is through greater consideration of whole life costing in patient pathways and the removal of silo budgeting.

At this moment of great adversity, following COVID-19, where patients are waiting over a year for procedures that they relatively recently could expect to have within weeks, the health system and those procuring within it needs to make a real decision to value certain outcomes. These are easy to define when working within a system with a big waiting list, and a fixed capacity and include outcomes such as reduction in length of stay, reduction in length of procedure, reduction in re-do rates, reduction of side-effects that require additional treatment, use of non-acute setting for procedures, treatment by day case versus inpatient stay, use of a local anaesthetic rather than a general anaesthetic, reduction in the number of follow up visits required and the ability to monitor and manage patients remotely.

The value that technologies, supported by evidence, NICE guidance and registries bring to achieving these outcomes cannot be captured through blunt procurement tools. What is necessary is a collaborative approach to contracting for outcomes and value.



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