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India

A global review of value-based care

theory, practice and lessons learned

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Acronyms

ABDM	Ayushman Bharat Digital Mission
AB-PM-JAY	Ayushman Bharat Pradhan Mantri Jan Arogya Yojana
ACA	Affordable Care Act
ACO	Accountable Care Organization
AHRQ	Agency for Healthcare Research and Quality
API	application programming interface
APM	alternative payment models
ASMR	Amelioration du Service Medical Rendu
ATV	additional therapeutic value
BIS	beneficiary identification system
BPCI	bundled payments for care improvement
CADTH	Canadian Agency for Drugs and Technologies in Health
CAHPS	consumer assessment of healthcare providers and systems
CDC	Centre for Disease Control
CDE	Centre for Drug Evaluation
CEA	cost-effectiveness analysis
CEO	chief executive officer
CGHS	Central Government Health Scheme
CHO	community health officers
CHOP	Children’s Hospital of Philadelphia
CJR	comprehensive care for joint replacement
CMMI	Centre for Medicare and Medicaid Innovation
CMS	Centre for Medicare and Medicaid Services
CONITEC	National Committee for Health Technology Incorporation
COPD	chronic obstructive pulmonary disorder
CROMs	clinician reported outcome measures
DALY	disability-adjusted life year
DGITIS	Department of Management and Incorporation of Health Technologies
DHR	Department of Health Research
DICA	Dutch Institute for Clinical Auditing
DMS	Dell Medical School
DRGs	diagnosis related groups
EHCP	empaneled health care provider
EHR	electronic health records
ERP	external reference pricing
ESIS	Employee State Insurance Scheme
ESRD QIP	End-stage Renal Disease Quality Incentive Programme
FFS	fee-for-service
GDP	gross domestic product
GIRFT	getting it right the first time
GP	general practitioner
GPPS	General Practice Patient Survey
H2O	health outcomes observatory
HAI	health care associated infections
HCX	health claims exchange

HEFTA	Health Financing and Technology Assessment Unit
HEM	hospital empanelment module
HES	hospital episode statistics
HIC	high income country
HIE	health information exchange
HIRA	Health Insurance Review and Assessment Service
HITAP	Health Intervention and Technology Assessment Programme
HOPE	health outcomes and patient experience
HOS	Health Outcomes Survey
HRQoL	health related quality of life
HRRP	Hospital Readmissions Reduction Programme
HTA	health technology assessment
HTAIn	Health Technology Assessment in India
HWC	health and wellness centre
IAA	innovation assessment algorithm
IAPO	International Association of Patients’ Organizations
ICHOM	International Consortium for Health Outcomes Measurement
ICS	Integrated Care System
INNE	individual, node, network and enabling environment
IPPS	inpatient prospective payment system
IPU	integrated practice unit
IQWIG	Institute for Quality and Efficiency in Health Care
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
IT	information technology
LIC	low-income country
LMIC	low-middle income country
M&E	monitoring and evaluation
MCDA	multi-criteria decision analysis
MIC	middle income country
MSAC	Medical Services Advisory Committee
NECA	National Evidence-based Health Care Collaborating Agency
NHA	National Health Authority
NHIC	National Health Insurance Corporation
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NSW	New South Wales
OCM	oncology care model
OECD	Organization for Economic Co-operation and Development
OOPE	out-of-pocket expenditure
P4P	pay-for-performance
PBAC	Pharmaceutical Benefits Advisory Committee
PBF	performance-based financing
PBMA	program budgeting marginal analysis
PCMH	patient-centred medical home
PFS	physician fee schedule
PHR	personal health record
PLAC	Prostheses List Advisory Committee

PM-ABHIM	Pradhan Mantri Ayushman Bharat Health Infrastructure Mission
PREMs	patient reported experience measures
PRISMA	preferred reporting items for systematic reviews and meta-analyses
PM-JAY	Pradhan Mantri Jan Arogya Yojana
PPE	public private engagement
PRMs	patient reported measures
PROMs	patient reported outcome measures
PROMIS	patient-reported outcomes measurement information system
PSHI	publicly subsidized health insurance
QALY	quality-adjusted life year
QoF	Quality Outcomes Framework
R&D	research and development
RBF	results-based financing
RSBY	Rashtriya Swasthya Bima Yojana
SHA	State Health Agency
SHAPE	sustaining health care across integrated primary care efforts
SHI	statutory health insurance
SOP	standard operating procedure
STF	special task force
STG	standard treatment guideline
SUS	Sistema Unico de Saude
TDABC	time-driven activity based costing
THC	transitional home care
THE	total health expenditure
TMS	transaction management system
TV	therapeutic value
UHC	universal health coverage
UK	United Kingdom
UMIC	upper-middle income country
UT	union territory
VA	Veterans' Health Administration
VBC	valued-based care
VBHC	value-based health care
VBP	value-based pricing/purchasing
VPHS	Victorian Population Health Survey

Introduction

The role of publicly subsidized health insurance and AB PM-JAY in India

Health is a central element of the sustainable development agenda for India. As part of the country's development agenda, the country has implemented a flagship scheme "Ayushman Bharat". This scheme is a four-pronged programme for the implementation of:

a) Enhanced primary healthcare reform through the health and wellness centres (HWCs),
b) Improved financial protection and service coverage for secondary and tertiary care through Pradhan Mantri Jan Arogya Yojana (PM-JAY) scheme for the poor and vulnerable (40% of the total population).
c) Improved digital health systems and interoperability through Ayushman Bharat Digital Health Mission (ABDM).
d) Improved public health infrastructure for pandemic preparedness and response and for UHC through Pradhan Mantri Ayushman Bharat Health Infrastructure Mission (PM ABHIM).

The four pillars work in a cohesive manner to ensure the attainment of UHC. They complement other programmes that are being implemented in the sector.

PM-JAY is a publicly subsidized health insurance (PSHI) scheme that focuses on the poor and vulnerable population and provides cashless cover up to approximately US$ 6000 (INR 500 000 in 2024 prices) per annum for the household (approximately 4.5 people). It covers inpatient care for secondary and tertiary care services as well as up to three days of pre-hospitalization and 15 days of post-hospitalization expenses such as diagnostics and medicines[1].

The implementation of PM-JAY follows a long legacy of implementation of PSHIs including the erstwhile Rashtriya Swasthya Bima Yojana Health Scheme (RSBY), a health insurance cover for individuals or families below the poverty line and workers belonging to unorganised sectors. The scheme offered a coverage of approximately US$ 350 (i.e. INR 30 000) on a floater basis for households for secondary and tertiary services. It covered only inpatient care. The implementation experience of RSBY was critical in shaping the design and implementation of PM-JAY. Other schemes including the Central Government Health Scheme (CGHS) and the Employees' State Insurance Scheme (ESIS) also influenced the design of several elements of the scheme.

PM-JAY is managed by the National Health Authority (NHA), an agency formed by Gazette Notification Registered No. DL –(N) 04/0007/2003-18. It is an attached office of the Ministry of Health and Family Welfare (MoHFW) with full functional autonomy. With reference to the governance of the NHA, it is governed by a Governing Board chaired by the Union Minister for Health and Family Welfare. It is headed by a Chief Executive Officer (CEO), an officer of the rank of Secretary to the Government of India, who manages its affairs. The CEO is the ex-Office Member Secretary of the Governing Board.

The implementation of PM-JAY is done by NHA in partnership with the State Health Agencies (SHA) that are set up by the states. The scheme is financed by the Union and state governments in a ratio of 60:40 respectively for most states and 90:10 in the case of North and North-eastern states (90% covered by Union) and 100% covered by the Union government in case of Union Territories (UTs). The scheme is also implemented in partnership with public and private health care providers to ensure service coverage and provision is accessible, equitable and of

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[1] About Pradhan Mantri Jan Arogya Yojana (PM-JAY): https://PM-JAY.gov.in/about/PM-JAY

good quality. Thus far, as of July 2024, the scheme has empaneled 30 174 hospitals of which 17 036 (56.5%) hospitals are public and 13 138 (43.5%) hospitals are private.

The role of National Health Authority and its impact as an institution on UHC (purchaser)

As a result of this engagement as purchaser of services from public and private hospitals for secondary and tertiary care for 40% of the population, the NHA has great influence on the quality of services, the efficiency of service delivery and in improving equity in care. These elements of value for money are critical for ensuring UHC. Thus, the NHA, is positioned as an influential stakeholder in the health sector to use its instruments and policy levers to drive value for money.

The genesis for the review

Thus far, the NHA has implemented several interventions to drive value for money including:

a) To improve the quality of care, NHA has implemented an accreditation system for hospitals empaneled with the scheme with additional incentives above the base package rate to ensure quality services. It has also implemented standard treatment guidelines to drive quality of care according to agreed standards of care. These have been implemented for three years now and have shown some influence on driving improvements in quality of care and claim adjudication. There is however room for improvement in the design and implementation of the guidelines [1]. Others include the grievance redressal mechanisms for both beneficiaries and providers.

b) Diagnosis related groups (DRGs) pilot that is being implemented by NHA to review alternative payment mechanisms to improve provider reimbursement, payment rates as well as quality and efficiency.

c) The process for developing and revising the health benefit package and the price-setting mechanisms that have been implemented by the scheme. These mechanisms have been implemented to drive improvements in service coverage and equity, in quality of care, in efficiency and cost-containment. There is a need however, to improve the process of rationalization and price-setting to achieve policy goals.

d) Digital modules relating to beneficiary identification systems (BIS) for beneficiary enrolment and management, hospital empanelment module (HEM) for hospital empanelment and a transaction management system (TMS) for claims adjudications. Currently, interoperability of the system with other information systems in the sector is limited.

NHA is also implementing other reforms in strategic purchasing to optimize efficiency and equity, including a value-based care (VBC) pilot that is implementing performance incentives based on robust indicators to improve the quality of care. This document is a synthesis of the global evidence on the implementation of the VBC concept, the evidence of effectiveness and cost-effectiveness of different practices and what lessons India can draw form the global empirical experience to better design the reforms for VBC.

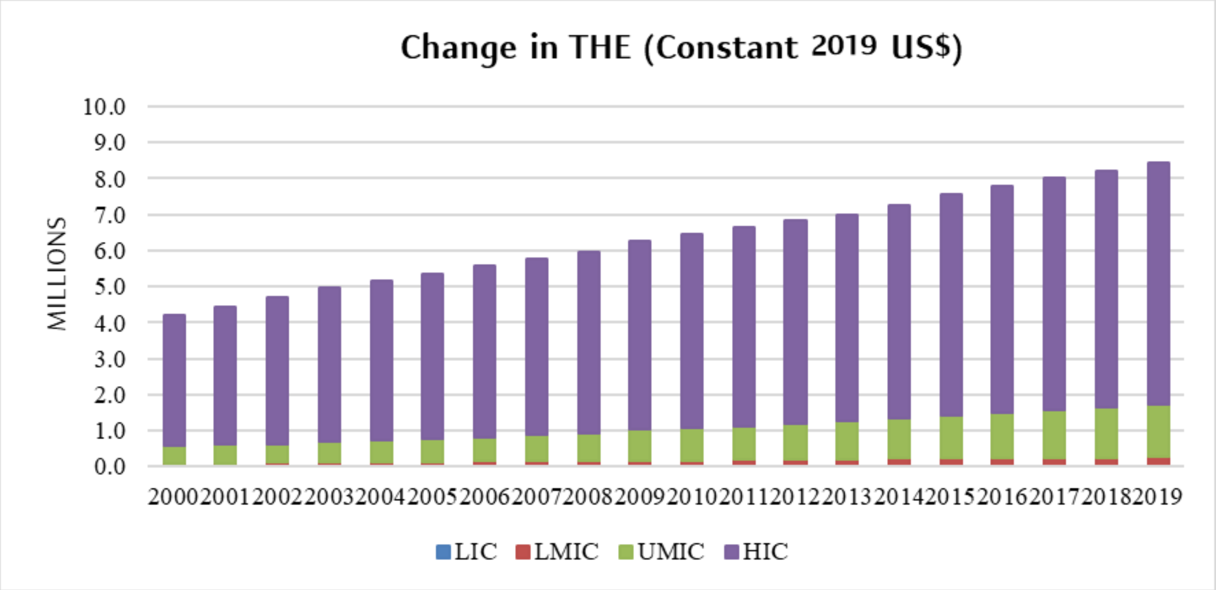
Background on value-based care

In many contexts around the world, the challenge of increasing health expenditure is a concern. The WHO reports that health expenditure has doubled over the past two decades reaching US$ 8.5 trillion in 2019 and 9.8% of global gross domestic product, that is, GDP (up from 8.5% in 2000) [2]. Inequalities in spending between countries have persisted and far outstrip inequality in the distribution of global GDP. For instance, the report shows that high-income countries accounted for nearly 80% of global spending on health (with the USA alone accounting for more than 40%).

Across middle- and high-income countries, the share of health spending financed by domestic public sources has risen over the past 20 years, and out-of-pocket spending has reduced. The increasing reliance on public sources of spending has resulted in increasing attention to the rise in health expenditure. This is more so following recent economic shocks globally including the 2008 economic recession and the recent COVID-19 pandemic that caused significant contraction of economies globally.

The rise in health expenditure in many countries has been attributed to increasing costs of adoption of health technologies and interventions such as chemotherapy, organ transplant, treatments for rare diseases and genomics, new effective vaccines that do not substitute for those previously on the immunization schedule and thus requiring more investment; increasing healthcare demand because of increasing population as well as the high costs related to care for the elderly. This has prompted concerns regarding financial sustainability and the exploration of policy levers for curbing growth in costs and for improving value for money.

Fig. 1. Global changes and distribution of THE (2000-2019)



Source: Global Health Expenditure Database

Recent evidence in OECD countries also shows that there are unwarranted variations in the care provided by providers [3]. This variation may be due to underuse of services, overuse of services or supply challenges related to oversupply of low value care and overuse or underuse of effective care. Others have suggested that these variations may result from differences in demand for services that are sensitive to the preferences of the patients (preference-sensitive) or that are supply-sensitive resulting in inequities and inefficiencies in health spending [4]. These variations occur within and across countries and vary with the type of service. In the United Kingdom, it was estimated that these unwarranted variations in care cost the National Health Service (NHS) at least £5bn of the £55.6bn spent annually by acute hospitalizations [5]. Additionally, a multi-country assessment by the OECD showed variation within and across countries for services.

The notion of VBC has become increasingly popular globally in many settings as a plausible solution to enable health systems to improve the value of health services offered whilst curbing growth in health expenditure. This notion has been defined as:

> "[Patient value is defined as] patient-relevant outcomes, divided by the costs per patient across the full cycle of care to achieve these outcomes. value-based healthcare focuses on maximizing the value of care for patients and reducing the cost of healthcare." [6]

The concept described by Porter and Teisberg calls for a focus on health outcomes of value to the patient rather than a focus on reducing costs. The framework described by Porter and Teisberg includes six main components [7]. These six themes are discussed briefly in this section but will be explored more deeply in the subsequent sessions in Part B. They include:

1.a.1. Organize integrated practice units

The framework proposes the development of integrated practice units (IPUs) which are organized around a medical condition or a set of closely related conditions (or around defined patient segments for primary care). In these IPUs, care is delivered by a multi-disciplinary team of physicians, nurses, etc., who provide care across the full care cycle including outpatient, inpatient, rehabilitation, supporting services (such as nutrition, social work, and behavioral health). In these units, patient education, engagement, and follow-up are integrated into care.

1.a.2. Measure costs and outcomes for every patient

This component of the framework makes the argument for greater and deliberate measurement of outcomes that are of value to the patient rather than driven by the perspective of the provider. Porter and Teisberg proposed an outcomes hierarchy that accounts for improvements in health status, improvements in the functionality of the patient (across the full care cycle) and the sustainability of the outcomes. It also proposes tracking of healthcare costs across the full care cycle accounting for all resources consumed during the entire care cycle. The proposition is premised on the need for tracking outcomes and costs to understand how outcomes relate to costs to enable providers to re-program and re-allocate health services for greater value for money.

1.a.3. Move to bundled payment for the care cycle

This component recognizes the limitations of payment models like fee-for-service (FFS), global budgets, and capitation with regard to incentivizing focus on value and improved outcomes. Global budgets and capitation payments provide lumpsum amounts to providers and should ideally incentivize them to maximize output while saving on spending and reducing costs. This often has deleterious effects of compromising quality of care and encouraging shifting of patients from one service provider to another. Other traditional payments have included FFS payments that reimburse providers for every service provided. This often has the effect of encouraging an oversupply of services (which may not be necessary) and may also result in poor quality care.

1.a.4. Integrate care delivery across separate facilities

This theme is premised on the argument that the traditional organization of services in health facilities is designed to cover everything for everyone and therefore compromising on value for money and efficiency. It therefore argues for organizing services within a network of facilities where each facility covers services of a leaner scope that it is best suited to provide and eliminating or transferring those where they cannot realistically achieve high value. This may entail creating partnerships with facilities best suited to cover those services, for example, community centres or primary care units.

1.a.5. Expand excellent services across geography

This theme addresses services that are provided by some specialized centres that may need to extend service delivery beyond the immediate vicinity of the facility. Targeted geographic expansion is required to ensure that services provided by superior providers (providers providing the best quality care) extend to more patients than they can physically serve.

Targeted expansion may include models such as hub-and-spoke models where the provider develops satellite facilities that are staffed by clinicians and other personnel employed by the parent organization. Another model includes the creation of affiliations with similar and smaller clinics in which the facilities and capacities of those clinics are used by the IPU instead of increasing their own capacity.

1.a.6. Enable a suitable information technology platform

This enhances the efficacy of the five elements of the framework above. Integrated information systems should be patient-centric, collect data in a standardized manner and collect all manner of relevant patient information (clinical notes, treatment, laboratory tests, imaging tests, etc.). This data should be able to be retrieved by all relevant parties whilst ensuring data security and privacy for clinical and policymaking use. This shall be explored in greater detail below.

Objectives of the review

a) To review the various conceptualizations of value and VBC globally and in India.
b) To review the design and implementation of VBC to identify the models that have demonstrated effectiveness and value for money, design features that have facilitated this as well as enabling and constraining factors.
c) To provide options for defining value, a framework for design and implementation of VBC adaptation for India and models for each component of the framework that is suited to the context in which NHA and its stakeholders are operating.
d) To propose implementation arrangements and necessary shifts to be considered for the successful implementation of VBC in PM-JAY.

Flow of the document

This document is divided into four main sections. The flow of the document is to enable the reader to follow what has been gleaned in the literature thus far on VBC in terms of the lessons that are important for the design, implementation, and evaluation of VBC for UHC to the development of a revised framework of the same, and finally to how the same can be applied to the India health financing landscape for impact.

Part A: This section summarizes empirical experience of implementing VBC in the real world from a policy perspective. The main issues of concern addressed by the review include whether the whole framework is adoptable at the national level or even at a state-level and, if so, whether it is best adopted incrementally or as a big-bang reform. It further explores, the common elements countries implement and the reasons behind the same. It also explores the broader systemic concerns that are needed to successfully implement VBC. It also explores the issue of valuation in healthcare and what that means for the implementation of the approach. Lastly it explores the question of what level is best to adopt VBC.

Part B: In this section of the document, each element is described in detail and elements that are important including: how that element is implemented with case studies of best practice; what is the real-world evidence of effectiveness, cost-effectiveness and affordability, sustainability, inter alia, what are the challenges or enablers in the implementation of this pillar and finally; what can be said about its scalability and adoption for the long term. Additionally, this section also sheds light on some international experiences and examples of VBC in practice, with detailed country examples provided in the accompanying supplemental report.

Part C: It includes a synthesis of findings from the previous sections and proffers our thoughts on a new framing for VBC for UHC and includes a synthesis of lessons for the implementation of VBC.

Part D: This section provides recommendations for how India can systematically approach VBC to further its UHC agenda. It also includes suggestions for an implementation roadmap and what is needed for it.

Methods

The assessment was largely a secondary scoping review of the literature. We reviewed literature sourced from:

a) Peer-reviewed journal articles were included from electronic databases that included Google Scholar and HINARI/GIFT, PUBMED. We included articles that were published between January 2010 to August 2023. Search terms included "value-based care", "value-based care" and "health" and "universal health coverage".

b) We searched government documents from government websites including web pages of Ministries of Health and equivalent, purchasing agencies for health insurance schemes in countries and any other agency that is critical for formulating policy documents. Countries that were included in the search were those where peer-reviewed literature had indicated that there was implementation of VBC at a national or subnational level. These included – USA, United Kingdom, Netherlands, Norway, Sweden, Finland, Denmark, Australia.

c) The websites of multilateral organizations and regional bodies were also searched to identify policy documents or strategies on VBC that are being employed, these include the European Union, African Union, World Bank, Asian Development Bank and more.

A narrative synthesis of findings was adopted for the review. This included grouping the findings according to themes emerging in the literature on the practical experience of VBC and the issues that emerge regarding motivation for the transition towards, the feasibility of implementation, barriers and facilitators to effective implementation and the sufficiency of the framework given the UHC agenda globally.

Part A

Theory and empirical experience

Findings of the review

Literature review on empirical experience of VBC implementation across the world

A recent review assessed the extent of implementation of VBC in 25 countries [8]. It concluded that in countries with health spending less than 5% of GDP, there was very little alignment with the pillars of the VBC framework while in contrast, countries with spending higher than 5% tended to have higher alignment to VBC pillars. The former tended to be developing countries, the latter more higher income countries including the USA, United Kingdom, Sweden, Canada, Australia, and Japan.

The VBC concept was born in the USA as one of the means to check the growth in health expenditure resulting from uncontrolled FFS payments driven by prioritization of the volume of services produced, instead of the value offered to patients in terms of the outcomes of care. In the wake of healthcare reforms geared towards increasing service coverage and financial protection through the Affordable Care Act (ACA) [9], the USA has implemented numerous VBC reforms to improve value for money. The ACA and other associated laws have provided an enabling legal framework and policy framework [10, 11] for facilitating the implementation of VBC in the USA. This strategic direction has benefitted from a decade-long experience of implementing and testing over 50 models of VBC including bundled payments, accountable care organizations (ACOs), home-based value programmes and the quality payment programmes [12-15]. It has also led to national programmes rolled out based on VBC principles including the programmes shown in Table 1 below:

Table 1. VBC programmes in the USA

VBC programme	Definition
Hospital Acquired Conditions Programme	Encourages hospitals to improve patients' safety and reduce the number of conditions people experience during their time in a hospital [16].
Hospital Readmissions Reduction Programme (HRRP)	Encourages hospitals to improve communication and care coordination to better engage patients and caregivers in discharge plans and, in turn, reduce avoidable readmissions [17].
The Hospital Value-Based Purchasing Programme	Rewards acute care hospitals with incentive payments for the quality of care provided in the inpatient hospital setting using the Inpatient Prospective Payment System (IPPS) based on the quality of care they deliver [18].
The End-Stage Renal Disease Quality Incentive Programme (ESRD QIP)	Promote high-quality services in renal dialysis facilities by linking a portion of payment directly to facilities' performance on quality of care measures [19].
The Physician Feedback/Value-Based Payment Modifier (Value Modifier) Programme	Provided for differential payment using a value modifier to payments on the Medicare Physician Fee Schedule (PFS) based on the quality of care compared to the cost of care during a performance period [20].

Skilled Nursing Facility Value-Based Purchasing	Award incentive payments to skilled nursing facilities (SNFs) through the SNF value-based purchasing programme to encourage SNFs to improve the quality of care (measured by all-cause hospital readmissions) they provide to Medicare beneficiaries [21].
Expanded Home Health Value-based Purchasing	Home health associations are provided incentives for better quality with efficiency in healthcare provision [22]. It is an expansion of the original home health value-based programme that was piloted in nine states.

Despite similar motivations for adopting VBC practices in the United Kingdom (UK), the experience varies slightly from that in the USA. The main drivers for VBC in the UK have been increasing evidence of inefficient and inequitable care demonstrated by evidence of unwarranted variations in service access and availability with pockets of overuse of some services, underuse of others and incidences of low-value care. Furthermore, reviews have demonstrated potential cost-savings to the NHS if these inefficiencies are addressed.

Though the constitution of the NHS states that 'The NHS is committed to providing the best value for taxpayers' money', there is no agreed consensus on what defines value in the NHS and what VBC in this context means [23]. Despite early attention by the National Institute for Health and Care Excellence (NICE) in the UK to improving efficiency in health through institutionalized health technology assessment (HTA) to determine the interventions funded by the NHS, and the development of standard treatment guidelines (STGs), there has been no overarching policy framework that comprehensively addressed the notion of VBC until recently.

The drive for VBC commenced with the NHS Wales through the implementation of the "Prudent Health Care" initiative which was a collaborative effort between patients and their providers to improve the quality of care and equity, reduce unwarranted variations in practice, and irrational prescribing [24]. VBC has since been used as a vehicle for implementing "Prudent Health Care" within the national policy for "A healthier Wales" [25]. A national VBC team has also been assembled to implement it.

VBC in NHS England has followed a more incremental approach with the NHS implementing discrete programmes at different levels of scale until more recently. Table 2 summarizes some of these initiatives.

Table 2. VBC initiatives in the United Kingdom

VBC initiative	Programme elements
Getting it right the first time (GIRFT)	• This is a national programme that was designed in response to the challenge of unwarranted variations in health services [26].

VBC initiative	**Programme elements**
	• It is premised on improvements in clinical practice and quality without much investment required to make it functional. The implementation of the model includes 40 surgical and medical workstreams and several other cross-cutting, system-wide projects which are led by a prominent clinical specialist. The specialist and team visit the Trusts to discuss the findings of the review and the areas that need improvement. Hospital Episode Statistics (HES) and other relevant registry or professional body data and inputs from a standard questionnaire regarding service or pathways are filled in by Trusts under review. Reports are developed annually on the performance of Trusts. Trusts implement improvements supported by regional teams. Review metrics feed into the Model Hospital portal detailed below. The programme is aligned with the integrated care systems strategy.
NHS right care	• This is a programme that has been implemented to support health and care systems to improve care quality, population health and system sustainability through three delivery strategies [27]: It does this through three modalities i) Direct support – clinical commissioning group development and embedding operational support; ii) Facilitative support – for example, enhanced commissioning support unit development and promoting and commissioning innovations; iii) Creating the right environment – develop via a concordat with other arms-length bodies, monitoring programmatic variations and stakeholder engagement such as with Public Health England.
Model health system	• This is a data-driven model (portal-based) that includes metrics on care quality, responsiveness and productivity across systems, Trusts and hospitals that can be used for benchmarking leading to service improvements [28].
Integrated care system (ICS)	• This is an integral part of the NHS England long-term plan for health. • Recent legislation (the Health and Care Act 2022) makes ICSs statutory thus facilitating the implementation of this strategy. • The journey to integrate service delivery in England started in 2014 with some pioneer boards and has been scaled up nation-wide following the development of 42 Integrated Care Systems that are integrating care across community trusts and primary care providers as well as specialist hospitals [29]. It is aligned with the programmes highlighted above.
Atlas of variation	• A tool developed by the NHS to track and document variations in practice across geographic areas, boards, Trusts and Boards [30]. • E-products include an interactive tool that can be used to compare practice, compendium atlases and themed atlases, for example, for liver disease. The data is contextualized using a description of the variation and provides options for action. • This is used as part of the identification of intervention conditions for the GIRFT programme.

VBC initiative	**Programme elements**
Shared decision making	- Is at the heart of person-centric care in which the individuals and the clinicians work together to understand the diagnosis, tests and treatments, management and support packages so as to make the most of the patient's knowledge of themselves and the clinician's expertise to determine the appropriate treatment course [31]. - Is part of a broader comprehensive model of personalized care (36) that includes five other pillars including i) personalized care and support planning; ii) enabling choice, (including legal rights to choose); iii) social prescribing and community-based support; iv) supported self-management and v) personal health budgets and integrated personal budgets.
National Institute for Health and Care Excellence (NICE)	- This is a national programme that provides evidence-based assessments of health technologies and services using economic and epidemiologic models to drive the adoption of innovations that provide value for money for health in the UK [32]. NICE does this through the development of standard treatment guidelines, quality standards and indicators, a clinical knowledge base that has been developed to summarize the evidence on clinical care and Health technology assessments for the British National Formulary.
National Consultant Information Programme	- This is a portal that has been developed to support consultants in benchmarking their performance on clinical activity and patient outcomes [27]. The tool is useful for continuous learning and development for the consultants and is used to improve their practice.

The experience in the UK shows barriers that often arise at the policy level, in the implementation of VBC, which include:

A. Limited access to comprehensive and good quality data to define and accurately measure outcomes for all conditions.
B. The lack of a roadmap that defines the path to VBC and how all the disparate elements implemented by the NHS align and what the anticipated outcomes will be.
C. Multi-disciplinary engagement across different stakeholders including patients. This requires evidence-based mechanisms for effective citizen engagement.
D. A systemic approach to VBC that places the reforms within an enabling financing, information, and governance environment.
E. Better evidence on effectiveness (not efficacy data) that can be used for resource allocation purposes.

The implementation of VBC in Australia has taken on a very varied approach with pilots of some programmes in states like Victoria and Western Australia and a state-wide initiative in others such as New South Wales (NSW) [33]. The government of NSW has implemented a state-wide strategy for the implementation of VBC through the Integrated Care Approach [34].

Regarding the implementation of VBC in the EU, there is no overarching strategy for the implementation of VBC. The European Union (EU) has a longstanding Expert Panel on

Investment in Health that has been commissioned to provide non-binding guidance on investing for health [35]. The Expert Panel has provided recommendations for improving the value for care by reducing investments in low-value care and increasing investment in high-value care. Central to this is the definition of value. The panel proposes four aspects of value that need to be considered to incorporate the principle of solidarity, which is one of the core values from the European standpoint.

Table 3. Aspects of value in EU framework on VBC

Value attribute	Definition
Allocative value	Equitable distribution of resources across all patient groups.
Technical value	Achievement of best possible outcomes with available resources.
Personal value	Appropriate care to achieve patients' personal goals.
Societal value	Contribution of healthcare to social participation and connectedness.

Adapted from: Defining value in 'Value-Based Healthcare'[35]

The panel has provided some proposals for improving VBC in the European Union including:

- Creating greater awareness of health as an essential investment for an equal and fair European society and of the centrality of it as a European value to achieving UHC.
- Develop a long-term strategy for a step-by-step value-based approach towards the change of culture.
- Support research and development (R&D) of methodologies on appropriateness and unwarranted variation by creating collaborative avenues for research and enabling data creation and sharing.
- Encouraging health care practitioners to be more aware of value in their practice and discouraging low-value care.
- Support the creation of learning communities, including communities of health professionals, to bring together the best expertise, experiences, and practices.
- Encourage and support patient engagement in policymaking and shared decision-making for their care considering their knowledge, experiences, and preferences.

Despite the lack of a strategy on VBC, there are some union-wide initiatives that have commenced to further VBC, including the Regulation on Health Technology Assessment (Regulation (EU) 2021/2282) [36, 37]. Since 2004, the European Union has instituted a mechanism for joint HTA across the member states [38-40]. In 2005, the EU commissioned a network of organizations at the national level to conduct joint assessments for health technology to facilitate ease of market entry of devices and medicines. The EU collaboration on HTA consisted initially of two components that is the HTA network and the EUnetHTA Joint Actions. The HTA Network connected national authorities or bodies responsible for HTA. The network was introduced by Directive 2011/24/EU on the application of patients' rights in cross-border healthcare to provide strategic guidance and policy orientation for scientific and technical cooperation. The voluntary network included the participation of all the member states of the EU who were represented by the national HTA organizations or institutions. They set the policy direction for the HTA and included potential areas for collaboration across the member states. More recently, the EU Commission has developed regulation for HTA (Regulation (EU) 2021/2282)[37] which provides a framework for the establishment of a coordination group of national or regional HTA authorities, a stakeholder network and lays down rules on the involvement in joint clinical assessments and joint scientific consultations of patients, clinical experts, and other relevant experts [41]. It replaces the HTA Network and EUnetHTA and has taken effect since January 2022 and is effectual till January 2025.

VBC in Latin America is not as well integrated into the health system design as in Europe and the USA. A few studies have summarized experiences in countries like Argentina, Brazil, Chile, Colombia and Mexico [42]. A global review of 25 countries shows that the implementation of VBC in this region is not very advanced, with the exception of Chile and Colombia which are more advanced adopters [8]. The study assessed enabling factors and institutional factors for VBC as well as the implementation of outcomes-based care, patient-centred care, bundled/ block payments; payment for performance linked to quality and quality standardization.

Regarding the presence of enabling factors, Chile was the only Latin American country assessed that had a national strategy for VBC while Colombia was the only country that had a quality standardization mechanism. Colombia and Chile were also the only countries in the region where the Government and/or major payer(s) are actively collecting patient treatment cost data in some areas. There was no such mechanism in Brazil and Mexico. The study highlighted Chile as the only country that is implementing bundled payments in several areas.

More recently however, there have been privately-led initiatives to standardize Patient-Reported Outcome Measures (PROMs) in Brazil using the tools available from International Consortium for Health Outcomes Measurement (ICHOM) [42-44]. This has been initiated by Hospital Israelita Albert Einstein, a private, nonprofit hospital system in São Paulo, Brazil that is implementing VBC comprehensively through the installation of a Value Management Office that works with the medical practice group of the hospital to coordinate care in IPUs and provide necessary training, coordinate outcomes and measure costs through adopting the ICHOM standard sets in low backpain, hip and knee osteoarthritis, breast cancer, and coronary artery disease. It has also begun the development of bundled payments for some conditions as well as coordinating with the financial management section of the hospital to collect data across disease episodes rather than discrete services.

VBC elements in Asia are rife but with no comprehensive implementation of the entire framework of VBC envisaged by Porter and Teisberg. The earlier-mentioned review of 25 countries found that in selected countries in Asia such as China, India, Indonesia, and South Korea there are elements of systematic approaches of quality standardization[8]. The review found that in South Korea and in the United Arab Emirates, there was moderate alignment to VBC with the implementation of systematic approaches of quality standardization as well as implementing outcomes-based care and patient-centred care. In countries like Japan, there was no element of VBC found at the time of the assessment. Asia also has a vibrant HTA element which is not part of VBC per se, but is a critical input in the definition of care pathways [45]. This includes countries like Thailand, South Korea, and Taiwan.

Early experiences include the implementation of VBC for congenital heart disease in Pakistan [46]. The authors describe the feasibility of implementing the agenda including the challenges that emerge in the process. These include the challenges of political buy-in at the provider level. They also highlight the data quality and availability challenges particularly due to poor information systems. The measurement of costs and outcomes is particularly challenging in this context and requires upfront investments in human and financial resources which can affect sustainability. Challenges in defining care pathways as well as the development of IPUs arise from resistance to change as well as the structural challenges due to fragmented service delivery.

There is limited evidence of a comprehensive approach to the implementation of the VBC agenda in Africa. In Kenya, a community-based approach, called MomCare to implementation of VBC for improving maternal child health outcomes has been implemented using a mobile-based digital solution for enabling bundled care payments [47]. The cohort-based model includes follow-up of mothers using a care pathway and bundled payments, where outcomes are defined using ICHOM for outcome measures. The mobile-based app enables bi-directional communication between the providers and patients. PROMs data is collected using standardized forms that are filled in through telephone conversations by the providers. The model has shown that VBC is feasible in this context enabled by simple digital solutions and enables delivery of care for mothers at predictable cost per enrollee with improved adherence.

There have been several tentative efforts to use and systematize HTA at the country level [48-51] but more recently, at a regional level, the continent of Africa is beginning to systematically address local needs of HTA for health products including vaccines [52-54]. The recent endeavor enabled by a specially created unit at the Africa Centre for Disease Control is developing systematic procedures and has begun undertaking assessments on behalf of member states. This has been particularly spurred by the recent COVID-19 pandemic.

Conclusions from implementation experience

We sought to review the implementation experience of VBC as a policy or strategic approach within countries. The literature reviewed has shown that VBC, as a holistic strategy, has had very limited implementation. Much of the implementation experience has come from high-income countries at a national scale in NHS Wales and in some cases at a sub-national level such as NSW in Australia [8, 47]. Even in these instances, the implementation has been partial, with some elements implemented and not the approach in its entirety. There has been much less implementation in LMICs. The literature shows limited but growing interest in VBC in LMICs as buttressed by the findings from the global survey of 25 countries on the implementation of VBC, even though these contexts need VBC approaches more than the high-income counterparts. The major challenges affecting adoption are weak human resource capacity, as well as information, communication, and technology systems for good data. These affect the measurement of costs and outcomes, the development of IPUs and care pathways and bundled payments.

The review highlighted some common themes that emerge across countries that are worth noting, that are critical for successful adoption and implementation of VBC as well as for framing of VBC in general. These are also informed by some of the barriers that were identified in the experience in the UK in implementing VBC. These include:

An enabling legal and policy environment: This will help anchor VBC firmly in the health systems policy agenda and is critical for the adoption and scale up of VBC. This was made clear in the implementation experience in the USA and in NHS Wales. The policies or strategies they adopted highlight the key elements and the linkage to broader health goals, identify human and financial resources as well the implementation arrangements, including the roles of different stakeholders.

Furthermore, the enactment and enforcement of laws have enabled greater implementation of VBC in some instances. This was evident in the USA, where legal instruments were leveraged to change payment systems and improve the adoption of electronic health records (EHR). These are also important for driving HTA, and value-based pricing for pharmaceuticals and diagnostics as elements that we contend, need to be included in the VBC framework. The congruence between different laws and policies regarding each element of the framework must be examined to ensure that synergies are harnessed and there are no conflicts. This includes the designation of roles and responsibilities for the different elements. Confusion in the institutions responsible for different elements can hamper the progress that is realized in implementing VBC. Therefore, a steering team is critical in providing oversight in the congruence of different policy and legal instruments. This also implies that this team should be sufficiently influential within the system as to be get an informed assessment of this congruence and offer solutions that can be practically implemented.

A broader agenda for VBC: The empirical experience shows that many countries are including broader definitions of VBC than what Porter and Teisberg propose in the framework. In particular, the empirical experience in the UK, EU and Australia shows that realizing value for money regarding pharmaceutical pricing, is a critical element to address in order to ensure VBC at a system and patient-level. It is therefore important that framing VBC include elements that contribute to pharmaceutical pricing.

A transition plan that charts the path for adoption of VBC: As earlier noted, the framework has been implemented to varying degrees in several contexts. No one context has comprehensively implemented the entire framework at either level of the health system. The most common elements of the framework that have been implemented and are documented with evidence are integrated care, bundled payments, outcome measurements and to a lesser extent estimation of the costs, and IPUs. The integrated information systems and to an even lesser extent, the geographical expansion of services, have been adopted.

The implication of this is that for any country pursuing an agenda of VBC to improve performance on UHC and patient outcomes, there is need for a transition plan. As has been seen, implementation initially starts with one or a few pillar(s) of the framework being implemented, and usually starts out at the provider level or subnational level. Even the few countries that have scaled up at the national level or state-level started with implementation at a lower level of scale. This transition plan should sequence reforms based on what currently exists, leveraging current reforms and building on them instead of replacing them where possible. It should identify which areas are amenable to immediate change with little cost and sequence them accordingly. It should include clear timelines for execution as well as identifying roles and responsibilities and resources needed (human, financial, IT, etc.). It should be objectives-oriented with clear policy goals and the means identified.

It is important to understand that the introduction of VBC into a health system requires an understanding of the interventions that are relevant at different levels of engagement. This ranges from the broader systemic and institutional setup under which VBC will operate (macro), down to the level of the clinician-patient interaction (micro) at the downstream level. Thus, different sets of interventions are necessary when actioning the move towards VBC.

- **Micro level:** At the patient-provider interface, the patient’s clinical pathways and ensuring continuity of care should be paramount. That entails considering the goals and preferences of patients alongside established guidelines.

- **Meso level:** A need for optimal allocation of resources and optimization of all interventions across the whole pathway of care, underpinned by a person-centred approach.

- **Macro level*:*** Putting in place institutional, regulatory and governance systems and safeguards to steward the actions of all system stakeholders in the general direction of VBC principles.

The VBC agenda should be embedded within a broader health system agenda for UHC. The design and implementation of VBC should not be divorced from other reforms in the health system. This is to ensure that the reforms in VBC benefit from any synergies that may already be built in the system and are planned for implementation and that there are no conflicts in the design and implementation of other reforms in health systems.

Strategic stakeholder engagement in design and implementation: The health system includes many different actors that are important in the VBC ecosystem. These include but are not limited to health care providers, legislature, Ministries in charge of health, the purchaser(s), beneficiaries, etc. Implementation of VBC requires a comprehensive approach in terms of the stakeholders in the system. To facilitate effective stakeholder engagement, a VBC steering team should be instituted to spearhead the consultations of different stakeholders and involve them in the design of the reforms. The steering team must have the legitimacy and power to convene different stakeholders to deliberate on the reforms. This should ideally include stakeholder mapping and ensuring a shared understanding of VBC across stakeholders.

One of the dividends of stakeholder engagement is the identification of the values that should drive the VBC agenda in the country. Value is very much context-driven, largely by prevailing culture and social beliefs and norms as well as the economic status of the context. Within a context, different values may drive the prioritization of services at different times. It is important therefore, to define values for the context by local stakeholders and to include an agreed mechanism for aggregating findings.

The implementation experience of VBC in decentralized contexts is varied: The evidence shows that in decentralized contexts like the UK, USA and Australia varied models have been implemented depending on the context. The literature, however, is largely silent on the impact of these varied models on UHC at a population or national level. Regarding some potential barriers in transitioning to VBC, there exists a possibility that over-reliance on decentralized or devolved models may create fragmentation within the system. This may not necessarily pose a problem in the initial pilot or experimentation phase, but it is essential that a more coordinated and streamlined approach to VBC is adopted in the medium to short term. The USA provides an example in which the varied approaches have been used within a more generic framework developed by the Centers for Medicare and Medicaid Services (CMS) and may well be worth emulating. Variations in models are co-developed with CMS and evaluated for impact and to enable learning.

The role of champion: The presence of an influential decision-maker is critical for the successful adoption and continued implementation of VBC. The experience in the case of the USA where the Congress provides oversight on the innovation models and makes decisions on the scaleup of programmes is a good example of the role of champions in furthering an enabling legal-policy environment and for securing financing for the initiative. Similarly, in NHS Wales, the involvement of the Minister was a critical enabler in the adoption of VBC for the implementation of the ‘Prudent heath care’ in Wales.

Human resource capacity for VBC: There is a need to have a dedicated VBC team that interacts with providers and other stakeholders as was shown by the NHS Wales, NHS England as well as the CMS innovations team in the USA. The team works with the stakeholders to monitor service delivery and course-correct during the implementation period to enable the teams to provide more agile and responsive healthcare. The experience in these contexts also shows that a training and awareness-raising plan is needed for the implementation of VBC. This is necessary for every stakeholder and most critical for providers who must adjust to new ways of implementing care in IPUs, across networks, undertake performance measurement, develop awareness of costs, etc.

Relatedly, more upstream measures of inculcating the values, understanding and practice of VBC within the medical education system are critical [246]. Moving to a system of VBC requires that physicians and physicians-in-training learn to think differently about their role within the larger care team, about what constitutes an effective care solution, and about the importance of measuring the health outcomes that matter most to patients. That learning should begin during medical school. A good example of this is at the University of Texas at Austin's Dell Medical School (DMS). At DMS, students study the principles of VBC delivery and are also expected to apply the same during their clinical rotations at the University of Texas Health Austin's affiliated clinics.

Monitoring and evaluation and learning culture systems: A learning culture is important for entrenching VBC in the system. It is critical to inform the design of the reforms and to adapt to the changing needs of health system. This should be based on a clear M&E plan that deliberately creates evaluation models embedded in the implementation process. This will help enable the VBC team to pick up any lessons for reconfiguration of the scheme. This requires the generation and maintenance of robust, up-to-date and quality information databases for creating the necessary evidence base for decision making. Nurturing structures and processes for continuous M&E at a policy and operational level is also essential to ensure a continuous cycle of improvement based on learning.

Public-private engagement: A collaborative approach between private and public actors to further the VBC agenda, including academia and private providers, is critical. Collaborations with the private sector in the US and in Wales have reshaped the VBC agenda and facilitated uptake. These could be used to inform the design of models for payment for outcome measurement and for the design of IPUs. They could also create opportunities for learning from the public sector for the private sector and vice-versa.

Active change management strategy: Transitioning to VBC extends beyond solely financial or clinical reforms and requires a cultural shift in the way value is perceived within a health system. The proposition of a change in 'culture' for VBC is highlighted extensively in the literature [55]. Thus, a change management plan and strategy are critical for improving the adoption of VBC.

What is value in health?

One of the major contributions of VBC to the public health discourse has been the broadened understanding of valuing health. The notion has generated debates and fostered greater clarity, albeit with lingering questions on:

a) What is the value in health?
b) How is value defined and measured?
c) What values are important for decision making in health?
d) Whose values are important to consider?
e) How should these values be elicited?
f) How do values that are seemingly contradictory reconcile to inform fair priority setting?

Value in health?

It has been said that value like beauty, is in the eyes of the beholder [56]. There is no single agreed definition for value. Porter and Teisberg have certainly contributed to the current conceptualization with the framing of value in terms of "patient health outcomes per unit of cost" [7]. However, value or the values that undergird priority setting in health should account for more than economic criteria for judging the worth of investments in health. Arguments have been made for "socially reflexive and responsible valuing of healthcare that accounts for the socioeconomic and political processes that make a thing valuable for society and its implications"[57]. In so doing, these arguments recognize that values maybe contextual in nature, drawing from social constructs as well as the need to not only pay attention to social justice (fair distribution of resources) but also pay attention to procedural justice (due process in decision making) to ensure fair and legitimate priority setting processes. These processes, therefore, include consideration of multiple values or decision criteria as well as multiple stakeholders and a means for collating and reconciling differing views and the relative importance of different values. This section synthesizes key issues in the literature on the issues raised in valuing healthcare.

What values should be considered in health?

The long history of assessing value in care in HTAs and other priority settings has been dominated by concerns for cost-effectiveness and related economic frameworks for technical and allocative efficiency. However, more recently, these have been broadened to incorporate other conceptualizations of value in various jurisdictions. In the EU for instance, the Expert Panel on Effective Ways of Investing in Health, proposes a concept built on four pillars including [35]:

- appropriate care to achieve patients' personal goals (personal value),
- achievement of best possible outcomes with available resources (technical value),
- equitable resource distribution across all patient groups (allocative value) and
- contribution of healthcare to social participation and connectedness (societal value).

The NICE in the United Kingdom has also defined its principles for valuing care in terms of [32, 58]:

A) Moral principles including respect for autonomy, non-maleficence, beneficence; distributive justice.
B) Distributive justice with a particular focus on balancing the tensions between the utilitarian and egalitarian approaches to welfare. The utilitarian approach aims to involve allocating resources to maximize the health of the community while the egalitarian approach involves distributing healthcare resources to allow everyone to have a fair share of the opportunities available, as far as possible.
C) Procedural justice ensuring public participation in decision-making as well as ensuring relevance of decisions for most of the population, allows for appeals process (challenge and revision) and processes for public regulation of the process to ensure that it adheres

to all the principles set for procedural justice.

D) Evidence-based decision-making that emphasizes clinical and public health effectiveness, cost-effectiveness, individual choice, rare conditions and rule of rescue.

E) Avoiding discrimination by race, gender disability, socio-economic status, age, stigma related conditions as well as behavior-related conditions.

Recent reviews on value in health have suggested a broad set of values emerging in practice. Cromwell et al in a review of 33 papers, identified that programme effectiveness, equity, affordability, cost-effectiveness, and the number of beneficiaries were the most frequently used decision criteria [59]. More recently, Zhang et al found that commonly occurring value categories in different contexts were: health benefits (n = 53, 96%), affordability (n = 45, 82%), societal impact (n = 42, 76%), burden of disease (n = 36, 65%), quality of evidence (n = 32, 58%), cost-effectiveness (n = 31, 56%), ethics and equity (n = 27, 49%), unmet needs (n = 21, 38%), and innovation (n = 15, 27%). In general, the conclusion has been that the criteria and number of values used in decision-making as well as the relative weight accorded to different values varies based on the context, the interventions assessed and may also vary over time in a particular context [60].

There are some attempts that have been made to define value frameworks for assessing health technologies that include broader value considerations, which cost-effectiveness analysis (CEA) alone, may not include. These include the efforts of the Second Panel on Cost-Effectiveness that broaden original work done by the Panel of Cost Effectiveness [61]. Beyond the recognition of cost and outcome measures (Quality Adjusted Life Years - QALY) in the reference case proposed for CEA, the panel proposes that other values should be considered including patient’s expectations; legal, ethical, equity, cultural, and political concerns; and pragmatic issues of logistics and feasibility.

Most recently, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Special Task Force (STF) on US Value Assessments has developed a value framework that defines values that should be used to guide decision-making for new technologies in the USA including medicines and vaccines [62, 63]. This was spurred by the rising costs of vaccines and medicines. The ISPOR Value Flower includes several criteria related to economic rules of value, social justice including equity as well as other societal values related to externalities of technologies, burden, and severity of disease, etc.

Whose values are important to consider?

Another issue in valuing care is whose values should be considered. Values may differ with the stakeholder in question. A patient-level valuation of health may contrast with a policymaker’s valuation of health, with the latter’s aim being to maximize health at a population level or other efficiency and equity concerns. On the other hand, the patient-level valuation of maximizing individual health outcomes or utility may be at variance with the policy maker’s valuation. This has been the case in situations like immunization drives, where the individual preference for no vaccination (as a right) may conflict with broader population goals of increasing herd immunity.

Traditionally, policymaking considered the policymaker’s perspective regarding maximizing values important to society. Thus, most priority-setting exercises have included concerns for efficiency or cost-effectiveness, maximizing health gains and equity. However, experiences in countries like the United Kingdom [64] and states like Oregon in the USA [65, 66] have highlighted the growing need to incorporate broader perspectives than the policymaker’s perspective. Furthermore, public health movements like person-centred care and shared decision-making have emphasized the need to engage citizens in the policymaking process. An interesting issue related to the engagement of citizens is what "citizen" is to be engaged. Should this include patients themselves or should representatives of patient groups be engaged or should the public be engaged [67-70].

The emerging themes from the literature indicate that in general, there is an increasing recognition by governments in upper-middle and low-middle income countries, to formally engage multiple stakeholders, including the citizens, in the process of valuing care. The NICE in UK uses the citizen's council as a formal mechanism for engaging the public. In other contexts, the government uses other citizen engagement mechanisms including citizen's juries or town hall meetings, opinion polls, consultation documents, shared with certain groups on electronic consultations and more [67].

Aggregating values in health

Considering varying perspectives on value in health by stakeholders, the deliberative approaches to priority setting for value have resulted in the evolution of various frameworks for the aggregation of criteria. These frameworks include Assessing Cost-Effectiveness [71]; Multi-criteria Decision Analysis (MCDA)[72], Evidence and Value: Impact on Decision Making– the EVIDEM framework [73]; and the Programme Budgeting Marginal Analysis (PBMA)[74]. The frameworks combine technical decision rules-based analyses with the deliberative process involving multiple stakeholders to elicit their criteria for determining the worthiness of investment in a technology or public health intervention. In some of the frameworks, criteria may be weighted to reflect their relative importance in the priority setting process. Weights may be determined through deliberative approaches such as Delphi panels or through quantitative approaches such as discrete choice experiments.

Conclusion

The review suggests that there is no one way of eliciting values that are pertinent for prioritizing or measuring health. Values that undergird healthcare systems are necessarily informed by the context, including societal norms and values prevalent therein. Furthermore, the weight that different values carry may vary with the context and therefore systematic mechanisms for arriving at a consensus within a deliberative process are key.

Related to VBC, this means that beyond the framework adopted that considers costs and outcomes measured as health benefits such as clinical reported outcome measures (CROMs), patient-reported experience measures (PREMs) and patient-reported outcome measures (PROMs), there may be scope for considering or weighting these against other value considerations including equity, etc.

Part B

Implementation experience for each pillar of VBC

Detailed review of the implementation of each pillar of VBC

This section describes with relevant experiences in various contexts, the evidence of implementing the pillars of thematic areas in VBC. This section describes the pillars in detail and then highlights experiences of implementation and the effects of implementing the VBC component in those contexts. Evidence of effectiveness, cost-effectiveness, impact on equity and other factors of importance for the health system is presented from the literature, where available. Some reflection is also made regarding the generalizability of such practices in contexts like India.

1. Integrated practice unit (IPU)

An essential component of VBC is to move away from silos and paying providers through FFS organized around medical specialties. The aim of VBC is to create integrated health systems by reorganizing service delivery and placing the focus on the patient as the organizing principle of services delivered by the providers and the clinicians [75]. Essentially, care is organized around the patients instead of the medical skills of the doctors/physicians. It delivers a full cycle of care which includes patient treatment, education, engagement, and follow-up, outpatient and inpatient services as well as rehabilitative and support services like nutrition and social work [7].

Table 4. Key features of an IPU

1. An IPU is organized around a medical condition or set of closely related conditions. In primary care, which is by its very nature holistic, IPUs are organized around defined patient segments in terms of their primary and preventive care needs, such as weight loss, atherosclerosis risk reduction, chronic condition management, or smoking cessation.
2. Care is delivered by a dedicated, multidisciplinary team whose members devote a significant portion of their time to working together to care for the medical condition.
3. Providers identify themselves as part of a common organizational unit and distinct from their specialty department.
4. The team takes responsibility for the full cycle of care for the conditions including the responsibility for preparing patients before and after procedures or consultations. The team is also experienced in recognizing variation among patients in their needs and clinical complexity and adjusting care accordingly.
5. Patient education, engagement, monitoring, adherence, and follow-up are integrated into team composition and the care model.
6. The IPU has a single management and scheduling structure.
7. To the extent feasible, the team is co-located in dedicated facilities tailored to the care processes and technology needs.

8. A physician team captain or a clinical care coordinator (or both) is responsible for overseeing each patient's overall care process across time and locations of care, including the patient's home.
9. The team measures patient outcomes, care processes, and overall costs for each patient using a common measurement platform.
10. The team meets formally and informally on a regular basis to discuss outcomes, processes, and technology and employs a structured approach to improving results.
11. The team accepts joint overall accountability for outcomes and costs.

Source: Integrated Practice Units: A Playbook for Health Care Leaders [76]

The benefits of IPUs are vast and include:

- A dedicated medical team consisting of specialist surgeons/physicians working in proper coordination, to provide complete care to patients thus resulting in an ease in access to healthcare.

- Reduced duplication of investigations by different providers, delays in treatment and lengthy admission processes in various settings as an IPU team is focused on providing care in a collaborated way even if it involves different providers, thus increasing efficiency.

- Improved healthcare outcomes by establishing new treatment/care pathways and protocols and better monitoring of patient's health by the dedicated team consisting of various specialists.

- Patient awareness and engagement through involving them in their own health decision-making by creating awareness and promoting shared responsibility for their own health. It also covers all the possible complaints of the patient during the cycle, thus increasing patient satisfaction.

- Aggregating care for a condition within an IPU creates volume, which enables teams to rapidly accumulate and share experience for target patients [7, 55, 77-79].

Some examples of implementing IPUs in practices have been documented in the literature, providing lessons on effectiveness, what conditions are amenable to this model and lessons on factors affecting successful design and implementation.

- The IPU approach taken by the Virginia Mason Medical Centre in Seattle is an example of IPU in practice. In this case, patients having lower back pain can call a central phone number and can be seen the same day. The "spine team" consists of a board-certified physician and a physical therapist and patients usually visit both on their first visit. Serious cases of back pain with severe causes like malignancy or severe infection are quickly identified and are allowed to enter a process designed to address the specific diagnosis. Patients at Virginia Mason's Spine Clinic miss fewer days of work (4.3 versus 9 per episode) and need fewer physical therapy visits (4.4 versus 8.8). In addition, the use of MRI scans to evaluate low back pain has decreased by 23% since the clinic's launch in 2005, even as outcomes have improved [7].

In primary care, IPUs are multidisciplinary teams which serve patients that require similar primary and preventive care needs—for example, chronic conditions such as diabetes, or frail elderly patients. Usually, for each patient group, the appropriate clinical disciplines and preventive services team and education can be assembled to ensure value for money for the patient and provider.

Thus far it has been used for high-risk, high-cost patients through so-called Patient-Centred Medical Homes. However the opportunity to substantially enhance value in primary care is far broader.

- The West German Headache Centre is an IPU that includes neurologists, physical therapists, and psychologists in one team. The patient sees all the experts they need in a single visit. If diagnostic imaging is needed, it is obtained from a nearby partner provider [78]. By restructuring to create an IPU, a West German migraine headache centre was able to lower costs by 20% as well as improve clinical symptoms of patients by 54%. This has enabled them to expand, opening more centres in other cities and developing new programmes for conditions such as vertigo, rheumatoid arthritis, and acute back pain [77].

- In Netherlands, a collaboration of seven hospitals focusing on VBC (Santeon) introduced a pilot programme at one of the hospitals which involved teams responsible for four medical conditions; they are accountable for the quality outcomes but not for the financial side [55]. Consistent with a formal learning system, at each of the hospitals multidisciplinary improvement teams regularly meet to share learnings based on data and develop improvement plans.

- Both England and Norway, have introduced teams of general practitioners, specialized nurses, physiotherapists, and psychologists to organize care around patients' needs in primary care. In specialized care, the governments seek to integrate care along defined standardized clinical patient pathways, such as cancer or mental health, [Ibid].

Effectiveness of IPUs

Evidence from a study focused on evaluating the effectiveness of a Transitional Home Care (THC) programme that applied the IPU concept (THC-IPU) in reducing 30-day readmission for patients with functional dependence, admitted to the Singapore General Hospital, showed a reduction in acute hospital utilization where care was delivered in form of home visits organized through an IPU [80]. The study showed that the THC-IPU programme was associated with a reduced likelihood of hospital readmission and emergency department attendance rates at 30 days and up to 90 days after hospital discharge. This suggests a positive contribution from transitional care organized as an IPU. Extending the programme into the pre-hospital discharge phase to include discharge planning is likely to have incremental effectiveness in reducing avoidable hospital readmissions.

In an IPU study conducted at a safety net clinic in central Texas, providing musculoskeletal care through an FFS model, it was observed that among the patients undergoing hip or knee replacement, the length of stay was 1.4 days compared to 2.6 days for patients referred to the parallel fee-for-service clinic ($p < 0.001$), and 92% were discharged home versus 89% ($p = 0.46$). The IPU increased access and improved short-term surgical outcomes in a population of uninsured and underinsured patients seeking musculoskeletal care, but more studies are required to understand the effectiveness of the IPU model (47).

A systematic review of the impact of person-centred interventions for serious physical illness in terms of outcomes and costs reported that in an IPU and modified virtual ward model in Singapore, unplanned readmissions at 30, 90 and 180 days were significantly lower in the intervention group than the control group and emergency department attendance were significantly lower at 30, 90 and 180 days in the intervention [81]. Likewise, an interdisciplinary, collaborative practice intervention involving a primary care physician, a nurse, and a social worker for community-dwelling seniors with chronic illnesses, showed significant changes in the number of hospital admissions per patient per year, percentage of patients with one or more hospital readmissions within 60 days and mean number of visits to all physicians. It also showed fewer attendances at physical, occupational or speech therapy units compared with the control group. However, the change in percentage of patients with one or more visits to the emergency department, the change in proportion of patients with one or more home care visits and the change in number of patients with one or more nursing home placements and emergency visits were not significant.

In the same review of the six studies that reported data on costs, five found that person centred care resulted in the reduction of costs of care. Two studies from this review demonstrated that person-centred interventions were effective in reducing pain outcomes, while five studies showed that interventions had no effect on pain and physical symptoms such as fatigue and shortness of breath in chronic obstructive pulmonary disorder (COPD) and heart disease populations (ibid).

Mortality was significantly reduced in the community-based integrated care for frail patients with COPD. Mortality was significantly lower in an integrated practice unit and modified virtual ward model (48). A comprehensive care programme with multidisciplinary input for patients with COPD reported a reduction in mortality rates compared with usual care. However, a team intervention for the multimorbid elderly reported that mortality risk at 3- and 6-months follow-up were all non-significant.

Conclusion on IPUs

It is clear from both the literature and practice that the successes of IPUs are somewhat mixed (though largely in favor of IPUs), as they work for some conditions whilst they are less favorable for others. This is important in planning the adoption of VBC at any scale and using them for conditions in which they have demonstrated effectiveness. This should be done taking cognizance of the considerable management and staff efforts required, for which restructuring costs and undertaking cost-effectiveness, and budget impact studies are much needed [82]. Despite the encouraging evidence, the global implementation of IPUs is very much limited as the changes required to effectively implement them are not aligned to the organizational structure of hospitals where care is organized along the lines of traditional academic disciplines. The reorganization of care from the traditional approach to an IPU model requires concurrent reconfiguration of budgets and authority which is often a barrier to the adoption of this approach [45].

2. Outcome and costs measurement

Outcomes measurement

The emphasis of this pillar of VBC is to ensure that outcomes of importance to the patient are reported. Porter and Teisberg argue that traditional methods of measuring health status improvements have focused on clinician reported outcomes that often do not cater for the patient's experience of care and the outcomes of importance to the patient. They therefore argue that outcomes of importance to the patient should be the focus of outcome measure. They further note that outcomes should be across all relevant specialties, ensuring that accountability for value is shared amongst the providers involved. The outcomes should also be defined for patient groups with similar needs. Principles for determining the group of relevant outcomes to measure for any condition or patient population follows several principles including:

- Outcomes include health circumstances relevant to patients.
- They cover both short-term and long-term health, addressing a period that is long enough to encompass the ultimate results of care.
- It should also include sufficient measurement of risk factors or initial conditions to allow for risk adjustment.
- Lastly, for any condition or population, multiple outcomes collectively define success.

Measuring, reporting, and comparing outcomes are perhaps the most important steps toward rapidly improving outcomes and making good choices about reducing costs. Outcome measurements should include medical conditions and circumstances associated with the patients, as well as sufficient measurements of the associated risk factors. Porter and Teisberg propose an outcomes hierarchy in which the progression in health is contingent on success in the higher tiers of results. The hierarchy is shown in the Table 5 below:

Table 5. Tiers in outcomes hierarchy

Tiers	Levels	Outcome dimensions
Tier 1- Health status achieved or retained	Survival	- Survival rate in terms of time - Mortality rate
	Degree of health or recovery	- Freedom from disease - Functional status
Tier 2- Process of recovery	Time to recovery and time to return to normal activities	Time needed to complete various phases of care
	Disutility of care or treatment process	Any diagnostic/medication errors, complications, adverse effects, etc.

Tiers	Levels	Outcome dimensions
Tier 3- Sustainability of health	Sustainability of health or recovery and nature of recurrences	Recurrences
	Long-term consequences of therapy	Care-induced new illness

Source: What Is Value in Health Care? [83]

Different outcomes are described in the literature. These include, Clinician Reported Outcomes Measures (CROMs), Patient Reported Outcomes Measures (PROMs) and Patient Reported Experience Measures (PREMS).

Clinician-reported outcomes are measurable changes in a patient or participant's symptoms, overall health, ability to function, quality of life, or survival that require the knowledge and/or judgement of a medical professional to be interpreted and reported. According to the National Centre for Advancing Translational Sciences in the USA, Clinician-reported outcomes (CROMs) include clinically observable signs, behaviors, and clinical manifestations of the disease [56]. Biomarkers may aid in measuring CROMs, but changes that only the patient can report, such as pain intensity are not included. These are the traditionally used measures for monitoring progress in the health status of a patient by health providers but do not include the patient's perspective on progress in health status. PROMs are directly reported by the patient without interpretation of the patient's response by a clinician or anyone else and pertains to the patient's health, quality of life, or functional status associated with healthcare or treatment [84]. Varying facets of health from a patient perspective may be analyzed (pain, mobility, etc.), owing to which patient involvement becomes an integral part in their development [85].They include PROMs and PREMs.

The initial use of PROMs can be traced back to 1975, when Sweden established the nationwide use of PROMs using disease-specific clinical databases known as quality registers [86], with other countries such as Australia, United Kingdom and USA adopting PROMs into their health systems during the 90's and early 2000's. USA was the first country to implement nationally mandated patient-reported measures, that is, PREMs, beginning with the Consumer Assessment of Health Care Providers and Systems (CAHPS) Health Plan Survey in 1997. This was followed by the implementation of the General Practice Patient Survey (GPPS) in England, which focuses on the experiences of patients with healthcare services provided by general practitioner (GP) practices and dental care [87]. The use of PROMs and PREMs to determine quality, financial payments and as tools for gathering performance information have been gaining increased acceptance across health systems in high-income settings. These measures are discussed in detail below:

- **PROMs:** PROMs are standardized, validated questionnaires that are completed by patients before, during or after their care episode to ascertain perceptions of their health status, perceived level of impairment, disability and health related quality of life (HRQOL) [88].Broadly, there are two basic categories of PROMs [86]:
    - ▶ **General health PROMs:** Used to survey patients with any condition. They usually focus on general well-being, mental health and/or quality of life.
    - ▶ **Condition-specific PROMs:** Usually concentrate on the symptoms of a particular disease. They may ask questions about mobility, function, or pain levels in certain areas of the body.

There exist several generic (Short Form-36 or SF-36, EuroQol-5D or EQ-5D) and disease-specific PROMs, of which the former are used to measure HRQoL. HRQoL is a multidimensional concept encompassing the different assessable aspects of a patient's life that can affect physical or mental health such as health risks, functional status, social support and socioeconomic status [89]. However, even within such generic PROMs, there exists considerable variation in their length, number of dimensions as well their accessibility vis-à-vis open source or license-based. Thus, while SF-36 consists of 36 items under eight dimensions, EQ-5D consists of six items under five dimensions (with the former placing emphasis on the dimension of mental health). Additionally, while the Patient-Reported Outcomes Measurements Information System (PROMIS) is a free open-source tool, the others are offered on payment of a license fee [88].

Disease-specific PROMs on the other hand, measure outcomes that are important for particular target populations or particular outcome dimensions, be that disease (for example, depression, asthma, etc.), group of patients (for example, children, cancer patients, etc.) or an outcome dimension (for example, pain, mobility, etc.), and are usually not suitable for comparing health status of individuals with different health conditions [90]. A large set of disease-specific PROMs are developed through the ICHOM, an international not-for-profit agency committed to using PROMs to unlock the potential of VBC by defining global sets of such measures [91]. Despite their different objectives, generic and disease-specific PROMs should be used in a complementary manner to capture the overall quality of care and patient outcomes.

- **PREMs:** PREMs focus on the care experience in terms of the service quality and humanitarian aspects of care (dignity, wait time, etc.). They gather information on the process of care as perceived by the patient, rather than the outcomes. Though often conflated with the concept of 'patient satisfaction', PREMs differ from satisfaction surveys in that they gather more tangible information on how a service can be improved, rather than the patient's overall satisfaction level and may be less prone to the influence of patient expectation, known to be influenced by varying factors [92], beyond solely the care experience [93]. The difference has been framed in terms of their linkage to process against outcomes respectively, owing to which PREMs are more amenable to objective measures of patient centricity. Methodologically, PREMs typically employ frequency-base response scales (for example, never, sometimes, often always), while patient satisfaction measures use agreement-based response scales (for example, strongly disagree, disagree, etc.), the latter of which is often critiqued for being biased by acquiescence (tendency to agree with an item irrespective of what is being asked) and straight lining (tendency to given identical or near identical responses to consecutive questions) [94].

PREMs are typically structured around certain dimensions which are recognized as important to patients or in providing patient-centred care. In contexts where they are formulated or used, such as NHS England, Institute of Medicine (USA) and through the International Alliance of Patients' Organizations (IAPO), a common theme that emerges in aspects measured includes respecting patient's value and preference, coordination, and integration of care, providing adequate information to the patient and their care givers as well as support for accessing care. In NHS England, additional specifics such as patient's physical comfort, emotional support and alleviation of fear and anxiety, feature as additional measurement dimensions used [90]. Patient experiences can be classified as relational for example, did they feel they were listened to? Or functional, for example, coordination of care [95]. They are also informed by societal values and preferences, and therefore development of PREMs necessitates an understanding of what matters to the patient. To develop context-relevant and appropriate PREMs, it is essential that experiences that matter to the patient are captured. This involves direct engagement through dialogue and structure or semi-structured interviews with the relevant population, a practice that appears to be standard as part of the development of PREMs in countries such as the UK [96-98].

Country examples of using PROMs and PREMs

Some illustrative applications of PROMs and PREMs within the VBC framework is provided in the Table 6 below:

Table 6. Illustrative applications of PROMs and PREMs

Country	PROM[#]/PREM[@]/Payment Linkages with PROMS-PREMS[&]	Year Launched	Purpose
United Kingdom	General Practice Patient Survey (GPPS)[@]	1998	National survey on quality perception and experience from patient perspective in GP setting
	Quality Outcomes Framework (QoF)[&]	2004	Pay for performance (~25%) of GP income based on performance across clinical, organizational and patient experience
	Department of Health PROMs Programme[#]	2009	Outcomes measurement for four common elective surgical procedures (later linked to payment under the National Tariff Payment System)
USA	Consumer Assessment of Health care Providers and Systems (CAHPS)[@]	1995	A programme by Agency for Healthcare Research and Quality (AHRQ), which works with a consortium of research organizations to generate insight into patient experience of healthcare
	Medicare Health Outcomes Survey (HOS)[#]	1998	First PROM used in Medicare managed care and used in QI activities, programme oversight and pay for performance
	1. Hospital Value-Based Purchasing Programme[&] 2. Hospital Readmission Reduction Programme[&] 3. Medicare Advantage Quality Bonus[&]	2012	Payment-linked programmes using PROMs/PREMs such as Health Outcomes Survey (HOS) and CAHPS
Australia	Victorian Population Health Survey (VPHS)[#]	2001	VPHS collects information on health status of adults in Victoria State
	NSW Health Patient Experience Survey[@]	2007	Patient experience in public health system

Source: Reproduced from [87]

Additionally in 2013, value-based reimbursement models were introduced in Sweden for spinal surgery, with small performance-based payments (representing approximately 10% of the base payment for an episode of care) linked to improvements in patient-reported pain scores that are compared with national registry outcomes data [99]. More recently, PRMs are also being adopted at a wider scale rather than for specific value-based purchasing programmes. Two such emerging examples are the Health Outcomes and Patient Experience (HOPE) platform in Australia [100] and Health Outcomes Observatory (H2O) in the European Union [101].

In the USA, they are being used to support the development of person-centred learning health systems [102], which involves continually collecting experiences, priorities and values of patients and their caregivers and feeding them into data systems to monitor ongoing quality improvement and performance benchmarking, accounting for contextual determinants. A noteworthy example is the Veterans Health Administration (VA) in the USA, deployed in the area of mental healthcare, wherein the integration of evidence-informed practice, measurement and quality improvement significantly improved clinical processes and outcomes for persons with mental health issues, including improved access to care [103]. Table 7 summarizes the evidence in the literature of the multi-faceted benefits arising from the deployment of PROMs and PREMs:

Table 7. Benefits arising from the deployment of PROMs and PREMs by the level of system engagement

Level	Purpose	Type of measure	Use
Micro	Shared decision making and care in partnership with patients	Condition-specific PROMs	• Screening • Diagnosis • Monitoring of disease progression • Support of treatment decisions • Communication (patient-provider; provider-provider)
Meso	Information to drive quality improvement (QI) initiatives	• PREMs • Condition -specific PROMs	• Identify areas for quality improvement • Public reporting to allow informed provider choice • Monitoring patient-reported adverse events • Comparing providers and organizations or benchmarking them to identify poor performers and learn from good performers
Macro	Population health monitoring	• PREMs • Generic PROMs (Health-related quality of life)	Supportive information for public health activities: • Prioritization of patient groups, conditions, etc. • Designing public health initiatives • Monitoring of effects of policy initiatives

Level	Purpose	Type of measure	Use
Macro	Reimbursement decisions	Generic and/or condition-specific PROMs	• Assess the relative effectiveness of treatments and services • Assess patient issues associated with condition and treatment
	Contracting services and payment models	Generic PREMs (Pay for performance) or (condition specific) PROMs (meeting minimum thresholds of outcomes)	• Pay-for-performance • Contracting decisions

Source: KCE Report 2018 [104]

Effectiveness of PROMs in improving VBC

With regard to empirical evidence supporting the case for patient-reported measures, evidence indicates that when self-reported symptom monitoring was integrated with clinical management, clinical benefits, including increased survival, were observed [105]. The literature has also shown that there exists a positive correlation between experience and outcomes and that patients can distinguish between clinical effectiveness, safety and their experiences [106]. Patient outcomes can increase patients experience ratings by 10%, similarly, improving patient experience ratings will cause a 3% improvement on outcome scores [95]. Based on a review of 15 reviews, PROMs also showed an impact on healthcare processes. However, evidence about the impact of PROMs on the disease management and patient outcomes is mixed. Patient satisfaction seems to increase when PROMs are used for clinical purposes. For health outcomes, it is difficult to demonstrate an isolated impact because there are multiple determinants of health outcomes. Nevertheless, no studies showed statistically significant negative results: results were either non-significant or significantly positive [104]. No evidence yet exists regarding impact of PROMs and PREMs on the macro level, that is, payment models and reimbursement decisions.

While there is increasing use of PROMs and PREMs in VBC models as well as provider quality monitoring, there also exists vocal opposition to the premise and application of such tools. Clinicians have pointed out the shortcomings of patient satisfaction tools for value-based purchasing due to a lack of risk-adjustment of patient experiences attributable to their subjective assessment, given their varying health status. Additionally, clinicians have also highlighted the danger of overreliance on PROMs within value-based purchasing models, citing the case of the opioid epidemic in the United States, where improvement in patient outcome measures (lowered pain) for payment decisions, may prove detrimental for the overall health status of the patient [107]. Researchers have also pointed out the need for ensuring inclusivity and equity within patient measures, as a number of issues regarding these have recently been highlighted in patient-reported outcomes ethical guidelines relating to barriers to completion and racial and ethnic disparities vis-à-vis patient-reported outcomes tools [108]. Widely available measures tend to underrepresent participants from low- and middle-income countries (LMICs) and local validation and adaptation of patient measures is essential, prior to their deployment in such settings. Potential solutions to some of these have also been highlighted by the very same researchers [108].

Critiques like these point to the need for complementarity in the use of PRMs in monitoring patient progress in VBC and patient-centred care. The over-emphasis of one type of measure over the other only serves to undermine the quality of care provided. This means that countries that adopt this approach require additional investments in scale-up of PRM systems and integrating them into the routine health information systems, curricula for health professionals and more. Few countries have made this leap as yet.

Costs of care

Measurement of costs in VBC is a critical component, as the definition of value is relative to the costs required for the healthcare provided. Kaplan and Porter argue that poor measurement or estimation of costs in healthcare is a driver for the spiraling costs of care[109]. They note that the challenges in estimating costs of care stem from differences in perspectives on costs between purchasers and providers and patients. The costs will necessarily differ depending on which perspective is taken as has been noted elsewhere[110]. Kaplan and Porter further argue that the use of one perspective may mean that other stakeholders must bear the brunt of cost-subsidizing healthcare. They further note that this will result in efficient and effective producers of healthcare often being left unrewarded while the inefficient have little incentive to improve. Furthermore, the costs of care are defined at specialty or departmental level and not at the level of the patient care cycle.

Time-driven activity-based costing is a methodology developed by Kaplan and Anderson for calculating costs to the healthcare system during a patient-care cycle [111, 112]. It addresses many of the shortcomings of traditional cost accounting methods. The methodology has recently been used to estimate the cost of care and inform the reorganization of care delivery to ensure patient-centric care and value for money. Taking a “bottom-up” approach, Time-driven activity-based costing (TDABC) more accurately estimates cost by allocating indirect/support costs to activities performed by capacity-supplying resources such as clinical/nonclinical staff and equipment. Cost estimates for TDABC are based on two parameters: (1) per-minute cost for each resource involved in the process of care and (2) average time of each resource required.

While the unit of analysis in activity-based costing is the activity, in TDABC the estimation is based on the time required of a resource. This is then valued against the cost capacity rate of that resource, for example, human resources, equipment, floor space, etc., with the cost capacity alluding to how much it costs per unit time for a resource to be available for a patient.

$$\textit{Capacity cost rate for resource}_i = \frac{\textit{Expenses Attributable to Resource}_i}{\textit{Available capacity of resource}_i}$$

It determines costs at the patient-level over the entire care cycle, allowing for population variability, while simultaneously identifying cost drivers that might inform risk stratification for future alternative payment models. Through process mapping, TDABC also reveals areas of variation or inefficiency that can be targeted for optimization and empowers physicians by focusing on costs in the control of the provider.

TDABC could be a strategy for increasing cost accuracy in real-world settings, and the method could help in the transition from fee-for-service to value-based systems. The results could provide a clearer idea of the costs, help with resource allocation and waste reduction, and might support clinicians and managers in increasing value in a more accurate and transparent way. TDABC methodology should be viewed as a gold standard to achieve better cost accuracy, understand healthcare resource allocation, reduce waste, and improve transparency in real-world settings. This is critical as we continue to transition from fee-for service to value-based systems.

TDABC contributes by identifying opportunities to make patient episodes of care flow more efficient by reducing the resources used in each activity based on real patient demand [113]. According to Kaplan and Porter, the seven steps of TDABC include:

- A medical condition is selected. This includes describing the entire care cycle including the associated complications and comorbidities which may affect processes and resources used during the patient's care.
- The care delivery value chain is described by identifying the principal activities involved in a patient's care for a medical condition along with their locations. This is important for identifying the relevant dimensions along which outcomes will be measured and for mapping the processes that make up an activity.
- Process maps generated for each step of a patient's care delivery chain. The maps encompass the paths patients may follow as they move through their care cycle, including all the resources that supply the capacity, that is, personnel, facilities, and equipment. This also includes consumables that may be consumed in care.
- Time estimates are obtained for each process step. This estimation of time is critical for identifying costs variation for same conditions at the patient level.
- The cost of supplying all patient care resources is calculated, including direct and indirect costs. This is the cost of the capacity of each resource. It may include costs related to salaries, allowances, etc., or costs of maintenance for equipment, etc.
- Capacity cost rates are then calculated for each resource, typically by estimating 80% of theoretical cost rates.
- Finally, total costs are calculated by multiplying capacity cost rates for each resource used in each step by the time spent by the patient with each resource.

TDABC has proven a very useful method for estimating costs for healthcare for orthopedic interventions, cancer (including breast cancer) where it has been used for screening diagnostic and treatment interventions [114], obstetric and gynecologic conditions, and radiology. In the instances that it has been used, it has been shown to:

a) Reduce costs of care. A recent review of studies showed that in the case of CT scan, the conduct of TDABC resulted in the identification of CT scan as the driver of spending (80% of cost) and that identified areas for reducing costs, for example, finding lower cost resources for substitution and increasing CT utilization efficiency [111]. Further still, the same review showed that in another instance TDABC facilitated the implementation of process modifications to reduce staff time by 16% and cost by 13%.

b) In instances of costing in total joint replacement, TDABC has been used for increasing operational efficiency, reducing wasted resources, mitigating risk and in providing more granular information on the costs of care [115]. It has also been used to estimate costs for hip fractures, where it has been used to identify cost drivers and patient variability in spending to stratify patients for alternative payment models.

c) It has been used as a basis for redefining payment modalities structured along the patient care cycle. It has also been used to optimize care by reducing inefficiencies and empower physicians to focus on costs within the control of the provider [109, 116].

d) It has been helpful in informing the return on investment in healthcare where value-based strategies have been deployed.

A critique of the use of TDABC is the fact that they can be quite challenging to conduct as the process mapping needs to be done in different healthcare services and settings. They demand a lot of time and effort in real case scenarios. They also require data on the costs of the inputs. This is not easy to come by in most LMICs.

Conclusion on outcome and costs measurement

Measuring outcomes and costs is a key input to transition to VBC. While outcomes are often measured in clinical health outcomes, there has also been a recent transition to ensuring the factoring in the patient perspective in outcomes. This is in line with the aspirations and intent of VBC which is to place the patient at the centre of care. On the costs front, a fine balance must be maintained between the thoroughness and feasibility of cost measurement. However, given the interlinked nature of VBC across levels and specialties of care, a fair and adequate estimation of cost inputs should necessarily account for the material and time input for the patient episode, as opposed to a focus on interventional cost input.

3. Payment models

This pillar in the Porter and Teisberg framework has been premised on the fact that open-ended payment systems like FFS payments and global budgets have resulted in inefficiencies and in inflation of costs to healthcare systems in many areas. This is largely due to practices such as supplier-induced demand as well as the lack of regulation in many markets. Porter and Teisberg recommend the move to payments that incentivize maximizing patient health outcomes and more bundled payments which cover the entire scope of services provided during the care cycle of a patient. Value-based supplements to FFS or bundled payments may serve as a "stepping stone" toward greater accountability [117]. This type of payment rewards both efficient use of healthcare services and increased buy-in. The primary goal of bundled payments and the episode of care models is the same: to improve outcomes for patients, to improve patient experience, and to reduce costs of unnecessary care [118]. For all intent and purposes, the goals, regardless of whether called episodes or bundles, are the same, regardless of whether a risk component is involved.

Porter and Teisberg specifically make the case for bundled payments although the implementation of VBC programmes in various contexts involves experimentation of alternative payment models of which bundled payments are one component on the path to more VBC purchasing models. In practice, the implementation of VBC has not taken on purely episode-payment based models but instead, a spectrum of payment models or a combination of a few.

In this section, we review the implementation experience of different payment models that are being used globally within the VBC framework including bundled payments and pay-for-performance. We review the mode of implementation, the scale at which implementation has been done so far and the effectiveness of the payment models. We also review implementation barriers and enablers.

Bundled payments

What are bundles payments?

Bundled payments are a set of 'Alternative Payment Models' (APMs) that actively promote coordination of care and system efficiency over a longer time horizon [119]. In contrast to DRGs, which tend to be inpatient episode-oriented, bundled payments provide a pre-determined, single aggregated payment that covers post-acute expenditures as well [120] and in some cases a bundle of primary care-linked services.

The risk in a bundled payment system should ideally be assumed by the provider, with the implicit intention to get providers to deliver care efficiently. Moreover, bundled payments may or may not be linked to outcomes or other measures of performance and within themselves can constitute a wide variety of design elements, depending on the intended objectives of the payment model [121]. However, the underlying rationale for adopting bundled payments lies in the fact that they take a 'person-based' as opposed to 'patient-based' approach and aim to address the entire continuum of a health episode rather than specific, procedure-oriented medical or surgical interventions as is usually done with FFS payment models. Thus, bundled payments align with the VBC agenda vis-à-vis providing an incentive for establishing a continuum of care and would be able to reach their full potential in the presence of IPUs given the requirement of aligned service channels under such a model [122].

Designing and implementing bundled payments

Deploying bundled payments for healthcare episodes begets the question as to what constitutes an 'episode of care'. In the context of bundled payments, an episode often entails an entire care continuum for a single condition or event which includes all aspects of medical care, pre- and post-operative, and in an ideal form, social care support as well.

Some of the key design and implementation components and considerations are tabulated below:

Table 8. Design and implementation consideration for bundled payments

Component	Variations	Considerations
Perspective	Provider-led versus payer-led	• The stakeholder initiating the bundled payment and the rationales they hold for initiating the bundled payments affects the scope of bundling. • In some cases, the bundled payments are initiated by the providers, motivated largely by the need to improve quality of care and efficiency within the framework of the services provided by them.

Component	Variations	Considerations
		• In the case of the purchaser, the rationale is usually to improve efficiency and contain growth in expenditure. Thus, the tendency is to prioritize high volume interventions and those in which the highest cost savings can be realized by deploying bundled payments.
Scope of definition	Narrow versus broad service/ benefit bundles	This step is critical to identify the following: • The medical condition or the procedures that are to be included in the bundled payment. This is largely dependent on the quality of the claims data and the analytical capability required to determine the volumes and related costs. • Define the services related to the procedure or medical condition to be included. This is dependent largely on the perspective and motivation of the bundling. It will require significant clinical expertise for judgment on what should be included. • Discussion on the scope will also include whether to include consumables such as drugs, implants, and/or prosthetics in the bundled payments. • Purchasers are more likely to prioritize a higher degree of services bundled in one payment than providers would be. This is to realize greater efficiencies. • On the other hand, providers would prefer bundles that are more narrowly defined as they offer more predictability and stability for them.
Focus of definition	Procedures versus medical condition focus	• Focus on procedures as the basis for bundling incentivizes providers and purchasers to enhance efficiencies by eliminating wasteful services in the delivery of services but does not necessarily lend itself to person-centred care. They are also, however, prone to gaming by providers in which patients that benefit from other more cost-effective procedures may be managed by more costly procedures thereby undermining efficiency. • A condition centred approach provides more scope for person-centred care in which a range of procedures are available for managing the patient and the most cost-effective approach is prioritized based on the severity of the condition.

Component	Variations	Considerations
	Universal or population-specific	• In some cases, the scope includes a specific population group or can be broader based or population wide. For instance, bundled payments for the frail elderly in the Netherlands [121] or for pregnant women in California [123].
	Level-specific versus hospital-wide	• In the Netherlands, a bundled payment focusing on diabetes care in a primary care setting was initiated in 2007 [124-126], while the Bundled Payment for Care Improvement (BPCI) initiative under CMS used different models that focused on acute care or post-acute care or both in a hospital setting [127, 128].
Timing of design and price-setting	Prospective versus retrospective	• Prospective bundled payments are designed and priced ex-ante along with the determination of the eligible patients. These tend to transfer more risk to the provider resulting in greater scope for realizing policy objectives of efficiency. However, these are more administratively complex than retrospective payments. • Retrospective payments involve reconciling episode costs against bundled payment price targets for patients who may not ex-ante be identified as being in an eligible episode until the end of a bundled payment performance period. These are helpful in minimizing the risk to the provider and promote greater risk-sharing between the provider and purchaser [129].
Administrative capabilities		• The key considerations for implementing bundled payments are the claims processing and analytical capabilities of the entity. The better the claims processing abilities, the easier to design and manage prospective payments. Thus, entities with less ability are less likely to use prospective payments. • As implementation proceeds, reviewing the codes for the bundled payments and the scope included will naturally evolve resulting from stakeholder feedback. Thus, there is need for sufficient capacity to facilitate this.

Despite the complexity involved in setting up bundled payment systems, a categorization of key design and implementation considerations into pre- and post-contracting phases and the stakeholder interaction that it entails is a useful starting point for countries thinking of experimenting with bundled payment reforms. While the detailed design and implementation considerations entail a total of 53 elements, [130] the figure below highlights the stakeholder interaction required across both phases and along the six dimensions of pre- and post-contracting.

Fig. 2. Framework of key design and implementation elements of bundled payment contract

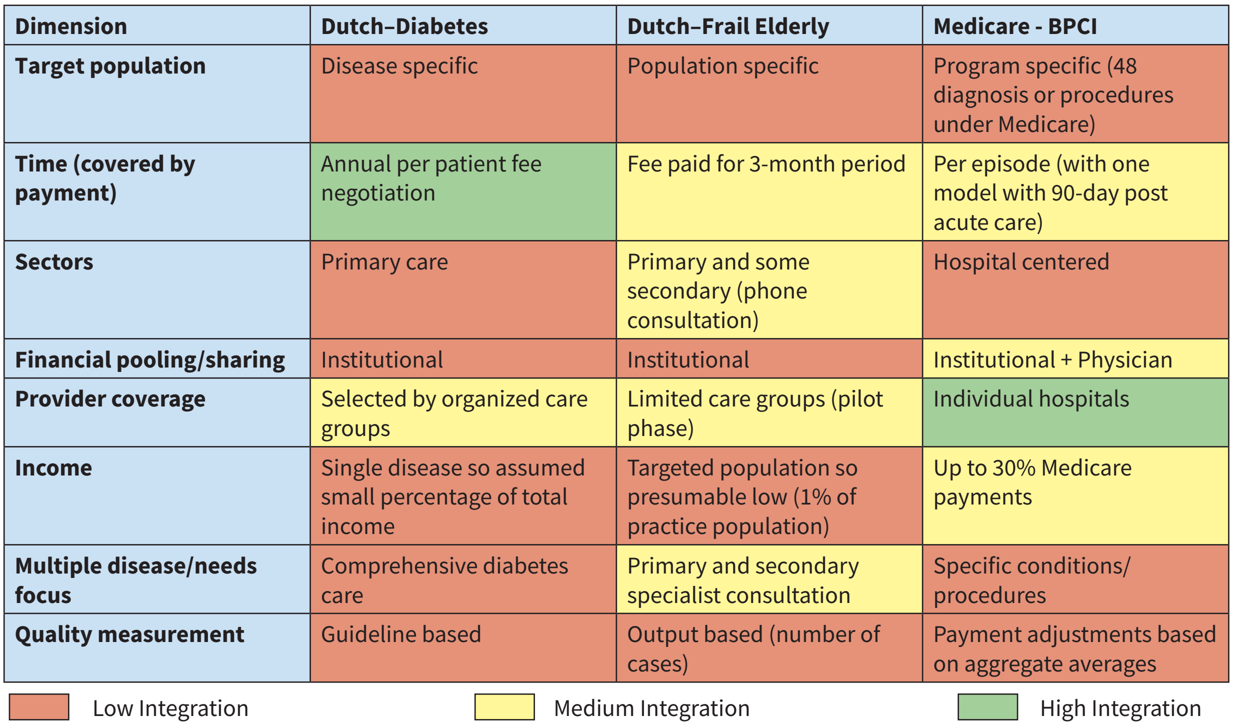
Health System Levels	Precontracting Phase			Post contracting Phase		
	Specify Bundle	Select Provider(s)	Negotiate and Sign Contract	Identify and Include Patients	Deliver and Monitor Bundle	Payment and (Financial) Results
Regulator and Payer/Provider	▨					
Payer and Payer	▨					
Payer and Provider	▨	▨	▨		▨	▨
Payer and Patient			▨		▨	
Provider and Provider			▨		▨	
Provider and Professional			▨		▨	
Professional and Professional					▨	
Professional and Patient				▨	▨	

Source: Adapted from Steenhuis, S. et al. [145]

Evidence around bundled payments

In practice, most bundled care models still tend to compartmentalize within certain levels or aspects of care. However, some examples of a more holistic approach do exist (though on a more experimental basis), such as the 'Gesundes Kinzigtal' in Germany [131], which adopts a 'shared-savings' model while maintaining FFS as the central payment mechanism. Most well-documented experiences such as from Netherlands or the Bundled Payments for Care Improvement (BPCI) under Medicare, tend to focus on specific conditions. However, considerable evidence exists for such programmes which provide insight into real world experiences with different permutations of bundled-payment design. As can be seen in the illustration below, thus far, both in the Netherlands and the USA, bundled payments are in a nascent and evolving stage vis-à-vis integration on multiple dimensions, though this is expected to coalesce in time. However, what remains clear is that considerable variability exists in the way bundled payment models can be designed.

Fig. 3. Bundled payment model features and dimension in Netherlands and USA and their degree of integration



Dimension	Dutch–Diabetes	Dutch–Frail Elderly	Medicare - BPCI
Target population	Disease specific	Population specific	Program specific (48 diagnosis or procedures under Medicare)
Time (covered by payment)	Annual per patient fee negotiation	Fee paid for 3-month period	Per episode (with one model with 90-day post acute care)
Sectors	Primary care	Primary and some secondary (phone consultation)	Hospital centered
Financial pooling/sharing	Institutional	Institutional	Institutional + Physician
Provider coverage	Selected by organized care groups	Limited care groups (pilot phase)	Individual hospitals
Income	Single disease so assumed small percentage of total income	Targeted population so presumable low (1% of practice population)	Up to 30% Medicare payments
Multiple disease/needs focus	Comprehensive diabetes care	Primary and secondary specialist consultation	Specific conditions/ procedures
Quality measurement	Guideline based	Output based (number of cases)	Payment adjustments based on aggregate averages

🟥 Low Integration 🟨 Medium Integration 🟩 High Integration

Source: Adapted from Stokes, J. et al. [118]

Despite their differing arrangements, the impact of bundled payments on varying system outcomes has been documented in the literature. A systematic review of the systematic reviews of the impact of reimbursement systems on patient care analyzed impact using the Donabedian framework, that is, structure (unintended consequences, organizational changes), process (resource utilization, access, and behavior) and outcome (quality/health outcome, efficiency, and economic effects) as performance variables [132]. Based on the inclusion criteria adopted for the selection of literature, a total of five systematic reviews on impact of bundled care showed largely heterogenous outcomes in domains of unintended consequences (that is, risk selection and spillover effects), resource utilization (readmission rates and length of stay), access (inequalities of utilization in services), health outcomes (mortality and treatment quality) and economic effects (effect on total social expenditures). However, some of these reviews also showed a positive correlation of bundled payment models with resource utilization, health outcome and efficiency, the latter of which saw most reviews showing a positive correlation [133].

Another systematic review that analyzed the impact of VBC models on networks of care and transmural care showed that outcome measures of clinical and cost outcomes, patient experience and organization related outcomes had mixed results when analyzed for bundled payments. More specifically, on the clinical outcomes front, two papers showed no conclusive evidence, with only one showing mixed outcomes based on length of stay and discharges. All three papers reviewed for cost outcomes (that is, total payments) showed positive effect of bundled payment while there was no conclusive effect measured on patient-reported outcomes or experiences from the one study analyzed. Finally, the organization related outcomes and experience remained a mixed bag with equal number of studies showing positive and negative effect based on aspects of adoption of coordination activities, physician engagement and provider opinion [134].

A third systematic review which primarily constituted evidence from controlled studies, analyzed the impact of bundled payment models from a disease-specific and episode-specific lens. Four out of five studies on disease-based bundled payments (primarily for diabetes care), showed that institutional post discharge facilities did reduce under this payment model, though there was a negative impact on total and medication-related spending with some positive impact on process quality and collaboration among physicians. Moreover, no negative impact was reported vis-à-vis quality indicators [135]. Some of the available and emerging evidence around these bundled care programmes in specific countries is highlighted below:

Netherlands

The bundled payment experiment in the Netherlands was initiated as a pilot in 2007, with an initial focus on diabetes care in a primary care setting. Based on the 'managed competition'; model of the Netherlands, wherein private insurers operate under a government regulated system. Insurers were given the flexibility to use a single fee to contract newly created entities known as 'care groups', which individually or as a collective, assumed financial responsibility for all patients enrolled in the programme under their catchment area [125, 136]. The services to be covered in the care bundles were set by national disease-specific healthcare standards, though the prices are negotiated between insurers and providers [126]. The programme was later expanded to other disease-specific areas such as COPD and vascular risk management in 2010, though participation continued to remain voluntary.

An evaluation of the programme conducted in 2012 by the National Institute for Public Health and Environment on the diabetes programme indicated that costs of curative care for patients enrolled under the bundled care programme were higher than for those not enrolled (mainly deriving from higher specialist care costs), though overall utilization at a specialist level (which was one of the aims of focusing on bundled payments for primary care) had fallen within the bundled payment patients by 25% compared to care as usual patients [125]. This was potentially explained by a lack of incentive linkage between primary and specialist care, the latter of which continued to be offered on a fee-for-service model. Moreover, while a standard bundle was recommended to include 12-months and 3-months check-ups, annual eye and foot examinations and laboratory examinations, there were differences between the contracts among care groups for additional diabetes-related GP consultations, such as help and guidance in smoking cessation or reduction, or foot care. This resulted in variations in bundled costs and inability to determine the real costs of the diabetes care bundles [137]. Quality of care outcomes and patient satisfaction also did not seem to suggest any significant improvement under the bundled care programme as compared to the baseline.

It was purported that the above findings reflected the outcome of the bundled payment model at a very early stage and that the model would require time to stabilize before a firmer conclusion can be reached about the programme's effectiveness. However, another longitudinal evaluation published in 2020 [138], showed a consistent increase in overall healthcare expenditure among bundled payment patients over a seven-year period (2008–2015), which was notably higher in patients presenting with multimorbidity and was not accounted for under the disease-specific programmes. Thus, the authors of the above evaluations suggested a more comprehensive payment model that can account for other related costs such as specialist care, medicines, multimorbidity, etc., as a potential logical conclusion for improving effectiveness of bundled payment models.

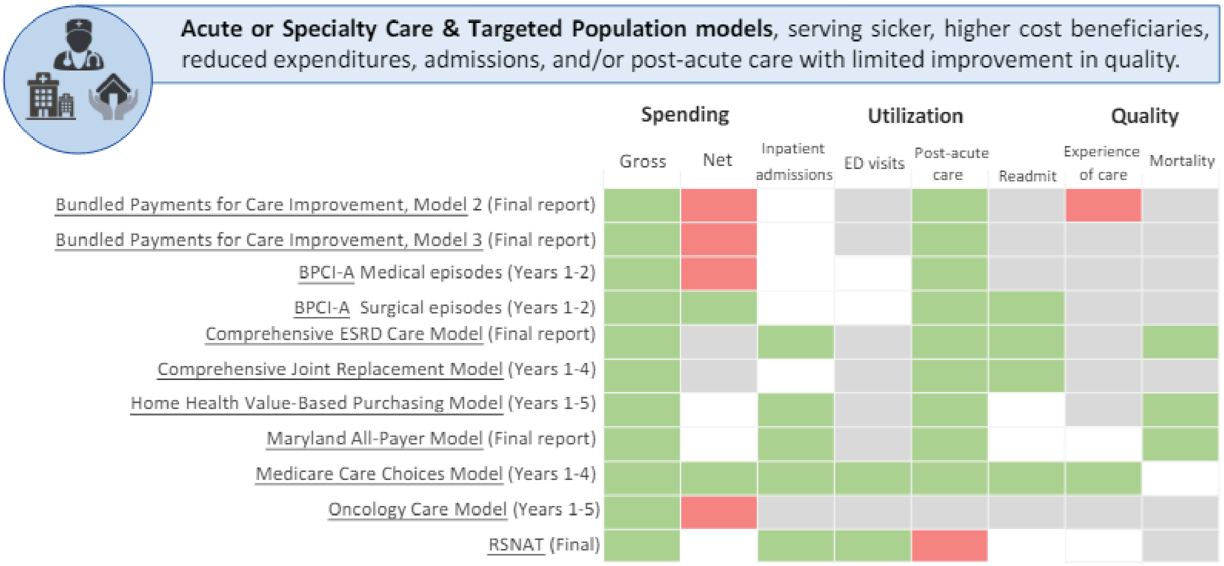
USA (Bundled Payments for Care Improvement - BPCI)

Traditionally, Medicare made separate payments to providers on a fee-for-service basis, which has the inherent issue of driving up service utilization and expenditures. To influence these patterns and bring in efficiency within the system, the Centre for Medicare and Medicaid Innovation (CMMI) introduced BPCI from 2013–2018 with a new BPCI Advanced Model being launched thereafter to sustain efforts to transition to episode-based payments. The original BPCI consisted of four different experimental models which were:
BPCI Model 1 – Acute care hospital stay only
BPCI Model 2 – Acute and post-acute care episode
BPCI Model 3 – Post-acute care only
BPCI Model 4 – Prospective acute care hospital-stay only

BPCI Advanced model on the other hand, built on the experience from the individual BPCI models with a fixed inclusion of a 90-day post-acute care services (earlier hospitals could choose between 30,60 or 90 days as part of the payment) Additionally, fewer exclusions are allowed under the Advanced model with an introduction of a 10% payment linkage to quality. Thus, the advanced model looks to progress to more holistic value-based care with increased risk for physicians and less flexibility compared to the original programme [127]. CMS also undertook experimentation with a host of other disease-specific bundled payment models such as the Comprehensive Care for Joint Replacement (CJR) Model and Oncology Care Model (OCM), etc., which have been operating as the others, on a voluntary basis.

A synthesis of evaluation of all of these models released by CMS shows a broadly positive trend on outcomes of spending, utilization and quality though the number of models showing such positive outcomes differed depending on the outcome in question and is illustrated below [128]:

Fig. 4. System effects of episode-based payment models under CMS, USA



Acute or Specialty Care & Targeted Population models, serving sicker, higher cost beneficiaries, reduced expenditures, admissions, and/or post-acute care with limited improvement in quality.

	Spending		Utilization				Quality	
	Gross	Net	Inpatient admissions	ED visits	Post-acute care	Readmit	Experience of care	Mortality
Bundled Payments for Care Improvement, Model 2 (Final report)	🟩	🟥		▨	🟩	▨	🟥	▨
Bundled Payments for Care Improvement, Model 3 (Final report)	🟩	🟥		▨	🟩	▨	▨	▨
BPCI-A Medical episodes (Years 1-2)	🟩	🟥			🟩	▨	▨	▨
BPCI-A Surgical episodes (Years 1-2)	🟩	🟩			🟩	🟩	▨	▨
Comprehensive ESRD Care Model (Final report)	🟩	▨	🟩	▨	🟩	🟩	▨	🟩
Comprehensive Joint Replacement Model (Years 1-4)	🟩	▨		▨	🟩	🟩	▨	▨
Home Health Value-Based Purchasing Model (Years 1-5)	🟩		🟩	▨	🟩		▨	🟩
Maryland All-Payer Model (Final report)	🟩		🟩	▨	🟩			🟩
Medicare Care Choices Model (Years 1-4)	🟩	🟩	🟩	🟩	🟩	🟩	🟩	
Oncology Care Model (Years 1-5)	🟩	🟥	▨	▨	▨	▨	▨	▨
RSNAT (Final)	🟩		🟩	🟩	🟥			▨

Source: Centre for Medicare and Medicaid Services [134]

Thus, what is evident from above is that while most bundled care programmes have resulted in savings at a gross level for CMS, following the factoring in of incentives and performance payment to providers, only two of the programmes have shown a positive effect at a net savings level. However, most models have shown a positive impact on post-acute care (that is, reduction in post-acute care) and for models where it was relevant, quality outcomes have largely been positive save a negative reporting in experience of care for Model 2 BPCI. The net losses witnessed under BPCI Model 2 and 3 have been attributed to the earlier model not mandating downside risk to providers, which has been changed under BPCI Advanced Model, though estimates suggest that Model 3 would have still experienced losses [139]. The above findings have been further substantiated by other analyses which showed that while the payment models helped in slowing growth in relative spending, it did not necessarily reduce absolute spending. Moreover, there exists no evidence of compromised quality of care under this payment model [140, 141].

The experience from the earlier models point to the importance of setting appropriate target prices to ensure that providers neither make undue profits, leading to reduced cost savings, nor discontinue with bundled payment programmes in the event of the models not being commercially viable. Additionally, clear service boundaries and interlinking episode payment models to broader-population health focused initiatives (including infrastructure development) are other lessons learned and documented through the bundled payment experience in the USA [142]. Moreover, it should be noted that bundled payment contracting often involves trade-offs in that increase in scope of the bundle may reduce willingness of providers to adopt bundled payments compared to FFS [140].

Facilitators and barriers for bundled care models

Though several payment models are being experimented with under the value-based agenda across countries, bundled payments have an allure in their conceptual simplicity of payment for a range of services through a single payment and their potential to bring in efficiency into healthcare purchasing [143]. However, design and implementation of bundled payments remains a challenge given their potentially large scope and the necessity for coordination across a range of providers and levels of care, as well as the inherent design characteristic of transferring some or all the financial risk to the providers.

Some of the recurrent issues identified in the literature relate to gaming by providers, defining appropriate bundles, integrated service models and linking of quality outcomes to payment rates to name a few [144-147]. Moreover, real world experiences point to a tendency on part of providers to avoid high-risk patients or cases when they may lead to a higher cost outflow, that is, cream-skimming or cherry-picking. Such perverse incentives can pose a barrier to effective implementation of a bundled payment model and should be addressed ensuring risk adjustments or robust monitoring [148, 149].

Several articles have attempted to identify some of these specific facilitators and barriers based on experiences where deployment of bundled payments has been attempted. One such article relates bundled payment models specifically to facilitating and inhibiting factors vis-à-vis their linkage to different outcome dimensions (clinical, cost, patient outcomes and organization outcomes), based on a review of several documents. Some of the recurrent facilitators across most dimensions speak of a small organizational size, active involvement of medical specialists and physicians as well as high motivation of stakeholders and diversity in composition of professionals involved. Organization outcomes highlight the facilitating factors such as prior experience, transparency, adequate training and sufficient resources and infrastructure as key to realizing the success of bundled payment models. On the flipside, for the clinical and cost inhibiting factors, the possibility of opportunistic behavior by provides, rewarding low performers, inadequate adjustment for patient mix and cumbersome administrative measures were found, within the literature reviewed. These also extended to patient outcomes and organization outcomes, the latter of which highlighted limited data and lack of trust as a key inhibiting issue [134].

Pay-for-performance

Pay-for-performance (P4P) has been an integral part for promoting VBC as it is designed to ensure that payments to providers are tied to objective measures of output and/or outcomes. P4P (the term we use to encompass all these measures from hereon) is referred to by several terms such as results-based financing (RBF), performance-based financing, (PBF), etc. Definitionally all these terms have a common thread running through them. Accordingly, P4P can be defined as payment made to a health care provider, and in some cases even a lower tier of government, following the collation and validation of predefined outputs or outcomes linked to an individual or group of individual's health [150]. Though technically P4P's can be designed to address the supply or demand side, for the purpose of VBC, we allude specifically to the supply side wherein funding to health care providers or facilities is based on an established 'performance contract' with a set of specific 'performance indicators' [151].

Despite an established definition, P4Ps are, in practice, very diverse in terms of their design which primarily stems from the indicators and dimensions of performance that are rewarded under each programme [152]. Ranging from their level of deployment (primary, specialist or inpatient setting) to the dimensions of care, to their associated financial arrangements, there is a plethora of P4P experiences that exist across varied settings. The relevance of P4P initiatives to VBC emanates from their basic premise of ensuring objective measures of outcomes which determine the level of payment to be made to a facility or provider. A review of P4P initiatives in improving maternal and child health in low and middle income countries also highlights the plurality of P4P not only in their design vis-à-vis structural, institutional and organizational factors but also their outcome and impact which is influenced by a multitude of factors [153].

Designing and implementing P4Ps

Design and implementation of P4Ps is a complex process and requires to be adapted to the context within which it is being used. When devising such payment systems, there are some fundamental questions that need to be answered prior to their deployment. These have been highlighted in the literature [154] and have been illustrated below:

Fig. 5. Attributes of pay-for-performance

What is incentivized?

- ***Which measures are used to assess performance?***

Who is incentivized?

- ***Whose performance is measured?***
  - ***Who (ultimately) receives the payment?***

Payment Attributes

- ***Frequency, size, payments with salary, lag time between reporting and payment, rewards vs penalties and use of money***

Basis for Payment

- ***Performance threshold & type of ranking***
  - ***Payment adjustment (equity, quality, etc.)***

Gaming safeguards

- ***Performance audits***
  - ***Penalties***

Source: Kovacs, R.J. et. al. [154]

However, P4P rarely works in isolation of a broader health system approach and its importance in VBC can be seen as complementary to other financing and system measures, which are better placed to align incentives towards maximizing value and efficiency [155, 156].

With regard to their impact in meeting their established goals in outpatient and inpatient settings, the evidence regarding P4P is mixed and often weak [157, 158]. However, this is often influenced by factors such as the volume of payments as P4P has been documented to work better in UK as opposed to the United States, with the former taking a more comprehensive approach to performance measurement and providing larger monetary incentives to drive behavior change [159]. However, effective operationalization also necessitates attention to aspects of organizational commitment, adequate infrastructure, human, financial and information technology resources, change champions and a personal and political commitment to quality of care to help P4P models achieve their designated objectives [160]. Though evidence in support of P4P may not be conclusive, there are a number of global use cases which have shown positive effects vis-à-vis select health system goals, especially in a primary care setting. These are tabulated below and highlight the performance domain and measures, basis for reward or penalty and data reporting and verification methods.

Table 9. Performance frameworks in various countries

Country and name of programme	Performance domains and measures (examples)	Basis for reward or penalty	Nature of the reward or penalty	Data reporting and verification
England QOF	Clinical, public health and quality domain (a total of 68 indicators and a total of 567 points can be accrued)	Each indicator has a point value. The value of one QOF point for 2021-22 is £194. 83	Absolute percent of target met after minimum threshold is reached	Electronic health record
New Zealand Primary Health Organization (PHO) Performance Programme	Chronic disease screening, prevention of infectious diseases	Per cent attainment of target	Absolute	Electronic health record
Germany Disease Management Programmes	Covers documentation and clinical indicators for six major chronic disease areas	Flat rate for participation and per service	Absolute	Claims data
France Rémunération sur Objectifs de Santé Publique	Prevention and screening (7 indicators and 1 index); Chronic disease management (6 index and 8 indicators); Practice organization (5 indicators)	Achievement rate- progress toward target relative to baseline performance	Absolute	Claims data
Australia Practice Incentive Programme	Quality stream; Capacity stream; Rural support stream	Flat rate for participation, targets, and per patient reached	Absolute	Claims data

Source: Yousefi, M., et. al. [161]

Thus, it is evident that linking payments to objective performance measures are widely used and contribute to the VBC agenda. However, as also highlighted, P4P rarely works in isolation and a singular focus on P4P can narrow the scope of the efficiency and quality gains and work detrimentally towards a more holistic approach to maximizing VBC.

Pay-for-performance in LMICs

Pay-for-performance (P4P), or the provision of financial incentives to health care providers based on pre-specified performance targets, first emerged as a strategy to improve quality of care in the United States, Europe, and other high-income countries (HICs), and was subsequently adopted in low-middle-income countries (LMICs) with the further aim of increasing service coverage [162].

The term pay-for-performance (P4P) has acquired a wider use in LMICs and refers to supply-side financial incentives where payment depends explicitly on quantity of services delivered and “on the degree to which services are of approved quality, as specified by protocols for processes and outcomes” [163].

Challenges

Despite the benefits of P4P in LMICs, there has been some criticism that it is often analyzed as a system in isolation. Over the past few years, a large number of P4P initiatives in LMICs have been designed and implemented as separate projects or programmes, frequently without due consideration to the rest of the health system and, more specifically, of how these link to existing provider payment mechanisms and broader public finance reforms [164].

Hence, it is crucial to pay greater attention to the overall health system reforms and how provider payment arrangements interact with these to influence health outcomes, as opposed to looking almost solely and more narrowly at the details and impact of a P4P mechanism, divorced from the underlying health system [165]. P4P is a category of provider payment mechanisms part of strategic purchasing, the effectiveness of which depends critically on its connections with the wider environment of purchaser– provider relations.

Conclusion on payment models

In conclusion, bundled payments and P4P can serve as important models to drive the VBC agenda and help surmount the shortcomings inherent in traditional FFS. With bundled payments, there is yet, much experience and iteration required to determine the range of bundles that work best within the specific settings and their complementarity with other provider incentives outside the targeted services under the bundle. This is especially relevant in cases where co-morbid conditions exist among patients outside of the service bundle (for example, the elderly). Though bundled payments exist along a spectrum of permutations, similar to other provider payments mechanisms, they are prone to gaming and manipulation which in turn requires a clear alignment of the design elements with the payment reforms objectives and robust monitoring and accountability.

With P4P, evidence of impact, given the aspiration of less spending and more value in terms of quality, is mixed. However, on balance, these payment systems seem to work in favor of improving value-for-money within the heath systems and on interventions with a relatively narrower focus. The key consideration for PM-JAY in transitioning to these APMs is how these models create and ensure the necessary linkages between the current hospital-based approaches and other primary or specialist areas of care as a first step to such a transition.

4. Integrated care

The European Regional Office for WHO defines integrated care as: “an approach to strengthen people-centred health systems through promoting delivery of comprehensive and quality services across the life-course, designed according to the multidimensional needs of the population and the individual. This is to be delivered by a coordinated multidisciplinary team of providers working across settings and levels of care. It should be effectively managed to ensure optimal outcomes and the appropriate use of resources based on the best available evidence, with feedback loops to continuously improve performance and to tackle upstream causes of ill health and to promote well-being through intersectoral and multisectoral actions” (4).

This definition incorporates a multisectoral element in order to tackle commercial, social, and other determinants of health which is beyond what was envisioned by Porter and Teisberg. They propose the following elements in ensuring integrated care including:

a) Defining the scope of the services to be provided by the integrated care network which in some cases, may require some of the providers to exit a line of service or partner with others in a more complex specialty line.

b) Concentrating volume in fewer locations to maximize value. The higher the volume concentrated in a practice, the more precise the care quality and in turn, better outcomes and lower the costs.

c) Choosing the right location for the services so as to ensure better value of services with less complex and routine services moved to the lower cost facilities and more complex ones managed in more complex settings like teaching hospitals to optimize resource use and productivity.

d) The deliberate integration across the provider network for coordinated care of the patient. For instance, initial diagnosis and test conducted at the centrally located specialty e.g., orthopedic centre for instance, and subsequent interventions conducted at the provider closest to the patient’s home. Care is coordinated across the entire IPU to ensure follow up and good quality care.

Porter and Teisberg note that this is a particularly difficult component of the framework owing to the politics that is involved in every step of designing and implementing the integration of care. In the upcoming section, we describe some examples of integrated care in some countries and the evidence of impact.

Country examples of implementation of integrated care systems

Australia: National health reform agreements have ensured that all states and territories have set aside small budgets for pilot programmes of integrated care which are managed at the state-level [166]. Some pilot programmes, such as those centred on the Gold Coast and in Ipswich in Queensland, have attempted to create a continuum of care between general practice and secondary care systems [167]. Multidisciplinary teams were established to oversee patients with escalating risk, and care pathways were developed to reduce chances of hospital admissions. These steps have better met the needs of high-cost frequent hospital attenders. Progress has also been made in generating algorithms to detect patients with rising risk of hospital admissions, but these investments have not addressed longstanding gaps in communication between primary and tertiary care [168]. Some examples of integrated care systems from Australia include:

1. **Integrated HealthOne Services (NSW, Australia):** Started in 2006–2007, HealthOne is a hub-and-spoke model of Mt Druitt and includes a co-location of service models and a virtual integration model in which separately located providers are linked by communication technologies [169]. The evaluation found significant improvements, with a reported 26 % reduction in the number of emergency visits per patient (from 3.1 to 2.3), a 52 % reduction in the hours spent in emergency (from 12.5 to 6.6) and a 41 % reduction in the hours spent in hospital (from 6.3 to 3.7). HealthOne has now been operationalized through a local hospital networks at twenty-five locations around NSW.

2. **Hospital Admission Risk Programme (Victoria, Australia):** This programme aims to reduce demand for hospital services through care coordination, self-management support and specialist care of those with complex and chronic needs who either frequently use hospitals or who are at risk of hospitalization. An evaluation over 2004–2005 reported that the 80 pilot projects resulted in 35% fewer emergency department attendances, 52% fewer emergency admissions and 41% fewer days in hospital [170]. Compared with the situation of participants before they entered the programme, there was a 64% reduction in hospital separations, a 55% reduction in emergency department presentations and a 39% reduction in clients presenting to emergency after being discharged.

UK: Following several years of locally-led development, recommendations of NHS England and passage of the Health and Care Act (2022), 42 Integrated Care Systems were established across England on a statutory basis on 1 July 2022. The NHS Five-Year Forward View Plan published in 2014 sets out how services need to change, and emphasizes the requirement for greater integration of care [171, 172]. New models of integrated care are charged with achieving more care beyond the hospital walls, change in the size and shape of acute hospitals, and increased attention to prevention and population health [173].

In 2014, NHS England outlined plans to develop `New Care Models' supporting the creation of prototypes for integrating health and social care services to be subsequently spread across England. Introduced in 2015 and financed until March 2018, the Vanguard `New Care Models' was a major and innovative programme, which aimed to design and test prototypes for integrating health and social care services. The scale of the Vanguard piloting programme was large. Between 2015 and 2018, NHS England invested about £389 million in supporting Vanguard sites to develop and evaluate new care. This covered a population of around 5 million – around 9% of the entire population in England. Evidence so far from the Vanguards is emerging and mixed, with a net reduction in emergency admissions occurring mainly in third year of implementation. However, there was found to be no significant net effect on total bed-days rates attributable to the integrated care and care home Vanguard schemes.

United States: Over the last decade in the USA, the burden of chronic disease, healthcare costs, and fragmented care delivery have increased at alarming rates. To address these challenges, policymakers have prioritized new payment and delivery models to incentivize better integrated health and social services [174].

Within the CMS, Medicaid Programme initiatives like the ACOs have been developed to integrate care. An evaluation of one such programme in CMS evidenced savings of US $ 526.4 million in Medicare spending across three performance years (US$ 381.5 million in net savings) [128]. Major lessons that emerged as facilitators of the model were leveraging relationships with management companies to support ACO operations, sharing performance feedback with health care providers, and providing stability, given rural workforce challenges. Independent evaluations have observed similar findings with a reduction in readmissions of 2.1% each year and participation solely in the Meaningful Use programme resulting in reductions of 2.3% each year. Moreover, hospitals that participated in all three programmes saw readmission rates drop by 2.9% per year and realized cost savings in 2015 of nearly US$ 32 million [175].

Other initiatives and models include the patient-centred medical home(s) which is a physician-directed group practice that can provide care, which is accessible, continuous, comprehensive, coordinated and delivered in the context of family and community. The model adopts a holistic approach to managing patients with chronic diseases and co- and multimorbidities by offering an alternative individual model of primary care where patients are assigned to medical homes and physicians (25). Other initiatives that are being implemented include the Veterans Health Administration (VA), a health system that provides integrated services to older people with chronic conditions in the USA. The VA employs physicians, owns and runs hospitals, medical offices and manages services within its network. Transformed from a hospital-based system, the VA currently consists of 21 regionally-based integrated service networks. The structural changes were guided by the assumption that gains in effectiveness and efficiency can be achieved through better coordination between facilities, the synergy of resources and provision of care in the most appropriate settings [180]. Resources received from the federal government are not allocated to facilities but rather to networks – a mechanism through which service integration and shared accountability are achieved [170]. A transformative vision and effective change management have been a cornerstone in achieving integration within the VA network. A distinctive feature of the VA system is the well-praised culture of measurement and reporting, which supported the mechanisms of accountability and continuous performance improvement. Measures are determined by groups of indicators distributed according to several value domains, which are closely monitored in each of the networks. The VA model has put a great deal of effort in organizing care processes around patients' needs and enabling patient self-management through investments into supportive information technology. Much of the transformations were achieved by virtue of fostering clinical governance and the VA's own health service research.

There are various other state-driven initiatives in implementing integrated care. These initiatives have varied implementation across population groups and disease conditions. They are largely disease-specific models. Table 10 summarizes a few of these experiences but is by no means an exhaustive account:

Table 10. State experience of implementing integrated care in the USA

State	Programme	Components	Outcomes
California	The Integrated Behavioral Health Project	An initiative launched in 2006 to accelerate the integration of behavioral health services into primary care settings in California.	Statistically significant improvements in patient physical, mental, and general health, and primary care providers reported a lower level of integration between physical and behavioral health at the clinic [176].
Colorado	Sustaining Health care Across Integrated Primary Care Efforts (SHAPE)	SHAPE aims to understand the impact of global payment methods on the integration of behavioral health and primary care and test real world applications to inform policy.	Initial projections indicated potential savings of US$ 656 Million on a population of one million patients who have conditions like arthritis, asthma, diabetes, or hypertension in conjunction with a behavioral health condition. A Colorado-based PCMH reported a 15% decrease in emergency department visits, an 18% reduction in inpatient admissions, and a return on investment of US$ 4.50 for every dollar spent. Another Maryland-based PCMH stated that it saved US$ 98 million and increased its quality scores by 10% in one year [177, 178]. Another study showed that the SHAPE payment generated approximately US$ 1.08 million in net cost savings for their public payer population [179]
Massachusetts	The Massachusetts Child Psychiatry Access Project	An interdisciplinary healthcare initiative that assists primary care providers who treat children and adolescents for psychiatric conditions.	A statewide data study, showed improvements in as much as 57% in various categories of care. [177] Further still, a separate assessment found that the screening rate for youth with Medicaid has increased from 17% to 80% [180].

Sweden: Chains of care is an integrated care model developed in Sweden with the aim of linking primary, hospital and community care through integrated pathways based on local agreements between the providers [181]. Typical chains of care include screening element in a primary care centre, treatment plans developed in specialist centre and rehabilitation provided in centers. Contractual agreements and alignment of incentives that enable efficient use of resources are distinctive features of the Swedish model. Healthcare-associated infections (HAI) have decreased from 11% in 2008 to 9.6% in 2015. 458 365 fewer antibiotic prescriptions in 2014 compared to 2010. In the country there are 323 prescriptions/1000 inhabitants in 2015. In 10 years, the annual number of deaths that may have been caused by preventable adverse events has decreased from 3000 to 1400 permanent injuries related to adverse events has decreased from 10 000 to 3000.

Canada: The Program of Research to Integrate Services for the Maintenance of Autonomy (PRISMA) is a Canadian model designed to integrate service delivery for community-dwelling people with moderate to severe impairment, who need coordination between two or more services [182-184]. The aim of the model is to preserve the functional autonomy of individuals. The model is designed to serve as a single entry-point to the system and to coordinate care across a network of different providers. Case-management and the use of computerized charts are essential components for coordination. According to the model, integration is achieved through an established joint governing board of health and social care. The board defines the strategy, allocates resources to the network and manages provider groups. An assessment of the impact has shown that the PRISMA model sustained the functional stability of individuals, decreased the extent of unmet needs, and reduced the burden placed on care givers. Individuals enrolled to the PRISMA programme also decreased their risk of hospital readmissions [181].

Over the four years, satisfaction with services improved in the experimental areas by 13.9% whereas it did not change significantly in the comparison group. The two subscales relevant to the PRISMA intervention (satisfaction with the delivery of care and services and organization of care and services) also showed significant positive change over time ($p < .001$). Empowerment was also better in the study group because it was preserved (−1% change), whereas it declined in the comparison group (−11.7%) [183].

Conclusion on integrated care

Integrated care is a useful strategy for ensuring continuity in the care of the patients, minimizing complications, and ensuring that gains in health are maintained. The examples reviewed highlight that when implemented well, the strategy is able to realize gains in health and reduce unnecessary hospitalizations especially for patients with chronic conditions.

The implementation experience shows that despite the political complexity in realizing these kinds of service delivery arrangements, it is possible to successfully implement the models when there is:

a) An enabling policy framework at a national, sub-national level or organizational level that provides the vision for change, including specifying the service delivery model to be adopted as was the case with the UK's NHS Five-Year Forward View Plan which set the stage for the Vanguard "New Care Models". Similarly, the ACOs under the USA CMS' Medicaid Programme are embedded within a broader strategy designed to engender, inter alia, VBC.

b) Dedicated funding for the strategy to enable the necessary human resource and IT investments, needed to realize the strategy. As seen above, the UK allocated £389 million on supporting Vanguard sites to develop and evaluate new care. Similarly, the ACOs in USA are implemented with dedicated funding provided by the USA government through CMS.

c) Transformative leadership and deliberate change management are critical governance components that steer the implementation of the care coordination across providers within the network as shown by the VA, foster the culture of continuous improvement and ensure services are organized around patient's needs.

d) Accountability framework that engenders monitoring the implementation of the program to inform decision-making and continuous learning. The VA has developed indicators that enable performance measurement and strengthened information systems to foster monitoring and evaluation and health services research which drive improvement in performance.

Any adoption of the integrated care will need to ensure that at the least these key facilitators are included in the program in institutional design of the strategy to contribute to its success.

5. Expansion across geographic areas

To establish high value healthcare systems, it is essential that IPUs which are specific to medical conditions should expand geographically. Traditionally, expansion of health care providers has largely been focused on acquiring healthcare facilities that merely reproduce the same services in different geographical areas without focusing much on value outcomes for the patients. Such types of expansions of health providers resulted in similar care and services for the patients where it remained organized around traditional medical specialties and every site delivered healthcare with an aim to provide comprehensive healthcare services. While that strategy was effective when hospitals had little to offer, the ever-increasing complexity of medical care today means that every hospital should not be performing highly complex procedures or treating exceedingly complex patients. For example, not every hospital needs a heart transplant programme, or even cardiac surgery, yet that is what usually happens.

Geographic expansion of healthcare facilities must be rational and should look to adopt a hub-and-spoke model of satellite centres or through clinical affiliations with existing providers**.** Strategic principles for achieving geographic expansion under VBC include:

- Organize care by condition in IPUs (the hubs)
    - Multi-disciplinary teams
    - Responsibility for full care cycle
- IPUs allocate services across the care cycle to sites based on site capabilities, care complexity, patient risk, cost, and patient convenience
- Incorporating telemedicine, home services, and affiliated provider sites into the care cycle
- IPUs developing formal systems to direct patients to the most appropriate site [61]

Several premier organizations have already begun this geographic expansion. The Cleveland Clinic expanded but the main centre in Cleveland serves as the hub with its condition-based IPUs. As they expanded their affiliate programme, they did so in areas of their IPU expertise like cardiac care and care of end stage renal disease. They maintained Cleveland Clinic quality care through education and careful measurement. Another system that expanded geographically through affiliation agreements is the Vanderbilt Health Affiliated Network. With their main facility in Nashville as their hub, they expanded their care network over a

9-state area through affiliations [185, 186]. Additionally, the Rothman Institute in Philadelphia, a regional orthopedic practice, represents a different type of a value oriented regional expansion. With the new arrangement they were able to provide the same outcomes and significantly reduce cost to selected low risk patients operated on in an ambulatory surgery facility whilst avoiding the academic facility [187]. The Children's Hospital of Philadelphia (CHOP) system expanded outside of Philadelphia with the aim of improving the care for all children in the area by providing the right care in the right location [187]. IPUs have been effectively expanded to regional care centres, community hospitals and pediatric practices through affiliations, acquisitions, and building CHOP facilities. There was no evidence on impact that we could find.

In Massachusetts, each of the two large systems, Mass General Brigham, and Beth Israel Lahey Health, have premier academic hospitals and different centres of excellence. Within the systems, smaller hospitals refer complex surgery patients to the academic hospitals for treatment. However, according to a study, collaboration on complex care within the systems can substantially be improved. There seems to be a lack of conviction among the providers that the academic hospitals can deliver better care than their non-academic counterparts, and smaller hospitals are reluctant to refer patients that they are able to treat themselves, due to associated loss of revenue. In contrast to government-run systems, the Massachusetts has no mandate to improve the organization of complex care [55].

In case of UK, the NHS has several specialized centres spread across the country, including children's cardiac centres, craniofacial units, and cancer centres. There are plans to designate more services to specialized centres, like stroke treatment, where specialists have more time and more resources at their disposal to treat the most complex patients [55]. In the London Stroke Initiative, for example, the decision that acute stroke care would be concentrated in just eight of London's 34 hospitals led directly to a 25% decrease in mortality and a 6% decrease in costs per patient [188].

The Dutch healthcare system has eight independent academic hospitals spread across the country, acting as tertiary referral centres for the most complex patients, similar to the centres of excellence in Norway and England. There are also a few national cancer centres of excellence, like the well-known Antoni van Leeuwenhoek Hospital providing high-quality cancer care to patients across the Netherlands and abroad, and the Prinses Máxima Centrum, which focuses on pediatric cancer and collaborates with 20 hospitals across the country to cover full cycle of care, from psychological support, developmental assessments, to cancer treatment. These centres of excellence were initiated by the providers themselves [55].

Ways for expansion

Steps for leading/superior health care providers include:

- Grow/establish areas of excellence across geography:
    - Expand satellite pre- and post-acute services using a hub and spoke model.
    - Affiliate with community providers to extend the reach of IPUs
- Increase the volume of patients in medical conditions or primary care segments rather than widening service lines locally or adding new broad line units.

Steps for community providers include:

- Affiliate with excellent providers in more complex medical conditions and patient segments to access expertise, facilities, and services to enable high-value care.
- Rural and community hospitals can take on new roles through affiliation.

In all successful examples of regional expansion of care, the most common elements were an IPU structure that spans the sites, a common EHR, unified scheduling, standardized measurement of outcomes and cost, physician alignment through either employment or affiliation, integrated communication and education, and a common culture.

Challenges/risks: A significant risk of geographic expansion is the damage associated with the reputation of the main centre if the healthcare services at distant geographical sites do not result in similar quality outcomes. Without rigorous outcome measurement, those assurances cannot be made to the organization or the public [43].

Role of health ministry/regulatory body

Geographic expansion can surely increase the access of primary healthcare services within the population through a network of satellite centres at the periphery and the specialty facility at the centre. The model is of significance especially for rural areas. Private sector has a promising opportunity to start their satellite centres for primary care and diagnosis. At the same time there is a scope of public private partnerships as well as contractual agreements between the private sector for which government can take initiatives. Advocacy for the geographic expansion should be conducted by the government and orientations and consultations for the providers and the clinicians should be organized to understand the possible opportunities for collaborations, strengthening the facilities, identifying the challenges and gaps and working on the possible solutions. Government should also release guidelines and promote geographic expansion by providing incentives to the providers. Creating a favorable environment for the geographic expansion will lead to better functioning of the system and can lead to better health outcomes for the population.

Conclusion on expansion across geographic areas

Expanding services geographically is essential from an equity standpoint and is one area where equity should be a major consideration in the overall VBC framework. The global examples show that thus far, strategic and equity focused geographical expansion has been largely provider-initiated, with the exception of the government's role in the UK through the NHS. It is plausible that a collaborative approach involving a combined bottom-up and top-down approach will contribute to ensuring a successful implementation of this pillar from a societal perspective.

6. Information systems for VBC

What is the role of information systems for VBC?

The foundations for the implementation of VBC is data and information technology. It provides the information needed to integrate services as well to connect different services or teams in IPUs and for determining the costs and outcomes of care. It can also enable the implementation of new payment models for providers. In most countries, information systems have been siloed along the disease conditions or a health facility, with little integration or interoperability. Patient data such as costs, PROMs, CROMs, treatments, diagnoses, and medication use as well as the administrative data are often scattered across multiple (data management) systems. As a result, it is difficult to develop a holistic understanding of a patient's health and the care received.

Patient engagement technologies breaks down the barrier for determining doctor- patient relationship and how much care is needed for a patient. By using information technology, both doctors and insurance companies can work together to provide the best possible outcomes, so patients receive treatment without concerns regarding the cost.

An IT system that responds well to VBC pillars ideally has the following characteristics [7]:

- **The IT system is designed to foster patient centred care:** Meaning that the flow of information follows the patient wherever the patient interacts with the health system during his /her episode of care. The unit of aggregation for data is not hospital or conditions but the patient. This system can therefore capture care sought for co-morbidities, investigations, and prescriptions. It will also track out-of-pocket payments that the patient has paid. Ideally it should be able to furnish the data to other physicians or providers that need information on the patient in a chronological or longitudinal manner. Thus, a personal health record (PHR) is a critical feature of this system.

- **It uses common data definitions:** The system uses standardized language and nomenclature of disease, conditions, and procedures or laboratory investigations and pharmaceutical products. This enables ease of communication, performance monitoring and costing across the system, not limited to a small group of providers.

- **The medical record is accessible to all parties involved in care:** The information technology (IT) system ideally, can store the patient's data in a secure longitudinal record with all the necessary features guaranteeing security of the data whilst enabling access to all providers who need to access the data related to the patient's diagnosis, diagnostic tests and prescription medicines that have been undertaken as well as medical interventions and procedures. This access is usually authorized by facility or patient directly to ensure that only those that need to look at the data can access it.

- **The system includes templates and expert systems for each medical condition:** The system should have standardized templates for data entry for different conditions developed with clinicians to make them easy to use and collect data that is standardized across all facilities.

- **The system architecture makes it easy to extract information:** The data related to patients should be easily extracted for analysis and visualization through measures such as dashboards, etc.

Informatics is defined as the combination of data standards, information IT architecture, and analytic capabilities to support the systematic tracking and analysis of health outcomes, relevant risk-adjustment factors, segment-specific interventions, and the corresponding costs of care. The more that health informatics systems share common data standards and a common architecture, the easier it will be to share data across databases and organizations.

An appropriate IT infrastructure is needed to ensure that health care providers have access to the right information during all processes of a healthcare pathway and can compare this information with each other in order to improve their services [189]. A value-based IT health system should be centrally accessible to all health care providers involved in treating a patient during a cycle of care while ensuring a high level of privacy and security. The system should allow for easy capturing and sharing of stakeholder data, for example PROMs, CROMs, patient journey, diagnosis, costs, and treatments. Additionally, it should be compatible with most data extensions found within the healthcare industry so that data delivered from other systems can be integrated.

Improving data management to ensure improved access to relevant and recent data will help in stimulating VBC. For example, a well secured online health platform where patients have full control over their own health data. Patients themselves determine what they want to add to the platform and can, for example, upload data from wearable medical devices. The aim of the platform should be to improve data management and set standards for exchanging medical data between patients and health care providers.

Several VBC programmes in many settings have implemented such information systems to enable the VBC programmes. The NHS Wales has a well established VBC strategy and national programme [190]. Part of this includes the implementation of the National Data resource which is a health information exchange (HIE) platform that enables the NHS to federate data from all providers in the system including PROMs data.

The CMS in USA has also invested in several programmes for promoting interoperability of health information systems and meaningful use of the data. These programmes have included financial incentives for participating providers to adopt IT solutions such as EHRs. The use of EHRs within hospitals participating in the VBC programmes run by CMS has been extensively assessed, showing improved adoption and use of the systems to access data for patients during clinical visits compared to hospitals that did not adopt the EHRs [191-194]. They also show that the hospitals participating are able to get the data from other hospitals participating in the regional HIE organization. However, none of the studies assesses how the adoption of these technologies furthers the adoption of the various strategies of VBC per se.

NSW is another example where health information systems are being used as an enabler for the implementation of VBC programmes successfully. The department has established the HOPE platform for the implementation of PROMs programme interlinked with the EHR systems in facilities. These are in turn interlinked with the broader data portal for the government [195]. No evaluation has been done as to how the system is influencing the design and outcomes of the VBC programmes.

In Kenya and Tanzania, a maternal child health value-based purchasing programme called MomCare has successfully used a digital exchange platform and is compatible with existing information architecture that connects mothers with health care providers and payers (for example, insurers) enabling payments through mPESA, patient engagement, data collection, and provides actionable feedback through dashboards [47]. The drawback is that the platform requires internet connectivity, which can pose a challenge in LMICs. It also enables collection of patient socio-economic data as well as medical history. It allows the care provided to be aligned to the history of the mother. It includes a mechanism for collecting PROMs data from the mother using telephone calls that gather information, which is filled in short questionnaires in the app. SMS based reminders ensure compliance of mother to visits. The platform analyses the collected data and provides participating clinics with dashboards showing data on health usage, costs, adherence, and outcomes. Providers can access the patient record through journey tracker, an app that requires login credentials provided to staff.

While examples exist of increasing use of integrated health information systems, there is no evidence on how the information systems are actively being used to inform the implementation of the five pillars of VBC. This is an area of research that needs to be addressed to improve our understanding on the role of HIE systems for VBC and how best they can be leveraged.

Conclusion on information systems for VBC

Information systems are key enablers for facilitating data flow across systems, which is an important prerequisite for VBC. From patient medical records to PROMS/PREMS, as well as facilitation of payment systems, information systems play an important role in linking the various pillars of the VBC framework. To do this, a clear articulation and establishment of a digital information and data framework needs to be ensured with the supportive tools required. The underlying blueprint should provide the necessary form and functionality to facilitate data flows for enabling VBC reforms and monitoring.

7. VBC for pharmaceuticals

Pharmaceutical spending is one of the major categories of expenditure in health systems across the globe. However, there also remains a large variation in spending across countries suggesting that efficiency gains are possible in many settings [196]. An important element of evolving technology, health innovation, is often related to development of new pharmaceuticals with added therapeutic value [197]. While these developments come with significant improvements in population health and welfare, they also come with higher costs associated with the increased use of higher quality but more expensive pharmaceuticals. Notwithstanding issues of supply, distribution, and wastage (which are important areas of redressal), purchasing of drugs under a value-based system should establish ways and means of ensuring that level of spending on pharmaceuticals is informed by their current and/or additional therapeutic value and other perspectives of value that are relevant in the setting they are deployed.

Several pricing modalities are employed by countries [198]. One of the more widely used methods for determining prices of drugs is by using ‘External Reference Price System’ (ERP). This is especially true in settings such as low and low-middle income countries where technical capacity to conduct necessary HTAs, etc., to inform price setting may be limited. WHO [199] defines ERP as “the practice of using the price of a pharmaceutical product (generally ex-manufacturer price or other common point within the distribution chain) in one or several countries to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country”. The objective of ERP is to link the price of new drugs in the regulating country to the price of the same drug in a specified set of reference countries. The application of ERP across countries varies depending on the input criteria used, that is, choice of reference countries. However, the challenge with the ERP is its lack of linkage of the price to the expected benefit or value of the therapeutic agent. The notion of value-based pricing has been gaining popularity in many countries in light of the limitations of traditional pricing mechanisms. Countries like UK, Sweden, France, etc., have increasingly adopted this as a part of their pricing mechanisms to ensure value for money.

Defining value for pharmaceuticals

At the outset, it is important to establish and characterize the concept of value for pharmaceuticals that reflect societal values. Traditionally, therapeutic value (TV) and additional therapeutic value (ATV) have been used for decision making around pricing. The notion of TV and ATV is closely tied to the practice and application of HTA and its constituent tools such as cost-effectiveness and cost-utility analysis. A review of six countries [200] documented the diversity of how value is conceived for pharmaceuticals. In addition to ascertaining value, based on the clinical merits of a drug intervention and its cost-effectiveness, some countries such as France also factor in the innovativeness of the drug to determine their value to the health system. In the United Kingdom, TV category includes the more sophisticated metric of QALY as well as broader social benefits offered by the drug (ability to engage in society, etc.). In Sweden, equity is a TV category considered especially in the case of innovative drugs, while in Canada, aspects such as adherence, caregiver benefits, etc., also feature within the TV categories. Thus, defining TV or ATV is closely tied to the societal notion of value and drug pricing and reimbursement reflect these very factors.

8. Health technology assessment

The proliferation of healthcare technology and expanding benefit coverage under health systems have contributed to burgeoning healthcare costs. However, this relationship is variable, complex, and evolving as multiple factors reinforce the market for health technology and benefit design options, such as ageing population, increasing prevalence of chronic diseases and consumer demand, to name a few. Given this correlation between evolving health technologies and increasing cost pressures faced by governments and payors, health technology assessment (HTA) provides an important tool to ascertain the added value that these technologies can offer from varied perspectives of policy inquiry.

Definitionally, HTA is 'the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational, and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform policy decision-making [201].' The purpose of HTA is nested in the notion of ensuring value for various stakeholders within the health system contingent on the perspective deployed and ranges from an assessment of safety, efficacy, legal/ethical or economic impact of technologies and interventions. More specifically, HTA can help advise/inform varied domains of health systems decision making as shown in the Table 11 below:

Table 11. Domains of health systems decision making for HTA

Domain	Applications
Research	• Research agencies about evidence gaps and unmet health needs • Impact of epidemiological trends on health systems design (for example, Burden of Illness)
Clinical decision making	• Clinicians and patients about the appropriate use of healthcare interventions for a particular patient's clinical needs and circumstances • Health professional associations about the role of a technology in clinical protocols or practice guidelines
Organizational efficiency	• Hospitals, healthcare networks, group purchasing organizations, and other healthcare organizations about decisions regarding technology acquisition and management • Disinvestment of obsolete interventions

Resource allocation	• Payers (healthcare authorities, health plans, drug formularies, employers, etc.) about technology coverage (whether or not to pay), coding (assigning proper codes to enable reimbursement), budgetary impact (budget impact analysis) and reimbursement (how much to pay) • Government health department officials about undertaking public health programmes (for example, immunization, screening, and environmental protection programmes)
Policy and regulation	• Lawmakers and other political leaders about policies concerning technological innovation, research and development, regulation, payment and delivery of healthcare • Regulatory agencies about whether to permit the commercial use (for example, marketing) of a drug, device or other regulated technology • Standards-setting organizations for health technology and healthcare delivery regarding the manufacture, performance, appropriate use, and other aspects of healthcare technologies

Other potential applications of HTA relate to product development and market analysis among private sector players as well as evidence for investors and companies concerning venture capital funding, acquisitions and divestitures, and other transactions concerning health care product and service companies. An example of application of HTA in Brazil [202, 203] is provided in the Box 1 below:

Box 1. Use of HTA in clinical practice guidelines in Brazil

In Brazil, 100% of the population have access to healthcare through the Brazilian Unified Public Healthcare System (Sistema Único de Saúde; SUS) and approximately one-quarter of those enrolled have additional private health insurance coverage or pay directly for services received. The Brazilian Ministry of Health (MoH) develops national practice guidelines (PGs) for health professionals and policymakers based on technologies that are used across the SUS in order to establish standards for the diagnosis and treatment in public healthcare settings. New technologies are first subject to a systematic assessment by the National Committee for Health Technology Incorporation (CONITEC).

While PGs developed by the professional societies primarily aim to inform health care professionals about best practices, MoH PGs also aim to standardize practices for the public health system. Different departments in the MoH may produce documents with healthcare recommendations, but PGs developed by CONITEC have a normative role, defining the available technologies and circumstances for their implementation in the SUS. These PGs are developed by academic and healthcare institutions, commissioned by the MoH, responsible for evidence review and guideline panels. The PGs are reviewed by CONITEC, ensuring that recommendations are aligned with services currently provided by the public health system, and CONITEC may request modifications or even a new HTA assessment if a new technology is recommended. An important strength of PG development in Brazil is that its healthcare system uses a centralized process for guideline development and approval, which leads directly to the implementation of PG recommendations in the public sector. The Department of Management and Incorporation of Health Technologies (DGITIS) of the Brazilian MoH is responsible for managing and coordinating activities related to the development of guidelines for the public healthcare system. This process is followed by a CONITEC assessment and public consultation, and the document is finally approved by the responsible manager of the SUS and officially published. As these PGs are official documents with guidance for health care professionals and policymakers, they shorten the gap between the development and implementation of recommendations in the public health system. Additionally, the representative composition of the CONITEC increases the legitimacy and transparency of the recommendations, as does the public consultation process.

As can be seen from the examples above, HTA provides an empirical basis for evidence-based decision making for governments, payors and other stakeholders to systematically evaluate properties and/or impact of health technologies including their direct, indirect and unintended consequences. However the term 'technology' is a broader, encompassing term which includes a range of health system inputs such as [204]:

- Medicines
- Programmes to prevent ill health (for example, vaccination programme)
- Procedures (such as surgeries)
- Medical devices
- Organizational and managerial systems used within health sector

Determining value under HTA – economic evaluations

An integral part of HTA application is measuring the economic dimension to inform resource allocation decisions considering resource scarcity. Economic evaluation for HTA is specifically designed to evaluate these economic consequences and feed into decision-making regarding the most judicious and efficient allocation of healthcare resources. There exist different types of economic evaluations depending on the use of costs and consideration of consequences/benefits [205] and range from partial to full economic evaluations. The former tend to focus on the cost implications of interventions (cost-of-illness, programme cost analysis and cost minimization analysis), while full evaluations also factor in the incremental benefits accrued across comparator interventions relative to their costs. These full evaluations include cost-effectiveness, cost-utility and cost-benefit analysis, each of which use different units or measures of benefits/outcomes to inform the choice of intervention.

The detailed description of the process of conducting each type of evaluation method is beyond the scope of this paper. The details of these can be found in Drummond et al [110]. Nevertheless, for the purposes of the consideration of the policy and practice of adoption of HTA for VBC, we discuss further issues related to institutionalizing and financing HTA.

Institutionalization of HTA within health systems

Beyond the technical exercise of conducting HTA's, structuring and deploying an enabling policy environment is essential to the successful adoption of HTA in a country context. Some of the key policy and implementation considerations that should be accounted for as part of institutionalization of HTA mechanisms and structures in a country are:

Fig. 6. Elements of HTA institutionalization

Legal framework	Governance and institutional arrangements	Monitoring and evaluation
Human resources	Data and information	Finance

Source: Asian Development Bank [206].

As a precursor to the operational institutionalization of HTA mechanisms, it is important to establish and clarify the mandate of the HTA body to be instituted to establish boundaries and limits within which the HTA body is to function. HTA agencies around the world vary in the extent to which they generate, inform and implement recommendations vis-à-vis health policy system decision. For example, the Australian Pharmaceutical Benefits Advisory Board Committee (PBAC) makes recommendations specifically for drug reimbursements [207-209] while the NICE in UK has a much broader mandate, recommending interventions for reimbursement and development of clinical guidelines [210, 211]. Moreover, the extent to which recommendations of an HTA agency are legally binding to the national payor or Government also differs and needs to be informed by the strategic goal for which such an HTA agency is being developed.

Legal framework: To ensure the effective operation of the HTA to serve policy development, the governance of the HTA system needs to be aligned with the existing legal system of each country [206].

The legal framework for the development of an HTA system can be developed into a separate law [212] or in a primitive form, integrated in the guiding documents for health service provision [213]. This empowers and legitimizes the voice of HTA in policy formulation [214].

In the absence of this, HTA evidence may not be aligned to policy cycles as in China and Vietnam or may be underutilized as is the case in Netherlands. Table 12 below provides an overview of legal frameworks deployed by a host of countries in building their HTA system.

Table 12. Overview of legal frameworks deployed by countries in building their HTA system

Country	Legislation	Binding power
UK	Legislation in 1999 to make NICE a non-Departmental Public Body	The UK National Health Service (NHS) is mandated to implement the recommendations provided by the technical appraisals (HTAs) conducted by NICE.
Germany	The Federal Joint Committee (G-BA) has the legal mandate to define coverage benefits, including new technologies. G-BA was established by law in 2004	Decisions are binding for social health insurances (SHI)
Colombia	IETS established as an independent agency by law 1138 of 2011	IETS positive assessment not required for inclusion in national programme. Prices set based on classification for new intervention determined by IETS
Korea	The Health Care Law 2000 stipulates the process of evaluating health interventions before they are included in the health insurance system; at the same time establish Health Insurance Review and Assessment Service (HIRA) in charge of HTA to determine the level of health insurance payment for each employee [215].	Health technologies that are assessed as suitable after HTA appraisal will be issued a permit by HIRA and National Health Insurance Corporation (NHIC).
Indonesia	Presidential Decision No. 111 in 2013 stipulating the use of HTA in formulating the national health insurance payment policy	HTA assessment recommendations are not binding. In some cases, even if the President has accepted the committee's recommendations, they are hard to enforce

Adapted from: Asian Development Bank [206]

Monitoring and adjustment of the legal framework for the HTA process can prove instrumental to its relevance over time. Obsolescence, conflict of norms and failure to incorporate new statutory rules into the HTA process could prove tangible risks and end up hampering its efficiency or lead to judicial review. Thus, setting of a legal framework for HTA is not a one-off process but requires continuous review and adaptation to the contextual realities in which they operate.

Governance and institutional structures: While the legal codes and statutes establish the boundaries within which HTA bodies will operate, a clear setting out of the governance and institutional structure is essential to ensure effective execution of the functions expected. An important consideration in setting up HTA agencies is to determine the extent of autonomy and responsibility the agency exercises. HTA models vary from small committees to strong virtual networks, technical hubs in academia coordinated by a small central secretariat to agencies that perform all HTA activities in-house. Different models may also co-exist depending on the delegation of assessment and appraisal mandates of the HTA review.

For example, in a more centralized setup such as South Korea and Thailand, there exists a single agency that manages and coordinates the conduction and application of HTA. This helps save resources if assessment or appraisal are performed within the same agency.

However, some countries such as Spain, UK or Canada have built the HTA system in a decentralized form. Spain has eight regional agencies and one Spanish HTA Network, which acts as a joint coordinating network of regional agencies. This Spanish collaboration is based on the strengths of each agency, and medical technologies are prioritized for assessment by the Interregional Health Council of the Ministry of Health [216]. In England, Scotland, and Wales there are separate HTA bodies that conduct independent HTAs. The Scottish HTA Regulatory Authority does not conduct HTAs but will make a decision based on HTAs submitted by the manufacturer [217]. In Canada, Alberta and Quebec have their own HTA agencies, which operate separately from the national HTA agency – Canadian Agency for Drugs and Technologies in Health (CADTH) [218]. This is considered appropriate for the state apparatus in these countries because the regional health regulator is empowered in the policy-making process.

For LMICs, not much information has been reported on the advantages and disadvantages of these forms of organization, though some key considerations in designing and building an HTA institution include:

- Affordability of each option for the country and the funding available.
- Human resources required and available.
- Appraisal of national HTA capacity and where it is located.
- Potential options for locating the HTA mechanism, if appropriate.

The last could be an independent public agency or a function spread across the Ministry of Health, or an arm's length agency tied to the Ministry for instance, depending on the country's legal and institutional practices. The institutional arrangements, such as separation of the assessment and appraisal processes and management of conflicts of interest, should be the same whether the recommendation from the HTA process is advisory or binding; however, the mechanism for communication to and feedback from policymakers may differ.

Monitoring and evaluation: M&E is informed by the value proposition of the stakeholder under consideration (access, affordability, quality, etc.). It is important first and foremost, to explicitly define within the M&E framework the focus of the HTA being undertaken. Moreover, a consensus should be developed regarding the 'logic model' or monitoring indicators, to ensure that the M&E activity is able to provide relevant policy information based on the evaluation conducted. Moreover, results of M&E and the actions taken in response must be communicated regularly and transparently, with attention to the modes of communication to different audiences (policy champions and stakeholders). This will ensure public accountability and can provide evidence for increasing value for money of the HTA mechanism. WHO has provided guidance for institutionalizing, operationalizing and sustaining M&E efforts for HTA [219].

Human resources: Human resources for HTA is a pressing challenge especially in the LMIC context. A lack of in requisite technical and managerial expertise can impact the credibility, validity and applicability of HTA assessment and appraisal findings. The INNE (Individual, Node, Network and Enabling Environment) approach framework has been proposed as a means of building capacity for HTA (54). In the framework, the key stakeholders and required resources are classified into three main groups in the HTA application process. The required organizations/units, resources and recommendations of each stakeholder are presented Table 13 below:

Table 13. Stakeholder elements and roles and responsibilities for HTA

Stakeholders	Consumer of HTA evidence	Producers of HTA evidence	Knowledge brokers	Role and responsibility
Government	X			Policymaking agencies: • Commission, receive and utilize HTA evidence. • Coordinate and participate in prioritization and evaluation of topics for HTA. • Monitor impact of HTA in policymaking. • Increase awareness of HTA. National HTA organization: • Coordinate HTA topic selection and appraisal process. • Coordinate evidence generation and translation for policy.
Academia	X	X	X	• Support topic selection activities. • Support in implementing HTA studies. • Provide technical advice to HTA organization. • Applying HTA results in policy development. • Developing human resources for HTA.
Health professionals	X		X	• Participate in policy formulation using HTA. • Propose topics for HTA.
Industry		X		• Provide evidence of proof of efficacy, safety and cost-effectiveness to HTA organization. • Contribute to the development of HTA in the country.

Stakeholders	Consumer of HTA evidence	Producers of HTA evidence	Knowledge brokers	Role and responsibility
Patient/ community	X		X	• Participate in HTA decision making through citizens engagement mechanisms, for example, through patients' panels as in NICE. • Contribute to HTA topic prioritization process by proposing topics for evaluation.

Adapted from: Asian Development Bank [206].

Data and information: At the heart of HTA lies the key processes of generating, maintaining and analyzing data which is the basis of evidence-based policymaking. Given its centrality in HTA, institutions and processes to ensure availability of good quality data is a first order condition to maximize impact and relevance of HTA findings. WHO has pointed out that the two main obstacles in building HTA systems in countries come from including the lack of data relevant to the domestic context and limited capacity in data analysis and application in the process of policy formulation [214].

Thus, at fundamental level it is important to consider two key aspects of data and information for HTAs which includes:

a. Data management

Data for HTA can come from a wide variety of sources including clinical trials which are essential to gauge preliminary effectiveness and safety measures as per defined protocols. The use of real-world data provides richer detail and insight into how interventions translate onto the ground vis-à-vis their real-world effectiveness, efficacy, safety, costs, etc. This is important keeping in mind the policy context within which HTAs are to be applied. Across countries, a range of data sources are used for such input such as national health insurance database as in Taiwan and Republic of Korea [220, 221], national surveys as in Republic of Korea and Vietnam [222, 223], personalized medical information as in the USA and in Sweden [224, 225] and other international data sources especially in LMICs [226, 227].

b. Data usage

Regarding use of HTA data, WHO recommends that countries improve their capacity to synthesize, analyze and apply available decision-making data [227]. To do this, it is recommended that a formal delegation be handed out to a unit or institution, which could be under the Ministry since access to population data through surveys, insurance database maybe required. However, at a broader level, to make HTA usable for policy use, the underlying data should be:

- **Sufficient and accurate:** As noted above, volume of data is contingent on the available public database that researchers and practitioners have access to for their HTA assessments. In terms of the data expected to be captured by an HTA, different countries have different needs. In Thailand for example, the Health Intervention and Technology Assessment Programme's (HITAP's) requirement vis-à-vis data to be used for HTA, varies based on the type of health technology being used. The most basic data include clinical efficacy and safety data; cost-effectiveness; budget impact; influence on moral and social aspects [228]. In Europe, the HTA database requirements are different from Thailand, but most of the evaluation criteria are similar. Specifically, countries in Europe require an HTA assessment database with five main components: safety; clinical efficacy/effectiveness; cultural, social and ethical consideration; economic impact assessment; practical application [229].

- **Transparent:** Needless to say, transparency regarding how data is used within the HTA is essential to ensure its acceptability by all stakeholders and credibility of the conclusions derived. This relates back to aspects of institutionalization and governance wherein clear guidelines and processes must be laid down vis-à-vis the type of data required for an HTA and how it is to be requisitioned. Formally laying this out and building consensus with stakeholders on the same will help ensure that the findings are not met with resistance from different stakeholder groups.

Finance: Sustainable financing for HTA institutions is important not only from the perspective of conducting HTA appraisals but will also help ensure that interference by vested interests is contained. Moreover, such financing should provide a stable flow of funding such that activities can be planned prospectively in a more strategic way rather than as a reactionary exercise. To that end, it is advisable that HTA agencies be funded through public sources to ensure stability, while ensuring independence and avoiding conflict of interest in the working process. However, to complement government funding, 'fee' collected by agencies from industry institutions to conduct HTAs can be considered as one of the options for financing. Different countries use different sources of funding for their HTA institutions, the total quantum of which is contingent on the complexity of the HTA appraisals conducted and the corresponding expertise required. Some examples of how different agencies across countries fund their HTA institutions are provided in the Table 14 below:

Table 14. Funding mechanisms for HTA

Country	HTA organization	Funding sources
Germany	Institute for Quality and Efficiency in Health Care (IQWIG)	Fees for each ambulatory visit and hospitalizations
Australia	Prostheses List Advisory Committee (PLAC)	Application fee US$ 600
	Medical Services Advisory Committee (MSAC)	Department of Home Affairs (DoHA) programme funding, cost recovery
	Pharmaceutical Benefits Advisory Committee (PBAC)	Mainly application fees to be paid when requesting an evaluation, complemented by DoHA programme funding
The Netherlands	Commissie Pharmaceutische Hulp	Public, mainly from social insurance premiums
United Kingdom	National Institute for Health and Care Excellence (NICE)	Public resources of the general budget

Country	HTA organization	Funding sources
Poland	Polish HTA Agency	70% of support from the general budget. The rest comes from other sources, including statutory fees paid by pharmaceutical companies
Thailand	Health Intervention and Technology Assessment Programme (HITAP)	HITAP receives its main funding support from four public institutions: the Thai Health Promotion Foundation; the Health Systems Research Institute; the Health Insurance System Research Office; and the Bureau of Policy and Strategy, Ministry of Public Health
Taiwan	Centre for Drug Evaluation (CDE-HTA)	Public resources of the general budget
Korea	National Evidence-based Health care Collaborating Agency (NECA)	Public resources of the general budget

Adapted from: Asian Development Bank [206].

Rate of return regulation

This is used commonly in the UK by the Pharmaceutical Price Regulation Scheme that seeks to regulate the profits of the pharmaceutical companies in a manner that ensures medicines are affordable whilst remaining profitable for companies [230]. The implicit value is the value of R&D. The primary concern is value for money for the NHS followed by promotion of R&D. The scheme also ensures access to new technologies that would otherwise be inaccessible.

Assessment of clinical/therapeutic benefit

In countries like France and Italy, the therapeutic benefit of the drug has more significance in the valuation process than other factors. The therapeutic benefit (Amelioration du Service Medical Rendu, ASMR) determines the negotiations between the pharmaceutical industry and the purchasers. The ASMR is grouped in five categories or levels of benefit ranging from ASMR 1 that specifies significant innovative and substantial clinical benefit to ASMR 5 in which there is no improvement in clinical benefit as compared to existing therapeutic products.

In Italy, an innovation assessment algorithm (IAA) that accounts for i) the therapeutic innovation (that is, molecules for which there was no drug that provided satisfactory treatment) and industrial innovation (that is, discovered through an advanced technology or new administrative route); ii) the evaluation of effectiveness related to patient centred issues such as compliance and tolerability and lastly; iii) clinical effectiveness such as clinical outcomes improved, is used to determine therapeutic benefit.

Results-based VBP for pharmaceuticals

At the level of pricing and reimbursement, there have been several experiments with regard to tying quantitative and tangible real-world outcomes to decide drug reimbursement, thus situating VBP in real world data and impact. Some of these experiments have also aligned the idea of value from the patient outcomes, which broadens the 'value' horizon beyond that of purely clinical aspects of care, cost containment or efficiency. Few such experiments over the decades of how an outcomes focused approach has shaped VBP for drugs is provided in the Table 15 below [231].

Table 15. Examples of successful outcomes-based approaches for value-based pricing for drugs

Country	Year	Modality
Denmark	2005	Bayer entered into a "no cure, no pay" initiative on Levitra (vardenafil). As per this agreement Bayer's had to refund all those patients on treatment with Levitra (vardenafil) who were not satisfied with its response for erectile dysfunction
United Kingdom	2007	Johnson and Johnson agreed to forgo medication charges in all patients with no adequate medication response to Velcade (bortezomib)
Sweden	2010	A case study on Duodopa (levodopa/carbidopa) in advanced Parkinson's disease offered meaningful insights into VBP agreements in combination with conditional coverage. The study concluded that all stakeholders can benefit immensely from analysis of real-world (post market) data in addition to pre-launch, trial-based data
USA	2014	Incyte's use of "Patient- Reported Outcomes" with myelofibrosis was vital element in the decision to approve "Jakafi". Incyte's efforts have been recognized in marketplace too

In Germany, legislation regulating the reimbursement of new innovative drugs within the statutory healthcare system (Arzneimittelmarktneuordnungsgesetz) was introduced on 1 January 2011 [232]. According to this law, new products are subject to an assessment to determine whether there is sufficient evidence of added clinical benefits compared with appropriate therapeutic alternatives. If such added benefits are confirmed, manufacturers and representatives of the SHI are expected to agree on an appropriate reimbursement price within six months, starting from the completion of the benefit assessment by the German Federal Joint Committee. If drug-makers and health insurers cannot agree on the price, a final decision on the reimbursement price will be made by an arbitration body. If one of the parties involved wishes so, the Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen; IQWiG) will be commissioned with a formal evaluation of costs and benefits of the product in question.

Similarly, many states in the USA under their Medicare-Medicaid programmes, have been experimenting with varying value-based pricing arrangements [233]. These can often take the form of a "results-based" arrangement, in which a manufacturer pays a high rebate if the drug fails to meet clinical metrics. In 2018, several state Medicaid programmes advanced value-based pricing for pharmaceuticals. Oklahoma's Medicaid programme has been a leader in such arrangements, announcing four value-based purchasing contracts with manufacturers; using supplemental rebate agreements. According to press reports, one such contract is with the biopharmaceutical firm Melinta Therapeutics regarding its antibiotic Orbactiv, which treats bacterial skin infections. Under the contract, Melinta will pay higher rebates to the state if patients taking the medication are hospitalized for conditions the drug is intended to treat. In exchange, the state no longer subjects the drug to prior authorization.

In another contract, designed to encourage patient adherence, the drug company Alkermes will pay higher rebates for the antipsychotic Aristada if patients remain on the therapy. Oklahoma has also entered contracts regarding the antiseizure drug Fycompa and the antipsychotics Invega Sustenna and Invega Trinza using a model similar to the one employed for Orbactiv. A capped financing model, in which a state sets a ceiling on the aggregate payment for certain drugs and receives unlimited access to such drugs, has also been experimented with.

While attaching tangible outcomes from varying perspective under value-based purchasing for drugs is important, there exist inherent challenges in translating this into practice. A review of systematic reviews which looked to identify challenges of outcomes based contracting for medicines in Europe [234] found five main areas that require careful consideration in devising outcome based contracts for medicines. These were: negotiation framework; outcomes; data; administration and implementation; and laws and regulation.

Defining such outcome-based contracting through value-based evidence becomes even more challenging for innovative and advanced therapies given the need to balance out their therapeutic uncertainty with the need to ensure equitable access to potentially lifesaving drug interventions. Again, different countries adopt different value frameworks for such advanced therapies. Norway, for example, uses patient benefit, resource use and severity of the disease as the three main sources of value for priorities in the healthcare system [235].

Conclusion

The review above shows that beyond the Porter and Teisberg framework, there exists scope for improving VBC through value-based pricing mechanisms for drugs and indeed diagnostics and medical devices. HTA is one of the important tools to inform value of interventions and in turn, help transition to a system of VBC. However, the design and contours of HTA are themselves determined by the value system within a country's health system. This extends beyond the purely technical aspects of cost-effectiveness, efficiency, etc., and includes aspects of institutional design and processes, available financing, data systems and the like. Use of HTA to build a value-based system requires a bottom-up and incremental approach to its institutionalization. While many considerations determine the precise approach, some of the important takeaways for institutionalizing HTA relate to sustainable financing, organization autonomy, requisite expertise as well as legal and regulatory codification of the mandate of said institution and the value framework within which it provides evidence for policy decision making.

In time, as low resource countries build the required capacity to conduct HTAs, lessons and experiences already exist on how these can be responsive to the need for ensuring value-based pricing for pharmaceuticals. A detailed review of how eight European countries assess value of new pharmaceuticals [236] studied the practices, processes and policies of value-assessment involved therein. The review proposed that while all countries assess similar types of evidence; the specific criteria/endpoints used, their level of provision and requirement, and the way they are incorporated (for example, explicitly vs. implicitly) varies across countries, with their relative importance remaining generally unknown.

In summary, value-based pricing for pharmaceuticals is very much contingent on the value framework adopted by the individual countries. While the clinical outcomes, HTA (cost-effectiveness, cost-utility), are central to determining such value, the need for patient centricity has also brought in newer elements of PROMS and adherence, etc., as viable metrics for measuring outcomes for drugs under a value-based pricing arrangement.

Part C

Reconceptualizing VBC

The genesis of the literature review was to determine inter alia, a) how value and VBC are conceptualized and, b) to review the design and implementation of VBC to identify the effects of VBC, the enabling and constraining factors. Additionally, we set out to proffer recommendations for the reconceptualization of VBC as well as options for consideration for the implementation of VBC in India's PM-JAY.

We did this by reviewing how countries have adopted the strategy and to what extent they implemented it. We also looked at the evidence of the implementation of the individual thematic areas. In doing so we explored the evidence of effectiveness, the feasibility of implementations as well as the enabling and constraining factors, with a view to draw lessons for future design and implementation of VBC.

Synthesis of the literature review

The literature review of VBC as implemented in various contexts, has identified several issues that are pertinent for consideration for any country embarking on a systematic reform towards VBC for UHC. It has also highlighted important issues in the framing of VBC and for the implementation of VBC for UHC. The framing of VBC in general will not only impact the way it is implemented but also have an impact on UHC goals and objectives. Table 16 below provides a high-level summary of the findings we gleaned.

The Porter and Teisberg framework has spurred a lot of movement in several contexts including supranational (that is, EU), national, subnational (county or province or states) and institutional, to re-define the approach to service delivery. This change in approach is based on prioritization of the patient and reimagining of the notion of value created within the healthcare system, from a largely volume-driven approach to one centred around outcomes. Implicit in this framing is the assumption that reorganizing service delivery and the way providers are paid is sufficient. Current understanding of health systems globally, highlights that while these elements are necessary, they are by no means sufficient to realize value for money, improved patient outcomes and broader goals of UHC.

However, it is important to realize that the majority of implementation experiences for VBC globally have occurred in high-income countries. Implementation experience for VBC in LMICs is limited and is largely experimental and provider initiated. The paucity of evidence in this context constrains the generalizability of the findings to LMICS in regard to the adoption of VBC and policy makers must be cognizant of this while using available evidence from different contexts.

Table 16. Summary of findings from VBC literature review

Thematic issue	Key issues
Empirical experience in countries implementing VBC	• An enabling legal and policy environment is a core pre-requisite for guiding the implementation of VBC at a national scale and provides necessary safeguards to nest VBC within system design and decisions. This is the case for countries like NHS Wales, New South Wales, Australia and lastly USA that have scaled up programmes for VBC. • A transition plan that charts the path for adoption of VBC and an outcome-driven approach for VBC is critical. This should identify the elements of the framework that are already in place and how they can be leveraged to further the implementation of VBC and health systems outcomes. A sequenced approach highlighting short, medium and long-term plans for transition enables successful implementation. • While the technical inputs are important, inculcating a culture of value is another key input to ensuring that efforts are sustainable in the long run. This requires active change management strategies for such cultural and technical change as part of successfully implementing VBC. • Timely, consultative, and collaborative stakeholder engagement plays an essential role in being able to design and operationalize VBC strategies and plans. This helps foster the legitimacy and fairness of the process. • The implementation experience of VBC in decentralized settings is varied. This mainly relates to the often contradicting regulatory and/or health design setups across national and sub-national governments. In such cases, a national strategy would harmonize adoption across sub-national contexts. Additionally, the presence of champions who can drive the agenda with the necessary adaptation and flexibility usually contributes to better outcomes. • Building human resource capacity for VBC and instituting learning systems through effective and well-designed M&E systems contribute to the success of VBC. Additionally, engaging with the private sector, who drive a lot of the service delivery in most settings and is also more agile in its ability to system incentives are elements that strongly facilitate the introduction of VBC.

Values	• Value in health care necessarily should reflect the prevalent societal values. • The valuing of care necessarily entails attention to distributive justice based on explicit identification of the values and the technical rules and methods for measuring them. It also entails attention to procedural justice/due process to ensure fairness and inclusion in the valuing process. • Several countries or political jurisdictions like the EU are increasingly making the value frameworks that are used to prioritize health care. • Whilst some values are similar across different contexts reviewed, these may vary in the manner in which they are framed, when similar, or may differ from context to context. • While policy-makers and providers have been in the driving seat with prioritizing and valuing care, many countries are including other stakeholders in the process of valuing care. • Patient involvement and patient representatives are increasingly involved in valuing care. • There are various mechanisms for ensuring patient representation in the process of valuing care. The choice of which mechanism to adopt is dependent on what is societally feasible. • Various mechanisms have been developed that can facilitate the aggregation of disparate values across different stakeholders.
Integrated practice units	• IPUs entail a reconfiguration of the delivery of care for conditions with the patient as the focus. Multiple specialties are included in the care pathway for the condition to enable effective follow-up. • This may require co-location of services and the coordination to ensure effective implementation of the IPU. • Resistance to rearrangement of patient flows, co-location of services, changes in budgeting processes to follow the new configurations of care delivery may affect the implementation of IPUs. • Variation in different contexts in the extent to which IPUs are implemented in different countries. Countries that have developed strategies on VBC including IPUs have been more successful in implementing in IPUs. • There is mixed evidence on IPUs (though largely in favor for IPUs), as they work for some conditions whilst they are less favorable for others.

Outcomes and costs measurement	• In order to increase value in health, it is important to create a culture for outcome and costs measurement and estimation. • The P&T framework emphasizes the measurement of outcomes that are of importance to the patient. • In light of this, PROMs and PREMs have gained prominence in the implementation of VBC in countries like Australia, the UK, and the USA. • Experience shows that there is a correlation between PROMs and PREMs. • Evidence also shows that when self-reported symptom monitoring was integrated with clinical management, clinical benefits, including increased survival, were observed. • Nevertheless, medical professionals have raised criticisms regarding over-reliance on PROMs and PREMS as they are not risk-adjusted. • Critiques like this make the case for complementarity of clinician -reported outcomes and PROMS and PREMs in order to get a holistic valuation of the benefit of heath care. • TDABC is increasingly implemented by providers to ensure accurate estimation of the costs of implementing care. • Techniques like TDABC require a lot of data and technical expertise and therefore adoption has not been as widespread. • Nevertheless, practical measures to ensure the adoption of TDABC will require a fine balance between the thoroughness and feasibility of cost measurement.
Provider payment mechanisms	• Bundled payments and P4P have been proffered as solutions to purchasers to mitigate the negative consequences of using open-ended systems like fee-for-service payments and rigid ones such as line-item budgets. • Country experiences exist but are largely in the high-income countries such as the USA. • There is as yet, much experience and iteration required to determine the range of bundles that work best within specific settings and their complementarity with other provider incentives outside the targeted services under the bundle. • Like other payment mechanisms, they are prone to gaming and manipulation which in turn requires a clear alignment of the design elements with the payment reform objectives and robust monitoring and accountability. • The evidence of impact of pay-for-performance, given the aspiration of less spending and more value in terms of quality, is mixed. • However, on balance, these payment systems seem to work in favor of improving value-for-money within heath systems and on interventions with a relatively narrower focus and should be seen as playing only a supplementary role in the financing of VBC. • The key consideration for PM-JAY in transitioning to these APMs is how these models create and ensure the necessary linkages between the current hospital-based approach and other primary or specialist areas of care as a first step to such a transition.

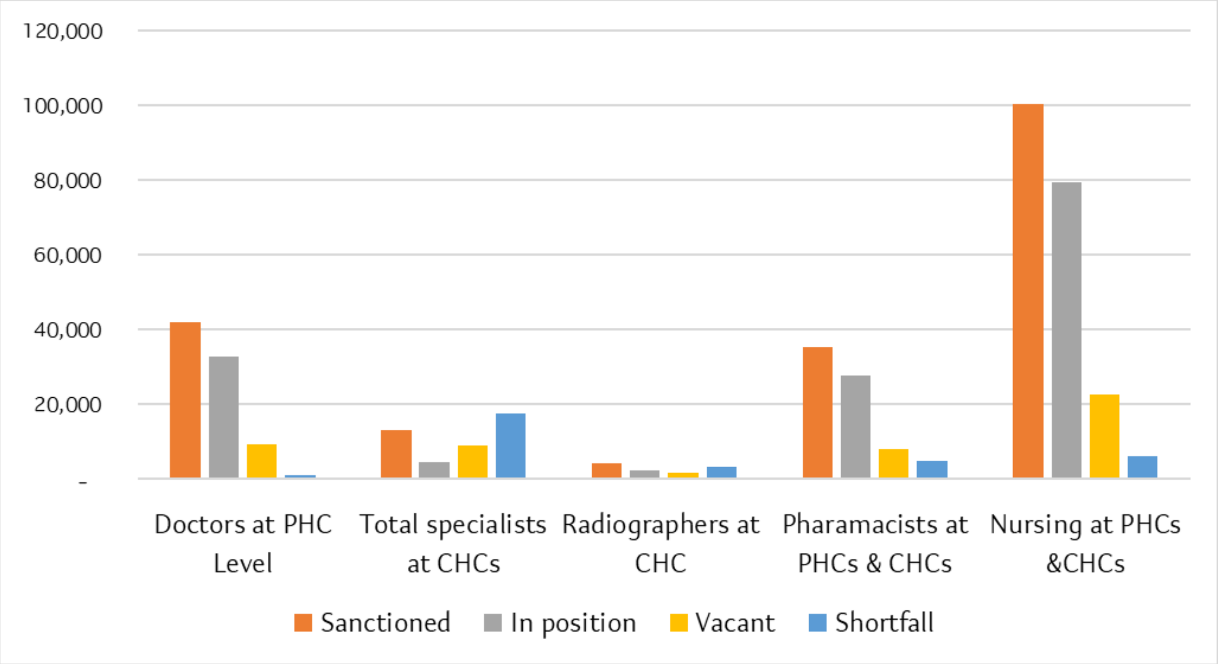
Integrated care	• Integrated care is a useful strategy for ensuring continuity in the care of the patients, minimizing complications, and ensuring that gains in health are maintained. • The evidence reviewed shows that when implemented well, the strategy is able to realize gains in health and reduce unnecessary hospitalizations especially for patients with chronic conditions. • Nevertheless, there is a need for political analysis and management of stakeholders involved in the development of the integrated care networks in order to ensure success. • An enabling policy framework, dedicated financing, transformative leadership, and an accountability framework are critical for the implementation of integrated care networks.
Geographical Expansion of care	• In order to increase the reach of high-function IPUs, it is essential that IPUs which are specific to medical conditions expand geographically. • The framework proposes a strategic expansion and investment to ensure that services adopt a hub-and-spoke model of satellite centres or through clinical affiliations with existing providers in order to ensure that services are located in areas where there is best value created. This includes ensuring site selection accounts for site capabilities, care complexity, patient risk, cost, and patient convenience. • Successful examples of the regional expansion of care in the literature show that, the most common elements were an IPU structure that spans the sites, a common EHR, unified scheduling, standardized measurement of outcomes and cost, physician alignment through either employment or affiliation, integrated communication and education, and a common culture. • Literature reviewed shows that thus far, geographical expansion has been largely provider-initiated, with the exception of the government's role in the UK through the NHS. • We propose a collaborative approach involving a combined bottom-up and top-down approach, which will contribute to ensuring a successful implementation of this pillar from a societal perspective.
Integrated information systems	• Information systems are key enablers for facilitating data flow across systems, which is an important prerequisite for VBC. • The systems enable the flow of information across the different themes and in turn enable the operationalization of the development of care pathways, costing of services and measurement of outcomes as well as the development of payment mechanisms and monitoring of the success therein.
Value-based pricing	• The review above shows that beyond the Porter and Teisberg framework, there exists scope for improving VBC through value-based pricing mechanisms for drugs and indeed diagnostics and medical devices. • Various modes are explored but the most common measure is the use of HTA to prioritize medicines and to determine the prices of the medicines. This has translated well in LMICs and can be institutionalized as well.

Critiques of the approach as conceptualized and implemented

The framing of the Porter and Teisberg framework implicitly assumes the presence of certain pre-existing elements that is not necessarily true, especially in LMICs. These gaps need to be addressed in order to successfully implement VBC in such contexts. For instance, the framework assumes that the decisions related to implementing VBC across all the thematic areas are within the purview of the reforming team/organization/network. The implicit assumption is that a team within the provider(s) network will drive the change process(es). However, some of the thematic areas require more stakeholders than providers and patients and the involvement of governments (national and sub-national). This is especially so for the integrated care networks as well as the geographic expansion of services. These may require the involvement of government Departments for Health, and Departments of Planning as well as institutional factors like supporting or enabling laws. Moreover, the value system in most cases will necessarily be broader than the patient's outcomes and costs of care. This is from the perspective of maximizing distributive justice beyond an individual patient's need and ensure that there is maximum capacity to benefit from greater availability of services through geographic expansion and ensuring other determinants of equity in health care access for the population at large.

Moreover, the framework assumes that at a minimum, the complement of factors required for the production of health services are adequately provided in the system. The figure below shows the shortfalls of primary care doctors and nurses and other cadres in rural India. This limits the feasibility of formation of IPUs in this context and would be more so in some LMICs with health systems that are less well-resourced than India or HICs. The figure below shows the shortfalls and vacancies that exist compared to what has been indicated as the sanctioned need. Thus, in order for the framework to be adequately implemented, there is a need to improve the complement of health workers in concert with a transition plan that scales up VBC over time.

Fig. 7. Status of health workforce in rural areas in India



Source: Ministry of Health and Family Welfare, Government of India [237]

Similarly, on measurement of costs and outcomes, the framework alludes to adjustments in payment mechanisms, but does not make the necessary linkages with upstream functions of the health financing system that have implications for how these factors perform within a scheme and across the entire system. These include functions such as revenue raising and pooling. Thus, a focus on provider payment and bundled payments is not sufficient to address the myriad points of inefficiency and poor outcomes in health, let alone the contextual factors that affect health system design and the effectiveness of reform. For instance, focusing on VBC within a provider network does not account for the system-wide effects that incentives created by bundled payments may have on providers paid through other mechanisms in the system and what impact they may have on the patient outcomes and experience. The effects of mixed provider payment systems on the attainment of UHC goals have been documented elsewhere. It is important to ensure that any new payment mechanism reinforces rather than undermines system-wide efficiencies and equity objectives of the system. It is important, therefore, that any planning for implementation of VBC is cognizant of the broader health financing and system factors including the state of fragmentation, the alignment of the provider payment mechanisms, the public financial management systems and the changes that need to be made to facilitate the changes to bundled payments.

WHO and OECD identify irrational prescribing patterns as a major source of inefficiencies and waste in the system. Some of these are related to supplier induced demand arising from the use of payment mechanisms such as fee for service. However, inappropriate prescriber incentives and inadequate regulatory frameworks also contribute to inefficiency and sub-optimal patient outcomes. The framework does not address the important issues related to the manner in which the drugs and diagnostics used in the service delivery system are identified and financed. Thus, while a system that is compliant with all the pillars laid out in the framework is sufficient, it is possible that the same system could have no systematic approach to appraising new health technologies and is paying for low value and expensive technologies with poorly designed procurement and supply management systems. This could undermine any value gains achieved by the implementation of the reforms in a VBC framework. HTA and value-based pricing strategies can be used as entry points to ensure value for money at the system level and within the IPUs, as they inform on the drugs and diagnostics to be included in the care pathways to derive the intended value within the system. Thus, we propose a broader framing that explicitly regards HTA as well as value-based pricing for pharmaceuticals as part of the elements critical for attaining VBC (see Fig. 8).

Additionally, the framework should outline the enabling environment for VBC to be successful in any context. Except for the pillar on information systems as an enabler for VBC, there is no inclusion of other factors that the review highlights as critical enablers for VBC. Fig. 8 highlights components of the enabling environment that emerge from the literature as critical enablers for VBC.

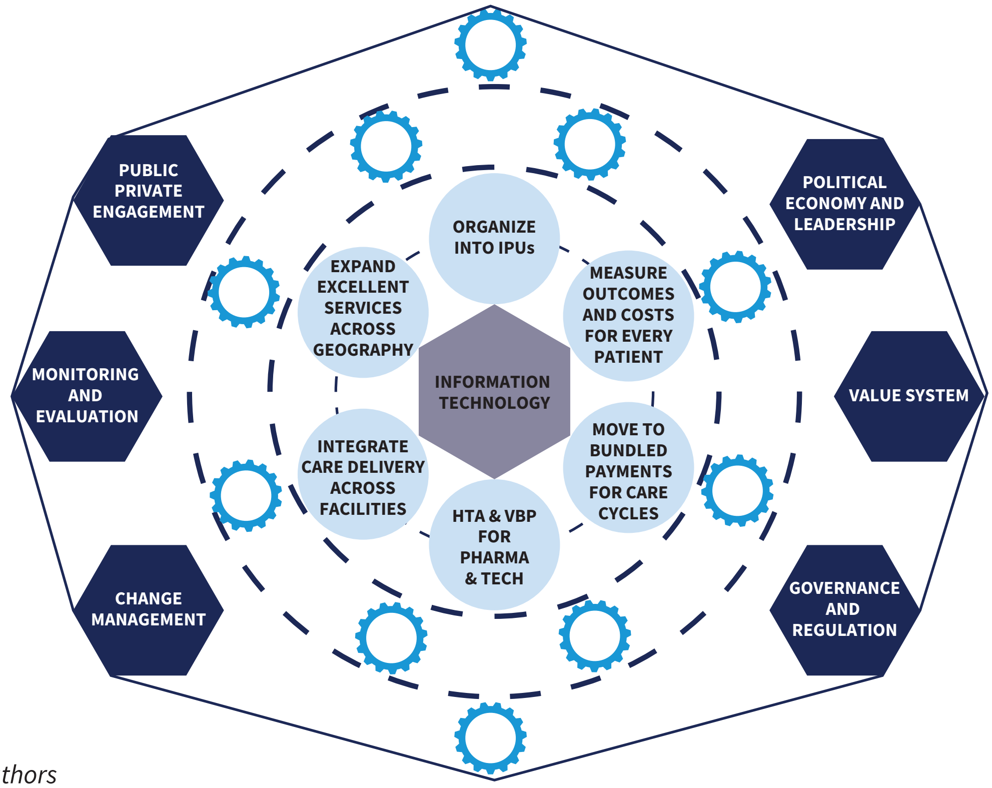
Re-framing VBC

In light of the above findings and considerations, we propose new elements in the framing of VBC in addition to the very valuable elements that Porter and Teisberg proposed. These additional elements are meant to embed any strategy for implementing or scaling up VBC within the broader financing and health systems elements that extend beyond the framework in its current form. System-wide framing of VBC has similarly been proposed by Smith et al, in which they call for a broader framing of value in terms of well-being.[238] Finances in the system should result in increased well-being through increased value creation in the form of financial protection, efficiency, responsiveness of the system, improvement in health, equity. This enables design and implementation to leverage existing processes that may be beneficial for the strategy, as well as to ensure that it is complementary or synergistic to existing arrangements to ensure maximum impact of interventions. These factors include:

- **System-wide assessment of the health system:** We propose that planning and implementation of VBC, especially for the nation-wide implementation, should include a system-wide assessment that includes the health financing and other system elements such as service delivery landscape, mix of fund flows, provider payment mechanisms, the pharmaceutical regulatory systems including pricing and prioritization mechanisms. It should explore synergies or opportunities for complementarity that can be leveraged to enable the system to meet its goals. It should also provide an opportunity to explore the potential consequences of the VBC strategies on other system-wide interventions, providers, and patients.

- **Political economy and leadership:** VBC is inherently political because it makes the issue of values explicit, which creates various interests. Furthermore, the approach involves a change in the way service delivery and payments are structured and implemented which affects some stakeholders like providers. Successful adapters of the VBC framework are those that have managed the engagement of stakeholders strategically. Including the right stakeholders in the design and implementation of the VBC reform is critical. Leadership is also critical for the adoption of VBC. Visionary leadership that can steer the process, including stakeholder mapping, analysis and engagement is a critical enabler for successfully managing the design, the changes needed and the implementation. It is also critical for ensuring the sustainability of the changes.

Fig. 8. VBC revised framework



Source: Authors

- **Governance and regulation:** Legislation is an important public policy instrument as it provides a mandate for action, thereby enabling enforcement and compliance [239]. Laws are critical for setting the rules by which the health system functions. It also provides avenues for redress if one of the involved parties does not comply with the legal mandate as per their responsibility. In the countries reviewed, laws that were enacted furthered the adoption of several components of VBC, including the information systems and in some cases of HTA.

  Important steps will include a review of the existing legal framework to determine the aspects of the framework that may facilitate or present barriers to VBC and how these can be mitigated. This may require amending legal instruments to include some aspects that further VBC or altering some laws to ensure that they align better with VBC.

  Similarly, the policy framework is important. The alignment of VBC to the policy imperatives that are guiding the health sector is critical to ensure synergies with other policy directions that have been chosen to steer the system to UHC. Thus, as seen from the empirical experience reviewed, a transition plan that is coherent with the legal and policy environment should be drawn up as a critical aspect of building an enabling environment for VBC. Critically, this plan should also spell out the roles and responsibilities of different actors and institutions in implementing VBC.

- **Value system:** Given the influence of the socio-economic, political, and cultural context on values that are important for prioritizing health, we propose that any VBC strategy should include a mechanism for explicitly identifying what these values are. These should be derived in a consultative manner to ensure procedural fairness and legitimacy of the planning process. Moreover, we propose that for some specific VBC pillars such as integrated care and geographical expansion of care, equity should be a determining criterion for design to ensure fairness in the distribution of health services.

- **Value-based pricing for pharmaceuticals:** This draws from the empirical experience that value-based pricing of health technologies and pharmaceuticals using HTA and other such methods, is critical to ensure a holistic approach to VBC. A meaningful approach for VBC at any level of the system must include strategies for value-based pricing for pharmaceuticals as well as for prescribing medicines. The latter will involve more than addressing the payment mechanisms for providers. It will involve the use of guidelines for rational prescribing and awareness raising for providers. This will enhance the effects of the bundle payments and inform the formulation of care pathways that are best suited to enhance the value objectives of a health system.

- **Change management:** This function is a critical aspect as an enabler of VBC. As alluded to earlier, VBC is inherently value-laden, which may mean a shift in the way services are organized and reimbursed. This implies a need for a strategic approach to the management of these changes. This includes strategic stakeholder engagement throughout the policy cycle. It also includes a strategic communication strategy tailored to specific stakeholders. The strategy should include a mechanism for collecting, synthesizing and using feedback from stakeholders to ensure timely action to redress and improve the system.

Another component of change management inherent in this framework is capacity building for VBC. Capacity building at the institutional level is critical for the implementation of VBC as a strategy. Building the skills and numbers of the VBC team that supports planning, implementation and accountability for the approach is critical. This also means that capacities for teams implementing VBC, such as those within the IPUs, care networks, and health information systems, will be critical for change management and the successful adoption and implementation of VBC.

Capacity building also entails institutional capacity building vis-à-vis putting in place relevant systems. This will include standard operating procedures (SOPs) for cost surveillance for instance, for outcome measurement, etc. It will also require the organization of the institutions, that is, ensuring that internal functions and structures are suited to fully deliver the VBC mandate attached to them. Roles and responsibilities and reporting mechanisms should be clearly defined to ensure that no duplication of functions occurs.

- **Monitoring and evaluation:** An accountability framework that ensures routine M&E of the implementation, outputs and outcomes of the approach is critical. The success of policies is contingent on good design and fidelity to the implementation of the policy designed. Thus, M&E is essential to ensure that the implementation of the policy is in accordance with the implementation model designed. Furthermore, it is critical to determine the early and overall effects of the policy. This enables the system to be reconfigured to ensure progress towards the intended goals. M&E frameworks should be developed through a multi-stakeholder consultative process to ensure legitimacy and buy-in.

  The framework also recognizes the role of learning and adaptive systems which are systems that are responsive to evaluation of performance and evidence of approaches that work [240, 241]. Learning systems that enable continuous innovation, adaptation and improvement of the VBC approach can expedite health system reform. The innovations centre in CMS and the learning hub in NHS Wales are good examples of this.

- **Public private engagement (PPE):** The framework as implemented in the USA and NHS Wales has highlighted VBC as a model that can be used not only as an intervention for improved PPE in service provision but also for policy formulation. The private sector can work together with the public sector to produce evidence for reform for VBC and can participate in the policy formulation process. However, the framework assumes a well-regulated and organized provider landscape that can provide a seamless linkage across the entire health service landscape, be it public or private. As is well known, most LMICs, including India, face considerable challenges in convincing and/or coercing the private sector into strategic partnerships. Even when this is successful, the core mandate and objective of these sectors diverge at a critical juncture of commercial interests versus public health, stymying the ability to work and coordinate on an equal footing and understanding of end goals or values. Thus, collaborative and cooperative PPE is critical for finding common ground and aligning the public and private sector in pursuit of VBC and UHC goals.

The framing proposed in this paper is one that can be used to design VBC reforms with a view of creating a conducive environment for the implementation of the core elements of VBC. It offers a potentially useful framework for reviewing the implementation of VBC reforms.

Part D

Moving forward with VBC in India

Current approach to VBC in PM-JAY

NHA has proposed an approach to ensure continuity of care to provide holistic medical care to patients through a large network of Health and Wellness centres (HWCs) using public providers and also empaneled hospitals under AB PM-JAY which includes both, public and private providers.

HWCs is an ambitious initiative of the Union government which aims to deliver quality primary care to the population, focusing on health prevention and promotion. HWCs are basically public primary health centres located in both urban and rural areas which are upgraded vis-a-vis infrastructure and service portfolio, to take care of the population's primary healthcare needs. These centres are located within the community so that the community has easy access to the primary care. On the other hand, AB PM-JAY, through a network of empaneled private and public hospitals, provides secondary and tertiary care to it's beneficiaries. The scheme provides a financial cover of INR 5 lakhs per annum to eligible households. The proposed plan of NHA includes packages for follow-up care and day care packages. However, currently the scheme does not provide out-patient services. As HWCs are further strengthened with access to a suite of guaranteed services, PM-JAY should explore establishing the continuum of care within current bounds of operational feasibility in an incremental and progressive manner.

The NHA, under PM-JAY, has put in place some important first steps in its transition to VBC [242]. The main features of the proposed transition from volume-based care to VBC are shown in Table 17 below:

Table 17. Transition plan from volume-based care to VBC in PM-JAY

Pillar of VBC	Action taken by NHA
Organize IPUs	Comprehensive primary health care: The Ayushman Bharat initiative by the Government of India includes the HWCs that provide comprehensive primary care through an enhanced primary healthcare package. PM-JAY provides cashless cover for the secondary and tertiary inpatient services for 40% of the population that is poor and vulnerable. PM-JAY which is governed by NHA, should work towards linking HWCs to its network of hospitals and incentivize integrated practice units across these levels with the intention of introducing VBC within the system.
Measure costs and outcomes for every patient	Use of HTA evidence (Health Financing and Technology Assessment Unit): The NHA has established a Health Financing and Technology Assessment (HeFTA) unit that is driving the incorporation of health technology in the scheme for functions such as benefit package design. It also takes the role of measurements of costs and outcomes. This unit can drive decision-making on the costing and pricing of new technologies. The HeFTA unit should establish a mechanism for price discovery and promote the use of economic evidence to inform the design of STGs.

Move to bundled payment for the care cycle	The NHA has been using case-based payments to reimburse providers. Over the last two years, a pilot to determine the feasibility of transitioning to DRG-based payments has been conducted. The ongoing pilot once scaled up, will facilitate the transition to more bundled payments. The NHA has also been piloting the use of value-based incentives to healthcare providers based on measurement of quality parameters such as readmission rates, HRQoL, extent of OOPE, etc. In time, these experiences should be institutionalized within the design and operational dynamics of the scheme to establish systems of VBC and value-based payments.
Integrate care delivery across separate facilities	A continuum-of-care approach has not yet been implemented but has been proposed by the NHA and the MoHFW. As mentioned above, NHA should initiate efforts to ensure the linkage of HWCs to its empaneled network of hospitals and leverage the existing cadre of community health officers (CHOs) at HWCs, telemedicine for specialist care (e-Sanjeevani) and existent referral transport networks. Follow-up packages should also be expanded and included as part of the PM-JAY benefit package.
Expand excellent services across geography	NIL
Enable a suitable information technology platform	As part of the ABDM, NHA has developed an integrated platform for data collection, storage, and exchange to enable patient-centred care. The ABDM is a federated system that applies principles of interoperability using Application Programming Interface (APIs) to enable the exchange of information across providers, purchasers and public health programmes and registries for professionals and facilities. ABDM also proposes a dedicated personal health record for all citizens to maintain longitudinal health records using ABHA health IDs. These tools should be leveraged and should supplement current digital tools used under PM-JAY to provide the necessary upward and downward linkages to ensure the possibility of patient centricity in care, which is an important prerequisite for VBC.

Source: Adapted from NHA [242]

There is a proposed plan for performance assessment of the hospitals based on certain outcome-based indicators under the AB PM-JAY, which is further linked with value-based incentives. These indicators include:

- Beneficiary satisfaction rate
- Hospital readmission rate
- Extent of out-of-pocket expenditure
- Confirmed grievances
- Improvement in health-related quality of life

The plan by NHA was developed through a consultative process, including a public call for review and inputs from various stakeholders at the union and state levels. Relative to the reframing of VBC that we propose following the review, the approach adopted by NHA to transition to VBC is indeed cognizant of the value framing adopted by Porter and Teisberg and some of the elements proposed by us in the reframing section. The NHA plan also proposes to strengthen outcome measurement and to value care provided by using the EQ 5D. The EQ 5D can be used to introduce and institutionalize PROMs to assess details on quality of life after treatment, or the effect of the treatment on the body, restored body functions, etc. It can be made a mandatory practice in all the hospitals and facilities to ensure that the feedback from patients is captured and to determine how treatment pathways can be designed or adapted to achieve maximum value for the patients. The role of government is of utmost significance in this case, as strong regulations will need to be formulated and implemented by them. It is likely that this will be met with resistance from the providers and the medical fraternity, for which the government needs to engage with them to reach a mutual understanding and vision regarding the role of institutionalized measures for recording patient outcomes.

The VBC approach provides a broader scope for improvement in service delivery than is currently envisioned under NHA's conception of it. Leveraging the Ayushman Bharat flagship, service delivery can be improved within empaneled care providers for the scheme using the IPU model. This can be piloted, similar to the experience in the USA. For instance, some high-value, high-volume services in the scheme like joint replacements can be delivered as a pilot testing through the IPU model with care pathways drawn up and multi-disciplinary teams to determine the feasibility of the practice. The pilot would also involve exploring the creation and utilization of bundled payments. The move to institutionalize cost surveillance to inform the refinement of HBPs and DRGs which combines the clinical logic with the economic one provides an opportunity for enabling the mindset change that is required for providers to transition from volume-based to value-based purchasing.

Additionally, the VBC approach can be leveraged to further the agenda of continuity of care between the HWCs and PM-JAY empaneled hospitals. Developing networks between the HWCs and empaneled care providers can be facilitated, in part, by the ABDM. Tools under ABDM can enable backward and forward referral of patients which can inform formulation of payment incentives. However, it will require considerable coordination between the centre and the states as well as the providers, with a strong focus on partnership for integration of health services. Another significant requirement for this will be a robust IT system, that can ensure information flow across levels of care. Beneficiary awareness will be required at a mass level to make this initiative a success. Health-seeking behavior of the community will be a challenge along with the availability of human resources in the rural areas.

Geographic expansion of healthcare facilities through a hub-and-spoke model should also be explored. This would require the creation of a network consisting of a main centre or few specialized centres providing tertiary/specialty care and the peripheral centres, which will provide comprehensive primary healthcare and basic diagnostic services. It is an area which needs to be explored by the private sector considering what may be the beneficial factors associated with it for their growth.

Regarding the HTA agenda, engagement and collaboration will be required with the Department of Health Research (DHR), which is the nodal agency for the implementation and institutionalization of HTA in India. Since its inception in 2017, the DHR has established 18 regional centres for HTA in 13 states of the country [243-245]. HTA has been included in the National Health Policy of India and relevant policy documents have also been developed, including the HTA in India process guide and manual [246]. Moreover, the Parliamentary standing committee affirmed the role of health technology assessment in India (HTAIn) in reducing OOPE in health services. The centre has developed the India EQ-5D-5L value set for measuring quality of life in health [247], a costing manual and guidelines for Budget Impact Analysis [244, 245]. The DHR has also developed Quality Assessment Checklists [244] and institutionalized the process of topic prioritization as well as the Economic Evaluation Reference Case for India [248].

To shift the medical/healthcare systems from a volume-driven approach to value-driven approach, it is imperative that the policy makers and the medical community including the clinicians/physicians understand and adopt the philosophy of VBC. For this, learnings through data and advocacy for VBC is required, mainly in the form of orientations, meetings, dialogues and learning seminars which include all the relevant stakeholders. It is essential that the medical fraternity, especially the doctors, understand the principles of this model and practice, in collaboration with other doctors. India has a well-established medical system of high standards, and the clinicians are proficient and open to the new concepts and advancements in the field. The biggest challenge in implementation is the fragmented and unregulated private for-profit sector of India which has minimal presence in rural areas.

Proposed implementation plan for adoption of VBC

Based on the learnings from the global review of VBC and reframing of the approach proposed, we provide recommendations for an implementation plan under PM-JAY at the macro, meso and micro levels. We frame the implementation plan and actions therein based upon the basic pillars of VBC and the enabling system (see Table 18).

Table 18. Proposed implementation plan for VBC adoption in PM-JAY

Thematic areas that need to be addressed for VBC	Action to be taken at the macro level (union level)	Action to be taken at the meso level (state-level)	Action to be taken at the micro level (provider level)
Pillars			
IPUs	Review the current service delivery arrangements and develop options for adopting VBC. Set up a design for the IPU: A model that can be adopted in the VBC approach that India adopts. Engage stakeholders in finalizing the IPU approach at the primary and secondary levels to ensure legitimacy. Also, explore feasibility of organized private sector participation in integrated care models.	At the state and EHCP level, participate in the design of the model and pilot and implement the model.	At the state and EHCP level, participate in the design of the model and pilot and implement the model.

Outcome measurement	The NHA has instituted a system for collecting costs for health systems. A pilot is in place to collect patient-level costs. Therefore, there is a need to institutionalize and scale up the patient-level costs for the scheme. There is also a need to set up a mechanism for systematically collecting primary healthcare costs. The EQ-5D has been developed but it is yet to be used to collect PROMs data. The NHA must set up a system for collecting data for PROMs. This can be done by leveraging the ABHA accounts (personal health records in India) within ABDM. A portal can be created to collect PROMs data at visits. There is also a need to evaluate the pilot that has been conducted for quality improvements, as well as scale up the final model of the approach.	States should participate in the design of the model and pilot and implement the model to ensure that it is responsive to the reality in the states. States should also establish state or regional-level cost surveillance units to track input costs and variations in service provision across different levels of hospitals and clinical specialties.	Healthcare providers can participate in the design of the model and pilot and implement the model.
HTA	The HEFTA has been set up, though there is need to increase the staffing for the unit as well as to continually build the capacity of the team. Develop guidelines for adaptive HTA and to systematize the process for horizon scanning. Develop a system for prioritizing the technologies and interventions to be considered for HTA by the unit of DHR.	To participate in the prioritization processes by suggesting state-specific priorities for HTA. States to adapt guidelines by NHA on adaptive HTA for designing the state specific HBPs. Capacity building for State Health Agencies (SHAs) in conducting local HTA or adaptive HTA for developing their state specific benefit packages.	Participate in post-market surveillance for health technologies.

Bundled payments	The NHA has implemented the DRG pilot. The next step is to undertake an evaluation of the pilot. The DRG transition roadmap should be implemented, including the development of the grouper and the DRG weights and the piloting of the DRG grouper. This includes delineation of clinical 'bundles' with scope for state-level contextualization depending on case mix and input costs.	Participate in the model piloting, evaluation, and adaptation process of provider payment mechanisms.	Participate in the model piloting and adaptation process.
Integrated services network	Stakeholder engagement for the development consensus and the need for the network as well as consensus on the model. Develop a context-specific model for the integration of health facility networks.	Participate in the model piloting and adaptation process.	Participate in the model piloting and adaptation process.
Geographic expansion of VBC	Develop a model and conduct a pilot.	Participate in the model piloting and adaptation process.	Participate in the model piloting and adaptation process.
Information systems for VBC	The NHA has developed ABDM and PM-JAY 2.0 as well as health claims exchange (HCX), the latter of which aims to streamline and standardize health insurance claims processing and enhance efficiency in the insurance industry to improve patient experience. These should be integrated. Develop a plan for data usage and for including the relevant fields for VBC. Promote the adoption of ABHA and linked PHR for better-informing benefit design and tracking epidemiological trends over time.	Implement state-level activities related to improving uptake of ABDM and PM-JAY. Capacity building, awareness raising, data quality assessments. Operationalize PHR linkage through ABHA accounts	Uptake of the new systems and ensuring data quality and usage. Collection of data with regular data quality reviews and potentially linked incentives.
Enabling system			
Legal system	Review of laws pertaining to health and VBC in particular. Stakeholder consultation on the review viz VBC and consensus building. Development of bill and related regulations.	Participate in the reviews of the legislative framework and development of the Bill.	Participate in the reviews of the legislative framework and development of the Bill.

Policy	Review of National Health Policy and other related documents including National Digital Health Blueprint, pertaining to health and VBC. Stakeholder consultation on the review viz VBC and consensus building. Development of new plan or policy on VBC.	Participate in the reviews of the policy framework and development of the policy.	Participate in the reviews of the policy framework and development of the policy.
Strategic stakeholder engagement	Development of steering and technical working groups to steer engagement. Conduct stakeholder mapping and stakeholder engagement meetings. This should include consultation on values that should guide integrated care and geographical expansion including location of different services for maximum impact.	Participate in the stakeholder engagement exercises.	Participate in the stakeholder engagement exercises.
VBC Champions	Identify champions to lead dialogue with stakeholders on legal and regulatory frameworks for a strategic plan on transitioning to VBC models and practices in India.	Identify champions to lead initiatives on real-world testing and piloting of VBC innovations as well as inform state-level adaptation prerequisites.	Identify provider level champions who can implement the strategy in real-time and provide necessary insights on the feasibility of such a model at the delivery-level
M&E and learning culture systems	Identify collaborating centres through systematic appraisal. Agree on formative and process evaluations as well as operational research to guide the VBC agenda in the short and medium term. Develop M&E and performance matrix to routinely monitor VBC implementation.	Participate in the design of the M&E system. Participate in the implementation of the system by adapting the plan and indicators to the state.	Ensure data collection in their facilities. Participate in review processes.

		Setting systems for data collection and evaluation. Enforcing data quality assessments and course corrections.	
Public-private engagement	Develop a strategic plan for engaging the private sector (insurers and providers) in the VBC agenda.	Facilitate engagement of private actors through consultative engagement.	Participate in engagement processes (design and implementation).
Change management	Develop a change management plan regarding awareness raising, communication, capacity building and retooling or reskilling.	Identify change management teams and systems and implement them according to the plan adapted for the state.	Identify change management and implement action plan adapted at the facility level.

The implementation arrangements for the plan

To realize the successful implementation of the proposed plan it is important to be cognizant of a few issues including:

Sequencing: The quest to achieve value for money is not a new thing in the health sector in India. The government has implemented a few approaches with this view. Considering this, we propose a short to medium-term approach to planning and implementation. In this regard NHA should attempt to adopt a sequenced approach that could start with leveraging those interventions that are foundational and are already in place, to lay the foundation for other aspects that may not be feasible to implement in the short term. Some entry points include the digital mission that can be further strengthened through interoperability to support PROMs and linkages between the HWCs and empaneled care providers in PM-JAY.

Using pilots to demonstrate feasibility and increase learning: Some aspects of the VBC approach may not be feasible to implement at scale without understanding the key enabling and constraining factors that must be mitigated to ensure successful implementation. These include the IPUs and the care pathways therein as well as the integrated care networks. We propose that such system features should first be piloted by provider type (public versus private), condition(s)-type, etc. This should then be implemented alongside a robust evaluation framework that enables formative, process, and impact evaluation to enable the learnings realized here to inform policy design.

Governance arrangements: This should include the coordination arrangements for activities and follow-up of the implementation of the plan. It also includes spelling out the roles and responsibilities of all the stakeholders. The coordination arrangements should ideally be led by the government. More specifically, this should be led by the institution with the mandate for the thematic area, that is, MoHFW, who would need to drive the policy engagement on the design of IPUs and integrated care networks. On the other hand, NHA may be better placed to drive the engagement on the measurement of outcomes and costs as well as the design of the bundled payments. It could also co-lead the discussions with MOHFW on leveraging ABDM for continuity of care.

The coordination structures would necessarily include institutionalized multi-stakeholder working groups, including representatives of state governments, providers, academia and civil society organizations, which would meet routinely to ensure implementation of the plan successfully and inform areas that require course correction.

The roles and responsibilities of each stakeholder should also be spelled out to avoid duplication of efforts and enable accountability. This also empowers the different stakeholders to implement the areas of intervention under their purview.

Financing the plan for VBC: To ensure the sustainability of the approach, budgeting for VBC must be included in the NHA and National Health Mission budgets. Whilst funding from partners may be useful in the beginning with reference to pilots, for the longer term, government prioritization in the budget will ensure longevity and commitment to the implementation of the approach.

Change management: As earlier indicated, this will be a crucial aspect for the successful implementation of VBC in any context. This is even more pertinent in the decentralized environment of India, wherein health is a state subject. It will necessarily entail strategic stakeholder engagement and communication. Involving stakeholders right from the start including awareness raising of what VBC is and is not, the design of different approaches and the implementation and their evaluation, will be critical. Active soliciting of feedback by the NHA is critical to ensure continued ownership of the approach by different stakeholders and course correction for successful implementation.

Conclusion

In an era of increasing healthcare costs and consumption, ensuring value in healthcare spending is a priority for countries the world over. While several notions and approaches to maximizing ‘value’ exist explicitly and implicitly in health systems design, the Porter and Teisberg framework has helped anchor these various elements of value maximization, ranging from service delivery, measuring costs and outcomes as well as the factoring in of patient perspectives in attaching value to care received by the end user.

Building on the strengths of this framework and highlighting the potential gaps in design, this global review document has attempted to collate experiences of the application of the suggested VBC pillars. Additionally, the review has identified existent lacunae in the proposed VBC design by Porter and Teisberg and attempted to expound on these additional core (HTA, VBP) and enabling (IT systems, M&E, etc.) pillars to provide a broader conception of VBC.

Furthermore, the review has also provided some suggestions on implementation of the VBC reforms for countries and given an example in the context of the Indian scenario.

While this review and its proposed recommendations are in no way exhaustive, it is hoped that it will contribute to providing a new and more holistic perspective on the Porter and Teisberg framework, as well as learnings for countries looking to maximize value within their health systems.

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Value-based care (VBC) is fast emerging as a central consideration for health systems design. This document collates and reviews global experiences and evidence to inform policy-makers on initiating their journey towards VBC.

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