

Can Performance-Based Risk Sharing Arrangements (PBRSA) for Medtech Address Procurement and Market Access Challenges?

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Disclaimer



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Todays Agenda

Moderator: Richard Charter	Vice President, MedTech Market Access EU & Asia Pacific Chair – ISPOR Medical Devices Special Interest Group	Alira Health	
Panelist 1: Mark Sculpher	Professor of Health Economics	University of York	
Panelist 2: Payam Abrishami	Senior Advisor on Medical Innovation Assistant Professor Medical Innovation & Policy	Zorginstituut Nederland Erasmus School of Health Policy & Management	 
Panelist 3: Giuditta Callea	Associate Professor of Practice	SDA Bocconi	

Managed Entry Agreements / Risk Sharing / Accelerated Coverage

Regardless of the many names for risk sharing agreements (managed entry agreements), the purpose is still the same: payers, and providers needs to ensure improved health outcomes with manageable costs, industry needs to have some certainty of revenue.

1

Risk Assessment Criteria for CE Mark (No Comparator needed)

1. Is the product **safe to use on patients**?
2. Is the product **effective on patients**?

The purpose of CE mark and reimbursement are different. **CE mark (regulatory) determines acceptability while Reimbursement determines value.**

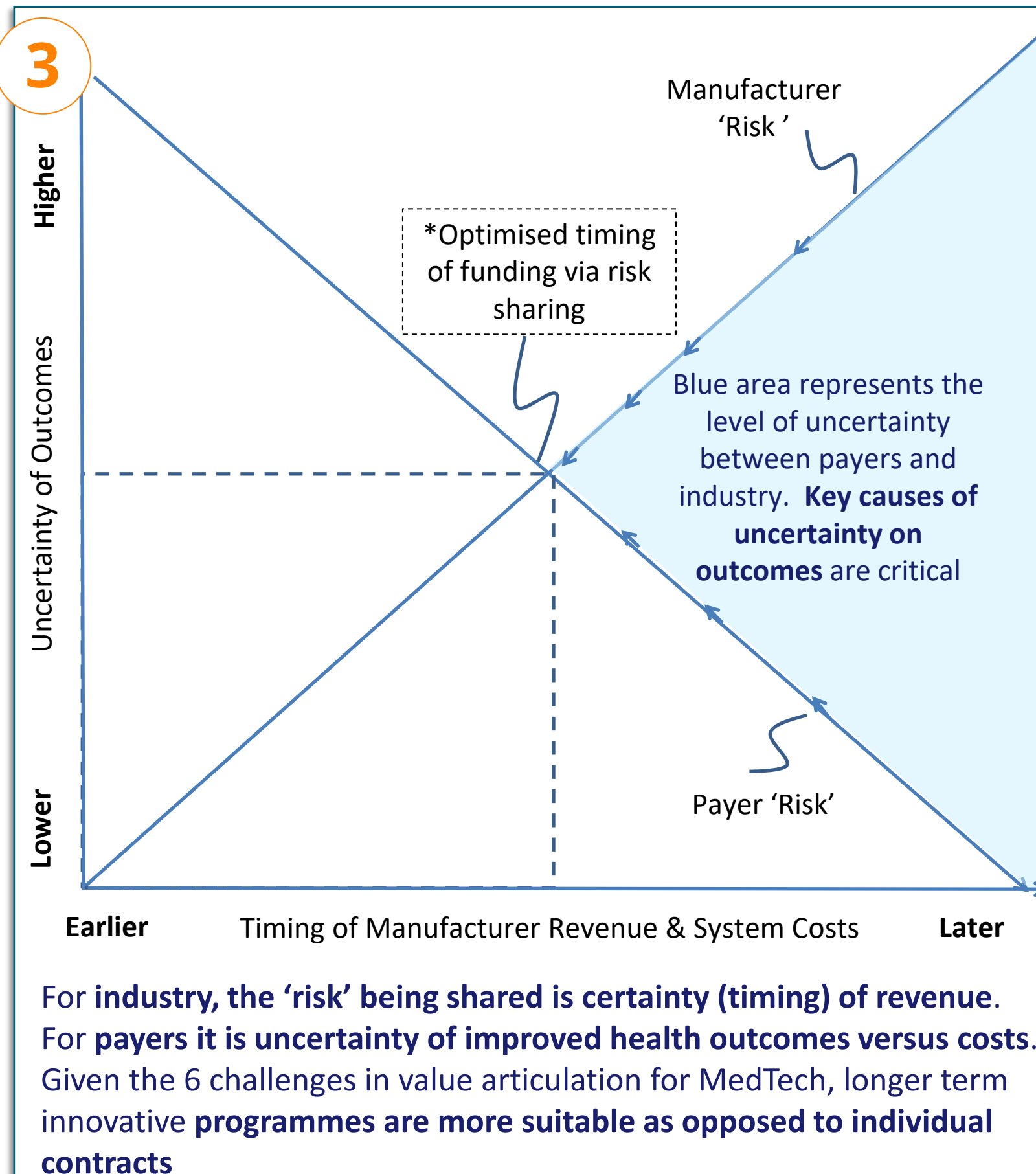
2

4 Post-CE Mark Criteria Guide Evidence Requirements for Reimbursement:

1. Are **comparator products** available?
2. Are comparator products used in the same **care setting**?
3. Is **coverage and coding** available for the products
4. Do the pricing strategy align to expectations

If the answer to any of these questions is 'no', **the payer engagement strategy** is significantly more involved.

3



Causes of Uncertainty on Improved Outcomes

1. Diversity of the MedTech industry:

- Devices, diagnostics & Digital health
- Diversity of care setting
- Diversity of therapeutic area usage
- Diversity of reimbursement pathways

2. Evidence requirements to demonstrate value:

- Ethical or practical challenges to RCT's
- Internal RCT validity vs External RWE validity of devices
- Improved statistical methods & trial design

3. User Learning Curve

- User has to 'learn' how to use a device
- Increased usage can lead to improved outcomes

4. Organisational Impact

- Impact on patient pathway
- Impact on hospital flow
- Impact on care pathway

5. Incremental Product Innovations

- Shorter/less applicable patent protection
- Iterative nature of MedTech

6. Rapid Price Changes

- Older innovations depreciate as product evolves
- Changes in ICER given comparator / SoC changes

Source: Alira Health Analysis, MedTech Europe, Bocconi University

Identified Accelerated Coverage Pathways for Innovation (ACPI's)

26 active pathways have been identified across Europe, each with their own scope, evidence requirements, stakeholders, access pathways and timelines.

Definition

Accelerated Coverage Pathways for Innovations (**ACPI's**) are **bilateral or multilateral agreements** that enable **patient access to a health technology** subject to specific conditions **outside the general reimbursement/funding frameworks**



Identified Pathways¹

Austria 🇦🇹

- Provisional/analogous MEL Procedure Codes

Belgium 🇧🇪

- Limited Clinical Application

England 🇬🇧

- Artificial Intelligence in Health and Care Award²
- Innovation Technology Payment (ITP) programme²
- MedTech Funding Mandate²
- NHS Innovation Accelerator²
- Rapid Uptake Products²

France 🇫🇷

- Article 51 of Social Security law (2018 & 2019)
- Health Economic Research Programme – PRME
- Hospital Clinical Research Program – PHRC
- Forfait Innovation
- Repository of Innovative Acts Outside the Nomenclature of Biology and Anatomical Pathology - RIHN
- ETAPES Program

Germany 🇩🇪

- 137e - Trial Regulation
- 137h – Trial Regulation for Highly Invasive Medical Devices
- Digital Health Applications (DiGA)
- Innovation Fund
- NUB
- Selective Contracts

Netherlands 🇳🇱

- Innovation for Small-scale Experiments
- Promising Care

Portugal 🇵🇹

- Medical Device Reimbursement

Scotland 🇬🇧

- IMTO Process by Health Technology Scotland

Spain 🇪🇸

- Monitoring Studies
- Supervised Use

Wales 🇬🇧

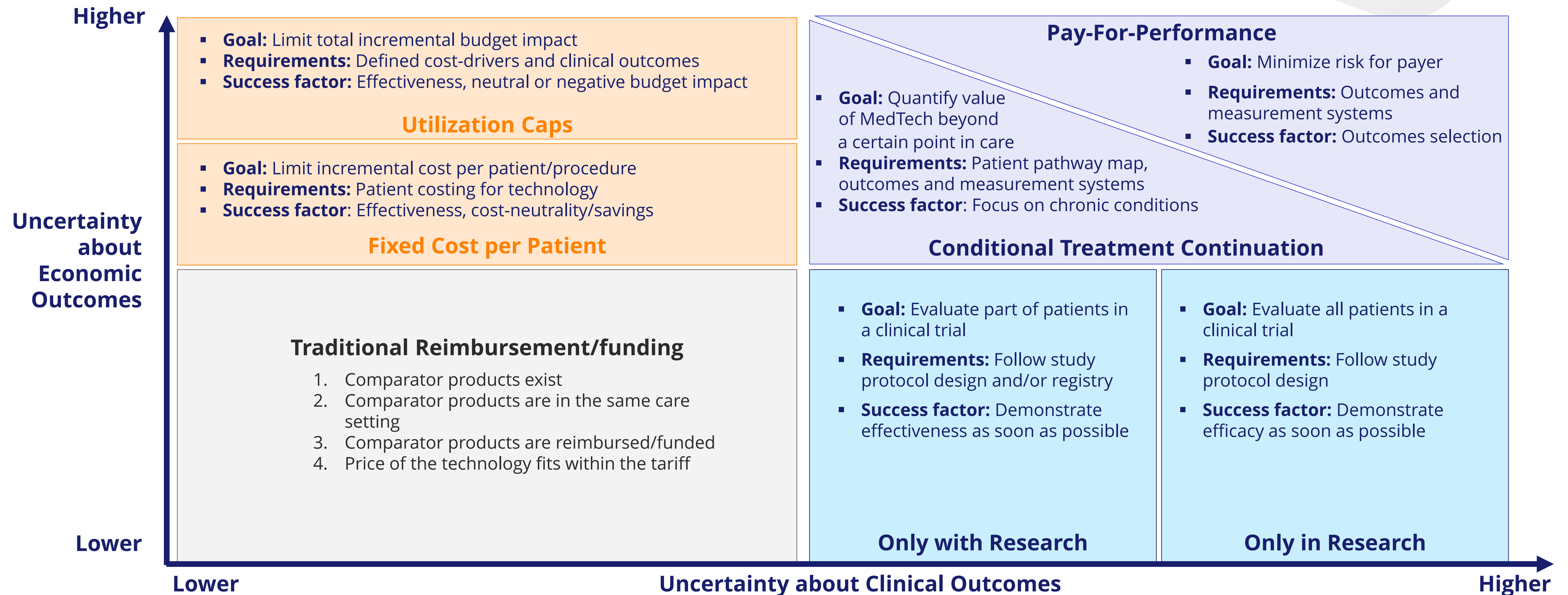
- NHS Wales

Notes: ¹Swiss pathways not included in the list ²Part of the Accelerated Access Collaborative, the umbrella department overseeing different programmes, including 5 ACPI's

Sources: Taxonomy of Value-Based Access Programmes MedTech Europe; Alira Health Analysis

Taxonomy of Accelerated Coverage Pathways for Innovations

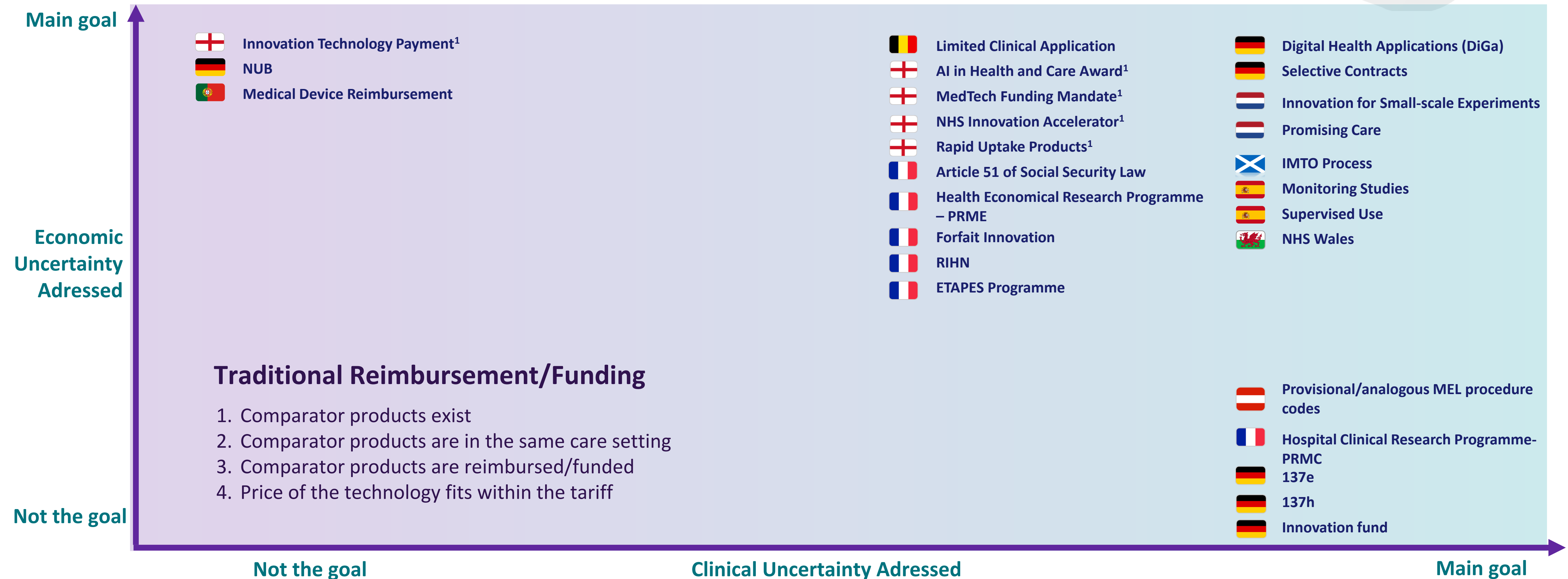
Builds on the second version of the taxonomy, newly added are the AI in Health and Care Award, the NHS Innovation Accelerator, the MedTech Funding Mandate, NHS Wales, Rapid Uptake Products, DiGa, Promising Care, IMTO Process, Monitoring Studies and the ETAPES Programme.



Sources: Taxonomy of Value-Based Access Programs MedTech Europe; Alira Health Analysis

Taxonomy of Accelerated Coverage Pathways for Innovations

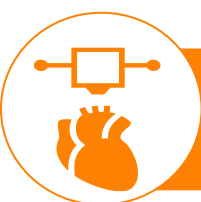
Builds on the second version of the taxonomy, newly added are the AI in Health and Care Award, NHS Innovation accelerator, the MedTech Funding Mandate, Rapid Uptake Products, DiGa, Promising Care, IMTO Process, Monitoring Studies and the ETAPES Programme.



Notes: ¹Part of the Accelerated Access Collaborative, the umbrella department overseeing different programs, including 5 ACPI's ²Swiss pathways not included in the list
Source: Alira Health & ValueConnected analysis

Industry can develop a structured approach to collaborative dialogue

7 enablers support stakeholder engagement.



How Industry Can Support Product Adoption

Patient & Therapeutic Area

1. Patient Centric Therapeutic Areas

Identify the primary therapeutic areas for your MedTech solution. A PICO framework can support this and define your core value proposition.

2. Develop patient cohorts with risk adjusted criteria and protocols

This ensures similar patients to drive comparability of outcomes in the clinical trial. This also helps to identify exactly where the value for a solution is derived from.

3. Define clear outcome measures for cohorted patients

The outcomes become the measurements for success, which define value, and set the foundation of pricing a MedTech solution

4. Define a clear timeframe to achieving optimal outcomes: trial and RWE settings Timeframes for patient outcomes, must align to economic savings to resonate with payer budgets

Business Fundamentals

5. Quantify baseline Outcomes & Costs for each patient cohort

A baseline is critical for cost benefit analysis for payers outlining why this may be better than the Standard of Care.

6. Determine prospective outcomes and cost improvement

This defines the quantifiable benefit that will drive pricing, volume and access discussions

7. Develop a simple business model.

A business model serves two purposes:

1. Internal and resourcing
2. Viability of payer investment



Value Based Procurement: Collaborative Dialogue



Providers & Hospital Management



Payment policymakers



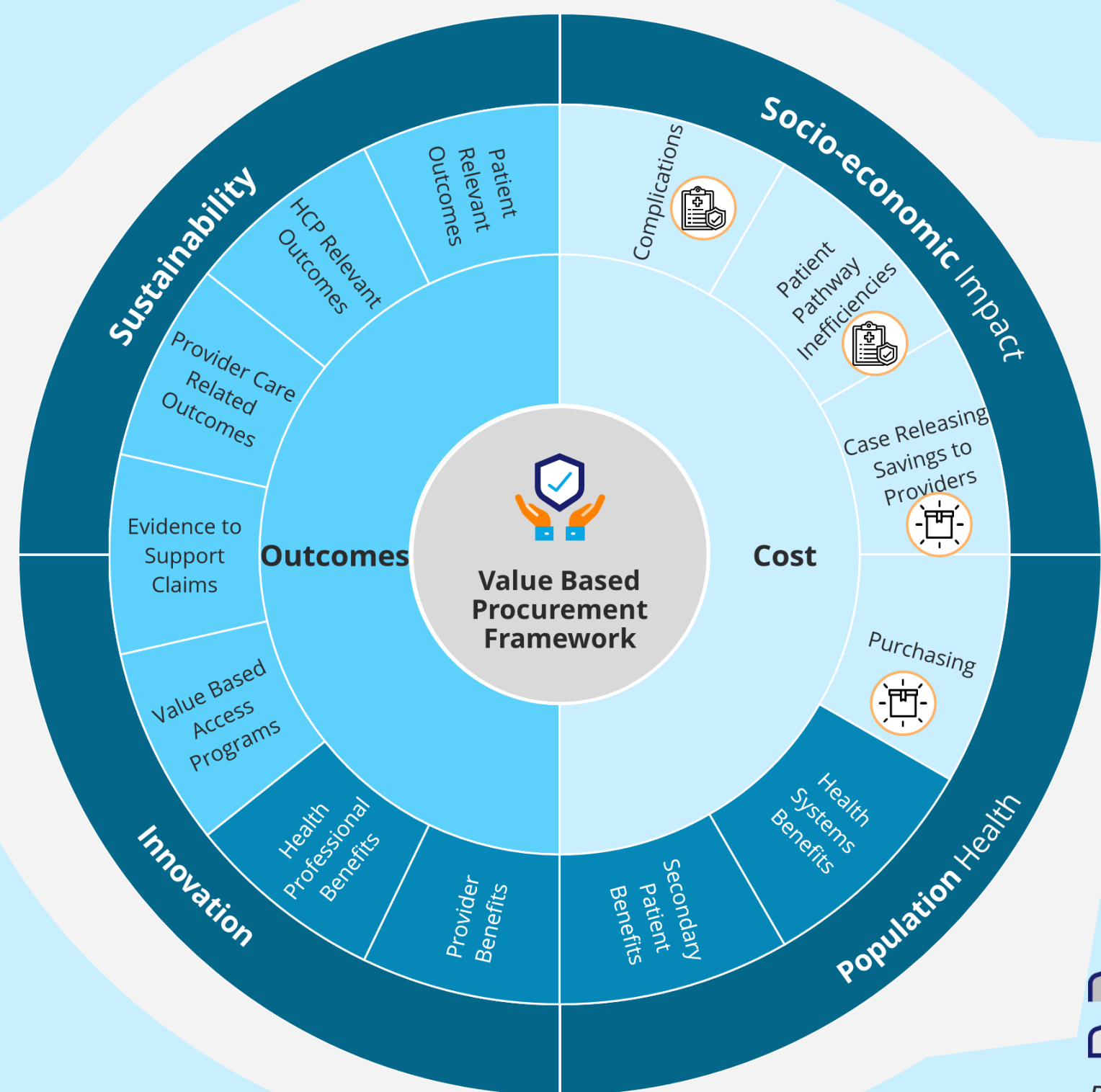
Physicians



Patients

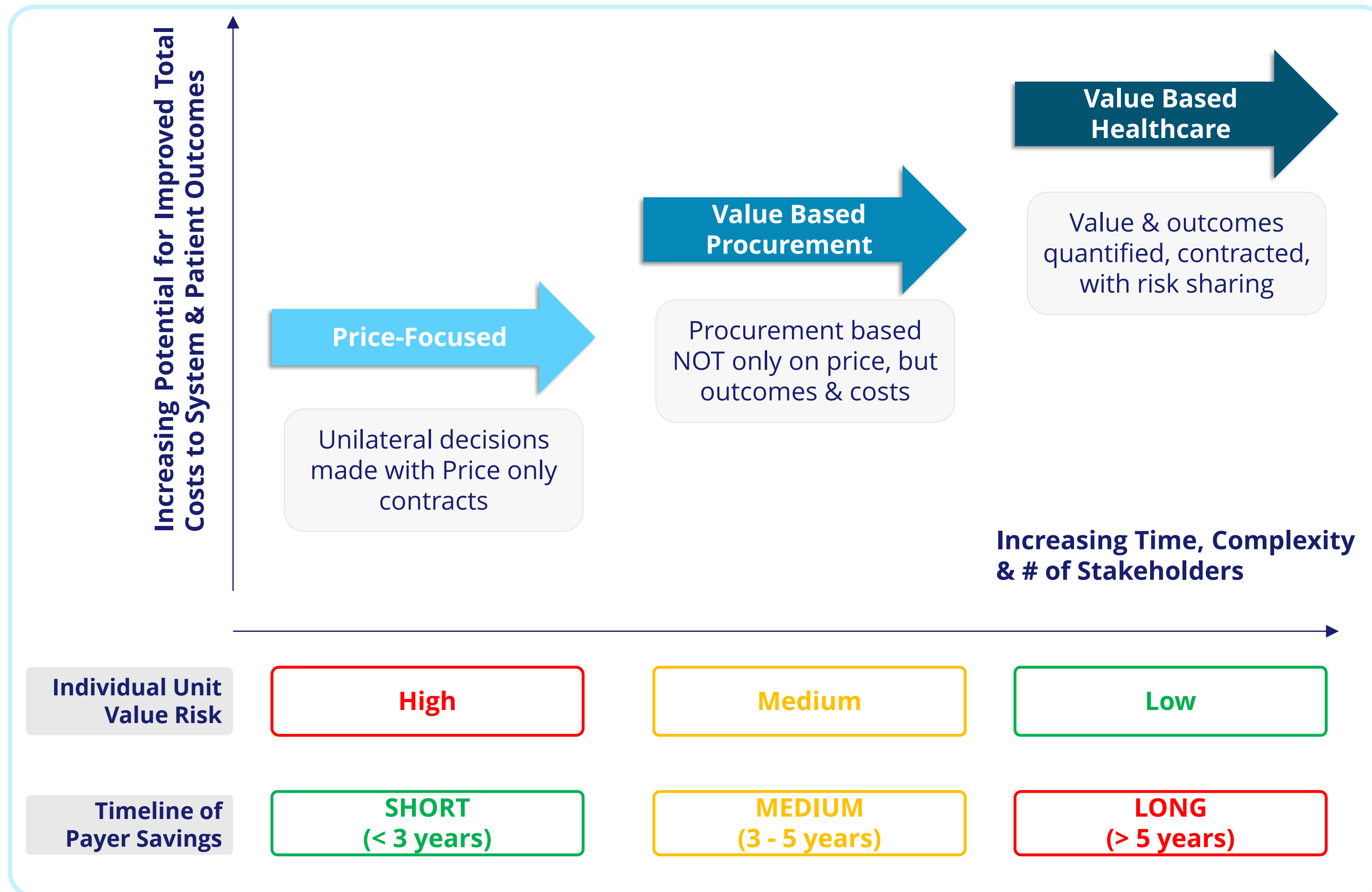


Payers



Value Based Procurement

Value based procurement in of itself is not the end goal. It is a stepping-stone to a more holistic and patient-centric buying process in healthcare. The MedTech companies that adapt the fastest will have a significant competitive advantage



NHS Supply Chain: Value Based Based Procurement Project Report & Findings

5 Domains of Clinical & Financial Value Determined:






1. Reduction in consumption
2. Shift in-patient to day-case
3. Change in Patient pathway
4. Operational Productivity
5. Reduction in Infection

Value Based Procurement & Risk Sharing

- Pricing pressure is one of the critical challenges facing the healthcare industry
- Price pressure puts innovation and distribution of essential healthcare solutions under pressure. Procurement is a key stakeholder to engage
- **Risk Sharing agreements can ensure purchasers are rewarded for the launch of innovation in a risk adjusted manner.**

Note: Adapted from: Mangan, B Kelley T, McGough R, & Meehan J. Value Based Procurement An alternative approach to total cost reduction, improved efficiency and enhanced patient outcomes in the NHS: A Framework for Delivery. NHS Northwest Procurement Development, 2018. University of Liverpool.

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When do we have enough evidence? A framework to support decisions on PBRsAs

Mark Sculpher, PhD

Professor

Centre for Health Economics

University of York, UK

Workshop session, Virtual ISPOR 2021

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- Claire Rothery
- Stephen Palmer
- Karl Claxton
- Simon Walker

I have no financial or any other conflicts relating to any specific products mentioned in my presentation.

Different forms of PBRsAs

VALUE IN HEALTH 15 (2012) 570–579



Available online at www.sciencedirect.com

SciVerse ScienceDirect

journal homepage: www.elsevier.com/locate/jval



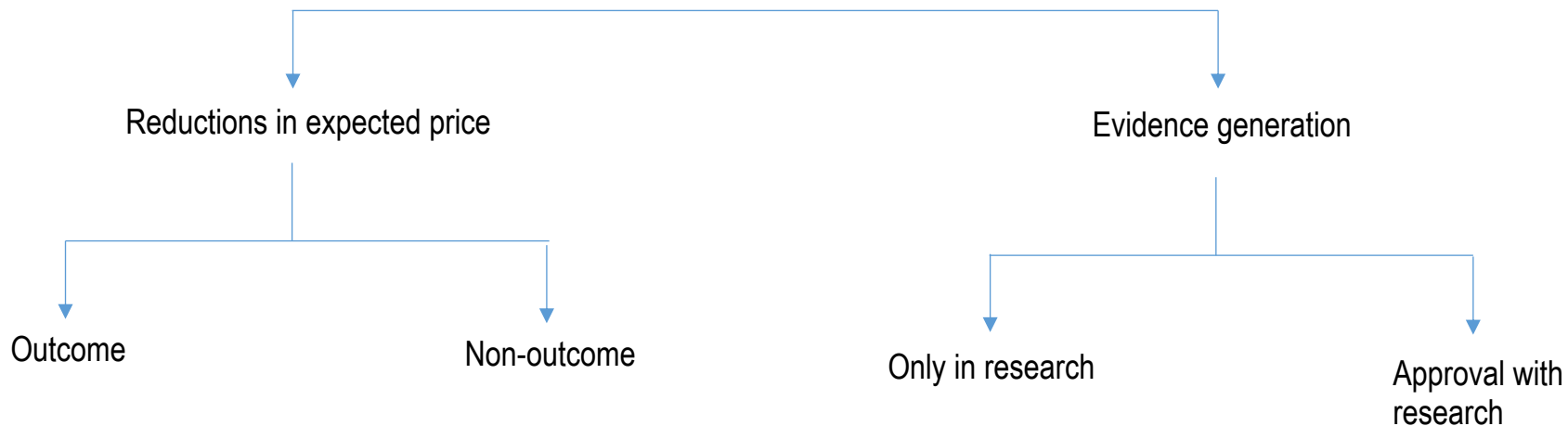
POLICY PERSPECTIVES

Coverage with Evidence Development, Only in Research, Risk Sharing, or Patient Access Scheme? A Framework for Coverage Decisions

Simon Walker, MSc^{1,*}, Mark Sculpher, PhD¹, Karl Claxton, PhD^{1,2}, Steve Palmer, MSc¹

¹Centre for Health Economics, University of York, York, UK; ²Department of Economics and Related Studies, University of York, York, UK

Different forms of PBRsAs



Uncertainty evaluation – why does uncertainty matter?

Evidential uncertainty

Including learning curves, incremental innovation

Decision uncertainty

Risk of wrong funding decision

Net reduction in population health

Funding non-cost-effective or failure to fund cost-effective

Further research to reduce costs of uncertainty

Is research of value? How can research be incentivized? What are the costs of changing decisions?

Expanding the decision options

Rejection
vs
Adoption

- Based on existing evidence, is health gained > health forgone?

vs
Approval with research
vs
Only in research

- Is the value of additional research greater than its cost?
- Can research be conducted if device is approved?
- Are there significance irrecoverable costs?
- What else do we expect to happen in the future (e.g. prices)?
- Are there issues regarding who should pay for research?

Summary

- Important distinction between PBRsAs that generate evidence versus those that reduce the effective price
- Analytically, key to understand the
 - Importance and cost of uncertainty
 - The potential value of research
 - The actual value of research

References

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- Claxton K et al (2012). A comprehensive algorithm for approval of health technologies with, without, or only in research: the key principles for informing coverage decisions, *Value in Health*, vol. 19, pp885-891
- Rothery C et al (2017). Characterising uncertainty in the assessment of medical devices and determining future research needs. *Health Economics*, vol. 26, Suppl S1, pp109-23.



National Health Care Institute



MEA's to Harness Value of Innovative Medtech: *A Payer's Perspective*

Payam Abrishami MD, PhD

Sr. advisor on medical innovations, National
Health Care Institute (ZIN)

Asst. Prof. medical innovation & policy,
Erasmus University Rotterdam

ISPOR Congress April 2021



National Health Care Institute

Disclaimer

The views expressed here are those of the presenter and may not be regarded as an official position of the National Health Care Institute.

I declare no personal conflict of interest related to this presentation.



National Health Care Institute



Content

- Medical technology into the health care system
- The Medtech innovation dynamics
- Managed entry access schemes for Medtech

The health care system box



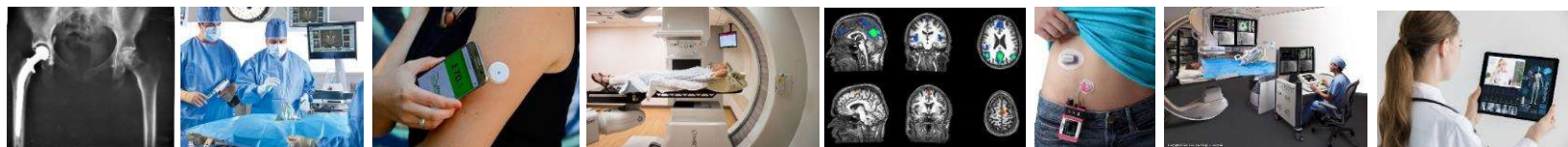
***Value-driven access to
medical innovations***



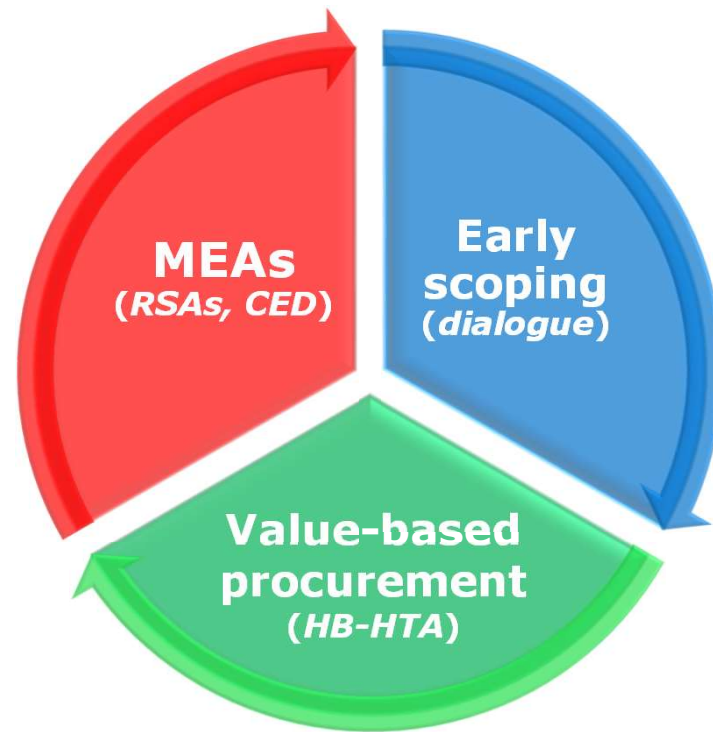


Medical innovations into the HC system

- Patients to be better
- The entire society to be better-off
- Premium/tax payers remain in solidarity with one another

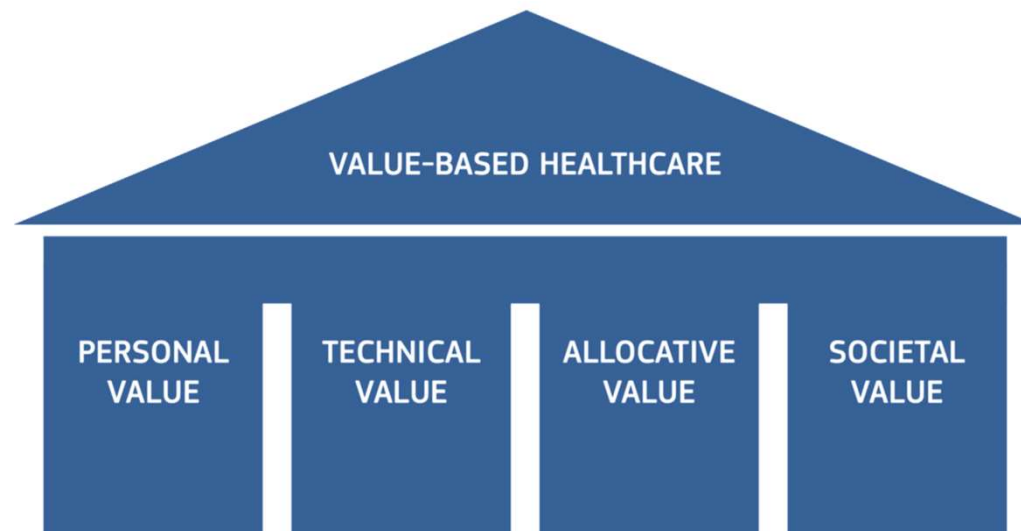


Value-driven entry of innovative Medtech



Value in 'value-based healthcare'

(European Commission, EXPH, 2019)

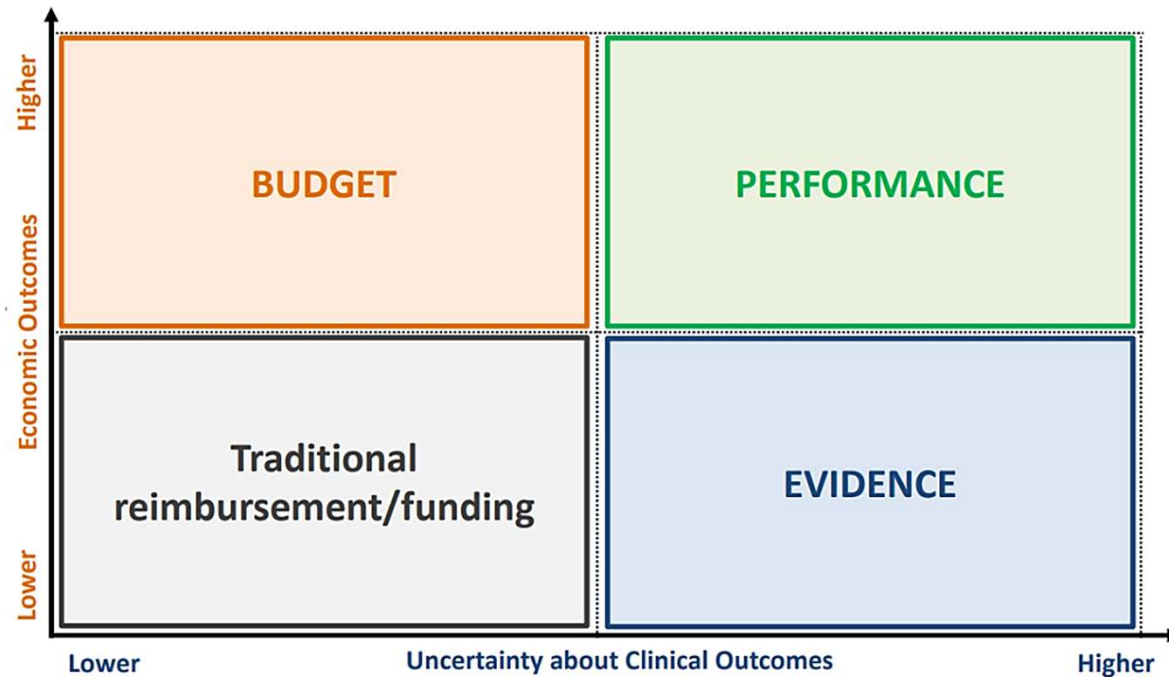


Advantages of MEAs

- Adoption largely via local procurement: national positive list infeasible
- Clinical value uncertain: (high-level) evidence not available or insufficient in the early stages
- Economic value uncertain: missing outcome data, uncoordinated evaluations, impact on public resources difficult to trace
- Short PLC, rapid incremental change, SME-dominant
- Implementation challenges: upscaling beyond pilot, soft skills, culture, data reuse, etc.

Adapting to the dynamics & pace of Medtech/Digitech

(MedTech Europe Taxonomy of Value-Based Access Programmes, 2019)



MEAs: flexible access schemes

Flexible

≠ lenient, arbitrary, exceptionalism

= agile, fit-for-purpose, proportional to value proposition & scale metrics

Optimising (post-market) value over time

- Ongoing evaluation, know-how learning, stepwise upscaling
- Attention to patients' engagement and de-implementing obsolete care

→ Balance between innovation and regulation

- Value delivery to the end-user without reducing time-to-market



The Dutch case



Regulated competition, decentralised development and uptake

‘Open’ entry into the statutory basic package (# pharma)

- Health professionals and insurers decide

National Health Care Institute (ZIN) stimulates evidence generation and appropriate entry

- Implementing the MEA program ‘Potentially Promising Care’
- Stakeholder dialogue through case study (Medtech/AI)
- Information provision on innovation pathways (ZvI)
- Limited (risk-based) explicit assessments

Dutch government to consider a ‘sluice’ for Medtech!



Thank you!

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Virtual ISPOR 2021

Can PBRsAs for Medtech Address Procurement and Market Access Challenges?
Scanning the Current Horizon and a View to the Future

PERFORMANCE-BASED RISK SHARING ARRANGEMENTS FOR MEDICAL DEVICES: STATE-OF-THE-ART OF IMPLEMENTATION IN ITALY

Giuditta Callea, PhD

Associate Professor of Practice of Government, Health and Non-Profit
Coordinator Observatory on Management of Public Procurement in Healthcare, Cergas SDA Bocconi School of Management



WP7 Coverage with Evidence Development for Medical Devices

- **Methods:**

- Structured interviews with 25 decision-makers from 23 jurisdictions to explore:
 - Characteristics of existing CED programmes for MDs
 - Perceptions regarding 13 pre-identified challenges associated with initiating and operating CED schemes for devices
- Data collection on individual schemes initiated or still ongoing in 2015-2020.



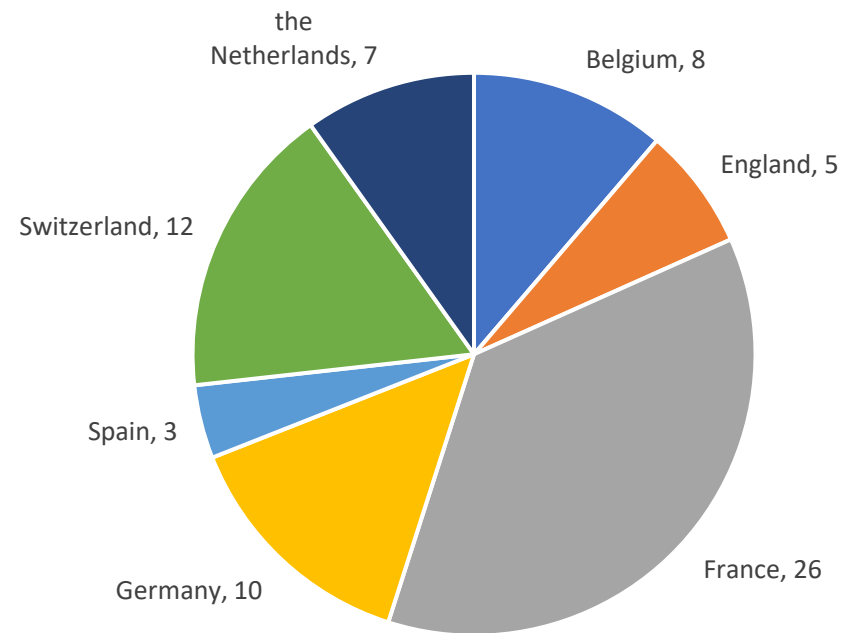
Challenges with CED schemes for medical devices

- 1 Deciding which medical devices are candidates for CED schemes
- 2 Obtaining stakeholder agreement on the scheme
- 3 Securing funding for the scheme
- 4 Determining the appropriate study design for data collection
- 5 Determining the relevant outcome measure(s) on which data are collected
- 6 Dealing with data collection and monitoring
- 7 Dealing with data analysis
- 8 Ex-ante definition of decision rule, based on possible outcomes of the scheme
- 9 Reaching an agreement on price, reimbursement or use of the device at the end of the scheme
- 10 Withdrawing a device from the market when evidence indicates the device is not (cost-) effective
- 11 Obtaining agreements about the duration of the scheme and the stopping rule
- 12 Adapting the scheme to account for product modifications or a learning curve
- 13 Dealing with the market entry of similar devices

OVERVIEW OF EUROPEAN CED PROGRAMS FOR MDs

- **Results:**

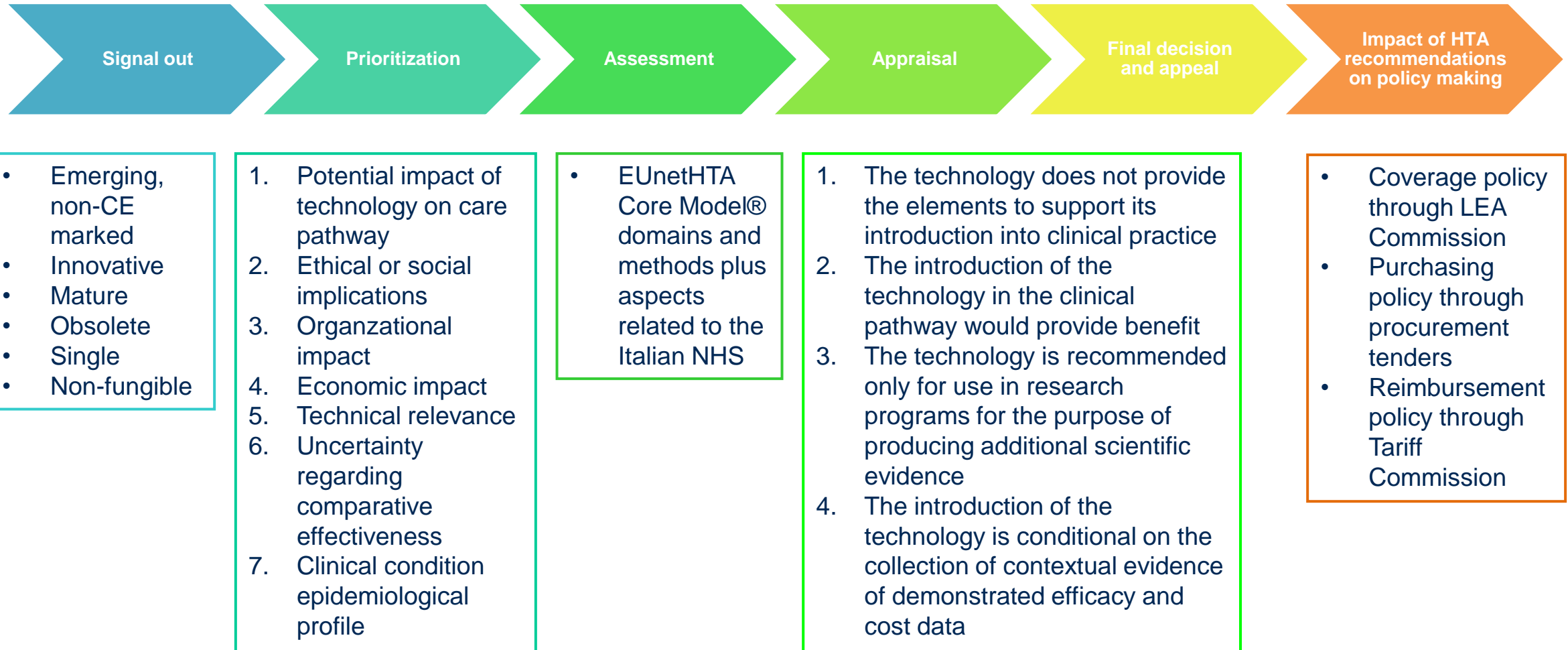
- 7 countries with CED programmes for MDs
 - Belgium, England, France, Germany, the Netherlands, Spain, and Switzerland
- 71 ongoing schemes in 2015-2020*



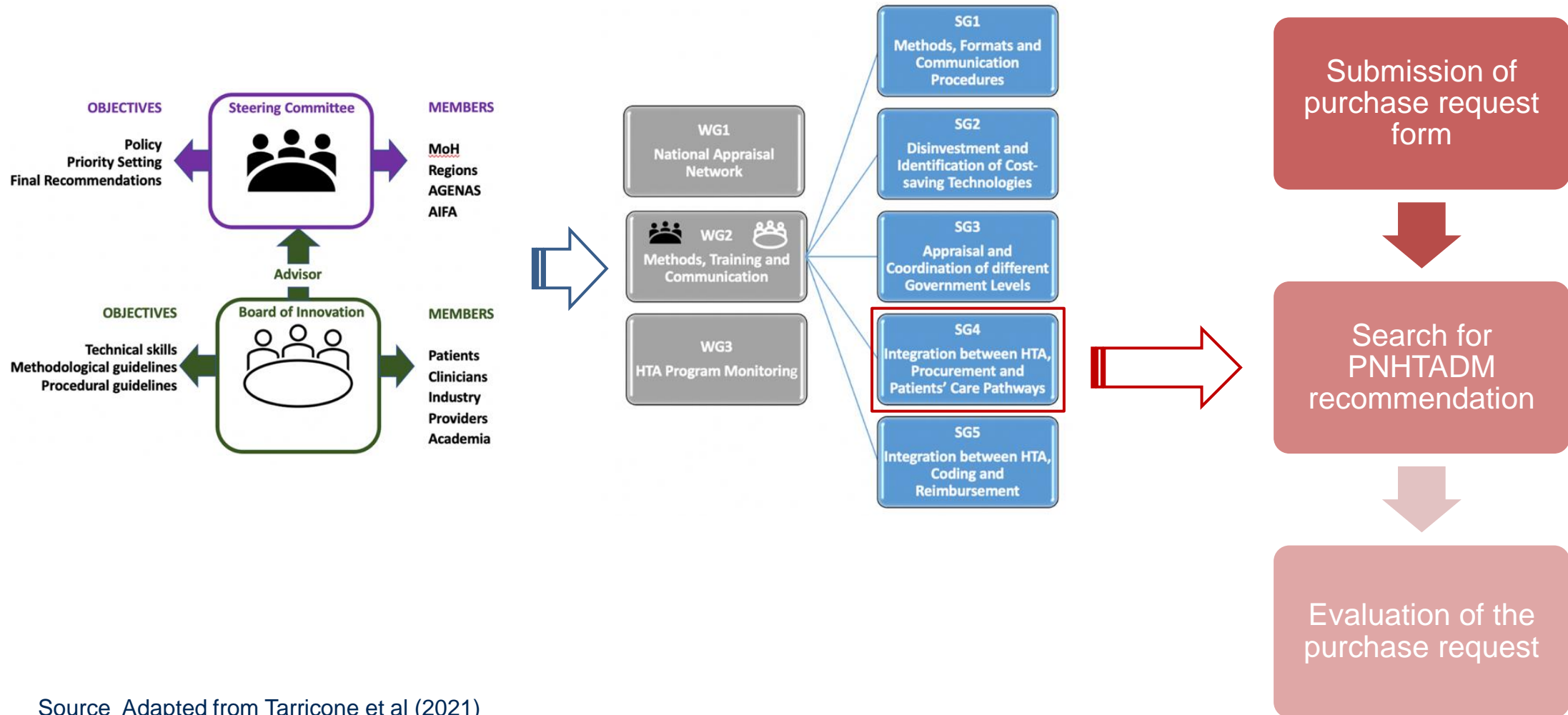
- Heterogeneity of CED programmes characteristics (eligibility criteria, roles and responsibilities of stakeholders, funding arrangements, type of decisions being contemplated at the outset of each scheme)
- High variability in how decision-makers perceived CED-related challenges possibly reflecting country-specific arrangements and different experiences with CED.
- One general finding: relatively little attention paid to the evaluation of schemes, both during and at their completion

* The dataset of CED schemes for MDs implemented in Europe in 2015-2020 can be downloaded from this [COMED outputs homepage](#).

THE ITALIAN NATIONAL HTA PROGRAMME FOR MEDICAL DEVICES (PNHTADM)

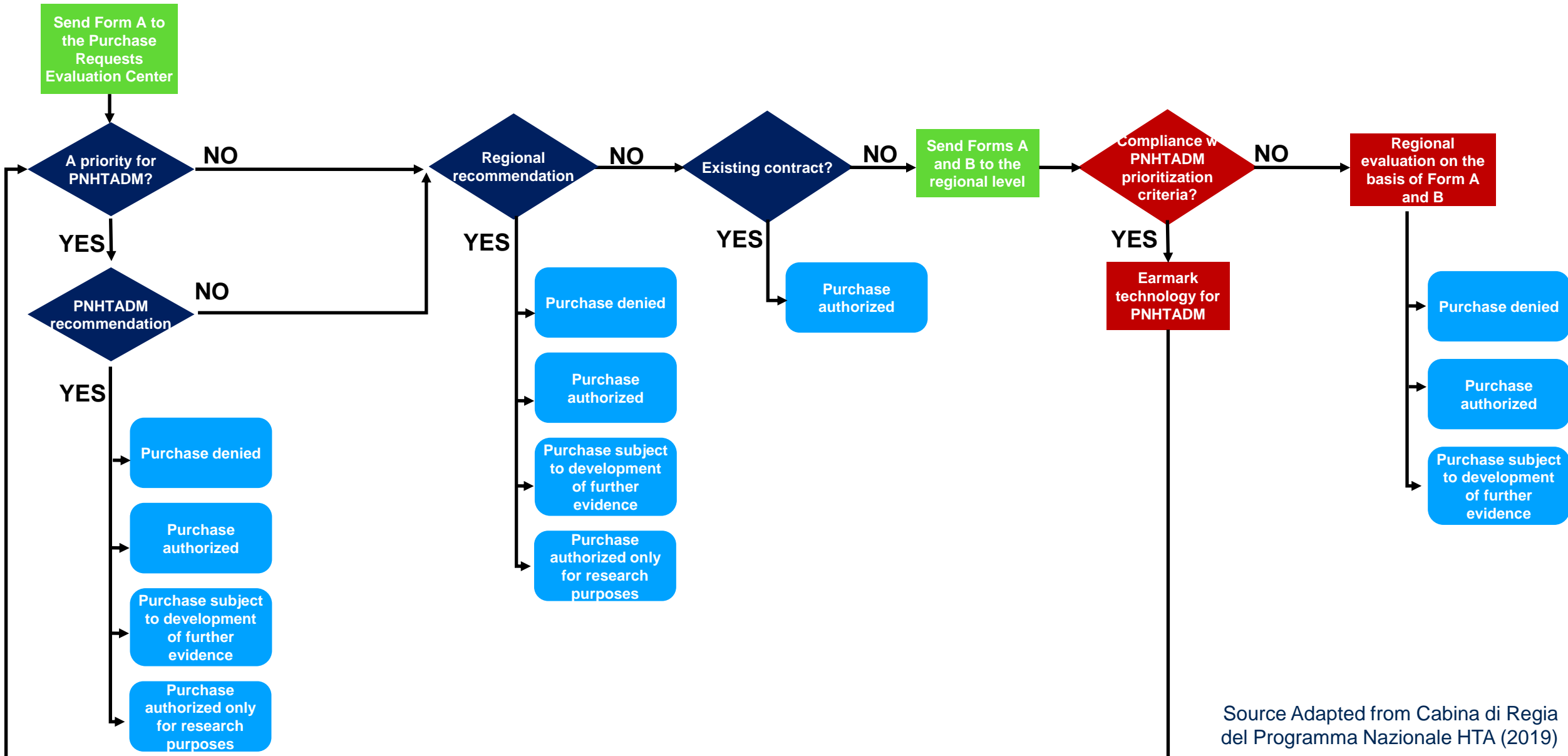


GOVERNANCE AND METHODOLOGY OF PNHTADM



Source Adapted from Tarricone et al (2021)

THE PROPOSED PATHWAY OF INTEGRATION BETWEEN HTA AND PROCUREMENT



IMPLEMENTATION OF THE PROPOSED MODEL BY ITALIAN REGIONS: VENETO

Bur n. 100 del 07/07/2020

(Codice interno: 422931)

DELIBERAZIONE DELLA GIUNTA REGIONALE n. 811 del 23 giugno 2020

Rinnovo della rete regionale per la governance dei dispositivi medici: istituzione del Tavolo tecnico regionale sui dispositivi medici e attivazione delle Unità di valutazione aziendali delle richieste di acquisto di dispositivi medici.

[Sanità e igiene pubblica]

Note per la trasparenza:

A seguito del recepimento del Programma Nazionale di HTA Dispositivi Medici avvenuto con DGR n. 967 del 6 luglio 2018, si approvano l'istituzione di un tavolo tecnico, denominato Tavolo regionale sui dispositivi medici e, a livello aziendale, l'attivazione di Unità di valutazione delle richieste di acquisto di dispositivi medici.

<https://bur.regione.veneto.it/BurVServices/pubblica/DettaglioDgr.aspx?id=422931>

VALUE-BASED PROCUREMENT AND RISK SHARING IN TUSCANY

1. Biological meshes for repair of inguinal hernias (awarded in 2019)



**Procedura aperta per la Fornitura di
“Matrici biologiche in derma suino cross e non cross-linked”
per le Aziende Sanitarie e Ospedaliere della Regione Toscana
N. Gara 7319615**

2. Cryoablation (awared in 2020)



**PROCEDURA APERTA IN MODALITA' TELEMATICA PER LA
CONCLUSIONE DI ACCORDO QUADRO PER L'AFFIDAMENTO
QUADRIENNALE, IN LOTTI SEPARATI, DELLA FORNITURA DI
DISPOSITIVI MEDICI PER ELETTROFISIOLOGIA (N.34 LOTTI) PER LE
AZIENDE SANITARIE ED ENTI DELLA REGIONE TOSCANA
GARA N. 6977868**

3. Carotid artery stents (awared 2021)



Regione Toscana



Soggetto Aggregatore

Allegato C

DISCIPLINARE DI GARA

**GARA EUROPEA A PROCEDURA APERTA PER LA CONCLUSIONE DI ACCORDI
QUADRO PER LA FORNITURA DI STENT CAROTIDEI PER LE AZIENDE
SANITARIE ED ENTI DEL SSR DELLA REGIONE TOSCANA
N. 2 LOTTI
GARA N.7803835**

PROCEDURA APERTA PER LA FORNITURA DI “MATRICI BIOLOGICHE IN DERMA SUINO CROSS E NON CROSS-LINKED” PER LE AZIENDE SANITARIE E OSPEDALIERE DELLA REGIONE TOSCANA

- Date of publication: December 2018
- Date of award: November 2019
- Duration: 48 months
 - (January 2020 – December 2023)
- Lots: 2
- Award criteria
 - Most Advantageous Economic Tender
 - Quality criterion: **Net Monetary Benefit***
 - Outcome measures
 - Rate of infections after 30 days
 - Rate of recurrences after 24 months
 - WTP threshold: 60,000€/QALY
 - Quality-weighting: 70
- Outcome monitoring and pay-back
 1. Establishment of a regional **registry**
 2. **Monitoring** of RW outcomes after 12 months:
 - Rate of infections after 30 days
 - Rate of recurrences after 24 months
 3. **Payback:**
 - In case the rates of infections and recurrences exceed 20% or more the figures declared in the technical offer, ESTAR will meet the Economic Operator to assess the causes.
 - If the device ineffectiveness will be verified, the Economic Operator will pay back 50% of the purchase price.

*For details on the application of NMB see Messori et al, 2020.

- Cabina di Regia del Programma Nazionale HTA (2019), Documento finale del Gruppo di lavoro 2 Metodi, Formazione e Comunicazione. Allegato 4 - Individuazione delle tecnologie da sottoporre ad Assessment ed integrazione dei risultati di HTA nelle fasi di procurement e nei PDTA. http://www.salute.gov.it/imgs/C_17_pubblicazioni_2855_ulterioriallegati_ulterioreallegato_3_alleg.pdf
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- Tarricone R, et al. (2021), Establishing a national HTA program for medical devices in Italy: Overhauling a fragmented system to ensure value and equal access to new medical technologies. Health Policy (in press), <https://doi.org/10.1016/j.healthpol.2021.03.003>.

THANK YOU!

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Parte A

(a cura del personale sanitario richiedente)

1. Dati del richiedente

Data della richiesta

.....

Nome e cognome del richiedente

.....

Telefono

.....

E-mail

.....

Unità Operativa (UO)

.....

Responsabile UO richiedente

.....

Il richiedente ha un conflitto di interessi rispetto al DM o alla tecnologia richiesti?

SI ☐ NO ☐

In caso affermativo, specificare quale

.....

2. Dati tecnici

La richiesta di acquisto è urgente?

SI ☐ NO ☐

Il DM/tecnologia è esclusivo o infungibile?

SI ☐ NO ☐

In caso affermativo, specificare la motivazione dell'esclusività o di infungibilità

.....

Tipologia di richiesta: ☐ Singolo prodotto

☐ Categoria di prodotti omogenei

Classe di rischio del DM o della categoria di DM richiesti:

I ☐ IIa ☐ IIb ☐ III ☐

Dati del prodotto o della categoria di prodotti richiesti

Nome/i commerciale/i (facoltativo se si richiede

l'acquisto di una classe di prodotti)

Produttore/i

Fornitore/i

Data/e marchio CE

Classificazione Nazionale dei DM (CND) (obbligatoria se si richiede l'acquisto di una classe di prodotti)

Numero/i di repertorio(non obbligatorio)

Destinazione d'uso riportata nelle Istruzioni per l'Uso

Descrivere la popolazione target beneficiaria della tecnologia proposta e la condizione morbosa oggetto di cura

.....

Come viene trattata attualmente la popolazione target?

.....

Esiste un percorso diagnostico terapeutico assistenziale (PDTA) di riferimento?

SI ☐ NO ☐

In caso affermativo, descriverlo:

.....

Il DM o la categoria di prodotti richiesti va in affiancamento o sostituzione di un dispositivo analogo già in uso?

SI ☐ NO ☐

In caso affermativo, indicare:

Nome commerciale del/i dispositivo/i o

CND

% di sostituzione

Specificare la motivazione della richiesta di acquisto (es. caratteristiche del prodotto attualmente utilizzato per quella indicazione, vantaggi della tecnologia proposta, motivo per cui il prodotto attualmente utilizzato non va più bene)

.....

3. Stima dei quantitativi richiesti

Indicare il numero stimato di casi da trattare all'anno nell'unità operativa

Indicare il fabbisogno stimato annuo della tecnologia (numero di pezzi)

Indicare il prezzo di acquisto indicativo o un range di prezzo del DM/tecnologia (in €)

.....

Indicare il prezzo di acquisto (indicativo) dell'attuale DM/tecnologia (in €)

4. Documentazione da allegare

Se la richiesta è relativa ad un singolo prodotto, inviare:

- Scheda tecnica del prodotto
- Istruzioni per l'Uso

Se la richiesta è relativa ad una classe di prodotti, inviare:

- Una scheda tecnica per ogni prodotto
- Le Istruzioni per l'Uso di ogni prodotto

IL RESPONSABILE di UOC/UOSD

IL DIRETTORE di DIPARTIMENTO

Parte B

(a cura del Centro di Valutazione delle Richieste di Acquisto)

Il Modulo B deve essere compilato solo per prodotti senza raccomandazioni - nazionali o regionali - e senza convenzioni/contratti in essere. Qualora esista una raccomandazione o la tecnologia richiesta sia riconducibile a convenzione/contratto in essere, l'esito della richiesta di acquisto sarà coerente le indicazioni regionali e non è richiesta la compilazione del Modulo B.

1. Evidenze cliniche a supporto della tecnologia

Il compilatore deve fornire la lista delle evidenze cliniche a supporto della sicurezza e dell'efficacia della tecnologia compilando le tabelle seguenti, che si basano sul GRADEpro.³⁷ Il compilatore deve elencare tutti i possibili *endpoint* relativi a sicurezza (Tabella 12) ed efficacia (Tabella 13), ed almeno uno studio per ciascun *endpoint* rilevante. Si raccomanda l'utilizzo di *endpoint* rilevanti per i pazienti. Gli *endpoint* surrogati possono essere riportati solo se esiste una correlazione con l'*endpoint* principale. Possono essere utilizzati quali fonti non solo studi primari, ma anche revisioni sistematiche e *report* di HTA.

Il compilatore, inoltre, deve rispondere alle seguenti domande.

Sono presenti Linee guida cliniche di riferimento regionali/nazionali/internazionali (ad esempio società scientifiche o autorità sanitarie)? SI ☐ NO ☐

In caso affermativo, specificare quali

Tabella 12 Sintesi evidenze cliniche a supporto della sicurezza

Riferimenti studio ³⁸				
Popolazione				
Disegno dello studio ³⁹				
Endpoint				
Definizione endpoint				
Metodo di misurazione				
Tempistica di misurazione				
Tipo di variabile ⁴⁰				
N° pazienti del gruppo dei trattati				
N° pazienti del gruppo di controllo				
Risultato/effetto:				
-Se l'endpoint è dicotomico:				
N° eventi del gruppo dei trattati				
N° eventi del gruppo di controllo				
-Se l'endpoint è continuo: ⁴¹				
Media del gruppo dei trattati				
Deviazione standard del gruppo dei trattati				
Errore standard della media del gruppo dei trattati				
Intervallo di confidenza al 95% del gruppo dei trattati				
Media del gruppo di controlli				
Deviazione standard del gruppo di controllo				
Errore standard della media del gruppo di controllo				
Intervallo di confidenza al 95% del gruppo di controllo				

2. Evidenze economiche a supporto della tecnologia

Esistono valutazioni economiche (es. analisi di costo-efficacia, analisi di costo-utilità, analisi di impatto sul budget) all'interno di report di HTA o pubblicate come articolo scientifico?

SI ☐ NO ☐

Tabella 14 Sintesi studi di valutazione economica

Riferimento bibliografico	Tipologia studio ⁴⁶	Sintesi delle evidenze disponibili

3. Costi legati alla tecnologia

Il DM/tecnologia necessita di altri dispositivi accessori per l'utilizzo? SI ☐ NO ☐

Il DM/tecnologia viene utilizzato con un'apparecchiatura? SI ☐ NO ☐

In caso affermativo, l'apparecchiatura è già disponibile? SI ☐ NO ☐

L'uso del DM/tecnologia richiede investimenti infrastrutturali? SI ☐ NO ☐

In caso affermativo, specificare quali

Servono competenze specifiche per poter utilizzare la nuova tecnologia? SI ☐ NO ☐

In caso affermativo, specificare quali

Sono già disponibili nella struttura le competenze per sfruttare appieno la tecnologia proposta? SI ☐ NO ☐

4. Rimborso della tecnologia

Codice ICD-9-CM di diagnosi.....

Codice ICD-9-CM di intervento.....

Codice DRG.....

Tariffa regionale ricovero (tariffa DRG in €).....

Tariffa regionale prestazione ambulatoriale (in €).....

Tariffa regionale prestazione territoriale (in €).....

5. Aspetti organizzativi legati all'uso della tecnologia

La nuova tecnologia comporta un cambiamento nel PDTA del paziente?

SI ☐ NO ☐

In caso affermativo, specificare quale

La nuova tecnologia può comportare il cambiamento di procedure organizzative?

SI ☐ NO ☐

In caso affermativo, specificare quale (ad es., impatto sulla durata della degenza, sugli accessi ambulatoriali, sulle liste di attesa, sulle infezioni intraospedaliere, ...)

Quali sono i tempi di introduzione del DM/tecnologia previsti sulla base delle valutazioni organizzative e operative?

6. Documentazione da allegare

Segnalazioni relative alla sicurezza (obbligatorio)

Dati non ancora pubblicati e autocertificazioni di pregresse esperienze applicative sperimentali e/o cliniche (se disponibili)

Budget Impact Analysis fatta secondo standard internazionali (facoltativo)

Analisi di costo-efficacia o di costo-utilità *ad hoc* fatta secondo standard internazionali (facoltativo)

IL CENTRO DI VALUTAZIONE DELLE RICHIESTE DI ACQUISTO

IL DIRETTORE GENERALE
