

UNLOCKING ACCESS

Overcoming Barriers and Harnessing Enablers for Innovative Payment Models for Pharmaceutical Innovation in Europe

Background

- Pricing and payment models play a pivotal role in balancing healthcare sustainability with patient access.¹⁻³
- As simple price discounts have insufficiently maintained this balance, several European countries have implemented innovative payment models (IPMs) to facilitate access to pharmaceutical innovations.^{4,5}
- IPM implementation faces significant barriers and critical enablers that heavily impact adoption.⁶⁻⁸
- Understanding stakeholder perceptions of barriers and enablers is essential for effective IPM implementation.⁸

Aim

To identify key barriers and enablers to IPM implementation, as perceived by stakeholders, and develop policy recommendations to strengthen enablers and address barriers.

Methods

We employed a two-stage qualitative approach to identify the barriers and enablers for five commonly used IPMs.

- We surveyed 31 experts from eight European countries and the UK, asking them to identify barriers and enablers across four phases of implementation.
- We held two virtual nominal group (NG) discussions, each focused on a selection of IPMs.
 - Participants discussed and ranked the barriers and enablers identified in the survey, scoring each between 0 and 100
 - Each session concluded with a roundtable on policy recommendations to address key barriers and leverage critical enablers.

Results: Top-Scoring Barriers and Enablers

MOST DIFFICULT BARRIERS TO OVERCOME, WITH MEAN SCORES

OBAs	IBP	IaAPs	FBRSA	PoBAs
Lack of infrastructure for data collection and monitoring (82.14)	Infrastructure and data limitations (85.00)	Legal and regulatory hurdles (81.43)	Negotiating an acceptable FRSAs design (71.25)	Negotiating an acceptable PoBAs design (83.75)
Negotiating an acceptable OBA design (71.43)	Legal and regulatory barriers (80.00)	Complex financial management (76.43)	Infrastructure and data limitations (70.00)	Infrastructure and data limitations (67.50)
Burden on clinical staff (66.43)	Designing an optimal model (63.57)	Negotiating an acceptable model (74.29)	Financial sustainability and stakeholder planning (55.63)	Challenges with relations and buy-in (64.38)

MOST IMPORTANT ENABLERS, WITH MEAN SCORES

OBAs	IBP	IaAPs	FBRSA	PoBAs
Sufficient infrastructure and funding (92.86)	Established data infrastructure and monitoring systems (85.71)	Agreed conditions of termination (85.71)	Sufficient infrastructure (89.38)	Early dialogue between stakeholders (71.25)
Clear legal and regulatory guidelines (83.57)	Change in legal framework to allow IBP (85.71)	Existing infrastructure (79.29)	Simplicity/ease of implementation (76.25)	Budget predictability and affordability (70.00)
Data accuracy and optimisation to achieve OBA's goals (79.29)	Rational design and application of IBP (68.57)	Pre-existing experience or frameworks to guide implementation (77.86)	Capacity to reduce financial uncertainty (75.00)	Enhanced financial planning and collaboration (63.13)

OBAs = Outcomes-Based Agreements; IBP = Indication-Based Pricing; IaAPs = Instalments & Amortisation Payments; FBRSA = Financial-Based Risk-Sharing Agreements; PoBAs = Portfolio or Bundling Agreements

Cross-Cutting and Model-Specific Themes

Several barriers and enablers appeared across several IPMs, revealing cross-cutting themes in implementation and potential targets for high-impact policy interventions

Cross-Cutting Barriers

- 1) Data infrastructure limitations
- 2) Negotiating an acceptable model design
- 3) Legal and regulatory hurdles

Cross-Cutting Enablers

- 1) Existing data infrastructure
- 2) Supportive legal or regulatory environments
- 3) Enablers facilitating the negotiation of an acceptable design

Barriers and enablers specific to certain IPMs reveal unique characteristics of those models.

- OBAs:** There exists a trade-off between imposing additional work on HCPs and collecting accurate, meaningful data on patient outcomes.
- IBP:** IBP's top three barriers and enablers reflected the same priorities identified across all IPMs.
- IaAPs:** IaAPs are associated with unique accounting difficulties, and there is a need for risk mitigation strategies because of its complex payment timelines.
- FBRSA:** FBRSA appear to be considered more straightforward to implement than other IPM options.
- PoBAs:** PoBAs require earlier conversations and collaboration due to countries' limited experiences implementing such payment models.

Stakeholder-specific perspectives revealed key differences in priorities

- Payers uniquely identified *financial sustainability* as a critical barrier for IaAPs. Survey responses suggest that this difference might reflect apprehension about IaAPs being used to 'obscure' unduly high medicine prices, raising long-term affordability concerns.
- For OBAs, academics highlighted *early stakeholder engagement and buy-in* as being critically important, while payers identified *willing and well-trained staff* and *pre-existing frameworks, experience and leadership* as two of the most important enablers.
 - These reflect differing priorities between those who study IPMs from a holistic perspective and those who are practically engaged with IPMs throughout the implementation lifecycle.
- Beyond the differences noted above, stakeholder groups showed consistent views on barriers and enablers.

Policy Recommendations

- There is a need to invest in shared data infrastructure that can be used across IPMs.
- Legal environments are viewed as primary enablers and major barriers across IPMs; to encourage use of IPMs, policymakers must ensure that laws and regulations allow IPMs to be operationalised.
- HTA processes should be used to identify areas of uncertainty that IPMs could meaningfully address.
- Knowledge exchange networks—including shared best practices and implementation frameworks—are important for supporting countries with less IPM experience.

Discussion and Conclusion

- Areas that affect several IPMs provide targetable objectives for flexible policy interventions aimed at increasing and enabling more efficient implementation and use of IPMs.
- The barriers considered most difficult are faced across the IPM implementation lifecycle, suggesting that successful adoption requires different types of expertise and resources across phases.
- Conversely, enablers disproportionately affect early stages of implementation, highlighting that actors must make upfront investments to harness the enablers deemed most critical.
- These findings provide a foundation for more targeted and flexible policymaking to support effective and sustainable IPM adoption.
- This study also underscores the value of addressing common implementation hurdles through international cooperation to enable effective and sustainable IPM adoption across Europe.

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