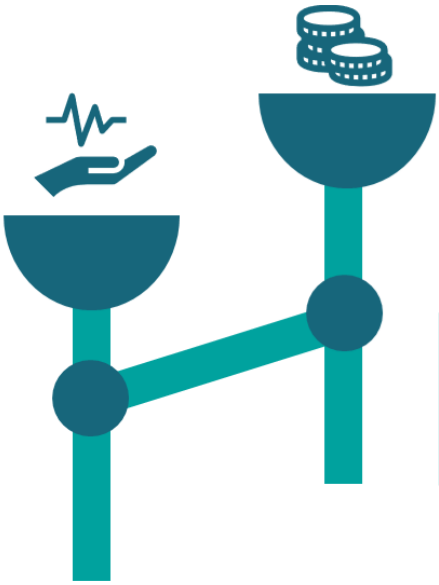
HEALTH **I**NNOVATION NE**X**T GENERATION **P**AYMENT & PR**I**CING MODELS **(HI-PRIX):**
Balancing Sustainability of Innovation with Sustainability of Health Care



HI-PRIX

M10: Key components in payment schemes for health care innovations included in health system provision

WP5: Novel payment schemes and methods and planning for purchasing and delivering services that incorporate novel technologies or products.

Task 1. Identifying and assessing the payment and non-payment models and incentives to incorporate innovation in health care delivery processes.

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COVER PAGE

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LIST OF ABBREVIATIONS

ATMP	Advanced Therapeutic Medicinal Product
DRG	Diagnostic-related Group
EBRD	European Bank for Reconstruction and Development
EEA	European Economic Area
HI-PRIX	Health Innovation Next Generation Payment & Pricing Models
NTAP	New Technology Add-on Payment
OECD	Organization for Economic Cooperation and Development
PAHO	Pan American Health Organization
SWOT	Strengths, weaknesses, opportunities, threats
VBP	Value-based Pricing
WHO	World Health Organization
WP	Work Package

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EXECUTIVE SUMMARY

The Health Innovation Next Generation Pricing Models (HI – PRIX) project, launched in January 2023 under HORIZON EU in Milan, represents an ambitious initiative aimed at revolutionising the payment and pricing strategies for health innovation. Drawing upon the collective expertise of 18 partners from across 10 European countries, this three-year collaborative project aims to develop a detailed map of novel pricing and payment strategies, assess the impact of these strategies on key industry metrics, and address stakeholder concerns about the balance between cost, innovation, and accessibility.

This milestone report focuses on Work Package (WP) Five Task One, which addresses the integration of innovative technologies within healthcare delivery processes. Moving beyond traditional isolated approaches to coverage and payment, WP5 emphasises the real-world application of innovations within care pathways, recognising the interconnectedness of innovation's effectiveness and cost to patients' ability to access innovative technologies. Task One is an initiative dedicated to identifying and assessing both payment and non-payment models and incentives. Examining existing and theoretical financial and provision models, Task one aims to reveal how innovative medical technologies can be integrated into healthcare delivery, factoring in various health technologies and system archetypes within OECD and EEA countries. Overall, Task One aims to summarise the financial and non-financial incentives for system integration of innovative medical technologies and identify contextual conditions for their success.

The methodology of WP5 involves a mixed-methods approach, starting with a scoping literature review to offer a complete picture of the current incentives. Following this, a SWOT analysis was conducted to evaluate the success or failure of these incentives in various contexts, including health system designs and therapeutic areas. The scoping literature review identified eight incentive mechanisms, six financial and two non-financial. Subsequently, eight SWOT analyses were conducted, one for each incentive mechanism identified. This analysis revealed each mechanism's strengths, weaknesses, opportunities, and threats in relation to the health system and therapeutic areas in which they are deployed.

Overall, this task aims to provide policymakers with insights into appropriately leveraging successful models and overcoming challenges to equitable access to medical innovations. The findings from WP5 task 1 contribute to the broader HI – PRIX initiative, aligning innovation with accessibility and setting the stage for a future where medical advances are available to all.

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Introduction

The Health Innovation Next Generation Pricing Models (HI – PRIX) project, inaugurated in January 2023 in Milan under HORIZON EU, is a three-year collaborative effort, drawing on the expertise of 18 partners from 10 European countries, including a diverse array of academic institutions, public authorities, healthcare providers, and independent research organisations.

HI-PRIX's objectives are threefold: firstly, to develop a comprehensive map of novel pricing and payment strategies applicable across various technology classes, therapeutic domains, and healthcare settings; secondly, to investigate the impact of these strategies on key industry metrics such as competitiveness, innovation, equity, and affordability; and thirdly, to address the challenges and concerns of stakeholders — payers, manufacturers, healthcare professionals, and patients — on the intricate balance between cost, innovation, and accessibility. The HI-PRIX research efforts are crucial in shaping a robust and equitable healthcare infrastructure and policy environment that fosters innovation, while ensuring that advancements remain accessible and affordable. This report focuses Work Package (WP) five Task one, concerning the incentive mechanisms for integration of innovative technologies within healthcare delivery processes.

Traditionally, the coverage and payment for innovative medical technologies have been approached in isolation, separated from the continuum of care for which they are designed. Recognizing that the true effectiveness and cost of innovation are intrinsically linked to their application within a care pathway, this WP seeks to advance beyond traditional methodologies by considering real world applications.

Task one is an initiative to identify and assess the payment and non-payment models and incentives that facilitate the incorporation of innovation into healthcare delivery. Through a review of existing financial and non-financial incentive models, the task aims to shed light on how innovative medical technologies can be effectively integrated into the healthcare framework in various health system archetypes. This exercise encompasses diverse incentive models, including theoretical and real-world financial and non-financial incentives, as well as diverse health technologies,

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including drugs, devices, diagnostics and digital health solutions, and health system archetypes, across OECD and EEA countries.

Methods

WP5 Task 1 employs a mixed methods approach. First, a scoping literature review was conducted to provide a summary of the current financial and non-financial incentives that aim to incorporate medical technology innovations into health systems and improve patient access. Subsequently, a series of SWOT analyses was conducted to understand the conditions under which these incentives thrive or underperform. The end goal of this process is to formulate a series of takeaways on the viability and practicality of each incentive model, considering the variances in healthcare systems and the unique characteristics of different medical technologies and therapeutic areas.

In the context of this research, an "innovative medical technology" encompasses innovations beyond pharmaceuticals. Though pharmaceutical innovations are eligible for inclusion in our analysis, health technologies include a broad scope of innovations, including medical devices, digital health technologies, advanced diagnostics, novel vaccines, and advanced therapeutic medicinal products (ATMPs).

Scoping Literature Review

The scoping literature review conducted under WP5 Task 1 constitutes a foundational component of the research methodology, designed to provide a summary of incentives for integrating innovative therapies into healthcare delivery systems. The intention was to obtain insights from a wide array of peer-reviewed and grey literature, aiming to identify and characterise financial and non-financial incentive mechanisms that have been theoretically proposed or practically applied within diverse health system frameworks across the OECD and EEA.

Our search strategy included databases such as PubMed, Scopus, Web of Science, and EconLit, to yield a substantial pool of peer-reviewed literature. In parallel, a grey literature search was conducted to identify insights from key international organisations and to uncover additional resources through targeted Google

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searches. Organisations' websites searched for grey literature included the OECD iLibrary, the World Bank, the World Health Organization (WHO), the Pan-American Health Organization (PAHO), the European Bank for Reconstruction and Development (EBRD), and the European Commission. This dual-pronged approach ensured that our review was not limited to academic discourse but also included practical insights from the field, including reports, policy briefs, and working papers that may not have undergone the traditional peer-review process.

The inclusion criteria were carefully crafted to ensure the relevance and specificity of the literature. We sought studies that discussed either theoretical models or actual examples of the implementation of incentive programs aimed at integrating innovative treatments or therapies into the healthcare delivery process and improving patient access to innovative technologies. This encompassed a broad spectrum of mechanisms, ranging from impact bonds to risk-sharing agreements and novel population health management approaches. Models of health system incorporation were only included if they examined strategies and incentives of a health technology post-marketing approval. Incentives for research and innovation pre-marketing authorisation, including public-private partnerships, were not eligible for inclusion.

Inclusion Criteria	Exclusion Criteria
1. Research discusses either theoretical modelling or actual implementation of an incentive program, a financial or non-financial mechanism to incorporate an innovative treatment or therapy in the healthcare delivery process 2. Study countries: OECD and EEA 3. CEA/budget impact studies that inform implementation 4. Pharmaceuticals, medical devices, ATMPs, novel vaccines, digital health technologies, and advanced diagnostics 5. Big data cases to do with innovative service delivery 6. English language texts 7. Literature reviews	1. Not an OECD or EEA country 2. Covid-19 vaccine research 3. CEA/budget impact without implementation mechanism 4. Research discusses stages before implementation/post-market authorization and does not discuss implementation 5. Budget impact analyses and CEAs that do not discuss implementation or financing tools 6. New vaccines without a novel mechanism of action, or associated with a financing, or delivery program 7. editorial/commentary/opinion pieces

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Our search terms were strategically chosen to capture the full breadth of innovation in healthcare (see Figure 1). We further refined the specificity of our search by focusing on literature that discussed the integration, implementation, and regulatory and policy environments that underpin these mechanisms.

Figure 1. Scoping Review Search Terms

("Innovative therapeutic*" OR "innovative medical device*" OR "digital health technolog*" OR "digital therapeutic*" OR "precision medicine" OR "personalized medicine" OR "personalised medicine" OR "gene therap*" OR "cell therap*" OR "stem cell therap*" OR "regenerative medicine" OR immunotherap* OR vaccine* OR antibiotic* OR genomics OR pharmacogenomics OR nanomedicine OR biotechnolog*)

AND

(Reinsurance OR "impact bond*" OR "outcomes-based agreement*" OR "performance-based agreement*" OR "pay for performance" OR "subscription model" OR "annuity payment*" OR "Risk-sharing agreement*" OR "value-based pricing" OR "innovative financing" OR healthcoin OR crowdfunding OR "public-private partnership*" OR capitation OR annuities OR amortization OR "population health management")

AND

(Integration OR Implementation OR regulat* OR "policy environment" OR "stakeholder engagement" OR access OR affordability OR sustainability OR adoption OR equit*)

The selection process for the literature included was rigorous. Following the initial search, duplicates were removed, and titles and abstracts were screened against our inclusion criteria. The selected studies underwent full-text screening to confirm their relevance, ensuring a focused and in-depth review. The final selection provided a comprehensive representation of the landscape of incentives for healthcare innovation, which serves as a foundation for the subsequent SWOT analyses.

The breadth of the scoping review was intentionally wide, including an international perspective with studies from OECD and EEA countries with varied health system designs. This viewpoint allowed for considering a wide range of healthcare systems, regulatory environments, and cultural contexts, which are critical to understanding the transferability and scalability of the various incentive mechanisms. The literature was confined to English-language sources to maintain consistency in analysis and interpretation.

SWOT Analysis

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The second stage of the mixed methods approach included a series of SWOT analyses to evaluate each identified incentive mechanism's strengths, weaknesses, opportunities, and threats. This assessment considers the complex relationships between the therapeutic area, health system design, and the broader policy environment. The literature review results identified various financial and non-financial incentive mechanisms to incorporate innovative medical technologies into health systems and improve patient access. An additional short, targeted search was conducted to summarise the health system characteristics of all countries discussed in the included literature. This exercise provided relevant background information to contextualise the SWOT analyses. Each identified incentive underwent a SWOT analysis that considered its relative successes within therapeutic areas and types of health systems.

Coordination with WP1

To ensure efficiency and avoid duplication of efforts, WP5 Task 1 was coordinated with WP1. Task 1.1.1 of WP1 developed a taxonomy matrix to characterise pricing and payment schemes for health technologies, and Task 1.1.2 conducted a scoping literature review of these financial incentives. By aligning the objectives and methodologies of both tasks, the project ensured a cohesive and integrated approach to analysing innovative health technology financing. While WP1 sought to identify innovative pricing and payment mechanisms, WP5 sought to investigate the extent to which financial and non-financial incentives are used to improve health service delivery and patient access. While WP1 investigated barriers and enablers of financial incentives for innovative technologies, WP5 investigated the relative strengths and opportunities of certain financial and non-financial incentives that aim to integrate innovations post-marketing approval. WP1 provided insights for WP5, illustrating the innovative financial mechanisms themselves, while WP5 illustrates how these incentives can enable the adoption of innovative medical technologies.

Results

2.1 Scoping Literature Review

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WP5 Task 1 has endeavoured to methodically capture a diverse range of scholarly articles and grey literature to form a comprehensive understanding of financial and non-financial incentives for incorporating innovative therapies into healthcare systems. The search across PubMed, Scopus, Web of Science, and EconLit generated a cumulative total of 1,696 articles (see Figure 2). During de-duplication, 541 duplicates were removed, leaving 1,155 unique records that underwent a rigorous title and abstract screening process. This stage resulted in 1444 papers being excluded. Consequently, 117 studies were sought for retrieval. Full-text PDFs were not available for 22 papers, which were excluded. The remaining 95 studies were individually assessed for eligibility against the inclusion/exclusion criteria above. 30 studies (31.6%) were excluded as they did not discuss an incentive to promote the implementation of innovations into healthcare delivery in the post-marketing authorisation stage. 16 (16.8%) of the assessed studies were excluded as they were not peer-reviewed (commentaries, editorials, dissertations, opinion pieces, conference proceedings). Finally, 1 (1.1%) study was excluded as it was a cost-effectiveness analysis, and 1 (1.1%) because the country of focus was out of scope.

The inclusion of grey literature is critical to the review as it often includes influential reports and policy papers that provide practical insights into the application of incentive models, supplementing the academic narratives obtained from peer-reviewed literature. Our examination of the OECD iLibrary resulted in 249 documents, with 2 advancing to full-text screening. The World Bank's resources provided 421 results, though none met the criteria for further consideration. From the WHO, we identified 4 out of 100 documents that were applicable to our research aims. Further, we identified 2 reports from international organisations which met our screening criteria. Despite the extensive search efforts within PAHO, EBRD, and the European Commission databases, no documents from these sources were selected for the next review phase. The above left us with 8 reports to retrieve and assess for eligibility. All reports were available online. Following the full-text screening, three (37.5%) reports were excluded as they did not discuss the implementation of incentives or focused on the pre-marketing authorisation stage. One (12.5%) report was also excluded as it was an editorial piece.

Figure 2. PRISMA Diagram

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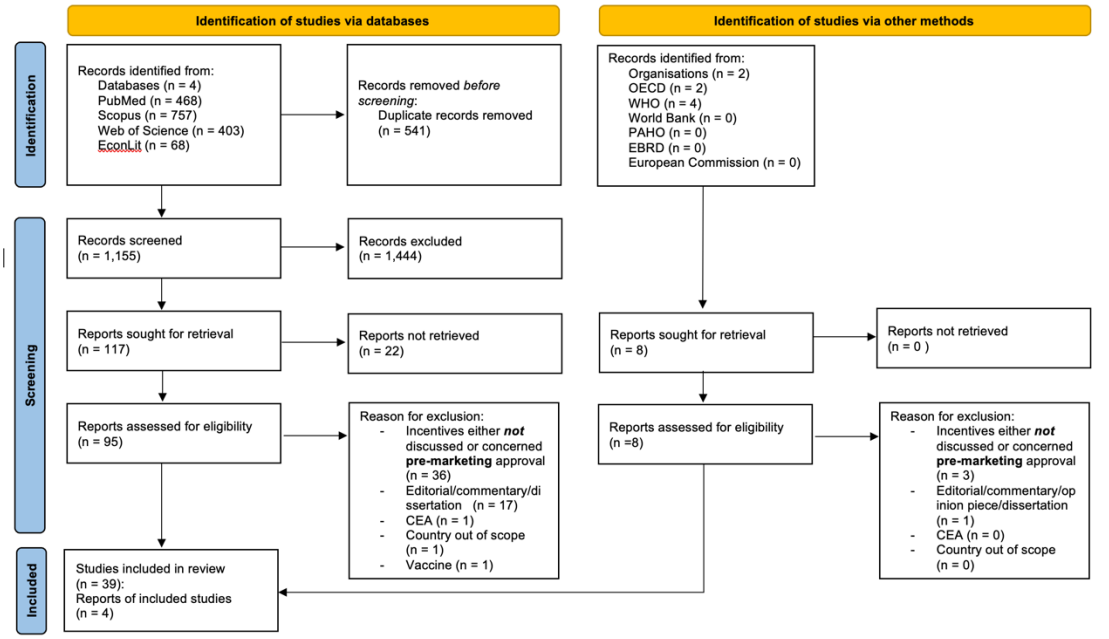

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/

Abbreviations: **OECD** = Organisation for Economic Cooperation and Development; **WHO** = World Health Organisation; **PAHO** = Pan American Health Organisation; **EBRD** = European Bank for Reconstruction and Development

The selected studies and reports cover incentives for various countries and geographical areas. These include Australia (n = 1), the European Union (n = 9), the USA (n = 16), the EU4 (Italy, Spain, Germany and France) + UK (n = 1), the UK only (n = 8), Sweden (n = 2), Italy (n = 4), Switzerland (n = 2), Spain (n = 2), France (n = 2), Germany (n = 1), Israel (n = 1), OECD (n = 2), Pan-European Region (n = 2), no country-specific focus (n = 2). Note that each paper may cover multiple countries or regions; thus, the total number of countries discussed will be greater than the number of studies and reports included.

There are two key features of the incentives described in the studies and reports we selected, namely whether the mechanism being discussed was real or theoretical, and whether it was financial or non-financial. 11 (28.2%) of the included studies outlined incentives with theoretical implementation, 23 (59%) with real-world implementation, and five (12.8%) comprised both. Further, 31 (79.5%) of the included studies concerned a financial incentive, three (7.7%) a non-financial one, and five (12.8%) described a combination of both. Three (75%) of the included reports assessed real incentive financial incentive mechanisms, and one (25%) a real non-financial incentive mechanism.

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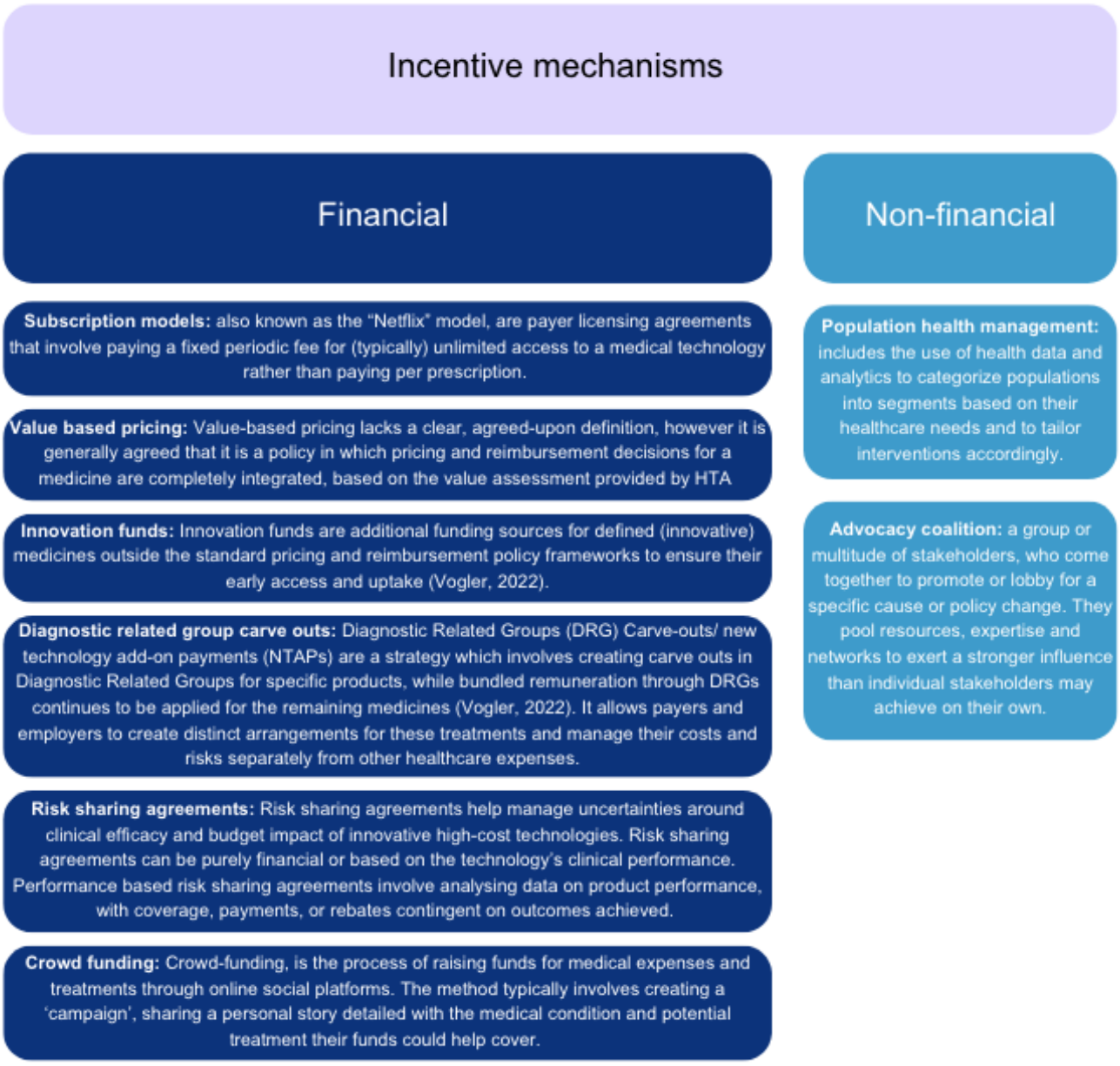
Incentive Mechanisms

Eight incentive mechanisms were identified in the literature review, six financial and two non-financial. These mechanisms are defined in the figure below (See Figure 3).

Figure 3. Incentive Mechanisms



2.2 SWOT Analysis

Health System Context

It is important to highlight that each country has a distinctive healthcare system with different financing mechanisms and approaches to care delivery. Therefore, it is

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important to discuss each country's characteristics in detail to facilitate the understanding of the subsequent SWOT analyses. The following background information is the result of a targeted search.

Australia presents a hybrid healthcare system. Medicare provides access to emergency care, consultations and routine hospital treatment to all citizens and residents for free at the point of use. It is paid through general taxation. Elements of a single-payer system are combined with high utilisation rates of private health insurance(1). In Australia, most drugs are either fully or partly funded under the Pharmaceutical Benefits Scheme (PBS), which reimburses drugs recommended by the Pharmaceutical Benefits Advisory Committee (PBAC). Medicines for rare and ultra-rare diseases life-threatening diseases which would not meet the PBS cost-effectiveness threshold may be financed under the Life Savings Drugs Program (LSDP)(2).

On the contrary, Italy has a predominantly tax-based, single-payer healthcare system, the Sistema Sanitario Nazionale (SSN). The healthcare budget and delivery are managed at the regional level, which may give rise to access inequalities. Drugs are evaluated by the national HTA Agency (AIFA),and can be rejected or positively reimbursed at the national (hospital) level, or regional level. In the latter case, each region decides whether or not to reimburse the treatment, and whether to impose additional restrictions. Italy has well-established legislative pathways to guarantee early access to innovative treatments for rare diseases (Law n.648), as well ringfenced funding for innovative and oncological drugs (Fondo per Farmaci Innovativi)(3).

The UK's health system is similarly structured to Italy's, funded through general taxation. It is, however, significantly more centralised. Drugs recommended by the National Institute for Health and Care Excellence (NICE) are made available across England and Wales, irrespective of the region of residence, through the National Health Service (NHS). Scotland follows a similar system under the Scottish Medicines Consortium (SMC) and NHS Scotland. Comparably to Italy, the UK also has dedicated schemes (Cancer Drugs Fund) to fund oncology medicines that would not meet the traditional cost-effectiveness thresholds or evidential requirements set by NICE(4). The Innovative Medicines Fund is a similar scheme designed to provide faster access to

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non-oncology drugs to patients in England and Wales. Scotland has a separate funding stream to reimburse high-cost drugs (mostly orphan) called the New Medicines Fund(5).

Conversely, France has a healthcare system predominantly based on social health insurance. Statutory Health Insurance covers all legal residents, and is funded through social security contributions. France lacks dedicated funding sources for expensive drugs like Italy or the UK. However, a large number of expensive therapies administered in hospitals are funded by the national government through an *add-on list*. This is in contrast with the vast majority of drugs, which are reimbursed through hospital budgets, thereby ensuring more equitable access(6).

Similarly to Italy, Spain has a single-payer (Sistema Nacional de Salud – SNS) highly decentralized healthcare system, with budgets managed by its 17 autonomous regions(7). Contrary to the countries analysed above, Spain does not provide ringfenced funding for orphan, oncology or innovative drugs.

Sweden's healthcare system shares several characteristics with Spain's: it is funded through general taxation, but it is decentralised, with finances and care delivery being managed by its 21 regions(8). The central government sets the overall health policy objectives, but financing is raised mainly at the regional level(9). Sweden has been an early adopter of HTA, establishing The Dental and Pharmaceutical Benefits Board (TLV) in 2002. Its role is to conduct HTA for inpatient and outpatient drugs; however, it is only responsible for reimbursement decisions on outpatient drugs
). A council representing all regions (NT Council) is responsible for reimbursing all inpatient drugs and generally follows the recommendation provided by TLV(10). There are no funds earmarked for innovative drugs in Sweden.

The healthcare systems of the four remaining countries relevant to this study all encompass high levels of Private Health Insurance coverage combined with Social Health Insurance elements. Israel has a National Health Insurance (NHI) program which covers all legal residents. It is a centralized system funded through general taxation and social security contributions. Individuals can enroll in one of four non-profit insurance providers that offer the same basic benefits(11). Over 80% of

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individuals also hold Voluntary Health Insurance (VHI) through their health plan or a commercial provider. Israel does not have a dedicated fund to finance innovative or high-cost technologies. Instead, it has a "healthcare basket" which includes all the drugs that insurers must provide under the NHI. The basket is regularly updated, and funding increased.

In contrast with Israel's centralised health insurance system, Germany's is decentralised and complex, divided between federal and state-level entities(12). Most individuals must enroll in a sickness fund funded by Statutory Health Insurance (SHI). This is a levy applied to the gross income of all individuals, and it is also supplemented by contributions from employers. Notably, general tax revenues may also be used to compensate the non-profit sickness funds that experience unexpected and large losses(13). In Germany, the pricing and reimbursement mechanism also differ substantially from those of the countries previously described. Overall, sickness funds have to reimburse prescription drugs unless they are placed on a "negative list" compiled by the Federal Joint Committee (G-BA), whose role is to advise on the inclusion/exclusion of prescription drugs to be reimbursed by the SHI(14). Pharmaceutical companies can freely set prices at launch (conditional on positive G-BA recommendation), and such prices will be maintained for the following twelve months. At that point, prices will be renegotiated based on the assessment of additional therapeutic benefit compiled by AMNOG (Arzneimittelmarktneuordnungsgesetz)(15). It should be highlighted that drugs which received orphan designation by the EMA do not have to be positively recommended by the G-BA to be reimbursed. In other words, reimbursement through SHI is secured by virtue of EMA approval, with free pricing available to manufacturers for as long as the total expenditure on the drug remains below 50 million euros per year(15). This creates a favourable reimbursement environment for manufacturers, promoting availability to patients and faster access.

The Swiss healthcare system shares some similarities to Germany's. It is decentralised, with cantons (regions) being predominantly responsible for care delivery(16). Individuals are mandated by law to enrol in a private non-profit health insurance scheme. As a result of the introduction of mandatory enrollment into the basic health insurance plan, as well as the introduction of subsidies for low-income families, health coverage is almost universal. For drugs to be reimbursed, they have to be placed on

a positive reimbursement list (List of Pharmaceutical Specialties - LS) approved by the Federal Office of Public Health (FOPH) upon a recommendation by the Federal Medicines Commission (FMC)(17). No ring-fenced funds exist for drugs that do not meet the inclusion on the LS as set out by the FMC.

Finally, the United States' healthcare system presents a complex combination of public and private elements. Medicare, which mostly covers individuals aged 65+, and Medicaid, which supports low-income individuals, are two major government-funded schemes, the majority of Americans obtain health insurance either through their employers or commercial providers. This creates varying levels of coverage and access to treatments, which may lead to health inequalities(18).

SWOT Diagrams

The following diagrams reflect the strengths, weaknesses, opportunities and threats identified from the literature review. The first six—subscription models, value-based pricing (VBP), crowdfunding, innovation funds, diagnostic-related group (DRG) carve-outs/new technology add-on payments (NTAPs), and risk-sharing agreements—are financial incentives and the final two—advocacy coalitions and population health management—are non-financial incentives.

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1. **Subscription models:** also known as the "Netflix" model, are payer licensing agreements that involve paying a fixed periodic fee for (typically) unlimited access to a medical technology rather than paying per prescription.

Strengths	**Weaknesses**
Therapeutic Areas: Antibiotics (19), Hepatitis C (20), rare diseases (21) Mechanism design: • Increased treatment coverage and patient access to all those that need it (19) • Predictable budget impact for health systems • Stable revenue for pharmaceutical companies (19) • Improved affordability and incentivized innovation for R&D (19)	Mechanism design- • Long-term commitment
Opportunities:	**Threats:**
Mechanism design- • Education and awareness • Collaborative data collection and insight sharing (i.e. prescription volume)	Mechanism design- • Data and monitoring requirements: effective implementation may require robust data collection, monitoring, and evaluation mechanisms to track patient outcomes, treatment access, and cost-effectiveness. Not all health systems are equipped for this and implementing data infrastructure and monitoring systems is a significant undertaking.

Subscription models are a strong option for therapeutic areas with variable patient demand but high need, as well as areas with high-cost therapies with curative potential. Subscription models provide predictable budget impact for health systems, predictable revenue for pharmaceutical companies, and incentivised innovation during R&D.

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Real-world examples:

a) Subscription models have been implemented for Hepatitis C in Australia. The Australian government finalised a five-year contract in 2016 with five manufacturers for the unlimited use of Hepatitis C medicines. The government paid a fixed sum of 1 billion AUD for the period between 2016-2021(19).

b) In the US, Louisiana also entered into a subscription-based model for Hepatitis C medicines (19).

c) The UK and Sweden are currently piloting the model for novel antibiotics, with the hope of it having a positive impact on R&D in the antibiotic space (19).

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2. **Value-based pricing:** lacks a clear, agreed-upon definition, however it is generally agreed that it is a policy in which pricing and reimbursement decisions for a medicine are completely integrated, based on the value assessment provided by HTA (19).

A fully-fledged VBP system is thought to include value consideration alongside other factors, such as manufacturing and R&D costs. An example of value-based pricing includes differential pricing, which allows tailored pricing based on the value of the medicine in different indications .

Value-based pricing also includes the theoretical diagnosis confirmation model, a dual pricing model for novel antibiotics (25). In the model, if a decision is made to de-escalate the novel therapy on or before diagnostic results are received (approximately at four days), then the price for the first few would be set to an 'empiric' price, which is lower than the full novel therapy price, but higher than other less expensive choices (i.e. generics). Comparatively, if the novel therapy is used after the fourth day (i.e. after diagnoses are traditionally received and the physician has deemed it necessary to remain on the antibiotic), a price reflecting the full value of the drug will be charged for the full course.

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Strengths:	**Weaknesses:**
Therapeutic Areas- bacterial infection (25), Oncology (26) Mechanism design- • Encourages high impact innovation: promotes pharmaceutical companies to focus on products with high clinical impact • Supports healthcare sustainability: promotes the use of resources to be allocated to treatments that offer significant clinical benefits • Increasing transparency as VBP requires clear criteria for defining value (Godman et al, 2021) • Encourages investment in R&D in follow-on indications with smaller potential incremental benefit (24) • Data collection required can help beyond the individual patient (25) Mechanism design – indication-based pricing • Offers increased cost-effectiveness by reflecting the value per indication (22,24) • Improved access in indications that are not cost-effective if the price is the same across indications (23) Mechanism design- Diagnosis confirmation model for hospital antibiotic use (25) • Encourages the optimum use of novel antibiotics, and therefore minimise the development of drug resistance	Mechanism design- • Implementation complexities including administrative complexities, equity considerations, data requirements, and transparency concerns (22) • Difficult to determine the 'true' value of a treatment due to difficulties measuring and agreeing on outcomes that reflect clinical benefit (26) • Potential for VBP to result in increased overall healthcare expenditures if not managed properly (26) • Concerns that the use of value assessment as the sole basis for reimbursement/pricing decisions means that further important components (i.e. need, prevalence and affordability) are disregarded as being distinct from value (19) Mechanism design- Indication based pricing • Assessing the value in each indication is difficult to get right because it requires comprehensive data and could result in equity issues if not calculated correctly (22) • Could potentially lead to higher prices for patients that benefit the most, especially for areas where there are already high patient co-payments (26) • Concern that if the low value indication is launched first, the cost of developing the high value indication may be prohibitive (26)
Opportunities:	**Threats:**
Mechanism design- key considerations	Mechanism design-

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• Incentives need to be designed to encourage the collection and use of reliable data including indication data eg in Italy, hospitals are incentivised to collect utilisation data for MEAs (26) • Registries need to be improved to allow incorporation of real world evidence into reimbursement and funding decisions (26) • Coordination needs to be enhanced at all levels for effective systems - this includes national level and regional level data, especially if there are already different prices for medicines across regions in a country • Needs to be better transparency regarding who benefits from the approach (26) • Contractual pricing arrangements need to be flexible in order to take into account of any new evidence surrounding existing or new indications (26) • Needs to be recognised need for further research to model potential budget impacts of differential pricing (26)	• Requirement of robust data infrastructure that collect data on indications as well as utilisation data (26) • Requirement of sophisticated HTA capabilities and infrastructure (26) • Resistance from industry if they threaten traditional pricing models which have resulted in high prices for their treatments which may not meet the predefined value criteria (26) Health system capabilities- • Different European nations are at different stages with their IT systems, especially regarding linking medicines dispensed with indications (26) • Different prices charged at the point of sale depend on the ability to track indications for which the drug is prescribed, which is not always possible within current data management infrastructures. Without this infrastructure, the administrative burden may outweigh the benefits (24) o DRG systems have experienced manipulated diagnoses, also known as up-coding (26) • High costs of data collection to support indication-based pricing decisions (22) • In the case of combination-based pricing there is a risk that the manufacturer of the anchor drug will not agree to lower the price when used in combination with the newer drugs (23)

Real world examples:

a) Sweden is the only country with a fully-fledged VBP system. However, severql other countries utilise indication-based pricing.

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b) Differential pricing per indication applied ex-ante (i.e. discounting at the point of sale) is used in Estonia and Latvia (22). Differential pricing per indication applied ex-post (i.e. through rebates) is used in Switzerland, Italy, France and Belgium; however, the ability to track use by indication is not available in Switzerland and is only available for certain indications in France and Belgium (22). Italy uses indication-based pricing, with incentives in place for the hospitals to collect utilisation data by indication as part of MEAs for new medicines (26)
c) A single weighted price, calculated based on the weighted average price per indication in the anticipated treatment populations, is available in Australia and Germany without the ability to track use by indication (22).

VBP requires strong HTA capabilities and comprehensive data infrastructure to be effectively implemented. It promotes high-impact innovation and sustainable health system financing but is complex to implement. Indication-based pricing may be controversial to some as it can cause equity issues if the technologies are not accurately valued. It can be difficult to determine the 'true' value of a treatment due to difficulties measuring and agreeing on outcomes that reflect clinical benefit. Decision-making transparency is needed alongside incentives to encourage data collection.

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3. **Crowd-funding:** the process of raising funds for medical expenses and treatments through online social platforms. The method typically involves creating a 'campaign', sharing a personal story detailed with the medical condition and potential treatment their funds could help cover.

Strengths:	**Weaknesses:**
Therapeutic Areas- Oncology Mechanism design- • Helps with out of pocket costs associated with medical care (27) • Helps improve access to clinical trials they otherwise could not afford, potentially speeding up development through sufficient enrolment in clinical trials (27) • Crowdfunding campaigns can increase public awareness and education about new therapies (27)	Mechanism design- • Equity issues as disproportionately available to the well connected, or social media savvy (27) • Incomplete information – campaigns often do not fully inform about the significant risks or success rates of the therapies, specifically CAR-T), which can lead to misinformed contributors and patients (27) • Uncertainty about the actual use of the funds donated (27)
Opportunities:	**Threats:**
Mechanism design- • The necessity of crowdfunding for some patients to participate in clinical trials calls for greater attention to the obligations of clinical trial sponsors increase equitable access to the such as covering non-medical costs associated with clinical trials (27) • The visibility of the financial toxicity of care through crowdfunding campaigns could influence healthcare policy reform to improve coverage and access (27)	Mechanism design- • Potential worsening of health disparities if access to innovative treatments relies on crowdfunding • Provides patients with access to unproven medical interventions which are not covered by the health system

Real-world example: Crowdfunding is commonly used within the United States to cover out-of-pocket medical costs.

Crowdfunding is an unregulated financial mechanism with no safeguards and major equity issues. It is not uncommon for it to be

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used for unvalidated and unregulated medical treatments. Donated money goes into private accounts, and there is no certainty that funds will ultimately be used for medical care. Individuals with the best 'marketing' skills of their story, social media savvy or connections are likely to get the most exposure and funds.

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4. **Innovation funds**: additional funding sources for defined (innovative) medicines outside the standard pricing and reimbursement policy frameworks to ensure their early access and uptake (Vogler, 2022).

Strengths	**Weaknesses**
Therapeutic Areas: oncology, ATMPs, rare diseases, gene therapies *Mechanism design:* • Direct financial support: earmarked funding sources which support development and implementation to innovative health technologies which may otherwise have been unaffordable for health systems (19) • Innovation encouragement: incentivise industry to develop and implement novel treatments, particularly for complex diseases where innovation is needed • Rapid implementation: by offering a separate pathway, earlier access can be facilitated compared to traditional funding mechanisms which are often limited by bureaucratic procedures and funding constraints (19)	*Mechanism design:* • Unclear whether innovation funds actually support access to innovation or whether they provide access to medicines which are not cost-effective and forego the proof of evidence (19) • Often limited scope, where funds are often targeted at specific diseases/treatments which can neglect other equally important areas • Risk of bias in the selection process for which innovations receive funding, decision-makers may be biased towards high-profile diseases or those with strong advocacy groups (28) • Weaken steering control of policy makers: innovation funds can require decision-making with a lack of evidence(19)
Opportunities	**Threats**
Mechanism design: • Link of innovation fund with a managed access agreements: fund drugs for a certain time period to enable real world data collection to resolve uncertainties in their assessment (19) • Given the risks of funding through separate budgets, at a minimum, mitigation measures should be put in place to ensure that clear eligibility criteria are defined and that regular monitoring and evaluation are conducted (19)	*Mechanism design:* • Financial unsustainability: dependency on finite financial resources makes innovation funds vulnerable to economic downturns (19) • When HTA is waived for products in innovation funds, pharmaceutical companies may be incentivised to charge higher prices (19)

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• Public backing, via concerted and coordinated patient foundation group advocacy, may help to support such investment (28)	

Real world examples:

a) In England, the Cancer Drug Fund (CDF) was introduced in 2010 to fund oncology medicines that the NHS would not normally cover, i.e. they were not considered cost-effective or NICE had not completed their HTA yet (19).The CDF experienced overspending in 2013-2014 as it was covering drugs with no proof of benefit for prolonged periods. In 2016, it was reformed to be linked to a managed access agreement, whereby the fund would pay for oncology medicines for a maximum of two-years to enable data collection for proof of benefit. In 2021, the Innovative Medicines Fund was established to enable funds and early access to potentially life-saving new treatments. It operates in the same way as the reformed CDF, i.e. funding is provided for the technology whilst data is collected and an HTA is conducted.

b) In Belgium, the Special Solidarity Fund exists to fund Orphan medicines and serves as a safety net to offer temporary funding for patients who have exhausted all other public and private reimbursement options at national, European or International levels.

c) In Croatia, the Especially Expensive Medicines Fund is typically used to pay for biologics for treating cancer, autoimmune and rare diseases. MEAs are often implemented for medicines on the list.

d) In Italy, two Fondi Innovati existed, one for innovative oncology medicines and one for innovative non-oncology medicines. However, in 2022 they were merged into a single fund. The fund provides financing for eligible medicines for 36 months. Eligibility criteria include unmet medical need, added therapeutic value and robustness of evidence. Eligible medicines are also provided with further benefits, such as exemptions from discounts and paybacks, alongside direct access to the market.

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Innovation funds play a unique role in implementing innovative technologies and can be used with other mechanisms. Innovation funds are often influenced by patient advocacy groups and can be biased towards 'high-profile' diseases. Additionally, to improve early access to potentially life-saving treatments, innovation funds are often linked with MEAs to allow manufacturers to collect more evidence on their proof of benefit, whilst enabling fast access. The initial organisation of the Cancer Drugs Fund in England showcases the risk of over-spending if there is no time limit in place for innovations to be reimbursed by innovation funds. They are not a sustainable method of financing but rather provide short-term options to enable early access to medicines.

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5. **Diagnostic Related Groups (DRG) Carve-outs/ new technology add-on payments (NTAPs)**: This strategy involves creating carve-outs in Diagnostic Related Groups for specific products while bundled remuneration through DRGs continues to be applied for the remaining medicines (19). It allows payers and employers to create distinct arrangements for these treatments and manage their costs and risks separately from other healthcare expenses.

Strengths:	**Weaknesses:**
Therapeutic Areas- Gene therapies, orphan drugs, new antibiotics, oncology medicines, *Mechanism design*- • Helps manage the financial risk for payers and employers associated with high-cost treatments by contracting a third party that assumes the reimbursement risk, making it easier to cover expensive drugs without compromising a plan's affordability (21) • Provide financial incentives for hospitals to adopt more expensive technologies that would not be adequately reimbursed under DRGs (29) • Help ensure separate funding early after marketing authorisation (19) • Encourage innovation through the provision of an alternate reimbursement schemes for high-cost medicines (19)	*Mechanism design*- • Potential administrative burden with determining eligibility for DRG carve outs/NTAPs and managing multiple payment streams *Therapeutic areas- antibiotics* • May not fully address the financial barriers to new medical technologies, especially where the cost of innovation is high relative to the reimbursement provided (29)
Opportunities:	**Threats:**
Mechanism design- • With the development of novel therapies, carve outs allow payers to adapt and offer treatments without destabilising the current payment structures (21) • Defining clear eligibility criteria and monitoring whether medicines still comply with the defined prerequisites is critical to using these incentives (19)	Mechanism design- • Requirement of digital infrastructure and monitoring mechanisms in place

Real-world examples:

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a) DRG carve-outs are utilised in France under the Liste en Sus. To be eligible, the medicine must predominantly be used in hospitals, have important therapeutic benefits and have a price too high to be covered by the DRG system. As soon as medicines no longer meet the criteria for the list, they are meant to be removed; however, due to the administrative burden, it has been seen that in practice, it is not the case. Medicines no longer meet the criteria but will not be moved back to the standard system, thus resulting in cost-inefficiencies and the use of funds which could be used elsewhere (19).
b) Austria has an additional fund for DRG carve-outs. The fund, called Single Medical Procedures, only includes oncology medicines (19).
c) Germany has fund for DRG carve outs called Neue Untersuchungs- und Behandlungsmethoden (NUB). Hospitals are able to request new technologies to be included in the list for upto one year to accelerate innovation, as consideration of the new medicines in the updated DRG calculations would take too long (19).
d) New Technology Add-on Payments are additional payments provided under Medicare's hospital inpatient prospective payment system for acute care hospitals.

DRG carve outs/NTAPs provide a valuable, separate funding source for health systems (typically hospitals) to implement innovative technologies which patients may otherwise not be able to access. These mechanisms may induce an administrative burden, which must be managed to ensure the mechanism is not cost-inefficient.

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6. **Risk sharing agreements**: help manage uncertainties around clinical efficacy and budget impact of innovative high-cost technologies. Risk-sharing agreements can be purely financial or based on the technology's clinical performance. Performance-based risk-sharing agreements involve analysing data on product performance, with coverage, payments, or rebates contingent on outcomes achieved (Wenzel 2020).

Managed entry agreements are a type of risk-sharing agreement, typically confidential, that enable patient access to new technologies that may not otherwise be available due to cost-effectiveness or budget impact concerns. When market entry is managed, agreements are in place to address concerns of clinical uncertainty and/or financial burden.

Strengths:	**Weaknesses:**
Therapeutic Areas- • ATMPs, enzyme replacement therapies, oncology, rare diseases, Hepatitis C, medical devices (cardiovascular disease), diagnostics Mechanism design- • Mitigate payer uncertainty and reduce financial burden of high-cost technologies on individual health systems by ensuring only effective technologies are reimbursed and, sometimes, spreading the budget impact over time. • Distribute risk of clinical uncertainty between manufacturer and health system. • Can be customised and flexible as appropriate to the health system and type of technology: spread payments/annuities, risk sharing ex-ante or ex-post (30) • Can improve early patient access to new technologies while evidence is still being collected (26)	Mechanism design- • Outcomes measured need to be determined in advance and are difficult to align on across stakeholders (31) while considering variations in patient populations and disease stages (32) • Highly reliant on RWE ongoing clinical data collection to obtain outcomes and, therefore, execute the agreements which is resource intensive (30) • Responsibility gap between the provider and the payer with increased administrative burden on the provider (33) • Agreements are complex to design and implement (30) • Always yield additional costs for the payer through monitoring, administration, and transaction costs (34)

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Opportunities:	**Threats:**
Mechanism design- • Agreements can incentivize manufacturers to develop new technologies that might otherwise not be financially viable (35) • Incentivize companies to identify subpopulations with higher probability of success and introduce measures for improving patient compliance to the treatment (34) • Increased data on diseases and novel therapies due to the integral data collection requirements (31) • Requirement of constructive patient registries that ideally cover continuity of care spanning care episodes not only in patients specialist centres but also able to link and capture clinical data from visits to hospitals and clinics further afield Health system- USA • Potential opportunity to carve out high cost medicines to a single national risk pool. The benefit of this approach would be to facilitate access to treatments equally across all payers and spread the risk (36)	Mechanism design- • Requires data infrastructure capable of linking clinical outcomes to financial payments. If this is not available, there is a high risk of inefficiency. • Risk of increase in administrative costs and burden – on the health system, manufacturer and health professionals (28) • Transparency concerns. • Premature market entry before the technology provides evidence up to regulatory standards (37) • Manufacturer prices may be higher overall to account for uncertainty (32) Health system-USA • Schemes rely on regular patient follow up and the collection of robust data, most often in the form of adaptive patient registries. In the USA, there are issues with privacy legislation which make it virtually impossible to implement without a change in legislation (28)

Real-world examples:

a) Australia, Belgium, Bulgaria, and the United Kingdom are examples of countries actively using MEAs for both financial and performance-based agreements for new medicines.

b) MEAs have also been used for non-pharmaceutical health technologies in the past, including medical devices, diagnostic procedures, and surgical interventions. MEAs have been used for medical devices, particularly in cardiovascular disease(38).

Risk-sharing agreements are a valuable way to mitigate payer uncertainty and distribute risk across stakeholders. They can be applied to multiple types of high-cost health technologies, including but not limited to pharmaceuticals, medical devices, and

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ATMPs. However, they are difficult to implement efficiently. Outcomes measured need to be determined in advance and are difficult to align on across stakeholders. Additionally, they are highly reliant on real-world evidence. Risk-sharing agreements require data infrastructure capable of linking individual patient clinical outcomes with system-level payments. There is a threat of increased administrative burden without the digital infrastructure to support this task.

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7. **Advocacy coalition**: a group of stakeholders who come together to promote or lobby for a specific cause or policy change. They pool resources, expertise and networks to exert a stronger influence than individual stakeholders may achieve on their own. Advocacy coalitions tend to be global collaborations of a variety of stakeholders, specifically between public and private sectors.

Strengths	**Weaknesses**
Therapeutic Areas- Advanced Therapy Medicinal Products (ATMPs) (39), novel high-cost medicines (40) Mechanism design- • Collaborative innovation: advocacy coalitions facilitate collaboration across a range of traditionally disconnected stakeholders (39,40) • Specialized knowledge and resources: coalitions bring together a range of expertise and resources (39) • Enables the adoption of technologies • Global collaboration (39)	Mechanism design- • Complex coordination: the significant variation amongst stakeholders can result in difficulties in coordination and alignment of goals (39) • Reliance on voluntary engagement (40) • Difficulties in quantifying and measuring impact (40) • Stakeholders may have varying priorities (40) • Financial constraints: high costs of novel therapies might restrict the extent that advocacy coalitions can advocate for them (40)
Opportunities	**Threats**
Mechanism design- • Ability to build on stakeholder progress from global initiatives (40) • Establishing a collaboration platform (40) • Reflecting on successes and lessons learnt from alternate consortia (39) Therapeutic area- • The complex challenges of ATMPs will require many of these initiatives working on some aspect of the value chain to come together through strategic connections to explore new combinations of their outputs (39)	Mechanism design- • Resistance to change from certain stakeholders (40) • Risk that stakeholders may not engage meaningfully or agree on joint solutions (40)

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• Exploring models of joint procurement can enable countries to negotiate for lower prices based on higher volume sales (40) Health system- • Opportunities for collaboration and stakeholder feedback with policy and regulatory frameworks – especially important for novel technologies (I.e. ATMPs) which will require alterations of organisational structures (39) • Opportunities for communication across the development pipeline (39)	

Real-world example:

a) The Oslo Medicines Initiative (OMI) was established by the Government of Norway and the WHO Regional Office for Europe with the aim of facilitating dialogue and creating a learning platform regarding the challenges to access novel, high-priced therapies. The OMI includes collaboration between countries, the pharmaceutical industry, patient organisations, professional organisations and other stakeholders (Larsen et al., 2021)

Advocacy coalitions are not a novel non-financial mechanism. However, these groups are important for the adoption of novel technologies and incorporation of advanced diagnostics. Particularly regarding high-cost novel therapies like ATMPs, advocacy coalitions can advocate for the structural change necessary to implement personalised medicine. Advocacy coalitions benefit from the ability to pool resources and knowledge, in addition to political strength in numbers.

8. **Population Health Management:** includes the use of health data and analytics to categorise populations into segments based on their healthcare needs and to tailor interventions accordingly. Population health management techniques and

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tools have been used in a variety of hospitals and with a focus on different disease areas, such as colorectal cancer screening, chronic kidney disease, among others (41,42)

Strengths:	**Weaknesses:**
Therapeutic Areas- preventative services (i.e. cancer screening, genetic testing for hereditary cancers), chronic diseases Mechanism design- • PHM programs have been used successfully to support chronic disease management using strategies such as protocol-driven care, risk stratification, care management and self-care (41) • Education based initiatives have been found to be effective for chronic disease management (41) • Equity promotion: proactively identifying individual with health inequities • Improved patient engagement: risk stratification, text messaging, conversational agents, and patient navigation to connect patients to services (41) • High accessibility and convenience: automated tools like text, email and chatbots can reach a wide audience, including those with low socioeconomic status as long as they have a smart phone. 76% of individuals with low socioeconomic status in the US (i.e., households with annual incomes less than $30,000) own a smart phone (Del Fiol, 2023) • Cost-effectiveness: by automating patient outreach and education, providers can potentially reduce manpower and resources for routine communications (Del Fiol, 2023)	Mechanism design- • Significant barriers to preventative care in primary care services such as low self-efficacy, lack of time and lack of access to services such as genetic counselling (41) • Patient dentification is inherently limited by screening efforts (42) • Dependence on digital tools which may exclude populations with limited access to technology or low technological literacy (41) • Complex implementation through a requirement of robust technical infrastructure which may be challenging to implement and maintain (41) • Administrative burden associated as it may increase workload for healthcare providers who have to manage additional data sources, technologies and outreach programs (41)

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Opportunities:	**Threats:**
Mechanism design- • Reliance on robust and scalable technical infrastructure with several components. PHM platform is a set of patient data sources coupled with population analytic tools (41) • PHM predicted to experience substantial growth with novel digital health technologies such as sensors, phone apps, conversational agents, virtual reality (41) • Requirement of Electronic Health Records with dynamic data sources such as labs, medication/prescription data, billing, clinician encounters (42) • Accessibility of data: data needs to be accessible for both health care providers and population health specialists/clinical management to enable population based interventions (42) • COVID-19 motivated the rapid implementation of technology innovations which are used in PHM techniques (41)	Mechanism design- • Requirement of extensive infrastructure, both digital, physical and human (41) • AI chatbots may hallucinate, citing incorrect information as fact Health system- • **Regulation compliance:** use of digital tools for communication must comply with healthcare regulations and privacy laws, which vary significantly across geographies and are constantly evolving • Fragmented care (42) • Fragmented electronic health records between different levels of care

Real-world example:

a) Population health management is used in the United Kingdom by integrated care boards and under the first population health agreement between England and Novartis to deliver the cholesterol-lowering drug inclisiran (Leqvio).

Population health management can help enable a shift from reactive to preventative care delivery, but it requires comprehensive data infrastructure to collect and share information across healthcare, social care, and other public service

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Conclusion

The HI-PRIX project aims to advance access to innovative medical technologies. The review conducted within WP5 Task 1 underscores the necessity for multifaceted approaches to improve access to innovative medical technologies. Both financial and non-financial incentive mechanisms have a role to play in implementing innovative medical technologies. All mechanisms must be carefully managed to complement each other and their respective health systems' inherent strengths.

Clearly, different types of medical technologies in different therapeutic areas have different needs. Areas with low or unpredictable utilization but high unmet need, such as antibiotics, can be well suited to subscription models. Subscription models have also shown considerable success in financing Hepatitis C direct-acting antivirals, which are highly effective and often result in a cure from a single course of treatment. These therapeutic areas have high unmet need, variable demand, and medical treatments with high efficacy rates, making them strong candidates for subscription model financing. However, other therapeutic areas such as oncology that have high unmet need, consistently high demand, and variable efficacy rates across treatments are better suited to value-based pricing. Value-based pricing, though not without significant implementation challenges, can enable indication-based pricing which prices the same drug differently depending on its value in the indication under which it is prescribed. Further, areas with low quality evidence or high rates of uncertainty in the evidence can be supported by risk-sharing agreements, which distribute the risk of reimbursing high-cost treatments between the manufacturer and the payer. By aligning payments with clinical outcomes or financial metrics, risk-sharing agreements help ensure that healthcare systems receive value for money while promoting patient access to cutting-edge therapies. This is particularly beneficial for technologies such as ATMPs, genomic diagnostics, and orphan/ultra-orphan drugs. These agreements require careful planning, clear definitions of success, and robust data management to be effectively implemented.

Population health management offers risk-stratification across therapeutic areas and at a population level. This non-financial mechanism incentives health systems to seek

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out high-risk subpopulations across therapeutic areas and offer tailored medical interventions to those who need them most. This approach can help enable systems to shift from reactive towards preventative care delivery. Like many of the other incentive mechanisms discussed, population health management requires a robust data infrastructure without which the incentive mechanism is unlikely to function as intended.

When carefully implemented, multiple incentive mechanisms can work in concert with each other, supporting different stages of implementation. For example, innovation funds can provide support while risk-sharing agreements or value-based prices are being negotiated. Similarly, technologies in DRG carve outs/NTAPs can be financed through risk-sharing agreements or innovation funds. Further, population health management analytics can support value-based pricing and advocacy coalitions influence innovation fund decision-making. Multiple incentives can work together, but they can also undermine each other if not thoughtfully enacted. Incentives work, so it is crucial that they are carefully designed and implemented in order to avoid unintended consequences.

Overall, the incentive mechanisms described in this report enable greater patient access to innovative medical technologies and improve their affordability for health systems, leading to greater sustainability. These incentives can also enhance evidence-based decision-making, ultimately enhancing patient outcomes and value-based resource allocation. Yet, inadequate data infrastructure remains a significant threat to most incentive mechanism's successful implementation. Weak data systems can undermine implementation of various incentive mechanisms and prevent the evaluation of their impact. Data infrastructure is a crucial priority for health systems seeking to benefit from real world data sources and implement value-based care.

This study highlights incentives that show promise within specific health systems and therapeutic areas. The varying needs of different therapeutic areas, such as low utilisation and high R&D areas like antibiotics and high-risk subpopulations, underscore the importance of tailoring incentive models to specific contexts. Furthermore, it is clear that data infrastructure plays a crucial role in the successful implementation of

these technologies. The insights derived are particularly valuable for policymakers, who are tasked with fostering equitable access to medical innovations. As we look toward the future, the findings from this project can policymakers leverage the most appropriate and successful models for their populations and health systems, while effectively addressing the barriers that may impede the equitable distribution of medical advances.

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Scoping Literature Review: Included Studies

Publication Year	Authors	Title
2012	Persson, Ulf; Svensson, Johanna; Pettersson, Billie	A New Reimbursement System for Innovative Pharmaceuticals Combining Value-Based and Free Market Pricing
2018	Jørgensen, Jesper; Servos, Spiros; Kefalas, Panos	The potential price and access implications of the cost-utility and budget impact methodologies applied by NICE in England and ICER in the US for a novel gene therapy in Parkinson's disease.
2020	Michelsen, Sissel; Nachi, Salma; Van Dyck, Walter; Simoens, Steven; Huys, Isabelle	Barriers and Opportunities for Implementation of Outcome-Based Spread Payments for High-Cost, One-Shot Curative Therapies.
2020	Dolores Edo-Solsona, Maria; Vitoria-Minana, Isidro; Luis Poveda-Andres, Jose	Implementation and results of a risk-sharing scheme for enzyme replacement therapy in lysosomal storage diseases
2017	Jørgensen, Jesper; Kefalas, Panos	Annuity payments can increase patient access to innovative cell and gene therapies under England's net budget impact test.
2021	Kohlhammer, Verlag W.; Buch, Charlotte; Schildmann, Jan; Zerth, Jürgen	Risk-sharing schemes to finance expensive pharmaceuticals: Interdisciplinary analyses.
2017	Vogler, Sabine; Paris, Valerie; Ferrario, Alessandra; Wirtz, Veronika J.; de Joncheere, Kees; Schneider, Peter	How Can Pricing and Reimbursement Policies Improve Affordable Access to Medicines? Lessons Learned from European Countries
2011	Barros, Pedro Pita	The Simple Economics of Risk-Sharing Agreements between the NHS and the Pharmaceutical Industry
2019	Lorente, Reyes; Antonanzas, Fernando; Rodriguez-Ibeas, Roberto	Implementation of risk-sharing contracts as perceived by Spanish hospital pharmacists.
2019	Carletto, A.; Cicchetti, A.; Coretti, S.; Moramarco, V.; Ruggeri, M.	Money Back Guarantee? A Cost-Benefit Framework of Performance-Based Agreements (PBAs) for the Reimbursement of Pharmaceuticals
2017	Levaggi, Rosella; Moretto, Michele; Pertile, Paolo	The Dynamics of Pharmaceutical Regulation and R&D Investments
2011	Antonanzas, Fernando; Juarez-Castello, Carmelo; Rodriguez-Ibeas, Roberto	Should Health Authorities Offer Risk-Sharing Contracts to Pharmaceutical Firms? A Theoretical Approach
2015	Navarria, Andrea; Drago, Valentina; Gozzo, Lucia; Longo, Laura; Mansueto, Silvana; Pignataro, Giacomo; Drago, Filippo	Do the current performance-based schemes in Italy really work? "Success fee": a novel measure for cost-containment of drug expenditure.

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2018	Persson, Ulf; Norlin, J. M.	Multi-indication and Combination Pricing and Reimbursement of Pharmaceuticals: Opportunities for Improved Health Care through Faster Uptake of New Innovations
2020	Cho, Eun; Yoo, Seung-Lai; Kang, Youngju; Lee, Jong Hyuk	Reimbursement and pricing of regenerative medicine in South Korea: key factors for achieving reimbursement.
2021	Godman, Brian; Hill, Andrew; Simoens, Steven; Selke, Gisbert; et al	Potential approaches for the pricing of cancer medicines across Europe to enhance the sustainability of healthcare systems and the implications.
2012	Kudrin, Alex	Reimbursement challenges with cancer immunotherapeutics.
2015	Jørgensen, Jesper; Kefalas, Panos	Reimbursement of licensed cell and gene therapies across the major European healthcare markets.
2014	Gibson, Shannon G.; Lemmens, Trudo	Niche markets and evidence assessment in transition: a critical review of proposed drug reforms.
2020	Dario, Picecchi; Katrin, Bertram; Dominik, Brucher; Michael, Bauer	Towards novel reimbursement models for expensive advanced therapy medicinal products (ATMPs)
2021	Kim, Dong-Sook; Lee, Geunwoo; Cho, Hyungyung; Bae, SeungJin	Regenerative Medicine in South Korea: Bridging the Gap Between Authorization and Reimbursement.
2020	Coyle, Doug; Durand-Zaleski, Isabelle; Farrington, Jasmine; et al	HTA methodology and value frameworks for evaluation and policy making for cell and gene therapies.
2019	Barlow, Jane F.; Yang, Mo; Teagarden, J. Russell	Are Payers Ready, Willing, and Able to Provide Access to New Durable Gene Therapies?
2016	Carr, David R.; Bradshaw, Steven E.	Gene therapies: the challenge of super-high-cost treatments and how to pay for them.
2020	Babbrah, Pooja; Cashman, Lisa; Demers, Richard; Deno, Sara; et al	AMCP Partnership Forum: What's Next for Specialty Medication Benefit Design and Reimbursement
2023	Lopata, Erin; Terrone, Christopher; Gopalan, Ami	Opportunities and challenges surrounding financial models for high-investment medications: A survey of access decision-makers and employers.
2017	Cutler, David; Ciarametaro, Michael; Long, Genia; Kirson, Noam; Dubois, Robert	Insurance switching and mismatch between the costs and benefits of new technologies.
2021	Hixson, Marc; Minkoff, Neil B.; Gwiazdzinski, Kim; Clement, Jim	The impact of reinsurance of gene therapies on employer financial risk.
2019	Garrison, Louis P.; Jackson, Tristen; Paul, Douglas; Kenston, Mike	Value-Based Pricing for Emerging Gene Therapies: The Economic Case for a Higher Cost-Effectiveness Threshold.
2022	Matthews, David W.; Coleman, Samantha; Razavi, Homie; Izaret, Jean-Manuel	The Payer License Agreement, or "Netflix model," for hepatitis C virus therapies enables universal treatment access, lowers costs and incentivizes innovation and competition.

2017	Papadaki, Magdalini	Adaptation through Collaboration: Developing Novel Platforms to Advance the Delivery of Advanced Therapies to Patients.
2016	Malik, Nafees N.	Pay-for-performance pricing for a breakthrough heart drug: learnings for cell and gene therapies.
2021	Lopata, Erin; Terrone, Christopher; Gopalan, Ami; Ladikos, Nicholas; Richardson, Terry	Meeting the affordability challenges posed by orphan drugs: a survey of payers, providers, and employers.
2021	Bardey, David; Kembou, Samuel; Ventelou, Bruno	Physicians' incentives to adopt personalised medicine: Experimental evidence
2022	Dabbous, Monique; Toumi, Mondher; Simoens, Steven; Wasem, Juergen; Saal, Gauri; Wang, Yitong; Osuna, José Luis Huerta; François, Clément; Annemans, Lieven; Graf von der Schulenburg, Johann-Matthias; Sola-Morales, Oriol; Malone, Daniel; Garrison, Louis P.	Amortization of gene replacement therapies: A health policy analysis exploring a mechanism for mitigating budget impact of high-cost treatments.
2018	Selby, Kevin; Bartlett-Esquilant, Gillian; Cornuz, Jacques	Personalized cancer screening: helping primary care rise to the challenge.
2018	Zullig, Leah L.; Blalock, Dan V.; Dougherty, Samantha; Henderson, Rochelle; Ha, Carolyn C.; Oakes, Megan M.; Bosworth, Hayden B.	The new landscape of medication adherence improvement: where population health science meets precision medicine.
2018	Lum, Ka; Bhatti, Taimur; Holland, Silas; Guthrie, Mark; Sassman, Stephanie	Diagnosis Confirmation Model: A Value-Based Pricing Model for Inpatient Novel Antibiotics.
2018	Lu, Christine Y.; Williams, Marc S.; Ginsburg, Geoffrey S.; Toh, Sengwee; Brown, Jeff S.; Khoury, Muin J.	A proposed approach to accelerate evidence generation for genomic-based technologies in the context of a learning health system.
2017	Luepke, Katherine H.; Suda, Katie J.; Boucher, Helen; Russo, Rene L.; Bonney, Michael W.; Hunt, Timothy D.; Mohr, John F. 3rd	Past, Present, and Future of Antibacterial Economics: Increasing Bacterial Resistance, Limited Antibiotic Pipeline, and Societal Implications.
2011	Lal, Jonathan A.; Schulte In den Bäumen, Tobias; Morré, Servaas A.; Brand, Angela	Public health and valorization of genome-based technologies: a new model.

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2022	Walton, Nephi A.; Hafen, Brent; Graceffo, Sara; Sutherland, Nykole et al	The Development of an Infrastructure to Facilitate the Use of Whole Genome Sequencing for Population Health.
2016	Zaric, Gregory S.	Cost Implications of Value-Based Pricing for Companion Diagnostic Tests in Precision Medicine.
2018	Ritchie, Christine S.; Leff, Bruce	Population Health and Tailored Medical Care in the Home: the Roles of Home-Based Primary Care and Home-Based Palliative Care.
2021	Wongvibulsin, Shannon; Habeos, Evagelia E.; Huynh, Pauline P.; et al	Digital Health Interventions for Cardiac Rehabilitation: Systematic Literature Review.
2019	Banks, Jordan T.	Exploration of HealthCoin: A Currency to Address US Private Payer Underfunding for Single or Limited Administration (SLA) Treatments with Long-term Effectiveness
2022	Hughes-McLure, Sarah; Mawdsley, Emma	Innovative Finance for Development? Vaccine Bonds and the Hidden Costs of Financialization
2019	['Mendu, M.L.', 'Ahmed, S.', 'Maron, J.K.', 'Rao, S.K.', 'Chaguturu, S.K.', 'May, M.F.', 'Mutter, W.P.', 'Burdge, K.A.', 'Steele, D.J.R.', 'Mount, D.B.', 'Waikar, S.S.', 'Weilburg, J.B.', 'Sequist, T.D.']	Development of an electronic health record-based chronic kidney disease registry to promote population health management
2020	['Visconti, R.M.', 'Morea, D.']	Healthcare digitalization and pay-for-performance incentives in smart hospital project financing
2018	['Minari, J.', 'Brothers, K.B.', 'Morrison, M.']	Tensions in ethics and policy created by national precision medicine programs
2020	['Dario, P.', 'Katrin, B.', 'Dominik, B.', 'Michael, B.']	Towards novel reimbursement models for expensive advanced therapy medicinal products (ATMPs)
2020	['Goitein, L.']	Analysis: Clinician-directed performance improvement: Moving beyond externally mandated metrics

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