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From Framework to Action: Precision Medicine Policy Assessment Toolkit for Oncology

Ana Rita González, Maria Isabella Grueso, Ahlem El Ghoul, Patricia Salazar, Teresa Marinetti*, and Margarita Quijano Serrano

Policy Wisdom LLC, 39 Calle G Garcia, Quebradillas, PR 00678-2705

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***Corresponding authors:** Teresa Marinetti, Policy Wisdom LLC, 39 Calle G Garcia, Quebradillas, PR 00678-2705.

Abstract

Background: Precision medicine (PM) is reshaping oncology through more accurate diagnosis, targeted therapies, and improved outcomes. However, the integration of PM into routine cancer care remains uneven globally, largely due to gaps in policy frameworks, infrastructure, financing, governance, and workforce capacity. These challenges risk widening existing health inequities, particularly in low- and middle-income countries.

Methods: The Precision Medicine Policy Assessment Toolkit for Oncology (PM Toolkit) was developed through an evidence-based, multi-stakeholder process, including literature review, expert consultation, and analysis of real-world case studies. The Toolkit is structured around nine core domains of health system readiness and applies a tiered framework aligned with World Bank income-level classifications to ensure context sensitive and feasible policy guidance.

Results: The PM Toolkit provides a country readiness framework, income-specific objectives, a self-assessment survey, and practical policy pathways to support stakeholders in prioritizing actions to integrate PM into public cancer pathways. Case studies from diverse settings demonstrate its applicability across health system contexts.

Conclusion: This PM Toolkit offers a practical, adaptable, and equity-oriented approach to translating precision oncology from innovation to implementation. It supports policymakers and stakeholders in advancing sustainable, context-appropriate PM strategies worldwide.

Keywords: Precision medicine; Personalized medicine; Oncology; Cancer care; Health system readiness; Health equity; Health systems; Patient access; Toolkit; Policy guide; Country assessment; Case studies

Introduction

Precision medicine (PM) has transformed the landscape of cancer care by enabling more accurate diagnosis, targeted treatment, and improved patient outcomes [1-3]. Yet, while scientific innovation in genomics, biomarker testing, and targeted therapies continues to advance at an unprecedented pace, health systems worldwide remain unevenly prepared to adopt these innovations into standard practice. A persistent gap between innovation and access has left millions of patients, particularly in low- and middle-income countries, without equitable access to the benefits of precision medicine in oncology [4,5].

This global implementation gap is largely related to the gaps in policy, infrastructure, financing, and governance. Without systematic approaches to guide national planning, investments, and stakeholder engagement, precision medicine risks reinforcing existing health inequities rather than bridging them. Policymakers, advocacy groups, medical societies, and the private sector increasingly recognize the urgency of embedding PM into health systems, but many lack the tools to assess readiness, prioritize actions, and develop evidence-informed strategies tailored to local contexts [6-8].

To address this need, the Precision Medicine Policy Assessment Toolkit for Oncology (PM Toolkit) was developed. It is a strategic policy guide to help countries integrate PM into their health systems. This resource is designed to help different stakeholders across various World Bank (WB) income levels [9] to evaluate a country's current level of PM readiness, set realistic priorities, and implement actionable steps in a context-specific and evidence-informed way. By doing so, the PM Toolkit provides a much-needed bridge between the promise of precision medicine and the policies required to make it a reality.

This brief introduces the Toolkit, explains its development process, describes its nine-domain framework and income-level stratification, highlights real-world case applications, and discusses its policy implications. The goal is to raise awareness of this practical resource and to help stimulate engagement among stakeholders who can drive forward the equitable implementation of precision medicine.

Methods

The PM Toolkit was created through a structured, iterative process designed to combine scientific evidence with pragmatic policy discussions and stakeholder engagement. The methodology included several sequential stages outlined below:

Evidence Mapping and Literature Review

The process began with an extensive review of peer-reviewed literature, grey literature, policy documents, and case examples across oncology and broader precision medicine implementation. This evidence-based review established a clear picture of existing challenges, policy gaps, and opportunities across diverse health system settings.

Identification of Core Domains

From the literature review, recurring themes were distilled into nine critical dimensions essential for advancing PM at the country level. These domains reflect the multi-dimensional nature of health system readiness, spanning legal frameworks, clinical practice, data infrastructure, financing, and partnerships.

Design of a Tiered Framework

Recognizing that one-size-fits-all solutions do not work in global health, a three-tier approach aligned with the World Bank income-level classifications is proposed. This stratification ensures that the suggested policy paths are realistic, feasible, and tailored to each country's fiscal space, technological readiness, and governance capacity.

Stakeholder Consultation and Validation

Draft versions of the framework and possible policy avenues were shared with a wide range of stakeholders, advocacy leaders, clinicians, and global health experts. Their feedback was used to refine objectives, framework, and validate relevance across contexts.

Toolkit Assembly and Design

The final Toolkit integrates assessment instruments, such as a self-assessment survey covering the nine domains, as well as income-specific objectives and actionable policy avenues. Practical guidance for different stakeholder groups was included to help translate the framework into action.

Case Study Collection

To demonstrate real-world applicability, illustrative case studies were gathered from countries at different income levels, for each of the nine dimensions. These examples showcase how targeted interventions, across the framework's domains, have advanced PM implementation.

Framework Description: The Nine Dimensions and Tiered Stratification

The PM Toolkit is based around a comprehensive nine-domain framework. Each domain represents a pillar of system readiness and policy action for PM:

1. **Policy & Regulatory Frameworks:** Establishing PM enabling laws, standards, and regulations.

2. **Patient-Centered Care & Equity:** Ensuring that all patients can access, understand, and benefit from PM equitably.

3. **Healthcare Infrastructure & Workforce**-Building laboratories, diagnostic networks, and a trained health workforce.

4. **Clinical Guidelines:** Translating evidence into practice through standardized protocols.

5. **Access & Reimbursement:** Addressing financial barriers and creating sustainable coverage mechanisms.

6. **Research & Innovation:** Supporting discovery, translation, and locally relevant clinical studies.

7. **Education & Awareness:** Building PM awareness among providers, patients, and other stakeholder groups.

8. **Data & Digital Health:** Harnessing high-quality data systems and digital platforms.

9. **Public-Private Partnerships & Sustainability:** Engaging stakeholders to ensure long-term viability.

While all domains are interdependent, the framework is designed to be adaptable. Countries may prioritize domains based on the prevalent and most pressing challenges, resources, and opportunities. The Toolkit segments guidance into three tiers based on WB income classifications:

Table 1: Income-Level Stratification and actionable recommendations

Low- and Lower-Middle-Income Countries (LMICs)	Foundational investments such as the inclusion of DNA testing in national cancer plans, building cancer registries, training the workforce, and leveraging international partnerships.
Upper-Middle-Income Countries (UMICs):	Integration of biomarker testing into national guidelines, development of genomic databases, and negotiated access to targeted therapies.
High-Income Countries (HICs)	Scaling comprehensive genomic testing, embedding precision medicine into universal health coverage, advanced data-sharing infrastructures, and public-private research consortia.

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This stratification ensures that the Toolkit is globally relevant while remaining context sensitive. It acknowledges that while the vision of precision medicine is shared, the pathways to achieve it differ significantly depending on health system maturity and implementation capacity.

The PM Toolkit consists of:

- **Executive Summary:** Provides an overview of the Toolkit framework and its contents.
- **"How-To" Stakeholder Guide:** Offers clear, practical steps to help stakeholders engage meaningfully in advancing precision medicine. It outlines how different groups, such as policymakers, patient advocacy organizations, and medical societies, can use the content and why it is relevant to their specific roles.
- **PM Toolkit Dimensions Summary:** Summarizes the nine essential domains for PM implementation.
- **PM Country Readiness Framework:** with Objectives by Income Level Serves as a comprehensive assessment and planning tool designed to help countries evaluate their current PM readiness and develop targeted action plans.
- **Country Self-assessment survey-by Income Level:** Helps to assess a country's status on Precision Medicine across the nine dimensions, identify areas for improvement, and link these to tailored possible policy avenues to achieve that objective.
- **Compilation of Case Studies:** Provides country-specific best practice examples for each dimension, organized by the three income levels.

Strengths of the PM Toolkit

- **Strong Evidence Base:** Grounded in an extensive literature review and expert validation, the Toolkit offers evidence-informed guidance.
- **Practical Policy Framework:** The nine-domain assessment structure provides a comprehensive, adaptable, and actionable roadmap for stakeholders.
- **Income-Level Stratification:** By segmenting guidance into three tiers, the Toolkit ensures relevance across diverse health systems, from resource-limited to high-income settings.
- **Real-World Applications:** Case studies from Brazil, India, and North Africa, among others, demonstrate feasibility and impact.
- **Stakeholder-Focused Approach:** With dedicated guidance for policymakers, advocacy groups, medical societies, and the pharmaceutical sector, the Toolkit helps each stakeholder understand its role in advancing PM.
- **Implementation Science Focus:** It bridges theory and practice, translating frameworks into action through milestones, surveys, and monitoring tools.
- **Offers a data-driven, adaptable approach:** Relevant to over 190 health systems, the Toolkit enables stakeholders to assess their country's status and take targeted, realistic steps to advance precision medicine readiness.
- **Global Health Equity Lens:** By embedding equity into its tiered approach, the Toolkit directly addresses disparities in access to precision medicine.

These strengths make the Toolkit not only a planning resource but also a catalyst for dialogue, alignment, and action across the global health ecosystem.

Policy Implications

1. **Guiding Evidence-Based National Strategies:** Governments can use the PM Toolkit to conduct baseline assessments, prioritize objectives, and design national precision medicine roadmaps. This ensures investments are grounded in local realities while aligned with global best practices.
2. **Supporting Equitable Access:** By tailoring the policy paths to income levels, the Toolkit helps countries avoid unrealistic models and instead focus on context-appropriate actions.
3. **Facilitating Multi-Stakeholder Collaboration:** The Toolkit provides a common language and framework for dialogue among policymakers, clinicians, advocacy groups, and industry. This fosters alignment, reduces duplication, and enables co-creation of sustainable solutions.
4. **Embedding Precision Medicine in Broader Health Reform:** Precision medicine does not exist in isolation; it intersects with digital health, universal health coverage, and innovative ecosystems. The Toolkit helps connect PM implementation to these wider reforms, amplifying impact.
5. **Enabling Monitoring and Accountability:** With its self-assessment survey and milestone-based progress tracking, the Toolkit empowers stakeholders to measure implementation, celebrate progress, and course-correct where needed.
6. **Informing Global Benchmarking and Donor Engagement:** Because it is aligned with widely recognized WB classifications, the Toolkit enables benchmarking across countries and regions. This makes it a valuable tool for international organizations and donors seeking to target investments effectively.

Conclusion

The Precision Medicine Policy Assessment Toolkit for Oncology represents a timely and practical contribution to global health, PM, and cancer policy. By offering an evidence-based, nine-domain framework stratified by income level, it equips stakeholders to systematically assess readiness, set realistic priorities, and implement tailored actions. Its real-world case studies illustrate that meaningful progress is possible across all

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resource settings, provided strategies are context-sensitive and inclusive.

The strength of the Toolkit lies in its combination of rigor and pragmatism. It is grounded in evidence, designed for diverse stakeholders, adaptable across income levels, and focused on moving from framework to action. Importantly, it emphasizes global health equity by ensuring that even resource-limited countries have a clear pathway to advance precision medicine.

As cancer incidence continues to rise globally, the need to make precision medicine a standard of care, rather than a privilege, has never been greater. This Toolkit provides policymakers, advocacy groups, clinicians, and industry with the tools they need to support this transformation.

More information and access to the full Toolkit can be found on the Policy Wisdom LLC website. Stakeholders are encouraged to explore, apply, and share this resource to advance equitable precision medicine implementation worldwide.

This Toolkit is intended for use by policymakers, advocacy groups, and medical societies involved in the design, evaluation, or implementation of precision medicine policies and strategies. It is provided for informational purposes only and does not constitute clinical, legal, or regulatory advice.

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