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Fostering a Culture of Health Innovation: A Review of Regulation and Integration of AI, Genomics, and Digital Therapeutics by the Ministry of Health

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Abstract

Background: The global health landscape is being redefined by a new era of emerging technologies, including artificial intelligence (AI), genomics, and digital therapeutics (DTx). The technologies hold the promise to shift healthcare from an episodic, reactive, and hospital-based system to a predictive, personalized, and participatory system. However, their incorporation in healthcare systems raises severe problems for regulation, ethics, equity, and implementation. The national Ministry of Health (MoH) is at the center of coordinating this transition, but its role must change beyond traditional roles such that it actively encourages a culture of responsible innovation.

Aim: The purpose of this narrative review is to synthesize existing literature for critically analyzing the multidimensional role of the MoH in spearheading the integration of AI, genomics, and DTx.

Methods: Systematic peer-reviewed and grey literature search between 2010-2024 on PubMed, Scopus, Web of Science, and WHO, FDA, and other regulatory sources. Thematic analysis with results structured around three core domains: governance, infrastructure, and adoption.

Results: The review suggests that holistic strategies are necessary for successful integration. In regulation, MoHs must implement flexible, risk-appropriate regulatory frameworks for adaptive AI and DTx that ensure ethical exploitation of genomic information. State investment in underlying infrastructure, such as national data governance arrangements and genomic biobanks, is needed. New value-based payment models, upskilling of human resources, and national clinical guidelines need to be fostered to drive adoption.

Conclusion: MoH is the indispensable conductor of health innovation. Through adopting a pro-reform, integrated stewardship strategy, MoHs can unlock the power of AI, genomics, and DTx to build more equitable, efficient, and resilient health systems, ultimately to speed progress towards Universal Health Coverage.

Keywords: Health Innovation, Ministry of Health, Artificial Intelligence, Digital Therapeutics, Health Policy.

1. Introduction

The 21st century has ushered in an unparalleled era of technological convergence, with digital, biological, and engineering innovation destined to revolutionize medicine. Artificial intelligence (AI), in the form of machine learning, is exhibiting superhuman capability to analyze complex medical images, predict disease outbreaks, and personalize treatment regimens (Topol, 2019). At the same time, the plummeting cost of genomic sequencing is making precision medicine a reality, enabling treatments that are tailored to the genetic makeup of a person (Collins & Varmus, 2015). Along with these, a new form of evidence-based software, which is termed digital therapeutics (DTx), is emerging to prevent, treat, or manage a medical condition directly, often without the administration of

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pharmaceuticals (Digital Therapeutics Alliance, 2023).

The promise of this triad—genomics, AI, and DTx—is a predictive, preventive, personalized, and participatory health system (a phrase known as "P4 Medicine"). But the path from technological promise to seamless, standard care is blocked by obstacles. They are regulatory uncertainty, data governance, evidence and reimbursement, equity and access, and workforce readiness. In this complex environment, the national Ministry of Health (MoH) has a core, but challenging, position. Its traditional functions of regulator, policymaker, and purchaser are being tested by the pace and nature of this change. A strict or responsive approach can create innovation "kill zones," driving research and development offshore and delaying patient access to beneficial technologies (Bergenstal, 2023). Conversely, an outright laissez-faire solution risks patient harm, market chaos, and wasted resources.

Therefore, this review contends that the MoH will have to actively cultivate a health-innovation culture. It does this by creating an enabling environment that not only safeguards patients and public health but is also responsible for research, development, and adoption. Global evidence is integrated into this narrative review to analyze the specific strategies, frameworks, and leadership actions required from the MoH to guide the integration of AI, genomics, and DTx. It is structured on three core regions where leadership by MoH is central: (1) Developing Adaptive Governance and Regulation, (2) Developing the Enabling Infrastructure for Innovation, and (3) Chipping in Strategic Adoption and Integration. Out of this analysis, this review aims to provide a blueprint for MoHs to navigate the Fourth Industrial Revolution in health.

Methodology

This is a narrative review, seeking to generate an integrative, critical, and interpretive synopsis of the evidence regarding the MoH role in driving health innovation, and with particular regard to AI, genomics, and DTx. The goal is to map the conceptual terrain, identify key policy issues and resolutions, and yield action lessons for leaders of health systems.

Search Strategy

A broad search of the main electronic databases like PubMed, Scopus, Web of Science, and the ACM Digital Library was performed. Key search terms and terms combined were: "Ministry of Health," "health policy," "health innovation," "digital health," "artificial intelligence," "machine learning," "genomics," "precision medicine," "digital therapeutics," "regulation," "health technology assessment," "reimbursement," "data governance," "implementation science," and "workforce training." The search was limited to English-language articles from 2010 to 2024 to capture the most current and applicable advances. Grey literature published by credible organizations such as the World Health Organization (WHO), the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), the Digital Therapeutics Alliance, and national government strategy reports was also included.

Selection Criteria

Reports needed to specifically state the engagement of national or regional health authorities in AI, genomics, or DTx policy, regulation, financing, or implementation. Papers that focused solely on the technological innovation of a technology and lacked a health systems or policy emphasis were excluded. Conceptual articles, empirical research (qualitative, quantitative, mixed methods), policy studies, and case studies were included.

Data Analysis

The synthesised literature was obtained through thematic synthesis. Key findings were established and listed according to the three pre-defined analytical domains of adoption, infrastructure, and governance. Sub-themes that emerged within each of the domains were agile regulation for software as a medical device (SaMD), value-based pricing for DTx, and genomic data biobanks. The review focused on comparing and contrasting different national approaches, ascertaining identified barriers and facilitators, and summarizing best practice recommendations for MoHs.

The Role of MoH in Health Innovation

The Ministry of Health (MoH) is well placed to be the system enabler of preference for health innovation. Its role to protect public health, combined with its overarching position regarding regulation, financing, and system-wide planning, makes it the only organization capable of guiding the diverse stakeholders—from technology developers to healthcare providers, payers, and patients—to the common goal of deploying advanced technologies safely and effectively (Weber et al., 2014). Passive stewardship in the face of rapid technology evolution is a recipe for a disarticulated healthcare system, leading to a patchwork of uncoordinated initiatives, widening health disparities, and collective failure to realize the population health potential of these innovations. An engaged MoH strategy, therefore, is not one of picking winners but of "writing the rules of the road." It is one of the de-risking the path to innovation for entrepreneurs through providing regulatory certainty, creating demand for established technologies through strategic procurement, and creating the foundational digital and data infrastructure upon which sustainable innovation relies (Su et al., 2012).

Domain 1: Creating Adaptive Governance and Regulation

The traditional and primary role of the MoH is to ensure the safety, efficacy, and quality of medical devices. However, the very interactive and evolving nature of Artificial Intelligence (AI), genomics, and Digital Therapeutics (DTx) necessitates the final break

from rigid, process-based regulation and embracing more dynamic, risk-based, and outcome-focused solutions.

Regulating Artificial Intelligence as a Medical Device

AI-based software, particularly when used for a health purpose, is generally classified as Software as a Medical Device (SaMD). The essential regulatory problem is that while the majority of AI algorithms are "locked" at launch, others are "adaptive" or "continuously learning," i.e., their performance evolves with time in accordance with new information, hence breaking the traditional pre-market approval paradigm (FDA, 2021). To address this, MoHs need to adopt agile and risk-balanced paradigms. Key regulatory agencies like the U.S. FDA have proposed models like the "Predetermined Change Control Plan," where developers would specify anticipated changes and their control measures in advance (FDA, 2023). The role of MoH is to implement such principles in its favor, creating a graded system where the level of regulation depends upon the risk of the AI application; for instance, triage AI software has lesser quality evidence than one that recommends doses of radiation therapy (He et al., 2019; Moro Visconti & Morea, 2020). Furthermore, a crucial regulatory function is to ensure equity and reverse bias. Since AI models learned from representative data can perform poorly with minority groups (Obermeyer et al., 2019), the MoH should make developers demonstrate fairness and reduction in algorithmic bias in diverse populations as a market authorization requirement, with diversified training data requirements and transparent performance reporting (Leslie, 2019).

Creating a Regulatory Pipeline for Digital Therapeutics (DTx)

DTx are evidence-based, software-based interventions for the prevention, treatment, or management of medical disease and, unlike wellness apps, require clinical confirmation and regulation in a strict manner (Dang et al., 2020). The MoH should implement a clear and open mechanism for its approval. A first step would be to legislate DTx by law in the country's law to distinguish them from lower-risk digital health products, to provide clarity to developers and investors. Germany's Digital Healthcare Act (DVG), implemented by the Federal Institute for Drugs and Medical Devices (BfArM), set the pace here with its own "DiGA" (Digital Health Applications) Fast-Track procedure, providing temporary listing on showing favorable healthcare effect and decent data protection (BfArM, 2020). Furthermore, the MoH, through its government regulatory body, should be receptive to new clinical trial endpoints. As opposed to traditional medicines, DTx generally exert their effect via behavior change, which may be measurable through patient-reported outcomes (PROs), ecological momentary assessment (EMA), or digital biomarkers, necessitating a turn away from traditional surrogate biomarkers during evidence review (Meyer et al., 2022).

Regulation of Genomic Testing and Data

Control of genomics has a sphere that stretches from the analytical validity of the test product itself, its clinical validity and usefulness, to the ethical use of the resulting genetic information. One specific concern is controlling Laboratory-Developed Tests (LDTs), in that numerous genomic tests are offered through this channel. The MoH must establish and implement standards of quality for the laboratories performing sequencing and bioinformatic analysis in order to offer accurate and trustworthy results to clinicians and patients (Phillips et al., 2018). Besides analytical quality, another critical function of the MoH is ethical regulation and assurances of genetic non-discrimination. This involves enacting and implementing thorough legislation that bans discrimination against individuals on the basis of their genes by employers or insurers. Moreover, robust regulation is essential for secondary use, sharing, and storage of genomic data in order to achieve truly informed consent and to enable patients to be in charge of their most personal information (Abacan et al., 2019). Table 1 shows the key regulatory challenges and MoH strategies for AI, genomics, and DTx.

Domain 2: Building the Foundations for Innovation

Regulatory systems in place alone cannot guarantee sustainable health innovation. The Ministry of Health must actively build the national infrastructure required to enable technologies to develop and scale equitably across the health system. That work is the foundation on which AI, genomics, and digital therapeutics rest in order to realize their full potential.

Data Governance and Interoperable Health Information Systems

Quality, compiled, and accessible data is the source of sustenance both for genomic studies and AI progress. Being the central agency in establishing a trustworthy data ecosystem, the MoH must lead the establishment of a national framework of health data stewardship. This strategic initiative requires legislation establishing data ownership in explicit terms, creating open patient consent frameworks—such as opt-in vs. opt-out systems for research purposes—and implementing strong security controls to protect sensitive health information. The European Health Data Space (EHDS) program is a trailblazer in this regard, creating a single market of EU-level health data while maintaining strong governance standards and citizen control (European Commission, 2022). Alongside governance, technical interoperability is also to be promoted. For data to be truly useful for innovation, it must be standardized and normalized across the health system. The MoH will therefore be

required to mandate the use of standardized common data structures, such as FHIR (Fast Healthcare Interoperability Resources), and harmonized clinical terminologies, such as SNOMED CT, to enable the meaningful and seamless exchange of data from electronic health records, genomic databases, and wearable devices between platforms and institutions (Lehne et al., 2019).

Table 1. Key Regulatory Challenges and MoH Strategies for AI, Genomics, and DTx

Technology	Core Regulatory Challenge	Proactive MoH Strategy	Exemplar National Approach
Artificial Intelligence (AI)	Regulating adaptive/continuously learning algorithms; mitigating algorithmic bias.	Implement agile, risk-proportionate frameworks with pre-specified change control plans; mandate bias assessment and fairness audits.	**USA:** FDA's "Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan" (FDA, 2021).
Genomics	Ensuring quality of Laboratory-Developed Tests (LDTs); ethical use and prevention of genetic discrimination.	Establish accreditation standards for genomic labs; enact comprehensive genetic privacy and non-discrimination legislation.	**USA:** The CLIA framework for lab quality; the Genetic Information Nondiscrimination Act (GINA) of 2008.
Digital Therapeutics (DTx)	Creating a clear approval pathway for software; validating clinically relevant digital endpoints.	Define DTx legally; create a fast-track process based on real-world evidence and patient-reported outcomes.	**Germany:** The Digital Healthcare Act (DVG) and BfArM's "DiGA" Fast-Track for digital health applications.

Genomics Infrastructure: Biobanks and Sequencing Capacity

Realizing the promise of precision medicine will take a massive commitment to physical and digital infrastructure that is intentionally designed to facilitate genomic medicine. A significant component of that infrastructure is the development of national biobanks and longitudinal cohorts. The MoH can facilitate or enable the development of large-scale, population-based biobanks that comprehensively link genomic data to full longitudinal health records. These repositories are precious assets for research and public health programs alike, with the UK Biobank being an exemplary model that has expedited hundreds of discoveries in human genetics (Bycroft et al., 2018). At the same time, there needs to be development of national sequencing capacity in order to provide equitable access. The MoH can make strategic investments in national sequencing centers or build networks of accredited regional laboratories to prevent the emergence of a two-tiered healthcare system where only the wealthy are able to afford more advanced genomic tests and resulting personalized treatment (Patrinos et al., 2020).

Domain 3: Driving Strategic Adoption and Integration

Once technology has passed regulatory approval and the necessary infrastructure is in place, the role for the MoH is to proactively encourage adoption into regular care. This will require a concerted effort focused on the primary areas of financing, workforce readiness, and systematic adoption.

Financing and Reimbursement Models

Without a well-defined and sustainable route to payment, even the most clinically effective innovations will never gain patients in volume. The MoH, frequently through its national health insurance or strategic purchasing department, will have to lead the way in developing new forms of reimbursement for these new technologies. This starts with modifying classical Health Technology Assessment (HTA) approaches so that they are better able to reflect the distinctive value proposition of digital and genomic technologies. The MoH must also task its HTA unit with developing new methodologies that will reflect the full value of such innovations, such as indirect benefits, such as productivity gains, caregiver burden reduction, and preventive long-term benefits not considered within conventional cost-effectiveness analyses (Drummond et al., 2015). Outcomes-based reimbursement models that provide payment based on real-world performance and patient outcomes are best applicable to digital therapeutics and AI interventions. For genomics, the MoH may explore new forms of payment such as bundled payment systems that cover the overall pathway of care facilitated by genomics, including the genetic test cost, interpretation by a genetic counselor, and related targeted treatment, thereby creating an affordable platform for tailored treatment plans (Trosman et al., 2023).

Workforce Transformation and Digital Literacy

An untrained or recalcitrant healthcare workforce is perhaps the single largest obstacle to new technologies being successfully implemented.

Overcoming this requires a two-fold strategy directed towards future and current healthcare professionals alike. For the next generation of workers, the MoH will have to collaborate with professional councils and ministries of education in order to re-engineer medical, nursing, and public health curricula so that they include core competencies in digital health literacy, rudimentary data science, and clinical applications of genomics (Richardson et al., 2021). For existing staff, the MoH would establish national continuous professional development (CPD) programs focused on informing current practitioners on interpreting AI-generated clinical intelligence, understanding and reacting to genetic test results, and appropriately "prescribing" evidence-based digital therapies. Such a broad upskilling effort is needed for building confidence and providing safe and proper use of technologies in the practice (Coiera et al., 2012).

Promoting Implementation Science and Change Management

The "last mile" problem of deploying new technologies into complex clinical workflows is where otherwise promising innovations tend to get stuck. To move past this, the MoH must actively promote implementation science and systematic change management. This can be achieved by directing research funds to implementation science to examine the most influential strategies for implementing AI, genomics, and DTx in diverse care settings, with a view to finding out what is most effective and scaling up successfully what is proven (Bauer & Kirchner, 2020). Moreover, the MoH can significantly improve adoption by mandating and disseminating authoritative national clinical guidelines that explicitly incorporate these new technologies. For instance, developing and promoting guidelines that state when genomic testing is medically appropriate for specific cancers or which DTx are single-line treatments for diseases like mild-to-moderate depression provides clinicians with explicit, evidence-based directions and supports standardization of care (Sverdlov et al., 2018). Table 2 illustrates the MoH levers for driving adoption of health innovations. Figure 1 provides an overview of the Ministry of Health's three domains of innovation leadership.

Table 2. MoH Levers for Driving Adoption of Health Innovations

Adoption Lever	Application to AI, Genomics, DTx	MoH Action	Intended Outcome
Strategic Reimbursement	Creating sustainable payment pathways for non-traditional technologies.	Develop value-based pricing models; pilot outcomes-based contracts; create specific billing codes for DTx prescriptions and genomic interpretation.	Accelerated market uptake; sustainable business models for innovators; demonstrated return on investment for the health system.
Workforce Capacity Building	Preparing the health workforce to use new tools effectively and confidently.	Mandate digital and genomic literacy in core curricula; fund national upskilling programs; create new roles (e.g., clinical informaticians).	Increased provider trust and adoption; reduced implementation resistance; improved patient counseling and outcomes.
National Guidelines & Standards	Providing clear, evidence-based guidance on *when* and *how* to use new technologies.	Commission and disseminate national clinical guidelines that integrate AI, genomics, and DTx; establish standards for validating and reporting algorithms.	Reduced variation in care; increased appropriate utilization; protection against misuse; enhanced patient safety.

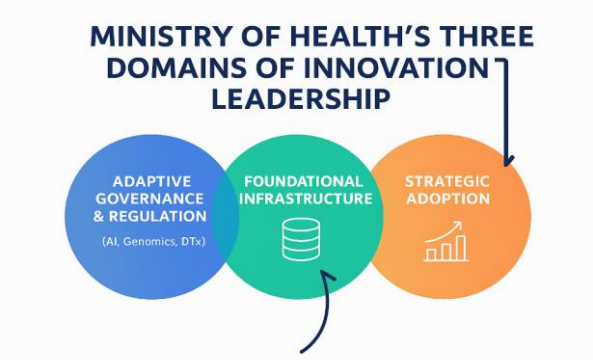

Figure 1. Ministry of Health's Three Domains of Innovation Leadership.

The Critical Role of Nursing in Health Innovation Implementation

The successful integration of transformative technologies such as artificial intelligence (AI), genomics, and digital therapeutics (DTx) into clinical practice is fundamentally dependent on the nursing workforce. As the largest group of healthcare professionals and the primary point of patient contact, nurses play an indispensable role in bridging the gap between innovative technologies and patient-centered care delivery (Pepito & Locsin, 2019). Their unique position at the frontline of healthcare enables them to ensure that technological advancements translate into tangible improvements in patient outcomes and care experiences. This section examines the multifaceted

responsibilities of nurses in adopting and implementing health innovations and outlines the strategic support mechanisms that Ministries of Health must establish to empower them in this rapidly evolving healthcare landscape.

Nurses as Frontline Implementers and Patient Advocates

Nurses serve as the crucial interface between complex technologies and patients, making their role in health innovation implementation particularly significant. In the context of AI-driven clinical decision support systems, nurses are typically the first healthcare professionals to interact with AI-generated alerts and recommendations. Their clinical judgment becomes essential for interpreting these outputs within the holistic context of patient care, ensuring that algorithmic suggestions align with individual patient needs, preferences, and unique clinical circumstances (Robert, 2019). This interpretive function requires nurses to maintain a delicate balance between trusting technological assistance and applying their professional expertise to validate and contextualize AI recommendations. Furthermore, nurses bear significant responsibility for patient safety in the digital health environment, requiring constant vigilance in identifying potential errors, limitations, or biases in AI systems that could compromise care quality. This safety monitoring extends beyond immediate clinical concerns to include the ethical dimensions of AI implementation, such as ensuring equitable access and preventing algorithmic discrimination.

In genomic medicine, nurses have emerged as essential providers throughout the genetic testing process. They facilitate comprehensive informed consent discussions, ensure patient comprehension of complex genetic information, and provide crucial psychosocial support throughout the genetic testing journey (Calzone et al., 2018). The nursing role in genetic healthcare has proven particularly valuable in primary care settings where access to specialized genetic counselors may be limited, allowing for more widespread integration of genomic medicine into routine healthcare. Additionally, nurses play a critical role in helping patients and their families understand the broad implications of genetic results, effectively bridging the gap between technical genetic information and practical health decisions. This includes guiding patients through considerations about preventive measures, family planning, and lifestyle modifications based on genetic risk factors, while providing ongoing emotional support through what can be a psychologically challenging process.

Regarding digital therapeutics, nurses are increasingly functioning as prescribers and coaches of evidence-based digital interventions. They conduct initial assessments of patient suitability for DTx, considering factors such as digital literacy, motivation, and clinical appropriateness. Once initiated, nurses provide comprehensive training on DTx use, monitor adherence and progress through digital dashboards, and integrate data from digital therapeutics with conventional clinical assessments to form a complete picture of patient status (Rassi-Cruz et al., 2022). This expanded responsibility requires nurses to develop new competencies in evaluating digital health literacy, addressing technological barriers, and motivating patients through digitally-enabled care pathways. The nursing role in DTx implementation also involves troubleshooting technical issues, providing ongoing encouragement, and helping patients interpret and act upon the insights generated by digital health tools, thereby ensuring these technologies deliver their intended benefits.

Nursing Informatics and Innovation Leadership

The specialization of nursing informatics has become increasingly vital in health innovation ecosystems, serving as a critical bridge between clinical care and technology development. Nurse informaticists possess the unique ability to translate clinical needs into technical requirements for AI and DTx development, ensuring that these technologies align with nursing workflows and patient care priorities (Collins et al., 2017). Their expertise enables them to advocate for user-centered design principles that accommodate the real-world constraints and complexities of clinical environments. These professionals lead the configuration and optimization of electronic health records to incorporate genomic data and AI outputs in clinically meaningful ways, ensuring that information is presented to support rather than disrupt clinical reasoning. Furthermore, nurse informaticists play a crucial role in data governance initiatives, advocating for ethical data use while ensuring that nursing-generated data contributes effectively to AI model training and refinement, thereby improving the relevance and accuracy of predictive algorithms.

Beyond informatics specialization, nurses are increasingly assuming leadership positions in health technology innovation teams and committees. Their frontline perspective provides invaluable insights into workflow integration challenges, usability issues, and implementation barriers that may not be apparent to technology developers or administrators (Fleiszer et al., 2016). This grounded understanding of clinical realities enables nurse leaders to anticipate unintended consequences of technology implementation and propose mitigating strategies before deployment. Nurse innovators are actively driving the creation of novel digital solutions to address persistent healthcare challenges, from remote patient monitoring systems to mobile health applications for chronic disease management. Their direct experience with patient care allows them to identify unmet needs and opportunities for technological innovation that might otherwise remain unaddressed. The growing influence of nursing leadership in health technology ensures that innovations remain grounded in clinical reality and

focused on genuine patient benefit rather than technological novelty alone.

Ministry of Health Strategies to Support Nursing in Health Innovation

To fully leverage nursing's potential in health innovation, Ministries of Health must implement targeted strategies across education, practice, and policy domains. Curriculum transformation represents a foundational strategy, requiring the integration of digital health literacy, genomics, and AI fundamentals into nursing education programs at all levels, from pre-licensure to advanced practice (Fridsma, 2018). This educational modernization must include developing competencies in data interpretation, ethical considerations in digital health, and patient education strategies for genomic medicine and digital therapeutics. Simultaneously, establishing comprehensive continuing professional development programs for practicing nurses is essential, with content focused on the practical application of AI tools, interpretation of genomic test results, and implementation of DTx in various care settings (Shinners et al., 2021). These educational initiatives must be complemented by the development of clear clinical guidelines that define nursing responsibilities in AI-supported care, genomic medicine, and DTx management, addressing crucial aspects such as delegation, documentation, and interdisciplinary collaboration in the context of technological innovation (Kleinpell et al., 2016).

Policy-level interventions are equally critical for supporting nursing's role in health innovation. Ministries of Health must ensure adequate nursing representation in health technology policy-making committees, regulatory bodies, and institutional technology acquisition teams to advocate for patient-centered design and workflow-compatible implementations (Farokhzadian et al., 2018). This representation ensures that nursing perspectives inform decisions about technology selection, implementation strategies, and evaluation frameworks. Additionally, dedicated research support for nursing-led investigations into the implementation science of health technologies is essential, with funding prioritized for studies focusing on usability, workflow integration, and patient outcomes in real-world care settings. These combined strategies—encompassing education, practice guidelines, policy representation, and research support—create an enabling environment that allows nurses to fully embrace their role as facilitators of responsible health innovation (Table 3).

Table 3. Nursing Roles in Health Innovation Implementation

Technology Domain	Key Nursing Responsibilities	Required Competencies	MoH Support Strategies
Artificial Intelligence	Interpreting AI-generated alerts; validating algorithmic recommendations; ensuring patient safety; providing contextual clinical judgment	Critical thinking; data literacy; ethical reasoning; patient advocacy	AI competency frameworks; clinical decision support training; safety reporting protocols
Genomics	Facilitating informed consent; explaining genetic information; psychosocial support; coordinating follow-up care	Genetic literacy; counseling skills; family systems assessment; ethical deliberation	Genomic education programs; referral pathways; psychosocial support resources
Digital Therapeutics	Assessing patient suitability; onboarding and training; monitoring adherence; integrating digital and clinical data	Digital health literacy; coaching skills; data interpretation; motivational interviewing	DTx prescription guidelines; reimbursement models; digital platform training

The successful integration of health innovations ultimately depends on nurses' capacity to blend technological capabilities with humanistic care principles. By strategically investing in nursing education, leadership development, and supportive practice environments, Ministries of Health can ensure that the adoption of AI, genomics, and digital therapeutics enhances rather than undermines the therapeutic nurse-patient relationship. This balanced approach contributes to the evolution of a healthcare system that successfully combines technological sophistication with compassionate care, ultimately leading to more personalized, precise, and patient-centered healthcare delivery. The nursing profession's unique position at the intersection of clinical expertise, patient advocacy, and technological implementation makes them indispensable partners in shaping a future healthcare system that leverages innovation to achieve better outcomes for all patients.

Discussion

The thoughtful analysis provided in this review is in favor of the proposition that the Ministry of Health's role in building a vibrant health innovation ecosystem is more than a to-do list of distinct, discrete steps. Instead, it is an integrated, system-level leadership function that requires strategic coordination across multiple, interconnected arenas. To succeed in the effort, it demands balancing and whole-of-action that simultaneously establishes resilient regulatory stewardship, builds resilient infrastructural columns,

and activates powerful adoption drivers. To provide an actionable handbook to MoHs within this multidimensional setting, we recommend the application of an integrative "Health Innovation Stewardship Framework," founded on four foundational, interlinked pillars with the objective of creating a clear and enabling environment for good innovation.

The first pillar, Foresight and Strategy, requires a paradigm shift from reactive to proactive policymaking. This involves the institutionalization of strategic intelligence within the MoH as specific Offices of Health Innovation. These offices would conduct constant horizon-scanning of emerging technological advances, undertake systematic analysis of their probable impact on the health system, and facilitate the development of forward-looking national strategies. These types of strategies—e.g., an overall National AI in Health Strategy or a bold National Precision Medicine Initiative—serve to outline a stated vision, orchestrate the action of multiple stakeholders, including government agencies, private enterprise, and research universities, and offer an integrated framework for public investment. This proactive measure ensures that the health system is not always playing catch-up with technology shocks but, instead, is prepared to strategically utilize them for the greater good.

The second pillar, Adaptive Governance, requires a shift in paradigm of the MoH regulatory culture—from being mostly restrictive, gatekeeping in nature, to one that is enabling and facilitative. This does not imply a lowering of safety standards, but rather the adoption of more agile and responsive regulatory methodologies that can keep pace with technological change. Practical mechanisms for achieving this include the implementation of regulatory sandboxes, which provide a controlled environment for testing innovations in real-world settings with temporary regulatory flexibilities, and the creation of innovation hubs that offer centralized guidance and support to developers. Moreover, establishing formal collaborative centers for ongoing discussion between regulators, industry, and academia early on in the pipeline for technology development can help to shape products to regulatory requirements more efficiently, risk-deaden investment, and accelerate the path from concept to clinic (Leckenby et al., 2021). This pillar is about establishing a stringent and responsive system of regulation.

The third pillar, Enabling Infrastructure, recognizes that innovation cannot succeed alone. Strategic public expenditure in fundamental digital and physical infrastructure is an absolute prerequisite for a modern, cutting-edge health system and a core state duty. This means not only establishing safe, nation-grade health data platforms with good governance, as already described, but also making key investments in genomic sequencing capacity, computing power, and universal digital connection. By turning this infrastructure into a public utility, the MoH can prevent the formation of proprietary data silos and ensure that the benefits of innovation accrue to many innovators and providers, rather than being focused in a few resourced hubs. This pillar provides the ground layer upon which the rest of the digital health ecosystem is built.

The fourth and no less crucial pillar is Inclusive Adoption. This calls for all policy, regulatory decisions, and investments to be made with a rigorous equity view. The MoH must strive against the built-in danger that the latest technologies could aggravate current health inequities. This involves implementing concrete policies to bridge the digital divide by ensuring access to the internet at an affordable price and promoting digital literacy, necessitating that diverse populations must be considered in genomic research to prevent biased algorithms and discriminatory therapeutic benefits, and deliberately structuring reimbursement models so that everyone can access breakthrough innovation, not the privileged elite (Weber et al., 2014). A technology that is still inaccessible to marginalized populations cannot be considered a public health success innovation.

Among the main and enduring challenges in applying this model is the conflict between the emergent, iterative pace of technological innovation and the often deliberate pace of government policymaking and procurement. Bridging the gap necessitates the creation of a learning, flexible, and nimble culture within the MoH itself. This includes adopting iterative policy design, testing programs with inherent evaluation measures, and showing a readiness to adjust frameworks and strategies in light of new real-world evidence. The long-term goal of this integrated Health Innovation Stewardship Framework is to allow Ministries of Health to move on from passive regulation towards becoming active architects of health systems who, as far as technology will allow, are technologically advanced, fair, resilient, and sustainably focused towards bettering the health outcomes for the entire population. Figure 2 summarizes the health innovation stewardship framework.

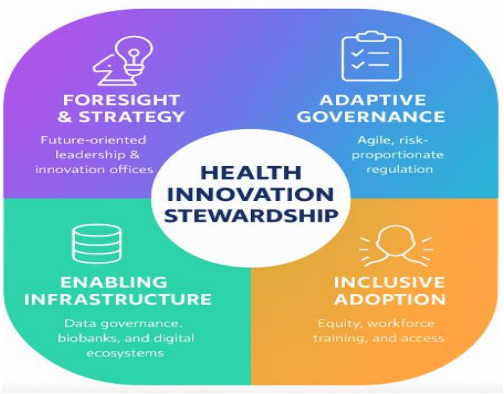

Figure 2. The Health Innovation Stewardship Framework

Conclusion

The potential of AI, genomics, and digital therapeutics to transform global health is enormous, promising a future with more customized, effective, and preventive care. Without the active, strategic, and fair governance of the national Ministry of Health, however, this promise will largely remain unfulfilled. The current review has sketched out the most important roles that the MoH must play as an agile regulator, a builder of essential infrastructure, and an accelerator of ubiquitous and fair adoption.

By creating open and responsive channels of regulation, heavy investments in robust data and genomic capabilities, new financial models, and the preparedness of the health workforce, the MoH can create the conditions for innovation to take place responsibly. The focus is not innovation itself, but its application as a powerful tool to surmount entrenched health conditions, reduce disparities, and advance the pursuit of Universal Health Coverage. The decision for MoHs is not whether to join this new technological age, but how to do so in a strategic manner, so that the future health systems are not only technologically advanced but also more equitable, resilient, and human-centered.

References

1. Abacan, M., Alsubaie, L., Barlow-Stewart, K., Caanen, B., Cordier, C., Courtney, E., ... & Wicklund, C. (2019). The global state of the genetic counseling profession. *European Journal of Human Genetics*, *27*(2), 183-197. https://doi.org/10.1038/s41431-018-0252-x
2. Bauer, M. S., & Kirchner, J. (2020). Implementation science: what is it and why should I care?. *Psychiatry research*, *283*, 112376. https://doi.org/10.1016/j.psychres.2019.04.025
3. Bergenstal, R. M. (2023). Roadmap to the effective use of continuous glucose monitoring: innovation, investigation, and implementation. *Diabetes Spectrum*, *36*(4), 327-336. https://doi.org/10.2337/dsi23-0005
4. BfArM. (2020). Federal Institute for Drugs and Medical Devices. (2020). The Fast-Track Process for Digital Health Applications (DiGA) According to Section 139e SGB V.
5. Bycroft, C., Freeman, C., Petkova, D., Band, G., Elliott, L. T., Sharp, K., ... & Marchini, J. (2018). The UK Biobank resource with deep phenotyping and genomic data. *Nature*, *562*(7726), 203-209. https://doi.org/10.1038/s41586-018-0579-z
6. Calzone, K. A., Kirk, M., Tonkin, E., Badzek, L., Benjamin, C., & Middleton, A. (2018). The global landscape of nursing and genomics. *Journal of nursing scholarship*, *50*(3), 249-256. https://doi.org/10.1111/jnu.12380
7. Coiera, E., Aarts, J., & Kulikowski, C. (2012). The dangerous decade. *Journal of the American Medical Informatics Association*, *19*(1), 2-5. https://doi.org/10.1136/amiajnl-2011-000674
8. Collins, F. S., & Varmus, H. (2015). A new initiative on precision medicine. *New England journal of medicine*, *372*(9), 793-795. DOI: 10.1056/NEJMp1500523
9. Collins, S., Yen, P. Y., Phillips, A., & Kennedy, M. K. (2017). Nursing informatics competency assessment for the nurse leader: The Delphi study. *JONA: The Journal of Nursing Administration*, *47*(4), 212-218. *DOI:* 10.1097/NNA.0000000000000467
10. Dang, A., Arora, D., & Rane, P. (2020). Role of digital therapeutics and the changing future of healthcare. *Journal of Family Medicine and Primary Care*, *9*(5), 2207-2213. DOI: 10.4103/jfmpc.jfmpc_105_20
11. Digital Therapeutics Alliance. (2023). Digital Therapeutics: Definition and Core Principles. Retrieved from https://dtxalliance.org/
12. Drummond, M. F., Sculpher, M. J., Claxton, K., Stoddart, G. L., & Torrance, G. W. (2015). *Methods for the economic evaluation of health care programmes*. Oxford university press.
13. European Commission. (2022). *Proposal for a Regulation on the European Health Data Space*. COM(2022) 197 final.
14. Farokhzadian, J., Dehghan Nayeri, N., & Borhani, F. (2018). The long way ahead to achieve an effective patient safety culture: challenges perceived by nurses. *BMC health services research*, *18*(1), 654. https://doi.org/10.1186/s12913-018-3467-1
15. Fleiszer, A. R., Semenic, S. E., Ritchie, J. A., Richer, M. C., & Denis, J. L. (2016). A unit-level perspective on the long-term sustainability of a nursing best practice guidelines program: an embedded multiple case study. *International journal of nursing studies*, *53*, 204-218. https://doi.org/10.1016/j.ijnurstu.2015.09.004
16. Food and Drug Administration. (2021). *Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan*. U.S. Department of Health and Human Services.
17. Food and Drug Administration. (2023). *Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions*. U.S. Department of Health and Human Services.
18. Fridsma, D. B. (2018). Health informatics: a required skill for 21st century clinicians. *BMJ*, *362*. https://doi.org/10.1136/bmj.k3043
19. He, J., Baxter, S. L., Xu, J., Xu, J., Zhou, X., & Zhang, K. (2019). The practical implementation of artificial intelligence technologies in medicine. *Nature medicine*, *25*(1), 30-36. https://doi.org/10.1038/s41591-018-0307-0

20. Kleinpell, R., Barden, C., Rincon, T., McCarthy, M., & Zapatochny Rufo, R. J. (2016). Assessing the impact of telemedicine on nursing care in intensive care units. *American Journal of Critical Care*, *25*(1), e14-e20. https://doi.org/10.4037/ajcc2016808
21. Leckenby, E., Dawoud, D., Bouvy, J., & Jónsson, P. (2021). The sandbox approach and its potential for use in health technology assessment: a literature review. *Applied health economics and health policy*, *19*(6), 857-869. https://doi.org/10.1007/s40258-021-00665-1
22. Lehne, M., Sass, J., Essenwanger, A., Schepers, J., & Thun, S. (2019). Why digital medicine depends on interoperability. *NPJ digital medicine*, *2*(1), 79. https://doi.org/10.1038/s41746-019-0158-1
23. Leslie, D. (2019). Understanding artificial intelligence ethics and safety. *arXiv preprint arXiv:1906.05684*. https://doi.org/10.48550/arXiv.1906.05684
24. Meyer, A., Wisniewski, H., & Torous, J. (2022). Coaching to support mental health apps: exploratory narrative review. *JMIR Human Factors*, *9*(1), e28301. https://doi.org/10.2196/28301
25. Moro Visconti, R., & Morea, D. (2020). Healthcare digitalization and pay-for-performance incentives in smart hospital project financing. *International journal of environmental research and public health*, *17*(7), 2318. https://doi.org/10.3390/ijerph17072318
26. Obermeyer, Z., Powers, B., Vogeli, C., & Mullainathan, S. (2019). Dissecting racial bias in an algorithm used to manage the health of populations. *Science*, *366*(6464), 447-453. https://doi.org/10.1126/science.aax2342
27. Patrinos, G. P., Pasparakis, E., Koiliari, E., Pereira, A. C., Hünemeier, T., Pereira, L. V., & Mitropoulou, C. (2020). Roadmap for establishing large-scale genomic medicine initiatives in low-and middle-income countries. *The American Journal of Human Genetics*, *107*(4), 589-595. https://doi.org/10.1016/j.ajhg.2020.08.005
28. Pepito, J. A., & Locsin, R. (2019). Can nurses remain relevant in a technologically advanced future?. *International journal of nursing sciences*, *6*(1), 106-110. https://doi.org/10.1016/j.ijnss.2018.09.013
29. Phillips, K. A., Deverka, P. A., Hooker, G. W., & Douglas, M. P. (2018). Genetic test availability and spending: where are we now? Where are we going?. *Health affairs*, *37*(5), 710-716. https://doi.org/10.1377/hlthaff.2017.1427
30. Rassi-Cruz, M., Valente, F., & Caniza, M. V. (2022). Digital therapeutics and the need for regulation: how to develop products that are innovative, patient-centric and safe. *Diabetology & Metabolic Syndrome*, *14*(1), 48. https://doi.org/10.1186/s13098-022-00818-9
31. Richardson, J. P., Smith, C., Curtis, S., Watson, S., Zhu, X., Barry, B., & Sharp, R. R. (2021). Patient apprehensions about the use of artificial intelligence in healthcare. *NPJ digital medicine*, *4*(1), 140. https://doi.org/10.1038/s41746-021-00509-1
32. Robert, N. (2019). How artificial intelligence is changing nursing. *Nursing management*, *50*(9), 30-39. *DOI:* 10.1097/01.NUMA.0000578988.56622.21
33. Shinners, L., Aggar, C., Grace, S., & Smith, S. (2021). Exploring healthcare professionals' perceptions of artificial intelligence: Validating a questionnaire using the e-Delphi method. *Digital Health*, *7*, 20552076211003433. https://doi.org/10.1177/20552076211003433
34. Su, L., Huang, J., Yang, W., Li, H., Shen, Y., & Xu, Y. (2012). Ethics, patient rights and staff attitudes in Shanghai's psychiatric hospitals. *BMC medical ethics*, *13*(1), 8.https://doi.org/10.1186/1472-6939-13-8
35. Sverdlov, O., Van Dam, J., Hannesdottir, K., & Thornton-Wells, T. (2018). Digital therapeutics: an integral component of digital innovation in drug development. *Clinical Pharmacology & Therapeutics*, *104*(1), 72-80. https://doi.org/10.1002/cpt.1036
36. Topol, E. (2019). *Deep medicine: how artificial intelligence can make healthcare human again*. Hachette UK.
37. Trosman, J. R., Weldon, C. B., Kurian, A. W., Pasquinelli, M. M., Kircher, S. M., Martin, N., ... & Phillips, K. A. (2023). Perspectives of private payers on multicancer early-detection tests: informing research, implementation, and policy. *Health Affairs Scholar*, *1*(1), qxad005. https://doi.org/10.1093/haschl/qxad005
38. Weber, G. M., Mandl, K. D., & Kohane, I. S. (2014). Finding the missing link for big biomedical data. *Jama*, *311*(24), 2479-2480. doi:10.1001/jama.2014.4228
39. World Health Organization. (2021). *Ethics and governance of artificial intelligence for health*. WHO.
40. World Health Organization. (2022). *Global strategy on digital health 2020-2025*. WHO.