UNITE
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HEALTH AI
The Global Agency for Responsible AI in Health

| POSITION PAPER

Digital Health

Position Paper for Parliamentarians on Responsible AI in Health

UNITE Parliamentarians Network for Global Health and HealthAI - The Global Agency for Responsible AI in Health

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POSITION PAPER FOR PARLIAMENTARIANS ON RESPONSIBLE AI IN HEALTH

1. INTRODUCTION

Artificial Intelligence (AI) holds immense potential to revolutionize healthcare by enhancing health outcomes, patient safety, accessibility to care, as well as improving operational efficiency and reducing costs. AI applications in health span a wide range of areas, including health promotion, prevention and early detection, more accurate and timely diagnosis, personalized treatment, remote monitoring, and drug discovery [1]. Additionally, AI can optimize resources and processes, reducing administrative workloads, enabling healthcare professionals to dedicate more time to direct patient care. Through predictive analytics, AI can forecast patient demand, allowing hospitals to better plan staffing, potentially increasing operational efficiency [2]. Furthermore, increasing investments in healthcare AI over the last few years also reflects the growing interest in this domain, with investors investing more than $30 billion into healthcare AI startups in the last three years and approximately $60 billion in the last ten years [3].

Despite the potential of AI innovations in health, it is essential to view AI as a tool that enhances human capabilities, supports health workers, and empowers patients, rather than replacing human expertise. In addition, skepticism and distrust remain with regards to the use of AI technologies in health due to reliability, scalability, and accessibility issues which can be heightened in complex socio-economic realities especially among low- and middle-income countries (LMICs) [4,5]. Thus, it is key to build trust in technology to enhance adoption. To do so, it is crucial to establish a comprehensive regulatory ecosystem which prioritizes ethical considerations aligned with human rights throughout the spectrum from research and development to deployment and monitoring, to enhance reliability and transparency of AI systems. As emphasized in the UN's Global Digital Compact, a balanced and inclusive approach to AI is essential, ensuring that all countries, particularly those in the developing world, can participate fully in this transformative technology [6].

Parliamentarians and legislators play a crucial role in establishing balanced regulatory frameworks to govern AI in health. They are responsible for implementing global principles, such as those outlined in the Global Digital Compact, within national health policies and regulations. Parliamentarians are key stakeholders in upholding principles of accountability, transparency, and equity, ensuring health remains a fundamental human right for all. Their position is pivotal in fostering a regulatory environment that encourages innovation, ensures privacy and data protection, and strengthens existing systems, infrastructures, and capacities to ensure effective deployment and adoption of Responsible AI innovations in health.

2. FOSTERING A REGULATORY ECOSYSTEM FOR RESPONSIBLE AI IN HEALTH: FROM GLOBAL TO LOCAL

Maximizing the potential of AI in health requires well-defined policies to create an enabling environment and facilitate effective integration into healthcare systems. While many governments look to international organizations and influential regions for guidance on establishing local regulatory mechanisms, **it is critical to balance international alignment with policies that are well adapted locally**. Given that the performance of AI systems is highly context-dependent, governance mechanisms must ensure that approved AI innovations in health are appropriately adapted to the local context, considering factors such as cultural nuances, linguistic diversity, local healthcare infrastructure, demographic characteristics, and specific health challenges. Participatory engagement of local stakeholders, including the public, is important in the development of AI policies and governance frameworks to ensure that they reflect societal needs, culture, and values.

While it is clear that the future of healthcare is embedded in technology, which is the core to strengthening the foundation of health systems, this technological advancement has also highlighted existing inequalities in health. Many countries still lack the basic digital infrastructure, availability of quality data, robust health data governance frameworks, inclusive policies, and resources needed to fully integrate AI and digital health technologies. This disparity risks exacerbating the existing digital divide as well as biases in outputs of opaque AI algorithms trained with incomplete datasets. Moreover, efforts to ensure safe and effective development and deployment of AI tools are marked by significant inequities between high-income countries and LMICs. For instance, while the US FDA has authorized 950 AI-based tools, the entire continent of Africa has approved less than 10 [7,8]. This stark contrast not only indicates that these tools aren't being developed at scale in certain regions of the world but also highlights that most of Africa and other LMICs lack clear safeguards for ensuring responsible AI in health [9]. From a public health perspective, this may lead to policy decisions with potential ramifications of harmful health consequences and an increase in inequality within nations, to the disadvantage of already under-privileged groups, especially in LMICs. **Policymakers are therefore crucial in the recognition of the challenges and gaps and the need to build on a concerted global effort to address infrastructure gaps, ensure equitable access, and establish robust governance systems with ethical considerations.**

2.1. DEFINITION OF AI

The diverse perspectives and evolving understanding of AI across social, cultural and professional contexts reflect the complexity to achieve harmonized AI policies and governance mechanisms. **This complexity is also evident in the varied definitions of AI used by international organizations, making it challenging to reach a universally accepted definition.** Among the main challenges are the rapidly evolving technology, alongside the different levels of AI capacity, and the various contexts, applications and perspectives that can be assumed when studying AI.

A good resource is the OECD's definition, as it is regularly reviewed to ensure alignment with the latest technological advancements and referenced by a majority of international organizations [10]. Despite the varied definitions, **AI is generally**

recognized as a machine-based system which involves algorithms and models to perform tasks that typically require human intelligence.

OECD	An AI system is a machine-based system that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments. Different AI systems vary in their levels of autonomy and adaptiveness after deployment.

2.2. GLOBAL AI REGULATORY FRAMEWORKS

The Global Digital Compact, adopted by world leaders at the 79th UNGA, is the latest of a number of documents laying down a set of shared principles and guidelines for the governance of digital technologies globally. According to a report by HealthAI on global AI governance landscape in health, international institutions, including the WHO, OECD, and others, have published a total of 30 AI governance and regulatory policies [11]. However, only approximately one-quarter is healthcare-specific. The WHO has released three documents specifically for AI in health, stating ethical principles to be upheld and general governance recommendations. The WHO, ITU, and WIPO also launched the Global Initiative on AI for Health (GI-AI4H) in July 2023, to enable, facilitate, and implement AI in health through strategic initiatives, guidance documents, and concerted global efforts [12]. The existing AI governance and regulatory policies encompass various thematic areas, incorporate diverse governance mechanisms and address a range of technologies. Most policies address thematic areas such as AI strategies, conceptual understanding of AI, ethical and/or procedural guiding principles, recommendations for the development and deployment of AI, as well as recommendations for regulatory frameworks. Over the past year, there has been a greater focus on large multi-modal models (LMMs) and Generative AI as well. However, an underlying theme in most of these global guidelines is the need to apply Responsible AI principles for effective governance of AI in health.

2.3. NEED FOR RESPONSIBLE AI PRINCIPLES FOR GOVERNANCE OF AI IN HEALTH

Responsible AI principles provide a solid foundation for the design, development, deployment and governance of AI systems in health. The most frequently referenced desired outcomes of these principles are to [11]:

i. Promote human and societal well-being;
ii. Ensure equitable access and outcomes;
iii. Establish clear mechanisms for accountability and responsibility;
iv. Avoid bias and discrimination;
v. Respect privacy and data security; and
vi. Ensure processes are transparent and understandable to different stakeholders including healthcare providers, patients, and the public.
vii. Other considerations, such as economic, social, and environmental costs, are less prominently reflected but nonetheless important.

In addition, governance of AI in health involves inter-related components such as data protection and cybersecurity. Reliable health data governance is an essential component for Responsible AI. It is essential to recognize the intertwined nature of

health data governance and AI governance to leverage and transform the analytics of health information into evidence-based policy decisions such as on outbreak management or health emergencies [13]. Depending on the country's context, strengthening health data governance laws can further safeguard individual and collective rights in the use of health data to train AI models, ensuring privacy and autonomy protection that is paramount for building necessary trust for individuals to share their data. An integrated approach can also simplify interoperability, ensure timely access to AI health tools, incentivize collaboration through partnerships for innovations, and address bias management to uphold justice and equity.

Having theoretical frameworks and principles is not enough. **Operationalizing these principles with assessment toolkits or checklists, guidelines, technical standards, as well as innovation and regulatory sandboxes can increase their applicability to the governance and validation of AI systems in health.** It will allow for developers, manufacturers, and regulators to assess whether the AI system is safe and effective overtime through the deployment of validation methodologies as well as establishment of robust and timely post market surveillance systems.

3. KEY RECOMMENDATIONS

1. Responsible AI principles and health data governance to be the foundation for AI governance in health

Governments must work inclusively with a wide range of stakeholders to turn commitments of the Global Digital Compact and other normative guidance concerning governance of AI, data governance, and human rights into implementable action. Human rights should be at the foundation of AI governance or laws to protect the right to health privacy and freedom of discrimination. Significant efforts should be made to strengthen national health data governance frameworks that encourage the availability and use of personal health data to serve health related public interest while promoting the protection of privacy and data security. Efforts to facilitate Responsible AI in health should focus on improving the quality, safety, and people centeredness of health care services through the establishment of effective guardrails, supporting scientific innovation to strengthen health systems, and investing in capacity building of the health workforce to use AI tools effectively and save costs.

Parliamentarians are in a unique position to propel governments to accelerate the adoption of Responsible AI in health with a focus on improving trustworthiness, building capacity, evaluating and evolving solutions, and accelerating progress together with all stakeholders. They play a central role in strengthening legal frameworks around health data governance that reflect the constantly evolving digital health landscape. Moreover, implementation of AI in the health sector requires robust technological infrastructure. Parliamentarians can also ensure right funding and drive allocation for national budgets towards investing in new and improving existing Digital Public Infrastructure (DPI) for health. This can significantly support an ecosystem that reduces complexity, lowers the cost of implementing new systems, and enables local actors to efficiently innovate and manage products that evolve with system needs.

2. Need for practical and process-oriented governance mechanisms

The private sector plays a critical role in ensuring the responsible governance of AI in health, as it is at the forefront of developing and implementing these technologies. Regulatory guidelines are essential to help navigate the complex landscape of AI in health, as they set the standards for quality, safety, and accountability. Moreover, well-defined regulations encourage innovation by providing a clear and predictable framework within which companies can operate and plan to ensure smooth transition to market. This fosters a stable environment that builds public trust in AI technologies and facilitates scalability which are crucial for widespread adoption of AI innovations in health and to create sustainable impact across diverse healthcare settings. Therefore, the private sector must actively participate in regulatory processes to drive responsible innovation and contribute to a future where AI technologies can scale effectively.

Adopting AI in the public sector for health requires a strong commitment to transparency, fairness, accountability, and the protection of privacy and human rights. Parliamentarians can ensure this and convene key stakeholders from both private and public sectors to implement effective mechanisms through impact assessments policies, robust oversight mechanisms, and ongoing monitoring. They can also drive innovation by collaborating with the private sector and offer incentives, such as grants, tax relief, and procurement opportunities, to encourage the creation of Responsible AI solutions that address societal needs. Public-private partnerships in the sector are vital for effective AI governance, as they foster collaboration with governments, industry, and civil society to ensure AI development aligns with ethical standards and societal values.

3. Strengthening existing regulatory mechanisms and enabling new ones for effective AI governance in health

Currently, governments and regulators around the world have been providing regulatory oversight largely through existing regulatory frameworks, such as medical device regulations, that provide a basis for the monitoring and evaluation of AI applications in health. Even in resource-limited settings, AI in health is not completely unregulated; rather, it is not explicitly regulated. While medical device regulations provide a valuable foundation for countries to create comprehensive regulatory frameworks for AI in health in the future, it is important to recognize that there are complexities in emerging AI systems such as their dynamic and evolving nature, that are insufficiently addressed in current regulatory frameworks. Furthermore, if regulations focus solely on AI explicitly intended for clinical use, the broader applications such as for health monitoring, preventive measures and promotion of wellbeing among the public may remain unregulated, posing potential risks to the safety of patients and communities at large.

A comprehensive regulatory approach can help to address significant market access barriers for AI solutions in health and build trust for the use of AI among diverse patient populations. Parliamentarians can advocate for and advance the strengthening of existing regulatory mechanisms by building additional layers of regulations and expanding the roles and responsibilities of health regulatory authorities to assess the safety, effectiveness, and societal implications of AI systems in health. They can also

push for regulations that mandate rigorous validation processes for AI tools, and continuous monitoring to assess performance, safety, and bias mitigation.

4. Need for better coordination and cross border collaboration

It is key to improve coordination and collaboration between existing institutions. Regulation of AI in health at the national level cannot be managed solely by medicines and devices regulators, the technology requires a more comprehensive multi-stakeholder approach to be effectively governed. At the global level, cooperation across countries will allow joint action that reduces the cost of the development of AI solutions, progresses regulatory effectiveness and efficiency, and improves the safety of AI solutions should there be poor outcomes or unintended consequences. Working together will unlock economic opportunity from AI as new innovations can scale within countries and across borders. Countries acting independently risks fragmentation of AI solutions that cannot scale across borders which would exacerbate existing digital inequities, prevent innovation from being shared, and not be prepared for future public health emergencies. Strengthening legislative framework to responsibly govern AI will ensure that local uses of AI are effective and safe, as well as promote wider uses of AI to achieve optimal health benefits for everyone. To ensure equitable AI innovations in health, coordinated international regulatory approaches are essential to reap the benefits of AI globally. Parliamentarians play a critical role in ratifying these agreements at the national level, thereby making their involvement in global AI governance discussions vital. By actively participating, they help shape policies that promote a fair digital health landscape, ensuring AI improves health outcomes for all without widening inequalities.

4. CONCLUSION

In conclusion, the responsible development and deployment of AI in health presents both immense opportunities and significant challenges. Parliamentarians play a crucial role in shaping the regulatory landscape to ensure AI technologies in health are safe, effective, and equitable. By fostering an enabling environment, strengthening existing regulatory mechanisms, adhering to Responsible AI principles, and promoting collaboration, we can harness the full potential of AI to improve health outcomes for all globally. As we move forward, a balanced approach that encourages innovation while prioritizing ethical considerations and human rights will be key to building trust and encouraging adoption of AI technologies in health. By facilitating inclusive dialogues and collaboration among diverse stakeholders, including governments, private sector, healthcare providers, patients, civil society, and the public, parliamentarians can ensure that AI technologies in health are developed, deployed, and governed in a way that addresses the needs of all members of society, leading to more equitable, effective, and trusted AI-driven health solutions.

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