World Research of Business Administration Journal
Vol. 4, No. 3, Nov2024

Future Directions: The Role of Government in Shaping Healthcare Engineering Decisions

https://www.doi.org/10.56830/WRBA11202405

Mahmoud Khalifa

College of Administrative Sciences, Applied Science University, Kingdom of Bahrain

Hagar M. Mohamed

Faculty of Medical & Health Sciences, Liwa College, Abu Dhabi, UAE

hagar.aly@lc.ac.ae

Abstract

Governments play an important role in shaping the health technology landscape in line with public health goals. This paper examines how government policies, laws, and policies interact with health technology. Focuses on the ways in which government services such as regulatory oversight and payment regulation directly influence healthcare engineers' decisions and policies The paper examines the challenges and opportunities presented by government intervention, noting that while early intervention can impede progress, public-private partnerships can create impact innovations in place. Through case studies of successful government initiatives, the paper demonstrates the real impact of this collaboration to improve public health care. The findings suggest that governments should adopt agile and proactive policies that seek to disrupt the current market in order to create a world-class healthcare system that targets the health needs of the population. By actively participating in health technology, governments can positively influence new products and strategies that benefit the population. This study highlights the critical role of government in shaping the future of healthcare technology.

Keywords: Healthcare, Role of Government, Administrative Decisions

Print ISSN 2771-1161
Online ISSN 2771-1153

1. Introduction

The government greatly impacts national healthcare systems, directly through policy and indirectly through affecting engineers' and others' practices. The project is working on discovering, creating, and promoting successful efforts - great, good, promising, emerging, and possible - to align healthcare engineering and services with public health. Previous research includes examining current and past gatherings of professionals taking the approach that current or future gatherings should be focusing on the role of government in this work. In the US, at least, policy, including legislation and regulations, is a promising leverage point for aligning healthcare engineering work with public health objectives. Alongside this opportunity are many challenges and more than a few examples of best practices in the very diverse domain. (Haldane, De Foo, Abdalla, Jung, & Tan, 2021)

Engineering healthcare systems to foster a population's health and well-being, instead of purely treating and quelling disease or reducing costs, is equally an engineering and a policy/practice issue. (Bartram & K. Setty, 2021) This paper is specifically about the role of government in shaping healthcare engineering (top executive branch personnel and elected officials are often some of the main targets on the government side of trying to enact new policies). Further complicating the engineering governance context is the state pushback against acceptance of the vaccine that has occurred since this work was started. (Cummings, Wells, & Trump, 2024). Given the diverse set of organizations and people that are working on this issue, we chose to focus on government's role to be able to comment on the plethora of informal networks and mechanisms that exist. Policymaking and attaining a political will to change the current system are two issues of central interest to this paper.

2. The Intersection of Government and Healthcare Engineering

Government entities play a variety of roles in shaping decisions related to healthcare engineering. Both mandates from legislation and regulations defining the scope of practice can be viewed as the government's way to directly influence the decisions of engineers in the field of healthcare. At a broader level, decisions made in departments and revenue are also laden with public policy that can change how healthcare will be engineered. (Health Organization, 2020). Additionally, government funding, through grants and at the level of RFPs released, can dramatically change the market dynamics of healthcare systems, specifically in the realm of health information technology. More broadly, government organizations help to influence decisions such as whether to invest in technology to mitigate the potential exposure of healthcare workers. These include a variety of different types of technologies such as wearable sensors, improved personal protective equipment, and sensors embedded into the engineered environment of care. (Ayo-Farai, Olaide, & Maduka, 2023)

Specifically, in the area of engineering medical devices and health information technology, the government has also been intimately involved in crafting the industry through the development of user-centered design and testing for medical devices, quality and safety metrics that influence medical device purchase contracts, quality and safety clusters, post-market surveillance mechanisms including database development for tracking individual device characteristics and device performance/outcomes, and regulatory science programs. (Manero, et al., 2020). These government

initiatives have shaped purchasing decisions for the devices as well as the actual engineered products designed, whether they are pharmaceuticals, medical devices, medical information technology, and others. Ultimately, throughout the course of this document, it is important to remain mindful that these government organizations would be appropriately responsible for driving the potential design and modifications to each of these suggested interventions. Additionally, the collaboration with the engineers in the development and modifications to one of these possible interventions for use in their specific systems setting is critical to the overall successful implementation. Government entities play an important role in this partnership with these engineers, empowering change. (MacNeill, Hopf, Khanuja, Alizamir, & M. Bilec, 2020).

3. Current Governmental Policies and Regulations Impacting Healthcare Engineering

As in any field that impacts public safety and health, there are governmental policies and regulations designed to ensure the safety and efficacy of medical, energy, and other devices engineered for health care. These policies and regulations are designed to encourage and support creativity and innovation in the device industry. In the U.S., regulatory agencies under the Department of Health and Human Services are the Food and Drug Administration and the Centers for Medicare and Medicaid Services. (Kramer, Xu, & Kesselheim., 2020). The two agencies have different roles; the FDA's oversight is designed to determine whether a device is safe and effective prior to entering the market, and the CMS regulatory oversight determines how the device will be used in the clinic as well as the amount of reimbursement the clinic will receive when using that device. In the U.S., medical devices are encouraged and regulated because they play a critical role, from a systems perspective, in reducing the cost of care for both individuals and some populations while increasing the quality of life and reducing the cost of disease for many. New devices are considered important to innovation, especially for overcoming barriers in the transition from pre-clinical to clinical research. (Health Organization, W., 2021)

For the medical regulatory policy and economic trade space, the interplay between the making and keeping of regulations and the changing of market dynamics and vice versa is crucial. The increased interactivity between the technological, economic, and regulatory aspects has made the appropriate technical, economic, and regulatory philosophies and methodologies indispensable. Public trust, which can be difficult to establish, maintain, and rebuild, can be driven by a desire to have a particular problem solved, by the public's fear, uncertainty, and doubt. Those considerations can drive technical investigation of the problem, and that problem definition can translate into a risk identification and management process. Regulatory systems address these risks through the requirements of law or government directive, chiefly in terms of a legal compliance obligation. (Markopoulou & Papakonstantinou, 2021).

The net effect is that engineers become key drivers of what is regulated, and the design of the regulatory questions, and in turn laws, can drive engineering design to meet the legal requirements. Thus, those who design and manufacture products quickly come to understand that regulations, in addition to market demands, are key drivers of their designs. For this reason, it is important to

Print ISSN 2771-1161
Online ISSN 2771-1153

consider the philosophies, methodologies, rules, values, and judgments' implications of the biomedical or health engineer, since these disciplines provide the products of biomedical engineering. Thus, policies designed to encourage technical innovation, creative design, and refinement will likely rely on technology designed, partly driven by anticipated regulatory focus on new technology at the regulatory interface. It will be important to employ vision domains to identify those items that can serve that purpose. (de Almeida, dos Santos, & Farias, 2021)

4. Challenges and Opportunities for Government Intervention in Healthcare Engineering

Embedding and spreading promising healthcare engineering improvements will often require a role for government. However, challenges facing governmental involvement in healthcare engineering are substantial. For example, government bodies typically exhibit robust bureaucratic inertia, and their purview is often limited to the funding they have and are likely to secure from the legislative process. Because radical harms can occur from governmental interference and governments are frequently much more risk-averse than industry, early government involvement can actually hamper good healthcare engineering improvements. Meanwhile, governmental involvement sufficiently late in the development process increases the chances that obstacles for incorporating the healthcare improvement have already been constructed by those same government agencies. In addition, the perennial gaps in regulations that always appear as health engineering speeds away from the regulatory process ensure that government leadership will be perpetually challenged. (Størkersen, Thorvaldsen, Kongsvik, & S. Dekker, 2020)

There are also emerging areas for good government work to spur innovation. These typically take the form of proactive policies that nurture research and development. Public-private partnerships have the potential, though not always realized, to be an especially productive form of collaboration. (Batjargal & Zhang, 2021) Governments bring significant resources to the table in public-private partnerships, and these can be used to target large and complex engineering challenges that are difficult to address on one’s own. Adaptive governance is especially important in dealing with new engineering solutions. (Othman & R. Khallaf, 2022)

5. Case Studies: Successful Governmental Initiatives in Healthcare Engineering

The case studies in this section showcase the government-initiated projects that touch upon the theme of healthcare engineering. For lack of a better definition, these are strategic policies, that is, procedures and structures that governments have put in place to solve some of the problems mentioned in the publication. Many of these initiatives are impacting the lives of people today. Indeed, they offer a roadmap towards some of the themes that have been identified for research, education, and innovation in healthcare and engineering, particularly around the role of early healthcare and the ways to engineer a better system. (Head, 2022).

Health i-Populi is a flagship project of Singapore's National Research Foundation. The central goal of the Health i-Populi Program is to develop AI-driven healthcare engineering technologies for the delivery of personal and precise intervention and prevention in public healthcare aspects, by

leveraging societal and environmental factors. Spain's ATI has long operated in the public health domain with a solid economic and social impact. In 2019, the bulk of this initiative included the 3rd and 4th calls for regenerative medicine products, from which 15 projects have been subscribed to the tune of 90 million euros. The returns are illustrated for a given period. This includes a compound progress index where the numerator is the estimated added value (assuming one or more products are put on the market, preventing the expenditure involved in conventional therapies, against the cost of the supplied initiative and against the spent invested in a discounted exploration trajectory with an assumed discount rate). The denominator is the amount of aid as prescribed by individual products. The investigation of progress constitutes part of a target delivery system designed cross-cohortally at the strategy's outset and at major review stages. The current ATI program runs from 2021 to 2023.

6. Conclusion and Recommendations

Conclusion This paper found that to secure healthcare engineering contributions to better health outcomes, governments must shape systems to promote that desired future and address current frustrations. It concludes that the roles and actions of government are key drivers of decisions by healthcare engineering companies. The long, complex, and risk-averse nature of the design process, the difficulty of getting new technologies adopted within the health service, and the patient and stakeholder involvement in engineering-based health decisions represent significant challenges. However, they also offer opportunities for developing a system with significant improvements to population health. Opportunities will not be seized with static policies that seek to correct one-off preconceived problems. Agile, responsive policies that seek to disrupt the current market are required if we are to create a world-class system to benefit the nation. We present a range of practical suggestions that would improve the links that will shape the contribution of healthcare engineering companies to the health sector. These suggestions set out ways to foster innovation, encourage innovators to choose to innovate for target conditions, exploit the use of digital healthcare data, develop adaptive health technology assessment in a more collaborative framework, make procurement bodies intelligent customers, and develop international standards of excellence. These would be the first steps on a journey to make the UK the best place in the world to develop and use technologies for the benefit of health. The basis of these suggestions is a commitment to an adaptive policy approach. Engineering companies will be more creative in their intentions if they feel involved in dialogues about the moral purpose of innovation beyond shareholder value within society. Research with companies suggests dissatisfaction with public and patient consultation exercises but enthusiasm for a meaningful dialogue with policymakers and engineering regulators. In the spirit of this, we invite the ongoing development of this work through dialogue and further research. Recommendations Government, in proactively interacting with healthcare engineering sectors in contextual terms, can positively influence the development of appropriate innovations that will better target population health needs of the future and influence both private and public actor healthcare engineering strategies in a wide range of areas. Our analysis suggests future research in the following areas will be valuable: to deepen and extend the contextual analyses undertaken in this study; the interaction of government policy, predominantly in relation to health technology assessment, with the private and social objectives, norms, and standards of healthcare engineering companies; the impact

Print ISSN 2771-1161
Online ISSN 2771-1153

of the legislative regulatory environment on companies; and alternative local interpretative frameworks.

References:

Ayo-Farai, O., Olaide, B. A., & Maduka, C. P. (2023). "Engineering innovations in healthcare: a review of developments in the USA,". *Engineering Science & Technology, vol. .*

Bartram, J., & K. Setty. (2021). "Environmental health science and engineering for policy, programming, and practice,". *Journal of Environmental Engineering, 2021. ascelibrary.org*.

Batjargal, T., & Zhang, M. (2021). Review of key challenges in public-private partnership implementation. *Journal of Infrastructure, Policy and Development, 5(2)*, 1378.

Cummings, L., Wells, E. M., & Trump, B. D. (2024). "Engineering and public health: converging disciplines for resilient solutions,". *Environment Systems and Decisions*.

de Almeida, P. G., dos Santos, C., & Farias, J. S. (2021). "Artificial intelligence regulation: a framework for governance," . *Ethics and Information Technology, vol. 23, no. 3,* , pp. 553-565.

Haldane, V., De Foo, C., Abdalla, S. M., Jung, A. S., & Tan, M. (2021). "Health systems resilience in managing the COVID-19 pandemic: lessons from 28 countries,". *Nature Medicine, vol. 27, no. 6*, pp. 964-967, .

Head, W. (2022). "Wicked problems in public policy: Understanding and responding to complex challenges,".

Health Organization, W. (2020). "Operational framework for primary health care: transforming vision into action,".

Health Organization, W. (2021). "WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products: revision VI," .

Kramer, B., Xu, S., & Kesselheim., A. S. (2020). "Regulation of medical devices in the United States and European Union,. *in *The Ethical Challenges of...**.

MacNeill, J., Hopf, H., Khanuja, A., Alizamir, S., & M. Bilec. (2020). "Transforming the medical device industry: road map to a circular economy: study examines a medical device industry transformation," . *Health Affairs*.

Manero, A., Smith, P., Koontz, A., Dombrowski, M., Sparkman, J., Courbin, D., et al. (2020). Leveraging 3D printing capacity in times of crisis: recommendations for COVID-19 distributed manufacturing for medical equipment rapid response. *International journal of environmental research and public health, 17(13)*, 4634.

Markopoulou, & Papakonstantinou, V. (2021). "The regulatory framework for the protection of critical infrastructures against cyberthreats: Identifying shortcomings and addressing future challenges: The …,". *Computer law & security review*.

Othman, K., & R. Khallaf. (2022). "Identification of the barriers and key success factors for renewable energy public-private partnership projects: a continental analysis,". *Buildings*.

Størkersen, K., Thorvaldsen, T., Kongsvik, T., & S. Dekker. (2020). "How deregulation can become overregulation: An empirical study into the growth of internal bureaucracy when governments take a step back,". *Safety Science*.

Print ISSN 2771-1161
Online ISSN 2771-1153