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VERCOMING HESITANCY: VACCINES, SOCIETY, AND EQUITABLE ACCESS

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PREFACE

Vaccination stands as one of the most significant public health achievements in human history, saving countless lives and preventing the spread of infectious diseases across the globe. Yet, in the 21st century, the promise of vaccines faces complex challenges — from the persistence of misinformation and cultural resistance to structural barriers in access and financing. This book brings together an interdisciplinary collection of research and reflections that illuminate these challenges and explore innovative strategies to overcome them.

The chapters compiled here examine vaccine hesitancy from multiple perspectives—social, cultural, economic, political, and religious—offering evidence-based insights into both its causes and potential solutions. From the gendered dynamics of health decision-making in conservative societies, to the transformative potential of Islamic philanthropic models like waqf in ensuring equitable vaccine access, the contributions in this volume shed light on the nuanced interplay between public trust, cultural contexts, and effective health communication.

By addressing issues such as digital misinformation, community engagement, religious endorsements, and sustainable financing mechanisms, the book not only enriches academic discourse but also provides practical guidance for policymakers, healthcare practitioners, and public health advocates. The diversity of case studies and analytical frameworks ensures that the findings and recommendations presented here will resonate beyond their immediate contexts, offering lessons for both local and global health initiatives.

This volume would not have been possible without the dedication of its contributors, whose scholarly rigor and commitment to improving public health have made this work a valuable resource for researchers, practitioners, and decision-makers alike. I extend my sincere appreciation to all authors for their insightful chapters, and to the editorial and publishing teams for their meticulous work in bringing this book to fruition.

It is my hope that the ideas and strategies articulated in these pages will inspire further research, foster cross-sector collaboration, and contribute meaningfully to the advancement of equitable, culturally sensitive, and sustainable vaccination efforts worldwide.

Dr. Demet ÇELEBİ
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CHAPTER 1

RESULTS OF ADDRESSING VACCINE HESITANCY: A SHORT VIEW

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INTRODUCTION

Achieving high levels of vaccine coverage is key to responding to and mitigating the impact of the pandemic on health and aged care systems and the community. In many countries, vaccine hesitancy, resistance, and refusal are emerging as significant barriers to immunization uptake and the relaxation of policies that limit everyday life. Vaccine hesitancy/ resistance/ refusal is complex and multi-faceted. Individuals and groups have diverse and often multiple reasons for delaying or refusing vaccination. These reasons include social determinants of health, convenience, ease of availability and access, health literacy understandability and clarity of information, judgments around risk versus benefit, notions of collective versus individual responsibility, trust or mistrust of authority or healthcare, and personal or group beliefs, customs, or ideologies. Published evidence suggests that targeting and adapting interventions to particular population groups, contexts, and specific reasons for vaccine hesitancy/ resistance may enhance the effectiveness of interventions. While evidence regarding the effectiveness of interventions to address vaccine hesitancy and improve uptake is limited and generally unable to underpin any specific strategy, multi-pronged interventions are promising. In many settings, mandating vaccination, particularly for those working in health or high-risk/ transmission industries, has been implemented or debated by Governments, decision-makers, and health authorities (1).

Common concerns underlying hesitancy include uncertainty about the need for vaccination and questions about vaccine safety and efficacy. Sociodemographic factors associated with parental vaccine hesitancy vary across locations and contexts. Studies about the psychology of hesitancy and how parents respond to interventions highlight the role of cognitive biases, personal values, and vaccination as a social contract or norm. Evidence-based strategies to address vaccine hesitancy include presumptive or announcement approaches to vaccine recommendations, motivational interviewing, and the use of immunization delivery strategies like standing orders and reminder/recall programs. A smaller number of studies support the use of social media and digital applications to improve vaccination intent. Strengthening school vaccine mandates can improve vaccination rates, but policy decisions must consider the local context (2).

Factors that promote vaccine hesitancy or acceptance: demographic factors influencing vaccination (ethnicity, age, sex, pregnancy, education, and employment), accessibility and cost, personal responsibility and risk perceptions, precautionary measures taken based on the decision to vaccinate, trust in health authorities and vaccines, the safety and efficacy of a new vaccine, and lack of information or vaccine misinformation (3).

Financial or other incentives for addressing vaccine hesitancy may have limited effectiveness with much evidence for benefit appearing to have been translated across from other public/preventive health issues such as smoking cessation. Multicomponent, dialogue-based (i.e., communication) interventions are effective in addressing vaccine hesitancy/resistance. Multicomponent interventions that encompass the following might be effective: (i) targeting specific groups such as unvaccinated/under-vaccinated groups or healthcare workers, (ii) increasing vaccine knowledge and awareness, (iii) enhanced access and convenience of vaccination, (iv) mandating vaccination or implementing sanctions against non-vaccination, (v) engaging religious and community leaders, (vi) embedding new vaccine knowledge and evidence in routine health practices and procedures, and (vii) addressing mistrust and improving trust in healthcare providers and institutions via genuine engagement and dialogue. It is universally important that healthcare professionals and representative groups, as often highly trusted sources of health guidance, should be closely involved in policymaker and health authority decisions regarding the establishment and implementation of vaccine recommendations and interventions to address vaccine hesitancy (1). Vaccine hesitancy (VH) is a leading cause of suboptimal vaccine uptake rates worldwide. The interaction between patients and healthcare providers (HCPs) is the keystone in addressing VH. However, significant proportions of HCPs, including those who administer vaccines, are personally and professionally vaccine-hesitant (4). By refusing or delaying vaccination, vaccine-hesitant individuals and communities undermine the prevention, and ultimately, elimination of communicable diseases against which safe and effective vaccines are available (5).

The key challenges and advantages of evidence-based community strategies for overcoming parent/caregiver vaccine hesitancy, specifically (i) community-participatory vaccine hesitancy measurement, (ii) communication

approaches, (iii) reinforcement techniques (eg, incentives, mandates), and (iv) community-engaged partnerships (eg, vaccine champion training, vaccination in community settings). This article also discusses important considerations when vaccinating children and adolescents in non-primary care settings (school-based health centers, pharmacies, and community events) (6). The determinants of vaccine hesitancy remain complex and context-specific. Betrayal aversion occurs when an individual is hesitant to risk being betrayed in an environment involving trust. In this pre-registered vignette experiment, we show that betrayal aversion is not captured by current vaccine hesitancy measures despite representing a significant source of unwillingness to be vaccinated (7).

Vaccine hesitancy is a problem attracting growing attention and concern. Communication can be an effective tool to counteract vaccine hesitancy and promote optimal vaccine uptake. Readability has been recognized as one of the more important aspects of health communication for achieving good health literacy (8). Vaccine compliance among schoolchildren is essential to the health of an entire community, given that many pediatric illnesses are vaccine-preventable. School nurses are involved in the promotion of vaccines in a school district, as they provide health education to students and families and are responsible for vaccine surveillance. Promoting vaccine compliance as a matter of public health can be challenging for school nurses, especially if a community holds strong beliefs regarding the necessity of pediatric vaccines. This article reviews the history of vaccine mandates, addresses challenges associated with vaccine compliance, and provides interventions school nurses can use when providing care to students and families regarding vaccine hesitancy. In following the nursing process, a school nurse can identify students missing vaccine(s) and evaluate for hesitancy, before implementing interventions that provide education to students and families. Several cost-efficient and accessible interventions can facilitate effective education and promote vaccine compliance (9).

Technology holds great potential to address many vaccine hesitancy determinants and support vaccine uptake given its ability to amplify positive messages, support knowledge, and enhance providers' recommendations. Modalities previously implemented with variable success have included

automated reminder systems, decision support for clinicians, online education programs, social media campaigns, and virtual reality curricula. Further research is needed to identify the optimal uses of technology at the patient/parent and provider levels to overcome vaccine hesitancy. The most effective interventions will likely be multipronged providing patients, parents, and providers with information related to vaccine status (10).

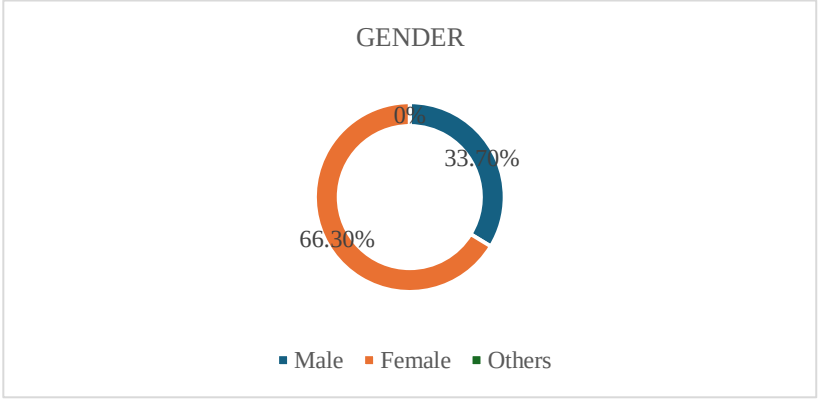
1. MATERIALS AND METHODS

This study used an online Google Form questionnaire as the instrument. The questionnaire was distributed in this way because each of the participants has his or her personal email account and most of them have their own Instagram account as well. The target respondents are the young people of Uzbekistan and India under 25 because the young people ratio is higher in this area. This work is done to create awareness of the developing vaccine hesitancy among the public.

2. RESULTS

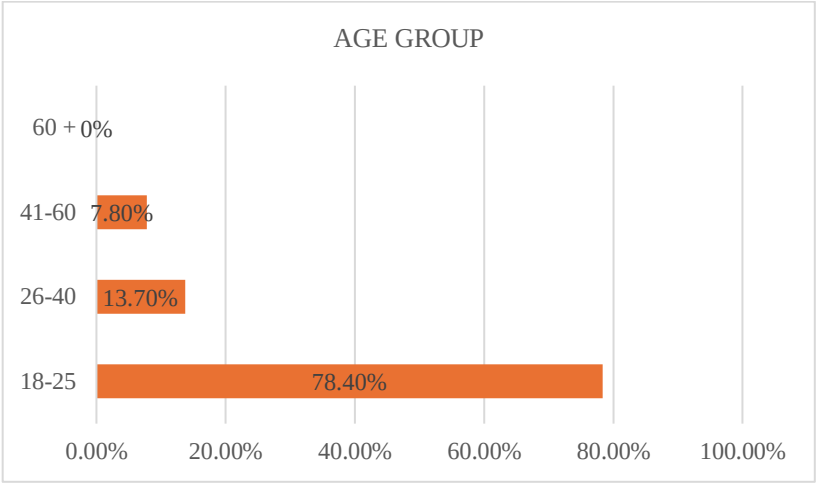
The survey was conducted all were asked to answer using a specially designed public awareness on vaccine hesitancy questionnaire. The part below shows the results of the survey. People of about 100 were under survey. Among them, Males (33.7%), Females (66.3%), and Others (0%).

Table 1: Gender



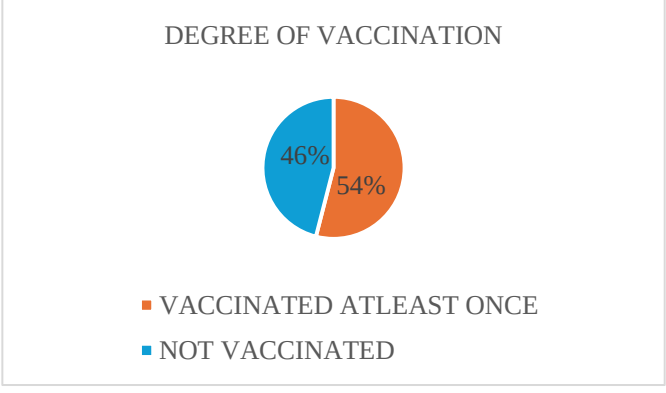
The age of the participants was from 18-25 years old (78.4%), from 26-40 years old (13.7%), from 41-60 years old (7.8%), and from 60 and above (0%).

Table 2: Age Group



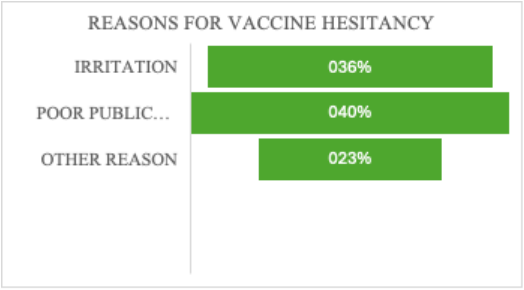
The respondents of my survey have taken a vaccine in their lifetime (more than half-54%). Increasing confidence in trustworthy information sources, expanding access to correct information about vaccinations, and combating misinformation can all help people make better vaccination decisions.

Table 3: Degree of vaccination



The people in the survey received some kind of irritation when they have been vaccinated (36.3%). So, they should have been by influenced vaccine hesitancy. But most people are not aware of vaccines and believe certain myths regarding vaccines. Many respondents hesitate to vaccinate due to the poor public health care system (40.4%). So, it contributes to recent outbreaks of measles, pertussis, and other diseases.

Table 4: Reasons for a vaccine hesitancy



CONCLUSION

As an objective of this survey, this paper presented to create and identify the reasons for vaccine hesitancy. The survey results made me realize concerns about vaccine safety, beliefs about the effectiveness of vaccines, and mistrust of the healthcare system are the reasons for vaccine hesitancy. It is also important to address the social and cultural factors that can contribute to vaccine hesitancy. This may involve building trust with communities that have been underserved by Government and engaging with community leaders and influencers to promote vaccination and address concerns. Vaccine resistance and hesitation continue to be substantial obstacles to providing individuals and communities with complete protection against serious illness, despite the positive effects of vaccination on the control and prevention of many infectious diseases. Persuasion and some kind of force, typically in the form of vaccination mandates, are the main responses to the issue of vaccine reluctance. Ensuring vaccines are affordable and accessible to everyone is important in addressing vaccine hesitancy.

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CHAPTER 2

WOMEN, MYTHS, AND MISINFORMATION: UNDERSTANDING GENDERED VACCINE HESITANCY IN CONSERVATIVE SOCIETIES

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INTRODUCTION

Vaccine hesitancy is presently among the most crucial 21st-century worldwide health issues, becoming officially endorsed by the World Health Organization (WHO) as being among the most important ten threats to world health (WHO, 2019). To safeguard vulnerable populations from severe complications due to infections, the WHO has set a target of reaching 90% global coverage for essential childhood vaccinations (WHO, 2021). Vaccine hesitancy was described by the WHO Strategic Advisory Group of Experts (SAGE) as "delay in acceptance or refusal of vaccines despite availability of vaccination services" (WHO SAGE, 2014). Despite widespread vaccine hesitancy being occurring in virtually every part of the globe, causes and forms are clearly diverse. In conservative societies, particularly in South Asia and Muslim-majority countries, vaccine hesitancy is influenced not only by individual risk perceptions and scientific skepticism but also by deeply entrenched cultural norms, religious beliefs, and gendered power structures (Closser, 2010; Yahya, 2007). In such contexts, women's health choices are rarely autonomous. Instead, they are embedded within patriarchal family systems, where male guardians (fathers, husbands, brothers) act as primary decision-makers for household health (Shaikh & Hatcher, 2005). Religious leaders, community elders, and extended kin networks further shape narratives about vaccines, which are often framed through religious, moral, and reproductive lenses (Bendixsen, 2020). Women, particularly in rural and low-literacy communities, rely heavily on informal health networks, such as family elders, female relatives, and community figures sources often saturated with misinformation (Ali & Asghar, 2021). Furthermore, gendered cultural myths, including the belief that vaccines cause infertility, violate female modesty, or contain haram (religiously prohibited) substances, disproportionately discourage women from seeking vaccines (Rehan, 2021). Silence can also be a form of avoidance, not just of the issue at hand but also of the emotional and personal toll that comes with addressing it and publicly engaging in activism for change. This can expose individuals to risks such as public backlash, shaming, harassment, or even violent attacks and legal repercussions. Examples include breaking the silence around abortions, discussing mental health, or challenging anti-vaxxers. Therefore, silence is ontologically neutral (Jaworski,

1993). Like voice, it can be perceived as good or bad depending on its moral and political context. However, it is often a strategic choice because it allows for indirect communication (Dimitrov, 2015).This chapter adopts a gender lens to examine how these cultural, religious, and digital narratives intersect to fuel vaccine hesitancy among women, while also exploring strategies for gender-responsive health communication that can improve women's health autonomy and vaccine uptake in conservative societies.

1. DEFINING VACCINE HESITANCY

The WHO's Strategic Advisory Group of Experts (SAGE) on Immunization defines vaccine hesitancy as a "delay in acceptance or refusal of vaccines despite availability of vaccine services" (WHO SAGE, 2014). Vaccine hesitancy is influenced by a "3C model": confidence, complacency, and convenience (MacDonald, 2015). Confidence relates to trust in vaccines, health authorities, and science; complacency reflects the perceived need for vaccines; and convenience involves physical and logistical access to vaccines. However, in conservative contexts, this framework alone is insufficient. Gender norms, family hierarchies, religious beliefs, and cultural anxieties heavily shape the decisions women make or are allowed to make about vaccines (Closser, 2010; Yahya, 2007). Therefore, a gender-sensitive understanding is essential to addressing vaccine hesitancy in patriarchal societies.

1.1 Gendered Dimensions of Health-Seeking Behavior

Women's health-seeking behavior in conservative societies is deeply gendered, influenced by patriarchal norms, cultural expectations, and structural inequalities (Manderson & Warren, 2016). In such contexts, women's autonomy over health choices is significantly restricted by a combination of limited mobility, male guardianship laws, and deep-seated cultural taboos surrounding women's bodies and reproductive health (Shaikh & Hatcher, 2005). Women often rely on male relatives—husbands, fathers, and even sons—to approve and facilitate access to healthcare (Qureshi & Shaikh, 2006). This collective decision-making dynamic place women's health within the realm of family honor, modesty, and obedience, discouraging independent or proactive health-seeking behavior. In South Asia, where conservative

interpretations of culture and religion further constrain women's agency, female literacy rates remain alarmingly low. According to UNESCO (2023), female literacy rates in Pakistan stand at 46%, in Afghanistan at 23%, and in rural India, the rates are similarly low, particularly among marginalized communities. Low literacy creates information asymmetries, where women lack the ability to critically assess health information and are more susceptible to myths and misinformation (Shaikh et al., 2018). Cultural modesty norms further complicate health communication targeting women. In many rural areas, male health workers are forbidden from directly interacting with female patients, requiring communication to pass through male family members or elder women acting as intermediaries (Haq et al., 2021). The filtering process greatly increases the risk of distortion or selective communication, especially when health interventions like vaccination are viewed as foreign, Western, or morally compromised (Closser, 2010). Health decisions are not purely medical but are shaped by religious interpretations and cultural anxieties (Ali & Asghar, 2021). Immunization efforts are often faced with cultural resistance when vaccines are presented as potential threats to the fertility or moral integrity of women fear fueled by networks of gossip and religious sermons (Rehan, 2021). In societies where female modesty and reproductive health issues are taboo, even basic information on vaccine safety and advantages may be absent from women's knowledge domains (Shaikh et al., 2018). Finally, an awareness of the gendered character of health-seeking behavior explains how structural inequality, patriarchal control, religious authority, and cultural silence intersect to affect women's vaccine choices. Intervening in these aspects requires the application of gender-sensitive health communication approaches empowering women as decision-makers, rather than viewing them as passive vaccine recipients.

1.2 Case Example: Vaccine Hesitancy and Gender Barriers in Rural Pakistan

In rural Pakistan, polio vaccination campaigns have consistently faced challenges in reaching women directly, particularly in conservative areas where cultural norms regarding female seclusion (purdah) limit women's mobility and their interactions with outsiders, including health workers (Closser, 2010). Female health workers, like Lady Health Workers (LHWs), who are essential

to community vaccination efforts, often encounter resistance from male family members who prevent them from entering homes, especially when male relatives are not present (Kadir et al., 2013). These gender-based access barriers not only hinder the vaccination process but also leave women without direct access to reliable vaccine information, making them reliant on informal sources such as female relatives, neighbors, and religious leaders (Ali & Asghar, 2021). Within these informal networks, health knowledge is often influenced by rumors, cultural myths, and religious beliefs. Conspiracy theories suggesting that vaccines are part of a Western agenda to sterilize Muslim women have gained significant traction in these communities, where a woman's fertility is closely linked to her social value (Rehan, 2021). This misinformation spreads through community gossip and religious sermons, where vaccines are sometimes depicted as haram or containing impure substances (Ali & Asghar, 2021). The gendered aspect of vaccine hesitancy in rural Pakistan highlights how women's health autonomy is systematically undermined by patriarchal control, limited health literacy, and restricted access to formal health communication channels (Shaikh & Hatcher, 2005). Consequently, women's decisions regarding vaccines are often mediated by male relatives and community leaders, reinforcing their passive role in health-related decision-making. This situation emphasizes the critical need for gender-sensitive communication strategies, such as engaging female religious scholars, organizing women-only health sessions, and promoting digital health literacy initiatives.

1.3 Focus on South Asia, Muslim Societies, and Conservative Cultural Contexts

Vaccine hesitancy in South Asia and Muslim-majority societies is deeply intertwined with cultural conservatism, patriarchal social structures, and religious interpretations that influence daily life in these areas (Shaikh & Hatcher, 2005). In nations such as Pakistan, Afghanistan, Bangladesh, and certain rural regions of India, health decisions especially those concerning women and children are often made collectively within families, typically under the influence of male elders and religious leaders (Closser, 2010; Qureshi & Shaikh, 2006). Women’s autonomy in health matters is significantly limited

by purdah norms, restricted mobility, and low literacy levels, which lead to reliance on informal health networks (Ali & Asghar, 2021). Additionally, religious beliefs significantly impact vaccine-related decisions. In many conservative Muslim communities, vaccines are often perceived as Western interventions that could jeopardize female fertility or contain haram ingredients (Rehan, 2021). This religious perspective, coupled with the spread of digital misinformation, heightens skepticism towards public health initiatives. In rural South Asia, the pursuit of health is woven into a complex tapestry of cultural myths, religious teachings, and family honor, presenting distinct challenges for women's vaccine acceptance (Manderson & Warren, 2016). Grasping this culturally rooted vaccine hesitancy is crucial for creating effective, gender-sensitive interventions that respect cultural and religious contexts.

1.4 Patriarchy and Health Decision-Making

In conservative societies, especially in South Asia and predominantly Muslim contexts, patriarchy influences every aspect of women's health autonomy (Hussain, 2010). Health decisions, including those about vaccinations, are seldom made by women themselves. Instead, male family members—husbands, fathers, brothers, and even sons serve as gatekeepers, deciding whether a woman can access healthcare, consult a doctor, or receive a vaccine (Shaikh et al., 2018). This gendered power dynamic mirrors broader patriarchal norms that perceive female health as a family issue rather than an individual right (Qureshi & Shaikh, 2006). When it comes to vaccinations, this male control is even more evident, as vaccines are often viewed not just as health measures but as moral and reproductive concerns that could affect family honor (Rehan, 2021). In rural areas of Pakistan and Afghanistan, for instance, rumors linking vaccines to infertility or Western population control agendas have been spread by male religious leaders and community elders, reinforcing male resistance to women's vaccination (Ali & Asghar, 2021). This paternalistic decision-making framework silences women regarding their own health and that of their children, heightening vaccine hesitancy through a gendered lens of suspicion, misinformation, and patriarchal dominance.

1.5 Religious Endorsement and Control

In conservative societies, especially in Muslim-majority areas, religious leaders play a vital role in shaping public views on health interventions, such as vaccinations (Yahya, 2007). Religious scholars, imams, and community preachers are often regarded as moral and spiritual authorities, particularly among rural women who may have limited access to formal education and health information (Shaikh et al., 2018). Their sermons, religious rulings (fatwas), and informal advice significantly impact how vaccines are perceived in terms of safety, religious acceptability, and alignment with Islamic beliefs. In Pakistan, the religious opposition to the polio vaccine has been especially impactful. Fatwas issued by some clerics claimed that polio vaccines contained haram substances or were part of a Western plot to sterilize Muslim populations (Ali & Asghar, 2021). Such religiously framed misinformation spread rapidly in rural areas, where women often receive health knowledge secondhand through male family members who attend mosque sermons or religious gatherings (Closser, 2010). This religious control over health messaging reinforces vaccine hesitancy and fosters a climate of suspicion, particularly when women's reproductive health and fertility are framed as moral and religious concerns. To improve vaccine acceptance, religious leaders must be engaged as allies, using their pulpits to promote accurate, faith-compatible health information, especially in rural and conservative areas.

1.6 Cultural Myths and Misinformation

In conservative societies, particularly in South Asia and the Middle East, cultural myths and misinformation surrounding vaccines disproportionately target women's reproductive health. These myths exploit deep-seated cultural anxieties about fertility, menstruation, and female modesty, presenting vaccines as a threat to women's biological and moral purity (Rehan, 2021). A persistent myth claims that vaccines especially polio and COVID-19 vaccines cause infertility, a fear that resonates strongly in cultures where a woman's social value is often tied to her ability to bear children (Yahya, 2007)

In many rural South Asian and Middle Eastern communities, vaccines are also portrayed as Western tools of population control, part of a broader

conspiracy to sterilize Muslim women and weaken the Ummah (Ali & Asghar, 2021).

Additional fears relate to loss of modesty if vaccination requires physical contact with male health workers, or disrupts menstrual cycles, adding further cultural resistance (Shaikh et al., 2018). These myths circulate primarily through informal female networks, including mothers-in-law, female relatives, and neighborhood gossip, as well as through religious sermons and social media platforms where misinformation thrives unchecked (Ali & Asghar, 2021). These gendered misinformation channels make it particularly difficult to deliver accurate, science-based health messaging directly to women.

1.7 Religious Interpretations and Vaccine Mistrust

Religious interpretations play a critical role in shaping vaccine acceptance in Muslim-majority societies, where religious permissibility (halal status) is a significant concern. In many conservative Muslim communities, vaccines are suspected of containing haram substances, particularly porcine gelatin or alcohol-based preservatives, both of which are considered religiously forbidden (Inhorn & Serour, 2011). These suspicions contribute to vaccine mistrust, particularly among rural and religiously observant communities, where religious rulings significantly influence health decisions (Yahya, 2007). Despite many Islamic scholars and health authorities issuing fatwas that clarify the acceptability of vaccines, these important messages often do not reach rural women. This communication gap is due to gender-related barriers, such as limited mobility for women, low literacy levels, and the dominance of men in religious discussions (Bendixsen, 2020). Women, who depend on male family members and religious leaders for health information, often receive these interpretations in incomplete or distorted ways, which further increases their doubts (Shaikh et al., 2018). Additionally, in areas where religious leaders have previously opposed vaccination efforts, like in Pakistan's polio campaigns, a legacy of mistrust persists, especially in conservative households. To effectively address religious interpretations that contribute to vaccine hesitancy, it is essential to work with trusted religious leaders to ensure that health messages compatible with their faith reach women directly.

1.8 Digital Misinformation and Social Media

The increasing availability of smartphones and mobile internet has changed the way women in conservative societies obtain health information. In many rural areas of South Asia and the Muslim world, social media platforms like WhatsApp, Facebook, and TikTok have emerged as key sources of health information, taking the place of traditional health education (Ahmed et al., 2021). However, this increased digital access also exposes women to misinformation, including anti-vaccine narratives, conspiracy theories, and religiously framed health myths (Chakrabarti, 2020). Women in low-literacy settings often rely on audio messages, images, and viral videos, which are easily manipulated to spread sensational claims about vaccines (Shaikh et al., 2018). For example, during COVID-19 vaccination campaigns, viral videos falsely claimed that the vaccine caused infertility or contained tracking chips designed to spy on Muslim women (Rehan, 2021). WhatsApp family groups and women-only online forums became echo chambers where cultural fears around reproductive health and Western medical agendas merged into compelling anti-vaccine content (Chakrabarti, 2020). With limited digital literacy, many rural women lack the skills to critically assess online content, leaving them vulnerable to manipulated religious endorsements or distorted health advice. Addressing digital misinformation requires targeted digital literacy programs and culturally tailored health campaigns that meet women where they are online.

CONCLUSION AND RECOMMENDATIONS

Addressing gendered vaccine hesitancy in conservative societies requires culturally sensitive, gender-responsive communication strategies that account for patriarchal control, religious influence, and informal female networks. Women's health decisions are rarely autonomous; they are mediated by male relatives, religious leaders, and community elders. Effective strategies must train female health workers to act as trusted messengers, ensuring health information reaches women directly. Religious leaders should be engaged to publicly endorse vaccines, helping to counter religious misinformation. Health campaigns should take advantage of female-only spaces, like mothers' groups and women's religious gatherings, to deliver accurate and culturally relevant

health education. Additionally, digital campaigns aimed at women, designed for low literacy levels and in local languages, can effectively address online misinformation.

The role of male gatekeepers in women's health decisions.

- The influence of religious leaders in shaping health narratives.
- The power of informal female networks in transmitting health information.

Recommendations

- Train female health workers to act as reliable and culturally sensitive sources of information.
- Leverage female-only spaces (mothers' groups, women's religious gatherings) for targeted health education.
- Encourage religious leaders to support vaccines during their sermons.
- Create digital campaigns aimed at women, designed to align with rural literacy levels and respect cultural sensitivities.

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CHAPTER 3

HEALTH WAQF FOR VACCINES: AN ISLAMIC FINANCING MODEL TO ENSURE VACCINE ACCESS FOR SOCIETY

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INTRODUCTION

Vaccination is widely recognised as one of the most effective and cost-efficient public health interventions. It plays a critical role in the prevention of infectious diseases, the reduction of morbidity and mortality, and the enhancement of overall public health (Bonanni & Azzari, 2018; Esposito et al., 2016; Hekimoğlu, 2016; Kahraman & Kara, 2024; Lévy-Bruhl, 2016; Lindstrand et al., 2021; Mbodji & Dramane, 2024; Salleras, 2015; Zhang, 2019). Nonetheless, in numerous developing nations, vaccine access is a significant challenge (Lindstrand et al., 2021; Mbodji & Dramane, 2024; Oladapo et al., 2024; Taha et al., 2022). Factors such as government budget limitations (Standaert et al., 2017), inadequate health infrastructure (Cuadros et al., 2023; Summan et al., 2022), and reliance on international aid often hinder the uneven and effective distribution of vaccines (Dian Effendi, 2023). For example, research by Ozawa et al. (2016) suggests that investing in vaccination can provide substantial economic benefits, but the financing challenge remains a significant obstacle to its implementation (Lindley et al., 2009; Shen et al., 2009).

In this context, Islamic financial instruments such as waqf offer great potential for sustainable alternative financing (Budalamah et al., 2019; Hassana et al., 2020). Waqf is traditionally used to fund a variety of social services, including education (Mohamed Nor & Yaakub, 2017; Usman & Ab Rahman, 2023) and Health (Çağlar & Doğtekin, 2022; Gürsoy & Özdeğer, 2022), adaptable to support vaccination programs (Vásquez & Trudeau, 2024). Studies by Cizakca (2000) emphasise that waqf has the potential to support the health sector through sustainable financing and Sharia principles (Aziz et al., 2013; Kachkar & Alfares, 2022; Zain et al., 2024). Thus, health waqf can be an innovative solution in addressing the challenges of vaccination financing in developing countries, ensuring that less-than-enabled communities have access to the necessary vaccines.

1. HEALTH WAQF AS A SUSTAINABLE FINANCING MODEL

1.1 Productive Waqf Concept: How Can The Waqf Fund Be Invested, and How Are The Results Used for Vaccine Financing?

Productive waqf is a financing model that could drive the people's economy and create sustainable economic resilience (Sugianto & Fadhel Mohammad, 2024). Productive management of land waqf can be a welfare factor of society, with a financing model based on community participation. The musharakah bi tamlikah bi tamlikah is seen as having a lower risk (Furqon, 2014). Productive waqf involves the development of assets and value-added, generating profits without reducing the principal assets (Nurul Fadhillah, 2021). Implementation can open new jobs, manage public services, and ease the economic burden of the community (Abrori, 2022). As a productive property development solution, waqf plays an important role in the activities of the general public and can spur economic growth in Muslim-majority countries (Abrori, 2022).

Productive Waqf is an important instrument in Islamic economics to improve social welfare, especially in the education, health, and economic empowerment sectors (Nuraini, 2024). Productive waqf management through Islamic investment, as practised by Global Waqf ACT, has been proven to comply with Islamic law and can distribute benefits for the public interest (Ziyad Ulhaq & Firda Anidiyah, 2020). Productive waqf can solve productive property development in society and help activities (Abrori, 2022). The new Waqf Act opens a broader opportunity for people to do charitable through money and potential waqf in other forms, such as gold and stocks (Nurfaidah, 2016). However, the implementation of waqf still faces challenges, such as a lack of professional management and low public awareness (Nuraini, 2024).

Waqf and sukuk are Islamic financial instruments that potentially support socio-economic development, including health and infrastructure sectors. Waqf has been proven effective in financing low-income people's education, health, and economic empowerment (Nuraini, 2024; Nurfaidah, 2016). Productive waqf, such as money waqf, can fund micro-business and educational programs (Nuraini, 2024). Sukuk also plays a role in financing infrastructure

development (Anik & Prastiwi, 2017). However, the implementation of waqf still faces challenges, such as a lack of professional management and public awareness (Nuraini, 2024). To optimise the potential for waqf and sukuk, regulation improvements, transparent management, and collaboration between managing institutions, governments, and communities (Nuraini, 2024; Rohim, 2021). The development of this Islamic financial instrument can support halal industry growth and society's welfare (Rohim, 2021).

Research shows that blockchain technology can improve transparency and accountability in waqf management, per Islamic financial principles (Arwani & Priyadi, 2024). The accountability of waqf institutions can be improved through internal and external audits, increasing public trust (Arief et al., 2011). Waqf Core Principle and PSAK 112 reference realising accountability and transparency in waqf management, including transaction arrangements and financial reporting (Aryana, 2022). The application of productive waqf that conforms to AAOIFI standards can improve the welfare of the people, as applied by the Solo Peduli Umat Foundation (Catur Wuragil et al., 2023). Implementing these principles can optimise the utilisation of waqf funds in various sectors, including health and vaccination.

Productive Waqf has great potential to support economic and social development, including health and education. Productive land waqf financing models can be applied with risk consideration, such as community participation-based financing and the musyarakah bi tamlikah (Furqon, 2014). Productive waqf can optimise people's assets for economic activities, create jobs, and support social programs (Sugianto & Fadhel Mohammad, 2024). Historically, waqf has been instrumental in financing Islamic education and health in various countries (Nurfaidah, 2016). An example of successful implementation of productive waqf for education is Al-Azhar in Egypt, which can finance education operations and provide scholarships to students worldwide without relying on government or student payments (Kasdi, 2016).

1.2 Mechanisms and Implementation: How Health Wakaf Supports The Health Sector, Especially Vaccinations

Wakaf, a key instrument in Islamic economics, significantly improves social welfare and supports economic recovery in Indonesia. It has proven

effective in various sectors, including education, healthcare, and economic empowerment of low-income people (Nuraini, 2024). Productive waqf, such as cash waqf used to fund micro-enterprises and education programs, has helped improve people's quality of life (Darwanto, 2012; Nuraini, 2024). During the COVID-19 pandemic, waqf funds have been utilised to support micro-businesses, though their effectiveness decreased compared to pre-pandemic levels (Nurani & Vahlevi, 2023). Waqf has also contributed to the National Economic Recovery program in six sectors: health facilities, social protection, business incentives, MSME support, corporate financing, and regional government initiatives (Sobiyanto et al., 2024a). However, challenges remain in waqf implementation, such as a lack of professional management and low public awareness(Darwanto, 2012; Nuraini, 2024).

The role of Nazhir (waqf manager) is crucial in optimising waqf fund management, including vaccination financing. Key characteristics of effective Nazhirs include faith, piety, trustworthiness, and professionalism (Rudianto et al., 2021). Accountability is the most important criterion in developing cash waqf strategies, with Islamic banks being recommended as the most suitable for Nazhirs (Wulandari et al., 2019). Nazhirs are critical in managing cash waqf and Cash Waqf Linked Sukuk (CWLS) yields, which can be channelled to education, economy, and health sectors (Ashfahany & Lestari, 2023). However, challenges exist in optimising Nazhir's role, as waqf fiqh and laws have not fully strengthened their position (Alfurqan, 2020). To improve waqf management for health sectors like vaccination programs, Nazhirs must enhance their knowledge, leadership, and experience in institutional management and promotion (Rudianto et al., 2021).

Wakaf, an Islamic philanthropic instrument, is crucial in supporting Indonesia's social welfare and economic development. It has significant potential to fund education, healthcare, and economic empowerment programs for low-income people (Nuraini, 2024). Implementing productive waqf, such as cash waqf for micro-businesses and education, has improved community living standards (Nuraini, 2024). Waqf has also contributed to Indonesia's National Economic Recovery program across six sectors, including health facilities, social protection, and MSME support(Sobiyanto et al., 2024b).

However, challenges remain in waqf management, including a lack of professional administration and low public awareness (Nuraini, 2024).

The introduction of the Waqf Law has opened new opportunities for waqf development, allowing for more diverse forms of waqf assets like money, gold, and stocks (Nurfaidah, 2016). To optimise waqf's potential, improvements in regulation, transparent management, and collaboration between stakeholders are necessary (Ash-Shiddiqy, 2019; Nuraini, 2024).

Recent research highlights the potential of blockchain technology to enhance transparency and accountability in Islamic finance, particularly in zakat and waqf management (Arwani & Priyadi, 2024; Jatnika et al., 2025). Blockchain implementation can significantly improve data security, transaction transparency, and decentralisation in Islamic financial practices (Arwani & Priyadi, 2024). The integration of digital platforms and blockchain technology offers convenient and secure payment systems, expands participation, and increases efficiency in zakat collection and distribution(Luntajo & Hasan, 2023). These technologies enable real-time tracking of funds, reducing fraud risks and facilitating targeted allocation for maximum welfare impact (Ali & Azzafa Nur Jadidah, 2024; Luntajo & Hasan, 2023). However, successful implementation requires robust governance, capacity building, and clear policies to ensure technological security, integrity, and effective utilisation in managing Islamic charitable funds (Ali & Azzafa Nur Jadidah, 2024; Luntajo & Hasan, 2023).

The success of implementing health waqf in support of vaccination programs depends heavily on the synergy of various parties, including governments, Islamic financial institutions, philanthropic organisations, and the private sector. The government has a key role in creating regulations that support optimal waqf management and ensure the distribution of its benefits to communities in need. Islamic financial institutions provide innovative funding mechanisms, such as cash waqf and sukuk waqf, enabling health programs' sustainability, including vaccinations (Nasriandani, 2023). Philanthropic organisations can strengthen the endeavour-based healthcare infrastructure through professional funding and management (Muhammad & Aji, 2024), while the private sector can engage in providing Waqf-based medical services, as has been applied in the model of An-Nur Wakaf Hospital in Malaysia

(Mohamed @ Haji Daud & Ab Rahman, 2017). With effective collaboration, health waqf can be a sustainable instrument in improving people's access to vaccination services, especially for vulnerable groups facing economic and geographical limitations.

1.3 Excellence of Waqf in Health Financing: Fund Stability, Sustainability Principles, and Compliance with Sharia

Waqf has high fund stability due to its nature that cannot be sold, inherited, or transferred to private ownership, thus making it a sustainable financial instrument in the Islamic economy. This uniqueness ensures that the waqf assets remain maintained for the benefit of the community in the long term, both in the form of property, land, and productively managed cash. Studies show that waqf has excellent potential to create economic stability through sustainable and innovative financial models, such as integration with social sukuk and Sharia-based crowdfunding (Kamaruzaman & Ishak, 2023). In addition, the sustainability of waqf is strengthened by applying transparent and accountable governance, which allows the waqf funds to develop without the risk of transferring individual assets (Mansor et al., 2018). Thus, the non-transferable nature of waqf makes it a very stable instrument in supporting society's sustainable social and economic development.

Waqf has a sustainability principle that allows its benefits to be felt by the community in the long run because waqf assets are irreversible and are used only for sustainable social interests. The concept is strengthened by innovative financial models that ensure sustainability, such as integration with social sukuk, sharia crowdfunding, and blockchain technology-based management to improve transparency and accountability of waqf assets management (Kamaruzaman & Ishak, 2023). Studies also show that the sustainability of waqf is strongly influenced by good governance and the involvement of various stakeholders, including governments, Islamic financial institutions, and civil society (Mohamad Yunus et al., 2024). In addition, using waqf in the education, health and economic empowerment sectors has contributed to sustainable development and reduced social inequality (Qurrata et al., 2024). Thus, waqf is not only a stable instrument of Islamic finance but also a long-lasting tool of social empowerment for the welfare of the people.

The main advantage of waqf as a financing mechanism is its compliance with the principle of sharia, which makes it a fair and based financial instrument of Islamic values. In the Islamic financial system, waqf serves not only as a form of philanthropy but also as an investment means that provides long-term social benefits without the elements of riba, gharar, or maysir (Syaichoni & Suminto, 2021). Studies show that implementing waqf in the financial sector, such as through Sukuk based on waqf and sharia crowdfunding, can increase Islamic financial inclusion and strengthen the economic stability of the people (Ahmad et al., 2021). In addition, the concept of Sharia maqashid in the management of waqf emphasises aspects of justice, transparency, and sustainability, which ensures the benefits can be felt by the wider community evenly (Hija, 2024). Therefore, waqf is a financing mechanism that is compliant with sharia and is an inclusive and social welfare-oriented financial solution.

Waqf strategically encourages community participation in health financing by providing funding alternatives for inclusive and sustainable healthcare facilities and services. Health Waqf models have contributed to developing hospitals and clinics in Muslim countries, focusing on medical services for underprivileged communities (Baqutayan et al., 2018a). Studies show that optimising waqf assets through innovative management, such as venture philanthropy and waqf-based property development, can be a solution to improve public access to better healthcare (CONTEH et al., 2020). In addition, temporary waqf schemes have been proposed as a microfinance instrument that can be used to finance basic health care for groups experiencing financial limitations. Thus, community participation in health waqf improves access to medical services for vulnerable groups and strengthens the overall health system through continuous contributions to social financing schemes.

With all these advantages, waqf can be an innovative, stable, sustainable solution by Sharia principles. In the context of vaccination, waqf can help overcome the inequality of access to vaccines by providing an ever-evolving funding source. With support from governments, Islamic financial institutions and philanthropic organisations, the implementation of waqf in the health sector can be expanded to create a more inclusive and independent healthcare system.

2. CASE STUDY AND BEST PRACTICES IN WAQF-BASED HEALTH FINANCING

2.1 Waqf Model in Muslim Countries: Examples of The Success of Countries Such As Turkey, Malaysia and Indonesia in Managing Health Waqf

The Waqf model in the health sector has been successfully applied in several Muslim countries, including Turkey, Malaysia and Indonesia. In Turkey, health wakaf has a long history since the Ottoman Empire, when waqf-based hospitals such as Darüşşifa were established to provide free health services to the public. The hospital's funding comes from waqf assets, which are professionally managed to ensure the continuity of medical services (Alias & Rozali, 2018). Until now, the concept of health waqf in Turkey has been maintained by modernising the management of waqf funds to contribute more to the national health sector.

Malaysia is also a successful example of implementing health wakaf through corporate models and public-private partnerships. Wakaf An-Nur Hospital (HWAN) is one example of a waqf-based hospital offering lower-cost medical services, making it accessible to low-income groups (Aris et al., 2017). In addition, the Malaysian government has been working to develop a corporate waqf hospital model, which integrates waqf with public healthcare systems to improve the quality of medical services and reduce the country's budget burden (Raja Adnan et al., 2022a). With this model, the waqf fund can be managed professionally and transparently to support sustainable health care.

In Indonesia, the implementation of health waqf continues to grow, one of which is through the management of cash and productive waqf utilised to fund health services for the less capable community. One example of success is the management of Malang Islamic Hospital based on productive waqf, where the results of the management of waqf funds are used to fund hospital operations and provide health services for data (Qurrata et al., 2019). The Indonesian government also began integrating the waqf scheme into the national financial system, such as through the issuance of sukuk waqf, which is expected to be a sustainable funding source for the health sector (Bahri, 2023). The success of this three-nation wakaf model shows that waqf can be an innovative solution in supporting more inclusive and sustainable healthcare.

2.2 Integration with Islamic Financial Instruments: The Role of Sukuk Waqf and Mutual Funds in Strengthening Health Funds

Integrating waqf with Islamic financial instruments, such as sukuk waqf and mutual Islamic funds, is important in strengthening health funds. Sukuk wakaf, which combines the principles of wakaf and Sharia-based sukuk, has proven to be an innovative solution in social funding, including the health sector. For example, in Indonesia, the Cash Waqf Linked Sukuk (CWLS) program has allowed the collection of cash waqf funds that are then invested in sukuk, with the investment results used to build health facilities and social infrastructure (Rahmani & Prasetyo, 2024). In addition, CWLS also contributes to improving Waqf-based hospital services, such as the case at Achmad Wardi Hospital, Banten (Ubaidillah et al., 2021). With this scheme, waqf can be managed productively without reducing its underlying assets, ensuring the continuity of funding of the health sector.

In addition to sukuk wakaf, Islamic funds are a financial instrument that can strengthen waqf-based health funding. Sharia mutual funds allow the management of waqf funds to be more flexible by referencing the principle of Sharia, such as not containing riba and speculation. Research shows that integrating Islamic funds with waqf funds can create sustainable funding resources for financing health facilities and assistance for less capable community groups (Johari & Alias, 2013). With the diversification of investments in halal and stable instruments, such as Sharia bonds and Sharia stocks, the results of this investment can be used to fund broader and longer-term healthcare programs (Kamaruzaman & Ishak, 2023).

Applying sukuk waqf and mutual funds in health financing requires strong policy support and public awareness of its benefits. Islamic financial institutions and governments need to develop more apparent regulations to ensure the management of waqf funds in sukuk and mutual Islamic funds is conducted transparently and accountably (Khamim et al., 2023). In addition, educating the community about the potential for Islamic investment in supporting the Waqf-based health sector is also key to increasing public participation (Cahyono & Hidayat, 2022). With an integrated approach and support from various stakeholders, the combination of sukuk waqf and mutual

funds can be an innovative solution to fund inclusive and sustainable healthcare in Muslim countries.

2.3 Learning and Challenges: Success Factors and Barriers in The Application of Waqf Models for Vaccines

Waqf model has proven its role in supporting healthcare financing, including vaccination programs. The main factors supporting this model's success are good governance, community participation, and integration with Islamic financial instruments such as sukuk waqf and mutual Islamic funds (Baqutayan et al., 2018b). Transparent and professional Waqf management allows the raised funds to be effectively allocated for vaccination needs, especially for vulnerable groups (Md. Mahmudul et al., 2018). In Malaysia, for example, the success of waqf in supporting public health facilities can be a model for other countries to develop similar schemes in vaccination programs (Raja Adnan et al., 2022b). In addition, the experience of various countries shows that the success of the Waqf model in health financing depends heavily on regulatory support and government incentives to ensure the effectiveness of the Waqf-based vaccination program (Radiamoda, 2022).

However, there are some significant challenges in implementing the waqf model for vaccination. One is the low public awareness of the concept of productive waqf and its potential to support the health sector (Haji-Mohiddin & Mas, 2015). In addition, the lack of integrated information systems often becomes an obstacle to ensuring transparency and accountability in managing waqf funds for vaccination(Janom et al., 2019). Another challenge faced in the context of vaccination is the public's doubt about the vaccine's effectiveness, which is influenced by social and cultural factors (Khankeh et al., 2021). Therefore, effective education strategies are indispensable to improve the public's understanding of the benefits of waqf-based vaccination and build trust in this program.

Innovating in managing waqf is necessary to overcome these obstacles by utilising digital technology and more inclusive financing models (S. N. I. Rofiqoh et al., 2020). Applying digital platforms in waqf information systems can increase transparency and expand the range of donations from different walks of life. In addition, collaboration between waqf, government and private

sector agencies in mixed financing schemes can help accelerate the implementation of this model (Lahsasna, 2010). With a more strategic and innovative approach, waqf can be a more effective instrument in supporting vaccination programs and strengthening Islamic finance-based health systems in various countries.

CONCLUSIONS AND RECOMMENDATIONS

Applying waqf in health financing, especially vaccinations has great potential in creating sustainable, inclusive, and Sharia principles. Various Muslim countries such as Turkey, Malaysia, and Indonesia have successfully developed health wakaf models that can support medical services for underprivileged communities. By utilising Islamic financial instruments such as sukuk wakaf and mutual funds, waqf funds can continue to grow and provide long-term benefits in ensuring access to wider vaccines. This suggests that waqf is not just a charitable instrument but can also serve as an effective social financing mechanism supporting the health sector.

For health wakaf models to develop more optimally, some strategic aspects must be strengthened. One of the main recommendations is to increase the capacity of waqf management, both in terms of transparency and professionalism. Waqf management agency (Nazhir) must have a strong understanding of asset management and sharia investment to manage the collected funds efficiently and have a broader impact. In addition, the application of technologies such as blockchain and digital platforms can improve the accountability and involvement of the community in supporting the financing of waqf-based vaccines.

In addition to increasing management capacity, government regulatory support is also a key factor. Governments must create more flexible policies to encourage innovation in healthcare waqf management, including developing Islamic financial instruments that support the sector. Tax incentives for waqf donors, ease in the administration of waqf investment, and legal protection for waqf managers will help accelerate the growth of the health waqf ecosystem. With supportive regulations, waqf can be more easily integrated into the national health system and help improve vaccination coverage for the wider community.

Another recommendation is encouraging collaboration between the public and private sectors in managing health waqf. Islamic financial institutions, pharmaceutical companies and philanthropic organisations can work together to create a more innovative and sustainable waqf-based vaccination program. For example, wakaf funds can be used to fund the research and development of halal vaccines, which are not only beneficial to Muslims but also for the global community. This cooperation model can improve waqf's effectiveness as a solution in the face of future health challenges.

As a final step, Islamic financial education and literacy on health waqf must be improved. Many people still do not understand how wakaf can contribute to the health sector, so broader socialisation is needed through various media and educational platforms. Campaigns on the benefits of productive waqf, transparency of the management of waqf funds, and investment opportunities in Islamic financial instruments can increase community participation in supporting this program. With the right strategy, waqf can be an innovative, broad, impactful Islamic financial solution to ensure health access for all communities.

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CHAPTER 4

SAFETY SIGNAL DETECTED: ANAPHYLAXIS AFTER ATTENUATED DENGUE VACCINE (TAK-003)

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INTRODUCTION

The live-attenuated tetravalent dengue vaccine TAK-003 (Qdenga) was created by Takeda Pharmaceuticals. Researchers at Bangkok's Mahidol University are credited with its inception. Millions of people throughout the world suffer from dengue fever, which is caused by any of the four dengue virus serotypes (DENV-1 to DENV-4). TAK-003 has undergone extensive clinical trials to ensure its safety and efficacy. The trials included participants of diverse ages and localities with endemic dengue cases. The trials assessed the vaccines' immunogenicity, effectiveness, and safety in both seronegative and seropositive populations. Its clinical signs vary from moderate febrile sickness to severe dengue, which is marked by hemorrhagic fever and shock. Vaccination remains a key component of dengue prevention methods. TAK-003, a live-attenuated tetravalent dengue vaccine, has shown effective in clinical studies and is already being used in several countries. Indonesia was the first country to ratify Qdenga in August 2022. The European Medicines Agency (EMA) authorized it in December 2022. In May 2024, the WHO prequalified the TAK-003 vaccination. It has also been approved in countries such as Brazil, Argentina, and Thailand. Its capacity to protect against all four dengue serotypes marks a significant improvement. The WHO recommends TAK-003 for children aged 6 to 16 in areas with a high dengue burden and transmission intensity. The vaccination is given in two doses, with a three-month delay between each. Unlike the previous dengue vaccine, Dengvaxia (CYD-TDV), TAK-003 can be delivered to individuals independent of previous dengue exposure. Anaphylaxis, a severe, sometimes fatal allergic reaction, is a documented side effect associated with immunization.While uncommon, its sudden onset and potential for serious consequences demand immediate detection and treatment. Recent reports have suggested cases of anaphylaxis following TAK-003 dosing, raising concerns and requiring additional investigation. This essay will look at the available knowledge on these safety signals, analyze their potential ramifications, and underline the significance of continuous safety monitoring.

1. ANAPHYLAXIS: THE SAFETY SIGNAL

It's a systemic allergic reaction, which means it affects several bodily systems. It occurs when the immune system overreacts to an allergen (a chemical that triggers an allergic reaction). This overreaction results in a surge of chemicals that sends the body into shock.

Common Triggers

Foods (including peanuts, tree nuts, milk, eggs, and shellfish) Stings from insects, such as bees, wasps, and hornets. Medications (such as penicillin and aspirin)

Symptoms

Anaphylaxis symptoms can occur within seconds or minutes of exposure to an allergen and may include:

- Skin reactions include hives, itching, flushing, and swelling.
- Respiratory symptoms may include throat tightness, difficulty breathing, wheezing, coughing, and more.
- Circulatory issues may include a rapid or weak pulse, low blood pressure, dizziness, or fainting.
- Common gastrointestinal issues include nausea, vomiting, abdominal cramps.
- Other symptoms may include confusion, anxiety, and loss of consciousness.

2. VACCINE COMPOSITION AND ADMINISTRATION

Composition: Following reconstitution, each 0.5 ml dose of Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized) contains the following

Active Ingredients: at least 3.0 log10 PFU of each of the following dengue virus serotypes: serotype 1 (rDEN-1Δ30), serotype 2 (rDEN-2/4Δ30), serotype 3 (rDEN-3Δ30/31), and serotype 4 (rDEN-4Δ30).

Inactive Ingredients: Dulbecco's Modified Eagle's Medium, water for injection, gelatin, mannitol, trehalose, sucrose, monobasic potassium phosphate (KH_2PO_4), dibasic potassium phosphate (K_2HPO_4), and monosodium glutamate. Reconstituted fluid: To be mixed with sterile

water and administered via injection. The recommended storage temperature for the lyophilized study medication product is 5 ± 3 °C.

Administration: A single, 0.5 ml dose of the vaccine (Batch No. TDNV 01801) is given subcutaneously in the adult deltoid region using needles designed for subcutaneous injection.

3. TAK-003 (DENVac)

Takeda conducted a phase I clinical trial in Rionegro, Antioquia, Colombia to evaluate the safety and immunogenicity of DENVax against four DENV serotypes. DENVax was administered intradermally (ID) or intramuscularly (IM) to DENV-naïve adults aged 18-45. The vaccination was safe and well tolerated by research participants, causing brief local reactogenicity and minimal systemic side effects. Vaccination increased the generation of neutralizing antibodies against all four DENV serotypes, however antibody titers against DENV-3 and DENV-4 were lower among participants.DENVax (now named TDV) was reformulated to increase the amount of the DENVax4 component. Different formulations and dosing schedules were tested in a randomized, multicenter, phase 1b study conducted in the USA with 140 DENV-naïve individuals aged 18 to 45 years. The study participants' seroconversion rates ranged from 84-100% (DENV-1), 96-100% (DENV-2), 83-100% (DENV-3), and 33-77% (DENV-4).

The evaluation of the safety and immunogenicity of a two-dose scheme (0, 90 days) of the TDV vaccine in DENV-exposed individuals during a randomized, double-blind, placebo-controlled phase II clinical trial carried out in Puerto Rico, Colombia, Singapore, and Thailand using a "high-dose" vaccine with higher titers of the DENVax3 and DENVax4 components revealed that the vaccine induced lower neutralizing antibody responses against the DENVax4 component regardless of prior.

A large-scale phase III clinical trial evaluating the efficacy of DENVax in a cohort of 20,071 healthy children aged 4 to 16 years in dengue-endemic countries in Latin America and Asia is in underway. Primary efficacy results at 12 months post-vaccination varied according to DENV serotype: 97.7% for DENV-2, 73.7% for DENV-1, and 62.6% against DENV-3, with unclear results for DENV-4. Interestingly, total vaccination effectiveness was comparable

amongst people who were seronegative at baseline (74.9%) and those who were seropositive at baseline (82.2%), regardless of age range. Overall vaccination effectiveness against dengue-related hospitalization was found to be 95.4% among seronegative persons and 94.4% among seropositive ones.

Data from the same trial after 18 months post-vaccination demonstrated an overall vaccine efficacy of 76.1% in seropositive persons and 66.2% in seronegative individuals, with overall efficacy against distinct DENV serotypes ranging from 95.1% against DENV-2 to 48.9% against DENV-3. The total efficiency against dengue that necessitated hospitalization was 90.4%, while 85.9% against DHF. However, when separated by age group, the vaccine's efficacy against requiring hospitalization was considerably lower in previously seronegative children aged 4 to 5 years (59.1%), compared to seropositive children of the same age (51.6%).

The cumulative efficacy results for the DENVax vaccine three years after immunization were recently released, revealing an overall vaccine efficacy of 62% against VCD, which is much lower than the efficacy reported 18 months after vaccination. A comparable result was reported in terms of overall efficacy against dengue necessitating hospitalization, which decreased from 90.4 to 83.6%. In baseline seropositives, vaccination efficacy against VCD varied from 52.3% for DENV-3 to 83.4% for DENV-2; however, in baseline seronegatives, the vaccine was only efficacious against DENV-1 and DENV-2 (43.5% and 91.9%, respectively), with no efficacy for DENV-3.The vaccine's efficacy against dengue necessitating hospitalization remained high among seropositive persons but not in seronegative individuals, despite the fact that it was only effective against DENV-1 and 2. Interestingly, there were no evident trends linking vaccine efficacy to participant age.

These significant variations in vaccine efficacy, assessed 18 months apart, should be investigated further during long-term phase IV surveillance trials to rule out the possibility that the observed protective efficacy is due to cross-protection and may decline over time, as seen in pediatric populations during natural infections.

4. METHODS TRIALS INCLUDED

The integrated study included safety data from five double-blind, randomized, placebo-controlled phase 2 and 3 trials with participants aged 4 to 60. Participants in all trials received two subcutaneous injections of TAK-003 or placebo, three months apart. Data from the continuing DEN-301 experiment were included until the trial's last milestone, 36 months after the second vaccine dose. The pooled analysis of data from the DEN-203 study only included placebo recipients aged ≥4 years old because to variations in the high-dose TAK-003 formulation utilized in this experiment and the other four placebo-controlled studies.Data from the DEN-204 study were only extracted for participants ≥4 years old in groups 1 and 4. The other two trial groups' exploratory dose regimens did not comply with the dosing schedule of two TAK-003 doses three months apart. The safety follow-up periods varied across trials, ranging from 6 to 48 months after the second vaccine dose.

The five trials involved adults, adolescents, and children . Individuals with hypersensitivity to any vaccine component, poor or changed immune function, planned or ongoing pregnancy or breastfeeding, or past dengue vaccination were not eligible for participation in any of the trials.All trials were approved by the appropriate institutional review boards/ethics committees and carried out in accordance with the Declaration of Helsinki and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) harmonized tripartite guidelines for Good Clinical Practice. Before registration, all participants or their legal guardians provided written informed permission.

4.1 Excluded Trials

Other clinical trials completed during TAK-003 development did not contain placebo controls or used the commercially planned TAK-003 formulation; these trials represented an additional 5571 persons who were removed from the integrated safety analysis.

5. SAFETY ASSESSMENT OF TAK 003

The TAK-003 (Qdenga®) dengue vaccine's safety is evaluated using data from clinical trials and post-marketing surveillance to better understand its

possible hazards and benefits. Here's a summary of important safety considerations:

- Clinical trial data
- Post marketing surveillance

5.1 Clinical Trial Data: Overall Safety Profile

Clinical trials, most notably the TIDES (Dengue Efficacy Study) experiment, have produced considerable data on TAK-003's safety. Overall, the vaccine has been demonstrated to be well-tolerated in a variety of populations, including those with different prior dengue exposure (serostatus).TAK-003 offers the advantage of being able to be delivered independent of prior dengue exposure. Clinical investigations revealed a comparable safety profile in both seropositive and seronegative patients.

5.2 Post-Marketing Surveillance

It is essential for identifying unusual adverse events that may not have been identified in clinical studies. This constant monitoring enables the detection of potential safety signals and the deployment of relevant risk reduction techniques.

TAK-003's overall safety profile is rated favorable.

- Mild to moderate adverse effects are common and typically well-tolerated.
- Although serious adverse effects are infrequent, continuous monitoring is necessary.
- Healthcare providers must be trained to recognize and manage anaphylaxis.

In short, the safety assessment of TAK-003 entails a thorough study of data from numerous sources, emphasizing both the known safety profile and the significance of continued observation.

6. RISK-BENEFIT ANALYSIS

Assessing Risks: This involves determining the incidence and severity of adverse events linked with the vaccine, such as anaphylaxis, as well as other potential side effects.

Risk stratification: It is the process of identifying populations that are more likely to experience undesirable occurrences. This may include taking into account age, underlying health issues, and previous dengue exposure.

Data Collection: Enough data from clinical trials and post-marketing surveillance are required to adequately estimate hazards.

Evaluating the benefits: Evaluating the vaccine's efficacy in preventing dengue illness, including different serotypes and severity levels (e.g., hospitalization, severe dengue).

6.1 Factors Influencing The Risk-Benefit Assessment of TAK-003

Dengue Epidemiology: The rate of dengue transmission in a specific area. In locations with a high dengue incidence, the advantages of vaccination may outweigh the dangers.

L Target Population: The age and health status of those being vaccinated.

Vaccine Efficacy: The vaccine's capacity to protect against dengue serotypes and prevent severe disease.

Safety Profile: The frequency and severity of vaccine-related side events.

In conclusion, a thorough risk-benefit analysis is required to ensure that the use of the TAK-003 dengue vaccine is justified and that public health choices are made using the best available data.

7. CASES REPORTED: LIST THE ANAPHYLACTIC REACTIONS THAT HAVE BEEN DOCUMENTED AFTER RECEIVING THE TAK-003 VACCINE

A total of 626 AEFI were recorded out of 380,358 TAK-003 doses that were given. Of these, 24 (63.1 cases per million) were anaphylactic shock, including three cases of anaphylactic shock, while 85 were cases of acute hypersensitivity. Within 15 minutes after immunization, responses started in 10

(41.7%) of the patients. Anaphylaxis-related fatalities were not documented. The Brazilian Ministry of Health released suggestions for stepping up efforts for safe vaccination, including post-vaccination monitoring and training for healthcare professionals, in response to the safety signal detection (increased frequency of anaphylaxis after dengue vaccine).Brazil, March 1, 2023–March 11, 2024. A descriptive study of anaphylactic cases following TAK-003 was carried out, as recorded in the National System of Surveillance of Adverse Events Following Immunization (AEFI). The percentages and notification rates for AEFI per million doses administered (DA) were computed. In total, 380,358 doses of TAK-003 were given, with 626 AEFI documented. There were 85 incidences of acute hypersensitivity, with 24 (63.1 cases per million) resulting in anaphylaxis, including three cases of anaphylactic shock. For 10 (41.7%) cases, responses developed within 15 minutes of immunization. There were no anaphylaxis-related deaths reported. In light of the safety signal discovery (increased frequency of anaphylaxis following dengue immunization),Brazil's Ministry of Health issued recommendations for expanding safe vaccination efforts, including healthcare professional training and post-vaccination observation.

8. CLINICAL SAFETY EXPERIENCE WITH TAK-003 FOR DENGUE FEVER

TAK-003, a live attenuated dengue tetravalent vaccine, has four dengue virus (DENV) strains with a DENV-2 backbone . Approximately 27 000 people from dengue-endemic and nonendemic locations provided safety data for the TAK-003 clinical development program, with long-term safety follow-up still ongoing in two trials. This report presents an integrated safety study of TAK-003's double-blind, placebo-controlled phase 2 and phase 3 trials. TAK-003 has a generally acceptable safety profile and has been well tolerated in patients of different ages, genders, and baseline dengue serostatus. Clinical investigations revealed that no substantial safety hazards were discovered. People aged 4 to 60 have participated in studies. According to certain research, adolescents and adults may exhibit greater local reactogenicity (such as discomfort or redness at the injection site) than children. Meta-analyses have confirmed that TAK-003 has a favorable safety profile and significant immunogenicity. In general,

clinical safety data indicate that TAK-003 is a relatively safe vaccine for dengue fever, with controllable side effects.

Clinical care of anaphylaxis following TAK-003 vaccination adheres to established procedures for allergic crises. Epinephrine must be administered immediately, coupled with supporting measures such as oxygen therapy and intravenous fluids, to ensure survival. Healthcare providers who give the immunization must be educated to recognize and treat anaphylaxis promptly. Furthermore, effective reporting systems are required for capturing and analyzing anaphylactic cases in order to enhance risk assessment and mitigation methods. Anaphylaxis as a TAK-003 safety warning has a wide range of ramifications. While anaphylaxis is considered rare, it highlights the significance of thorough patient selection and pre-vaccination screening. Individuals who have a history of severe allergic responses should be evaluated for potential contraindications or warnings. To detect immediate reactions, it is recommended to watch the patient for at least 15 minutes after vaccination.

CONCLUSION

The discovery of allergy following TAK-003 vaccination emphasizes the significance of continuous safety monitoring for all vaccines. While anaphylaxis is a rare occurrence, its potential severity requires awareness and immediate treatment. Continued research, increased surveillance, and effective communication are critical to ensure the safe and effective implementation of dengue immunization programmes. Recognizing anaphylaxis as a potential safety warning after TAK-003 vaccination requires a balanced and evidence-based strategy. While anaphylaxis is uncommon, its severity highlights the significance of rigorous post-marketing surveillance, clinical care practices, and continuous research. By proactively and transparently responding to this safety signal, we can ensure TAK-003's continuing safe and effective usage in the global drive to prevent dengue disease while retaining public trust in immunization programs. The value of preventing a potentially fatal disease must constantly be balanced against the hazards, and every effort must be done to reduce those risks.The overall value of the TAK-003 vaccine in avoiding Dengue fever is still thought to be highly significant, and the low rate of these adverse effects should be taken into account.

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