International Journal of Science and Research Archive

eISSN: 2582-8185

Cross Ref DOI: 10.30574/ijsra

Journal homepage: https://ijsra.net/

(REVIEW ARTICLE)

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Leveraging regulatory pharmacist expertise to develop a framework for drug repurposing in underserved areas of the USA

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International Journal of Science and Research Archive, 2024, 13(02), 390–393

Publication history: Received on 25 September 2024; revised on 02 November 2024; accepted on 05 November 2024

Article DOI: https://doi.org/10.30574/ijsra.2024.13.2.2133

Abstract

The United States continues to grapple with healthcare access disparities, particularly in underserved regions. Regulatory pharmacists, with their unique expertise in pharmaceutical laws, drug development, and safety regulations, can play a vital role in drug repurposing efforts. This paper proposes a framework for utilising regulatory pharmacist expertise to develop drug repurposing strategies to meet unmet medical needs in underserved areas. We explore the regulatory hurdles, the necessity for collaborative efforts between healthcare professionals, and the potential for drug repurposing to improve healthcare outcomes in rural and socioeconomically disadvantaged communities.

Keywords: Pharmacist; Drug; Pharmaceutical laws; Drug development; USA

1. Introduction

Access to healthcare remains a significant challenge in underserved areas of the USA, where geographical, economic, and systemic barriers prevent many from receiving timely and effective medical care. As of 2022, approximately 65 million Americans live in areas designated as Health Professional Shortage Areas (HPSAs) for primary care, dental, or mental health services. The disparities between rural and urban regions are well-documented, with rural populations often facing significant barriers to obtaining quality medical services (Baker and Fidler, 2015). These challenges include higher incidences of chronic illnesses, poorer health outcomes, and limited access to digital health care solutions. Despite initial hopes that digital health technologies could bridge the gap between rural and urban health care, rural areas often struggle with inadequate broadband internet access, further widening the gap in health service delivery (Baker and Fidler, 2015).

These factors collectively highlight the need for a more robust and targeted approach to improving health care access for rural populations. The ongoing disparities underscore the importance of addressing the unique challenges faced by these communities, particularly in ensuring that digital health innovations are accompanied by the necessary infrastructure improvements to be effective (Baker and Fidler, 2015). Addressing these issues is critical to reducing the rural-urban health divide and ensuring that rural citizens receive the care they need. The conversation around health care reform must prioritize these concerns, as addressing the specific health needs of rural populations is essential for fostering equity in health outcomes across all regions (Baker and Fidler, 2015).

This ongoing issue highlights the need for innovative solutions, such as drug repurposing, which involves identifying new therapeutic uses for existing drugs. Regulatory pharmacists, given their expertise in navigating the complex regulatory landscape of pharmaceuticals, are well-positioned to lead efforts in drug repurposing. By leveraging their knowledge of FDA guidelines, clinical research, and drug safety protocols, regulatory pharmacists can help optimize the repurposing process.

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1.1. Understanding the Need for Drug Repurposing in Underserved Areas

Drug repurposing, also known as drug repositioning, refers to the process of identifying new therapeutic uses for existing medications or those previously studied but not approved (Krishnamurthy et al, 2022). This approach has become a pivotal strategy in drug development, offering a potential shortcut to bringing effective treatments to market. Reports indicate that a significant portion of newly approved drugs, particularly those by the U.S. Food and Drug Administration (FDA), are repurposed. For instance, between 2007 and 2009, it is estimated that 30-40% of new drugs and biologics approved by the FDA were repurposed products (Graul et al,2009). Furthermore, about 35% of transformative drugs—those that have had a groundbreaking impact on patient care—approved between 1984 and 2009 were also repurposed drugs (Kesselheim et al, 2015).

The allure of drug repurposing lies in its potential advantages over traditional drug development. It is often seen as a faster, less expensive, and lower-risk pathway because the safety profile of the drug has already been established through prior testing (Ashburn and Thor, 2004). This allows researchers to bypass many of the early, time-consuming phases of development, such as safety and toxicity studies (Ashburn and Thor, 2004). Consequently, the chances of success are perceived to be higher with repurposed drugs compared to brand-new drugs, as much of the foundational work has already been done (Krishnamurthy et al, 2022).

Drug repurposing offers a promising avenue to address medical needs where access to novel drugs may be limited due to high costs or a lack of local healthcare providers. Many residents in underserved areas suffer from chronic diseases such as diabetes, hypertension, and mental health disorders, conditions for which existing drugs could be re-evaluated for alternative therapeutic purposes. Drug repurposing has several advantages, including a faster development timeline, reduced costs, and lower safety risks due to the pre-existing knowledge of the drug's safety profile (Pushpakom et al., 2019).

However, while the benefits of drug repurposing are clear, the actual savings in time, cost, and risk can vary (Krishnamurthy et al, 2022). Some studies suggest that approximately 30% of repurposing efforts lead to a successful product approved for market, a significantly higher success rate compared to the mere 10% of success in developing entirely new drugs (Hauser et al, 2017). On the other hand, other reviews suggest that repurposed drugs may not necessarily have higher success rates, as efficacy often poses a more significant challenge than safety in later stages of development (Hernandez et al, 2017).

The traditional drug development process can take between 10 to 17 years from initial discovery to market approval (Hernandez et al, 2017). In contrast, drug repurposing tends to shorten this timeline considerably, with approvals typically taking between 3 to 12 years (Deotarse et al, 2015). Not only is the timeline faster, but the financial costs are also notably lower—roughly half that of developing a brand-new drug from scratch (Krishnamurthy et al, 2022). Despite these benefits, drug repurposing remains underutilized in underserved regions. Regulatory barriers, limited research infrastructure, and insufficient collaboration between healthcare professionals are some of the reasons for this gap. A structured framework led by regulatory pharmacists can address these challenges by ensuring that regulatory pathways are efficiently navigated, and that healthcare stakeholders work in concert to optimize drug use for repurposing initiatives (Crommelin et al., 2020).

1.2. The Role of Regulatory Pharmacists in Drug Repurposing

Regulatory pharmacists bring a wealth of knowledge regarding the regulatory requirements of drug development, approval, and post-market surveillance. Their ability to interpret FDA regulations and guidelines is essential in ensuring that repurposed drugs meet all safety and efficacy standards before they can be used in clinical practice. This expertise is critical, especially when repurposing drugs for use in populations that are often excluded from clinical trials, such as the elderly, those with multiple comorbidities, or minority populations prevalent in underserved areas (Wong et al., 2020). Drug repurposing requires navigating various regulatory pathways, such as Investigational New Drug (IND) applications and New Drug Applications (NDAs), to bring a repurposed drug to market. Regulatory pharmacists can facilitate this process by ensuring that the necessary clinical trial data is collected and submitted, and that the drug's safety profile is thoroughly reviewed. They are also pivotal in post-marketing surveillance to monitor adverse effects in new patient populations (Wong et al., 2020). Compliance with FDA guidelines is paramount when repurposing drugs. Regulatory pharmacists are adept at interpreting these guidelines and advising on the proper documentation and processes required for approval. This is especially important in underserved areas where healthcare resources are scarce, and healthcare providers may not have the expertise to navigate regulatory complexities (Pushpakom et al., 2019)

1.3. Developing a Framework for Drug Repurposing in Underserved Areas

The proposed framework for drug repurposing in underserved areas is structured around three key components: collaboration, regulatory navigation, and patient-centred approaches. Regulatory pharmacists will serve as central figures in each component, working with other healthcare professionals to ensure the success of repurposing initiatives. Effective drug repurposing efforts require collaboration between various healthcare stakeholders, including physicians, researchers, pharmacists, and policymakers. Regulatory pharmacists can act as liaisons, bringing together these diverse groups to ensure that repurposing efforts are grounded in regulatory science and patient safety. Collaborative efforts can also foster the sharing of clinical data, helping to identify potential drugs that can be repurposed based on real-world evidence (Ashburn & Thor, 2004).

One of the primary barriers to drug repurposing is the lengthy regulatory approval process. The proposed framework emphasizes the need for regulatory pharmacists to streamline these processes by utilizing existing pathways for repurposing, such as the FDA's 505(b)(2) application, which allows for the approval of drugs based on already available data. By doing so, regulatory pharmacists can help reduce the time and cost associated with bringing repurposed drugs to market in underserved areas (Crommelin et al., 2020). A patient-centered approach is crucial for ensuring that drug repurposing meets the specific needs of populations in underserved areas. Regulatory pharmacists can contribute by ensuring that clinical trials and safety assessments include diverse patient populations, representative of those in underserved areas. They can also facilitate patient education and outreach to ensure that patients are aware of the benefits and risks of using repurposed drugs (Wong et al., 2020).

2. Case Study: Drug Repurposing for Mental Health in Rural America

One of the most pressing healthcare challenges in underserved areas, particularly rural America, is the lack of mental health services. Drug repurposing offers a potential solution for addressing the shortage of mental health medications. For example, medications initially developed for epilepsy or Parkinson's disease have shown potential in treating depression and anxiety (Huang et al., 2022). Regulatory pharmacists, working alongside mental health professionals, can help identify drugs that could be repurposed for treating mental health disorders. They can ensure that these drugs meet FDA guidelines for off-label use and provide guidance on how to collect and analyse clinical data from rural healthcare providers. This type of collaboration can lead to faster implementation of new treatments and improve mental health outcomes in rural populations.

2.1. Challenges and Solutions

Although regulatory pharmacists have the expertise to drive drug repurposing efforts, several challenges remain. These include limited funding for research in underserved areas, regulatory uncertainty surrounding off-label drug use, and the potential for safety concerns when repurposing drugs for new indications. To address these challenges, the framework should include mechanisms for securing funding through federal and state grants targeted at rural healthcare innovation. Additionally, regulatory pharmacists must work closely with the FDA to develop clear guidelines for off-label drug use and establish rigorous safety monitoring systems to mitigate risks associated with repurposed drugs (Ashburn & Thor, 2004).

3. Conclusion

Regulatory pharmacists are uniquely positioned to lead drug repurposing efforts aimed at addressing the healthcare disparities in underserved areas of the USA. Their expertise in regulatory science, coupled with their ability to collaborate with other healthcare professionals, makes them invaluable in the development of a framework for drug repurposing. By streamlining regulatory processes, ensuring compliance with FDA guidelines, and adopting a patient-centred approach, regulatory pharmacists can help bring repurposed drugs to underserved communities, ultimately improving health outcomes for vulnerable populations.

3.1. Recommendations

Based on the reviewed study, the following is recommended;

- Investigate sustainable funding models for drug repurposing in underserved areas.
- Address regulatory challenges surrounding off-label drug use in underserved communities.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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