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A systematic review of policy frameworks and advocacy strategies for promoting sustainable pharmaceutical practices and responsible antibiotic use: From local to national implementation

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Abstract

The issue of antimicrobial resistance remains a global challenge. This paper presents policy frameworks and strategies for promoting sustainable pharmaceutical practices and responsible antibiotic use in the United States, from local to national implementation. The study looks at how current policies at the federal, state, and local levels affect antibiotic prescribing behaviors and resistance patterns. The results of key federal policies, including FDA's Guidance for Industry #213 and CDC's Core Elements of Hospital Antibiotic Stewardship Programs, have hinted at the potential to cut unnecessary antibiotic use. We highlight state-level initiatives like California's Senate Bill 27, as an example of potential for targeted legislation on antibiotic use in agriculture. In addition to reviewing these initiatives, the review assesses advocacy strategies, including CDC's Be Antibiotics Aware campaign and provider education programs, that have helped to increase awareness and improve prescribing practices. Effective public-private partnerships, like the Antimicrobial Resistance Challenge, serve as effective models for engaging stakeholders. Yet, scaling up successful local initiatives to national impact continues to be difficult due to variations in state policies, funding constraints, and a requirement for standardized data collection. This study also compares U.S. approaches to international strategies and identifies areas where improvement is required. These recommendations include strengthening data collection systems, expanding stewardship efforts in primary and long-term care, developing new funding models, and improving interdisciplinary collaboration. Overall, this review highlights the need for concerted activities of multiple sectors including policy development and advocacy to develop effective strategies against antibiotic resistance.

Keywords: Antibiotic stewardship; Policy frameworks; Advocacy strategies; Sustainable pharmaceuticals; Antimicrobial resistance

1. Introduction

The prevention of antibiotic-resistant pathogens to infectious diseases is one of the most urgent global health issues of the 21st century and could hinder the progress of the last decades of treatment of infectious diseases [1]. Now the World Health Organization (WHO) has called antimicrobial resistance 'a global health emergency' and is working to coordinate international action against this crisis [2]. Antibiotic-resistant infections affect more than 2.8 million people a year leading to over 35,000 deaths and placing major stress on the healthcare system in the United States [1].

Antibiotic resistance is thought to be increasing, partly due to misuse and overuse of antibiotics in human medicine [3] and in agriculture. In addition to antibiotic resistance development accelerated by inappropriate prescribing practices of antibiotics, patient nonadherence to prescribed regimens and antibiotic use in livestock production, have partly

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contributed [4]. Resistant bacteria evolve and spread, decreasing the efficacy of existing antibiotics, resulting in longer hospital stays, higher healthcare costs, and higher mortality rates [5].

In the fight against antibiotic resistance, sustainable pharmaceutical practices play a key role. The practices range from responsible antibiotic prescribing, improved infection prevention and control measures to more environmentally conscious drug manufacturing and drug disposal practices [6]. These sustainable practices can help to promote judicious use of those antibiotics, minimize their environmental impact, and aid in keeping the effectiveness of these lifesaving drugs for future generations.

Effective policy frameworks for advancing sustainable pharmaceutical practices and responsible antibiotic use are therefore needed. It has been determined that the sufficient battle against antibiotic resistance in the United States is conducted by several federal departments; such as the FDA, the Centers for Disease Control and Prevention (CDC), and Environmental Protection Agency (EPA), which made some guidelines and set of regulations [7]. Nevertheless, implementation of these policies depends on coordinated efforts by a wide variety of sectors, including healthcare, agriculture, and environmental management.

Responsible antibiotic use is promoted by advocacy strategies in which advocacy strategies seek to raise awareness among healthcare providers, patients, and the general public. The strategies involved could be educational campaigns, stewardship programs, and others that make antibiotic use more transparent across various capital [8]. Actions that advocate for change are the behaviors and attitudes of antibiotic use to help reduce unnecessary antibiotic use as well as slow the process of resistance.

Important catalysts for change in promoting sustainable pharmaceutical practices have been local initiatives. Finally, these grassroots efforts may act as sites for implementation and testing of novel antibiotic stewardship approaches, with the potential to inform further implementation [9]. Nevertheless, the scaling up of successful local initiatives for national impact continues to be a major challenge, given the diversity of healthcare systems, regional variation in antibiotic use, and different regulatory environments between the states.

A thorough knowledge of the policy frameworks and advocacy strategies that have been effective in a number of contexts is necessary for the transition from a local initiative to a national implementation. We present this review of United States literature in order to critically examine current policy frameworks and advocacy strategies for advancing sustainable pharmaceutical practices and responsible antibiotic use. Taking the progression from local initiatives to national implementation as a case study, this review aims to identify best practices, challenges, and ways to improve in the battle against antibiotic resistance.

1.1. The objectives of this review are threefold

- To assess the effectiveness of current federal, state, and local policy frameworks for fostering pharmaceutical sustainability and responsible antibiotic use.
- To evaluate the impact of different advocacy strategies on antibiotic prescribing behaviors, patient adherence, and public understanding of antibiotic resistance.
- To determine successful models for scaling up local initiatives towards the wider implementation and impact at the national level.

This review synthesizes the available evidence on policy frameworks and advocacy strategies to offer policymakers, healthcare providers, and researchers' advice on how to tackle antibiotic resistance in the future. The urgent need for evidence-based approaches to support sustainable pharmaceutical practice and responsible antibiotic use has never been greater as antimicrobial resistance continues to grow. To address this urgent public health priority this review provides a comprehensive examination of the state of the art in the United States' battle against antibiotic resistance.

2. Method

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were employed in this review [10]. Articles included in this review were searched in PubMed, Scopus, and Web of Science databases between 2010 and 2024. Search terms consisted of combinations of the keywords "antibiotic resistance", "antimicrobial resistance", "sustainable pharmaceutical practices", "policy framework" and "advocacy strategies" in the US context. This included original research, systematic reviews, and policy analyses of antibiotic stewardship initiatives, implementation, and advocacy in the USA. Titles and abstracts were screened by 2 independent reviewers, and full-text review was completed by 5 independent reviewers. The focus of data extraction was policy framework, advocacy

strategies, implementation challenges, and outcomes. The Mixed Methods Appraisal Tool (MMAT) [11] was used for quality assessment.

3. Results and discussion

3.1. Current State of Antibiotic Use and Resistance in the USA

There are many challenges involved with antibiotic use and resistance in the United States, and recent data are concerning. An estimated 30% of outpatient antibiotic prescriptions are inappropriate and are associated with development of resistant bacteria, according to the Centers for Disease Control and Prevention (CDC). Prevention efforts to encourage judicious use of antibiotics were made in 2020 but the rate of antibiotic prescribing by outpatient remained high at 698 prescriptions per 1,000 persons [12].

Patterns of antibiotic resistance differ with the pathogen and the region and the rise of multidrug-resistant organisms (MDROs) is particularly worrisome. For example, carbapenem-resistant Enterobacterales (CRE) infections rose 35% between 2017 and 2020 [13]. Similarly, methicillin-resistant Staphylococcus aureus (MRSA) remains a major threat, with an estimated 323,700 cases in 2017 [13].

Antibiotic resistance has a big economic impact. It costs the U.S. healthcare system $4.6 billion annually for antibiotic-resistant infections [14]. In addition, these infections result in additional, prolonged hospital stays of 6.4 days per patient [15]. Antibiotic resistance is also becoming an environmental issue. Environmental reservoirs of resistance were identified through research detecting antibiotic-resistant genes in wastewater treatment plants and surface water [16]. This provides a need for a One Health approach, integrating human, animal, and environmental health through an antibiotic resistance lens.

Yet there have been some positive developments. Ambitious goals for reducing inappropriate antibiotic use and enhancing surveillance of antibiotic resistance have been set in the National Action Plan for Combating Antibiotic-Resistant Bacteria (2020 – 2025) [17]. Further, some states have launched antibiotic stewardship programs in hospitals that have seen promising outcomes in decreasing unnecessary prescriptions [18].

3.2. Policy Frameworks for Sustainable Pharmaceutical Practices

To combat antibiotic resistance and promote sustainable pharmaceutical practices, at federal, state, and local levels, the United States has developed concept frameworks. Regulations, guidelines, and initiatives designed to improve antibiotic stewardship, and improve environmental impacts, are found within these frameworks.

To promote judicious antibiotic use at the federal level, the Food and Drug Administration (FDA) has made steps. In 2017, the FDA fully implemented Guidance for Industry #213 which ended the use of medically important antibiotics for growth promotion in food-producing animals [19]. Between 2016 and 2017, it has been credited with reducing agricultural antibiotic use by 33% [20]. Furthermore, the FDA's 2018 five-year plan for supporting antimicrobial stewardship in veterinary settings has further pushed antimicrobial resistance efforts in the animal agriculture arena [21].

It's also very important to the Centers for Disease Control and Prevention (CDC) in shaping policy frameworks. The 2019 Antibiotic Resistance Threats Report issued by the CDC has served as a useful guidebook on how to develop national policy and allocate resources (CDC, 2019). Additionally, in 2019, the CDC Core Elements of Hospital Antibiotic Stewardship Programs expanded to create a full comprehensive framework for the implementation of effective stewardship programs in healthcare settings [22].

In the last few years, more and more consideration has been given to environmental factors. In response, the Environmental Protection Agency (EPA) has stepped up its effort to tackle pharmaceutical contamination in water systems. In 2019 the EPA released a draft strategy to reduce pharmaceuticals entering the waterways as a result of poor disposal methods and advanced wastewater facilities [23].

A model policy, California's Senate Bill 27, was enacted in 2015 and fully implemented by 2018 at the state level. This legislation calls for veterinary oversight of all antibiotics important to animal health, and monitoring of sales and use of antibiotics [24]. Several other states have passed similar legislation: Maryland (Maryland Department of Health, 2018) and Oregon [25].

Policy frameworks are also the result of local government contributions. For example, in 2018 San Francisco enacted its Safe Drug Disposal Stewardship Ordinance, which requires pharmaceutical manufacturers to pay and manage drug take-back programs to address the environmental footprint of unused medications [26].

These advancements have not overcome the difficulties of implementing and enforcing policy. A 2022 study by O'Leary et al. shows that the effectiveness of state-level antibiotic stewardship policies varied significantly, and this is likely because they were not implemented uniformly across states, or followed other deficiencies in the monitoring and standardization of such programs [18].

The COVID-19 pandemic has underscored even more the importance of having comprehensive policy frameworks for dealing with antimicrobial resistance. In alignment with this renewed focus, the 2020-2025 Nationwide Action Plan for Combating Antibiotic-Resistant Bacteria signifies the necessity of integrated, One Health methods to handle challenges of antibiotic resistance [17].

3.3. Advocacy Strategies for Responsible Antibiotic Use

In the United States, advocacy strategies are key to responsible antibiotic use in the fight against antimicrobial resistance (AMR). These strategies target stakeholders such as healthcare providers, patients, and the public, with the aim of changing the behavior and awareness concerning antibiotic misuse.

The CDC's most prominent advocacy initiative is the 'Be Antibiotics Aware campaign', which provides educational resources for healthcare professionals and patients [27]. The message of this campaign emphasizes the appropriate antibiotic prescribing and usage and has led to increased public awareness about AMR [28].

Another is advocacy for health care provider education. For instance, at Johns Hopkins Hospital, an Antimicrobial Stewardship Program (ASP) was established, educating clinicians in a way that includes regular workshops, as well as decision support tools. A 14% reduction in antibiotic use and an 11% decrease in C. difficile infections has been achieved with this program [29].

Promising results were obtained with patient education initiatives. According to the study by Rocha-Pereira et al. [30], the usage of such programs at primary care services results in a 23% reduction in antibiotic prescriptions for upper respiratory tract infections. Often, multimedia approaches, including video and interactive online modules, are used to increase engagement and understanding with these initiatives.

An advocacy strategy for industry collaboration is being developed. In 2017, the Antimicrobial Resistance Fighter Coalition was launched, which is more than 100 organizations across sectors to increase awareness about ARFC [31]. Global awareness campaigns and educational toolkits for diverse audiences are what this coalition has organized.

Advocacy efforts have grown to be more and more reliant on social media platforms. Goff et al. [32] conducted a study that showed that Twitter campaigns with the hashtag #AntibioticResistance reached more than 20 million users in a year, making clear that social media can help raise AMR awareness.

But there are still challenges in terms of advocacy. As Klein et al [33] reported in a survey, 45% of Americans think antibiotics work on viruses, and that knowledge gap lingers. Cultural and linguistic barriers also hinder the creation of efficacious advocacy strategies in diverse populations.

To enhance the reach of future advocacy messages, these messages should be tailored for specific demographics, and should increasingly employ digital technology, while simultaneously creating alliances between healthcare providers, public health agencies, and community organizations to facilitate a more comprehensive, and therefore more effective, campaign.

3.4. Local Initiatives and Their Impact

Promotion of sustainable pharmaceutical practices and responsible antibiotic use in the United States has been especially powered by local initiatives that helped drive the change. These grassroots efforts are often the testing grounds for innovative approaches and provide insights that can be applied to broader implementation.

California Antimicrobial Stewardship Program Initiative (CASPI) is one example, launched in 2010. For acute care hospitals, this program requires that ASPs be implemented. Doernberg et al. [34] study found that, over the course of

five years, hospitals participating in CASPI had a 33% reduction in broad-spectrum antibiotic use and a 13% decrease in Clostridioides difficile infections.

The Illinois PROUD (Preserving the Power of Antibiotics) program launched in 2017 targets outpatient antibiotic prescribing in the Midwest. This initiative is based on provider education in combination with patient-facing materials and has achieved a 16% reduction of inappropriate antibiotic prescriptions in acute respiratory infections in participating clinics [35].

The New York Antibiotic Resistance Project (ARP) is a case in point of how community engagement can generate power to fight antibiotic resistance. Public health departments, healthcare facilities, and community organizations are collaborating on this 2016 initiative. In a paper published by Kelly et al. [36], they reported that the ARP's multi-layered approach, which included public awareness campaigns and provider education, resulted in a 20 percent decrease in unnecessary antibiotic prescriptions in participating communities.

The environmental aspect of antibiotic resistance has also been addressed by local initiatives. California's New Drug Take-Back Law, enacted in 2019, requires pharmaceutical manufacturers to pay for and manage a statewide drug take-back system. Potentially reducing pharmaceutical contamination in waterways, this first year of this program collected over 50,000 pounds of unused medications [37].

However, these successes are not implemented and sustained at the local level. A survey by Thompson et al. [38] of 150 local health departments found that 68% imperiled the ability of local health departments to sustain antibiotic stewardship programs by reporting inadequate funding as a major barrier. In addition, the scaling up of successful initiatives may be impeded by variations in healthcare systems, regulatory environments, and the like, particularly in localities.

Some regions have however formed collaborative networks in order to overcome these challenges. Launched in 2018, the Southeast Antibiotic Stewardship Initiative (SASI) is a collaboration among hospitals in six states to learn from and support each other's antibiotic stewardship efforts. As reported by Vaughn et al. [39], participants who did not receive antibiotics for asymptomatic bacteriuria achieved a 25% reduction in antibiotic use, indicating that regional collaborations have the potential to do the same.

With the battle against antibiotic resistance still in progress, these local examples are invaluable lessons for designing effective strategies that can be adapted and scaled to the maximum effect.

3.5. Scaling Up: From Local to National Implementation

Promoting sustainable pharmaceutical practices and responsible antibiotic use is both an opportunity and a challenge as the transition occurs from successful local initiatives to national implementation. Careful consideration of diverse healthcare systems, regional variations, and need for standardization is required in this scaling process.

The National Healthcare Safety Network's (NHSN) Antimicrobial Use and Resistance (AUR) Module is one successful example of scaling up. This surveillance system was first pilot-tested in selected hospitals but is now being rolled out nationally, offering standard measures of antibiotic use and antibiotic resistance patterns. The potential for rapid scaling of data-driven initiatives was demonstrated by a CDC report [40] that showed AUR participation increased from 129 hospitals in 2011 to over 1,700 by 2018.

National implementation has become dependent on public-private partnerships. In 2018 the U.S. government launched The Antimicrobial Resistance Challenge, which brought together more than 350 different organizations across several sectors, working toward the end of antibiotic resistance. As a result of this initiative, commitments to better antibiotic use in health care, agriculture, and the environment [22].

Adapting national strategies to local contexts is key to the expansion of the Antibiotics Aware initiative, originally a CDC program, to include state-specific campaigns. According to CDC [40], states that implemented tailored Antibiotics Aware campaigns had a 12% greater reduction in unnecessary antibiotic prescriptions than states without such adaptations.

Nevertheless, national-scale implementation remains a challenge. A study by Barlam [41] showed large disparities in state policies regarding antibiotic stewardship programs, which require more standardized regulatory approaches. Pollack et al. [42] also revealed that only 59% of U.S. hospitals achieved the implementation, not just partial, of all seven core elements of hospital antibiotic stewardship programs that the CDC has recommended.

However, there is no doubt that funding is a major bottleneck in scaling up initiatives. To address this, the PASTEUR Act [43] introduced in Congress in 2021 introduced a subscription-based model for antibiotic development and stewardship. Although not yet enacted, this legislation represents an innovative approach to sustainable funding of national antibiotic initiatives.

National scaling promising avenues of technological solutions. In 2019, the Antimicrobial Resistance (AMR) Challenge Dashboard was launched as a centralized dashboard to track progress toward antibiotic stewardship commitments across the country [44]. This tool facilitates knowledge sharing and real-time monitoring of national efforts.

Pierce et al. [45] suggest a 'hub-and-spoke' model for scaling antibiotic stewardship programs in order to overcome implementation challenges. The second approach is to create regional centers of excellence (ROCE) to offer resources and expertise to smaller facilities, filling this gap between local successes and national implementation.

Efforts to combat antibiotic resistance will continue to evolve, but it will be critical for scaling successful initiatives to the national level. However, as the range of settings in which this process will occur increases, so does the need for continued collaboration between government agencies, healthcare providers, researchers, and industry partners to develop flexible, adaptable strategies based on consistent standards and goals that can be implemented in these diverse settings.

3.6. Comparative Analysis with International Approaches

The approach to sustainable pharmaceutical practices and responsible antibiotic use used by the United States has some parallel to international strategies and some distinct traits. Just like European Union's "One Health' approach [46], the U.S. follows a multi-sector approach involving human, animal, and environmental health [22]. But the U.S. has its own unique problems with a decentralized healthcare system. Countries such as Sweden have achieved large decreases in antibiotic use through central policies [47], while the U.S. relies far more on state actions and public-private partnerships [48]. U.S. policymakers can draw lessons from the U.K.'s successful use of financial incentives for hospitals to improve antibiotic stewardship [49], and how they might be able to create nationwide incentive structures.

3.7. Future Directions and Recommendations

Several key strategies should be the focus of future efforts to promote sustainable pharmaceutical practices, antibiotic use on the part of patients, and the use of antibiotics in the USA. To track antibiotic use and resistance patterns across healthcare settings we need to develop more robust and standardized data collection systems. We also need to expand antibiotic stewardship programs to primary care and long-term care facilities. Niche solutions to modern problems like those posed by antimicrobial resistance could include innovative funding models, as in the PASTEUR Act proposal model, that will motivate antibiotic development and stewardship. Another is that interdisciplinary collaboration between healthcare providers, veterinarians, and environmental scientists is needed through a One Health perspective. The effectiveness of antibiotics can be improved by making better antibiotic prescribing decisions, and by determining resistance patterns, with the help of AI and machine learning.

4. Conclusion

This paper discusses policy frameworks and advocacy strategies to promote sustainable pharmaceutical practice and responsible antibiotic use in the USA from local to national implementation. The results highlight great progress in constructing comprehensive systems to fight antibiotic resistance through the creation of antimicrobial stewardship programs, innovative public-private partnerships, and targeted advocacy efforts. However, scaling up successful local initiatives towards a national level remains a challenge. These include variations in state-level policies, funding constraints, and the need for more standardized approaches to data collection and reporting. The implementation of centralized policies and financial incentives for antibiotic stewardship are identified as potential areas that could be improved upon, compared with international approaches. With the growing threat of antibiotic resistance policymakers, healthcare providers, researchers, and the public must continue to work together to develop and refine strategies of sustainable pharmaceutical practices. The USA can close the focused gaps and build on successful efforts to fight this resistant scourge and maintain the ability of these drugs to save lives so that we can advance into the future.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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