

Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active. Vaccine 40 (2022) 2647-2649

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Commentary

Back to Basics: A general approach to improving Covid and adult immunization delivery focused on Pharmacy-Based immunization services

Andrzej Kulczycki^{a,*}, Richard Shewchuk^b

^a Department of Health Policy and Organization, University of Alabama at Birmingham (UAB), United States ^b Department of Health Services Administration, School of Health Professions, UAB, United States

ARTICLE INFO

Article history: Received 30 June 2021 Received in revised form 5 March 2022 Accepted 16 March 2022 Available online 28 March 2022

The Covid-19 pandemic has highlighted the importance of vaccines, along with challenges and deficiencies in approaches employed to achieve vaccination goals. In December 2020, the U.S. launched a massive Covid vaccination drive. However, in March 2022, the 2-dose vaccination rate among adults aged > 18 years stood at only 65%, with 28% of adults having received an additional third Covid shot [1]. These sub-optimal vaccination rates can be attributed to many factors and have received much commentary. A potential and very accessible approach to improving Covid and adult immunization delivery lies in plain sight, remains underdeveloped, and demands urgent attention. Over the past two decades, community pharmacies have emerged as important adult immunization sites as a result of training programs and state regulatory changes initiated in the mid-1990s. In the early 2018-19 season, pharmacists administered the influenza vaccine to 32% of all adults who received it [2]. Community pharmacies have now also become vital to Covid vaccination efforts. We would contend that the operationalization of community pharmacy-based immunization services (PBIS) would benefit from a re-tooling of its structures and processes to help meet Covid and other adult immunization goals.

Americans increasingly obtain annual influenza, pneumococcal, herpes zoster, Td/Tdap and other immunizations at their local community pharmacies which offer extended hours, increased convenience, and greater cost-effectiveness than traditional physician providers. According to the Centers for Disease Control and Prevention (CDC), over 90% of Americans live within 5-miles of a pharmacy and visit their local pharmacist 12 times more often than their primary care provider [3,4]. Chain and independent

pharmacies serve patients across nearly 60,000 locations nationwide. Community pharmacies are the logical primary venue for serving the public's immunization needs. However, PBIS face multiple constraints that have long included inadequate assessment and recommendation of needed vaccinations. Regulatory burdens, corporate miscalculations, and professional inertia have increased workloads and exacerbated reimbursement hurdles, and the pandemic has further magnified workflow shortages that could be potentially offset through the use of supplementary personnel. Thus, PBIS offers an effective means to help achieve national immunization goals, but its full potential remains unrealized. Adding Covid vaccination to adult and childhood immunization schedules should not occur at the expense of other immunizations and at the risk of undermining existing efforts. We argue that fundamental PBIS structures and processes need to be altered to achieve overall adult and Covid immunization goals.

In late 2020, pharmacists received federal emergency use authorization (EUA) to administer Covid and childhood vaccines during the public health emergency, with qualified pharmacy technicians and state-authorized pharmacy interns permitted to administer COVID-19 vaccines if supervised by an immunizing pharmacist [5]. After the vaccine roll-out transitioned from mass vaccination sites, the U.S. government has relied increasingly on retail pharmacies including traditional drug, supermarket and mass merchandiser stores. Over 41,000 pharmacies are providing Covid vaccinations through the Federal Retail Pharmacy Program. In addressing the continued anticipated demands of Covid vaccination and significant unmet adult immunization needs, pharmacies are being pushed to the limit. They will also have to attend to other health concerns neglected during the pandemic and those induced by it. How should all these pressing demands best be met in a sustainable way?







^{*} Corresponding author at: Department of Health Policy and Organization, UAB, 320 Ryals Public Health Bldg., 1665 University Blvd., Birmingham, AL 35294-0022, USA.

E-mail address: andrzej@uab.edu (A. Kulczycki).

Fortunately, there is evidence-based guidance for improving immunization rates. The National Vaccine Advisory Committee (NVAC) Standards of Adult Immunization Practice articulate the steps of vaccine assessment, recommendation, administration, and documentation [6]. However, healthcare providers do not always assess adult vaccine needs as part of their routine care, contributing to substantial unmet needs. Our nationwide survey of immunizing pharmacists shows that although nearly all believed they appropriately documented vaccinations and possessed upto-date knowledge of CDC guidelines, most did not assess or strongly recommend needed vaccinations [7]. Although most thought their patients were administered needed vaccines, we would suggest this is because pharmacists are being reactive to suboptimal existing consumer demand. Not assessing and not giving strong/presumptive recommendations to the vaccine complacent, indifferent, or otherwise hesitant constitute missed opportunities for meeting significant unmet needs.

Vaccine hesitancy at the patient and general population levels partly explains suboptimal immunization coverage [8]. For many people who show passive vaccine hesitancy, asking and presumptively recommending vaccinations may be is all that is needed. Studies consistently indicate that strong provider recommendations help achieve higher coverage [9]. Additionally, we would suggest these recommendations have to be systematically implemented by pharmacists and other healthcare providers to create new demand by asking patients about their immunization needs. This is not happening for multiple reasons that include workflow and time constraints, inadequate resource deployment and prioritization of immunization services in practice.

Weak adherence to critical NVAC Standards of vaccine assessment and recommendation is due to several misaligned sources of influence among PBIS stakeholders. For example, pharmaceutical companies have long favored traditional office providers and have not fully leveraged PBIS. Corporate entities that deliver PBIS have not sufficiently motivated pharmacists to consistently follow the Standards, nor deployed appropriately-designed resources to enable this [7]. Professional practice associations that have increased educational training requirements have not nearly done enough to help pharmacists realize opportunities within their potential purview. An overly restrictive view of appropriate role responsibilities by state boards of pharmacy has precluded effective use of other qualified personnel and inadvertently created obstacles for re-engineering PBIS in a way to further enhance immunization uptake. Our research suggests that during the pandemic, state pharmacy associations have pushed to lift more restrictions and state boards of pharmacy and legislatures may have become more accepting of some changes, but delivering on such progress is uncertain after the public health emergency is lifted [10].

Beyond re-evaluating their individual efforts, coordinated endeavors are needed to align key stakeholders and deploy more resources to help overcome barriers to immunization implementation. With community pharmacists increasingly called upon to focus on more complex roles in patient care, structures and processes should be implemented in novel ways for pharmacists to address adult immunization coverage gaps, assume expanded clinical roles they are now trained to do, and help meet ongoing and future Covid immunization demands. For example, corporate entities involved in PBIS need to better inform and reward store personnel to assume these additional responsibilities. Our data collected shortly before the pandemic additionally indicated that pharmacists did not think they received a clear message regarding the prioritization of immunization within the pharmacy business model, nor felt rewarded by their corporate employers regarding immunization [7]. The situation has since evolved and it is unclear how it may change as the pandemic recedes.

We posit further that there is much corporate stasis and latent hesitancy across all stakeholders and levels of the vaccination ecosystem. Beyond patient-centric strategies, more effective communications are needed at a systems-level. Pharmacy chains and pharmaceutical companies could coordinate efforts and deploy their significant resources to better target messages that communicate and promote a clearer vision of PBIS, highlighting the range of vaccinations available at pharmacies and helping overcome vaccine hesitancy issues. Such messages would vary by community and population. Pharmacy practice associations could work with pharmacy corporate entities to emphasize the importance of accomplishing all NVAC Standards, re-think what PBIS should look like to achieve them, and improve pharmacists' ability to address the immunization needs of their customers, potentially including all Americans.

The present fragmented mix of state-based regulations has inadvertently delineated an excessively narrow vision for PBIS, impeding pharmacists from performing more clinical services and overly constraining technician involvement [11]. To be more proactive, a supplementary workforce should be trained and tapped to perform perfunctory tasks outlined by NVAC Standards, similar to how physicians delegate routine immunization tasks to other clinic personnel. In 2020, 419,300 pharmacy technicians were employed whose work increasingly involves patient care services [12]. National pharmacy chains have since hired more technicians who have received emergency authorization to administer Covid vaccines, but later found it difficult to hire sufficient frontline staff as pharmacy personnel increasingly reported experiencing burnout due to increased workloads and corporate demands [13].

While the EUAs have for now eased restrictions, many professional and regulatory constraints limit technicians' ability to assist in the overall immunization process. Shortly before the pandemic, we found pharmacists generally approving of appropriatelytrained pharmacy technicians asking and assessing patients' vaccine needs, but few agreeing with technician-administered immunization [14]. Emerging evidence from Idaho, the first state to allow this in 2017, suggests technicians can perform the essentially mechanical task of vaccine administration [15]. More states now allow this, but none permit technicians to recommend vaccines [16]. Key stakeholders in the vaccination ecosystem, including pharmacists themselves, conflate this task with counseling.

The required multi-level approach calls for the coordination of planning and implementation across multiple stakeholders. For example, corporate pharmacy leaders can implement system-wide structural and process changes to significantly effect change on these issues at the scale of chain community pharmacies. They could collaborate with professional pharmacy associations to enable all pharmacy personnel to engage patients more fully and to help realize corporate, professional and public health goals. These key stakeholders could work together with state boards of pharmacy to re-consider how pharmacy personnel ask, recommend, and administer vaccinations. Such a multiple-stakeholder alliance could also re-consider the mix of regulations and bureaucratic and professional inertia that hinders the capacity of pharmacy personnel to provide immunization care.

The relaxation of scope-of-practice restrictions on pharmacists in response to the pandemic has increased their capacity as an essential healthcare workforce to care for patients. Post-pandemic, the status quo ante may return. Over 20 states relaxed scope-ofpractice restrictions on nurse practitioners during the pandemic, but these life-saving measures are now being allowed to expire on the basis of politics rather than evidence [17]. Pharmacists need to see their roles in delivering both Covid and adult immunizations as making them more primary care-oriented. Scaling back scopeof-practice expansion now or post-pandemic would reduce health-

A. Kulczycki and R. Shewchuk

care access, professional role opportunities, and the ability to meet immense unmet adult immunization needs.

The vaccination ecosystem needs to be re-conceptualized as a dynamic systems model where all critical stakeholders are engaged to reduce systemic vaccine hesitancy in a collaborative and coordinated effort. As the most accessible of all health care professionals, community pharmacists are uniquely placed to help overcome many barriers to adult immunization which has become increasingly integrated into their practice over the past two decades. Community pharmacies have increased adult immunization volumes and rates, yet they remain under-utilized as vaccination delivery sites. Pharmacists could administer even more Covid vaccinations if they were better enabled to do so. Despite growing optimism that SARS-COV-2 may become endemic or seasonal like influenza and other respiratory viruses, Covid vaccinations will continue to be needed by those not yet fully vaccinated and to protect against emergent SARS-COV-2 variants. Much progress could be attained by assisting healthcare providers achieve greater compliance with critical NVAC Standards, without minimizing the importance of further work dealing with those resistant to vaccination. Additionally, aspects of PBIS organization and delivery should be strengthened to meet current and future Covid and other adult immunization imperatives.

Funding

This study was supported in part by a research grant (PI: A. Kulczycki) from the Investigator-Initiated Studies Program of Merck Sharp & amp; Dohme Corp. (grant number 60215). The opinions expressed in this paper are those of the authors and do not necessarily represent those of Merck Sharp & amp; Dohme Corp.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

- New York Times. COVID-19 Vaccine Tracker. Last updated March 1, 2022. Available at: https://www.nytimes.com/interactive/2020/us/covid-19-vaccinedoses.html [accessed March 1, 2022].
- [2] CDC (2021) Early-Season Flu Vaccination Coverage–United States, November 2018. FluVaxView: Influenza Vaccination Coverage, Centers for Disease Control

and Prevention. Available at: https://www.cdc.gov/flu/fluvaxview/nifsestimates-nov2018.htm [accessed March 1, 2022].

- [3] National Association of Chain Drug Stores (NACDS). Pharmacies: a vital partner in reopening America. Alexandria, VA: National Association of Chain Drug Stores: 2021.
- [4] Strand MA, Bratberg J, Eukel H, Hardy M, Williams C. Community pharmacists' contributions to disease management during the COVID-19 pandemic. Prev Chronic Dis, 2020;17:200317. Available at: <u>http://dx.doi.org/10.5888/</u> pcd17.200317.
- [5] U.S. Department of Health and Human Services (HHS). Guidance for PREP Act coverage for qualified pharmacy technicians and state-authorized pharmacy interns for childhood vaccines, COVID-19 vaccines, and COVID-19 testing. Available at: https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf.
- [6] Orenstein WA, Gellin BG, Beigi RH, Despres S, LaRussa PS, Lynfield R, et al. Recommendations from the National Vaccine Advisory Committee: Standards for Adult Immunization Practice. Public Health Rep. 2014;129(2):115–23.
- [7] Kulczycki A, Grubbs J, Hogue MD, Rothholz M, Shewchuk R. Optimizing the immunization activities of community chain pharmacists: insights from a national survey. J Am Pharm Assoc. 2020;60(5):686–93.
- [8] Daly M, Jones A, Robinson E. Public trust and willingness to vaccinate against COVID-19 in the US from October 14, 2020, to March 29, 2021. JAMA 2021;325 (23):2397–9. <u>https://doi.org/10.1001/jama.2021.8246</u>.
- [9] Jacobson RM, St. Sauver JL, Griffin JM, MacLaughlin KL, Finney Rutten LJ. How healthcare providers should address vaccine hesitancy in the clinical setting: evidence for presumptive language in making a strong recommendation. Hum Vaccin Immunother. 2020;16(9):2131–5.
- [10] Kulczycki A, Grubbs J, Hogue MD, Shewchuk R. Evolving views on pharmacy technicians' authority to engage in immunization service delivery before and after the pandemic: perspectives of state pharmacy board and state pharmacy association leaders. Paper to be presented at the American Pharmacists Association (APhA) Annual Meeting & amp; Exposition, San Antonio, Texas, March 18-21, 2022.
- [11] Maine LL, Knapp KK, Scheckelhoff DJ. Pharmacists and technicians can enhance patient care even more once national policies, practices, and priorities are aligned. Health Aff 2013;32(11):1956–62.
- [12] U.S. Bureau of Labor Statistics. Occupational outlook handbook: pharmacy technicians. Last updated February 8, 2022. Available at: https://www.bls.gov/ ooh/healthcare/pharmacy-technicians.htm. [accessed February 26, 2022].
- [13] Blank C. Retail pharmacy has reached the breaking point. Drug Topics, 2022; 166(2):23-24. Available at: https://www.drugtopics.com/view/retailpharmacy-has-reached-the-breaking-point [accessed February 26, 2022].
- [14] Kulczycki A, Grubbs J, Hogue MD, Shewchuk R. Community pharmacists' perceptions of increased technicians' involvement in the immunization process. J Am Pharm Assoc. 2021;61(5):596–604.
- [15] Adams AJ, Bright D, Adams J. Pharmacy technician-administered immunizations: A five-year review," J Am Pharm Assoc., forthcoming (published online, Nov. 14, 2021).
- [16] Eid D, Osborne J, Borowicz B. Moving the needle: a 50-State and District of Columbia landscape review of laws regarding pharmacy technician vaccine administration. Pharmacy. 2019;7(4):168.
- [17] Poghosyan L. We trusted NPs to handle a pandemic. why not regular care? Women's Health Care: A clinical journal for NPs. March 22, 2021. https:// www.npwomenshealthcare.com/we-trusted-nurse-practitioners-to-handle-apandemic-why-not-regular-care/?utm_source=sendinblue& utm_campaign=WHC_20210407&utm_medium=email.