Pharmacy-Based Travel Health Services in the United States

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Abstract

Pharmacists and pharmacies are highly visible and accessible to the public and have long been regarded as a source for immunization services in the United States. As international travel continues to increase and grow in popularity in this country, there is a pressing need for expanded access to preventative health services including routine and travel vaccinations and medications for prophylaxis or self-treatment of conditions that may be acquired overseas. In the United States, the scope of pharmacy practice continues to expand and incorporate these preventable health services to varying degrees on a state-by-state level. As a result, pharmacists can help to increase access to and awareness of the need for these services to insure that patients remain healthy while traveling abroad and that they do not acquire a travel-related disease while on their trip. For those pharmacists interested in starting a travel health service, considerations should be undertaken that ensures that they have the necessary training, education, and skill set in order to provide this specialty level of care and that their practice setting is optimally designed to facilitate this service. Outcomes from studies that have evaluated pharmacy-based travel health services are positive, which further supports the role of the pharmacist in this setting. Therefore, the purpose of this paper is to highlight United States pharmacy laws and regulations, pharmacist training, travel clinic considerations, and patient care outcomes from pharmacy-based travel health services.

Keywords: pharmacy law, education, training, vaccines, community pharmacy, ambulatory care

Introduction

In 2017, United States citizens made over 38 million visits to overseas international destinations, representing a 9% increase from the previous year with this trend of increased travel expected to continue. According to the United States Department of Commerce, the most commonly reported purpose of travel was for vacation (55.8%), followed by visiting friends and relatives (26.7%).[1] Regardless of the reason for travel, there are many risks involved when traveling to international destinations, from travelers' diarrhea to malaria to yellow fever. Unfortunately, 22 to 64% of travelers report some kind of health problem that might have otherwise been prevented with travel health services.[2] However, the main source for trip planning and preparation were the airlines (52.8%), followed by an online travel agency (33.1%) which may not be ideal sources for personalized health information, recommendations, and any needed vaccines or medications.[1]

The field of travel medicine can be broken down into pre-travel and post-travel health care. Pharmacists more commonly practice pre-travel health care or simply travel health, which focuses on preventable services prior to one's trip abroad. There is a growing need to expand access to and increase awareness of travel health services among the United States population. However, most estimates show that only about one-third to one-half of international travelers seek any form of travel health care prior to their departure from the US.[3,4] Reasons for this include cost, accessibility, lack of awareness, and health disparities between specific US populations.[4-6] Pharmacists can play a vital role in patient education and disease prevention related to international travel due to their high visibility and accessibility to the public, particularly in community pharmacy settings, as well as their training. Pharmacists, depending upon state law, can often provide all necessary vaccines, medications, supplies and in-depth

patient counseling prior to their patient's departure. The purpose of this paper is therefore to highlight United States pharmacy laws and regulations as well as pharmacist training, travel clinic considerations, and patient care outcomes from pharmacy-based travel health services.

Pharmacists Scope of Practice in Travel Health in the United States: Laws and Regulations

In the United States, the practice of pharmacy is regulated by individual states, thus there is sometimes significant variability in the care pharmacists are able to provide from one state to another. Despite this, pharmacists are highly trusted, visible to the public, and help to improve access to a variety of health care services.[1-6] Pharmacists continue to gain legal recognition as health care providers who can help support a health care system that is short on primary care physicians, nurses, and other providers. As such, the scope of pharmacists practice in certain areas, including travel health, is expanding.

Pharmacists in the United States have been providing immunizations and travel health care services for over 20 years.[7-8] In addition, more than 7,000 pharmacists have received specialized travel health training.[9] Historically, pharmacists have provided travel health services under protocols or collaborative practice agreements (CPA) with physicians in ambulatory care settings, however several states and territories now allow for more independent practice. [7-8, 10]

The travel health services that pharmacists provide can be broken down into the provision of: 1) counseling, 2) administering vaccines, 3) furnishing prescription medications, 4) ordering/interpreting laboratory tests, and 5) providing self-care medications and other supplies. Of 51 jurisdictions (US States and Territories), 45 allow pharmacists to provide at least some level of travel health service beyond counseling and providing self-care medications and supplies (which are within the scope of practice for all pharmacists). This includes the administration of routine and travel health vaccines, self-treatment and secondary disease prevention medications,

and prophylactic medications. Travel health services may also include ordering laboratory tests such as titers to assess for immunity to vaccine-preventable diseases as well as G6PD deficiency testing.

Pharmacists in 15 jurisdictions can administer all routine vaccines independently. In 30 jurisdictions, a CPA or prescription is required. Pharmacists in 8 jurisdictions can administer all travel-related vaccines independently, while a CPA or prescription is required in 36 jurisdictions. Pharmacists in 25 and 19 of jurisdictions can furnish prescription medications and order laboratory tests under a CPA, respectively. There are also specific travel health training requirements in eight states: Alaska, Arkansas, California, Florida, New Mexico, Oregon, Rhode Island, and South Carolina.

Notable examples

In New Mexico, pharmacists can provide all aspects of care (administering vaccines, furnishing medications, and ordering laboratory tests) independently without collaborating with a physician. In California, pharmacists can independently provide routine immunizations and travel-related prescription medications that do not require a diagnosis, which includes chemoprophylaxis and self-treatment of travel-related conditions. A CPA, however, is still required in order to administer travel vaccines in this state. In Hawaii, pharmacists can independently administer all immunizations, including those for travel, but requires a CPA in order to furnish travel-related prescription medications. Pharmacists in these three states can also independently order laboratory tests. Finally, new laws and/or regulations are pending or were recently passed in at least six jurisdictions that will expand travel health scope of practice for pharmacists if enacted into law. Interestingly, pharmacy technicians in Idaho can now administer

routine vaccines to patients, which may help facilitate pharmacist provided patient care services in this state.[10]

Pharmacist Training

The discipline of travel health involves a comprehensive knowledge and resource base including infectious diseases, epidemiology, environmental, geographic, and consular matters related to travelers' health and safety.[11] Since this field is unique, dynamic, and a rapidly growing area of practice for pharmacists, it is important to maintain a high standard of practice. The following section outlines the educational and training requirements for pharmacists wanting to provide travel health services in the United States.

Providing comprehensive travel health services involves determining patients' specific travel health needs, providing immunizations, furnishing necessary medications, and counseling patients on health and safety risks specific to their destination and itinerary. Pharmacists in the United States interested in providing travel health services are encouraged to first complete a comprehensive immunization training program such as the American Pharmacists Association's (APhA) Pharmacy-based Immunization Delivery Certificate Training Program (https://www.pharmacist.com/pharmacy-based-immunization-delivery).[12] This program is comprised of a self-study and live training seminar offering 20 hours continuing education. Although a general immunization-training program such as this one does not address specific travel-related vaccines in detail, it does provide a very robust and strong foundation of knowledge, practices, decision-making skills, regulations, and techniques related to immunization delivery that is necessary in patient care and travel health.

The successful completion of the APhA Pharmacy-Based Immunization Delivery Training program and being an authorized provider of immunizations in their state is a

prerequisite to enroll in the APhA Advanced Competency Training Pharmacy-Based Travel Health Services program, which helps provide a solid foundation on which to build a travel health practice. This program offers 10 hours of continuing education and includes: self-study and live seminar components that will prepare pharmacists to evaluate travel itineraries, assess health and safety risks based on travelers' destinations, reasons for travel and medical history, and create and communicate a plan for patients to receive the necessary medications, immunizations, counseling and non-prescription medications and supplies for their trip (https://www.pharmacist.com/pharmacy-based-travel-health-services).[13]

The gold standard in the scope of travel health knowledge is the Body of Knowledge developed by the International Society of Travel Medicine (ISTM). This Body of Knowledge serves as the basis for the Certificate of Knowledge examination that is available through the ISTM for all travel health professionals. Those who successfully complete the exam are awarded the Certificate in Travel Health (CTH®) by the ISTM, which must be renewed every 10 years by continuous professional development or retesting. The CTH® is one of few credentials offered across health professions and is recognized internationally (http://www.istm.org/bodyofknowledge).[14]

References and Resources

Once initial training is complete, pharmacists should maintain a comprehensive knowledge base of travel-related issues in order to be prepared for any itinerary that may come their way. A well-informed travel health provider must have the appropriate resources to remain up to date on information such as disease outbreaks, changes in country entry requirements, and vaccine recommendations.[11] The U.S. Centers for Disease Control and Prevention (CDC)

maintains a list of Travel Medicine resources (https://wwwnc.cdc.gov/travel/page/travel-medicine-references).[15]

Pharmacist and physician partnership for travel vaccination protocols

State laws may require the use of a standing order, protocol, or CPA in order to administer routine and travel-related vaccines. According to the APhA Immunization Certificate Training Program, items that should be included for any vaccine protocol include:

1. Statement of physician authorization for the pharmacist to administer vaccines
2. Qualifications of person(s) administering vaccines
3. Vaccine(s) covered in the standing order/protocol
4. Policies
5. Screening patients for indications and contraindications
6. Information to provide to patients (e.g., VIS)
7. How to administer vaccine (e.g., dose, route, anatomic location)
8. Documentation requirements
9. Communication to physician and reporting requirements
10. Emergency precautions (e.g. use of epinephrine for allergic reactions) including specific protocol

Please note that only physicians can apply to become yellow fever vaccine stamp holders, but they can designate other appropriate licensed individuals at designated yellow fever vaccine centers (http://wwwnc.cdc.gov/travel/yellow-fever-vaccination-clinics/search) to administer yellow fever vaccine and sign the international certificate of vaccination (ICV-P).[16] Both the physician and pharmacist need to complete the appropriate yellow fever application and submit any additional documentation for certification as required by state law.

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Logistical Considerations of a Travel Health Service

Appropriate staffing and resources for starting a travel health clinic are critical for program success, to limit the interference with everyday operations and services, and to create time for the pharmacist to dedicate to the travel health service. Below are some areas for consideration and suggestions for effectively incorporating a travel health clinic into a community pharmacy or ambulatory care clinic. It is important that pharmacists in these settings ensure that patients get comprehensive travel health services. The basic elements that must be provided or arranged for are:

- Patient Education
- Immunization
- Prescription medications
- Laboratory tests
- Travel related supplies

Workflow

To create time for the pharmacist to provide patient care, one should identify all essential tasks performed in the pharmacy or practice setting and consider redefining roles and activities as needed. In a travel clinic, the pharmacists' primary responsibilities are to[12]:

- Perform the risk assessment based on the patient's travel health history
- Prepare patient specific education documents and recommendations
- Provide the travel consultation
- Provide appropriate immunizations and documentation

Other tasks involved in a travel clinic such as marketing, patient scheduling and reminders, and vaccine/prescription input and billing can be designated to a pharmacy

technician, clerk, or intern pharmacist (i.e. a student pharmacist in training). In an ambulatory care setting, nurses may also be utilized to perform clerical responsibilities and administer vaccinations. An intern pharmacist may also assist in the preparation of the consultation documents and recommendations, and preparation and administration of vaccinations if appropriately trained and supervised. Performing a time-motion analysis or estimation can help your site better determine the required time and personnel needed.

Space

The space used for existing services such as routine immunizations is usually appropriate for providing travel health services. A private clinic room is ideal, as patients may feel more comfortable discussing medical history and receiving immunizations in an enclosed area. However, in a pharmacy not equipped with a private room, a designated semi-private space with a desk or table and seating for a pharmacist and one or more patients is usually sufficient.

Scheduling

Developing an effective scheduling system for your practice will increase patient, provider, and staff satisfaction, and boost overall productivity and minimize interference with normal workflow and services. Travel clinic services can be provided by appointment, on a walk-in basis, or a combination of both. Appointment based services tend to be less disruptive to the pharmacy's normal workflow as patient volume is planned and expected, however it can limit the number of patients who can be accommodated. Walk-in based services are more convenient for patients, but may cause disturbances to the normal workflow to accommodate the patient. Walk-in services might also mean that the pharmacy has to stock a wide range of, if not all, vaccines at all times because the required vaccines and patient/destination risk assessments cannot be determined in advance. For walk-in bases services, patients may also not come

prepared or with all required information for the pharmacist to make a proper assessment and plan.

Establishing specific travel clinic hours of operation may also help the pharmacist and site anticipate and adjust workflow needs in advanced. For example, the pharmacy or site may only schedule travel appointments on specific day(s) of the week or block scheduling where only certain blocks of time in the day are set aside for travel appointments. A combination of these two may also work depending on the needs of the site, and can always be expanded as patient volume increases.

Other considerations for scheduling appointments are consultations for multiple travelers with the same itinerary (e.g., a family, study abroad cohort, group of friends). For these consultations where all travelers have the same itinerary, group consultations regarding fundamental risks and hazards of the group's destinations can be conducted with all travelers at once. However, the individual risk management and individualized care plan must be conducted individually with each traveler since each patient's specific vaccination history, allergies, medical conditions, and recommendations must be taken into consideration.

The time it takes to provide the comprehensive pre-travel consultation service can vary depending on the number of pharmacists or student pharmacists available, pharmacy dispensing volume, insurance billing versus paying out-of-pocket, completeness of the patient's pre-travel history form, number of patients traveling with the same itinerary, and individual patient needs. For each appointment, the pharmacist's primary responsibilities in a travel clinic stated above, should take between 30 to 60 minutes, with the face-to-face travel consultation between the pharmacist and the patient ideally taking between 20 to 30 minutes. When scheduling patients, these estimations of time should be considered.

Travelers should be scheduled and seen at least 4 to 6 weeks before departure considering the time it may take to establish immunity from vaccines. However, many travelers often seek out travel consultations shortly before their departure date. Such travelers should still receive consultation, appropriate medications and vaccinations, after a thorough discussion of risks, benefits and efficacy of medications and vaccinations so close to departure.

Furnishing Medications

Medications recommended for international travel that the pharmacists may furnish or provide generally fall into two categories 1) self-treatment or 2) chemoprophylaxis as outlined above. The CDC Yellow Book details all drugs and conditions that fall into these categories. Many travel health practices opt to use pre-populated checklist-type prescription forms as the regimens for common travel related medications are standard. This may help to increase efficiency, consistency and potentially reduce furnishing errors. All furnishing pharmacists in need to obtain an individual National Provider Identification (NPI).

Vaccines

With the exception of yellow fever vaccine, most immunizations are available to order through pharmacy wholesalers or other vaccine distributors. Yellow fever vaccine is supplied directly by the manufacturer and may only be ordered by facilities associated with an official yellow fever vaccine provider. As with basic immunization services, it is important that all necessary supplies and equipment for administration are available and easily accessible. Close attention should be paid to the storage requirements of all vaccines. See the CDC's recommendation for proper storage and handling of all vaccines. (http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html)[17]

Ordering Tests

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In the course of providing a travel consultation, laboratory monitoring may become necessary in certain situations such as looking for antibody titers for patient with unclear vaccination history or checking for contraindications to medications, such as G6PD testing for primaquine.[18] For pharmacists, this will involve getting approval and beginning a relationship with a commercial laboratory to obtain a contract and lab ordering privileges in order to send patients to laboratory locations for blood draws.

Documentation

It is important to ensure proper documentation of patient care activities to serve as a legal record of care and as a communication tool when shared with other healthcare providers. Specific items to include as part of documentation may include, but is not limited to:

- A patient progress note which fully documents the clinical assessment and travel medication plan
- A patient medication record for each medication provided to the patient by the pharmacist
- Documentation of the administration of vaccines (vaccine name, lot number, expiration date, site vaccine administered, initials of pharmacist, date vaccine given, date of VIS)
- Documentation of yellow fever vaccination on the International Certificate of Vaccination or Prophylaxis (ICV-P) form with associated official stamp from the state health department when yellow fever vaccine is administered.
- Documenting refrigerator and freezer temperatures at least twice a day following CDC recommendations. This is also a requirement of being a yellow fever vaccine provider.

In addition, any documentation should be stored in the physical or electronic manner and be readily retrievable. The pharmacist should also provide the patient's primary care provider or the patient themselves with a copy of their progress note and what vaccines were administered. Vaccines that were administered can be documented in an immunization registry or in the electronic health record, or be faxed to the physician's office.

Outcomes of pharmacist provided care in travel health

More than 300,000 pharmacists have been trained to immunize in the United States.[19] Further, pharmacists in all fifty states and territories are able to provide immunizations with varying degrees of restrictions dependent upon individual regulations. [10, 20] Pharmacists have been increasingly involved with providing direct patient care services that depart from the traditional dispensing role, and providing travel health services is one such activity.

In the literature, there are a few examples of pharmacists provided care in travel health services in a variety of settings such as: supermarket chain pharmacies, independent community pharmacies, telepharmacy services, multidisciplinary outpatient clinics, and student health centers.[21-24] Travel health care should include comprehensive patient consultations and include information on disease prevention and immunizations, malaria prophylaxis, travelers' diarrhea, insect protection, and safe food/water precautions as mentioned in the previous section.[7, 21-23] Depending upon the type of population that the clinic serves, more specialty services could include high altitude expeditions, wilderness survival, diving, or other forms of adventure travel.

There are limited studies in the literature that have evaluated health outcomes in pharmacist-run travel clinics in the United States. Hess et al evaluated over 250 patients' acceptance of pharmacist-made recommendations for vaccines and medications at an independent community pharmacy, with an 84.7% favorable patient response and a 96% patient

satisfaction rate with the appointment. Study authors also showed that there was a statistically significant increase in patient knowledge of travel-related issues (medication use, adverse effects of medications, how to use insect repellents and insecticides, and how to safely consume food and water) following patient consultation. Patient satisfaction of the service also correlated with patient acceptance of pharmacist-made recommendations. This paper also documented what is believed to be the first travel health clinic located in an independent community pharmacy in the United States run solely by community pharmacists. Details on travel health clinic operations and logistics are also provided for those interested in starting up a similar service.[22]

Tran et al evaluated over 350 patients at a supermarket pharmacy. This study evaluated health outcomes, acceptance of pharmacists' travel health recommendations, and patient satisfaction. Patients overwhelming accepted pharmacists' recommendations for immunizations (82%-100%). Non-pharmacologic recommendations made by the pharmacist were highly accepted at approximately 90% in regards to drinking bottled water, safe food recommendations and importance of washing hands. A reported 20% of patients experienced travelers' diarrhea while traveling; however, for those that experienced diarrhea and used the medications recommended by the pharmacist saw their symptoms alleviated. Approximately 79% obtained information on the prevention of malaria and insect protection. More than 90% reported they took the medications as directed and none contracted malaria while traveling. Both Hess et al and Tran et al reported high patient satisfaction rates 96% and 94% respectively with a pharmacist-run travel health clinic.[22, 25]

Durham et al compared recommendations between trained pharmacists at a pharmacist-run travel clinic in a University student health clinic versus primary care providers (PCP) without specialized training. Of the 513 travelers reviewed, pharmacists were more likely to follow

evidence-based guidelines in regards to prescribing antibiotics for travelers' diarrhea when indicated (96% vs 50%), prescribing appropriate antimalarial medications (98% vs. 81%) and ordering more vaccines for patients (mean 2.77 vs. 2.31). Patients were also more likely to fill antibiotic prescriptions from the pharmacists-led clinic than from prescriptions written by their PCP (75% vs 63%).[24]

These studies show high patient satisfaction rates with pharmacist-provided travel health services, including both pharmacologic and non-pharmacologic recommendations with promising health outcomes. Despite these high satisfaction rates, some patients refused the pharmacist's recommendation for various vaccines. Patient acceptance rates in Tran et al ranged from 10% (for Japanese encephalitis) to 100% (for yellow fever) for travel related vaccines but routine vaccine acceptance rates ranged from 0% to 31%.[25] Hess et al had similar acceptance rates of travel related vaccines ranging from 67 % (for polio) to 97% (for yellow fever). Patients cited self-perceived low risk of contracting illnesses or were only focused on the travel related vaccines such as yellow fever or typhoid and not about routine illnesses such as influenza or measles, mumps, rubella.[22, 25] Durham et al. demonstrated that pharmacists with specialty training and CTH® credentials were able to provide expertise care for their patients in regards to travel health.[24] All studies demonstrated that pharmacists are integral in educating patients to maintain their health while traveling abroad. In an effort to decrease refusal rates and increase immunization rates pharmacists need to be more effective informing patients on the risks of contracting vaccine-preventable travel related infectious diseases during the pre-travel visit. More research on the impact of such education and health outcomes for patients traveling is needed.

Conclusions

International Travel from the United States continues to grow. Despite this, health risks remain with travel, and those traveling overseas may not consult a healthcare provider prior to their departure from the United States for needed vaccines and medications. While the pharmacists' scope of practice in travel health in the United States remains varied at the state level, this service nonetheless helps to increase patient's access to care. For those pharmacists interested in providing travel health services, considerations should be given not only to state laws and regulations, but also to the education and training that one receives and how the service will be set up and run. Lastly, patient care outcomes presented in this paper suggest that the pharmacist's impact on care is positive which supports greater incorporation and expansion in travel health care in the United States. This, in turn, may help to increase awareness of travel-related disease risks among the public and drive utilization of travel health care in the pharmacy setting. As pharmacy practice laws and regulations continue to evolve and more pharmacist-based travel health services develop, more studies will need to be undertaken to further evaluate the impact of pharmacist provided care in travel health care services.

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