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Proposing an Educational Framework for Healthcare Professionals on the Topic of Substandard or Falsified Medications and Illegal Online Pharmacies

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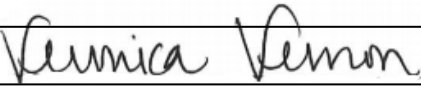
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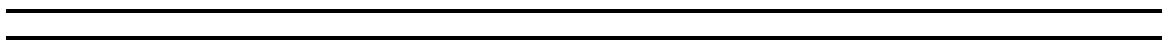
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Reader(s) May 5, 2021 Date

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Director, Honors Program



**Proposing an Educational Framework for Healthcare Professionals on the Topic of
Substandard or Falsified Medications and Illegal Online Pharmacies**

A Thesis

Presented to the Department of Pharmacy

College of Pharmacy and Health Sciences

and

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In Partial Fulfillment

of the Requirements for Graduation Honors

Margo Whitehead

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Background: Substandard or falsified medication prevalence in countries like the United States is documented with much more consistency than developing nations. On the contrary, although online pharmacies have been around for several decades, there is very limited data published establishing the prevalence of online pharmacy use by the general population (Fitler). Currently, there is no standardized curriculum regarding substandard or falsified medications and illegal online pharmacies offered to healthcare providers to combat the problems raised by counterfeits. Therefore, it is necessary to assess institutions' current stance on implementing concepts in the curriculum and to create an educational framework based on subjects deemed mandatory by those institutions and the researchers.

Objective: To (1) identify gaps and (2) assess various curricular elements best suited to educate healthcare professionals; particularly pharmacists, doctors, and nurses; on how to teach their patients about substandard or falsified medications and online pharmacies.

Methods: A mixed methods approach was used for this study. This included surveying colleges of pharmacy with quantitative techniques as well as utilizing a modified Delphi method to qualitatively evaluate experts' opinion on inclusion of topics of substandard or falsified medications and illegal online pharmacies in healthcare curricula.

Results: The Accreditation Council for Pharmacy Education (ACPE) does not require pharmacy schools to include the topics of substandard or falsified medications and illegal online pharmacies in their curriculum. Out of the 13 schools that submitted complete responses, 30.8% do not require their students to learn about these topics. Based on expert opinion, the final proposed curriculum includes recommendations for topics that

should be covered to give healthcare providers a deep understanding and appreciation of the topics' importance within the scope of patient care.

Conclusion: Based on previous studies, there is a serious need to close the educational gap. This study served to develop a proposed curriculum that would serve as a complement to the previous work done by International Pharmaceutical Federation (FIP) and the World Health Organization (WHO).

Keywords: substandard medications, falsified medications, illegal online pharmacy, curriculum development

INTRODUCTION

The growing popularity of online pharmacies is altering the landscape in which patients approach their healthcare and has been accelerated by the COVID-19 pandemic.^{1,2} At this time, Florida, Colorado, and Maine have passed legislation allowing drug importation from Canadian-based online pharmacies.³ Additionally, several other states have similar bills in process. These legislative proposals suggest that online pharmacies are becoming attractive options for patients to receive their medications at a potentially lower cost than a traditional United States pharmacy may offer.

With the ever-rising cost of healthcare, patients may find themselves in positions where they need to find cheaper options for their treatment.⁴ Online delivery services are also incredibly convenient. It can be appealing to a customer or patient that a product can be delivered within a short time-frame, especially for those with busy schedules. Online pharmacies give patients access to medications. In some cases, patients may live in areas that do not have easy access to healthcare, including the pharmacy deserts, which, unfortunately, are growing in larger numbers each year.^{5,6} In other instances, patients may be embarrassed to see a healthcare provider because of their medical conditions. Anonymity may be important to individuals with diseases like HIV-AIDS or even for individuals who wish to use lifestyle drugs like Viagra (brand name for sildenafil).⁷ Regardless of the patient's circumstances, cost, convenience, and access are the core reasons as to why a patient would knowingly or unknowingly risk receiving a substandard or falsified medication from an illegal online pharmacy.

Unfortunately, there are implications that relying on drugs from online pharmacies can result in patient harm due to drug shortages, falsifications, or

mishandling. As András Fittler, PharmD and colleagues concluded: “Improved patient-provider communication and promotion campaigns are needed to inform the public about the safe use of internet pharmacies, as these initiatives can directly prevent patient safety threats.”⁸ Therefore, it is necessary that pharmacists and other healthcare providers undergo training on how to educate patients on the risks and potential dangers of online pharmacies.⁷ The purpose of this work is to propose an educational framework that will educate healthcare professionals, particularly pharmacists, doctors, and nurses, on how to teach their patients about the topic of substandard or falsified medications and online pharmacies that allows the flexibility for educators to implement the topics into a professional program.

The underlying concern from a healthcare provider perspective is the danger that a patient can encounter when navigating illegal online pharmacies or using substandard or falsified medications. In developing nations, the main drug safety concerns are with substandard or falsified antibiotics and antimalarials.⁹ Because substandard antibiotics contain an insufficient amount of antibiotics to treat a patient’s infection, it can create antibiotic resistance that can be significantly more dangerous and difficult to treat than the original infection.⁹ With antimalarial drugs, there have been cases in which patients received products that were inadequate and ultimately ended in death. However, the documentation of these incidences is much more limited than that of more developed countries. Because the risks associated with the topics of substandard or falsified medications and illegal online pharmacies is dependent on location, this is a strong indication that the education available to practitioners and patients should also be location-specific.

To ensure successful outcomes, the educational framework must be applicable to the particular country in which it is taught. Recently, the International Pharmaceutical Federation (FIP) published a curriculum intended for use in Africa that addresses substandard or falsified medications.¹⁰ Because this curriculum was designed for use in Africa, there are specific elements that are only applicable to developing nations. This is due to the fact that language and culture greatly influence approaches to healthcare. Therefore, it was deemed necessary to create a curriculum for healthcare providers practicing in developed nations, especially in the advent of an up-and-coming arena such as illegal online pharmacies.

The following research was done within the context of pharmacy practice, but the curriculum ideally will be applicable to other healthcare providers. Because each of the topics of the curriculum were included based upon expert opinion from a variety of professions, this should allow easy incorporation of the educational framework within an institution's curriculum or an individual's own learning.

METHODS

Study Design

This study was conducted in a series of phases (see Table 1). The phases were established based on a previously completed curriculum development study that focused on the implementation of an antimicrobial stewardship program within pharmacy school curricula.¹¹ Phase I consisted of literature review in an attempt to find any information available about education pertaining to substandard or falsified medications and illegal online pharmacies. The American Journal of Pharmacy Education (AJPE), U.S. National Library of Medicine, and the Accreditation Council for Pharmacy Education was

consulted. Search terms included “substandard medication,” “falsified medication,” “online pharmacy,” “illegal online pharmacies,” and “pharmacy education.”

Phase II was used to collect data from colleges of pharmacy surrounding the curriculum offered to students on the aforementioned topics. Data was collected through an anonymous survey sent to 143 contacts at colleges of pharmacy throughout the United States and territories. The survey was open from June 29th, 2020 through September 15th, 2020, a total duration of 11 weeks.

Phase III was modeled based on a modified Delphi Method in which phone interviews were conducted with individuals deemed to be experts on the topics of substandard or falsified medications and illegal online pharmacies. These experts included pharmacists, lawyers, and other educators. Each expert has played a role within this field directly by teaching these topics to other professionals or to student professionals during the course of the expert’s career. Experts were initially asked to rate the importance of education about substandard or falsified medications and illegal online pharmacies using a Likert scale from 1 to 10, with 1 being very unimportant and 10 being extremely important. The experts were also presented with 20 topics and were asked to rank them on a scale from 1 to 5 with 1 meaning the topic should be excluded and 5 meaning it should definitely be taught (see Appendix, Figure 2). The importance of each topic was determined based on the most number of responses per rank. The importance was deemed high if the rank was 5, moderate importance with a rank of 4, and low importance with a rank of 3. Data was compiled to finalize the topics that were deemed most essential to include in the final proposed curriculum.

Finally, Phase IV was the curriculum design. Based on the feedback from the colleges of pharmacy and the deliberation of the experts, topics were included to create a thorough examination of themes pertaining to substandard or falsified medications and illegal online pharmacies.

Inclusion Criteria for Surveyed Participants

To be included in the study, colleges of pharmacy had to be located within the United States or United States territories. Experts were selected if they have a stake in the realm of substandard or falsified medications and illegal online pharmacies through their line of work.

RESULTS

Phase I - Literature Review

It was important to solidify the definitions of the terms “substandard or falsified medications” and “illegal online pharmacies” before beginning the study. There are several definitions of substandard medications, falsified medications, and illegal online pharmacies in literature because there are no universally-accepted definitions. For our purposes, we will be using the following definitions. According to the Food and Drug Administration (FDA), an online pharmacy is deemed illegal if any of the following statements are true: “Prescription only medicines are being offered to patients without requiring a valid prescription; the entity is not licensed as a pharmacy in the state where the patient is located; the medicines offered have not been approved for sale to the Americans by the U.S. Food and Drug Administration, or are otherwise counterfeit, misbranded, or adulterated; the medicines are not dispensed by a pharmacist licensed or otherwise recognized in the patient’s jurisdiction.”¹² According to the World Health

Organization (WHO), the definition of a substandard medication is “[a product] that fails to meet either quality standards or specifications, or both,” and a falsified medication is “[a product] that deliberately/fraudulently misrepresents their identity, composition, or source.”¹³ These definitions give a more focused perspective from which to proceed with the literature review.

In a study titled “Evaluation of Pharmacists’ Awareness of the Prevalence and Negative Consequences Associated with Illegal Internet Pharmacies,” 93% of the pharmacists who participated believed that less than 81% of internet pharmacies were operating legally in their respective jurisdictions.⁷ Nearly all of the participants believed that all of the medications sold on the internet to United States patients were not legally approved by the Food and Drug Administration. However, the pharmacists were unsure of how to determine if an online pharmacy was legitimate or illegal. The conclusion of the study was that more education is needed in order to give providers the tools they need to help empower patients to make informed decisions about accessing their care. Therefore, the next step in the literature review process was to assess whether or not there was a pre-existing, standardized curriculum covering the topic of illegal online pharmacies, and with it, substandard or falsified medications.

Using the targeted search terms, we consulted AJPE as well as the U.S. National Library of Medicine to find if anyone had published curriculum content covering substandard or falsified medications and illegal online pharmacies. Additionally, the current ACPE standards¹⁴ were reviewed to determine if the topics included in our study were mandatory for pharmacy school accreditation standards. In the end, our search was fruitless as no one at the time had published any such curriculum, nor were the topics

required to be covered for accreditation. However, the WHO was in the process of creating a curriculum covering the same topics during the time of our literature search. Eventually, we were able to draw comparisons from the FIP curriculum at a later date.

Phase II - Colleges of Pharmacy Survey

The survey was sent to 141 contacts at colleges of pharmacy throughout the United States and territories. There were three undeliverable emails, bringing the total “n” to 138. From these contacts, we received 18 responses totalling a 13% response rate. There were 12 respondents with 100% questionnaire completion, 1 respondent with 45%, 3 respondents with 18%, and 1 respondent with 0% completion.

When surveyed, an overwhelming number of the schools said that the largest barrier to including these topics in their curriculum is “limited time in the curriculum” with a smaller number citing “lack of expertise” and “not required in standards” as a secondary limitation (see Appendix, Figure 2). Those that require their students to learn about substandard or falsified medications and illegal online pharmacies were more likely to offer courses on the topics during the 3rd professional year of the program with two schools requiring it during three years of the program. Out of the 18 schools that responded, 4 of them (22.2%) do not require that their students learn about substandard or falsified medications and illegal online pharmacies. From that group of 4 schools, 3 of them (16.7% in total) do offer the subjects in an elective or voluntary format. Overall, only 8 (44.4%) of the respondents confirmed that they would be willing to introduce these topics to their institution.

Phase III - Expert Interview Results

There were a total of 11 experts interviewed to determine the results for this phase. The average from the initial question asking the experts to rate the importance of the topics of substandard or falsified medications and illegal online pharmacies ranked at 8.45, showing that these topics are important to be included in healthcare curricula. As for the 20 topics presented to the experts, there was no majority that fell between 1 or 2 for any of the topics. The “high importance” topics designated for the curriculum are as follows:

- History of incidences of SF medicines detection, including morbidity and mortality data.
- Health, social, and economic consequences.
- Contributing factors (e.g. medicines shortages, policy).
- Medicines most at risk for counterfeiting.
- Risks of illegal online pharmacies and internet sales.
- Resources for health professionals to help patients.
- Educating the public and counseling patients.
- Resources to help patients identify safe sources of medicines in the context of cost and access.

DISCUSSION

With the ever-rising cost of healthcare and the threats that arise from the global COVID-19 pandemic, patients may find themselves in positions in which they must seek out cheaper options for their treatment.⁴ However, patients are not the only population that has started to turn to the internet. Amazon, for example, is broadening its online

healthcare offerings as consumers increasingly shop from home during the pandemic.¹ It was also found that illegitimate online pharmacies are capitalizing on the pandemic by purchasing domain names that include COVID-19 words and phrases, registering domain names with fraudulent “safe haven” registrars, and even creating new website facades linking to non-coronavirus-related stores.²

As a consumer, the idea of receiving any substandard, falsified, or counterfeit product is disturbing. Any time a person buys a product, they are expecting to receive the product that was advertised. When these expectations are not met, it can be frustrating and disappointing that the money, time, and effort spent to acquire the product was essentially wasted. From the perspective of a healthcare provider, the idea of a patient receiving a substandard or falsified medication is terrifying. The risks that are posed to patients when they encounter substandard or falsified medications and illegal online pharmacies can elicit ill effects that impact not only the patient but their community as well. From no effect, to antibiotic resistance, to even death, patients are at risk of receiving subpar or detrimental care unless healthcare professionals are properly trained on identifying legitimate sources and properly counseling patients on safe options to access medications.

Regrettably, based on the literature (or lack thereof) that was found during Phase 1 of our study, there is little to no evidence showing that education surrounding illegal online pharmacies is accelerating at the same pace as the businesses. This indicates a clear need for education surrounding the topics of substandard or falsified medications and illegal online pharmacies.

Since many of the pharmacy schools indicated that “limited time in the curriculum” is the main barrier to including topics that are not required by accreditation standards, the “high importance” topics outlined by the experts will play a critical role in delivering impactful education to future healthcare professionals. It is noteworthy to mention that each of the “high importance” topics are also included in the modules of the curriculum developed by FIP, showing that these elements are critical in delivering comprehensive education on the topics.¹⁰ After discussing the idea of collaborating with FIP to create an educational framework here in the United States with a Technical Officer on the Incidents and Substandard/Falsified Medical Products Team at the WHO, it became abundantly clear that the educational framework must be applicable to the particular country in which it is taught. This is due to the fact that language and culture greatly influence approaches to healthcare, especially in an up and coming area such as illegal online pharmacies. Consequently, this led us to use a framework of phases previously used in a curriculum development study for antimicrobial stewardship, with the first phase consisting of soliciting input from colleges of pharmacy located in the United States and territories. The conversation surrounding and evaluation of FIP’s curriculum validated the need for a separate approach to the topics to be included in the curriculum.

Despite the widespread and global nature of this patient safety risk, this research suggests more education is needed to ensure our health professionals are equipped with the knowledge to properly address the sale of prescription medicines via the internet. Despite a packed curriculum, our education models must adapt to contemporary topics, especially those that have emerged as a result of an evolving pandemic. Schools and

colleges of pharmacy must respond by training future pharmacists in those areas that will impact our practice for years to come. This study highlights this need, while also providing a suggested list of high-priority topics (Figure 5) for inclusion in the pharmacy curriculum. Academicians should be encouraged to use this work as a resource, along with other published information to build a curriculum that prepares students for the age of e-commerce and self-care.

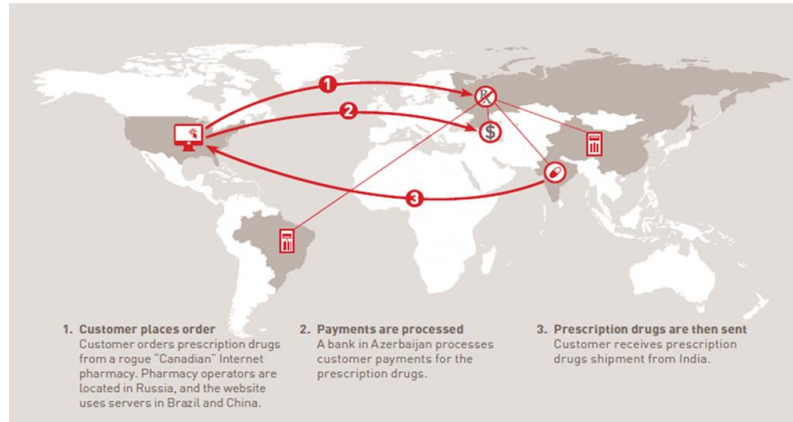
In spite of the use of multiple sources of data to inform the development of this curriculum, the study was not without limitations. The participation of 18 out of 141 schools of pharmacy throughout the United States and territories limited the access to objectives or syllabi for curricula in addition to other institutional insight that would have painted a more accurate picture of the amount of education offered to student pharmacists. Additionally, since this study was conducted with a focus on schools and colleges of pharmacy, there may be further considerations when incorporating the curricula into other professional healthcare programs.

CONCLUSION

A need for a standardized curriculum on the topics of substandard or falsified medications and illegal online pharmacies was established based on literature review and results from surveying United States and territories' schools of pharmacy. Experts were interviewed to aid in the creation of the curriculum by determining topics of highest importance needed in the curriculum. Further evaluation is needed for the implementation of the curriculum. Additionally, further consideration is needed for inclusion of other web-based platforms such as social media in addition to traditional websites.

APPENDIX

Figure 1



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Figure 1. This depicts an example of the way an illegal, Canadian online pharmacy operates¹⁰. A patient in the United States (US) orders medication through the online site, which is based in Russia. While the patient's payment is processed in Azerbaijan, the order is routed to servers located in Brazil or China. The drug is then processed and sent from India to Canada where an employee of the illegal online pharmacy repackages the product to make it appear as if the drug came from Canada. The package is then delivered to the patient back in the U.S. without them ever knowing about the process through which their order went.

Table 1

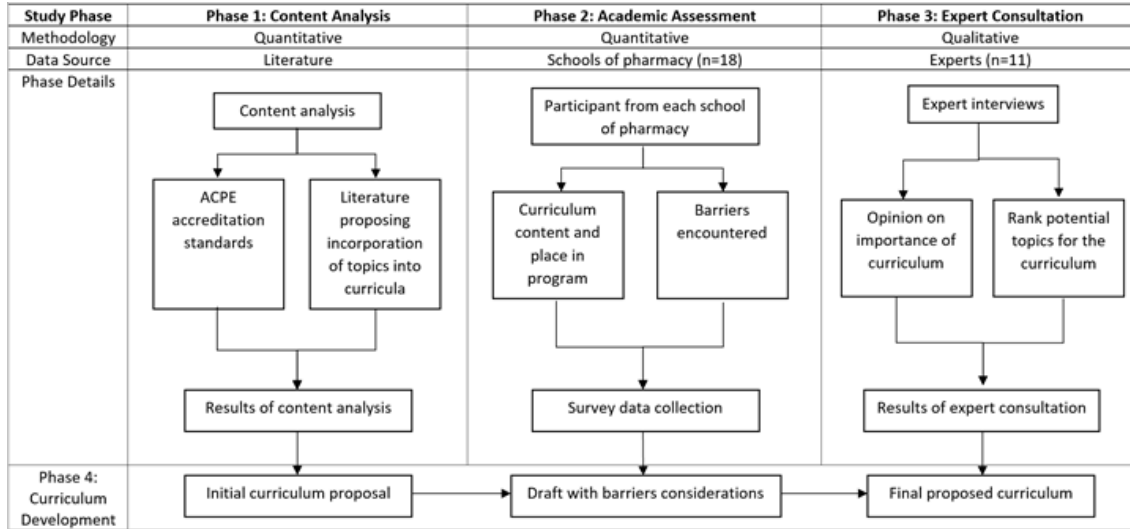
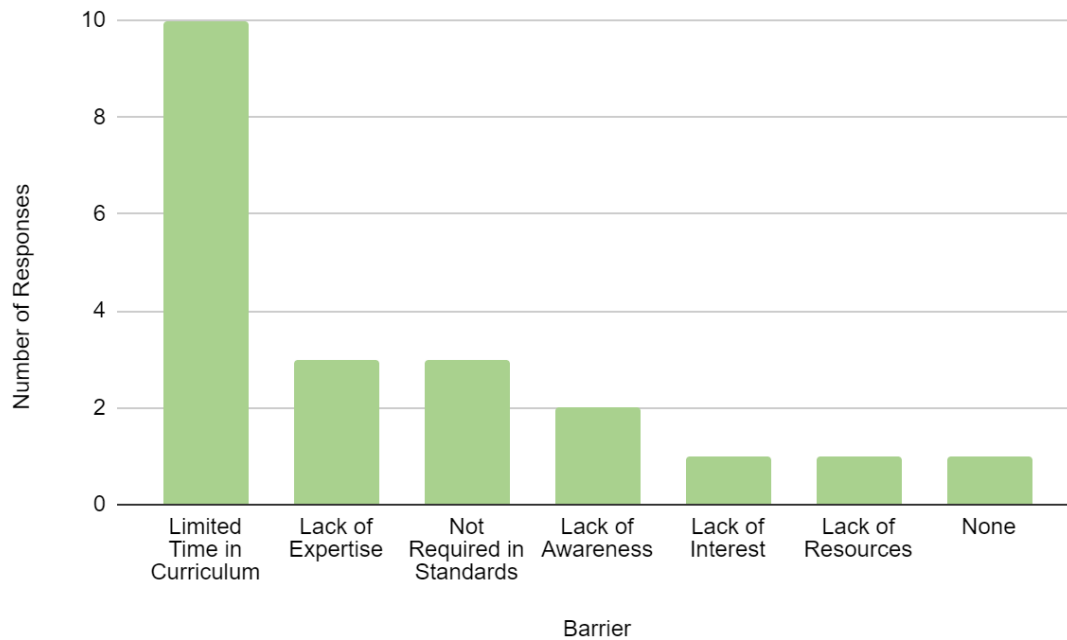


Figure 2



*Note: Some colleges of pharmacy selected more than one applicable barrier.

Figure 3

Does your school/institution require education on these topics?

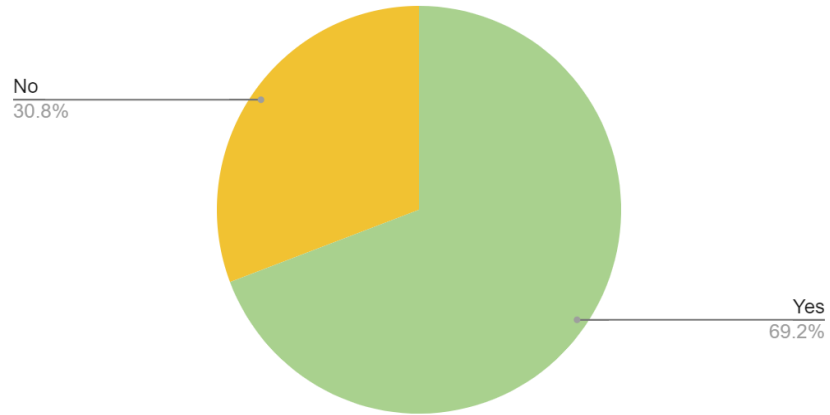


Figure 4

Where is its place in your program?

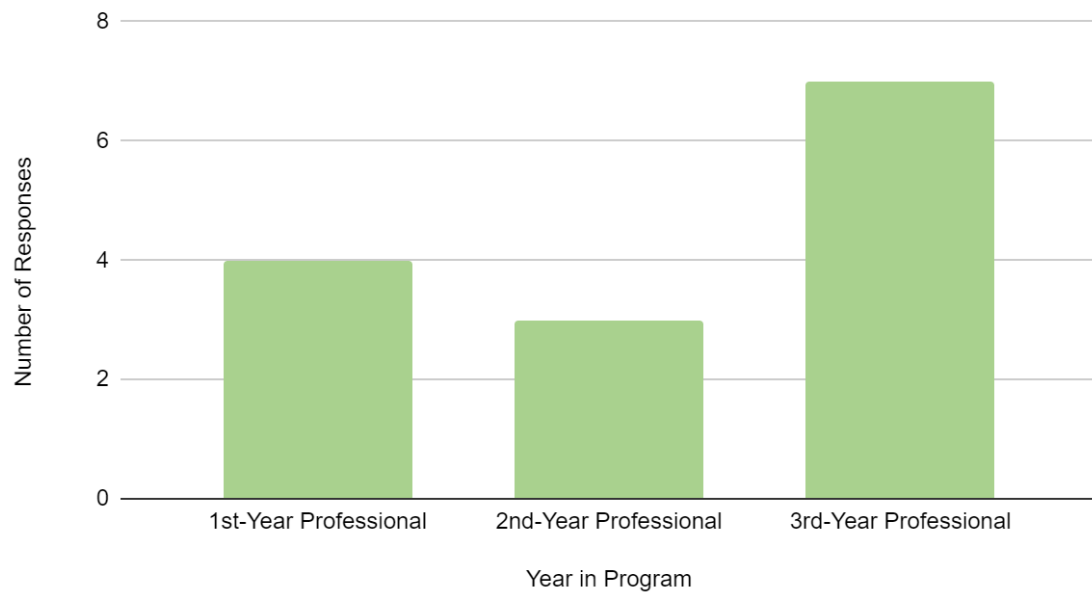
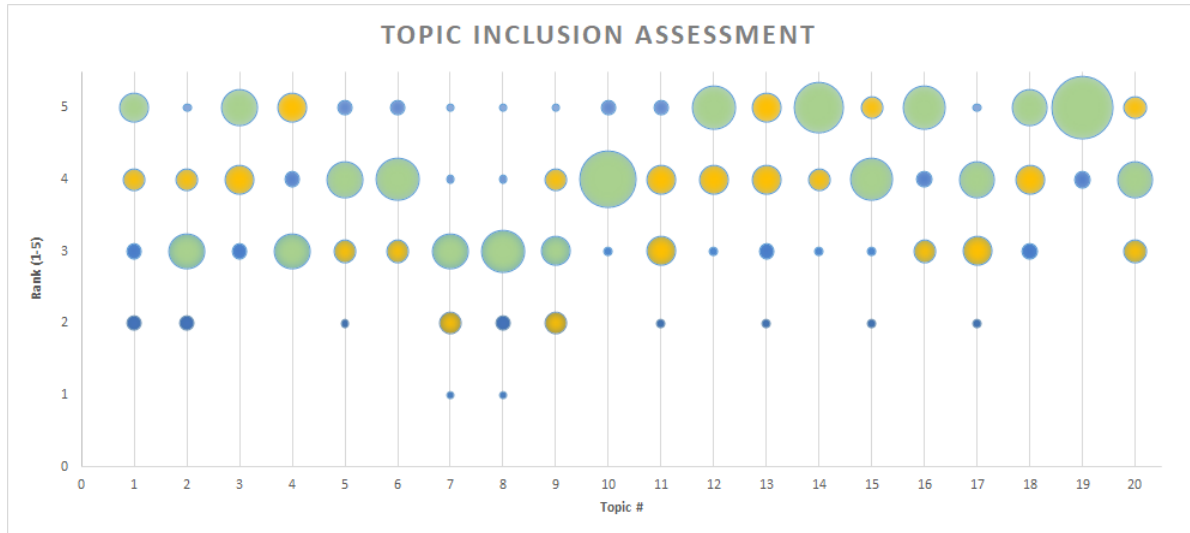


Figure 5



Green: Highest percentage of responses per topic | Yellow: $\geq 25\%$ | Blue: $< 25\%$

Table 2

Topic No.	Topic	Perceived importance in expert consultation
1	History of incidences of SF medicines detection, including morbidity and mortality data	High
2	Internationally accepted terminology	Low
3	Health, social, and economic consequences	High
4	Legislation and regulation	Low
5	Organizations and stakeholders involved in fighting SF medicines	Moderate
6	Role of pharmaceutical quality	Moderate
7	Principles of physical and chemical inspection	Low
8	Quality control and detection analysis tools	Low
9	Pharmacovigilance structure and activities	Low
10	Reporting issues with SF medicines	Moderate
11	Information frameworks that support analysis and improvement in SF medicines prevention	Low-Moderate
12	Contributing factors (e.g. medicines shortages, policy)	High
13	Medicines most at risk for counterfeiting	Moderate-High
14	Risks of illegal online pharmacies and internet sales	High
15	Identifying illegal sources of medicines	Moderate
16	Resources for health professionals to help patients	High
17	Safe supply chain management and medicine procurement	Moderate
18	Educating the public and counseling patients	High
19	Resources to help patients identify safe sources of medicines in the context of cost and access	High
20	Professionalism and social responsibility in the context of the role of the health professional	Moderate

High: Majority ranked 5 | Moderate: Majority ranked 4 | Low: Majority ranked 3

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