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Brief report

Vaccine shortages and suspect online pharmacy sellers

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ABSTRACT

Vaccines represent half the products on the FDA Biologics Product Shortages list. As a result, providers and patients may purchase them online, a process rife with patient safety risks. We examined vaccine online availability by assessing up to 5 identified online sellers. We determined if sites were accredited by the National Association of Boards of Pharmacy (NABP) VIPPS program, listed as US or international, employed social media linking to suspect online pharmacies, and if they were on the NABP Not Recommended list. All vaccines were advertised by online pharmacies and through data aggregation and social media sites, none were VIPPS-accredited, and most were on the NABP Not Recommended list. We found some online sellers advertising vaccines as over-the-counter. We extended our analysis to WHO Essential Medicines List vaccines and found all are also available online from suspect, non-VIPPS accredited sellers. Stakeholders should be aware of these online patient safety dangers.

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Drug shortages have created tremendous challenges for medical care. Considerable attention has been paid to these shortages and their impact in key areas such as cancer, anesthetics, and emergency department drugs [1]. Yet this critical shortage also includes vaccines, an important, cost-effective public health intervention [2]. As of September 23, 2011, half the biologics on the U.S. Food and Drug Administration Biologic Products Shortage list are vaccines: Hepatitis B, Pediatric and Adult Hepatitis A, and Zoster vaccines [3].

Due to these shortages, physicians, hospitals, and patients may seek alternative sources, specifically, searching and purchasing online. The Internet has become a tremendous source for all medical things. For example, the National Center for Health Statistics reported 51% of adults searched for health information online from January to June 2009, and a Harris poll estimated 175 million adults use the Internet for healthcare information [4]. The World Health Organization (WHO) has published criteria for vaccine information on websites, including sites fulfilling quality criteria, known as the Vaccine Safety Net (“VSN”) [5].

Yet online purchasing of medical products is rife with patient safety risks. The criminal element in combination with poor quality, suspect materials, questionable sourcing, diversion, and improper

storage create challenges when purchasing pharmaceuticals online [6]. These are amplified when taking into account the complexity of vaccines, including specialized quality control, storage and transport. Drug regulatory authorities and WHO continue to warn about the dangers of buying online, yet eHealth commerce in this arena continues to grow [6,7]. This growth has been exacerbated by social media sources such as Facebook and Twitter, which command the highest volume of traffic over the Internet [4]. These platforms have been penetrated by illicit online drug sellers and add to search engines as online environments used to sell products [4].

Importantly, vaccines have been subject to counterfeiting and falsification, placing global patient populations at risk. This includes the inoculation of 60,000 people with fake meningitis vaccine in Niger, 1400 people injected with fake flu vaccine in Texas, counterfeit rabies vaccines in China, and fake flu vaccines being sold to drugstores in the Philippines [8–11]. Even more worrisome is the potential for counterfeit and substandard vaccines to be used during pandemic influenza or disease outbreaks when scarcity is at its worst. Such dynamics may already have been realized during the H5N1 influenza outbreak, when FDA and Dutch Healthcare Inspectorate issued warnings regarding fake anti-viral oseltamivir (Tamiflu) sold online [7].

To assess these patient safety risks, we examined the online accessibility of shortage vaccines. We determined if sellers were accredited or listed as “not recommended” by the key US voluntary accreditor of online pharmacies, the National Association of Boards of Pharmacy Verified Internet Pharmacy Practice Site (“VIPPS”) program and identified characteristics that could have an impact on availability or legitimacy of product [12]. Not Recommended NABP

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Table 1
Vaccines and online pharmacy sites.

Vaccine	VIPPS	US or International	Suspect site ^a
Hepatitis B vaccine			
Online pharmacy A	No	US	Yes [Links; NABP Not Recommended]
Online pharmacy B	No	International	Yes [NABP Not Recommended]
Online pharmacy C	No	US	Yes [NABP Not Recommended]
Online pharmacy D	No	International ^b	Yes [NABP Not Recommended]
Pediatric and Adult Hepatitis A vaccine			
Online pharmacy E	No	International	Yes [NABP Not Recommended]
Online pharmacy F	No	International ^b	Yes [NABP Not Recommended]
Online pharmacy G	No	US	Yes [Links; NABP Not Recommended]
Online pharmacy H	No	International ^b	Yes [NABP Not Recommended]
Online pharmacy I	No	International ^b	No information
Zoster vaccine			
Online pharmacy J	No	International ^b	No information
Online pharmacy K	No	US	Yes [Links]
Online pharmacy L	No	International ^b	Yes [Links]

^a Links means links to suspect online pharmacies. NABP Not Recommended means on the National Association of Boards of Pharmacy Not Recommended Sites list of online drug sellers.

^b A “Canadian” online pharmacy.

Sites are Internet drug sellers that appear out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards [12].

1. Methods

FDA Biologic Drugs Shortage list vaccines include: Hepatitis B vaccine, Pediatric and Adult Hepatitis A vaccines, Zoster vaccine, and Measles, Mumps, Rubella, and Varicella—Varicella component [3]. Because the latter reflected only Varicella covered by the Zoster vaccine, we limited our analysis to Hepatitis B, Pediatric and Adult Hepatitis A, and Zoster vaccines. We then searched “buy DRUG” using Google, where “DRUG” was the name of the specific vaccine. The first 5 online vendors or total number identified as selling the vaccine in the first 5 result pages were examined. We used 5 sales offers as our number of hits to examine based on previous research that found consumers purchasing goods online visit 3–5 websites prior to purchase [13,14]. For our search purposes we identify an online pharmacy as any non-wholesale website engaged in sale of the identified vaccine. We then assessed if the online pharmacy or associated website was VIPPS-accredited, was a US or international site, and used social media linking to questionable online pharmacies, and/or was listed as an NABP Not Recommended Site. Non-VIPPS accredited, international, and/or sites selling or linking to sites with “no prescription” sales were deemed suspect sites. Searches were conducted from 8/1/2011 to 9/19/2011.

2. Results

All vaccines subject to shortage were available online and most sellers were suspect. Of the 12 online sellers, none were VIPPS-accredited. Indeed, 75% ($N=9$) of these online sellers were international, most claiming “Canadian” status (Table 1). Most online sellers (10/12) were listed on the NABP Not Recommended Site list, and at least one marketing link for each vaccine was to a data aggregation website advertising multiple illegal no-prescription online pharmacy sites. Further, access to online pharmacies selling vaccines was not limited to Google results. Both Facebook and Twitter had online drug sellers selling vaccines through these platforms. Importantly, beyond inherent risks of buying online, in a very disconcerting finding we found sellers claiming that these vaccines were over-the-counter drugs available for sale without prescriptions (Fig. 1). Such misleading advertisements may induce unknowledgeable persons, particularly patients, to purchase and self-administer without appropriate oversight.

Due to these troubling findings, we expanded our assessment to vaccines on the WHO Essential Medicines List (EML) [15], a list that defines medicines meeting priority healthcare needs for global populations, to determine if these, too, were accessible online (Table 2). Note that all FDA shortage vaccines are on the EML. We observed a similar pattern, with all vaccines advertised for purchase online, a large international presence of sellers, suspect links, and websites appearing on the NABP Not Recommended Sites list. Likewise, we also found that all of these vaccines were being advertised through suspect online drug sellers using Facebook and Twitter platforms. Of additional note, during the EML searches, we found one site—the only one in this study—indicating VIPPS accreditation. However a review of the VIPPS accreditation list shows no such accredited pharmacy.

3. Discussion

Vaccine shortages may lead some providers and patients to seek out alternative sources, including the Internet. Yet Internet purchasing is inherently dangerous with poor quality and/or counterfeit forms of various types of medicines that have injured and killed unsuspecting patients [6]. Unfortunately, these Internet risks

Table 2
World Health Organization Essential Medicines List of vaccines sold online.

Bacillus Calmette–Guérin vaccine
Cholera vaccine
DTaP/TDap ^a
Hepatitis A
Hepatitis B
Haemophilus influenzae type b vaccine
Influenza vaccine
Japanese encephalitis vaccine
Meningococcal meningitis vaccine
MMR [measles mumps rubella] ^b
Pertussis vaccine ^a
Pneumococcal vaccine
Poliomyelitis vaccine
Rabies vaccine
Rotavirus vaccine
Rubella vaccine
Tetanus vaccine ^a
Typhoid vaccine
Varicella vaccine
Yellow fever vaccine

^a DTaP is diphtheria, tetanus, and pertussis vaccines and TDaP is the booster. Diphtheria vaccine was searched using DTaP and TDap.

^b MMR is Measles, Mumps, and Rubella vaccine. Measles and mumps were searched using the measles, mumps, rubella vaccine term.

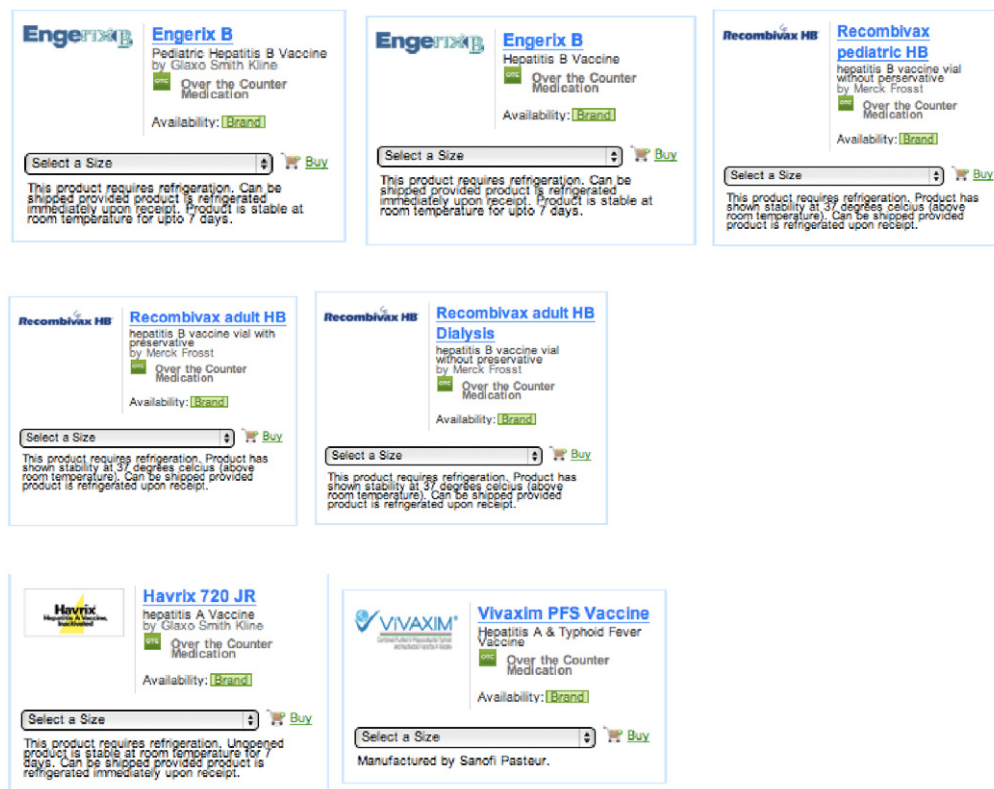


Fig. 1. Online drug seller advertising vaccines as over-the-counter drugs.

now include vaccines, globalized online. This creates tremendous patient safety concerns and potential inaccurate determinations of immune status.

Questionable sellers dominate Internet vaccine sales. First, the absence of any authorized VIPPS-accredited online pharmacy for shortage vaccines is a harbinger of poor quality and potential dangers of these predominantly international sellers. VIPPS accreditation is a rigorous accreditation system assessing and verifying licensure, facilities, and privacy rules recurrently. It is seen as the prime quality determinant for online drug sellers, and are the only ones recommended by FDA [16,17]. The absence of VIPPS-accredited pharmacies and findings that a majority were specifically “not recommended” by NAPB should place all stakeholders on alert that these sellers may or may not be legitimate, and/or the quality of their products may be questionable.

Second, the dominance of international pharmacies should also give one pause. FDA does not permit personal drug importation from international sites because of its lack of quality control and oversight over foreign materials [18]. Importing these drugs violates the Food, Drug, & Cosmetic Act [18]. Further, an argument for importation under an FDA “personal importation” exemption is inapplicable, since it generally requires the drug be commercially unavailable in the US and any approved importation requires medical supervision for use [17].

In addition, it is unlikely that these online drug sellers have proper knowledge and impetus to ensure proper cold chain storage for appropriate vaccine transportation to recipients [19]. From the patient’s perspective, drugs purchased from foreign sources are not eligible for Medicare reimbursement, and may lead to unnecessary patient expenditures [17].

Importantly, reifying the patient safety considerations are concerns online drug sellers have provided inaccurate, misleading

information with their marketing that could have tremendous patient safety impact. By selling drugs clearly needing a prescription, medical administration, and oversight as “over-the-counter” may mislead patients as to the relative use and safety of these products. Further, by advertising VIPPS-accreditation when they are not, suspect online drug sellers may mislead even more sophisticated buyers into believing these sites have been properly vetted.

Yet dangers posed by online vaccine sellers are not limited to the US. Indeed, the Internet provides illicit vendors access to anyone with Internet connectivity. With an estimated 1.7 million children under 5 currently dying worldwide from vaccine-preventable diseases due to low vaccination rates and economic disparities in developing countries, international global health initiatives, such as the Global Alliance for Vaccines and Immunizations, have responded by improving access and have enjoyed boosts in funding [20]. However, an influx of counterfeit products could deal a major setback to these efforts.

Further, issues with vaccine quality may rekindle debates as to the use of vaccines and potential harms. Parents experiencing clinically poor outcomes for their children and/or who are suspicious already of vaccine safety may point to poor outcomes from suspect vaccines being sold online as additional support against vaccination. Because of these domestic and global repercussions, all vaccine stakeholders should be fully aware of these online conditions.

Finally, to mitigate at least some of these effects, leading public health groups such as the US Centers for Disease Control and Prevention and WHO should lead educational efforts on vaccine safety, including procurement. Importantly, they may build upon VSN, which has extant “good information practices” for vaccine websites, to create robust accreditation systems like VIPPS for the

international vaccine community. Verification of VIPPS legitimacy and possible VSN accreditation of online vaccine sellers should be considered standard practice and a policy goal to ensure global patient safety in vaccine procurement.

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