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Criteria-based certification and validation of online pharmacies: Opportunities for improved quality and safety

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Abstract

Objectives: The objective of this study was to explore the conformity of online sites with established quality standards.

Methods: Online pharmacies with the NABP Verified Internet Pharmacy Practice Sites (VIPPS) designation were scrutinized for their conformity with select criteria established by the National Association of Board of Pharmacies (NABP) and FDA consumer guidelines.

Results: 36 VIPPS certified online pharmacy sites were included in the study. The sites were examined against VIPPS and FDA standards. The criteria related to the design and content of the web site and to the pharmaceutical services being offered through the site. Lack of clear terminological distinction between “online pharmacy” (a business) and “online site” (a tool for a business) was problematic. Sites did not adhere to uniform design principles. The scope and availability of pharmaceutical services for online consumers were not readily apparent.

Conclusion: The very legitimacy of existing criteria for online pharmacies remains to be established. Significant opportunities exist to improve the quality and scope of policies and to tie them more closely to longstanding best-practices in areas such as web usability and pharmaceutical care. Revision recommendations for VIPPS criteria are discussed.

Introduction

Technology-enabled services have become the bedrock of innovative healthcare and product delivery models. Decreasing cost of technology is allowing companies to satiate growing consumer appetite for convenient, just-in-time, and customized products. In this new era, the online marketplace for pharmaceutical care and pharmaceuticals has proven to be particularly vast, transnational, and ever expanding. As compared to the traditional brick-and-mortar shopping experience, the online marketplace offers consumers superior convenience, ability to comparison shop for prices, and anonymity.¹

Despite their monumental growth over the last two decades, however, online pharmacies remain sparsely regulated.² The lack of policies and mechanisms to ensure product quality and safety is especially troubling for pharmacies operating exclusively or largely via an online presence.^{3,4} Since their gain in popularity in the early 1990s, ensuring the legitimacy of such pharmacies has been a daunting task, thus hampering the fulfillment of a promise for innovative online service delivery and product procurement options.

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For consumers, ensuring the legitimacy of an online pharmacy is complicated primarily by resource limitations; limited health literacy and technological savvy preclude would-be users from discerning online pharmacies with safe products and services. Various agencies in the United States offer guidance to consumers in choosing online pharmacies and go so far as to certify vendors as being compliant with predetermined sets of criteria. Commercial services such as LegitScript and PharmacyChecker add further complexity to attempts at verification, a process that is yet to be uniformly defined and communicated to stakeholders.

While numerous criteria for online pharmacies have been proposed, no systematic attempt has been made to assess the validity of such standards. Furthermore, the impact of quality criteria on consumer decision-making remains to be established. In other words, the very legitimacy of the legitimacy criteria remains suspect at this time.

Objective

The objective of this study was to explore the conformity of online pharmacies with existing quality criteria. To establish best-of-breed practices, only online pharmacies on the National Association of Board of Pharmacies' (NABP) list of Verified Internet Pharmacy Practice Sites (VIPPS) were included in the study group.

Methods

Names and Uniform Resource Locators (URLs) of NABP-certified Internet pharmacies were obtained from the publicly available NABP database.⁵ As of December 23, 2014, the list included 46 sites operated by 39 registrants (ranging from 1 site to 5 sites per registrant). Attempts were made to access the sites on December 31, 2014 using Firefox browser, version 34.0.5. Member-only sites (n=9) and broken links (n=1) were eliminated from consideration, yielding a final sample size of 36.

Existing legitimacy considerations were compiled from NABP's Verified Internet Pharmacy Practice Sites (VIPPS) criteria and the FDA consumer guidance document for online pharmacies.^{6,7} We identified six criteria that consumers are urged to consider in choosing online pharmacies [Table 1].

Using said criteria, the first author created a codebook to standardize the examination of the sites and trained the second author on its use. The two researchers then tested out the codebook in exploring the first two pharmacies on the VIPPS list independently. Pursuant to a discussion of initial results, the codebook was modified for clarity. Where the codebook called for locating information on the site, we limited our attempts to navigating no more than 3 layers deep, inclusive of the entry page as linked from the VIPPS site.

For the initial review, the authors coded the Internet pharmacy sites (n=36) independently. The resulting codes were then compared and discussed with the goal of reaching consensus. Both authors took equal responsibility in the collection and analysis of data, and in preparation of the final manuscript.

The study protocol calls for use of no personal information or human participation and was deemed as exempt from IRB review.

Results

Both the VIPPS criteria and the FDA consumer guidance use the terms "online pharmacy" (i.e., a service entity) and "online site" (i.e., the web site for a service entity) rather interchangeably. Upon examination of the NABP-provided links to VIPPS certified sites, we found the term *online pharmacy* to refer to four types of *online sites*: 1) sites associated with exclusively Internet-based or mail order pharmacies; 2) sites associated with primarily store-based retail pharmacies, 3) sites associated with freestanding or independent pharmacies, and 4) sites with unclear associations [Table 2: Types of online sites].

Criteria related to web sites

Of the 36 VIPPS-accredited pharmacies included in our study, 26 sites (72%) displayed the VIPPS seal. No sites in our sample mentioned compliance with FDA consumer guidelines for online pharmacies. In the case of online sites associated with a brick-and-mortar entity (n=20; 56%), the NABP offered no direct URL link to the pharmacy portion of the operation; users need to go initially through the online site for the brick-and-mortar operation – typically a grocery store site – to locate the URL for the online pharmacy (see, for example, www.walmart.com). We did notice, however, a tendency for such corporate sites to drop browser cookies on the user computer which, upon subsequent visits, redirect the user to the last page visited. Depending on user navigation pattern, the last page visited may or may not have been one associated with the pharmacy department.

Privacy policies

Providing users with a privacy policy is among the VIPPS criteria for certification. We identified a small number of certified sites (n=3; 8%) that failed to meet this criterion. Additional policies displayed online included terms of use; patient bill of rights; return policy; web use; and medical information privacy. It was common for policy documents with similar titles to have dissimilar content and scope. For online sites associated with brick-and-mortar stores, the policies displayed were not uniformly tailored for pharmacy services or pharmaceutical products. For instance, one site for a retail pharmacy included return policies for perishable food items.

Accurate U.S. address

VIPPS criteria include that "the pharmacy must provide on the website an accurate U.S. address of the dispensing pharmacy or corporate headquarters." Similarly, FDA guidance to consumers is to seek sites that provide a physical address and telephone number in the United States. Online sites associated with multiple physical locations displayed addresses for all of their land-based operations. However, guidance for which location to choose in the event of a need to communicate via postal mail was not uniformly available.

Online sites associated with retail chains (n=13) tended to have a "store locator" feature. In such instances, it was not uniformly clear whether the consumer would be able to locate a pharmacy at said location or was being directed to a generic postal address for a retail store.

Web site transparency

VIPPS criteria state that "the pharmacy must not engage in practices or extend offers on its website that may deceive or defraud patients as to any material detail regarding the

pharmacy, pharmacy staff, prescription drugs, or financial transactions.” Our study did not focus extensively on this criterion due to the logistical impossibility of verifying and confirming claims based solely on information offered on the web sites. We did, however, make an attempt to verify claims where possible. We noted at least two occasions when a pharmacy web site appeared to be making a false claim. On one occasion, the pharmacy site referenced a national study to support the claim that customer satisfaction is highest among users of online pharmacies as compared to local and mail-order pharmacies. Upon review of the said study, we determined the opposite to be the conclusion of the authors, and that satisfaction is the lowest among online pharmacy users.⁸ On another occasion, an online pharmacy claimed to have been the first to have achieved the NABP Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) accreditation. Closer examination of the NABP DMEPOS database available online revealed a number of pharmacies with, indeed, earlier accreditation dates.⁹

Criteria related to patient services

The concept of “patient services” through online sites was ill-defined. The provision and scope of pharmaceutical services appeared to differ for consumers seeking such services exclusively online or at physical locations. For instance, one site claimed that information on the pharmacy website “is provided for informational purposes only and is not meant to substitute for advice provided by a licensed physician or other medical professional,” while another sites claimed that “any information supplied through the web site by any employee or agent of [company], whether by telephone, e-mail, letter, facsimile or other form of communication, is for educational purposes or general guidance, and does not constitute medical, legal, or professional advice.”

For chain pharmacies with online presence, it was not consistently clear whether the services displayed online could be procured directly from the online pharmacy. Based on the information provided, we could not discern whether listed services were merely informational in nature whereby their procurement would require the consumer to actually interact with a local, store-based pharmacist. Adding further to the lack of clarity around scope of service, only 13 pharmacies (36%) offered information on states they were licensed in or could ship to.

Online pharmacies tended to encourage consumers to seek direct consultation with a pharmacist rather than rely on static, generic information on their web sites. However, only a limited number (n=7; 19%) offered clear instructions for patient access to pharmacists or other qualified healthcare professionals. Where a telephone number or email address

was provided, it was not consistently clear whether the consumer would be connected to a customer service representative or to an actual healthcare provider.

All online pharmacies in the study group were found to offer educational materials. Rather than offering authentic information or resources, however, some online pharmacy sites redirected users to sites associated with other, non-NABP certified URLs (e.g., Mayo Clinic). We also noted instances of outdated information. For example, an online pharmacy site informed patients that “open enrollment for [the Affordable Care Act] begins October 1, 2013” – a date clearly in the past at the time of our study.

Discussion

Consumers are urged to exercise diligence in choosing online vendors of repute. However, the availability of validated and reliable criteria to guide consumer choices lags significantly behind the rate of proliferation of online pharmacies. Even sites that are certified by national accreditation bodies do not, on initial examination, uniformly make their legitimacy apparent to potential users. The criteria offered do not differentiate among “a pharmacy” versus “a web site for a pharmacy”. Furthermore, what little guidance does exist, it is not nuanced enough to acknowledge or accommodate potential differences among different types of pharmacy operations.

The term “online pharmacy” is difficult to define in practice. Whether an “online site” equates, by definition, to an “online pharmacy” is not clear. The ambiguities of definition beg the question; does the certification apply to the online site or a business with an online presence? As we attempted to apply the criteria to sites presumably already in compliance, we became aware of the uncertainty of whether the NABP list referred to “certified online pharmacies” or, perhaps more accurately, to “certified online presence for pharmacies.” There is a blurred line between Internet sites for exclusively Internet-based pharmacies (e.g., www.healthwarehouse.com) and Internet sites for traditionally mail-order or store-based pharmacies (e.g., www.cvs.com). Furthermore, some Internet pharmacies (e.g., www.allcarepharmacy.com) can be classified as either “specialty pharmacies with an online presence” or “mail-order pharmacies with an online presence”. While the distinction may be subtle, the failure to define an “online pharmacy” vis a vis an “online site” represents a significant hurdle to the consistent and meaningful application of criteria to ensure provider legitimacy.

The credibility and recognition of VIPPS certification among consumers remains to be established. There may be a need

for NABP to more widely educate patients and push for more aggressive name recognition. As a step toward such awareness, NABP should consider mandating VIPPS-certified sites to display the VIPPS logo. To ascertain currency of accreditation, certified pharmacies should disclose “last certified by VIPPS” and “certification expires by” dates. For the convenience of the user, NABP should provide links directly to the appropriate pharmacy page rather than to general entry portals for retail stores.

VIPPS certification is an optional, fee-based service of the National Association of Boards of Pharmacy. At the time of the writing of this article, fees for initial application ranged from \$5,000 for independent pharmacies to \$8,000 for chain and HMO-based pharmacies. This fee structure may be prohibitive for smaller operations to justify investing in this optional certification. It is our recommendation that VIPPS certification becomes a mandatory element for entities wishing to operate online. Mandatory certification would render the application fee a usual cost of operation across all pharmacies. Mandatory certification is also likely to improve the quality of online pharmacies in general. The increased volume may have the added benefit of lowering NABP’s cost of offering the certification service.

Poorly designed web sites weaken the credibility of the VIPPS accreditation designation (see, for instance, www.drugsdepot.com). VIPPS criteria should include guidelines for web site design with an eye toward accessibility, usability, and overall design quality. Incomplete sentences, typos or incomplete references detract from the legitimacy of online pharmacy sites. For instance, the claim on a pharmacy site that “[t]his includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of section 309” is not clear immediately as to what regulation is being referenced.

While it was not the aim of our study, we have noted distinct differences in quality of web site design between types of pharmacies; exclusively online pharmacies as a group have superior web sites with easier navigation, clarity of messaging, and ease of access to a pharmacist as compared to primarily land-based pharmacies that necessitate time-intensive searches on the part of the consumer to interact with the online pharmacy pages. In shaping their standards, NABP, FDA and other entities purporting authority for recommending quality standards are well advised to incorporate long-established industry standards such as the U.S Department of Health and Human Services web usability guidelines.¹⁰

Consistent with Bessell and colleagues’ finding that “e-pharmacies displaying [privacy statements, information disclaimers, and return policies] often placed all the risk and responsibilities with the consumer and little with the web site operator,” we found the status of medical advice on internet pharmacy sites to be questionable.¹¹ Where a pharmacy is linking to external sites for patient education materials, the company loses control over the quality, completeness, timeliness, and accuracy of the information. The average consumer may not have the ability to discern when a link is redirecting them to a 3rd party not affiliated with the certified online pharmacy. There is likely benefit to patient safety to modifying existing VIPPS criteria to include guidelines on the inclusion of external links on VIPPS-accredited Internet pharmacy sites.

We recommend that VIPPS criteria should include a stipulation for online pharmacies to designate a single mailing address for patients who are “non-tethered” to a physical location. Where online pharmacies are licensed to operate within limited geographic locations and where restrictions exist, pharmacies should disclose their scope of service so as to minimize patient inconvenience due to lost time. A single mailing address should be specified for those customers who use the online and mail-order services exclusively and/or may not have access to a local pharmacy.

Current VIPPS and FDA guidelines fail to address the use of social media on online pharmacy sites. Similarly, we did not encounter any guidance regarding access via mobile devices. Given the increasing ubiquity of mobile devices and their acceptance by consumers, future criteria should remedy this oversight.

Limitations

Neither NABP VIPPS criteria nor FDA guidelines mandate a uniform design for online pharmacy sites. When searching the sites for study-relevant information (e.g., list of pharmacy services, state license(s)), we aimed to replicate the consumer experience, and limited our navigation to only three levels deep. As such, it is possible that we may have failed to locate information that is, indeed, offered deeper within the web site. Rather than detract from the significance of our study, such potential omissions due to navigational choices should serve to underline the importance of uniform design criteria.

Conclusion

As more consumers are tempted to interact with online pharmacies, multiple entities offer criteria to guide would-be users toward choosing legitimate vendors. However, the very legitimacy of recommended criteria remains to be

established. Significant opportunities exist to improve the quality and scope of existing criteria and to tie them more closely to long-standing best-practices in areas such as web usability and pharmaceutical care. Future studies should focus also on the acceptance of criteria-based decision making among consumers as applied to choice of online pharmacies.

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Table 1: Select VIPPS patient Safety and pharmacy practice standards

Criteria for online pharmacies		Source
Web site	If the pharmacy web site transmits information that would be considered Protected Health Information (PHI) under the HIPAA Privacy Rule (45 CFR 164), the information must be transmitted in accordance with HIPAA requirements, including the use of Secure-Socket Layer or equivalent technology for the transmission of PHI, and the pharmacy must display its privacy policy that accords with the requirements of the HIPAA Privacy Rule.	VIPPS
	The pharmacy must not engage in practices or extend offers on its website that may deceive or defraud patients as to any material detail regarding the pharmacy, pharmacy staff, prescription drugs, or financial transactions.	VIPPS
	The online pharmacy should provide a physical address and telephone number in the United States	FDA; VIPPS
	The online pharmacy should be licensed through the consumer's state board of pharmacy	FDA
Patient services	The website should allow patients to contact or consult with a pharmacist regarding complaints or concerns or in the event of a possible adverse event involving their medication.	VIPPS
	The online pharmacy should have a licensed pharmacist to answer questions	FDA

Table 2: Types of online sites

Types of Online Sites	Examples
Associated with exclusively Internet-based or mail order pharmacies (n=12; 33%)	Healthwarehouse.com
Associated with primarily store-based retail pharmacies (n=13; 36%)	CVS Walmart Albertsons
Associated with freestanding / independent pharmacies (n=7; 19%)	Hometown Pharmacy, Inc.
Association not specified / unclear (n=4; 11%)	Foundation Care, LLC

Appendix
Verified Internet Pharmacy Practice Sites (VIPPS) (as of December 23, 2014)

Registrant	Web address
Allcare Specialty Pharmacy, LLC	www.allcarepharmacy.com
AmeriPharm, Inc dba MedVantx Pharmacy Services	www.medvantxrx.com
Arrow Pharmacy Holdings, LLC (Doing business as Arrow Pharmacy and Nutrition Center)	www.Familymeds.com
BI-LO Holdings, LLC	www.winndixie.com www.bi-lo.com
BioPlus Specialty Pharmacy Services	www.bioplusrx.com
Brawley Pharmacy, Inc (Doing business as Valley Medical Pharmacy)	www.drugsdepot.com
BriovaRx, LLC	www.briovarx.com
Curant, Inc	www.curanthealth.com
DrugSource, Inc	www.drugsourceinc.com
drugstore.com	www.drugstore.com
Foundation Care, LLC	www.foundcare.com
Giannotto's Specialty Pharmacy	www.giopharm.com
HealthPartners	www.HealthPartners.com
HealthWarehouse.com	www.healthwarehouse.com
HomeMed Pharmacy, LLC dba PlanTheFam	www.homemed.com www.planthefam.com
Hometown Pharmacy Inc	www.hometownpharmacy.com
HOOK SUPERX, Inc (Doing business as CVS/pharmacy)	www.cvs.com
Kmart Corporation	www.kmart.com www.mygofer.com
Liberty Medical Supply, Inc	www.libertymedical.com
Manifest Pharmacy, LLC	www.manifestrx.com
Meijer, Inc	www.meijer.com
New Albertson's Inc	www.acmemarkets.com www.Albertsons.com www.albertsonssavonpharmacies.com www.JewelOsco.com www.Shaws.com
North Coast Medical Supply (Doing business as Advanced Diabetes Supply)	www.northcoastmed.com
Pillpack, Inc	www.pillpack.com
Ridgeway Pharmacy, Ltd (Doing business as Ridgeway Mail Order)	www.ridgewayrx.com
Rx Outreach Inc	www.rxoutreach.org
Tel-Drug, Inc (Doing business as Cigna Home Delivery Pharmacy)	www.teldrug.com
Walgreen Co	www.walgreens.com