



11-15-2018

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Repository Citation

Kebodeaux, Clark D., "Prescription and Over-the-Counter Medication Record Integration: A Holistic Patient-Centered Approach" (2018). *Pharmacy Practice and Science Faculty Publications*. 40.
https://uknowledge.uky.edu/pps_facpub/40

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Notes/Citation Information

To be published in the *Journal of the American Pharmacists Association*, p. 1-5.

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Digital Object Identifier (DOI)

<https://doi.org/10.1016/j.japh.2018.10.002>

Contents lists available at [ScienceDirect](#)

Journal of the American Pharmacists Association

journal homepage: www.japha.org

COMMENTARY

Prescription and over-the-counter medication record integration: A holistic patient-centered approach

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ARTICLE INFO

Article history:

Received 1 April 2018

Accepted 3 October 2018

ABSTRACT

Objective: Nonprescription or over-the-counter (OTC) medications play a crucial role in a patient's ability to make choices to manage his or her own health care. Often these nonprescription choices are unknown to health care practitioners and thus are often not included as part of patients' health records. The exclusion of these therapies can pose risks to patient safety. There is a significant need to address the capture of OTC medication use in both the physician and pharmacy electronic health records (EHRs) and during the practitioner–patient medication history and reconciliation process.

Data sources: On October 26, 2016, the National Association of Chain Drug Stores Foundation hosted a forum for a select group of health care industry professionals to work on a series of recommendations to improve the documentation of OTC medication use by patients. This diverse group of more than a dozen stakeholders included community pharmacy leaders from multiple chain pharmacies, pharmacy system vendors, e-prescribing vendors, health information technology experts, and multiple industry representatives, including individuals from the public sector. This commentary is a summary of the insights and suggestions where the group was in general agreement.

Summary: Successful OTC medication EHR integration will require system-level buy-in across multiple layers of the health care industry to improve patient safety. Forum participants suggested incremental steps that could be taken by multiple stakeholders to lay the foundation for integration within an appropriate regulatory structure.

Conclusion: Based on the results of the stakeholder forum, an agreement formed around one approach that the group supported as feasible: the creation of a consistent and uniform identification method for OTC medications in cooperation with government regulatory authorities.

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The purpose of this commentary is to provide a summary of insights and suggestions by key community pharmacy industry stakeholders (Table 1) who were asked to evaluate the technological capability and opportunities to incorporate over-the-counter (OTC) medications into comprehensive electronic health records (EHRs).

Goals of the forum

The stated goals of the forum were: (1) to provide an environmental assessment of opportunities where OTC medication information can be collected beginning with point of sale; (2) to explain the role of technology in instances where OTC medications are documented or omitted in the normal process of care, including at the pharmacy; (3) to discuss the feasibility of OTC medications being included in the EHR through interoperability between physician and pharmacy record systems; and (4) to provide system-level recommendations to begin collaboratively incorporating OTC medications into EHRs.

For the purposes of this commentary, EHRs, as defined by the Centers for Medicare and Medicaid Services, are an electronic version of a patient's medical history that are maintained by the provider over time and can include all the

Disclosure: The authors declare no conflicts of interest or financial interests in any product or service mentioned in this article.

Funding: Funding for this project was provided by the NACDS Foundation.

Previous presentation: Presented previously at the American Association of Colleges of Pharmacy Annual Meeting, Nashville, Tennessee, July 16, 2017.

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<https://doi.org/10.1016/j.japh.2018.10.002>

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Key Points**Background:**

- The purpose of this commentary is to provide a summary of insights and suggestions by key community pharmacy industry stakeholders who were asked to evaluate the technological capability and opportunities to incorporate over-the-counter (OTC) medications into comprehensive electronic health records (EHRs).

Findings:

- There were 3 key points of agreement that shaped the recommendations:
- General Agreement, Point 1: Effective documentation systems for OTC medications in EHRs may help to provide patients and providers with the necessary information to increase appropriate OTC use.
- General Agreement, Point 2: System-level buy-in across multiple layers of the health care industry will be required for successful OTC-EHR integration.
- General Agreement, Point 3: Incremental steps by multiple stakeholders should be taken to lay the foundation for OTC-EHR integration, provided it is within an appropriate regulatory structure.

key administrative clinical data relevant to that person's care under a particular provider.¹ Currently, community pharmacy dispensing systems often do not collect OTC information, nor do they communicate with physician office EHRs.

Overview of nonprescription drug use

OTC medications play a crucial role in our nation's health care system by increasing access to effective medications and empowering individuals to make health care choices for themselves and their families. A recent consumer survey found that 89% of consumers value OTC medications as part of their health care and 81% of U.S. adults use OTC medicines as a first response to minor ailments.² Furthermore, in a survey of more than 500 health care practitioners, 89% of pediatricians surveyed either recommended or had no reservations recommending OTC medications to their patients.³

Enhanced access to these medications empowers patients to take an active role in their health and improves the health care system overall. Taken correctly, OTC medications are safe, affordable, and effective.

Patient safety and gaps in care

Although OTC medications improve the health of millions of patients, risks due to inappropriate use can pose a substantial risk to patient safety, including complications from drug–drug interactions, accidental drug duplication, and unforeseen drug–disease complications. The high prevalence of OTC medication use means that these risks are not insignificant. For example, in a survey of patients with heart failure, 88% reported

OTC medication use.⁴ The OTC medications used included nonsteroidal anti-inflammatory drugs (NSAIDs), proton pump inhibitors, antacids, and decongestants. NSAIDs, in particular, could have serious implications in patients with heart failure.

The risk of OTC medication interactions owing to lack of documentation has been confirmed in multiple studies. In a retrospective analysis of electronic patient health records in Dutch community pharmacies, 44% did not accurately include OTC medications.⁵ In another study, 60% of surveyed patients were unaware of the risks associated with NSAID use, and 30% thought that OTC medicines were safer because they were available without a prescription.⁶ Lastly, in a retrospective EHR chart review at a primary care center, pharmacists identified that nearly 75% of EHR entries had at least 1 discrepancy, and the omission of OTC medication use was the most common.⁷ Improved OTC documentation could reduce discrepancies to affect patient care positively.

How prescription documentation differs from OTC

There are major differences in the way that EHRs document prescription medications compared with OTC medications. Currently, it is easier to capture prescription medication use in EHRs because of electronic prescribing and the extensive insurance payment systems that exist to document and pay for prescription medications. Pharmacy benefit managers, e-prescribing systems, and pharmacy dispensing software must tightly function to adequately complete the prescription drug dispensing process. By contrast, most OTC medication transactions occur at a retail location, often outside the pharmacy, where a consumer does not use his or her health insurance but pays out of pocket. Few, if any, systems are in place to capture this OTC transaction information. Thus, OTC medication safety alerts and other prescribing information are not as readily accessible to prescribers and patients as their prescribed counterparts.

Because of these current challenges in documenting OTC medications, most of them are simply input into EHRs by providers as free-form text entries when conducting a medication history or medication reconciliation with the patient. This type of documentation can inhibit the accurate and efficient communication of OTC medication use across EHRs in the future, leading to potential exclusion from the alert screening process. Furthermore, lack of health information technology interoperability between disparate data systems limits exchange of data. EHR interoperability is a subject beyond the scope of the forum discussion. However, efforts led by the Office of the National Coordinator (ONC) will play a key role in any future documentation and communication of OTC medications, including the Pharmacist eCare Plan. Specific features related to the documentation of OTC medications within the IT construct were considered to help facilitate inclusion and implementation of health information technology interoperability efforts in the future.

Existing identifiers: NDCs, UPCs, and SKUs

Forum stakeholders noted that OTC medications each contain a National Drug Code (NDC), which is required for registration with the U.S. Food and Drug Administration. Participants suggested that the use of NDCs might offer the best short-term solution for the identification of specific OTC

Table 1
Stakeholder information

Participants
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<ul style="list-style-type: none"> • Rebecca Chater, BSPHarm, MPH, FAPhA, Ateb, Executive Healthcare Strategist • Tammy Devine, MBA, QS/1, President • Ajit Dhavle, PharmD, MBA, Surescripts, VP of Clinical Quality • Justin Heiser, PharmD, Thrifty White Pharmacy, SVP, Pharmacy Operations
<ul style="list-style-type: none"> • Jill Helm, PharmD, AllScripts Healthcare Solutions, Inc., VP, Business Development for Payer Life Sciences • Jeff Key, MCS, PioneerRx, President • Tammy Royer, BSPHarm, Rite Aid Corporation, SVP of Pharmacy Operations • Dan Snodgrass, BSPHarm, The Procter & Gamble Company, Senior Manager Strategy/Planning
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Acknowledgment of Contribution to the Stakeholder Forum
<ul style="list-style-type: none"> • Trygve Anderson, Elsevier, Clinical Executive • Thomas R. Bizzaro, First Databank Inc., VP, Health Policy and Industry Relations • Kim C. Coley, PharmD, FCCP, University of Pittsburgh School of Pharmacy, Professor of Pharmacy and Therapeutics • Melissa Somma McGivney, PharmD, FCCP, FAPhA, University of Pittsburgh School of Pharmacy, Associate Dean for Community Partnerships, Associate Professor • Patricia Milazzo, Walters Kluwer, Senior Director, Content

medication products because of the prevalence of NDCs within the existing regulatory structure.

Stakeholders noted that alternative solutions for identification of OTC medications outside the NDCs are currently being created in the private sector but shared that a lack of consistency in labeling and drug information for OTC medications poses a significant impediment to their widespread EHR adoption.

For example, unique product codes (UPCs) have a similar number, which is assigned by the product manufacturer. In some cases, the UPC is the NDC code with a 1 or 0 attached. However, UPCs are not required to have the same component consistency as an NDC code.

OTC medication products also contain an identification code at each business for price scanning and inventory purposes, commonly known as a stock keeping unit (SKU). However, SKU purchase history and data are not currently tied to any clinical data system, even within pharmacies.

Other technology-facilitated programs considered by Forum participants:

- **Loyalty Programs:** Loyalty programs are commonly used by retailers in marketing to offer deals and targeted advertising. A customer's shopping history could provide retail-specific data on OTC purchases. However, stakeholders noted that businesses might not be inclined to adapt their existing programs to embrace the inclusion of EHR integration. In addition, many loyalty programs are household-, not individual-based, making them less than ideal for identifying patient-specific OTC medication use.
- **Health Savings Accounts:** Some employer-sponsored insurance plans offer federal Health Savings Accounts,

allowing employees to use before tax dollars to pay for health care products not reimbursed by insurance, including OTC medications. This could serve some purposes of data collection. However, this option would be limited because Health Savings Accounts are only available to those covered by employer-sponsored health insurance.

- **Pharmacy Dispensing Software:** Commercially available pharmacy dispensing software can capture and record OTC medication use. However, most information is limited to data reported by the patient verbally during potential consultations or discussions between patient and pharmacist—a mere fraction of overall OTC use.

Challenges

Forum stakeholders agreed that for effective and accurate documentation within an EHR, the following overarching challenges must be addressed:

- **Many Retailers:** One of the top challenges was the availability of OTC medications through a vast array of retail outlets. In addition to pharmacies, supermarkets, wholesale clubs, and online merchants, OTC medications are available in places such as gas stations, convenience stores, hotel gift shops, airport newspaper stands, and many others. There are an estimated 750,000 total retail locations in the United States.⁸ While convenient, this poses a major challenge to EHR integration.
- **Purchaser versus End User:** Purchasers are not necessarily end users. Purchase history of OTC drug products alone does not necessarily describe individual OTC medication use. In many cases, consumers can purchase medications for someone within their family or can share their medicines with another individual not in their home, such as a neighbor, friend, or co-worker.
- **Privacy:** Effectively capturing OTC medication data with the consumer's active consent may require the health care system to meet privacy expectations like those in place for prescription medications. Stakeholders reinforced the importance of consumer trust to adequately address privacy concerns.

While these challenges are mostly logistical, the stakeholders of the conference offered a first-step consideration to begin addressing a few specific disease states, such as diabetes or cardiovascular disease where risks to patient safety are greater than for others. Selectively targeting specific medical conditions along with OTC medicines that contain warnings related to use in individuals with that same medical condition was considered a reasonable first step.

Patient–provider interaction

The current primary documentation of OTC medication use in the EHR still occurs as part of a one-on-one interaction with a health care provider. Often, when patients are asked about their medication use, they will defer to listing their prescription medications and possibly daily OTC medications. Yet, consumers use OTC medications far more frequently than they interact with their physicians. On average, consumers make 26

Table 2
Logic model: Progression concept for prescription and over-the-counter medical record integration

Strategy and activities	Short-term outcomes	Intermediate outcomes	Long-term outcomes
Selectively targeting specific medical conditions along with OTC medicines that contain warnings related to use of the OTC medicine in individuals with that same medical condition. An example of this would be CV disease and NSAIDs that have CV-related warnings.	Increased industry awareness of Rx/OTC EHR integration approach and strategy for achieving it	Increased number of private industry collaborators	Increased patient safety/ decreased incidence of preventable adverse drug reactions
Engage manufacturers and FDA regarding the creation of a uniform identification system.			Increased opportunities to engage patients and providers through technology
Create an industry and regulatory collaboration to enhance reporting of OTC medication-specific information.	Increased public–private collaboration	Increased testing and use of patient-driven innovations for EHR integration (including the Pharmacist eCare Plan)	
Anticipate patient-driven technologies by building adaptability into the data collection design.			

Abbreviations used: OCT, over-the-counter; CV, cardiovascular; NSAID, nonsteroidal anti-inflammatory drug; Rx, prescription; EHR, electronic health records; FDA, U.S. Food and Drug Administration.

trips to purchase OTC medications over a 12-month period compared with 3 visits to their physician over the same time span.⁸ This fact alone lends perspective to the challenge of OTC integration into EHRs.

Studies have shown that one method of improving medication record accuracy is to provide patients online access to their data before medical visits.⁹ However, stakeholders confirmed that inherent barriers exist when applying that same approach to reporting OTC medication use.

Patient-driven solutions

Software systems known as *applications* or *apps* can collect, document, and provide resources directly to a patient's laptop or mobile device, potentially enhancing patient understanding and documentation of OTC medications. Current technology, including scanning for QR codes or barcodes, could link to an NDC and specific medication information for each OTC medication. However, the creation and widespread use of such technology are in the early stages of development and adoption.

Furthermore, stakeholders identified the need for patients to be incentivized to report OTC medication use. To date, the usefulness of patient-driven electronic personal health records has been met with mixed results. One promising app was ultimately discontinued because of the inability to reach consumers effectively. Major contributing factors included lack of patient education, promoting patient usefulness, and encouraging trust from the user.¹⁰

Increasing patient awareness and education was considered outside the scope of the Forum discussion, but stakeholders agreed that any efforts to create a consistent uniform code for identification should take these considerations into account.

Payer-driven solutions

One way that changes in health care provision can be driven is by implementation of new, quality metrics. A performance measure around OTC documentation in the EHR

could incentivize providers to improve collection of OTC utilization during patient encounters.

Conclusion

The integration of OTC medications into patients' EHRs is a complex issue that has the potential to affect patient care positively and to improve outcomes. Table 2 represents stakeholders' recommendations to work toward OTC medication EHR integration:

1. Create a consistent, uniform identification method for OTC medications.
 - Target a narrow set of high-priority health conditions and related OTC medications as a starting place for uniform identification.
 - Enlist the participation of OTC manufacturers, the U.S. Food and Drug Administration, and appropriate government entities regarding the creation and consistent execution of a uniform identification system.
 - Create a public–private collaboration to enhance reporting of OTC medication specific information.
2. Anticipate the potential for future patient engagement through patient-driven technologies, such as apps, by building adaptability into data collection design.

A focus on standardized integration of OTC information for new and changing products could potentially increase the appropriate choice and use of OTC products for some individuals, allowing the basis by which they can be integrated into pharmacists' patient care process and team-based care. Lastly, payers can create value for patients, providers, and system vendors by aligning payments with developed quality measures and incentivizing documentation of OTC medications in EHR systems.

Acknowledgments

The authors thanks Kathleen Jaeger, Kathleen Wolff, and Jason Ausili, PharmD, for editorial support.

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