Title

Implementation of patient-centered prescription labeling in a safety-net ambulatory care network.

Journal

American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists, 75(16)

ISSN

1079-2082

Authors

Khoong, Elaine C
Cherian, Roy
Smith, David E
et al.

Publication Date

2018-08-01

DOI

10.2146/ajhp170821

Peer reviewed

Title:

A Case Study in Implementation of a Patient-Centered Prescription Label in a Safety Net Ambulatory Network

Abstract

Purpose: Medication nonadherence negatively impacts patient outcomes and safety. Nonadherence has been attributed to poor understanding of medication label instructions. Research demonstrates that a patient-centered medication label (PCL) can improve adherence and produce safer medication-taking practices. We are not aware of any health system that has pursued widespread adoption of PCL. Our study aimed to describe the factors that impacted PCL adoption at four health-system-run pharmacies within a single publicly-funded safety net healthcare system.

Summary: We used mixed-methods (audit of nearly 9,000 prescription labels and six informant interviews) to determine the rate of PCL-adoption and factors that impacted success. Descriptive statistics were used to analyze data from prescription label audits and the Consolidated Framework for Implementation Research to analyze interview data. Among the four sites, there were differences in the electronic prescribing platform and number of prescribers. Three pharmacies successfully converted >85% of audited prescriptions to PCL-language; one pharmacy converted <25% of prescriptions. Barriers to implementation included pharmacists' reluctance to modify prescriber instructions and inadequate real-time data on conversation rates. Interviewees perceived that leadership and policy directives promoted PCL conversion efforts. Successful pharmacies used adaptable software, had closer communication networks with prescribers, and/or automated PCL conversion.

Conclusions: Local factors affect innovation implementation. We observed greater success in settings where software could be customized, suggesting that flexible health information technology supports adoption of evidence-based practices. Collaborative practice between prescribers and pharmacists also fostered success. Implementation strategies that relied on repeated individual user actions, rather than automation, were less likely to be successful.

Introduction

Medication adherence and safety

Medication adherence for chronic diseases is ~50%.[1] Nonadherence is associated with worse patient outcomes and increased healthcare costs.[2–4] Studies have documented that complicated medication regimens, low literacy, and language-related barriers contribute to nonadherence and compromise patient safety.[5] Improved medication instruction comprehension can improve adherence and safe medication-taking practices.[6–11]

Patient-centered medication labels

To this end, the Universal Medication Schedule (UMS) utilizes standardized, patient-centered language for medication instructions. To promote recall and adherence, these plain-language instructions are anchored to four time periods: morning, noon, evening, or bedtime. (Appendix 1: Patient-centered label vs standard medication label.)[12] Standard medication labels have several possible instructions for medications that can be taken twice daily: take 1 tablet two times daily or take 1 tablet every 12 hours. Patient-centered labeling that uses the UMS provide only one option: take 1 tablet in the morning and take 1 tablet in the evening. Similarly, for medications that can be taken three times a day, providers may ask patients to take 1 tablet three times a day, every eight hours, or with each meal. UMS-based instructions make explicit to patients that they should take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening.

Studies comparing patient-centered prescription drug labels (PCL) with UMS language to standard labels show its efficacy in improving patient understanding, ability to consolidate medication regimens, and medication adherence, particularly for patients with low literacy, limited English proficiency, and complicated medication regimens (medications taken two or more times daily).[6,12,13] Consequently, the California Board of Pharmacy issued a recommendation advocating for a PCL.[14]

Based on this, the San Francisco Health Network (SFHN) decided to pursue widespread adoption of PCL. Although we first attempted implementation by modifying *prescribing* behaviors, due to implementation barriers discussed below, we shifted to *dispensing* medications with PCL at the four SFHN pharmacy sites. This effort builds on studies that attempted medication dispensing with PCL at retail pharmacies.[15] In this study, we used the Consolidated Framework for Implementation Research (CFIR) to identify factors that facilitated and impeded dispensing with PCL in the SFHN and to identify broader lessons for optimizing implementation of patient-centered innovations, particularly in safety net systems.

Methods

Aim: This mixed-methods study used an audit of prescription labels and six key informant interviews to determine the success of PCL implementation and factors that influenced success.

Setting: This study occurred in a city-and-county-funded, publicly-run integrated safety net health system (SFHN) that cares for publicly-insured and uninsured patients; the population is

low-income and racially/ethnically diverse, with a high prevalence of chronic illness, low health literacy and limited English proficiency.[16] SFHN has four ambulatory pharmacies serving distinct populations: jail health (JH), behavioral health (BH), skilled nursing and long-term care facility (LTC), and an outpatient pharmacy (OP). Although all prescribing is electronic, SFHN relies on multiple electronic health records (EHRs) across different settings. Each pharmacy has its own director, who reports to a chief of all ambulatory pharmacies in the San Francisco Department of Public Health (SFDPH).

Implementation strategies: Initial efforts to encourage PCL adoption focused on changing medication instructions in the prescriber EHR interface by making patient-centered wording the default option when prescribing medications. Prescribing-centered adoption of PCL was stymied at multiple levels. First, the EHR vendor failed to enact the requested change at a system level. Subsequently, local EHR staff attempted to customize the prescribing options to facilitate patient-centered prescribing. This local work-around resulted in prescribing errors related to constrained data entry field sizes, and consequently was halted because of medication safety concerns. Given these barriers, SFHN leadership decided to shift the project's focus from prescribing with patient-centered language to dispensing medications with PCL. We attempted to engage the most frequently used commercial pharmacy in our system in this effort but were unsuccessful. As a result, implementation efforts were limited to dispensing medications with PCL at the four SFHN-run pharmacies.

After both the California Board of Pharmacy and SFDPH leaders prioritized PCL, local leaders at each of the four sites worked with SFHN leadership to implement PCL. Each SFHN-run

pharmacy used various strategies to ensure conversion of standard instructions to UMS-language and encourage consistent medication dispensing with PCL. These are outlined in Table 1 and organized by CFIR construct.

After the initial planning process, most sites engaged stakeholders (prescribers, pharmacists, and pharmacy technicians) in the conversion process through education sessions and acquisition of prescriber approval prior to initiating any medication label changes. During the engagement process, in an effort to address concerns, two sites (LTC and OP) developed policies in their pharmacy policy committee that resulted in the exclusion of medications (e.g. injectable medications, medications that the prescribers indicated needed to be taken at specific times) from conversion to a patient-centered label. Each pharmacy then attempted to convert only medications determined to be "UMS-eligible" by their policy committee to PCL. Although no formal policy was created, BH pharmacy leaders also decided that prescriptions with customized sigs should be excluded from analysis.

After engagement, each site began execution of their strategy to encourage UMS implementation. Execution efforts varied widely among the four sites. Some attempted automated approaches dependent on health technology adaptations (JH and BH) while others used strategies dependent on individual action (OP).

Data collection and analysis: Investigators obtained human subjects approval from our institution's Committee on Human Research to conduct this study.

Each site provided data on the characteristics (personnel, number of medications dispensed, number of prescriptions processed, and pharmacy software) of their site. Pharmacy software characterization was determined based on publicly available data. Prescription auditing processes varied at each site. (Table 2) Overall, nearly 9,000 prescription labels were audited.

We conducted semi-structured interviews from November 2015 to January 2016 with six key informants: pharmacy directors from all sites and the chief of ambulatory pharmacies. One interview (BH) also included a pharmacist lead for implementing PCL. All informants provided informed consent. The study team used CFIR and its five main domains (intervention characteristics, outer setting, inner setting, individual, and process) to scaffold the interview questions.[17] Each interview lasted 30-60 minutes; four interviews were audio-recorded and transcribed. The policies at one site (JH) proscribed audio-recording, so the interviewer used extensive written notes.

After transcription, we analyzed interviews with qualitative data coding software (Dedoose, Los Angeles, USA). Two authors (ECK, RC) created codes based on the CFIR framework, separately coded all transcripts, and discussed coding differences to reach consensus. We chose CFIR because of its implementation focus and use in other studies in the safety net.[18,19] We also created project-specific constructs based on an inductive approach.[20] A finalized codebook is available as Appendix 2.

Results

Implementation Site Characteristics

Pharmacies varied in size and complexity (Table 3). JH processed the fewest prescriptions and had the fewest prescribers and pharmacy staff. OP had the largest number of prescribers and prescriptions processed each day. Both BH and JH used software systems that had fewer clients/users. At BH, JH, and LTC prescribers and pharmacy staff were co-located allowing for occasional informal interactions.

PCL implementation rates

BH, JH, LTC successfully implemented the UMS for >85% of eligible medications. Only OP had a persistently low rate of patient-centered prescription labels (Table 4).

Barriers and facilitators to PCL implementation

Interviews revealed facilitators and barriers to implementation of PCL within all CFIR domains (Table 5). There were variations in these factors across sites as well as some common to all sites.

Variations across sites

In three key areas, pharmacies with high rates of UMS-implementation differed from the less successful pharmacy.

First, adaptable software systems (an outer setting construct) enabled sites (JH, BH) to adopt PCL by quickly automating printing of medication labels with patient-centered language. More established software systems were less adaptable thereby inhibiting software facilitated automation of PCL implementation.

Sites (JH, LTC) with a circumscribed patient populations and closer communication between prescribers and pharmacists (inner setting characteristics) achieved more success. Complex sites (such as OP) with more prescribers, medications, and personnel involved in the prescription lifecycle (medication prescribing, prescription processing, label printing, and medication dispensing) were less successful.

Lastly, sites that automated the conversion process had the most success, regardless of where in the prescription processing workflow the automation occurred. Often this automation resulted from software adaptability (JH and BH). The PCL adoption effort at LTC coincided with already prioritized efforts to move to electronic prescribing, allowing all existing prescriptions to be manually entered into the EHR using the UMS language.

Barriers across all sites

One barrier related to the intervention itself was that evidence supporting PCL exists only for scheduled, ongoing oral medications; therefore pharmacists expressed concerns about extending UMS language to all medications (e.g. non-oral medications). UMS wording also often did not fit on prescription labels, especially given competing requirements from the Board of Pharmacy

regarding larger label font size. Since pharmacists felt that the Board of Pharmacy was more aggressively monitoring font size requirements, UMS-wording changes were considered lower priority changes.

Individual barriers such as pharmacists' personal experiences and beliefs about professional responsibilities impacted their attitudes towards PCL. Due to concerns about patient safety and liability, pharmacists expressed reluctance to change the wording of the prescriber's prescription despite clinician leaders endorsing PCL.

All sites had difficulty collecting real-time data to evaluate PCL adoption rates; without this, implementers were unable to conduct continuous quality improvement. Periodic assessments were performed only every six to nine months thereby slowing improvement efforts.

Facilitators across all sites

All pharmacists agreed that external factors such as the California Board of Pharmacy regulations and SFHN leadership's commitment facilitated PCL adoption. Creation of a local, internal policy that formalized prescriber consent of automatic conversion to UMS language was a crucial early step to support conversion without fear of negative repurcussions. Early engagement of stakeholders (prescribers, pharmacists, pharmacy technicians) also increased success.

Discussion

Implementation of a patient-centered label was a key focus within SFHN because our patient population has a high prevalence of communication barriers.[21] In low literacy populations, providers are less effective in enacting crucial elements of patient-centered care such as shared decision-making; we had also hoped that this patient-centered intervention would help address health disparities disproportionately experienced by our safety net patient population.[22,23] As an integrated heath system, we hoped that the leadership's commitment would translate into consistent implementation of PCL and therefore increased opportunities for patient-centered care. However, we found that challenges from unresponsive health technology vendors and perspectives on professional boundaries led to mixed success.

Implications for increased adoption of patient-centered drug labels

Competing requirements for a medication label's real estate impeded UMS adoption. The simultaneous increased font size requirement from the California Board of Pharmacy made it difficult to fit all the UMS-recommended language onto prescription labels. Since the Board of Pharmacy audited pharmacies for font size, that requirement took precedence and posed a barrier until pharmacists modified the UMS-language while maintaining its core value. For example whereas twice daily medications in strict UMS-wording would read, "Take 1 tablet by mouth in the morning and 1 tablet in the evening," pharmacies instead used "Take 1 tablet by mouth in the morning and evening." This mirrors implementation studies that have demonstrated the need for intervention flexibility, categorized as "adaptable periphery" using CFIR terminology, while maintaining the "core components" of the intervention.[24] Furthermore, while the initiative to

increase font size is also patient-centered, the tension between these two initatives demonstrate the importance for patient-centered efforts to be coordinated.

EHR limitations forced SFHN to shift focus from prescribing interventions to dispensing interventions. Prescriber-driven implementation would have mitigated pharmacists' concerns about professional roles. Despite interest in PCL, prescribers faced significant obstacles: workflows, large patient panels, and inability to automate UMS-concordant language during the electronic prescribing process. This finding supports studies that suggest providers' desires to innovate and provide patient-centered care is not enough; instead, health systems must also have infrastructure explicitly designed to support innovation and patient-centered care.[25,26]

Lastly, pharmacists were uncomfortable "owning" the PCL implementation effort and felt providers should prescribe in patient-centered language to ensure consistency between providers' verbal instructions and the medication label. Our pharmacists echoed previously described concerns regarding the liability of changing a transmitted prescription.[27,28] This underscores the need for bi-directional communication with all stakeholders to avoid resistance. We attempted to address these concerns through physician champion support and by securing pharmacy committee approval of PCL adoption before targeting front-line staff behavior change. Future PCL implementation efforts using dispensing-based strategies must address pharmacists' concerns of compromising patient safety and job security when translating prescribed instructions to PCL.

Implications for adopters of evidence-based, patient-centered innovations

Pharmacists cited that the California Board of Pharmacy regulations and priorities of SFHN leaders were key factors encouraging implementation. Prior research has shown that leadership support and policy changes substantially encourage behavior change.[29,30] Despite these facilitators, there was still variation in the extent of PCL adoption, suggesting that although necessary, strong leadership and supportive policies are not sufficient for success in adoption patient-centered innovations.

The impact of software adaptability, or lack thereof, was significant. SFHN pursued PCL dispensing strategies because the initial prescribing attempt was thwarted by the EHR vendor's unresponsiveness. Once the decision was made to pursue dispensing-based strategies, two sites (BH, JH) experienced nearly immediate success by directly modify the dispensing software. Dynamic infrastructure (including software) that responds to a changing environment is an important facilitator for innovation. Organizations must consider adaptability prior to entering long-term relationships with vendors and during contract renewals, especially for clinical software. Healthcare leaders have voiced concern regarding the undue influence of health technology impeding innovation as well as the need to be wary of assuming that technology will lead to more patient-centered care.[26,31] As a possible countermeasure, healthcare systems should consider consolidating purchasing power by utilizing group-purchasing organizations to pressure vendors to provide customizable software that keeps patients (not billing) at the center of functionality.

Sites with smaller networks of personnel and tighter communication had greater success. Smaller networks made it easier to develop internal policies since high-level decision-making was consolidated among fewer individuals. Implementation frameworks acknowledge the importance of the size and proximity of communication networks for adoption of innovation and provision of patient-centered care.[17,32–34] Collaborative relationships between prescribers and pharmacists are particularly crucial for patient safety and patient-centered care.[35] Therefore, as many organizations move towards team-based care model for improved patient-centered care, they should foster frequent communication among all providers.[34,36]

In our study, strategies that involved automation rather than daily vigilance resulted in greater adoption of PCL. At BH and JH, prescriptions were automatically converted to PCL with a software modification. At LTC, during the systemic conversion from a paper to electronic medical record, all prescriptions were entered into the prescriber's EHR using patient-centered language; therefore future refills also maintained the patient-centered language. In contrast, the implementation strategy ultimately employed at OP, after the failed prescriber pilot, asked technicians to manually retype newly received prescriptions using UMS language prior to printing labels. This strategy required continuous individual effort and resulted in lower implementation rates. This disparity demonstrates the importance of "default options," a behavioral economics concept that states when a desired behavior is made the default (rather than active) choice, the desired behavior is more likely to occur.[37] Implementers must maximize default options when seeking behavior change.

Although BH, JH, and LTC were the three sites with the greatest PCL-adoption rates because they had adaptable software, smaller communication networks, and/or automated processes for PCL-implementation, these sites are not where patients would have most benefited from PCL. Patient-centered labels are thought to be most impactful due to increased awareness and comprehension by the patient or caregivers who directly manage their own medications, which is not the case in BH, JH, and LTC. BH uses bubble packs, a method of packaging where pills are packaged in cells based on the time of day to be taken. (An example bubble pack might have 14 bubbles – two bubbles for each day of the week, with pills placed in a morning bubble and a separate nighttime bubble for each day.) This approach is akin to physically sorting pills in a manner that UMS spells out in language. Similarly, JH and LTC already have controlled medication administration; few patients are responsible for their own adherence. Of note, when patients are discharged from JH and LTC, their discharge medication supply retained the UMS-language on its labels. Since the LTC utilizes the same EHR as most of the OP clinics, patients who transition from LTC to OP clinics retained their medication instructions in UMS-language. In contrast, the OP clinic, where most patients are responsible for their own medication administration and where PCL could be most impactful, had the least success.

This discordance between where implementation is likely to succeed and where it could be most impactful illustrates both the great promise and great flaw of new interventions. Patient-centered care has been held as a potentially critical solution to addressing disparities in care and outcomes.[26] However, when patient-centered efforts rely on health technology that is unevenly adopted across various systems (and in fact are often more quickly adopted by privileged patients and healthcare systems) this may increase health disparities instead.[38–40] This underscores the

need for research on patient-centered interventions to include diverse, vulnerable patients. New interventions and strategies to improve quality of care may simply not be equally effective in all patient populations.

Strengths and limitations

Although this was a study in a single integrated healthcare system, it has strengths due to the diversity of patient population, prescribers, and dispensing sites. SFHN is a safety net system that serves 100,000+ patients with low socioeconomic status and limited English proficiency, as well as incarcerated individuals, patients with severe mental illness, and long-term care residents. These populations, and the systems that disproportionately care for them, are under-represented in research studies. We only included a limited number of leaders as key informants; front-line pharmacist, prescriber, and patient views will be explored in future studies. As a result of the barriers encountered with implementing EHR-based strategies for UMS prescribing, this study focused primarily on pharmacy-based strategies to implement PCL. Another limitation is the variability in how prescription labels were audited.

Conclusion

Despite significant barriers, SFHN achieved dramatic improvements in the rates of patient-centered prescription labels in three of four pharmacies. Adaptable software, tight communication networks, and automated workflows for adopting PCL increased the likelihood of PCL implementation success. Based on these findings, there are implications for healthcare

systems. Prior to purchasing technology, healthcare systems should recognize that vendors with many clients might be less likely to provide products adaptable to local patient needs. Patient-centered care is easier to provide in populations with fewer stakeholders, smaller networks, and more frequent communication; more research is needed to determine how to provide patient-centered care across complex and large networks. Automating implementation strategies, rather than relying on individual actions, can result in greater success when adopting to patient-centered care strategies. Settings in which patient-centered care may be more likely to successfully adopted may not be settings that have the most to gain from patient-centered care. We believe this study identifies key considerations for leaders of safety net healthcare systems and researchers studying patient-centered innovation implementation in vulnerable populations.

References

1. World Health Organization. *Adherence to Long-Term Therapies: Evidence for Action*.; 2003.
2. Fitzgerald AA, Powers JD, Ho PM, et al. Impact of medication nonadherence on hospitalizations and mortality in heart failure. *J Card Fail*. 2011;17(8):664-669. doi:10.1016/j.cardfail.2011.04.011.
3. Hsu KL, Fink JC, Ginsberg JS, et al. Self-reported medication adherence and adverse patient safety events in CKD. *Am J Kidney Dis*. 2015;66(4):621-629. doi:10.1053/j.ajkd.2015.03.026.
4. Bitton A, Choudhry NK, Matlin OS, Swanton K, Shrank WH. The impact of medication adherence on coronary artery disease costs and outcomes: A systematic review. *Am J Med*. 2013;126(4):357.e7-357.e27. doi:10.1016/j.amjmed.2012.09.004.
5. Brown MT, Bussell JK. Medication Adherence: WHO Cares? *Mayo Clin Proc*. 2011;86(4):304-314. doi:10.4065/mcp.2010.0575.
6. Bailey SC, Sarkar U, Chen AH, Schillinger D, Wolf MS. Evaluation of Language Concordant, Patient-Centered Drug Label Instructions. *J Gen Intern Med*. 2012:1-7. doi:10.1007/s11606-012-2035-3.
7. Wolf MS, Davis TC, Tilson HH, Bass PF, Parker RM. Misunderstanding of prescription drug warning labels among patients with low literacy. *Am J Heal Pharm*. 2006;63(11):1048-1055. doi:10.2146/ajhp050469.
8. Persell SD, Osborn CY, Richard R, Skripkauskas S, Wolf MS. Limited health literacy is a barrier to medication reconciliation in ambulatory care. *J Gen Intern Med*.

2007;22(11):1523-1526. doi:10.1007/s11606-007-0334-x.

9. Davis TC, Wolf MS, Iii PFB, et al. Literacy and Misunderstanding Prescription Drug Labels. *Ann Intern Med*. 2006.

10. Wolf MS, Curtis LM, Waite K, et al. Helping patients simplify and safely use complex prescription regimens. *Arch Intern Med*. 2011;171(4):300-305. doi:10.1001/archinternmed.2011.39.

11. Machtinger E, Wang F, Chen L, Rodriguez M, Wu S, Schillinger D. A Visual Medication Schedule to Improve Anticoagulation Control: A Randomized Controlled Trial. *Jt Comm J Qual Patient Saf*. 2007;33(10).

12. Wolf MS, Davis TC, Curtis LM, et al. A Patient-Centered Prescription Drug Label to Promote Appropriate Medication Use and Adherence. *J Gen Intern Med*. 2016. doi:10.1007/s11606-016-3816-x.

13. Sahm LJ, Wolf MS, Curtis LM, et al. What's in a label? An exploratory study of patient-centered drug instructions. *Eur J Clin Pharmacol*. 2012;68(5):777-782. doi:10.1007/s00228-011-1169-2.

14. National Council for Prescription Drug Programs. *Universal Medication Schedule White Paper*.; 2013.

15. Shrank WH, Parker R, Davis T, et al. Rationale and design of a randomized trial to evaluate an evidence-based prescription drug label on actual medication use. *Contemp Clin Trials*. 2010;31(6):564-571. doi:10.1016/j.cct.2010.07.004.

16. Sarkar U, Schillinger D, López A, Sudore R. Validation of self-reported health literacy questions among diverse english and spanish-speaking populations. *J Gen Intern Med*. 2011;26(3):265-271. doi:10.1007/s11606-010-1552-1.

17. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander J a, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci*. 2009;4(50):40-55. doi:10.1186/1748-5908-4-50.

18. Garg SK, Lyles CR, Ackerman S, et al. Qualitative analysis of programmatic initiatives to text patients with mobile devices in resource-limited health systems. *BMC Med Inform Decis Mak*. 2016;16(1):16. doi:10.1186/s12911-016-0258-7.

19. Liang S, Kegler MC, Cotter M, et al. Integrating evidence-based practices for increasing cancer screenings in safety net health systems: a multiple case study using the Consolidated Framework for Implementation Research. *Implement Sci*. 2015;11(1):109. doi:10.1186/s13012-016-0477-4.

20. Thomas DR. Method Notes A General Inductive Approach for Analyzing Qualitative Evaluation Data. *Am J Eval*. 2006;27(2):237-246. doi:10.1177/1098214005283748.

21. Schillinger D, Bindman A, Wang F, Stewart A, Piette J. Functional health literacy and the quality of physician-patient communication among diabetes patients. *Patient Educ Couns*. 2004;52(3):315-323. doi:10.1016/S0738-3991(03)00107-1.

22. Aboumatar HJ, Carson KA, Beach MC, Roter DL, Cooper LA. The impact of health literacy on desire for participation in healthcare, medical visit communication, and patient reported outcomes among patients with hypertension. *J Gen Intern Med*. 2013;28(11):1469-1476. doi:10.1007/s11606-013-2466-5.

23. Saha S, Beach MC, Cooper LA. Patient centeredness, cultural competence and healthcare quality. *J Natl Med Assoc*. 2008;100(11):1275-1285. doi:10.1016/j.biotechadv.2011.08.021.Secreted.

24. Kirsh SR, Lawrence RH, Aron DC. Tailoring an intervention to the context and system redesign related to the intervention: a case study of implementing shared medical appointments for diabetes. *Implement Sci*. 2008;3:34. doi:10.1186/1748-5908-3-34.

25. Paulus RA, Davis K, Steele GD. Continuous innovation in health care: Implications of the Geisinger experience. *Health Aff*. 2008;27(5):1235-1245. doi:10.1377/hlthaff.27.5.1235.

26. Epstein RM, Fiscella K, Lesser CS, Stange KC. Why the nation needs a policy push on patient-centered health care. *Health Aff*. 2010;29(8):1489-1495. doi:10.1377/hlthaff.2009.0888.

27. Bailey SC, Wolf MS, Lopez A, et al. Expanding the Universal Medication Schedule: a patient-centred approach. *BMJ Open*. 2014;4(1):e003699. doi:10.1136/bmjopen-2013-003699.

28. Kenning C, Protheroe J, Gray N, Ashcroft D, Bower P. The potential for using a Universal Medication Schedule (UMS) to improve adherence in patients taking multiple medications in the UK: a qualitative evaluation. *BMC Health Serv Res*. 2015;15:94. doi:10.1186/s12913-015-0749-8.

29. Clay-Williams R, Nosrati H, Cunningham FC, Hillman K, Braithwaite J. Do large-scale hospital- and system-wide interventions improve patient outcomes: a systematic review. *BMC Health Serv Res*. 2014;14:369. doi:10.1186/1472-6963-14-369.

30. Barker PM, Reid A, Schall MW. A framework for scaling up health interventions: lessons from large-scale improvement initiatives in Africa. *Implement Sci*. 2016;11(1):12. doi:10.1186/s13012-016-0374-x.

31. Mandl KD, Kohane IS. Escaping the EHR trap - the future of health IT. *N Engl J Med*. 2012;366(24):2240-2242. doi:10.1056/NEJMp1203102.

32. Greenhalgh, T., Robert, G., Macfarlane, F., Bate, P., & Kyriakidou O. Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations. *Milbank Q*. 2004;82(4):581–629. doi:doi:10.1111/j.0887-378X.2004.00325.x.

33. Feldstein AC, Glasgow RE. A Practical , Robust Implementation for Integrating Research Findings into Practice. *Jt Comm J Qual Patient Saf*. 2008;34(4):228-243.

34. Bernabeo E, Holmboe ES. Patients, providers, and systems need to acquire a specific set of competencies to achieve truly patient-centered care. *Health Aff*. 2013;32(2):250-258. doi:10.1377/hlthaff.2012.1120.

35. Pontefract SK, Hodson J, Marriott JF, Redwood S, Coleman JJ. Pharmacist-Physician Communications in a Highly Computerised Hospital: Sign-Off and Action of Electronic Review Messages. *PLoS One*. 2016;11(8):1-17. doi:10.1371/journal.pone.0160075.

36. Haidet P, Fecile ML, West HF, Teal CR. Reconsidering the team concept: Educational implications for patient-centered cancer care. *Patient Educ Couns*. 2009;77(3):450-455. doi:10.1016/j.pec.2009.09.020.

37. Smith N, Goldstein DG, Johnson EJ. Choice Without Awareness: Ethical and Policy Implications of Defaults. *J Public Policy …*. 2013;32(2):159-172. doi:10.1509/jppm.10.114.

38. Custodio R, Graham G. Health Information Technology: Addressing Health Disparity by Improving Quality, Increasing Access, and Developing Workforce. *J Health Care Poor Underserved*. 2016;20(2):301-307.

39. Jha AK, DesRoches CM, Shields AE, et al. Evidence of an emerging digital divide among hospitals that care for the poor. *Health Aff (Millwood)*. 2009;28(6). doi:10.1377/hlthaff.28.6.w1160.

40. Goldman DP, Lakdawalla DN. A Theory of Health Disparities and Medical Technology. *Contrib Econ Anal Policy*. 2005;4(1). doi:10.2202/1538-0645.1395.

Keywords

Medication adherence

Patient-centered prescription labeling

Implementation

Safety-net

Health literacy

Key Points

- Pharmacy software adaptability to local customizations impacts how quickly health systems can adopt innovative approaches to improve medication adherence.
- Collaborative care models that involve frequent communication between prescribers and pharmacists are crucial to quick adoption of new medication adherence technology.
- Implementation strategies that automate changes rather than relying on individual actions are more quickly adopted.

Table 1: Interventions to Increase Patient-Centered Drug Labeling at Each Pharmacy Site

CFIR Construct	Intervention	Pharmacy Site			
		Behavioral Health (BH)	**Jail Health (JH)**	**Long Term Care (LTC)**	**Outpatient Pharmacy (OP)**
Outer setting: external policies and incentives	California Board of Pharmacy requires patient-centered labeling				
	SFDPH requires pharmacies to dispense using Universal Medical Schedule (UMS) language				
Process: Planning	Meetings to discuss strategy for conversion to UMS				
	Audit to assess baseline use of UMS language				
Process: Engaging	Encourage prescribers to use UMS language				
	Policy and procedure committee approves pharmacist conversion of instructions to UMS language for "UMS-eligible" medications				
	Collaboration with software vendor to ease UMS conversion				
	Acquire prescriber approval to convert labels to UMS	Prescriber also dispenser			
	Educating dispensers about intervention				
	Educating prescribers about intervention				
Process: Executing	Staff medication review and protocol creation for UMS conversion/exceptions				
	Prescriptions entered in UMS language during roll-out of electronic prescribing software				
	Technicians add/test new UMS shortcut conversion codes				
	Staff rewrite shortcut conversion codes (e.g. BID becomes QAM & QPM)				
	Overnight conversion of short codes to UMS language				
Process: Reflecting and evaluating	Outcomes evaluation				
	Test new workflow				
	Downsize exception list and expand UMS				
	Modify UMS language to fit onto label				

	Executed successfully
	Attempted
	Not attempted or not applicable

Table 2. Characteristics of data collection process for prescription label audits

	Pre-implementation data collection		**Post-implementation data collection**	
SFDPH Pharmacy Sites	Time frame	Analyzed prescriptions (n) [a]	Time frame	Analyzed prescriptions (n) [a]
Behavioral Health (BH)	One week February 2014	All prescription labels without customized sigs (34)	One week August 2015	All prescription labels without customized sigs (32)
Jail Health (JH)	One month March 2008	Prescription labels for patients discharged from JH (80)	One month March 2016	Prescription labels for patients discharged from JH (86)
Long Term Care (LTC)	One month January 2015	Prescription labels for patients discharged from LTC (158)	One month February 2016	Prescription labels for all UMS-eligible medications (612)
Outpatient Pharmacy (OP)	One month March 2015	Prescription labels for all UMS-eligible medications (4317)	One month November 2015	Prescription labels for all UMS-eligible medications (3571)

[a] BH and LTC data were collected by a local pharmacist. JH and OP data were collected by a research team member.

Table 3. Characteristics of the 4 San Francisco Department of Public Health pharmacies

	Characteristic				
SFDPH Pharmacy Sites	Personnel	Number of unique medications dispensed	Average # prescriptions processed daily	% of prescriptions UMS-eligible	Characterization of pharmacy software [a]
Behavioral Health (BH)	10 pharmacists 5 technicians 250 prescribers	116 medications	71 prescriptions	100%	Visual Superscript (DAA, Brookline, MA; 500 systems installed)
Jail Health (JH)	3 pharmacists 5 pharmacy techs 10 prescribers	414 medications	43 prescriptions	100%	Jail Information Systems (locally developed)
Long Term Care (LTC)	16 pharmacists 11 pharmacy techs 38 prescribers	722 medications	113 prescriptions	58% (416/722)	QS / 1 (JM Smith, Spartanburg, SC; 6000+ systems installed)
Outpatient Pharmacy (OP)	10 pharmacists 10 pharmacy techs 749 prescribers	670 medications	310 prescriptions	52% (347/670)	Pharmacy 2000 (Parata, Durham, NC; 12000+ systems installed)

[a] Data acquired from http://www.computertalk.com/buyer/ or company website

Table 4. Rates of patient-centered labels (PCL) pre- and post-PCL implementation for UMS-eligible prescriptions only.

SFDPH Pharmacy Sites	Pre-Implementation	Post-Implementation
Behavioral Health (BH)	**0%** (0 / 34)	**94%** (30 / 32)
Jail Health (JH)	**14%** (11 / 80)	**99%** (85 / 86)
Long Term Care (LTC)	**34%** (54 / 158) [a]	**88%** (541 / 612)
Outpatient Pharmacy (OP)	**23%** (991 / 4317)	**23%** (835 / 3571)

[a] Data available only for all medications (including non-UMS eligible medications) but acquired only from prescriptions issued for patients discharged from the facility

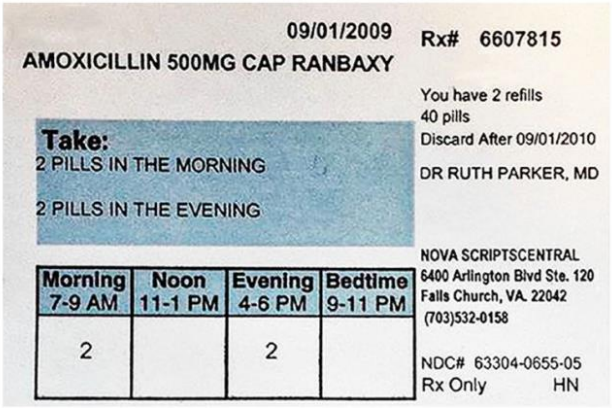
Table 5. Key barriers or facilitators to patient-centered drug label adoption at SFDPH pharmacies

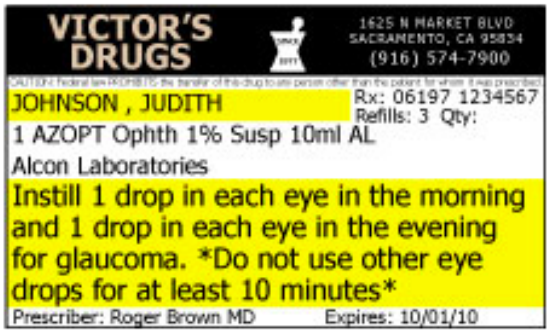
Factor	Short description	Barrier or Facilitator	Example Quote(s)
INTERVENTION			
Evidence strength & quality	There was good evidence to support the UMS but none tied to patient outcomes	Barrier	Until we have outcomes data, I think it's going to be hard…it's a lot of work to do this…You really want to know that you're improving outcomes as a result of it, not just patient understanding…
		Facilitator	There is data to show that it improves people picking up their prescriptions and likely improves adherence… we're definitely aligned with trying to do things that will foster that
Adaptability	The UMS language is long and poses logistic problems but if the UMS is perceived as adaptable, this can be overcome	Barrier	The standard is: take 1 tablet in the morning, take 1 tablet at noon and take 1 tablet in the evening. We consolidated take 1 tablet in the morning, noon, and evening. That fits in our labels, and so that was something that the group.
Complexity	Implementation of the intervention was more complicated than anticipated	Barrier	We also thought it would be relatively easy. How hard is it, right? You're just…modestly changing a sig and you have potentially a pretty significant impact on adherence and outcomes…it ended up being much more difficult than we ever expected that it would be to implement this.
Broad applicability to medications	The UMS does not seem applicable to all meds	Barrier	Some pharmacists... half their medications they feel uncomfortable using UMS. Then, it almost destroys… it because it doesn't really apply if you say, "Oh. Well, this drug maybe that doesn't quite fit," when you start slicing and dicing.
OUTER SETTING			
External policy & incentives	SFDPH pressure and board of pharmacy policy encouraged behavior change	Facilitator	I probably was most aware of it.. when the Board of Pharmacy Law was changed where they actually were going to require it...
		Facilitator	What was helpful for me… the executive team … made this one of our initiatives to do DPH-wide. There were times I'm ready to go to exec meeting, and I'm going, "Oh, my God! What have we done? I've got to go and report something." Without that… [pressure] ... it could have gotten just lost in the shuffle of all the different things we are doing.
Corporation responsiveness	The willingness of software vendors to accommodate custom requests impacted the ability to implement.	Barrier	Basically, we got no from [electronic prescribing software] and we got no response from the database vendors, and so realizing that that was not going to be a path that was going to be either quick or easy.
		Facilitator	I started working with our EHR in 2009... I've been working with the developer for 5 years... We know them all, and I go to conferences and I talk to him about what's important to us… that informs his next generation development... We see a lot of his development stuff before it happens… He's developed stuff that we'd asked for.
INNER SETTING			
Structural characteristic: patient population	Broader diversity of patients (and medications) made broad applicability of the UMS more difficult	Barrier or Facilitator	I think they had an easier time than we did because of the way they dispense their medications, just their more closed network and I think they have more control with the prescriptions that are being given out versus [Outpatient Pharmacy] where we have wider range of patients.
Internal policy	Implementation was more successful once an internal committee had approved the UMS conversions	Facilitator	We actually have created a policy for the pharmacy department on how we will utilize UMS language when dispensing prescription medications from our outpatient pharmacy. We obtained approval from the Pharmacy and Therapeutics Committee to automatically change any directions for use that come in a standard or traditional sig code to the UMS language...That gave staff the authority and they didn't feel like they were overstepping the physician.

Network and communication	Sites with tighter communication between pharmacists and prescribers adopted more quickly	Barrier	As UMS came up again and we actually took initiative to try to implement it here [Outpatient Pharmacy], some of the other issues that started to come up or concerns that started to come up was… for [the] provider… it's one direction and we changed it to another. Is that okay? How is the provider going to know we changed it? So the communication piece between the pharmacy and the provider.
		Facilitator	I think it is definitely easier to implement when you're a specialty pharmacy. Right now, we're working with [only] so many people... but... having the clinical pharmacists all get together and brainstorm like what is actually important versus like an entire system where there are a lot of opinions to be heard really helped narrow it... just 7 people have to get on the same page.
Readiness for change: Leadership Engagement	The commitment of the pharmacy leader to adoption was a facilitator	Barrier	I think partly, it's the leader of the Outpatient Pharmacy who did not buy into this very easily, so that outpatient pharmacy supervisor had her own concern.
		Facilitator	I think what helped was just having a lot of support from…our director
INDIVIDUAL			
Personal beliefs, knowledge, and attitude about intervention	Pharmacists' beliefs about ease of implementation and impact of the UMS on patients (safety, adherence, understanding, autonomy) affected adoption	Barrier	I think the staff still have it in their minds that - why would you want to change somebody's schedule or why would you want to dictate to somebody when to take something
		Facilitator	I felt with our patient population, very low literacy, not stable especially with healthcare coming in and out of the system, I felt UMS would be more of a benefit than versus maybe another healthcare system.
Personal beliefs, knowledge, and attitudes on professional role	Pharmacists' perceptions on their roles and responsibilities affected the UMS success	Barrier	There's always been a lot of hesitation because they feel like they need to write the directions exactly how they're written, and they don't want to stray from what the doctor said even if the doctor's plan is unclear. They put a lot of the pressure on the patient to figure out the directions on their own and just as a protective response, they don't want to stray from what was intended
Personal experiences	An individuals' own experiences w patient care impacts their perceptions on the utility of the UMS	Facilitator	Our clinical pharmacist's primary practice is actually indirect client care in our behavioral health clinics. I think, for them, their decisions are informed by reality of realizing what makes sense to a patient and what helps with compliance.
PROCESS			
Engagement	Engaging members across the implementation spectrum resulted in quicker adoption	Facilitator	There was initially I guess a lot of back and forth and conversation but once they agreed as a group on how to move forward and the fact that they could program their system, it was really quite simple.
Execution: automated changes	Success occurred in areas where changes were automated	Facilitator	Once you changed the labeling... the algorithm, QD if you typed that… which we usually type out once daily, they were all automatically converted... to UMS. Everything automatically converted.
Execution: policy	Internal policy changes provided pharmacists perceived approval from prescribers	Facilitator	So we put in an automatic substitution policy that essentially defined what – how the prescriptions were going to be translated and that … raised the comfort for the pharmacists dramatically
Evaluation	The ability to measure outcomes quickly was crucial for assessing impact of interventions.	Barrier	The other problem that the Outpatient Pharmacy has is they don't have a way of monitoring it or measuring their success… it has become a quality improvement project... collecting the data... that's a lot of work for them. They have not done a good job of seeing where they are at any one point in time to really try to identify the areas that are continuing to be challenges for them.

Appendix 1. Examples of Universal Medication Schedule instructions and patient-centered labels (PCL)

Standard instructions	UMS-based instructions
Take 2 tablets twice a day OR Take 2 tablets every 12 hours	Take 2 tablets in the morning and take 2 tablets at bedtime
Take 1 tablet four times a day OR Take 1 tablet every 6 hours	Take 1 tablet in the morning, 1 tablet at noon, 1 tablet in the evening, and 1 tablet at bedtime
Take 3 tablets daily	Take 3 tablets in the morning OR Take 3 tablets at bedtime
Take 2 tablets three times a day OR Take 2 tablets every 8 hours	Take 2 tablets in the morning, 2 tablets at noon, and 2 tablets in the evening





Appendix 2. CFIR-based codebook used for analysis

CFIR Construct	Sub-constructs	
Intervention	• Evidence strength & quality • Adaptability	• Complexity ○ Applicability to medications • Other unexpected outcomes

Outer Setting	• Peer Influence
	  ○ Peer pressure
	  ○ Non-Pharm support
	• Competing priorities
		• External policy & incentives
		  ○ State Board of Pharmacy
		  ○ San Francisco Department of Public Health
		• Corporation responsiveness

Inner Setting	• Structural characteristics
	  ○ Medication administration
	  ○ Diversity of medications
	  ○ Software
	  ○ Patient population
	• Networks and communication
	  ○ Organization size
	  ○ Pharmacy-prescriber relations
		• Implementation climate
		  ○ Internal competing priorities
		• Readiness for implementation
		  ○ Leadership excitement
		• Pharmacist responsibilities
		• Internal policy

Individual	• Personal beliefs, knowledge, and attitude about intervention • Willingness to be flexible	• Personal beliefs, knowledge, and attitudes on pharmacists' professional role • Personal experiences • Personal competing priorities

Process	• Planning
	• Engaging
	  ○ Involvement in policy development
	• Execution
	  ○ Prescriber-side
	  ○ Policy
	  ○ Automated changes
	  ○ Education
		• Reflection
		  ○ Iteration
		  ○ Decision-making support
		• Evaluation
		  ○ Iteration