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Peer Review of "Automating Individualized Notification of Drug Recalls to Patients: Complex Challenges and Qualitative Evaluation"

Alissa Russ, PhD, PharmD

Purdue University, 575 Stadium Mall Drive, West Lafayette, IN, United States

Related Articles:

Companion article: https://www.medrxiv.org/content/10.1101/2024.09.18.24312141v1

Companion article: https://med.jmirx.org/2026/1/e82609

Companion article: https://med.jmirx.org/2026/1/e68345

(JMIRx Med 2026;7:e82613) doi:10.2196/82613

KEYWORDS

notification system; drug recalls; patient safety; medication; electronic health records; prescriptions; decision support

This is a peer review report for "Automating Individualized Notification of Drug Recalls to Patients: Complex Challenges and Qualitative Evaluation."

Round 1 Review

General Comments

This manuscript [1] describes interesting and novel work with far-reaching patient safety implications. The authors developed an automated system in the electronic health record (EHR) of an academic medical center that scans for drug recalls, matches up National Drug Codes of recalled medication on a patient's medical list, and sends notifications through the EHR portal to the patient, providing them with more information on the recall. The authors then conducted a qualitative analysis of 9 patients' perceptions of a fictious recall notice. Despite successful development of the automated system, many limitations prevented the widescale adoption of this system in 2 clinics associated with the large academic medical center. The outcome of the work—a decision was made not to deploy the new software for drug recalls—was surprising, and it is important that "failed" implementation work also be published. That said, key weaknesses of the manuscript are the lack of important details, need for better organization of the content, and the need for much stronger scientific and technical writing to accurately interpret the methods, results, and implications. These weaknesses also made it much more difficult to read and evaluate the manuscript. Despite the importance of the topic, the small sample size of patients also limits the work's impact.

Specific Comments

Title

It would be helpful if the title were a bit more specific about the technology, study methods (qualitative), and notification recipients (patients, providers, etc).

Abstract

1. The Background section appears to be contradictory. Sentence 2 says the Food and Drug Administration has ways to notify health care professionals (HCPs) and patients, but then the following sentences seem to say the opposite.
2. A few more details here on the type of platform would be helpful…software app? Web-based platform, etc? And what are the intended user types? (HCPs and patients? Or just patients?)
3. The choice of methods doesn't seem to follow the Background section. Why was it necessary to include the clinics, rather than just work directly with the patients? Or, why was the focus on clinics, rather than pharmacies? (These comments apply to the main Introduction and Methods sections, as well.)
4. I expected the "program description" to appear in the Methods section, not the Results.

Introduction

1. The second and third sentences of the first paragraph of the Introduction: any studies or references to back up this claim?
2. No information is included on if/what literature explores this or similar topics.
3. I would recommend adding more information on the process pharmacies currently have in place for notifying patients of recalls. Also add any literature that exists showing how often patients then contact their providers or add quantitative data to highlight this extra burden on providers to emphasize the problem.
4. I expected the funding information in the last sentence of the first paragraph to be included in a funding statement or the acknowledgments (rather than the Introduction) and the rest of that statement to be described in the Methods.

Setting

1. I expected this to appear under a larger Methods section.
2. What was the goal sample size and rationale for the sample size? There is missing demographic information on the participating patients.
3. So the Fast Healthcare Interoperability Resources (FHIR) portion notified HCPs? The intended recipients are not specified for that part of the program.
4. "EHR build" was unexpected as a reader. Is that a third part? How does it fit into the first 2 parts?
5. The screenshots and figures are useful.
6. Even for a convenience sample, more details are needed on recruitment. How did you choose which patients to email? How many were emailed for recruitment? Were patients emailed and recruited sequentially, for example? Were there any exclusion or inclusion criteria for patients? Did any patients decline to participate? Why? What was the distribution of patients recruited from primary care versus cardiology?
7. More specific details are warranted for the methods used for qualitative analysis, such as whether an inductive versus a deductive design was used. Was a consensus approach used, or some other approach? See also the writing guidelines for qualitative studies (eg, the Consolidated Criteria for Reporting Qualitative Research [COREQ], Standards for Reporting Qualitative Research [SRQR]). Explain also the "additional verification" process during analysis. References should be cited for the qualitative methods used in this work.
8. Did any of the patients have prior experience with MyChart, and if so, what was the average number of years of MyChart experience?
9. These statements from the text appear to be contradictory, and the meaning of the first statement especially is unclear, and seems like an opinion: "[Patients expressed that the] widget should not ask patients to discuss the information with their healthcare provider." "Patients wanted to discuss the recall with their clinicians to 'close the loop.'"

1. The conclusion not to deploy the system seems dramatic based on the findings and makes me wonder if any other creative solutions were considered to address the concern of potential increased clinic burden. Also, how was it determined that the clinic burden outweighed safety risks to the patient? Maybe the system should only be used for certain types of recalls, for example. Or maybe the system could be integrated more with the pharmacy, rather than the prescriber's clinic, or the letter could read differently (advising against contacting the clinic unless the patient was unable to resolve the issue with the pharmacy). Or the letter could explain that only the pharmacy, not the clinic, would have a record of the patient's specific manufacturer and whether the recall applied to them.
2. It would be helpful to see the full interview guide and patient scenario details in a supplementary appendix to aid interpretation of the methods and results.

Discussion

1. The Discussion does not mention limitations of the study design and methods.
2. I expected at least some comparison to other, related literature.
3. Is anything stamped on the medication (eg, pill) itself to indicate the manufacturer? Or is that also inconsistent across medications?
4. A table of key recommendations could strengthen the paper.
5. In the last paragraph of the Discussion, there is no citation for the number of state boards of pharmacy that require the lot number to appear on the label.
6. I expected the Discussion to close with a Conclusions paragraph outlining key lessons learned and any generalizable findings.

Round 2 Review

General Comments

The authors addressed a few of my review comments and made some text changes, but unfortunately, most of my comments—about 15 of them—remain inadequately addressed. For the comments listed again below, the authors did not appear to change anything in the manuscript to address the comment. In many cases, even the authors' reply to the reviewers did not answer the question. Also, the authors describe adding the interview guide as an appendix, but I could not find this file on the reviewer website.

Unaddressed or inadequately addressed review comments are described in the following sections.

Specific Comments

Abstract

1. The Background section appears to be contradictory. Sentence 2 says the Food and Drug Administration has ways to notify HCPs and patients, but then the following sentences seem to say the opposite.

3. The choice of methods doesn't seem to follow the Background section. Why was it necessary to include the clinics, rather than just work directly with the patients? Or, why was the focus on clinics, rather than pharmacies? (These comments apply to the main Introduction and Methods sections, as well.)

Introduction

2. No information is included on if/what literature explores this or similar topics. (Lack of literature citations/review.)

Setting

2. What was the goal sample size and rationale for the sample size? There is missing demographic information on the participating patients.

3. So the FHIR portion notified HCPs? The intended recipients are not specified for that part of the program.

6. Even for a convenience sample, more details are needed on recruitment. How did you choose which patients to email? How many were emailed for recruitment? Were patients emailed and

recruited sequentially, for example? Were there any exclusion or inclusion criteria for patients? Did any patients decline to participate? Why? What was the distribution of patients recruited from primary care versus cardiology?

7. More specific details are warranted for the methods used for qualitative analysis, such as whether an inductive versus a deductive design was used. Was a consensus approach used, or some other approach? See also the writing guidelines for qualitative studies (eg, the COREQ, SRQR). Explain also the "additional verification" process during analysis. References should be cited for the qualitative methods used in this work.

8. Did any of the patients have prior experience with MyChart, and if so, what was the average number of years of MyChart experience?

9. These statements from the text appear to be contradictory, and the meaning of the first statement especially is unclear, and seems like an opinion: "[Patients expressed that the] widget should not ask patients to discuss the information with their healthcare provider." "Patients wanted to discuss the recall with their clinicians to 'close the loop.'"

10. The conclusion not to deploy the system seems dramatic based on the findings and makes me wonder if any other creative solutions were considered to address the concern of potential increased clinic burden. Also, how was it determined that the clinic burden outweighed safety risks to the patient? Maybe the system should only be used for certain types of recalls, for example. Or maybe the system could be integrated more with the pharmacy, rather than the prescriber's clinic, or the letter could read differently (advising against contacting the clinic unless the patient was unable to resolve the issue with the pharmacy). Or the letter could explain that only the pharmacy, not the clinic, would have a record of the patient's specific manufacturer and whether the recall applied to them.

Discussion

1. The Discussion does not mention limitations of the study design and methods.

2. I expected at least some comparison to other, related literature.

3. Is anything stamped on the medication (eg, pill) itself to indicate the manufacturer? Or is that also inconsistent across medications?

4. A table of key recommendations could strengthen the paper.

5. In the last paragraph of discussion, there is no citation for the number of state boards of pharmacy the require the lot number to appear on the label. (The statement that needs a literature citation is "Only three State Boards of Pharmacy require the NDC to appear on the dispensed medication label, and only five State Boards of Pharmacy require the lot number to appear on the dispensed medication label.")

Conflicts of Interest

None declared.

Reference

1. Gadgil M, Pavlakos R, Carini S, et al. Automating individualized notification of drug recalls to patients: complex challenges and qualitative evaluation. JMIRx Med 2026;7:e68345. [doi: 10.2196/68345]

Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
EHR: electronic health record
FHIR: Fast Healthcare Interoperability Resources
HCP: health care professional
SRQR: Standards for Reporting Qualitative Research

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Peer Review of “Automating Individualized Notification of Drug Recalls to Patients: Complex Challenges and Qualitative Evaluation”

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KEYWORDS

notification system; drug recalls; patient safety; medication; electronic health records; prescriptions; decision support

This is a peer review report for “Automating Individualized Notification of Drug Recalls to Patients: Complex Challenges and Qualitative Evaluation.”

Round 1 Review

General Comments

This paper [1] describes a qualitative study that aims to leverage the US Food and Drug Administration (FDA)’s Healthy Citizen prototype platform, which provides information about recalls, to automatically notify patients of relevant recalls.

Specific Comments

Major Comments

1. Because of the setup of this document, it is challenging to add comments or do any editing. Not sure what happened, but it treated every line as a single object when opened in Microsoft Word. Please check your formatting.
2. On page 2, within the abstract, under Background, there is an error in the formatting. There should be a section that begins with Aim. Instead, that section is folded into the Background section and needs to be corrected.
3. On page 8, with the MyChart message, I can see why patients felt too much wording was in this layout. Surprisingly, the Patient Advisory Council agreed to this layout and the wordiness. The focus must be on the patient’s needs, not what the FDA requires. We all have seen the Prescribers' Digital Reference, and we know that the information is too dense and too small. This is similar to that in terms of format. Enlarge the font, eliminate extraneous information, and only include information that is important to the patient and in simple English. This should be pretty feasible in the formatting of the Health Citizen and/or the MyChart message.
4. You identified problems and that patients would feel obligated to contact their provider regarding the recall. Instead of exploring how to address this so that patients wouldn’t do that, thereby increasing the significant workload on the provider’s health care team, you simply gave up. I think you could have done much more with this than say, “oh, it can’t be done.” How could you word the MyChart to direct the patients only to the pharmacy that dispenses their medication instead of the primary care provider? If you didn’t ask that question, you should have. This is not the time to give up. It’s time to inquire more to find the right answers so that this could move forward and better serve both the patients and their providers.
5. It is certainly possible, given the technical requirements to create this capability, that you ran out of time and money. However, you can still benefit your team and others by focusing on the lessons learned and how you would go forward with another study.
6. One of the things that you did not do is a first round of qualitative testing and using that feedback to make changes and do a second round. Per Nielsen [2], you only need about 5 test subjects per round to get the desired, usable results. What was preventing you from doing that? Put that in the manuscript as a limitation in your Discussion.
7. Also, on page 11, in the last paragraph of the page under Discussion, there is a comment regarding patients expecting their providers to know when a recall has occurred; I think we all know this is an unreasonable expectation. Part of the communication with the MyChart message is to inform the patients not to call their provider but to call the pharmacy that dispenses their medication, which should be right on the bottle. Again, one component of the MyChart portal messaging system, as well as any other portal messaging system, is to keep patients informed and educate them. That

should be a focus of this project, just as much as the technical components.

8. On page 12, in the last full paragraph on the page, you make a statement regarding the project that a strong case can be made for requiring each pill bottle to include the lot number (maybe) and National Drug Code of the pills. Since the FDA was a component of this project, that should probably have been something you recommended for the FDA to require and not leave to the state boards of pharmacy, as then you would get a patchwork of regulations. This would require the FDA to say that lot numbers and National Drug Codes are required on the bottles of all medications with an appropriate implementation period to allow for appropriate software and hardware adjustments. That is just as valuable a recommendation out of the study as any other.

Round 2 Review

General Comments

This paper describes a small qualitative study that aims to leverage the FDA's Healthy Citizen prototype platform, which provides information about recalls, to notify patients of relevant recalls automatically. The project team deemed the goal unattainable and provided limited lessons learned and recommendations for potential advocacy/future solutions.

Specific Comments

Major Comments

1. On page 11, in the section/paragraph beginning with "Major thematic findings included...": these are some of the lessons learned that I mentioned in my feedback.
2. On page 12, in the paragraph beginning with "The project team concluded that...": The "project team" felt this. Did the Patient Advisory Council and the test subjects share the same feeling?
3. On page 13, in the second paragraph on the page, in the sentence beginning with "Note that the FDA does not...": this would clearly be a lesson learned and could be advocated for via Congress and the Department of Health and Human Services.
4. On page 13, in the second paragraph, the next sentence, beginning with "The manufacturer and lot number of dispensed medications...": agreed. See previous comment.

Conflicts of Interest

None declared.

References

1. Gadgil M, Pavlakos R, Carini S, et al. Automating individualized notification of drug recalls to patients: complex challenges and qualitative evaluation. JMIRx Med 2026;7:e68345. [doi: 10.2196/68345]
2. Nielsen Norman Group. Why you only need to test with 5 users. URL: https://www.nngroup.com/articles/why-you-only-need-to-test-with-5-users/ [accessed 2025-10-14]

Abbreviations

FDA: Food and Drug Administration

Edited by CN Hang; submitted 18.Aug.2025; this is a non–peer-reviewed article;accepted 18.Aug.2025; published 13.Jan.2026.

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Peer Review for “Administration Technique of Intranasal Corticosteroid Sprays Among Nepali Pharmacists: Cross-Sectional Study”

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Tung Wah Eastern Hospital, So Kon Po, China (Hong Kong)

Related Articles:

Companion article: http://preprints.jmir.org/preprint/83042

Companion article: https://med.jmirx.org/2026/1/e91445

Companion article: https://med.jmirx.org/2026/1/e83042

(JMIRx Med 2026;7:e91439) doi:10.2196/91439

KEYWORDS

intranasal corticosteroid spray; allergic rhinitis; device use technique; pharmacist; patient counselling, continuing pharmacy education

This is a peer-review report for “Administration Technique of Intranasal Corticosteroid Sprays Among Nepali Pharmacists: Cross-Sectional Study.”

Round 1 Review

General Comments

This paper [1] addresses an important gap by evaluating pharmacists’ proficiency in demonstrating intranasal corticosteroid technique, using a standardized 12-step checklist with 5 critical steps. The sample size (n=365) is reasonable for a local study, and the use of multivariate logistic regression and Chi-square automatic interaction detection decision tree analysis adds analytical depth. The findings highlight systemic issues, such as inadequate training and curriculum gaps, which could inform policy changes to improve allergic rhinitis management and reduce adverse effects like epistaxis.

Specific Comments

Major Comments

1. Simple random sampling was used for pharmacies, but details on how wards were selected or how pharmacists within pharmacies were approached are vague. Please supplement and elaborate on further details of the randomization. More information on such would help lower the selection bias (eg, busier or more accessible pharmacies might be overrepresented).
2. The questionnaire’s validity is only face-validated by experts, with no content or construct validity testing mentioned. Reliability was assessed via Cronbach alpha (0.758) on a small pilot (n=15), which is acceptable but not robust. The cutoff for “adequate” proficiency (>6/12 marks) is based on the median score and expert opinion, which feels arbitrary and not clinically validated. Why not base it on critical steps alone, given their emphasis on efficacy and safety? Only 6% performed all 5 critical steps correctly, yet 47% were deemed “adequate” overall. This discrepancy suggests the threshold may be too lenient, masking true incompetence in high-impact areas like directing the nozzle away from the septum (to prevent epistaxis) or exhaling through the mouth (to optimize deposition). Please address these in the Discussion section.
3. Self-reported variables (eg, counseling frequency, use of materials) are prone to recall or social desirability bias, especially in an in-person interview setting. Please supplement these in the Discussion section.
4. The multivariate binary logistic regression identifies associations (eg, male gender, older age, higher qualifications linked to better proficiency), but potential confounders like pharmacy type (independent vs chain) or workload details are not controlled for. Odds ratios are extreme in places (eg, BPharm holders 97% less likely to perform inadequately, or frequent counselors 11 times more proficient), which may stem from small subgroups or multicollinearity.
5. Gender differences (males ~2 times more proficient) were found but underlying factors were not explored (eg, access to workshops, cultural biases). Please elaborate more or address the potential underlying factors in the Discussion section.
6. “Educational materials” are linked to better proficiency, but what constitutes these (eg, leaflets, videos)? Please specify for readers to enhance the proficiency on applying the study’s results.
7. Reference 16 has the wrong format for the volume, issue, and page numbers:Al-Taie A. A Systematic Review for Improper Application of Nasal Spray in Allergic Rhinitis: A Proposed Role of Community Pharmacist for Patient

Education and Counseling in Practical Setting. Asia Pacific Allergy. 2025:10-5415.The full information from PubMed is as below:Al-Taie A. A systematic review for improper application of nasal spray in allergic rhinitis: A proposed role of community pharmacist for patient education and counseling in practical setting. Asia Pac Allergy. 2025 Mar;15(1):29-35. doi: 10.5415/apallergy.0000000000000173. Epub 2025 Jan 13. PMID: 40051424; PMCID: PMC11882221.Therefore, "2025:10-5415" should be "2025 Mar;15(1):29-35."Please revise the whole reference list to see if any other typos exist.

Conflicts of Interest

None declared.

Reference

1. Chaudhary AP, Thakur S, Sah SK. Administration technique of intranasal corticosteroid sprays among Nepali pharmacists: cross-sectional study. JMIRx Med 2026. [doi: 10.2196/preprints.83042]

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Peer Review for “Administration Technique of Intranasal Corticosteroid Sprays Among Nepali Pharmacists: Cross-Sectional Study”

Ravi P Shankar

Manipal College of Medical Sciences, Pokhara, Nepal

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(JMIRx Med 2026;7:e91443) doi:10.2196/91443

KEYWORDS

intranasal corticosteroid spray; allergic rhinitis; device use technique; pharmacist; patient counselling, continuing pharmacy education

This is a peer-review report for “Administration Technique of Intranasal Corticosteroid Sprays Among Nepali Pharmacists: Cross-Sectional Study.”

Round 1 Review

General Comments

This is an important and well-written study [1]. My suggestions are listed below.

Specific Comments

There are some problems with language and with unnecessary capitalization of words.

Page 3: INCS sprays should be defined in full on first mention in the text.

Page 8: Can details of the ethical committee that provided the approval be provided?

Was the informed consent obtained in writing?

Scoring system: Should the crucial steps not be provided with greater marks compared to the other steps?

Page 17: Please explain the classification tree (Chi-square automatic interaction detection method) for the benefit of the readers.

Page 17: “This research is one of a kind, conducted in Nepal.” Can this sentence be modified?

Page 19: Instead of continuing medical education (CME), continuing pharmacy education (CPE) may be a better term.

Page 20: What educational aids are you referring to?

Are the educational leaflets available in the Nepali language?

Page 20: “In our study, both the increasing age (>26 y old) were significantly associated with improved INCS [intranasal corticosteroid] counseling proficiency.” This sentence mentions both but then highlights only one factor.

Was this study conducted only in Kathmandu city and not in Lalitpur or Bhaktapur?

Page 21, Limitations section: Some of the findings may be extreme due to small subgroups or model overfitting. Can this be explained?

Different fonts are used in different locations, and this should be corrected.

Conflicts of Interest

None declared.

Reference

1. Chaudhary AP, Thakur S, Sah SK. Administration technique of intranasal corticosteroid sprays among Nepali pharmacists: cross-sectional study. JMIRx Med 2026;7:e83042. [doi: 10.2196/preprints.83042]

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Authors' Response to Peer Reviews of "Automating Individualized Notification of Drug Recalls to Patients: Complex Challenges and Qualitative Evaluation"

Meghana Gadgil[1], MD, MPH; Rose Pavlakos[2], PharmD; Simona Carini[1], MA; Brian Turner[3], MBA; Ileana Elder[4], PhD; William Hess[4], BS; Lisa Houle[5], BA; Lavonia Huff[4]; Elaine Johanson[4], BS; Carole Ramos-Izquierdo[4], MS, MPM; Daphne Liang[4], PharmD; Pamela Ogonowski[4], MLS (ASCP); Joshua Phipps[6]; Tyler Peryea[4], BA; Ida Sim[1,3], MD, PhD

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Companion article: https://med.jmirx.org/2026/1/e82613

Companion article: https://med.jmirx.org/2026/1/e68345

Abstract

(JMIRx Med 2026;7:e82609) doi:10.2196/82609

KEYWORDS

notification system; drug recalls; patient safety; medication; electronic health records; prescriptions; decision support

This is the authors' response to peer review reports for "Automating Individualized Notification of Drug Recalls to Patients: Complex Challenges and Qualitative Evaluation."

Round 1 Review

Reviewer E [1]

General Comments

This paper [2] describes a qualitative study that aims to leverage the US Food and Drug Administration's (FDA's) Healthy Citizen prototype platform, which provides information about recalls, to automatically notify patients of relevant recalls.

Specific Comments

Major Comments

1. Because of the setup of this document, it is challenging to be able to add comments or do any editing. Not sure what happened, but it treated every line as a single object when opened in Microsoft Word. Please check your formatting.

Response: We're sorry reviewing the document was difficult; we uploaded the document following the instructions provided. We hope the problem will not present itself again in the revised document uploaded after the review.

2. On page 2, within the abstract, under Background, there is an error in the formatting. There should be a section that begins with Aim. Instead, that section is folded into the Background section and needs to be corrected.

Response: Thank you for the comment. This has been corrected in the revised manuscript.

3. On page 8, with the MyChart message, I can see why patients felt too much wording was in this layout. Surprisingly, the Patient Advisory Council agreed to this layout and the wordiness. The focus must be on the patient's needs, not what the FDA requires. We all have seen the Prescribers' Digital Reference, and we know that the information is too dense and too small. This is similar to that in terms of format. Enlarge the font, eliminate extraneous information, and only include information that is important to the patient and in simple English. This should be pretty feasible in the formatting of the Healthy Citizen and/or the MyChart message.

Response: Thank you for the comment. We agree that clear and concise information is key in any communication with the patient. The design balanced FDA requirements, the information available on the Healthy Citizens platform, and the need to be accurate. As for the font size, please consider that the figure is an artifact, as the original screenshot needed to be shrunk to fit onto the manuscript page.

4. You identified problems and that patients would feel obligated to contact their provider regarding the recall. Instead of exploring how to address this so that patients wouldn't do that, thereby increasing the significant workload on the provider's health care team, you simply gave up. I think you could have done much more with this than say, "oh, it can't be done." How could you word the MyChart to direct the patients only to the pharmacy that dispenses their medication instead of the primary care provider? If you didn't ask that question, you should have. This is not the time to give up. It's time to inquire more to find the right answers so that this could move forward and better serve both the patients and their providers.

Response: Thank you for the comment. The MyChart message refers the patient only to the dispensing pharmacy and never mentions the prescribing physician or the clinic. However, during the qualitative evaluation, it became clear that the patients still wanted to discuss the recall with their clinicians. We felt that stronger wording, something along the lines of "Please do not contact your physician or the clinic on this matter," would have been detrimental and turned patients off.

5. It is certainly possible, given the technical requirements to create this capability, that you ran out of time and money. However, you can still benefit your team and others by focusing on the lessons learned and how you would go forward with another study.

Response: Thank you for your comment. As detailed in the paper, recall alerts sent to patients are not precise, but contacting the right patient for the appropriate recall is of paramount importance to avoid unnecessary anxiety and, worse, treatment discontinuation. False positives and the fact that patients expect their prescriber to be aware of, and involved in, responding to a drug recall, while prescribers don't have easy access to the relevant information, create an obstacle that another study would ultimately encounter and currently not be able to solve.

6. One of the things that you did not do is a first round of qualitative testing and using that feedback to make changes and do a second round. Per Nielsen [3], you only need about 5 test subjects per round to get the desired, usable results. What was preventing you from doing that? Put that in the manuscript as a limitation in your Discussion.

Response: Thank you for your comment. The study was planned based, among other things, on a project timeline. See the answer to comment 5 above.

7. Also, on page 11, in the last paragraph of the page under Discussion, there is a comment regarding patients expecting their providers to know when a recall has occurred; I think we all know this is an unreasonable expectation. Part of the communication with the MyChart message is to inform the patients not to call their provider but to call the pharmacy that dispenses their medication, which should be right on the bottle. Again, one component of the MyChart portal messaging system, as well as any other portal messaging system, is to keep patients informed and educate them. That should be a focus of this project, just as much as the technical components.

Response: Thank you for your comment. As mentioned in our answer to comment 4 above, we feel that a stronger wording, something along the lines of "Please do not contact your physician or the clinic on this matter," would have been detrimental and turned patients off.

8. On page 12, in the last full paragraph on the page, you make a statement regarding the project that a strong case can be made for requiring each pill bottle to include the lot number (maybe) and National Drug Code (NDC) of the pills. Since the FDA was a component of this project, that should probably have been something you recommended for the FDA to require and not leave to the state boards of pharmacy, as then you would get a patchwork of regulations. This would require the FDA to say that lot numbers and NDCs are required on the bottles of all medications with an appropriate implementation period to allow for appropriate software and hardware adjustments. That is just as valuable a recommendation out of the study as any other.

Response: Thank you for your comment. The FDA does not have the legal authority to regulate the practice of pharmacy in any state, and therefore the FDA cannot require that the lot number and NDC (or anything else, including the name of the drug) be placed on each prescription that a pharmacist dispenses to a patient. We clarified this in the Discussion section of the revised manuscript.

Reviewer F [4]

General Comments

This manuscript [2] describes interesting and novel work with far-reaching patient safety implications. The authors developed an automated system in the electronic health record (EHR) of an academic medical center that scans for drug recalls, matches up NDCs of recalled medication on a patient's medical list, and sends notifications through the EHR portal to the patient, providing them with more information on the recall. The authors then conducted a qualitative analysis of 9 patients' perceptions of a fictious recall notice. Despite successful development of the automated system, many limitations prevented the widescale

adoption of this system in 2 clinics associated with the large academic medical center. The outcome of the work—a decision was made not to deploy the new software for drug recalls—was surprising, and it is important that "failed" implementation work also be published. That said, key weaknesses of the manuscript are the lack of important details, need for better organization of the content, and the need for much stronger scientific and technical writing to accurately interpret the methods, results, and implications. These weaknesses also made it much more difficult to read and evaluate the manuscript. Despite the importance of the topic, the small sample size of patients also limits the work's impact.

Specific Comments

Title

1. It would be helpful if the title were a bit more specific about the technology, study methods (qualitative), and notification recipients (patients, providers, etc).

Response: Thank you for the suggestion. We edited the title to Automating Individualized Notification of Drug Recalls to Patients: Complex Challenges and Qualitative Evaluation."

Abstract

1. The Background section appears to be contradictory. Sentence 2 says the FDA has ways to notify health care professionals (HCPs) and patients, but then the following sentences seem to say the opposite.

Response: Thank you for your comment. The website referenced in the paper, "Recalls, Market Withdrawals, & Safety Alerts" [5], provides information to the public about recalls, but it does not notify HCPs about individual patients in their care who may be affected.

2. A few more details here on the type of platform would be helpful...software app? Web-based platform, etc? And what are the intended user types? (HCPs and patients? Or just patients?)

Response: Thank you for your comment. We added some details to the abstract.

3. The choice of methods doesn't seem to follow the Background section. Why was it necessary to include the clinics, rather than just work directly with the patients? Or, why was the focus on clinics, rather than pharmacies? (These comments apply to the main Introduction and Methods sections, as well.)

Response: Thank you for your question. As the study was implemented at an academic institution, we followed the institution's rules for engaging with patients.

4. I expected the "program description" to appear in the Methods section, not the Results.

Response: Thank you for your comment. The section was moved as suggested.

Introduction

1. The second and third sentences of the first paragraph of the Introduction: any studies or references to back up this claim?

Response: Thank you for your question. The paper's authors, who are HCPs, have extensive experience managing drug recalls in their daily practice. Published studies have focused on analyzing and classifying the recalls themselves (eg, the reason for the recall, the class).

2. No information is included on if/what literature explores this or similar topics.

Response: Please see the response to comment 1 under Introduction above.

3. I would recommend adding more information on the process pharmacies currently have in place for notifying patients of recalls. Also add any literature that exists showing how often patients then contact their providers or add quantitative data to highlight this extra burden on providers to emphasize the problem.

Response: Thank you for your comment. The process pharmacies follow is explained in the Drug Recall Process section. We found no literature on the topic.

4. I expected the funding information in the last sentence of the first paragraph to be included in a funding statement or the acknowledgments (rather than the Introduction) and the rest of that statement to be described in the Methods.

Response: Thank you for your comment. We moved the paragraph as suggested.

Setting

1. I expected this to appear under a larger Methods section.

Response: We added a Methods section.

2. What was the goal sample size and rationale for the sample size? There is missing demographic information on the participating patients.

Response: A convenience sample was used based on outreach to patients and their responses. Given the nature of the study, we feel we provided sufficient information on the patients interviewed.

3. So the Fast Healthcare Interoperability Resources (FHIR) portion notified HCPs? The intended recipients are not specified for that part of the program.

Response: The notification was meant for patients only.

4. "EHR build" was unexpected as a reader. Is that a third part? How does it fit into the first 2 parts?

Response: We added a clarification.

5. The screenshots and figures are useful.

Response: Thank you for your comment. We are glad the figures are useful.

6. Even for a convenience sample, more details are needed on recruitment. How did you choose which patients to email? How many were emailed for recruitment? Were patients emailed and recruited sequentially, for example? Were there any exclusion or inclusion criteria for patients? Did any patients decline to participate? Why? What was the distribution of patients recruited from primary care versus cardiology?

Response: Recruitment techniques were not a subject of this study. Patient inclusion was based on active use of the MyChart portal.

7. More specific details are warranted for the methods used for qualitative analysis, such as whether an inductive versus a deductive design was used. Was a consensus approach used, or some other approach? See also the writing guidelines for qualitative studies (eg, the Consolidated Criteria for Reporting Qualitative Research [COREQ], Standards for Reporting Qualitative Research [SRQR]). Explain also the "additional verification" process during analysis. References should be cited for the qualitative methods used in this work.

Response: We added the interview script as an appendix. Analysis of the responses was repeated and the results compared.

8. Did any of the patient sample have prior experience with MyChart, and if so, what was the average number of years of MyChart experience?

Response: Active use of MyChart was an inclusion criterion.

9. These statements from the text appear to be contradictory, and the meaning of the first statement especially is unclear, and seems like an opinion: "[Patients expressed that the] widget should not ask patients to discuss the information with their healthcare provider." "Patients wanted to discuss the recall with their clinicians to 'close the loop.'"

Response: Figure 2 shows the information provided by the FDA's Healthy Citizen platform, which complies with the FDA's requirements and is not customizable by the system using it.

10. The conclusion not to deploy the system seems dramatic based on the findings and makes me wonder if any other creative solutions were considered to address the concern of potential increased clinic burden. Also, how was it determined that the clinic burden outweighed safety risks to the patient? Maybe the system should only be used for certain types of recalls, for example. Or maybe the system could be integrated more with the pharmacy, rather than the prescriber's clinic, or the letter could read differently (advising against contacting the clinic unless the patient was unable to resolve the issue with the pharmacy). Or the letter could explain that only the pharmacy, not the clinic, would have a record of the patient's specific manufacturer and whether the recall applied to them.

Response: The MyChart message explains that the pharmacy has more information about the drug given to the patient; the message cannot state for certain that the pharmacy can match the recall precisely to the patient.

11. It would be helpful to see the full interview guide and patient scenario details in a supplementary appendix to aid interpretation of the methods and results.

Response: We added the interview script as a multimedia appendix.

Discussion

1. The Discussion does not mention limitations of the study design and methods.

Response: Our project was technically successful. The lack of availability of the data needed to accurately target patients—particularly the lot number of the drug dispensed—makes false positive notifications unavoidable, independent of the study design.

3. Is anything stamped on the medication (eg, pill) itself to indicate the manufacturer? Or is that also inconsistent across medications?

Response: As described in the Discussion section, what data pertaining to the drug appears where is not consistent. (And while the pharmacy records the NDC of filled prescriptions, pills from different lot numbers can be dispensed together.)

5. In the last paragraph of the Discussion, there is no citation for the number of state boards of pharmacy that require the lot number to appear on the label.

Response: While we understand the interest in learning which state boards of pharmacy require the lot number to appear on the label, considering that the number is one-tenth of the states, the takeaway is that the problem described applies to the vast majority of the states.

6. I expected the Discussion to close with a Conclusions paragraph outlining key lessons learned and any generalizable findings.

Response: In the Conclusions we reiterate the need for consistent availability of the data needed to accurately address patients affected by a drug recall.

Round 2 Review

Reviewer E

General Comments

This paper describes a small qualitative study that aims to leverage the FDA's Healthy Citizen prototype platform, which provides information about recalls, to notify patients of relevant recalls automatically. The project team deemed the goal unattainable and provided limited lessons learned and recommendations for potential advocacy/future solutions.

Specific Comments

Major Comments

1. On page 11, in the section/paragraph beginning with "Major thematic findings included...": these are some of the lessons learned that I mentioned in my feedback.

Response: Thank you for your suggestion. We added content to the Conclusions paragraph summarizing lessons learned and outlining the generalizability of some of them.

2. On page 12, in the paragraph beginning with "The project team concluded that...": The "project team" felt this. Did the Patient Advisory Council and the test subjects share the same feeling?

Response: Thank you for your question. We did not go back to the Patient Advisory Council or to the test subjects after the conclusion of the project. While their support for expanding the

pilot would have been encouraging, their support could not solve the challenges encountered during the project implementation. An expansion would have required institutional support. While the project implementation provided important lessons, it did not provide a solid enough business case to justify expanding the pilot. We added this to the Program Evaluation section.

3. On page 13, in the second paragraph on the page, in the sentence beginning with "Note that the FDA does not...": this would clearly be a lesson learned and could be advocated for via Congress and the Department of Health and Human Services.

Response: Thank you for your comment. We added the following content to the Conclusions paragraph to address it: "While a change at the federal level would be ideal, advocating individual State Boards of Pharmacy to require the NDC and lot number to appear on the dispensed medication label may provide interim needed progress allowing development and deployment of solutions supporting patients' needs."

4. On page 13, in the the second paragraph, the next sentence, beginning with "The manufacturer and lot number of dispensed medications...": agreed. See previous comment.

Response: Thank you for your comment. We added content to the Conclusions paragraph to address it. See our response to comment 3 above.

Reviewer F

General Comments

The authors addressed a few of my review comments and made some text changes, but unfortunately, most of my comments—about 15 of them—remain inadequately addressed. For the comments listed again below, the authors did not appear to change anything in the manuscript to address the comment. In many cases, even the authors' reply to the reviewers did not answer the question. Also, the authors describe adding the interview guide as an appendix, but I could not find this file on the reviewer website.

Response: Regarding the interview guide: the file was uploaded on April 12 on the authors' submission website, ahead of the resubmission and recirculation of the manuscript. Right-clicking on the file name identifies the URL [6].

Specific Comments

Abstract

1. The Background section appears to be contradictory. Sentence 2 says the FDA has ways to notify health care professionals (HCPs) and patients, but then the following sentences seem to say the opposite.

Response: The FDA has public-facing resources, including the Recalls, Market Withdrawals, & Safety Alerts website [5], which can be consulted by anyone. However, as mentioned in the Abstract, prescribers are not notified individually and specifically about which of their patients are affected by a recall. We added some words to clarify the distinction between general and specific and deleted the last sentence.

3. The choice of methods doesn't seem to follow the Background section. Why was it necessary to include the clinics, rather than just work directly with the patients? Or, why was the focus on clinics, rather than pharmacies? (These comments apply to the main Introduction and Methods sections, as well.)

Response: The project's premise was that patients seek answers to recall-related questions from their HCPs. Therefore, we wished to answer the question at the levels of primary care and a cardiology clinic. We worked with the project principal investigators' clinics and patients and did so following the applicable requirements.

Introduction

2. No information is included on if/what literature explores this or similar topics.

Response: We added 4 references, 3 of them to recently published papers focused on the analysis of recall-related data (see the response to question 2 under Discussion below for summary details]

Setting

2. What was the goal sample size and rationale for the sample size? There is missing demographic information on the participating patients.

Response: As previously noted, the convenience sample was based on outreach to patients and their responses. Given the exploratory nature of the study, we feel we provided sufficient information on the patients interviewed. Power calculation and balancing the sample for certain variables were not relevant.

3. So the FHIR portion notified HCPs? The intended recipients are not specified for that part of the program.

Response: Thank you for your question. No, the HCPs did not receive any notification. The Healthy Citizens (SMART-on-FHIR) widget was launched from the MyChart message sent to the patient. We added a sentence between Figures 1 and 2 to clarify.

6. Even for a convenience sample, more details are needed on recruitment. How did you choose which patients to email? How many were emailed for recruitment? Were patients emailed and recruited sequentially, for example? Were there any exclusion or inclusion criteria for patients? Did any patients decline to participate? Why? What was the distribution of patients recruited from primary care versus cardiology?

Response: Thank you for your questions. We added some details to the manuscript in response. Established patients at the Department of General Internal Medicine (primary care) clinic who were members of the Patient Advisory Council, used MyChart, and were prescribed at least one medication received a recruitment letter. Patients at the cardiology clinic who were scheduled to see the pharmacist during a random week, who actively used MyChart (or their family members who used MyChart on their behalf), and who used at least one prescription medication were deemed eligible for the study and sent a recruitment letter. Interested patients contacted the study team to participate. Nine patients were interviewed.

7. More specific details are warranted for the methods used for qualitative analysis, such as whether an inductive versus a deductive design was used. Was a consensus approach used, or some other approach? See also the writing guidelines for qualitative studies (eg, the COREQ, SRQR). Explain also the "additional verification" process during analysis. References should be cited for the qualitative methods used in this work.

Response: Thank you for your question. The objective of the interviews was to obtain qualitative feedback from patients and identify the feedback's main themes using a consensus approach (a reference has been added to the manuscript). As detailed in the manuscript, the recordings of the interviews were transcribed and separately analyzed by 2 investigators to identify common themes, then 2 other team members verified the initial analysis. These themes are described in the manuscript in the paragraph starting with "Major thematic findings included the following..."

8. Did any of the patient sample have prior experience with MyChart, and if so, what was the average number of years of MyChart experience?

Response: The 9 patients interviewed were all MyChart users. We clarified in the manuscript that MyChart use was an inclusion criterion. We did not consider the number of years of MyChart experience as a relevant data point.

9. These statements from the text appear to be contradictory, and the meaning of the first statement especially is unclear, and seems like an opinion: "[Patients expressed that the] widget should not ask patients to discuss the information with their healthcare provider." "Patients wanted to discuss the recall with their clinicians to 'close the loop.'"

Response: The suggestion to discuss the recall information with the health practitioner was displayed on the FDA Health Citizen widget and could not be modified. We clarified this in the manuscript. The interviews confirmed that the statement led to confusion. The MyChart message recommended calling the pharmacy, as it would be the entity with more information to help the patient verify whether the recall applied to them (Figure 1).

10. The conclusion not to deploy the system seems dramatic based on the findings and makes me wonder if any other creative solutions were considered to address the concern of potential increased clinic burden. Also, how was it determined that the clinic burden outweighed safety risks to the patient? Maybe the system should only be used for certain types of recalls, for example. Or maybe the system could be integrated more with the pharmacy, rather than the prescriber's clinic, or the letter could read differently (advising against contacting the clinic unless the patient was unable to resolve the issue with the pharmacy). Or the letter could explain that only the pharmacy, not the clinic, would have a record of the patient's specific manufacturer and whether the recall applied to them.

Response: The MyChart message recommended calling the pharmacy as it is the entity with more information to help the patient verify whether the recall applied to them (Figure 1). Patients contacting the clinic received the same instructions. Most pharmacies have protocols in place to handle recalls, which may include outreach to customers. Integration with pharmacies was out of scope for this project and would have been a substantial undertaking: just the 2 clinics involved in the project serve over 37,000 patients, who fill their prescriptions in different pharmacies, from large chains to small local pharmacies to online ones. In the manuscript, we mention integrating with Surescript via claims data. However, such integration would not cover all the institution's patients, and Surescript records do not include dispensed lot numbers, so the problem of false positive notification would still exist. Should funding become available, we do not rule out exploring alternative solutions in the future. In response to a comment from the other reviewer, we added in the Program Evaluation section that while the project implementation provided important lessons, it did not provide a solid enough business case to justify expanding the pilot, which would have required institutional support.

Discussion

1. The Discussion does not mention limitations of the study design and methods.

Response: The project did not move forward for reasons that go beyond the qualitative evaluation we performed (see also our response to comment 10 under Setting, above).

2. I expected at least some comparison to other, related literature.

Response: We added references to recently published papers:

An analysis of FDA drug recall data (2012-2023) showing that drug recalls are frequent [7]. The paper talks about the causes of drug recalls and suggests improvements to the relevant FDA database, but it doesn't discuss the impact of recalls on clinical care.

A study of drug recalls in the Netherlands, which also identifies the issue that pharmacists do not always know which batch was dispensed to a patient [8].

An analysis of the clinical impact of the 2018 recalls of several angiotensin II receptor blockers and the impact in terms of medication gap and clinical outcomes [9].

These are recently published supporting articles that analyze existing data. None includes a program such as ours.

3. Is anything stamped on the medication (eg, pill) itself to indicate the manufacturer? Or is that also inconsistent across medications?

Response: What is printed on an individual solid oral-dosage-form product (eg, tablet or capsule) depends on the manufacturer complying with 21CFR206.10(a) in the Code of Federal Regulations [10]. In the United States, most solid oral-dosage-form drug products are required to have an imprint code (eg, logo, letters, numbers, or a combination). As detailed in the manuscript, at the federal level, the FDA does not have the legal authority to regulate the practice of pharmacy in any state and cannot require that specific information be placed on each prescription label that a pharmacist dispenses to a patient. Individual states (via their state boards of pharmacy) regulate what appears on the pill bottle label and on the leaflet provided to the patient alongside the medication.

4. A table of key recommendations could strengthen the paper.

Response: Thank you for your suggestion. We have added a list of lessons learned and a recommendation at the end.

5. In the last paragraph of the Discussion, there is no citation for the number of state boards of pharmacy that require the lot number to appear on the label.

Response: We added the requested details to the statement pertaining to lot number requirements and added the relevant supporting references. No peer-reviewed synthesis exists on this point, so we relied on primary legal sources. We also amended the original statement pertaining to the NDCs to clarify the rules and the issuing body: "As of August 2025, our review of state regulations identified the following jurisdictions with explicit requirements. Four State Boards of Pharmacy (Colorado, Delaware Oklahoma, Wyoming) plus the U.S. territory of Puerto Rico require the lot number to appear on the dispensed medication label [12-16]. The Pennsylvania State Board of Medicine requires the NDC to appear on the dispensed medication label if the prescriber specifies that the drug name not appear on the label [17]. The State Boards of Pharmacy of New Hampshire and Ohio, allow the use of NDC as abbreviation for the manufacturer / distributor name [18-19]."

Acknowledgments

The manuscript's contents are solely the responsibility of the authors and do not necessarily represent the official views of the US Department of Health and Human Services (HHS) or the FDA. Any policy recommendations in this manuscript are offered for discussion and do not represent HHS or FDA policy or commitments.

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
EHR: electronic health record
FDA: Food and Drug Administration
FHIR: Fast Healthcare Interoperability Resources
HCP: health care professional
NDC: National Drug Code
SRQR: Standards for Reporting Qualitative Research

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Authors' Response to Peer Reviews of "Administration Technique of Intranasal Corticosteroid Sprays Among Nepali Pharmacists: Cross-Sectional Study"

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KEYWORDS

intranasal corticosteroid spray; allergic rhinitis; device use technique; pharmacist; patient counselling, continuing pharmacy education

This is the authors' response to peer-review reports for "Administration Technique of Intranasal Corticosteroid Sprays Among Nepali Pharmacists: Cross-Sectional Study."

Round 1 Review

Reviewer AH [1]

General Comments

This paper [2] addresses an important gap by evaluating pharmacists' proficiency in demonstrating intranasal corticosteroid technique, using a standardized 12-step checklist with 5 critical steps. The sample size (n=365) is reasonable for a local study, and the use of multivariate logistic regression and Chi-square automatic interaction detection decision tree analysis adds analytical depth. The findings highlight systemic issues, such as inadequate training and curriculum gaps, which could inform policy changes to improve allergic rhinitis management and reduce adverse effects like epistaxis.

Specific Comments

Major Comments

1. Simple random sampling was used for pharmacies, but details on how wards were selected or how pharmacists within pharmacies were approached are vague. Please supplement and elaborate on further details of the randomization. More information on such would help lower the selection bias (eg, busier or more accessible pharmacies might be overrepresented).

Response: Thank you for this valuable comment. We agree that additional clarification regarding the sampling process is important to demonstrate methodological rigor and minimize concerns about selection bias. In the revised manuscript, we have now expanded the description of the sampling procedure. We have clarified how the wards in Kathmandu district were included, how the list of pharmacies was prepared, how simple random sampling of pharmacies was actually conducted, how pharmacists within each selected pharmacy were approached, and how the accessibility or busyness of pharmacies was handled.

2. The questionnaire's validity is only face-validated by experts, with no content or construct validity testing mentioned. Reliability was assessed via Cronbach alpha (0.758) on a small pilot (n=15), which is acceptable but not robust. The cutoff for "adequate" proficiency (>6/12 marks) is based on the median score and expert opinion, which feels arbitrary and not clinically validated. Why not base it on critical steps alone, given their emphasis on efficacy and safety? Only 6% performed all 5 critical steps correctly, yet 47% were deemed "adequate" overall. This discrepancy suggests the threshold may be too lenient, masking true incompetence in high-impact areas like directing the nozzle away from the septum (to prevent epistaxis)

or exhaling through the mouth (to optimize deposition). Please address these in the Discussion section.

Response: Thank you for this comment. The 12-step intranasal corticosteroid checklist was developed from established international guidelines (eg, ARIA, Benninger et al [3], NHS), ensuring content relevance. As this tool assesses observed procedural technique, construct validity testing is not applicable. We have clarified this and acknowledged the limitation in the Discussion.

We agree the pilot sample was small. Cronbach alpha of 0.758 represents acceptable internal consistency for an observational checklist. The limitation has now been explicitly acknowledged.

The score of more than 6 is not arbitary; we conducted a sensitivity analysis using alternative cutoffs (>5 and >7). Receiver operating characteristic analysis could not be performed because the total score forms the derived outcome without an external gold standard. Sensitivity analysis showed that (1) predictors remained stable and significant at >5 and >6 and (2) the >7 cutoff produced unstable models due to sparse cell counts. Thus, the >6 threshold is empirically supported, aligns with >50% competency, the median distribution, and expert opinion. Relevant text was added to the Methods and Discussion.

Only 6% of participants completed all critical steps; using this as the cutoff would create extremely low event counts and make regression analysis unreliable. Moreover, international guidelines require all 12 steps for complete patient counseling. We expanded the Discussion to highlight the clinical significance of poor critical-step performance.

3. Self-reported variables (eg, counseling frequency, use of materials) are prone to recall or social desirability bias, especially in an in-person interview setting. Please supplement these in the Discussion section.

Response: Thank you for the concern. The risk of recall or social desirability bias is mentioned in the Discussion section.

4. The multivariate binary logistic regression identifies associations (eg, male gender, older age, higher qualifications linked to better proficiency), but potential confounders like pharmacy type (independent vs chain) or workload details are not controlled for. Odds ratios are extreme in places (eg, BPharm holders 97% less likely to perform inadequately, or frequent counselors 11 times more proficient), which may stem from small subgroups or multicollinearity.

Response: In Nepal, most of the pharmacies are independently owned and very few are chain pharmacies. In this study, only independent pharmacies were used, therefore pharmacy type is not one of the potential confounders in this study. However, workload details as potential confounders were not measured, which may have partly contributed to the large adjusted odds ratio of some predictors. It is mentioned in the Discussion.

5. Gender differences (males ~2 times more proficient) were found but underlying factors were not explored (eg, access to workshops, cultural biases). Please elaborate more or address the potential underlying factors in the Discussion section.

Response: We thank the reviewer for highlighting this point. Additional contextual explanation has been added to the Discussion to address potential underlying factors.

6. "Educational materials" are linked to better proficiency, but what constitutes these (eg, leaflets, videos)? Please specify for readers to enhance the proficiency on applying the study's results.

Response: Thank you for the concern. The term "educational materials" mean the leaflet and now it is clearly mentioned in the Results.

7. Reference 16 has the wrong format for the volume, issue, and page numbers:

Al-Taie A. A Systematic Review for Improper Application of Nasal Spray in Allergic Rhinitis: A Proposed Role of Community Pharmacist for Patient Education and Counseling in Practical Setting. Asia Pacific Allergy. 2025:10 - 5415.

The full information from PubMed is as below:

Al-Taie A. A systematic review for improper application of nasal spray in allergic rhinitis: A proposed role of community pharmacist for patient education and counseling in practical setting. Asia Pac Allergy. 2025 Mar;15(1):29 - 35. doi: 10.5415/apallergy.0000000000000173. Epub 2025 Jan 13. PMID: 40051424; PMCID: PMC11882221.

Therefore, "2025:10 - 5415" should be "2025 Mar;15(1):29 - 35."

Please revise the whole reference list to see if any other typos exist.

Response: Thank you for the concern. All the references have been revised.

Reviewer AL [4]

General Comments

This is an important and well-written study. My suggestions are listed below.

Specific Comments

There are some problems with language and with unnecessary capitalization of words.

Page 3: INCS sprays should be defined in full on first mention in the text.

Response: Thank you for the concern. INCS spray is defined in full on first mention.

Page 8: Can details of the ethical committee that provided the approval be provided? Was the informed consent obtained in writing?

Response: The ethical committee details are now added in the manuscript. Yes, written informed consent was obtained from the participants.

Scoring system: Should the crucial steps not be provided with greater marks compared to the other steps?

Response: We thank the reviewer for this insightful suggestion. Although the five steps marked as "critical" have a greater clinical impact on efficacy and safety, we deliberately assigned equal weight (1 mark per step) to all 12 steps to maintain consistency with previously published studies that used similar checklist-based scoring systems and to avoid introducing subjective weighting without formal validation.

To address the clinical importance of critical steps, we analyzed them separately and reported their performance independently. Notably, although 47.1% of pharmacists met the overall adequacy threshold, only 6% correctly demonstrated all five critical steps, highlighting a substantial gap that would have been masked even if weighted scoring were used.

We agree that weighted scoring systems may better reflect clinical risk; however, such systems require prior validation. We have therefore added this point to the Limitations section and recommend weighted or competency-based scoring models in future studies.

Page 17: Please explain the classification tree (Chi-square automatic interaction detection method) for the benefit of the readers.

Response: We thank the reviewer for this helpful suggestion. We have now added a brief explanation of the classification and regression tree analysis using the Chi-square automatic interaction detector method in the Statistical Analysis and Results sections. The revised text explains the purpose of the method, the basis of variable splitting, and how the resulting tree should be interpreted. This addition is intended to improve clarity and accessibility for readers who may be unfamiliar with decision tree–based methods.

Page 17: "This research is one of a kind, conducted in Nepal." Can this sentence be modified?

Response: Thank you for the insightful suggestion. The sentence has been modified.

Page 19: Instead of continuing medical education (CME), continuing pharmacy education (CPE) may be a better term.

Response: Thank you for the suggestion. Continuing pharmacy education (CPE) has been used instead of continuing medical education (CME) in the manuscript.

Page 20: What educational aids are you referring to?

Response: Educational aids means the leaflets and that has been clarified in the manuscript now.

Are the educational leaflets available in the Nepali language?

Response: The educational leaflet was available in the English language and the pharmacist used it for reference while counseling the patients.

Page 20: "In our study, both the increasing age (> 26 y old) were significantly associated with improved INCS [intranasal corticosteroid] counseling proficiency." This sentence mentions both but then highlights only one factor.

Response: Thank you for the suggestion. It was a typing error in the manuscript and has been corrected.

Was this study conducted only in Kathmandu city and not in Lalitpur or Bhaktapur?

Response: This study was extensively conducted only in Kathmandu district.

Page 21, Limitations section: Some of the findings may be extreme due to small subgroups or model overfitting. Can this be explained?

Response: Thank you for the suggestion. This has been explained in the Limitations section.

Different fonts are used in different locations, and this should be corrected.

Response: Thank you for the comment. Font size has been corrected.

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Automating Individualized Notification of Drug Recalls to Patients: Complex Challenges and Qualitative Evaluation

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Companion article: https://med.jmirx.org/2026/1/e82609

Abstract

Background: Consumer-level drug recalls usually require action by individual patients. The Food and Drug Administration (FDA) has public-facing outlets to inform the public about drug safety information, including all recalls, but individual consumers may not be aware of them. And there is no system in place to notify individual prescribers which of their patients are affected by a specific recall.

Objective: We aimed to leverage the FDA's Healthy Citizen prototype web-based software platform, which provides users with information about recalls, to automatically notify patients of relevant recalls.

Methods: We developed and evaluated an electronic notification system in the primary care and cardiology practices at a large, urban, academic medical center. The health care portal scanned the FDA Healthy Citizen application programming interface nightly to detect new recalls, identified patients who had those medications in their electronic health record (EHR) medication list, and sent them a message through the EHR patient portal with a link to a customized FDA information display. Using structured interviews, we assessed qualitative feedback on the system and portal messaging from a convenience sample of 9 patients.

Results: The system was technically functional, but it was not possible to trace a medication prescription from the EHR to specific lot numbers dispensed to that patient by a community pharmacy. The qualitative feedback obtained from patients showed convergence of topics.

Conclusions: Lack of an accurate electronic audit trail from prescription to dispensed medication precludes clinical deployment of automated drug recall notification.

(JMIRx Med 2026;7:e68345) doi:10.2196/68345

KEYWORDS

notification system; drug recalls; patient safety; medication; electronic health records; prescriptions; decision support

Introduction

Background

In the United States, the Food and Drug Administration (FDA) is responsible for assuring the safety and efficacy of marketed drugs. When a safety concern arises on a marketed drug, communicating this information to patients is essential, and timely clinical action by prescribers is often required. Yet, patients and prescribers often lack relevant, timely information, leaving patients and health systems unable to efficiently manage drug recalls and their impacts. Recognizing this problem, the FDA developed prototype technology for patients and health systems to automatically be notified of drug recalls through their health care portals as part of the FDA's Healthy Citizen prototype platform that seeks to allow "citizens and those who care for them, research organizations, and FDA to communicate and collaborate in a single, seamless environment connected through the healthcare portal and leveraging the trusted relationships between providers and patients to improve public health outcomes" [1].

Drug Recall Process

Firms, including manufacturers and own-label distributors, can initiate a recall, either on their own or in response to an FDA recommendation, request, or order. Common reasons for recalls include contamination, mislabeling, adverse reactions, defective products, and incorrect potency [2,3]. The FDA works with firms as they develop their recall strategy, which is dependent on a variety of factors, including, but not limited to, the product's degree of hazard, the ease of identifying the product, and the extent of distribution. Depth of recall is one component of this strategy: consumer-level recalls should be extended to consumers and patients; retail-level recalls affect community pharmacies and health care providers; and wholesale-level recalls affect manufacturers and distributors.

For consumer-level recalls, which were the focus of this project, consumers may learn of a recall through FDA.gov [4], news media, or notification from the recalling firm or pharmacy. (Most pharmacies have protocols in place to handle recalls, which may include outreach to customers.) Consumer notifications often recommend that patients consult their health care provider about the best course of action. However, recalls often affect only certain lots of pills, and prescribers have no way of knowing the lot number of the medication dispensed to the patient and therefore whether the patient is affected. The patient often cannot identify the lot number, either, as most dispensing pharmacies are not required to document the lot number on pill bottle labels (see Principal Findings section for details). Thus, if patients contact their health care providers about a recall, the only action providers can take is to redirect patients to their pharmacy. The pharmacy then either replaces the pills with those from an unaffected lot or, if no substitute is available, notifies the prescribing clinician to issue a new prescription for a different medication, dosage, or formulation.

This partnership with the FDA aimed to address the inefficiencies in recall notification by demonstrating timely, fully automated, and individualized communication of drug recalls and recommended actions to patients.

Methods

Study Setting and Participants

The University of California, San Francisco (UCSF), an academic medical center, partnered with the FDA [5] to demonstrate use of Healthy Citizen tools to automate individualized drug recall notifications to outpatient primary care and cardiology patients.

We developed an electronic notification system and conducted this study in the Division of General Internal Medicine (DGIM) and Division of Cardiology at UCSF, a large, urban, academic medical center in San Francisco, California. The DGIM primary care clinic serves 25,000 patients with approximately 70,000 visits yearly. The cardiology clinics serve over 12,000 patients with approximately 30,000 visits yearly. The clinics use the Epic electronic health record (EHR) with the MyChart patient portal. At the time of the study, approximately 45% of patients had actively used MyChart at least once.

We created and tested the notification system within Epic's ACE6 development environment, with the intent to migrate it to production after successful testing. The project team comprised clinicians and programmers from the medical center, FDA leaders from the Office of Health Informatics and other sections, and developers of the Healthy Citizen platform. For testing purposes, fictitious patients were created in the Epic ACE6 environment with medication lists that contained prescriptions matching fictitious medication recalls issued by the FDA.

The prototype system was shown to a convenience sample of 9 patients via remote videoconferencing to obtain initial formative feedback.

Ethical Considerations

Ethical approval for this program evaluation was obtained from the UCSF Institutional Review Board (19 - 27668). Informed consent was obtained from each participant via electronic signature before the interview. Interviews were conducted by 2 investigators (MG and RP). Transcripts were analyzed for common themes by the same, with additional verification by 2 other investigators (SC and IS). Transcripts were stored in a secure location behind an institutional firewall. No identifying data were shared or presented beyond summary statistics (number and gender of patients). Upon completion of the interview, each patient was paid US $25 for their time.

Results

Program Description

The notification system comprised two major technical parts. The first part, within the medical center's firewalls, checked for new consumer-level drug recalls and notified affected patients via MyChart (see the EHR Build section below). The second part was the FDA's Healthy Citizen prototype platform, which provided an application programming interface (API) for external systems to request the latest drug recall information and mechanisms to launch a widget displaying details about a specific recall (see the Healthy Citizen Build section below).

The widget was a SMART-on-FHIR software module that could be embedded into and accessed within an EHR without the need for any additional sign-in.

EHR Build

The EHR build had three major parts: (1) checking for new drug recalls; (2) matching recalls to the patient medication lists; and (3) preparing and sending personalized MyChart notifications to patients. Each part proved extremely challenging to build for technical and data availability reasons.

First, the system issued a nightly call to the Healthy Citizen API to retrieve the National Drug Codes (NDCs) of newly recalled drugs. The next step, matching recalls to a patient's EHR medication list, can result in false negatives and false positives. False negatives can occur if a patient's prescription is missing from the medication list [6], or if the algorithm fails to detect a true match. False positives can arise from two inaccuracies. Crucially, EHR medication lists contain the *prescribed* drug, not the *dispensed* drug. To identify a prescribed drug, Epic uses RxNorm codes that do not include the manufacturer name. To identify recalled drugs and their manufacturers, the FDA uses NDCs, which are unique, 3-segment numbers that identify a drug's labeler (ie, manufacturer or distributor), product, and trade package size [7]. Thus, for example, the NDC from a lisinopril recall from a specific manufacturer will match the RxNorm code for all lisinopril prescriptions of the same strength, regardless of manufacturer. This will erroneously identify patients who were prescribed lisinopril but were not dispensed pills from the affected manufacturer. Secondly, recalls often involve only specific lots, information that is unavailable in the EHR, thereby contributing to false positives, as discussed above.

The third part of the EHR build was to send a MyChart notification to patients once a match was made, alerting them that they may be taking a recalled medication (Figure 1).

The Medication Recalls link led to the FDA Healthy Citizen's display widget, launched as a new window within MyChart showing details of the matched recall, including affected manufacturers (Figure 2). Because the matching algorithm could not restrict matches to affected manufacturers, the MyChart message asked patients to compare the manufacturer name on their pill bottle's label to the manufacturer or manufacturers listed in the FDA informational display and to call their pharmacy if it matched. The patient advisory council of the primary care clinic provided input on the wording and endorsed the importance of the project aims.

Figure 1. MyChart notification of potentially relevant recall.

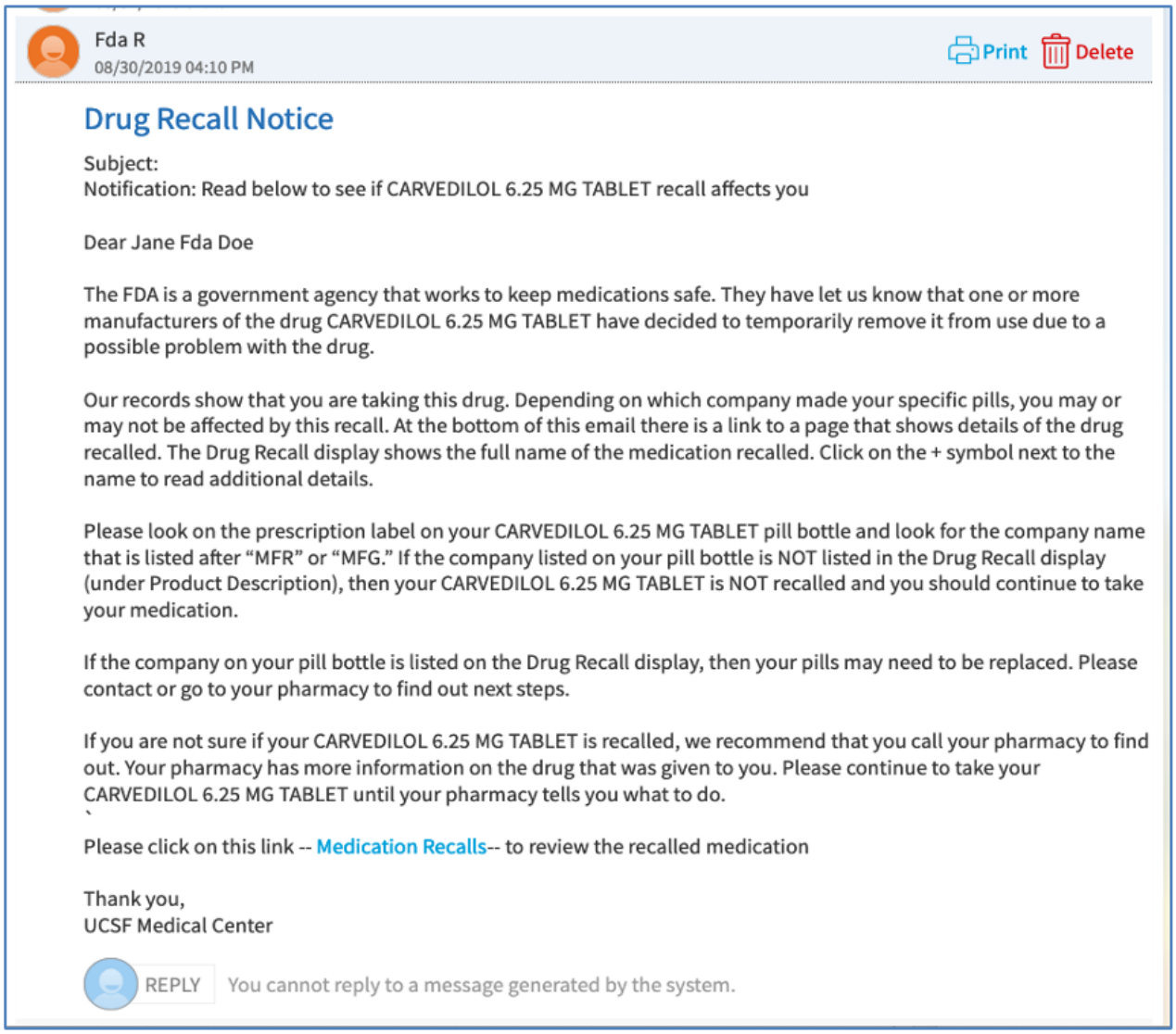
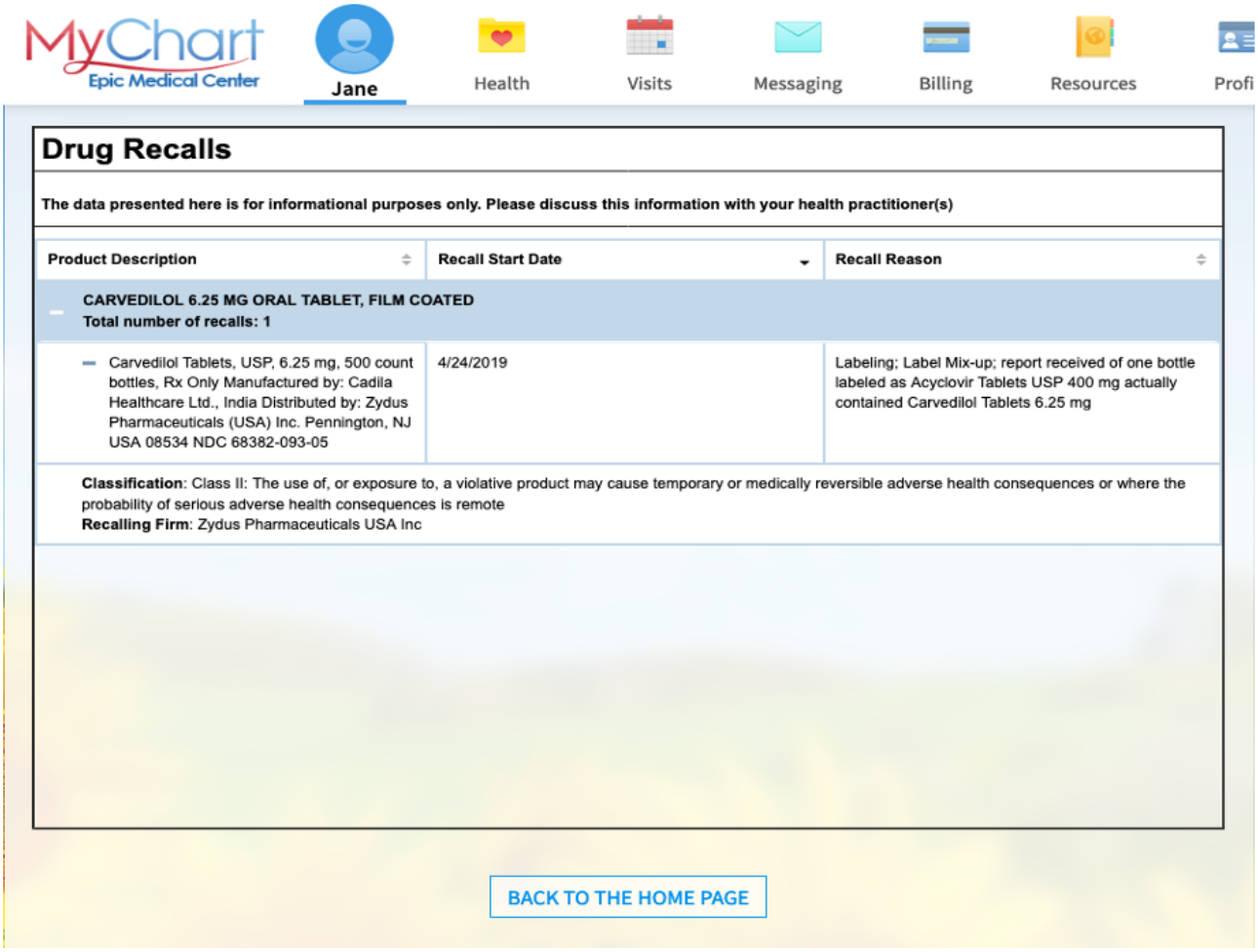


Figure 2. Food and Drug Administration Healthy Citizen information display widget showing official information about a drug recall.



Healthy Citizen Build

Substantial technical work was performed on the Healthy Citizen platform to satisfy the use case needs. For example, technical and internal FDA administrative changes were required to make the depth of recall (ie, retail or consumer level) searchable and to distinguish between new and ongoing recalls. The SMART-on-FHIR widget needed to be available on Epic's App Orchard, and modifications were required for the widget to be called by and launched within Epic. The contents of the widget display were modified to exclude information not relevant to patients, such as the status of the recall (eg, whether it was ongoing or completed), or to move it from the main display to the Additional Details section. The text immediately below the title could not be modified.

Program Evaluation

The system was able to automatically detect a new fictitious medication recall using the Healthy Citizen API, compare and detect matches to each (fictitious) patient's list of prescribed medications, send a MyChart message to affected (fictitious) patients, and launch a display for the correct recall or recalls. The system responded correctly to test patients with zero to multiple affected medications.

Established patients at the primary care clinic who were members of the patient advisory council, used MyChart, and were prescribed at least one medication received a recruitment letter. Patients at the cardiology clinics who were scheduled to see the pharmacist during a random week, who actively used MyChart (or their family members who used MyChart on their behalf), and who were taking at least one prescription medication were deemed eligible for the study and sent a recruitment letter. Interested patients contacted the study team to participate.

We obtained qualitative feedback by interviewing a convenience sample of 9 patients (5 female, 4 male). Two of the 9 participants had personal experience with recalls. Participants were interviewed individually using Zoom (Zoom Communications, Inc). During the session, they were presented with a scenario for fictitious patient Jane Doe, who was prescribed carvedilol (6.25 mg). Using structured interviewing techniques, we evaluated participants' understanding of the MyChart message, widget, and example pill bottle label. Throughout the process we asked for descriptive feedback. Recordings of the interviews were transcribed and separately analyzed by 2 investigators (MG and RP) for common themes [8], with additional verification by SC and IS.

All 9 participants understood the purpose of the MyChart notification message but thought it was too wordy. All 9 were able to identify the medication manufacturer on the example pill bottle label. Only 2 would have clicked on their own on the link at the bottom of the MyChart message to launch the widget; the other 7 needed the interviewer's prompting and guidance

to do so. As advised by the MyChart message, all 9 users would have contacted their pharmacist, but 5 of the 9 would also have contacted their doctor's office, as advised by the widget. Given the choice, all 9 would have liked to receive MyChart notification of potential drug recalls.

Major thematic findings included the following: (1) Patients appreciated being notified of recalls by their clinic, even though their actual medication may not have been affected by the recall, because they trusted the clinic, and the notification showed that the clinic was aware of patient medication issues. (2) Patients saw communicating through the MyChart patient portal as a trusted, efficient, and reliable notification method. Mailed letters can be ignored, and several users said they did not answer phone calls from unknown phone numbers (eg, their pharmacy). (3) Patients suggested that the widget content should be displayed directly in the MyChart message rather than in a new window. (4) Patients felt that the widget itself should be redesigned to more directly meet patient information needs (much of the widget content was either confusing or irrelevant to patients, eg, recall start date, manufacturer address), that the recall reason was appreciated but unnecessary, and that the widget should not ask patients to discuss the information with their health care provider. (5) Patients wanted to discuss the recall with their clinicians to "close the loop."

The project team concluded that operational deployment of this system may lead to unnecessary and unacceptable patient anxiety generated by false positive notifications. In addition, because patient feedback suggested that patients would contact their clinicians regardless of the advice to contact their pharmacy, the system was likely to increase staff burden for responding to patient inquiries. While the project implementation provided important lessons, it did not provide a solid enough business case to justify expanding the pilot, which would have required institutional support. We therefore decided not to proceed with implementation of the FDA drug recall notification system into clinical care.

Discussion

Principal Findings

Drug recalls are an ongoing challenge in the United States [3] and other countries [9]. According to an analysis of FDA recall data, between 2012 and 2023 there were on average 330 recalls per year [3]. When, in 2018, several angiotensin II receptor blockers (prescribed to treat hypertension, heart failure, and chronic kidney disease) were recalled for carcinogenic impurities, the availability of treatments in the same or similar drug class facilitated patients' transition to alternatives [10]. Sustained media attention highlighted communication needs and challenges among the parties impacted.

Patients and clinicians need an accurate system for identifying which patients are affected by which drug recalls and acting on them in a timely and appropriate manner to prevent patient harm and erosion of trust in prescribers and the health care system.

This project demonstrated the technical and clinical feasibility of using the FDA's Healthy Citizen drug recall tools to automatically alert patients, via Epic's patient portal MyChart, to relevant drug recalls. While our project was technically successful, it revealed substantial challenges to responding to drug recalls. Chiefly, while patients want and expect their prescriber to be aware of, and involved in, responding to a drug recall, prescribers have no easy access to the manufacturer and lot number of the actual medication dispensed to their patients. Without these details, health systems cannot accurately target patients and false positive notifications are inevitable. A partial technical solution could be to access Surescripts records, which include the NDC for dispensed drugs as reported to Surescripts via claims data. However, only 70% of patients at UCSF Medical Center use a Surescripts-participating pharmacy, and Surescripts records do not include dispensed lot numbers, such that false positive recall notifications would still be an issue.

Our project showed that a strong case can be made for requiring each pill bottle to include on its label the lot number and NDC of the pills (which links to the manufacturer, labeler, or distributor), so that patients could definitively determine if a recall affected them. Current federal regulation allows such information to appear on an internal leaflet or a label on the outer carton or wrapper of manufactured medications [11], which many patients discard even if the pharmacist includes them with the dispensed medication. As of August 2025, our review of state regulations identified jurisdictions with explicit requirements. Only four state boards of pharmacy (Colorado, Delaware, Oklahoma, and Wyoming), plus the US territory of Puerto Rico, require the lot number to appear on the dispensed medication label [12-16]. In addition, only three state boards of pharmacy (Pennsylvania, New Hampshire, and Ohio) have regulations about the NDC appearing on the dispensed medication label [17-19]. The Pennsylvania State Board of Medicine requires the NDC to appear on the dispensed medication label if the prescriber specifies that the drug name *not* appear on the label [17]. The state boards of pharmacy of New Hampshire and Ohio allow the use of the NDC as an abbreviation for the manufacturer or distributor name, though they do not require it on every dispensed medication label [18,19]. The FDA does not have the legal authority to regulate the practice of pharmacy in any state and therefore cannot require that the lot number and NDC (or anything else, including the name of the drug) be placed on each prescription that a pharmacist dispenses to a patient. The manufacturer and lot number of dispensed medications should routinely be available electronically to prescribing clinicians via standard APIs so that health systems can meet patient expectations that they are trusted guides in properly responding to drug recalls. Policy and data infrastructure changes are required at the regulatory, health IT, and consumer pharmacy levels before automated recall notification can be widely deployed.

Conclusions

The need of patients and clinicians to identify applicable drug recalls and appropriately act on them is currently unmet. Through our project we learned several lessons, which in some cases can be generalized beyond its scope: (1) Patients appreciated receiving a notification showing that the clinic was aware of the patient's medication issues. (2) The MyChart patient portal was seen as a trusted and reliable notification method. (3) Patients preferred the notification content to be

displayed directly in the MyChart message rather than in a new window. (4) Patients considered that the content of the notification should directly address patient information needs, avoiding content that is not strictly necessary. (5) Prescriptions being a sensitive topic, patients wished to discuss the recall with their clinicians, even when directed to contact the dispensing pharmacy.

Our project showed that access to the manufacturer and lot number of the drug dispensed via standard APIs is a requirement for the development and deployment of technical solutions that implement accurate automated recall notifications to patients. While a change at the federal level would be ideal, advocating for individual state boards of pharmacy to require the NDC and lot number to appear on the dispensed medication label may provide needed interim progress for allowing development and deployment of solutions supporting patients' needs.

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Conflicts of Interest

None declared.

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Abbreviations

API: application programming interface
DGIM: Division of General Internal Medicine
EHR: electronic health record
FDA: Food and Drug Administration
NDC: National Drug Code
UCSF: University of California, San Francisco

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Administration Technique of Intranasal Corticosteroid Sprays Among Nepali Pharmacists: Cross-Sectional Study

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Abstract

Background: Allergic rhinitis is a common condition affecting up to 40% of people worldwide, with a notably high prevalence in South Asia. The primary treatment for moderate to severe allergic rhinitis is intranasal corticosteroid sprays (INCS), the use of which is typically demonstrated to patients by registered pharmacists. However, many patients do not use these sprays correctly.

Objective: This study evaluated the proficiency of pharmacists in demonstrating the correct technique for using INCS and the factors contributing to proper technique.

Methods: In a cross-sectional survey of 365 registered pharmacists in the Kathmandu Valley, Nepal, a trained observer used a standardized 12-step checklist to assess each pharmacist's technique for using INCS. The 12-step checklist was created after studying international guidelines, studies conducted in Nepal, international research articles, and instructional pamphlets. Simple random sampling was done to collect the data from community pharmacies in Kathmandu district. Demographics, education, experience, previous training, and instructional materials use were recorded. A total of 12 marks were awarded for all 12 steps, with one mark given for each step. Proficiency was classified as "adequate" if more than 6 marks were obtained.

Results: Out of 365 pharmacists, 239 (65.5%) were male and 126 (34.5%) were female. Overall, 216 pharmacists (59.2%) were aged 26 years or younger and 235 pharmacists (69.9%) held a diploma in pharmacy. We found that 193 (52.9%) pharmacists demonstrated inadequate technique, while only 172 (47.1%) showed adequate skill overall. However, only 22 pharmacists (6%) demonstrated all 5 critical steps. The likelihood of providing appropriate counseling on the use of INCS was significantly correlated with multiple independent factors. Those with a diploma in pharmacy had a 97% lower likelihood of providing appropriate counseling compared with those with a bachelor's degree in pharmacy and above (P<.001). Pharmacists who perform counseling sessions 1 - 4 times per week had 11-fold greater odds of doing so correctly compared with those who do not (P=.002). Pharmacists who do not use educational leaflets were 96% less likely to provide adequate counseling (P= .005) . Similarly, pharmacists under the age of 26 are 89% less likely than older pharmacists to provide adequate counseling (P=.001). It is interesting to note that men were found to have almost 2.3 times higher odds of providing appropriate counseling than women (P=.02).

Conclusions: More than half of the registered pharmacists in Nepal demonstrated inadequate technique when using INCS. The inadequate patient counseling on INCS use can significantly increase the risk of adverse drug reactions and reduce the efficacy of the therapy. Thus, there is a strong need for educational interventions and policy change for improved proficiency.

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KEYWORDS

intranasal corticosteroid spray; allergic rhinitis; device use technique; pharmacist; patient counselling, continuing pharmacy education

Introduction

A chronic inflammatory condition of the nasal mucosa, allergic rhinitis (AR) is brought on by immunoglobulin E–mediated responses to allergens breathed in. There are many causes of AR, including pollen, dust mites, cockroach waste, animal dander, fumes and odors, changes in environment, smoke, and certain foods or spices. The most common symptoms of AR are sneezing; stuffy nose; runny nose; itchy nose, throat, eyes, and ears; nosebleeds; clear drainage from the nose; snoring; and breathing through the mouth.

AR affects 10% to 40% of the world's population, and its prevalence is increasing in many countries [1,2]. AR and other allergy disorders are also common in Nepal and the surrounding South Asian nations. A recent school-based study in Nepal, for example, found rhinoconjunctivitis symptoms in 28% of children [3]. AR was responsible for almost 25% of allergy illnesses in Nepal's Gandaki Province [3]. Adolescent AR prevalence in India is estimated at 22%, whereas in adults it was found to be 11% among the general population and 33.3% in asthmatics [4,5]. Similarly, a large-scale study conducted in Europe discovered that up to 20% of the population is impacted by AR [6]. The prevalence of AR in the United States is slightly lower (7.7% in adults and 7.2% in children) [7].

Therefore, the treatment of AR is very important as it impacts daily life activities. The objective of AR treatment is to control the disease. Antihistamines, leukotriene receptor antagonists, azelastine, and intranasal corticosteroid sprays (INCS) are used for treating AR according to the Allergic Rhinitis and its Impact on Asthma guidelines 2019 [8]. Effective pharmacotherapy is crucial for symptomatic control of AR. INCS are the most potent medications for moderate to severe AR and are recommended as first-line therapy [9]. When used correctly, INCS reduce nasal congestion, rhinorrhea, sneezing, and itching by suppressing mucosal inflammation.

The most common adverse drug reactions to INCS include dyspnea, anosmia, ageusia/dysgeusia, epistaxis, and headache [10]. A study conducted at the ear, nose, and throat outpatient clinic at Aberdeen Royal Infirmary found that 15.5% reported epistaxis due to an ipsilateral hand technique [11]. Similarly, a study in Thailand discovered a 3.6 times higher risk of adverse events in patients who did not point the tip of the spray away from the nasal septum [12]. Maintaining a neutral head position and exhaling through the mouth are crucial for proper drug disposition and enhanced efficacy [13]. Therefore, using the correct technique is vital for better efficacy and a reduced risk of side effects. Standard guidelines recommend instructing patients to shake the spray, remove the dust cap, blow the nose, hold the spray bottle while pointing the tip of the nozzle up with the hand, place the index and middle finger on the pusher and the thumb at the bottom of the spray bottle, maintain a neutral head position, insert the tip slightly upward and laterally (away from the septum), close the opposite nostril, inhale gently while actuating the spray, then exhale through the mouth, wipe the nozzle with a tissue or hankerchief, and replace the cap [12,14].

However, a study conducted by Rattanawong et al [12] found that only 4% of patients performed all 12 steps, while only 29% completed all the crucial steps. Similarly, a study by Gurung et al [15] in Nepal revealed that only 7.2% of patients executed all the steps correctly, and 18.2% managed to perform all 5 critical steps accurately (blow the nose, maintain a neutral head position or slightly tilt the head forward, point the tip slightly outward away from the septum, squirt the spray into the nose while breathing in, breathe out through the mouth). A systematic review indicated that approximately 73% of patients did not receive proper advice regarding INCS [16].

Health care professionals, especially pharmacists, are responsible for counseling patients regarding the drugs they dispense. Given this context, it is essential to assess how well Nepali registered pharmacists themselves understand and can demonstrate correct INCS technique. No prior studies have examined this. By identifying gaps in pharmacist knowledge and technique, targeted interventions (eg, curriculum changes or training modules) can be designed to improve AR care. This study therefore evaluated the proficiency of registered pharmacists in Kathmandu Valley in demonstrating INCS administration and analyzed professional factors associated with adequate technique.

Methods

Study Design and Study Period

A cross-sectional observational study was performed from November 1, 2023, to May 28, 2024, through interviews of registered pharmacists. They answered a semistructured questionnaire containing questions about their sociodemographic information, professional details, and INCS counseling steps. STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) principles were adhered to in the study's reporting [17,18].

Study Population and Study Site

The sample was selected from pharmacists registered at the Nepal Pharmacy Council working at community pharmacies registered at the Department of Drug Administration (DDA) in Kathmandu, Nepal. Being Nepal's capital, Kathmandu is a heavily populated city. The respective site had a large number of community pharmacies, about 4000, with many registered pharmacists [19].

Sampling Method

Simple random sampling of the community pharmacies in different wards of Kathmandu district, Nepal, was done using Statistical Package for Social Sciences software (version 26; IBM Corp). The details of all the registered community pharmacies were obtained from the DDA database. No ward-level sampling was performed to avoid geographical clustering.

This cross-sectional study identified potential participants from the registered pharmacists working at community pharmacies. If the community pharmacy had more than one pharmacist, one pharmacist was selected for the study randomly. If the community pharmacy was closed or the pharmacist was not available, a total of three visits were made on different dates; if a pharmacist was still not available, another pharmacy was

selected based on a pregenerated reserved list of random samples. These potential participants were approached and the study's purpose, procedures, and potential risks and benefits were explained to them. The same interviewer interviewed all the participants to overcome interobserver variability in participants' responses.

Sample Size

The survey study was completed using the Raosoft sample size calculator to capture the appropriate sample size [20]. A minimum of 363 samples was required for a 95% confidence interval and a 5% margin of error for the population distribution of 21,000 registered pharmacists at a 40% response distribution [21]. Thus, a total of 365 registered pharmacists participated in this study.

Measures

After the pharmacist's sociodemographic and professional information were obtained through interviews, the 12-step nasal spray application technique as given in Textbox 1 was demonstrated by the participant and examined by the researcher [12,13,22-24]. Each correct step was assigned 1 mark, while incorrect or missed steps were assigned 0 marks. Hence, the maximum score obtained was 12 marks. Five steps in INCS counseling (indicated in Textbox 1) were considered critical based on their impact on patient outcomes and the risk of adverse drug reactions. The median value of the total marks scored was 6.

Textbox 1. Steps for the administration of intranasal corticosteroid sprays.

1. Shake the spray in a vertical plane.
2. Remove the dust cap.
3. Blow the nose (critical).
4. Hold the spray bottle, pointing the tip of the nozzle up with the hand.
5. Place the index and middle finger on the pusher and the thumb at the bottom of the spray bottle.
6. Put the tip of the nozzle into one nostril and close the other side.
7. Maintain a neutral head position or slightly tilt the head forward (critical).
8. Point the tip slightly outward, away from the septum (critical).
9. Squirt the spray into the nose while breathing in (critical).
10. Breathe out through the mouth (critical).
11. Wipe the nozzle with a tissue or handkerchief.
12. Replace the cap.

Determination of the Cutoff Score

To determine the cutoff score, a sensitivity analysis was conducted for alternate cutoffs (ie, >5 and >7). The direction and significance of the main predictors remained stable at >5 and >6, indicating robustness of the findings as shown in Table S1 in Multimedia Appendix 1. The >7 cutoff produced unstable estimates due to small cell sizes. Based on a study conducted by Kc et al [25], expert suggestions, the median value, and sensitivity analysis, more than 6 marks was established as the cutoff score. Therefore, anyone with a score higher than 6 marks was categorized as performing adequately, and anyone with marks equal to or less than 6 was categorized as performing inadequately.

Reliability and Validity

The initial questionnaire was validated by a panel of subject experts, composed of advisors, professors, and teachers, for correctness, clarity, appropriateness, and jargon use. This validation was conducted using face validity approaches. An interrater reliability test was conducted on 15 participants and found a Cronbach α value of 0.758.

Inclusion and Exclusion Criteria

This study only took into account pharmacists aged 18 years and above who were registered with the Nepal Pharmacy Council and employed in community pharmacies. Participants needed to have a Diploma in Pharmacy (DPharm), Bachelor of Pharmacy (BPharm) degree, Doctor of Pharmacy (PharmD) degree, or Master of Pharmacy degree. Participants needed to have a minimum of 1 year of experience. No unregistered pharmacists, pharmacy students, or interns were considered for this study.

Data Collection Procedure

The essential information was then gathered from participants using a semistructured questionnaire administered through an in-person interview. A standardized protocol was followed during interviews. Prior to their enrollment in the study, all participants were informed of its purpose, and their consent was acquired.

Statistical Analysis

Using Microsoft Excel (Microsoft Corp) and Statistical Package for Social Sciences software (version 26; IBM Corp), the gathered data were analyzed. Factors related to the administration technique were evaluated using multivariate binary logistic regression to understand their independent impact. The decision tree analysis was done using Chi-square automatic interaction detector to explore hierarchical relationships and interactions among predictors of INCS

counseling proficiency and to complement the findings of binary logistic regression. When $P<.05$ and the confidence level was 95%, it was deemed statistically significant.

Ethical Considerations

Ethical approval reference number 210 (6-11) E2, 080/081, was provided by the institutional review committee of the Institute of Medicine, Tribhuvan University, before the commencement of the study. Written informed consent was provided by participants before any data were collected from the study site (Multimedia Appendix 2). The identity of participants will not be revealed in any information that will be published or released to third parties. The participants were not compensated for this study.

Results

Participant Characteristics

Pharmacists' professional and demographic traits are listed in Table 1. The study involved 365 registered pharmacists as participants. Of the 365 pharmacists, 216 (59.2%) were ≤26 years old, and 239 were men (65.5%). In addition, 244 (66.8%) were single. Only 110 participants (30.1%) had a BPharm degree or above, whereas 255 (70%) had a DPharm degree. Moreover, 267 participants (73.2%) were early career (1 - 4 y), whereas 98 (26.8%) were mid-career or late career (5 y and above). In all, 194 participants (53.2%) reported counseling patients on intranasal corticosteroids 1 to 4 times per week, but only 30 participants (8.2%) acknowledged any formal training in INCS administration. Additionally, only 75 participants (20.5%) used leaflets to counsel the patients.

Table . Demographic and professional characteristics of pharmacists (N=365).

Variables	Frequency	Percentage
Sex		
Male	239	65.5
Female	126	34.5
Age		
≤26 years	216	59.2
>26 years	149	40.8
Marital status		
Unmarried	244	66.8
Married	121	33.2
Qualification		
DPharm	255	69.9
BPharm and above	110	30.1
Years of experience		
1 - 4 years	267	73.2
5 years and above	98	26.8
Intranasal corticosteroid spray counseling (per week)		
Occasionally	119	32.6
1 - 4 times	194	53.2
More than 4 times	52	14.2
Received training		
Yes	30	8.2
No	335	91.8
Use of information material		
Yes	75	20.5
No	290	79.5

Administration Technique Adherence and Proficiency Level

Among 365 participating pharmacists, adherence to INCS administration steps varied widely, as shown in Table 2. High adherence (>80%) was observed in 4 basic steps: removing the dust cap, replacing the cap, shaking the spray, and holding the bottle upright. In addition, moderate adherence (40% - 80%) was noted for 3 steps: inhaling while spraying, finger positioning, and nozzle insertion. However, low adherence

(<40%) was observed for 5 steps, of which 4 were critical: blowing the nose, pointing the nozzle away from the septum, exhaling through the mouth, proper head positioning, and wiping the nozzle after use.

Table . Performance of each administration step by pharmacists (N=365).

Step	Steps for the administration of intranasal corticosteroid spray	Frequency	Percentage
1	Shake the spray in a vertical plane	309	84.7
2	Remove the dust cap	365	100
3	Blow the nose (critical)	39	10.7
4	Hold the spray bottle, pointing the tip of the nozzle up with the hand	293	80.3
5	Place the index and middle finger on the pusher and the thumb at the bottom of the spray bottle	220	60.3
6	Put the tip of the nozzle in one nostril and close the other side	146	40
7	Maintain a neutral head position or slightly tilt the head forward (critical)	122	33.4
8	Point the tip slightly outward, away from the septum (critical)	36	9.9
9	Squirt the spray into the nose while breathing in (critical)	287	78.6
10	Breathe out through the mouth (critical)	43	11.8
11	Wipe the nozzle with a tissue or handkerchief	123	33.7
12	Replace the cap	359	98.4

The participants' median score across all 12 steps was 6. However, the 5 crucial steps only had a mean score of 1.9 (SD 1.09). Twelve points were awarded for completing all INCS counseling steps, of which 5 points were awarded for the 5 critical steps. Just 22 participants (6%) were able to accurately complete all 5 critical steps. We found that 193 (52.9%) of the registered pharmacists were inadequately knowledgeable on INCS patient counseling. Only 172 participants (47.1%) had adequate knowledge of INCS counseling.

Factors Associated With Proper Administration Technique

Several professional and sociodemographic factors were shown to be substantially correlated with the degree of administration technique proficiency by the multivariate binary logistic regression analysis (Table 3). Years of experience, training, and marital status did not show statistically significant relationships, while sex, age, qualification, frequency of patient counseling weekly, and the utilization of information material were found to be significant predictors.

The likelihood of male pharmacists exhibiting proper technique was about 2 times higher than that of female pharmacists (P=.02). The probability of using an inappropriate INCS counseling technique was 89% lower for individuals who were older than 26 years (P=.001). Proficiency was substantially predicted by having used educational materials. Pharmacists who used educational materials were 96% less likely to perform inadequately (P=.005). Pharmacists with a BPharm degree or higher were also around 97% less likely to counsel inappropriately than those with a DPharm (P<.001). According to this study, individuals who advise patients on INCS 1 - 4 times per week were 11 times more likely to demonstrate proficiency as opposed to those who counsel occasionally (P=.002).

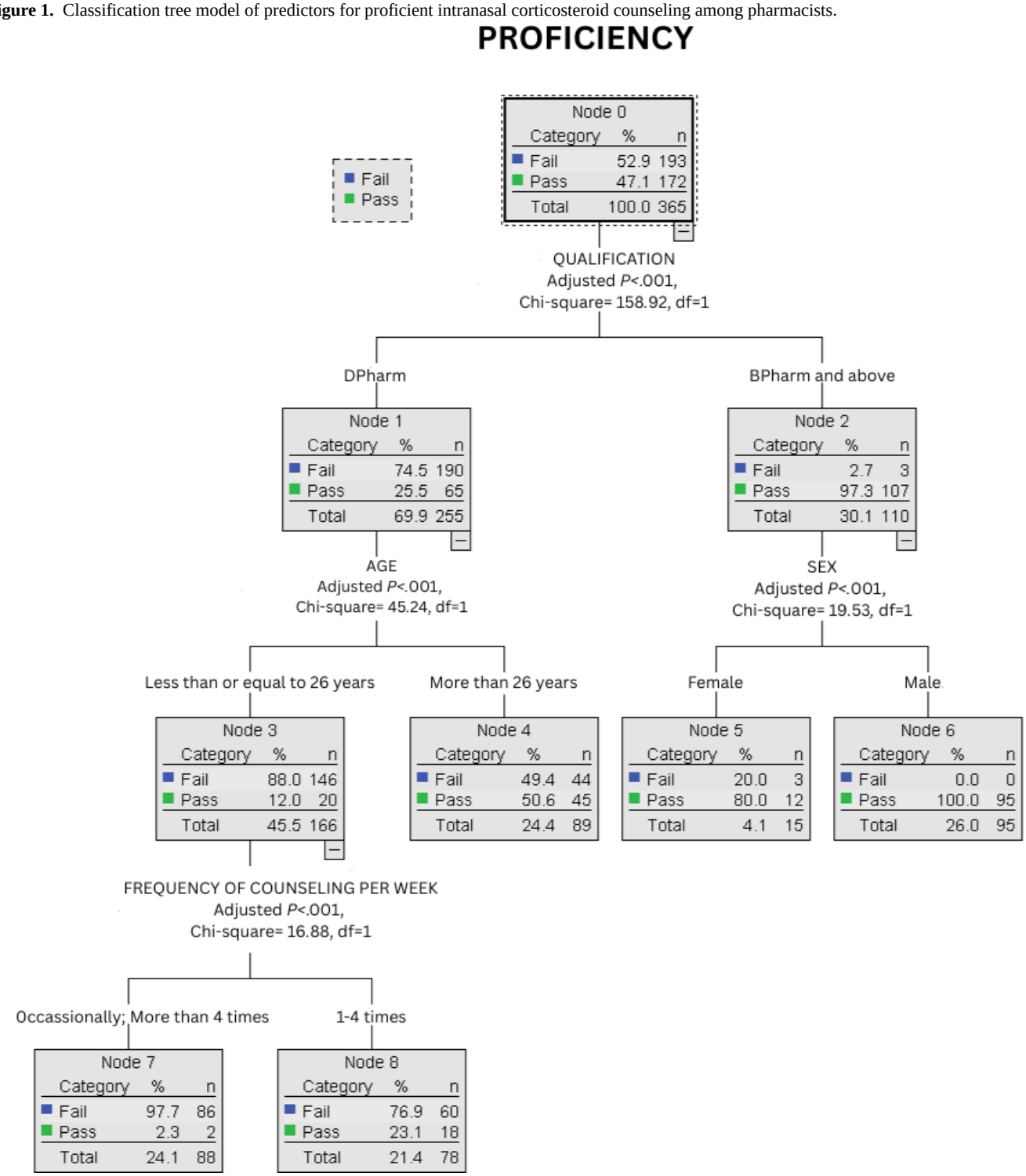
The classification tree (Chi-square automatic interaction detector method), as shown in Figure 1, was developed to identify key predictors of pharmacist proficiency in INCS counseling. The final pruned classification included 5 levels with 9 terminal nodes, achieving an overall classification accuracy of 81.6%. The root node shows the entire study population, and subsequent splits identify variables that best differentiate proficiency levels. Terminal nodes represent final subgroups, displaying the proportion of pharmacists classified as proficient or nonproficient within each subgroup.

Table . Binary logistic regression analysis of proficiency level of administration technique and different sociodemographic and professional details variables.

Variable	Adjusted odds ratio	95% CI	*P*
Sex			
Male	2.30	1.11 - 4.75	.02
Female	Reference		
Age			
≤26 years	0.11	0.03 - 0.41	.001
>26 years	Reference		
Marital status			
Unmarried	2.39	0.71 - 8.06	.16
Married	Reference		
Training			
No	—[a]	—	>.99
Yes	Reference		
Use of educational leaflet			
No	0.04	0.004 - 0.38	.005
Yes	Reference		
Qualification			
DPharm	0.03	0.007 - 0.14	<.001
BPharm and above	Reference		
Years of experience			
1 - 4 years	0.80	0.33 - 1.94	.62
5 years and above	Reference		
Intranasal corticosteroid spray counseling (weekly)			
Occasionally	4.80	0.91 - 25.30	.06
1-4 times	11.21	2.35 - 53.53	.002
>4 times	Reference		

[a]Not applicable.

Figure 1. Classification tree model of predictors for proficient intranasal corticosteroid counseling among pharmacists.



The first and the most significant split was based on the participants' educational qualifications. Only 65 of 255 (pass rate: 25.5%) pharmacists with a DPharm degree had adequate proficiency. However, of 110 pharmacists with a BPharm degree or higher, 107 had adequate proficiency (pass rate: 97.3%). Among the DPharm group, age was another significant predictor. Among those aged less than 26 years, only 20 of 166 participants (12%) had adequate proficiency, whereas among the older peers, 45 of 89 had adequate proficiency. Similarly, among the BPharm group, another major factor was gender. Male pharmacists were found to be 100% proficient in INCS counseling, with all 95 participants demonstrating adequate proficiency, whereas only 12 of 15 female participants had adequate proficiency.

Finally, for younger DPharm degree holders (≤26 y old), the frequency of INCS counseling was another predictor. Those younger participants who counseled occasionally or more than 4 times per week had significantly lower proficiency (2/88 had adequate proficiency) compared to those who counseled 1-4 times per week (18/78 had adequate proficiency).

Discussion

Principal Findings

This study addresses a critical gap in pharmacist competency regarding INCS within resource-constrained health systems, where pharmacists are front-line care providers. This study is among the first in Nepal to assess pharmacists' proficiency with INCS counseling. The survey revealed a significant gap in the participants' understanding of INCS counseling, which helps in understanding its impact on the health outcomes of patients. Approximately 50% of the pharmacists lacked adequate INCS counseling abilities. According to this study, only 6% of pharmacists were able to complete all the essential patient counseling steps that are crucial for appropriate drug administration and to minimize the risk of adverse drug reactions. Classification tree analysis showed that educational degree was the primary predictor of INCS counseling proficiency. Those with BPharm degrees or higher were far more proficient than DPharm degree holders.

The survey's conclusions about the inadequate INCS administration abilities of Nepali registered pharmacists are in line with the findings of patients and medical professionals worldwide [2,14,26]. Only 22 of 365 of pharmacists (6%) performed all recommended steps correctly, which was similar to a study of health care workers in Thailand [14]. However, even in a developed country like the Netherlands, it was found that only about 36% of health care workers were able to complete all the critical steps [26]. These observations suggest that there is a major gap in skill related to INCS counseling across nations, rather than it being a local issue. Due to this inadequate proficiency among pharmacists, there is a high risk of an increase in adverse drug reactions in patients. Therefore, the educational system must be improved to include simulation-based training and mandatory hands-on workshops that allow students and professionals to practice essential steps repeatedly and understand their rationale.

The high proportion of pharmacists demonstrating steps 1, 2, 4, and 12 correctly (>80%) likely reflects common-sense knowledge (shake, remove dust cap, hold the bottle, replace the cap) that is often taught in basic therapy discussions. However, steps like bending the head forward or cleaning the nozzle were rarely done correctly (<40%). This may cause improper drug disposition, irritation in the throat, and increased risk of contamination [27]. Similarly, only about 10% of participants were counseled about pointing the nozzle away from the nasal septum, which reduces the risk of nasal irritation, dryness, and epistaxis, and improves drug absorption from the lateral nasal wall [12,27]. In addition, the steps necessary to remove mucus or debris or obstruction from the nose and reduce throat irritation (ie, blowing the nose before use and exhaling through the mouth) were only performed by about 10% of participants [12]. Patients who are not taught to clean the spray tip may experience clogging or contamination.

These differences align with prior studies indicating that procedural complexity and a lack of continuing pharmacy education (CPE) or training contribute to inconsistent adherence to medical device protocols [28]. This study highlights that even pharmacists, who are trained professionals, often lack full mastery of device use and suggests there is a need to improve the pharmacy curriculum and landscape of CPE in Nepal.

One of the important differences was the pharmacist's qualification. BPharm graduates were about 97% less likely to demonstrate incorrect technique than DPharm graduates. The latter finding reflects the differences in Nepal's educational system. The 3-year DPharm program in Nepal has traditionally emphasized dispensing skills, whereas the BPharm and PharmD curricula include more clinical training.

Shrestha et al [29] found that Nepal's conventional pharmacy education is mostly lecture-based and industry-oriented, with limited practical training in hospitals. Bhuvan et al [30] also documented the challenges in transitioning to PharmD in Nepal, with a focus on patient care and pharmaceutical care. This highlights a need for a gradual change in current policy. Medical devices training should be included in the DPharm degree, and seminars and workshops should involve DPharm students and graduates. Pharmacy regulators in Nepal, such as the Nepal Pharmacy Council or the DDA, may consider upgrading community pharmacists' credentials or introducing minimum competency assessments for patient counseling.

In this study, it was found that pharmacists who used educational leaflets were much more proficient. This is similar to findings of other studies where pharmacist-led interventions with practical demonstrations and the use of leaflets dramatically improved patient technique [25,31]. These educational leaflets significantly reduce the cognitive load of pharmacists and ensure the completeness of all steps. These aids also engage patients through teach-back, reinforce learning beyond completeness, and boost the pharmacist's confidence and professionalism. Therefore, pharmacists should be encouraged to use educational leaflets during counseling sessions on INCS use.

In our study, increasing age (>26 y) was significantly associated with improved INCS counseling proficiency. A study conducted in Korea also found that proficiency in patient counseling regarding topical corticosteroids significantly improved with increasing age [32]. Thus, suggesting increased clinical exposure, more trainings, mature communication skills, and more frequent patient interaction may contribute to better proficiency. In order to succeed in INCS counseling, younger pharmacists must receive sufficient training throughout their time in pharmacy school. They should also attend workshops on medical devices, communication techniques, and patient counseling.

Interestingly, participants counseling on INCS use 1 - 4 times per week have a much higher proficiency (almost 11 times higher) compared with that of participants counseling only occasionally. This relationship likely reflects that a moderate counseling volume provides sufficient repetition to hone skills and confidence, while excessive patient load and task interruptions may reduce time for careful demonstration and feedback [33,34]. Simulation training could help low-counseling pharmacists achieve similar proficiency without relying on clinical exposure.

The analysis of this survey revealed that, among BPharm graduates, males have about 2 times higher odds of proficiency than females regarding INCS counseling. However, the existing literature does not present any conclusive or consistent evidence of sex-based differences in nasal spray or inhalation administration technique among pharmacists. Therefore, the observed difference may reflect contextual, educational, or practice-related factors rather than true gender-based differences.

In our study, 335 of 365 pharmacists (91.8%) lacked specific training. This suggests that continuing professional development for pharmacists in Nepal is sorely needed. According to a recent analysis of continuing professional development in Nepal, CPE is still in its infancy; therefore, working pharmacists are not informed of the latest treatments or best practices [35]. Establishing regular INCS technique workshops or integrating device training into the curriculum could narrow the gap. Given pharmacists' accessibility in rural and urban Nepal [36,37], such measures could rapidly propagate correct practice.

Pharmacists' poor INCS technique skills are concerning but can be resolved. Targeted training in Nepal could help pharmacists improve their skills quickly. Emphasizing AR and device technique in undergraduate pharmacy programs and requiring competency demonstrations during examinations could have a lasting impact. In addition, public health campaigns might encourage patients to ask pharmacists for a demonstration of INCS technique. In the long term, strengthening pharmacy education and integrating pharmacists into asthma/allergy care pathways will benefit Nepal's health care system by improving primary-level management of chronic respiratory diseases.

Limitations

This study was conducted in urban Kathmandu, so findings may not generalize to rural areas, where pharmacies are fewer and mainly operated by trained dispensers. This study has a cross-sectional design, so it cannot prove causality. Potential confounders like workload details were not measured, which may have partly contributed to the large adjusted odds ratio of some predictors. Some of the findings may be extreme due to small subgroups such as pharmacists who had received formal training or those providing frequent INCS counseling. A small sample count can result in unstable estimates and inflate the results. In addition, model overfitting can occur due to the inclusion of multiple interrelated predictors during logistic regression. This study used a small sample size for the reliability test and only used an expert-based face validity test, which may limit the robustness and generalizability of the study. Even with anonymized, behavior-focused questions, self-reported variables like the frequency of counseling and the usage of educational leaflets may be overestimated due to recall and social desirability bias, especially in in-person interviews. This shortcoming is highlighted and the necessity of objective assessment is supported by the observed difference between overall self-reported sufficiency and inadequate performance on critical steps. We recommend a weighted or competency-based scoring model in future studies. Finally, the presence of an interviewer might have influenced the participants' performance (ie, the Hawthorne effect), possibly inflating technique scores. However, due to the low proficiency observed among the participants, any such effect was limited.

Conclusion

This study highlights that more than half of the participants did not have adequate skills to demonstrate proper INCS usage technique. This can lessen its effectiveness in treating AR and increase the likelihood of adverse drug reactions in patients, such as dyspnea, anosmia, ageusia/dysgeusia, epistaxis, and headache. The lack of knowledge is mainly due to poor exposure to this topic in pharmacy school. In addition, training and seminars are limited both during school and after registration as a pharmacist. Resolving this problem should be one of the most important tasks for the Nepal Pharmacy Council and the Health Ministry as AR is very common in Nepal. Upgrading pharmacy curricula, mandating continuing education, and providing standardized counseling materials may empower pharmacists to counsel patients on the correct technique.

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Data Availability

The data that support the findings of this study are uploaded here [38].

Authors' Contributions

Conceptualization: APC, SKT
Methodology: APC, SKT
Formal analysis and investigation: APC
Writing – original draft preparation: APC, SKT
Writing – review and editing: APC
Supervision: SKS

Conflicts of Interest

None declared.

Multimedia Appendix 1
Sensitivity analysis.
[DOCX File, 17 KB - xmed_v7i1e83042_app1.docx]

Multimedia Appendix 2
Informed consent form.
[PDF File, 100 KB - xmed_v7i1e83042_app2.pdf]

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Abbreviations

AR: allergic rhinitis
BPharm: Bachelor of Pharmacy
CPD: continuing professional development
CPE: continuing pharmacy education
DDA: Department of Drug Administration
DPharm: Diploma in Pharmacy
INCS: intranasal corticosteroid spray
PharmD: Doctor of Pharmacy
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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