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Identification of undocumented over-the-counter medications in an academic nephrology clinic

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Abstract

Objectives: To explore how accurately over-the-counter (OTC) medications were documented in an academic nephrology clinic and the benefits of using a novel short questionnaire as part of medication reconciliation (MR).

Methods: We developed a 3-item tailored questionnaire with questions about use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), and proton pump inhibitors (PPIs), which clinical leadership identified as medications of interest. Over the course of 20 days, medical assistants administered the questionnaire to clinic patients immediately after the standard MR. We summarized the rate of inaccurate medication documentation by individual drug and drug class, comparing the standard MR process with the questionnaire. We also calculated diagnostic performance characteristics of the questionnaire. We evaluated the severity of drug-drug interactions between OTC medications discovered using the OTC medication questionnaire and patients' other prescription medications.

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Results: Nearly 30% (n = 133 of 450) of the participants had at least 1 inaccurately documented OTC medication after the standard MR. The sensitivity and specificity of the standard MR were 79.2% and 93.5%, respectively, for aspirin; 14.5% and 99.5% for NSAIDs; and 80.4% and 97.3% for PPIs. Medication omissions were resolved in the electronic health record approximately two-thirds of the time using the questionnaire. At least 1 drug-drug interaction (DDI) involving active use of an OTC medication was identified in 9.6% of the patients. Of the DDIs, the most common portended effects were increased nephrotoxicity (52.9%), increased bleeding risk (22.9%), and enhanced antiplatelet activity (7.1%).

Conclusion: Despite the standard MR process, inaccurate documentation of commonly used OTC medications occurred in nearly one-third of outpatients in a nephrology clinic. A brief OTC medication questionnaire may be a scalable and effective strategy to address this problem.

Background

Over-the-counter (OTC) medications are accessible, affordable, and trusted by consumers in the United States.[1] They are generally considered safe and effective when used according to the package labeling, and patients frequently take them without consulting a health care provider. However, OTC medications can pose safety risks if used at an excessive dose, for too long, or with contraindicated medications.[2,3] Because the inclusion of OTC medications in the electronic health record (EHR) depends on self-report by patients, OTC medications may be less accurately documented than prescription medications, increasing the risk of adverse drug events.

Patients with kidney disease are at particularly high risk for complications owing to both prescription and OTC medications because they are more susceptible to kidney injury and may require renal dosing and frequent monitoring for changes in creatinine clearance.[4] Several OTC classes of medications that may be particularly concerning are aspirin and nonsteroidal anti-inflammatory drugs (NSAIDs) because of the risk of nephropathy, gastrointestinal bleeding, and cardiovascular events and proton pump inhibitors (PPIs) because of the risk of acute kidney injury and chronic kidney disease.[5-11] In 1 study, more than 80% of people with chronic renal insufficiency took at least 1 OTC medication, and 9% of patients took 1 that was classified as contraindicated.[12]

Objectives

Our primary objectives were to explore the accuracy of standard medication reconciliation (MR) for OTC medications in an academic nephrology clinic and the benefits of using a novel short questionnaire as part of MR. Our secondary objective was to explore the prevalence of drug-drug interactions (DDIs) between OTC medications identified using the tailored OTC medication questionnaire and patients' other prescription medications.

Methods

Setting and pre-existing MR process

We collaborated with an adult general nephrology clinic at a large academic medical center. The clinic was staffed by attending physicians and nephrology fellows. The standard MR

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process for all visits involved patients reviewing a printed list from the EHR of all their medications while they were in the waiting room. The form prompted patients to add medications, including OTC medications, and to indicate whether medications that were previously added to the EHR were still being used. After rooming the patient, the medical assistant (MA) reconciled the updated form with the mediations listed in the EHR.

OTC medication questionnaire development and training

Through discussions with the clinic's physician leaders, we learned that they were most concerned about 3 OTC drug classes—aspirin, NSAIDs, and PPIs—and that they were most interested in learning about any use in the past 30 days. Using this information, we developed a 3-item tailored questionnaire in consultation with an expert in health communication and survey design (Appendix 1). We prioritized limiting the number of questions to increase the likelihood that it would be a practical tool that could be integrated into the existing workflow. We included both the brand and generic names of OTC medications to help patients recognize medications that they may be taking. We did not include questions about the medication dose, frequency of use, or whether the medication was obtained by purchasing an OTC product or by prescription as this would have substantially lengthened the questionnaire.

One member of the study team (A.N.K.) trained the MAs (n = 4) on how to administer the questionnaire and incorporate it into the existing workflow. The training took approximately 20 minutes. This was completed during a standing huddle team meeting at the nephrology clinic. We then piloted the form on 1 clinic day (n = 37). The only change that was made as a result of this pretesting was adding a checkbox, "None of these medications were added to the EHR based on this form," to be ticked by the MA if the patient was given the form but did not indicate using any OTC medications. Data from the pretesting were included in our analysis.

Questionnaire administration

The MAs administered the questionnaire to all patients who attended the nephrology clinic visit over the course of 20 clinic days in July and August 2019 (including the day we completed the pilot testing). MAs completed the standard MR process when they entered the examination room. Then they handed the questionnaire to the patient and asked that they complete it either by themselves or with help from the MA, if needed. After reviewing the OTC medication questionnaire, the MAs then made any necessary corrections to the EHR for the 3 OTC medication classes. Per long-standing clinic policy, the MAs were able to add medications and indicate which medications were not being taken, but they were not allowed to directly remove any medications from the EHR. In addition, they were instructed to mark in the "staff use only" section of the OTC medication questionnaire if they added any medications to the EHR as a result of using the questionnaire. Finally, the MAs placed the completed form in a designated location for the study team to collect.

All patients with clinic visits during the data collection period were included. If a patient had multiple clinic visits during the study period, only the first encounter was included in the data analysis. Patients with incomplete forms were excluded.

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Data management and analysis

We extracted data from the EHR regarding each patient's age, sex, most recent estimated glomerular filtration rate (eGFR), visit type (new or returning patient), and use of certain prescription medications that have DDIs with aspirin, NSAIDs, or PPIs. The list of medications for which information was extracted was generated before starting data collection by reviewing the list of all possible DDIs involving aspirin, NSAIDs, or PPIs in Lexicomp (Lexicomp, Hudson, OH). We then shortened the list using the team's clinical expertise to include only prescription medications that are commonly used in practice. The final list included 39 medications, including the OTC medications on the tailored questionnaire.[13]

After the study period, the research team reviewed the completed questionnaires and the pre- and postvisit medication lists in the EHR to assess performance characteristics of standard MR for the identification of OTC medication use in the previous 30 days. A medication was determined to be inaccurately documented if the patient either indicated that they were taking a medication on the OTC medication questionnaire that was not recorded in the medical record or if a medication was recorded in the medical record that they did not endorse taking. We used exact Clopper-Pearson confidence intervals to estimate the sensitivity, specificity, and accuracy and standard logit confidence intervals to estimate the positive and negative predictive values of standard MR for the documentation of aspirin, NSAID, and PPI use.[14] As a sensitivity analysis, we also calculated the diagnostic performance characteristics of standard MR if active medication use were defined as at least 10 days in the previous 30 days.

We have provided definitions for how we calculated each outcome in Appendix 2. We used the Lexicomp DDI tool and risk rating system to identify and rate DDIs as either class X (avoid combination), D (consider therapy modification), or C (monitor therapy). We also evaluated for DDIs by assessing for use of ibuprofen or naproxen discovered by the OTC medication questionnaire among participants with an eGFR <60 mL/min/1.73 m^2 (in whom chronic use is discouraged) or an eGFR <30 mL/min/1.73 m^2 (in whom any use is discouraged).[15]

We recorded study data in Health Insurance Portability and Accountability Act—compliant Research Electronic Data Capture tools hosted at the University of Michigan.[16,17] We analyzed the data using Microsoft Excel (version 16.35) and MedCalc (MedCalc, Ostend, Belgium). The University of Michigan Medical School Institutional Review Board deemed this study exempt from review and waived participant consent because of its status as a quality improvement initiative.

Results

The MAs distributed 489 questionnaires to patients, and 460 (94.1%) were returned. Data from 10 forms were excluded from the analysis because of incompleteness (n = 8), no record of the visit in the EHR (n = 1), and a second encounter at the same clinic during the study period (n = 1). A total of 450 patients were included in our data analysis.

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Participants' average age was 60 years, and 74.2% had an eGFR of 59 mL/min/1.73 m^2 or below (n = 334) (Appendix 3). Three-fourths of the participants identified as white (n = 336, 74.7%) whereas one-half identified as female (n =227, 50.4%). Most participants (n = 321, 71.3%) were seen for a return visit.

Questionnaire results and EHR accuracy

Using data gathered from the 3-item questionnaire, the most common OTC medications that patients reported taking in the past 30 days were aspirin (38%), omeprazole (19%), and ibuprofen (12%), whereas fewer than 5% of the patients reported taking naproxen, esomeprazole, or lansoprazole. Most participants who reported taking a PPI (n = 89 of 97, 91.8%) or aspirin (n = 157 of 173, 90.8%) reported taking the medication for 10 or more days during the preceding 30 days (Appendix 4). However, approximately three-fourths of the participants who reported taking an NSAID used it fewer than 10 days during that time period (n = 51 of 69, 73.9%).

In comparison with the results of the 3-item questionnaire, nearly 30% (n = 133) of the participants had at least 1 inaccurately documented medication in the EHR (Figure 1) after the standard MR. Overall, omissions of current medications (n = 114) were twice as common as inclusions of discontinued medications (n = 56); however, it varied greatly on the basis of the different medications. The medications that were most frequently missing from the EHR after standard MR were naproxen (n = 13 of 14, 92.9%) and ibuprofen (n = 46 of 55, 83.6%). Omeprazole was commonly reported in the EHR even though patients reported no longer taking the medication (n = 31 of 84, 36.9%). The MAs corrected the EHR medication list in two-thirds of the instances when a medication omission was identified using the OTC medication questionnaire (n = 72 of 114).

The sensitivity of standard MR for correctly listing OTC medications used in the past 30 days was highest for PPIs (80.4%) and aspirin (79.2%) compared with NSAIDs (14.5%) (Table 1). The specificity ranged from 91.5% (omeprazole) to 100% (naproxen). The accuracy ranged from 88.0% (aspirin) to 99.6% (lansoprazole). Sensitivity and specificity of the standard MR were similar even if "active use" were defined as at least 10 days in the previous 30 (Appendix 4).

DDI

Nearly 10% of patients (n = 43 of 450) had at least 1 DDI as a result of an interaction between a prescription medication and an OTC medication that was identified using the 3-item questionnaire (Appendix 5). Most were classified as class C (n = 43 of 70, 61.4%) whereas the remaining were class D (n = 27 of 70, 38.6%). We did not identify any class X interactions.

The most common DDIs were ibuprofen interacting with angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers (class C) (n = 22 of 70, 31.4%) followed by prescription NSAIDs interacting with aspirin or ibuprofen (class D) or naproxen (class C or D, depending on the NSAID) resulting in a duplication of therapy (n = 16 of 70, 22.9%). The most common potential adverse effects of interactions between the prescription and

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OTC medications were nephrotoxicity (n = 37 of 70, 52.9%), increased risk of bleeding (n = 16 of 70, 22.9%), and enhanced antiplatelet activity (n = 5 of 70, 7.1%).

A total of 32 patients with an eGFR <60 mL/min/1.73 m^2 reported using ibuprofen or naproxen using the OTC medication questionnaire; however, only 15.6% (n = 5) had a record of this in the EHR using the standard MR process. Furthermore, our questionnaire revealed 3 instances of patients with an eGFR <30 mL/min/1.73 m^2 taking either ibuprofen or naproxen (and 1 participant taking both) that was missed by the existing process.

Discussion

Despite standard MR, nearly 30% of patients attending an outpatient nephrology clinic had an incorrectly documented OTC medication that was identified using our novel OTC medication questionnaire. Aspirin, ibuprofen, and naproxen were frequently missing from the EHR, and omeprazole was often incorrectly included on the EHR active medication list. Although it is not possible to ask about every potential OTC medication, using a preidentified list that aligns with the needs of the patient population and clinician preferences may be a feasible and effective method to improve EHR accuracy. In this particular clinic, an abbreviated questionnaire that asks about only aspirin, ibuprofen, and omeprazole would capture most of the missing medications that were identified as being important to the clinical team.

We were surprised to find that approximately one-third of the time, the MAs failed to correct the EHR after the OTC questionnaire identified an omission. We provided the MAs with a short training on questionnaire administration at the start of the study. Additional research is needed to identify effective strategies, such as audit and feedback with MAs, to improve the accuracy of transferring data from the OTC questionnaire to the EHR.

A critical problem with having an inaccurate medication list is preventable adverse DDIs. Our questionnaire revealed that nearly 10% of the patients had a DDI involving an OTC medication that was missed by the standard MR process. Of the DDIs identified, approximately 40% represented a class D interaction with recommendation to consider therapy modification. Many of these DDIs involved increased bleeding risk, enhanced antiplatelet activity, or increased nephrotoxicity, which are particularly important for patients with reduced kidney function.

Although the use of this questionnaire would uncover many DDIs that are currently being missed, the questionnaire itself only prompts medical staff to correct the medication list and does not necessarily alert the clinician to monitor for specific interactions. To make the questionnaire more effective from a safety and quality standpoint, it should be used in conjunction with existing software to check for medication interactions, such as those already present in many EHRs. For particularly high-risk combinations, we suggest that the addition of concerning medications to the EHR by the MA trigger an electronic warning to the clinician when they open the electronic encounter. Such an intervention would serve to improve overall patient quality and safety.

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The primary limitation of this study was that it was conducted for a short time period at 1 nephrology clinic in an academic medical center, thus potentially limiting generalizability. We relied on the patients' self-report using our 3-item questionnaire to determine the most accurate medication list for each patient; however, this likely resulted in an under-reporting of OTC medications and therefore would be unlikely to invalidate the main findings of this study. An alternative strategy that may be used in some clinics is comprehensive medication reviews by pharmacists. However, this takes notably more resources than the intervention we tested. Another limitation is that we compared the OTC questionnaire with the EHR medication list and did not perform a dedicated review of encounter notes to identify other documentation of OTC medications. However, medications should ideally be entered into the EHR medication list, where DDI checking can be performed, to maximize safety. Finally, we acknowledge that documenting all OTC medications that have been used 1 or more times in the past 30 days may not align with preferences for all clinics or clinicians. Therefore, if the questionnaire is adopted in other clinics, it is important for the criteria for adding medications to the EHR to be modified, if necessary (e.g., limit the addition of medications to those used in the past 7 days).

Conclusion

Despite a standard MR process, OTC medications were frequently inaccurately recorded in the EHR in an outpatient nephrology clinic. Given the risk of patient harm from medication errors, this represents a notable area for improvement. Our 3-item OTC medication questionnaire may be an effective method to address this problem with the potential for broad adaptation.

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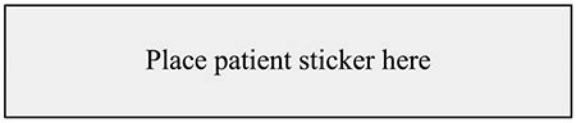
Appendix 1

OTC Medication Checklist



Dear Patient:

We want to make sure that your medical record contains the most up-to-date information. We specifically want to make sure that we have not left any over-the-counter medications off your medication list. This is part of a clinic quality improvement project.

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Instructions:

In the blank spaces below, write in the number of days from **zero (0) to thirty (30)** that you have taken each of the following medications in the past **30day**s.

- If you took any of these medications more than once per day, count each day only once.
  - For example, if you took Advil 3 times per day for the last 30 days, write '30'.
- If you did not take the medication at all in the past 30 days, write '0' (zero).

1. In the past**30day**s, on how many days have you taken **aspirin**?

Write in response à _____ days

2. In the past **30day**s, on how many days have you taken the following **NSAIDs** (non-steroidal anti-inflammatory drugs)?

2a. Ibuprofen (Advil or Motrin)

Write in response à _____ days

2b. Naproxen (Aleve)

Write in response à _____ days

3. In the past **30day**s, on how many days have you taken the following **PPIs** (proton pump inhibitors)?

3a. Omeprazole (Prilosec or Zegerid)

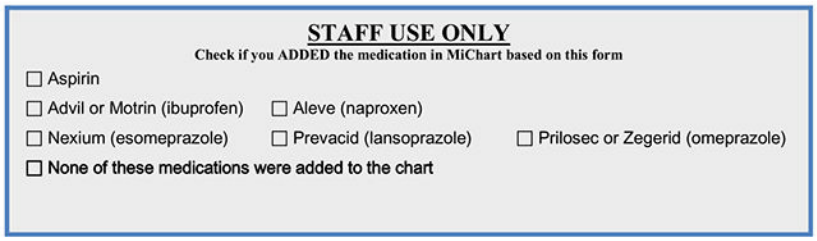
Write in response à _____ days

3b. Esomeprazole (Nexium)

Write in response à _____ days

3c. Lansoprazole (Prevacid)

Write in response à _____ days



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Appendix 2.: Approach to calculating results

Part A. Standard definitions

General formula				*Definitions*
		Taking per questionnaire		• **Sensitivity:** [A/(A+C)] x 100 • **Specificity:** [D/(B+D)] x 100 • **Positive predictive value:** [A/(A+B)] x 100 • **Negative predictive value:** [D/C+D)] x 100 • **Accuracy:** [(A+D)/(A+B+C+D)] x 100
		Yes	**No**	
Taking per electronic health record (EHR)	**Yes**	A	B	
	No	C	D	

Part B. Raw data used to calculate results

Aspirin

		Taking per questionnaire		
		Yes	**No**	**Total**
Taking per EHR	**Yes**	137	18	155
	No	36	259	295
	Total	173	277	450

Esomeprazole

		Taking per questionnaire		
		Yes	**No**	**Total**
Taking per EHR	**Yes**	7	2	9
	No	1	440	441
	Total	8	442	450

Ibuprofen

		Taking per questionnaire		
		Yes	**No**	**Total**
Taking per EHR	**Yes**	9	4	13
	No	46	391	437
	Total	55	395	450

Lansoprazole

		Taking per questionnaire		
		Yes	**No**	**Total**
Taking per EHR	**Yes**	4	1	5
	No	1	444	445
	Total	5	445	450

Naproxen

		Taking per questionnaire		
		Yes	**No**	**Total**
Taking per EHR	**Yes**	1	0	1
	No	13	436	449
	Total	14	436	450

Omeprazole

		Taking per questionnaire		
		Yes	**No**	**Total**
Taking per EHR	**Yes**	67	31	98
	No	17	335	352
	Total	84	366	450

Appendix 3: Demographics, clinical characteristics, and OTC medication use using questionnaire for participants in nephrology clinic (n = 450)

Variable	**No. people (%)**
Gender	
Female	227 (50.4)
Male	222 (49.3)
Transgender or other	1 (0.2)
Age (mean, SD)	60 (16.2)
Race	
White	336 (74.7)
Black	78 (17.3)

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Variable	No. people (%)
Other	36 (8.0)
Visit type	
Return visit	321 (71.3)
New visit	129 (28.7)
Chronic kidney disease stage (eGFR)	
Stage 1 or 2 (≥60)	116 (25.8)
Stage 3 (30–59)	196 (43.6)
Stage 4 (15–29)	105 (23.3)
Stage 5 (<15)	33 (7.3)
Reported OTC use	
Aspirin	173 (38.4)
Ibuprofen	55 (12.2)
Naproxen	14 (3.1)
Omeprazole	84 (18.7)
Esomeprazole	8 (1.8)
Lansoprazole	5 (1.1)

Abbreviations used: OTC, over-the-counter; eGFR, estimated glomerular filtration rate.

Appendix 4: Diagnostic performance characteristics for OTC medications on the EHR medication list among people who reported taking the medication for 10 or more days in the past 30 days (n = 450)

Medication	No. active users (≥10 d)	Positive predictive value % (95% CI)	Negative predictive value % (95% CI)	Sensitivity % (95% CI)	Specificity % (95% CI)	Accuracy % (95% CI)
Aspirin	157	85.8 (80.1–90.1)	91.9 (88.6–94.2)	84.7 (78.1–90.0)	92.5 (88.9–95.2)	89.8 (86.6–92.4)
NSAIDs	18[a]	14.3 (3.9–40.9)	98.2 (97.9–98.5)	11.1 (1.4–34.7)	98.6 (97.6–99.3)	96.9 (95.5–97.9)
Ibuprofen	13	15.4 (4.3–42.5)	97.5 (96.9–98.0)	15.4 (1.9–45.5)	97.5 (95.5–98.7)	95.1 (92.7–96.9)
Naproxen	5	0	98.9 (98.9–98.9)	0 (0–52.2)	99.8 (98.8–100)	98.7 (97.1–99.5)
PPIs	89	67.0 (59.3–73.8)	98.9 (98.2–99.3)	84.3 (75.0–91.1)	97.1 (96.0–97.9)	96.2 (95.1–97.2)
Omeprazole	76	65.3 (57.4–72.5)	96.6 (94.4–98.0)	84.2 (74.0–91.6)	90.9 (87.5–93.6)	89.8 (86.6–92.4)
Esomeprazole	8	77.8 (46.1–93.5)	99.8% (98.6–100)	87.5 (47.4–99.7)	99.6 (98.4–100)	99.3 (98.1–99.9)
Lansoprazole	5	80.0 (35.0–96.8)	99.8 (98.7–100)	80.0 (28.4–99.5)	99.8 (98.8–100)	99.6 (98.4–100)

OTC, over-the-counter; EHR, electronic health record; NSAID, nonsteroidal anti-inflammatory drug; PPI, proton pump inhibitor.

[a]Two patients were actively using both ibuprofen and naproxen for 10+ days each.

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Appendix 5: Summary of potential drug-drug interactions by over-the-counter medication identified using questionnaire with class D interactions highlighted

Over-the-counter medication	Prescription medication					
	Angiotensin-converting enzyme inhibitors or angiotensin receptor blockers	Nonsteroidal anti-inflammatory drugs	Loop diuretics	P2Y12 platelet antagonists	Antineoplastic agents	Direct oral anticoagulants
Aspirin	7	3	7	2	–	–
Ibuprofen	22	9	4	2	1	–
Naproxen	–	4[a]	3	–	–	1
Omeprazole	–	–	–	2	2[b]	–
Esomeprazole	–	–	–	–	–	–
Lansoprazole	–	–	–	1	–	–
Total (n = 70)	29	16	14	7	3	1

[a]Three of these 4 cases were a class D interaction (naproxen with aspirin). The additional case was a class C interaction (naproxen with ibuprofen).

[b]One of these 2 cases was a class D interaction (omeprazole with tacrolimus). The other case was a class C interaction (omeprazole with cyclosporine).

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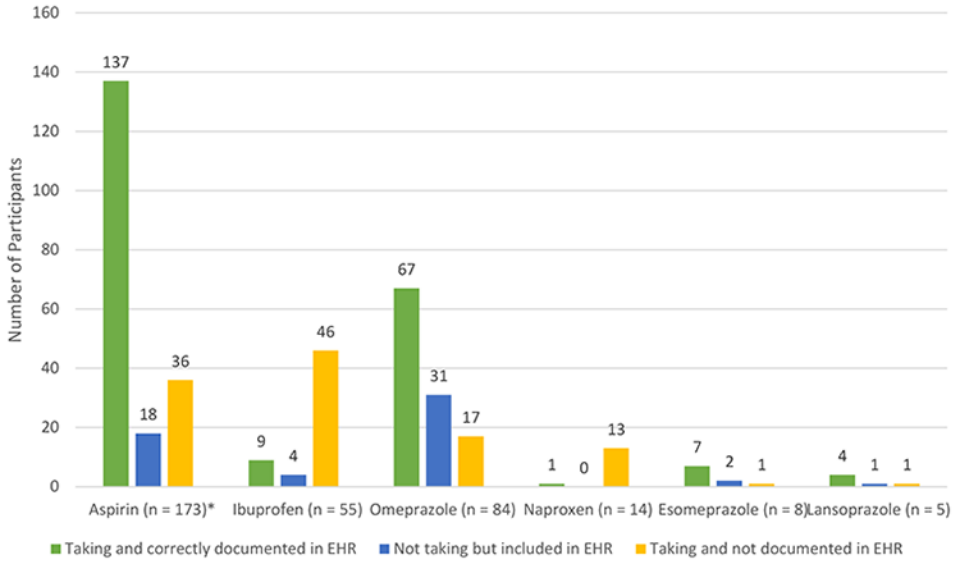

Figure 1.

Discrepancies between patient self-report and EHR by over-the-counter medication (n = 450 patients). Abbreviation used: EHR, electronic health record. *Total number of participants taking medication.

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Table 1

Diagnostic performance characteristics for OTC medications on the EHR medication list (n = 450)

Medications	No. active users	Positive predictive value % (95% CI)	Negative predictive value % (95% CI)	Sensitivity % (95% CI)	Specificity % (95% CI)	Accuracy % (95% CI)
Aspirin	173	88.4 (82.3–93.0)	87.8 (83.5–91.3)	79.2 (72.4–85.0)	93.5 (89.9–96.1)	88.0 (84.6–90.9)
NSAIDs	69[a]	71.4 (44.6–88.6)	93.3 (92.7–93.9)	14.5 (7.2–25.0)	99.5 (98.8–99.9)	93.0 (91.1–94.6)
Ibuprofen	55	69.2 (41.8–87.6)	90.5 (89.4–91.4)	16.4 (7.8–28.8)	99.1 (97.7–99.8)	88.9 (86.9–92.4)
Naproxen	14	100 (N/A)	97.1 (96.7–97.5)	7.1 (0.2–33.9)	100 (99.2–100)	97.1 (95.1–98.5)
PPIs	97	69.6 (61.9–76.4)	98.5 (97.7–99.0)	80.4 (71.1–87.8)	97.3 (96.2–98.1)	96.1 (94.9–97.1)
Omeprazole	84	68.4 (60.3–75.5)	95.2 (92.8–96.8)	79.8 (69.6–87.8)	91.5 (88.2–94.2)	89.3 (86.1–92.0)
Esomeprazole	8	77.8 (46.1–93.5)	99.8% (98.6–100)	87.5 (47.4–99.7)	99.6 (98.4–100)	99.3 (98.1–99.9)
Lansoprazole	5	80.0 (35.0–99.5)	99.8 (98.7–100)	80.0 (28.4–99.5)	99.8 (98.8–100)	99.6 (98.4–100)

Abbreviations used: OTC, over-the-counter; EHR, electronic health record; NSAID, nonsteroidal anti-inflammatory drug; N/A, not available; PPI, proton pump inhibitor.

[a]Three patients were actively using both ibuprofen and naproxen.

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