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Community/Ambulatory Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Is an indication-based prescribing system in our future?

In the July 28, 2016, issue of *The New England Journal of Medicine*, Schiff et al.[1] provide a compelling argument in favor of incorporating indications into the medication ordering process. A longtime proponent (along with ISMP and other organizations) of including the purpose of medications on orders and prescriptions, Schiff et al. note that, since most prescriptions and medication orders are now electronic, the format for implementing indication-based prescribing is within our grasp. The authors suggest that electronic prescribing systems are currently handicapped because they do not include the indication, alluding to the fact that, although legibility issues have been resolved with electronic prescribing, the risk of errors is still present due to the complexities with drug choices and regimens, and the risk of selecting the wrong medication among several look-alike drug names from a drop-down list. The authors suggest it's time to enter the age of reason in medicine and believe that indication-based prescribing is the missing link with electronic prescribing. As such, they are currently building and testing a prototype, funded by the Agency for Healthcare Research and Quality (AHRQ), that will enable electronic indication-based prescribing to be achieved.

Potential Benefits of Indication-Based Prescribing

1 Helps prevent errors by narrowing medication choices

One in every 1,000 medication orders in a hospital or prescriptions in a community/ambulatory pharmacy has been associated with selecting the wrong drug while prescribing, transcribing, dispensing, or administering medications.[2-5] One of the primary causes of these errors is drug name similarity.[6] In fact, **ISMP's List of Confused Drug Names** (www.ismp.org/sc?id=2832) comprises close to 400 different drug name pairs, which include only those that have been published in the *ISMP Medication Safety Alert!* acute care and community/ambulatory newsletters. Recent examples of published mix-ups between look-alike drug names, some of which have not yet been added to **ISMP's List of Confused Drug Names**, include:

- risperi**DONE** and r**OPINIR**ole
- hydr**OXY**zine and hydr**ALAZINE**
- **RAPAFLO** (silodosin) and **RAPAMUNE** (sirolimus)
- acetaminophen and aceta**ZOLAMIDE**
- penicill**AMINE** and penicillin

Many of these errors happened during order entry when selecting a drug from a computer drop-down menu or pick list.

For years, ISMP has recommended including the medication's purpose with prescriptions and hospital orders to prevent errors. Knowing the medication's purpose helps healthcare

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SAFETY briefs

HIGH-ALERT

Confused drug names. ISMP recently received a report of confusion between two sound-alike drug names **TRESIBA** (insulin degludec) and **TARCEVA** (erlotinib). Tarceva, a kinase inhibitor for the treatment of metastatic non-small cell lung cancer and pancreatic cancer, was mistakenly documented on the patient's home medication and discharge lists instead of Tresiba. A nurse caught the error when reviewing the medication list with

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In deepest sympathy…

We were saddened to learn of the cancer-related death on October 22nd of one of the most respected medication safety researchers of our time, **Betsy Allan Flynn**. Dr. Flynn worked closely with Dr. Kenneth Barker at Auburn University (AU). Together they furthered methods for prospective monitoring of medication systems in hospitals and community pharmacies. They developed AU MEDS, which was later commercialized and adopted by a number of hospitals to help proactively identify flaws in their medication safety systems. Dr. Flynn was a co-investigator on over $5 million of research, and conducted studies in over 250 sites in the US, France, the United Kingdom, and Italy. She published or presented more than 125 papers. She is a former recipient of the ISMP Cheers Award, among many other honors and recognitions. She also served on the Institute of Medicine's Committee on Identifying and Preventing Medication Errors and the US Pharmacopeia Safe Medication Use Expert Committee.

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practitioners avoid confusion between medications with look-alike names, as most are used for different purposes. It's also crucial to know the drug's indication when conducting an independent double check to prevent or detect drug selection errors, dosing errors, or wrong patient errors. If a check is needed, a second practitioner must match the drug's indication to the patient's diagnoses to verify that the medication is being used appropriately for the patient's condition, and that it is dosed properly for its intended use. Some medications have multiple uses, each with a different dosing schedule, such as oral methotrexate for oncologic or nononcologic indications and mefloquine and **MALARONE** (atovaquone/proguanil) for prophylaxis or treatment of malaria. Thus, providing information about the indication also helps prevent dose, dosage form, or dose frequency errors.

Schiff et al.[1] agree and suggest that, by providing an indication, medication choices, dosage forms, and dosing regimens are narrowed, so the risk of choosing the wrong drug, form, or dosing schedule is lessened. Pharmacists, nurses, and patients/families will be able to more easily recognize and intercept prescribing or dispensing errors.

2 Helps empower and educate patients, increasing patient adherence

Knowing the indication helps patients and their caregivers keep their medications straight, and most patients prefer prescription labels that list the medication's indication.[7] Yet, according to Schiff et al.,[1] patients often do not understand why they are taking prescribed medications. Without this knowledge, patient adherence to the medication is decreased.[8]

Not knowing the purpose of prescribed medications has also led to patient misunderstandings, prescriber distrust, and a refusal to take the medication, particularly when drugs are used off-label. For example, ISMP has published several reports in which patients with head and neck pain were angry with their physicians after learning from a pharmacist or a drug information leaflet that amitriptyline, which had been prescribed by their physicians, was an antidepressant. Neither the patients nor the pharmacists were aware that the drug had been prescribed for an off-label use to treat neuropathic pain.

Additionally, not knowing the purpose of medications can contribute to diagnostic errors. Oto et al.[9] described two patients who had been prescribed car**BAM**azepine for neuropathic pain without clearly understanding the medication's intended use. After developing blackouts, the patients and their treating physicians, who had not prescribed car**BAM**azepine, inferred from the drug therapy that the patients had epilepsy. Both patients underwent unnecessary diagnostic tests and treatment.

3 Improves communication with the healthcare team and patients/families

The entire healthcare team must have knowledge of the intended indication of prescribed medications to understand what is being treated, the desired outcome, and what to teach the patient.[1] For example, pharmacists should never be expected to dispense a medication without knowing its intended use for that specific patient, which typically is the case in community/ambulatory pharmacies. Would other health professionals feel that he or she is providing safe and quality care while working without this crucial information? For decades, pharmacists have advocated for including the indication on prescriptions, but prescribers were worried about confidentiality—a legitimate concern.

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the patient at discharge. Including the purpose of the medication on medication lists as well as prescriptions can enable practitioners to match the drug's indication to the patient's condition.

OTC's with similar names but totally different ingredients. **CLARISPRAY** is fluticasone propionate, a corticosteroid nasal spray, which is generically equivalent to **FLONASE ALLERGY RELIEF**. In the upper right-hand corner of the ClariSpray package label (**Figure 1**, left), Bayer, the distributor of the product, notes that it is "from the makers of **CLARITIN**." Claritin is loratadine, an antihistamine. With this product association, similar package colors and graphics, and since each name starts with "CLARI-," it's possible that some patients may think that ClariSpray is a spray form of loratadine.

Figure 1. ClariSpray (L) is labeled "from the Makers of Claritin," but it doesn't contain loratadine (R).

Similarly, **MUCINEX ALLERGY** is fexofenadine, an antihistamine, and generically equivalent to **ALLEGRA ALLERGY**. However, despite carrying the Mucinex name, it doesn't actually contain guai**FEN**esin, an expectorant, which is the only ingredient in the original Mucinex product and included in most other Mucinex formulations.

No cases of mix-ups have been reported yet, but one reporter did indicate that the use of the Mucinex name for a non-guai**FEN**esin product has contributed to quite a bit of confusion in her long-term care facility. Please keep in mind the possibility of confusion and mix-ups if you have these products in your pharmacy. Consumers and pharmacists need to be aware of the differences between these products. If you encounter any errors with

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However, better communication with the healthcare team is still compatible with protecting patient information, and protections provided under the Health Insurance Portability and Accountability Act (HIPAA) allow for this communication between professionals who are providing care to the patient.

ISMP has previously published that, per the US Department of Health and Human Services (HHS), listing a medication's purpose or the patient's diagnosis on a prescription, for example, does not violate HIPAA.[10] Although a patient's diagnosis or purpose for using a medication would qualify as protected health information (PHI), communicating this information on a prescription does not require separate, special authorization because the information is used for the purpose of treating the patient. A violation would occur only if the prescription was then used for a purpose not defined by HIPAA, such as copying it for a marketing company. We've also heard concerns that listing a purpose on prescriptions may not meet the qualifications of providing only the minimum amount of information necessary to treat the patient. However, the "minimum necessary" rule does not apply when PHI is disclosed between providers treating the same patient.

For sensitive indications, such as those related to mental health or human immunodeficiency virus (HIV) infection, the authors note that systems could be designed to permit prescribers or patients to opt out of having the indication included on prescription container labels.[1] However, ISMP believes it might still be possible to include descriptions such as "for mood" or "for infection" on prescriptions and labels to communicate the drug's general purpose. In the end, inclusion of indications on the prescription and on the prescription container label may require different implementation strategies to advance indication-base prescribing as a standard of practice.

4 Helps with medication reconciliation

As described by the authors,[1] an indication-based prescribing system could support the reorganization of the patient's medication list into a more logical grouping around indications, which makes the task of medication reconciliation infinitely less difficult and aids in the re-prescribing of medications during transitions of care. Knowing the reason why medications were prescribed for the patient, and grouping the drugs by indication, makes it easier to spot duplicates and permits an accurate evaluation of whether adjustments or discontinuations are in order.

5 Helps prescribers choose the best medications for their patients

Prescribers need and want help choosing the best medications for their patients, while allowing them to make the final decision and maintain their autonomy.[1] With drug choices and regimens becoming increasingly complex, support for prescribing decisions would be an extremely important resource when using electronic systems. A system is envisioned in which prescribers could enter an indication, or click on a problem in the patient's problem list, and be presented with the best medications to choose from based on data in the patient's electronic health record. Such data includes allergies, current and prior medications (to avoid repeating a drug that previously failed), insurance coverage, and formulary requirements. The idea is that such an indication-based prescribing system could increase efficiency, support the selection and appropriate use of medications, improve documentation of the problem list, allow integration of the problem list with the prescribed medications, facilitate reimbursement coding, and streamline the prior authorization process.

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these products, please report them to ISMP at: www.ismp.org/merp.

HIGH-ALERT

More outpatient oral cancer drugs should be in blister packs. Certain oral cancer drugs would benefit greatly from safer packaging, such as child-resistant blister packs. We've asked the US Food and Drug Administration (FDA) to give this more consideration. Our medication safety colleagues at *Prescrire*, a French publication, recently wrote about a 30-month-old child who swallowed 8 tablets of mercaptopurine 50 mg (400 mg). The drug was actually prescribed for his 7-year-old sister with acute lymphoblastic leukemia. Although the child initially suffered liver cell damage, this resolved within 12 days, and there were no permanent sequelae. It was learned that the tablets were dispensed in a prescription bottle with a child-proof cap. It is unknown how the drug was actually accessed by the child. However, improperly replaced caps are a well-known problem with bottles.

Incidents like this one are a reminder that child-resistant blister packaging that meets the requirements of the Poison Prevention Packaging Act can help reduce the risk of poisoning. Still, it is critically important to remind patients to keep all medications and vitamins up and away and out of a child's reach and sight. Dispensing chemotherapeutic agents, and other hazardous drugs in blister packs, can also better protect pharmacy employees from exposure to hazardous drugs and prevent any potential cross-contamination that might occur if the drugs are counted on a counting tray that is not cleaned before use for a subsequent prescription. Also, blister packs designed as calendar packs can improve adherence in addition to preventing errors, including fatal oral methotrexate errors as a result of inadvertent daily instead of weekly dosing.

Revision to drug name pairs with tall man letters. As a result of ISMP and ISMP Canada harmonizing certain drug

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6 Aids in measuring drug effectiveness and learning from off-label use

Schiff et al.[1] remind readers that a drug's effectiveness cannot be measured meaningfully without knowing its reason for use. Thus, an indication-based prescribing system would permit clearer assessments of drug effectiveness, could be used to support drug outcomes research, and could possibly provoke labeling changes or prescribing improvements, including with off-label drug use.

Addressing the Challenges

Because indication-based prescribing represents such a compelling opportunity to improve patient safety and quality, AHRQ has funded a 3-year project spearheaded by Schiff et al.[1] to create and test a prototype system while identifying and addressing the challenges inherent with its development and use. Rather than burdening prescribers with adding indications to prescriptions, the team is working with human factors and information technology experts and policy leaders to build an electronic prescribing system that will allow prescribers to start with an indication or the patient's problem list and then guide them toward the best medication choices.

Development of this prototype is not without its challenges. According to the team,[1] the key to designing the system is making sure it fits into and enhances the typical prescribing workflow and leverages other information technology systems. To date, some of the challenges associated with this process include:

- Defining the best terminology to use for the indications
- Differentiating billing codes for reimbursement versus drug indications
- Deciding how to manage empirical treatment when no definitive diagnosis exists
- Determining how to manage drugs given for multiple different indications
- Complexities in creating "smart" drug recommendations based on indications that incorporate patient allergies, contraindications, avoidance of current medications or past medications that have failed, and insurance or formulary restrictions
- Complexities in transmitting indication information between prescribing systems, pharmacy systems, and electronic health records
- Limited real estate for placing indications on prescription container labels
- The potential for inhibiting legitimate off-label use if the indications do not include these uses

Conclusion

We agree with Schiff et al.[1] that indications are a missing link connecting patients to their prescribed drugs, and that electronic prescribing systems must incorporate drug indications. We look forward to learning more about the development and testing of the prototype indication-based prescribing system.

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name pairs that utilize tall man letters, a change was made to two name pairs on the US **ISMP List of Look-Alike Drug Names with Recommended Tall Man Letters** (www.ismp.org/Tools/tallmanletters.pdf). The name pairs with revised tall man letters (followed by the other look-alike drug name in the pair in parentheses) are dil**TIAZ**em (diaze**PAM**) and s**AX**agliptin (**SIT**agliptin). We regret any confusion that this may have caused.

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