Is an Indication-Based Prescribing System in Our Future?

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In a 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. Longtime proponents (along with ISMP and other organizations) of including the purpose of medications on orders and prescriptions, Schiff et al. note that, as most prescriptions and medication orders are electronic these days, the format for implementing indication-based prescribing is within our grasp. The authors indicate 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 through electronic prescribing, the risk of errors is still present because of the complexities with drug choices and regimens, and the possibility of selecting the wrong medication among several look-alike drug names from a drop-down list. The authors suggest that it's time to enter the age of reason in medicine, and they believe that indication-based prescribing is the missing link in electronic prescribing. As such, they are building and testing a prototype that will make electronic indication-based prescribing possible.

The Sixth Right

The authors[1] start out with a quote from an 1833 article in the *Boston Medical and Surgical Journal* (forerunner of *The New England Journal of Medicine*) that clearly expresses the prevalent, paternalistic medical model at the time for preventing patients from knowing the names and indications of prescribed medications, which was the writing of all prescriptions in Latin. The 19th-century article suggests that very few patients possess the firmness of mind to reason calmly about the effects of medications and diseases, and that the only way patients can rest during severe illness is to implicitly rely on the physician and acquiesce to the prescribed course of treatment without the slightest question or argument. Given our current transparent, patient-centered medical model, such sentiments would hardly be accepted now. However, the authors remark that, even today, patients are often still in the dark regarding the purposes of their prescribed medications.

In addition to the five rights of safe medication use—right patient, drug, dose, time, and route—there is a sixth element[1] that must be included and that is conspicuously absent: the right indication. Such a "right" would inform patients and enhance the safety of every prescription and medication order.

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 the selection of the wrong drug while prescribing, transcribing, dispensing, or administering medications.[2-5] One primary cause of these errors is drug-name similarity.[6] In fact, ISMP's List of Confused Drug Names comprises close to 400 different drug-name pairs, which include only those involved in errors 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 the List of Confused Drug Names, include:

- risperi**DONE** and r**OPINIR**ole
- hydr**OXY**zine and hydr**ALAZINE**
- hydroxychloroquine and hydroxyurea
- **RAPAFLO** (silodosin) and **RAPAMUNE** (sirolimus)
- acetaminophen and aceta**ZOLAMIDE**
- val**ACY**clovir and val**GAN**ciclovir
- penicill**AMINE** and penicillin

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

Even before 1996, which was the first publication year of *ISMP Medication Safety Alert!*, ISMP recommended including a medication's purpose with prescriptions and hospital orders to prevent errors. Knowing the purpose of a medication helps health care practitioners avoid confusion between medications with look-alike names, as most drugs 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 diagnosis 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, mefloquine and **MALARONE** (atovaquone/proguanil) for prophylaxis or treatment of malaria, and dinoprostone for the cervical ripening of women in labor or evacuation of the uterine contents. Thus, providing information about the indication also helps prevent dose, dosage form, or frequency errors.

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

2) Empowers Patients, Increasing Patient Adherence

Knowing a drug's indication helps patients and their caregivers to 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 a prescribed medication. Without this knowledge, patient adherence to the medication is decreased.[8]

Not knowing the purpose of prescribed medications has also led to patient misunderstanding, prescriber distrust, and a refusal to take the medication, particularly when drugs are used off-label. For example, ISMP has published several reports of patients with head and neck pain who 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.

In addition, 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 inferred from the drug therapy that they had epilepsy, as did their treating physicians, who had not prescribed carbamazepine. Both patients underwent unnecessary diagnostic tests and treatment.

3) Improves Communication Between the Health Care Team and Patients/Families

The entire health care team must have knowledge of the intended indication of prescribed medications to understand what is being treated, what the desired outcome is, 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. What other health care professional would feel that he or she is providing safe and quality care while working in the dark without this crucial information? For decades, pharmacists have advocated for the inclusion of the indication on prescriptions, but prescribers were worried about confidentiality—a legitimate concern. However, better communication with the health care team is still compatible with protecting patient information, and protections provided under the Health Insurance Portability and Accountability Act (HIPAA) allow for such communication between professionals who are providing care to a patient.

ISMP has previously notified its readers that, per the 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 regulations.[10] Although a patient's diagnosis or purpose for using a medication would qualify as protected health information (PHI), communicating that information on a prescription does not require separate, special authorization because the information is being 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 have 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 infection, Schiff et al. 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.

4) Helps with Medication Reconciliation

As described by Schiff et al.,[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 being able 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 on 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 include 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 the documentation of the problem list, allow integration of the problem list with the prescribed medications, facilitate reimbursement coding, and streamline the prior authorization process.

6) Helps Measure 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 the reason for its 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 for off-label drug use.

Addressing the Challenges

Because indication-based prescribing represents such a compelling opportunity to improve patient safety and quality, the Agency for Healthcare Research and Quality funded a three-year project, spear-

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headed by Schiff et al.,[1] to create and test a prototype system while identifying and addressing the challenges inherent in its development and use. Rather than burdening prescribers with the requirement of adding indications to prescriptions, the team is working with 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.

Developing this prototype is not without its challenges. According to the team, 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 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

ISMP agrees 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. Hopefully, the development and testing of the prototype indication-based prescribing system will lead to a safer, more efficient means of ordering medications.

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