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ADverse Drug Reaction/Event Screening System

Executive Summary

The **AD**verse **D**rug **R**eaction/**E**vent **S**creening **S**ystem (ADDRESS) "side-effects"† screening system is designed to easily, rapidly, and efficiently screen patients who are receiving prescription drug therapy for the presence of acute or on-going side effects. ADDRESS is not intended to predict or prevent side effects, but to discern those already being experienced. Pharmacists are well aware that some percentage of the patients they serve are experiencing side effects, ranging from the mundane to problems of sometimes horrific severity.

This is especially true in the community practice environment, where the vast majority of prescriptions are prepared and dispensed. Community pharmacists may only rarely have the opportunity to influence the first steps of the prescription drug use process, to influence prescribing choices - but they witness the consequences of those prescribing decisions every minute of every day. Community pharmacists are uniquely positioned to assess the success or failure of pharmaceutical therapy. They are the health care professionals best positioned to discern side effects of pharmaceutical therapy - IF they had the time.

Or perhaps ADDRESS could become part of the waiting period at the physician's office, bringing the result directly to the prescriber.
The problem is not what to do if a side effect has been identified. Ample evidence exists for the ability of pharmacists and physicians to resolve drug related issues, including side effects. The problem is, in the modern practice environment, how can we identify which specific patients are suffering side effects, and how could this be done in an inexpensive and timely manner?

This is the function of the ADDRESS application. Sophisticated psychometric and data synthesis methods have been systematically applied to develop a proprietary set of questions for each of the top 470+ drugs (as determined by the # of prescriptions written) dispensed in the United States. Questions for each drug are ranked beginning with the single most common side effect "symptom cluster" (multiple ADRs may produce similar symptoms) and then proceeding to sequentially lower incidence problems. The questions are limited to the top 5 symptom clusters for each drug, resulting in short, 5 question checklists, suitable for daily use in the practice setting, with the provision for additional checklists to be completed at subsequent refill interactions. The sophistication of these checklists is such that, across all drugs in this group, on average, some 60% of known side effects will be identified using the first of these 5 question checklists.

These checklists have been integrated into a tablet based application with a user-friendly interface. The pharmacist or attending nurse would select the patient's drugs from a drop down menu (a process requiring far less than a minute, on average), and the patient then completes the checklists. The patient is handed the device (an I-Pad) and usually can complete the checklist in 2 minutes or less. Questions that duplicate across multiple drugs are only asked once; the incidence in each drug is reported to the practitioner, to begin differential diagnosis of the most likely culprit, pharmacologically).The application automatically synthesizes a summary report, and when the practitioner calls up the results, they see only those questions the patient has responded to as being an issue they are indicated they are experiencing, as well as an estimate of the severity of the side effect, based on the frequency at which the side effect occurs, and the patient's rating of how bothersome the side effect is when it does occur.

Now, when addressing the patient during the counseling session, instead of spending considerable time attempting to discover if the patient has any issues, the pharmacist can begin the counseling session addressing the problems the patient has identified, starting with that issue most problematic to the patient. The difference in the nature of the ADDRESS-driven counseling interaction from that of established methods for patient counseling such as the prime questions is profound. Problem solving begins in the first few seconds of pharmacist/patient interaction. In the physician's office, modifications to therapy could be initiated immediately, in order to modify pharmacotherapy.

ADDRESS also maintains a complete database of the interaction, recording all salient information, including a HIPPA-compliant non-identifying identifier, to allow us to follow patients through the system anonymously. An option exists for printing out the summary page for transmittal to the attending prescriber or for scanning into the electronic medical record. Questions are available in English, French, and Spanish. We know physicians respond well when made aware of patient problems with ADRs; the challenge is closing that feedback loop and moving from an "off the rack" approach to pharmacotherapy (e.g., recommended dosing) to a more "tailored" version of the Medication Consumption Experience (MCE).

While the system does not currently retain patient specific data on the mobile device, once fully developed and deployed, the system will provide automatic collection of patient level data suitable for reimbursement billing, documentation of quality assurance, and true comparative effectiveness data of drugs used in specific populations.

† - Technically, Expected Adverse Drug Reactions (ADRs) and Adverse Drug Effects (ADEs). The lay-term “side effects” is used in this document for the purposes of enhancing readability, but as used here refers to expected ADE/ADRs throughout.

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