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An Automated Medication Adherence Tool

Ruth A. Maulucci, *Senior Member, IEEE*, and Daniel Somerville

***Abstract*—Misuse of medications is a major cause of morbidity and mortality. The pervasiveness of non-adherence to medications is having significant health care implications, including costly and distressing hospitalization. This paper presents a new method for delivering medication instructions that incorporates all aspects of all medications in a regimen into one chronological schedule, rather than using an independent instruction set for each medication as is currently done. It is an automated tool that accepts as input only the name, dose, and frequency of each medication, and generates a chronological schedule that respects all medication constraints and contains the essential directions for use. The potential users of the system are health care environments in which a log of all of a patient's medications, including over-the-counter medications, resides in one place.**

I. Introduction

MISUSE of medications is a major cause of morbidity and mortality. Inadequate adherence to medications can have severe health care implications, and is a significant contributor to the costs of medical care in every therapeutic area [1].

Low adherence with prescribed treatments is ubiquitous and can have serious negative consequences such as unplanned hospitalization [2], [3]. Adherence to instructions is considered necessary for the success of drug treatment in chronic diseases, essential to the avoidance of complications in ambulatory surgery, an essential attribute of effective treatment for persons who are discharged from the emergency department, and contributory to improved outcomes in patients with major illnesses [4].

No matter how severe the consequence, there is no assurance that all patients will take their medications as prescribed. Nonetheless, numerous interventions aimed at improving adherence to medication regimens have demonstrated that adherence can be modified [5], [6], and that compliance aids facilitate adherence [7], [8]. Additionally, various standards for improved medication instructions have been proposed [9].

It may be argued that there are three distinct types of non-adherence. First, some patients deem it unnecessary or futile to comply with the directives for medication. Second, some patients possess a willingness to comply but are physically or cognitively unable to do so. Third, some patients possess the willingness and ability to comply, but experience difficulties under the current system of home medication [10].

This paper presents an automated tool that addresses the third type of non-adherence. We have designed and implemented the first stages of a method for delivering medication instructions, particularly in the case of multiple medications, that incorporates all aspects of all medications into one chronological schedule, rather than using an independent instruction set for each medication as is currently done. This consists of two elements. First, for each medication, the essential directions for use are identified. Second, the dose and dose frequency of each medication together with the directions for use are combined to generate one cohesive temporal schedule of all the medications. The resulting document consists of one page for each time an action must be taken with regard to medication and the directions that must be followed at that time. The system will be referred to as the Annotated Chronological Medication Schedule (ACMS). The system is appropriate for all health care environments in which a log of all of a patient's medications, including over-the-counter (OTC) medications, resides in one place. Examples of such users are hospitals for one-time discharge of in-patients or emergency department patients, primary care physicians following each visit, the VA central pharmacies and its online Healthy Vet program, health insurance companies, assisted living facilities, and commercial medication adherence services. The system works by accepting as input only the name, dose, and frequency of each of a patient's medications, and generating the chronological schedule and directions. The output is given to the patient by the provider every time a medication regimen is assigned or changed.

II. The Traditional Method Versus the Chronological Method

The traditional style of imparting instructions for a group of medications to a client for at-home self-administration or family-administration is a set of individual prescription leaflets, each of which pertains to one medication and each independent of all the others, and instructive phrases on the container for each medication. This requires that the set of leaflets or the containers be consulted constantly throughout the day to determine if the time for one of the medications is at hand. We have developed a different strategy which is to have a set of individual pages, one for each time of the day that some action must be taken with regard to the group of medications; this will be called the chronological method.

The following illustrates the traditional and chronological methods for the medication course of a hypothetical patient.

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Ruth A. Maulucci is with MOCO, inc., Scituate, MA, 02066 USA. Phone: 781-545-2040; fax: 781-545-8141; e-mail: maulucci@mocoinc.com.

Daniel Somerville is with MOCO, inc., Scituate, MA, 02066 USA.

The seven medications are Fosamax 70 mg, Citracal +D, Wellbutrin XL 300 mg, Wellbutrin XL 150 mg, Cymbalta 60 mg, Trazodone 100 mg, and Nexium 40 mg.

A. Traditional Method

Using the traditional method, the pharmacy dispenses the six prescription medications with one leaflet for each medication. Each leaflet contains the basic information required to take the medication properly. It also contains a great deal of additional information about the medication, such as the reason it is prescribed, side effects, precautions, drug interactions, overdose. Thus, each medication is on a separate page, the page is quite full, and the order of the pages is irrelevant. The seventh medication, Citracal, is an OTC with directions for use on the label. This is illustrated in Fig. 1.

While the additional information is important, it is not necessary to read it each time the medication is taken. Deleting the additional information from each page and leaving only what is essential when taking the medication simplifies the medication taking process considerably, and this is what is done by means of labels and stickers on the medication containers. This is depicted in Fig. 2.

Although the extraneous information has been removed, there is still substantial writing on the labels that is not necessary at usage time, such as pharmacy and patient addresses, physician identification, dispensing and expiration dates, refill authorization. The directions are often obscured by this writing, incomplete, and not all in one place on the label, some conveyed with stickers randomly attached to the container. Of greater note is that the instructions cannot be ordered temporally, and it is still necessary to glance at the containers throughout the day to capture the next event. Further complicating the task is that stipulations such as fasting must sometimes be incorporated into the decisions as to when to take the medication. Organizing the instructions according to time, making certain decisions, and settling options result in a page presentation that greatly simplifies the medication taking task. This is the chronological method.

B. Chronological Method

Using the chronological method, the health care professional dispenses a set of pages each time a medication regimen is designed or changed. Each page corresponds to a time when one or more of the seven medications must be taken and contains only the basic information necessary at the time of use with all choices already made. The pages also contain a picture and description of the drug form. The pages are kept in chronological order and the patient only need attend to medications at the indicated times. The previous example now becomes Fig. 3.

III. The ACMS System

The first version of the ACMS has been produced. It is described next.

A. Design and Implementation

A list of phrases used to impart medication directions was compiled by consulting several online internet drug indices, such as *RxList*. The list contains medication orders such as "inhale", "every three hours", "taken after meals", "taken with juice", "remain upright for 30 minutes", "do not operate machinery", and other stipulations. The essential directions for use for a set of the most dispensed drugs in the U.S. were then extracted from the online drug indices. Similarly, the essential directions for popular over-the-counter (OTC) medications were obtained. The results were used to build a medication procedures database.

In addition to the procedures database, the system also contains a practitioner data module resulting from interviews with physicians and pharmacists. This sometimes produces disagreements between the database and the health professional. In such cases, the information from the health professional overrides the information from the drug index.

Also embedded in the system is a current practices module that contains generalized precepts. For example, a current goal in pharmaceuticals is to minimize the number of times per day that the patient has to attend to his or her medication. Another current goal is to schedule as many of the medications as possible in the morning time slot. These are essential to promoting adherence, since studies show that adherence diminishes dramatically the more dosing times there are during the day and the later in the day they are scheduled, most notably in the elderly [7], [10].

Software was implemented to produce the chronological schedule for medication sets. The software accepts as input only the drug name, the number of times taken per day, and the amount taken each time for each medication in the set. It then uses the medication procedures database and the auxiliary modules to produce a temporal schedule that does not violate any directions for any of the drugs in the set. The system has the capability to resolve conflicts and options and make decisions. It handles situations in which one drug may decrease the absorption of another drug, where this conflict can be resolved by scheduling the taking of each drug a given number of hours apart. It selects an appropriate option when one medication requires food and another fasting. It merges certain aspects of the orders such as when one calls for "taken with water" and another for "mix with juice or water" so that duplicate directions are condensed into one when the two medications can be taken at the same time. It imposes some decisions such as associating the medication with two specific meals when the direction is "take twice a day with meals". The software issues an alert when the constraints are such that a schedule is not logically possible for the medication set.

The ACMS is implemented in Microsoft Access, a relational database system. This allows multiple views of the data, such as the number of drugs to which a particular directive applies. It also simplifies the process of maintaining the software as new drugs are added.

B. End User

All of the above is transparent to the end user, i.e., the health care professional does not have access to the data modules or the internal operations. To produce a schedule for a particular patient, the user calls up the system, enters the name, dose, and dose frequency for each medication, and generates the schedule with one keystroke. All of this is done through pull down menus that contain all drugs, all dose possibilities, e.g., one tablespoon, and all dose frequencies, e.g., twice every day. The ACMS automatically sets the times and incorporates the appropriate directions.

C. Scheduling Algorithm

The following is an overview of the scheduling strategy and the resolution of conflicts, with reference to Fig. 3 for examples. In contrast to most other compliance devices, the system can handle liquids, inhalers, drops, injections, moisture-sensitivity, and refrigeration as easily as it handles pills. Consider 8 time slots: 1) upon rising, 2) 1 hour before breakfast, 3) after breakfast, 4) 1 hour before lunch, 5) after lunch, 6) 1 hour before dinner, 7) after dinner, 8) at bedtime. The goal is to schedule as many medications as possible in Slot 3, and to use the minimum number of slots.

1. Let Set 1 consist of all medications in a patient's regimen.
2. Place all medications in Set 1 in Slot 3.
3. Examine each medication in Set 1 to see if it requires a specific slot. For example, Fosamax must be taken immediately upon rising and Trazodone must be taken at bedtime with food. Place those medications in Slots 1 and 8, respectively, and tag them as unmovable without permission. If any medication must be taken at bedtime with food, examine Set 1 to see if there is any medication that implies that the subject should not eat at bedtime. If so, consult the practitioner data module to see if it can be taken with the next earlier food time slot. If yes, move it to that earlier time slot and tag it as unmovable without permission. For example, Nexium implies that the subject should not eat at bedtime, and the practitioner module allows Trazodone to be taken earlier with food, so Trazodone is moved to Slot 7.
4. The remaining medications now comprise Set 2.
5. Examine each medication in Set 2 to see if it must be taken on an empty stomach. Place it in the first fasting time slot that does not contain a medication that conflicts with it. For example, Nexium must be taken on an empty stomach, it cannot be taken upon rising because it will conflict with Fosamax, so it is placed in Slot 4.
6. The remaining medications now comprise Set 3.
7. If a medication in Set 3 must be taken twice a day, place the second dose in Slot 7 or 8. The decision depends on whether there is a medication in the slot that conflicts with it, whether it requires food and the subject should not eat at bedtime, and whether it can be placed with another medication to reduce the number of dosing times. Hence, the second dose of Citracal is placed in Slot 7.

IV. Conclusion

The ACMS is a software package that can be used by health groups to generate a chronological medication schedule with only and all necessary usage directions for each client. It requires minimal input from the users, and will permit them to better serve their clients by enabling the client to use pharmaceuticals with greater success.

In the next version, the ACMS will be expanded in several directions. More medications and more human knowledge from experts in major specialties will be embedded. To accommodate the new information, we will investigate the possibility of recasting the system as an expert system. Customized interfaces will be developed for automated retrieval of medication name, dose, and frequency from a patient's electronic records as they exist in a physician's or hospital's system. Customized interfaces will be developed to output the schedule on displays that are part of commercial adherence devices that reside in a client's home. A capability will be implemented so that once generated by the provider, the schedule can be given to the patient on a disc or USB flash drive and displayed on the patient's home computer screen with auditory prompts. A routine that allows the user, i.e., health care professional, to override system decisions will be developed. The user will be able to modify some items, such as the time for a particular drug, by requesting to input and entering the changes. The system will accept the changes and regenerate the schedule with the modifications.

A formal validation study will be conducted to investigate whether the ACMS improves medication adherence and whether it poses a risk to patient safety. Subjects will be required to be living and functioning independently, have a working knowledge of spoken and written English, read a large print page with corrected vision, be taking at least three medications, and be non-compliers of the third type. Subjects will be selected who are typically taking significantly less than the prescribed amounts of medication, since this is a major area of non-adherence [1]. They will spend four months using the hard copy schedule. They will be monitored by visits and telephone calls, and will have access to a 24 hour hotline. They will be encouraged to read the leaflets periodically for information not included in the ACMS. Medication measurement and pharmacy refills will be examined to determine if the ACMS promotes a better correspondence between the amount of medication taken and the amount prescribed, and any adverse effects from using the system will be documented.

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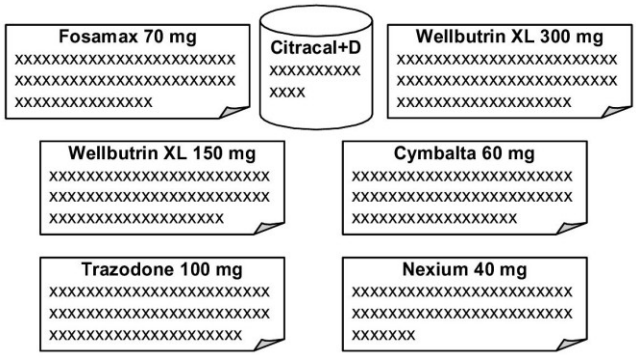

Fig. 1. The traditional method with leaflets.

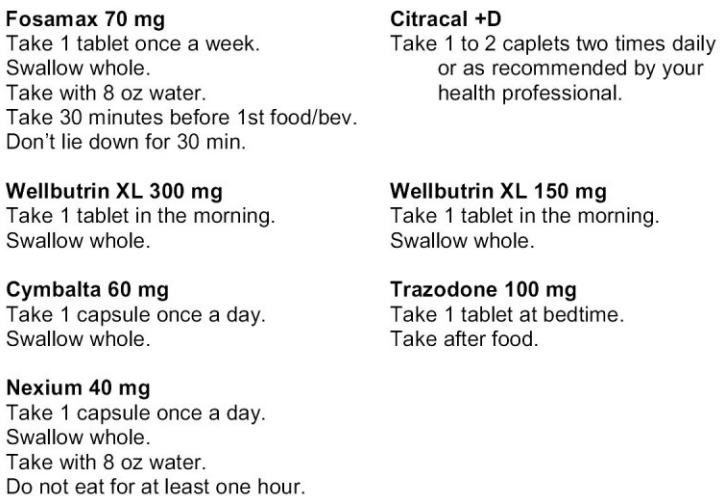

Fig. 2. Essential information conveyed with labels and stickers.

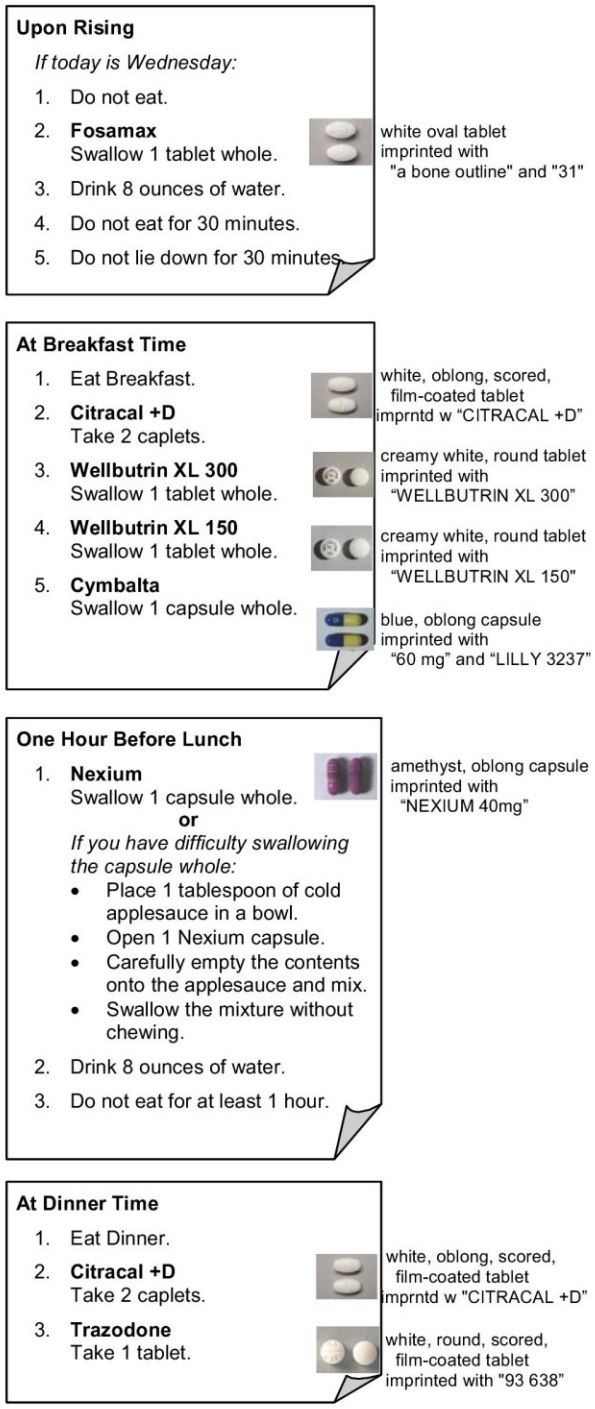

Fig. 3. The chronological method.