The issue of medication compliance

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Patient noncompliance is a major medical problem in America. Consequently, numerous studies and reports have been performed to articulate the meaning of the problem and to suggest improvements. The literature however, in its effort to explore all facets of the current compliance situation, has produced a complex construct, making it exceedingly difficult for clinicians and researchers to understand the problem. This report was undertaken to unify the current spectrum of compliance literature, to make sense of the adherence situation. A variety or research methods was used, including MEDLINE and PubMed searches, university medical library searches, general Internet searches, and clinical text reviews. The result was a categorization of the literature into six segments, including articles identifying adherence as a problem, identifying the causes of noncompliance and exploring possible solutions, analyzing adherence with respect to specific ailments, and exploring the patient's role, the pharmacist's role, and the physician's role with respect to compliance. After the exploration and synthesis of the current literature, we suggest that future research concentrate on the practitioner for a better understanding of the compliance situation and the creation of a universal method of ensuring compliance.

Introduction

Over the past 25 years, literally thousands of articles have been published on the issue of medication compliance, also known as adherence, approaching the issue from various angles and ending in confused conclusions. The multiplicity of studies focusing on adherence has resulted in conflicting data and contradictory results. Areas of research on this issue include identifying adherence as a problem, identifying the causes of noncompliance and

exploring possible solutions, analyzing adherence with respect to specific ailments, and exploring the patient's role, the pharmacist's role, and the physician's role with respect to compliance. Traditionally, research has concentrated on recognizing why patients are noncompliant and the strategies that various providers can use to increase compliance. After more than 25 years of research on this issue, we still have yet to outline an optimal approach that insures high compliance levels. However, it is crucial that we improve our understanding of the issue because at the very least, costs as a result of patient noncompliance are estimated at $100 billion a year and are the result of adverse outcomes such as hospitalization, development of complications, disease progression, premature disability, or death. 1-8 What follows is a summary of the current status of adherence research, in other words, what we do know.

Methods

The analysis of the current literature was undertaken in a variety of ways. We began our research by exhausting online medical journal search engines such as Medline and PubMed. We included all articles, regardless of publication date, so that we could understand the progression of compliance research. We spent considerable time collecting and reviewing journal articles in order to gain an understanding of the current situation as seen from other medical researchers. We then moved to a broader Internet-based search to include articles and information specifically for patients and practitioners. We then studied medical texts concerning patient compliance, such as the American Heart Association's Compliance in Healthcare and Research and Achieving Patient Compliance, by M. Robin DiMatteo and D.

Dante DiNicola. When we believed that we had exhausted all avenues of compliance research, we began the arduous task of synthesizing the information into a review of the literature as a whole. This report discusses that review.

Analysis of the Current Literature (Results)

Identification of Noncompliance as a Major Medical Problem

Much of the research concerning patient compliance deals with the identification of adherence as a medical problem. This area of research aims to convince the reader that something needs to be done about the current patient noncompliance situation. As expected, much of the data behind this type of study exists in the form of factual and numerical information. The following is a list of typical compliance statistics: 9

-Approximately 125, 000 people with treatable ailments die each year in the USA because they do not take their medication properly.

-Fourteen to 21% of patients never fill their original prescriptions.

-Sixty percent of all patients cannot identify their own medications.

-Thirty to 50% of all patients ignore or otherwise compromise instructions concerning their medication.

-Approximately one fourth of all nursing home admissions are related to improper self-administration of medicine.

-Twelve to 20% of patients take other people’s medicines.

-Hospital costs due to patient noncompliance are estimated at $8. 5 billion annually.

Noncompliance is typically cited as occurring in from 50% to 75% of patients. In other words, in the United States, 50% to 70% of patients do not properly take prescribed medication. The rate of noncompliance is even higher in patients with chronic illnesses. 10 This is because the drug regimens for these patients are often long-term, complex regimens that alter existing behavioral patterns. In addition, children are less likely than adults to follow a treatment plan because of their dependence on an adult caregiver. 11 Clearly, the research has proven that noncompliance is a serious medical issue. It is a major medical problem that may lead to death and elevated costs, both for patients and providers.

Noncompliance in Regard to

Specific Ailments

Both complexity of regimens and rates of compliance differ with respect to specific ailments. Part of the body of research conducted on drug compliance deals with rates of compliance and reasons for noncompliance for specific diseases and medical conditions. Perhaps the most commonly studied condition in relation to patient compliance is hypertension.

Hypertension is a chronic condition that may result in stroke and heart failure. Researchers estimate that 58. 8 million Americans (one fifth of the population) have some form of cardiovascular disease. 12 Noncompliance is a major factor in the increasing number of deaths related to cardiovascular

disease. According to a recent study by a team of researchers from the University of Lausanne in Switzerland, “ as many as half of ‘ failures’ of treatment to bring elevated blood pressure down to normal levels may be due to unrecognized lapses by patients in taking antihypertensive drugs as prescribed.” 13 Clearly, noncompliance with regard to hypertension is a major medical problem. But the question is why hypertension patients do not take the prescribed medical regimens? The major problem for compliance and hypertension is that patients often do not feel any adverse physical effects. Because of this, patients do not experience any physical improvements due to the strict compliance to the medical regimen. The most commonly cited reasons for noncompliance include, not being convinced of the need for treatment, fear of adverse effects, difficulty in managing more than 1 dose a day, or multiple drug regimens. 14 The recommendations for improvement of patient compliance are even more numerous and nonspecific as the reasons for noncompliance themselves. The following is a list of recommendations given to physicians in an effort to improve compliance: 12

-Make it clear to patients that they themselves perceive the medication as being important.

-Provide clear instructions.

-Tailor the drug regimen to the patient’s individual schedule.

-Review the importance of compliance with patients.

-Teach patients to self-monitor.

-Establish regular contact with patient.

-Provide cognitive aids for the patient.

-Ask the Patient to buy and use a medication container.

The list continues with countless other recommendations. Clearly, both the reasons for and the methods of improving treatment and compliance with regard to hypertension are complex.

Another example of this type of research relates to diabetes. Diabetes affects 17 million people or 6. 2 percent of the American population. 16 Diabetes is a chronic illness, like hypertension, which involves a complex, long-term medical regimen. Researchers estimate that 95% of diabetes care is performed by the patient. 17 The treatment plan for diabetes involves more than simply taking prescribed medication. Patients must adhere to strict diets and exercise plans as well as properly taking doses of insulin or drugs. Again, it is noted that the complex nature of the medical regimen for diabetes leads to high rates of noncompliance. Because patient involvement in the treatment plan is so high, the most common suggestion for improvement of adherence is for physicians to take a patient-centered approach to treatment.

AIDS, a worldwide epidemic effecting millions of people, is another disease with an extremely complex medical regimen. There have been recent breakthroughs in the effectiveness of AIDS treatments including HAART (highly active antiviral therapy), which provide the possibility of significantly controlling the effects of AIDS. Unfortunately, adherence acts as the Achilles'

heel of AIDS treatment. In clinical trials, the HAART treatment resulted in low or undetectable viral load levels in as much as 85% of the patients in the study. 17 But out of the laboratory and in the real world of AIDS treatment, only 50% of patients were positively affected by the HAART treatment. The explanation for this alarming disparity of results was that “ the main reason for these ‘ failures’ was poor adherence to HAART regiments.” 17 AIDS is a very complex disease, and it is certainly true that many patients simply do not understand the importance of adhering to the medical regimen. Patients may also believe that the negative side effects of AIDS medications outweigh the life-lengthening effects and may decide to discontinue treatment. Again, the literature suggests that physicians should make sure that patients understand both the seriousness of the disease and the importance of strictly adhering to the medical regimen.

Clearly, adherence significantly affects the results experienced by patients with these diseases. Among the current literature are seemingly countless articles identifying adherence as a problem as it relates to a specific disease. Other examples not mentioned in this article include, asthma, schizophrenia, and disabilities. But what does this all mean? What is tantamount in all of these articles or studies is that adherence is a problem. Most of these articles identify the problem of adherence and provide suggestions for improving adherence. The great majority of articles suggest that physicians pay more attention to the patient and place more emphasis on adherence.

Proposed Solution to the

Adherence Problem

Another type of article on adherence is geared toward physicians looking for either solutions to adherence problems or ways of protecting themselves against patients who do not adhere to medical regimens. A rising concern among physicians is that patients will sue them for poor outcomes of medical treatment. 18 Physicians worry that they may still be sued, even if failed treatment is the result of the patient's noncompliance. Because of this concern, part of the adherence literature focuses on ways for physicians to safeguard themselves against patient noncompliance. Experts suggest that physicians keep careful documentation of patient activities such as missing appointments because this can be used as evidence of patient noncompliance. 19 Other suggested methods of improving patient compliance and limiting physician liability include patient reminders such as telephone calls or mailed reminders to make an appointment or to pick up a prescription. Repeat RX and RepeatVisit are two available nationally operating programs for patient reminders. For a fee, these programs will contact patients for physicians and pharmacists. Other articles however, suggest that patient reminders are wholly ineffective. One article claims, " one of five patients who were frequently reminded did not take their medication as prescribed." 20

Although these articles discuss adherence issues and possible solutions, they do not provide any useful information on attacking the adherence problem as a whole. For example, one typical reminder research study21 consists of a summary of the results of 5 clinical trials examining the effect of using patient reminder cards, patient education, an incentive for patients, help from peer group or community, and intensive self supervision. The study

concluded that all of these factors improved compliance but that none was significantly exceptional.

The Role of the Patient and Compliance

Much of the current literature on noncompliance concentrates on the patient's role in determining adherence to treatment. Being " compliant" encompasses the patient's " active participation in his or her own health care: seeking medical advice, keeping appointments, following implicit and overt recommendations concerning life style, diagnostic investigations, and medical and surgical regimens." 19 Noncompliance is typically associated with a patient characteristic. The most common examples or reasons for noncompliance deal with the patient's behavior and include the following: 21

-Failure to take medication: This includes missing doses, premature cessation of therapy, and ineffective methods of taking medications.

-Taking too much medication: Some patients, hoping for additional benefit, increase the number of doses or the amount taken each time, incorrectly assuming that if some is good, more must be better.

-Taking a drug for the wrong reason: This may arise from confusion about the purpose of using a drug, particularly if several drugs are being used.

-Improper timing of drug administration is more likely to occur if the medical regimen is complex: the administration of numerous medications at frequent or unusual times during the day.

These patient behavioral factors may or may not be perceived by the physician. A real problem exists when physicians do not recognize

noncompliance because they will inevitably increase prescription dosage. Physicians will increase the dosage, thereby increasing the risk of side effects and even worse compliance. In this sense, the cycle of noncompliance can be represented as a downward escalating spiral.

Although the patient noncompliance literature contains many contradictions, one piece of information is both crucial to adherence understanding and unanimously agreed on. This is that “ none of the common demographic factors such as age, marital status, living alone, sex, race, income, occupation, number of dependents, intelligence, level of education, or personality type have been shown to be consistently related to noncompliance”. 21 Examples of patient-centered compliance studies are discussed in the following sections.

Physician-Delivered Smoking Intervention Project: This study, funded by the National Cancer Institute in 198622 found that the patient-centered approach was more effective than physicians simply giving personal advice to patients. Patients were randomized into three groups: those who received advice, those who received the patient centered approach, and those who received the patient-centered approach plus a Nicorette prescription. The results were that 9% of those receiving advice quit smoking, 12% receiving the patient-centered approach quit, and 17% of those receiving the patient-centered approach in combination with medication quit.

Review of financial incentives to enhance patient compliance: 23 This article includes the results of 11 studies performed in an effort to determine the effect of financial incentives (cash, vouchers, lottery tickets, or gifts) on

compliance with medication. Ten of the 11 studies found improvements in patient adherence with the use of financial incentives.

Review of trials to improve antihypertensive drug adherence: 24 This article summarizes the results of 29 blinded and unblinded clinical trials undertaken to determine the effect of worksite care, physician education, an electronic vial cap, patient cards, and calendar packaging. The article described insufficient evidence to support the effectiveness of mailed reminders alone, according to unblinded trials. Adherence results were conflicting for patient education and inconclusive for patient counseling. Self-monitoring was deemed ineffective according to single-blind trials.

The Role of the Pharmacist

A new trend within the noncompliance literature is to examine the role that the pharmacist plays in determining patient compliance. Furthermore, articles suggest that pharmacists, having direct contact with patients while patients are engaged in their medical regimen, have a better ability to detect compliance problems. A new trend that is being proposed to improve patient compliance is to implement a system around the community-based pharmacist. A community-based pharmacist is one that has direct involvement in a patients treatment plan, has direct and frequent contact with physicians, and has an active role in changing or altering a patient’s medical regimen. 25 The community-based pharmacist can improve compliance because “ the pharmacist is often the only member of the health care team who has access to information about all of the patient’s drugs”. 25

The community-based pharmacist shares this information with the physician to improve patient care and compliance.

IMPROVE (Impact of Managed Pharmaceutical Care on Resource Utilization and Outcomes in Veterans Affairs Medical Centers:)25 An example of a pharmacist-based study, this study looked at the influence that the pharmacist has on determining patient compliance. This study included 78 ambulatory care clinical pharmacists who documented 1, 855 contacts made with 523 patients over 12 months. The pharmacists were responsible for adjusting patients' drug regimens as well as identifying and preventing drug-related problems. The study found that this type of pharmacist intervention improved patient adherence.

The Role of the Physician

There is a whole area of compliance research dedicated to examining the role of the physician and compliance. Articles within this body of research suggest methods for physicians to use to improve patient compliance. The great majority of these articles focus on doctor-patient communication.

There are limitless theoretical models for medication compliance including social cognitive, reasoned action, planned behavior, stage models, self-regulation, and the patient centered approach among others. These models for compliance improvement share at least one common thread. These models deal specifically with the doctor-patient consultation process as it is divided into three sections, " the patient's input, interaction (both verbal and non-verbal) in the consultation, and the doctor's verbal output". 21 With all of these models, the basic idea is that through an increased understanding

of the consultation process, doctors are able to manipulate consultations in such a way as to increase compliance. Perhaps one of the biggest problems facing physicians is that patients often remember little of the information disseminated during a given visit.

On average, patients forget approximately 40% of what they are told. 21 Furthermore, patients often do not fully understand the information that they do remember. The literature suggests that the main method physicians can use to combat the comprehension situation is through better communication. Some of the techniques that physicians can use to increase compliance include " the use of primacy and importance effects, explicit categorization, simplification, repetition, and the use of specific advise statements." 21 Although these techniques have proven somewhat successful, a study done by the University of Sydney found that these methods resulted in a mean percentage of improvement in recall ranging from 19% to 219%. Rather than discuss each theoretical doctor-patient communication model, it would be useful to discuss the two leading and most cited models, patient-centered approach and the social cognitive model.

The basic premise of the social cognitive theory as it applies to compliance is that the patient's perceptions of vulnerability, severity, treatment effectiveness and costs could be assessed, and it should then be possible in theory to devise messages for that patient which alter perceptions in a compliance-conductive direction. 24 This model deals primarily with the fact that a patient's compliance is a factor of his or her comprehension of information during the consultation as well as their perception of the effects

of not taking medication. Furthermore, these factors will play out unconsciously and will determine the patient's level of satisfaction with the drug regimen. In a recent study, Ley et al. 26 found that giving practitioners suggestions for improving communication led to increases in patient's recall of what they are told.

Another commonly used method for improving patient compliance is the patient-centered approach. As the title for this model suggests, the patient-centered approach places the patient at the center of the treatment. The first step in this approach is for physicians to " accept the patient where she is" 27 In other words, the physician must first accept the fact that the patient may be noncompliant without blaming the patient. Rather, the physician must talk with the patient to understand the reasons for noncompliance. The basic premise of this theory is that the physician does not have all of the treatment answers. In actuality, the patient has a better grasp of the situation and therefore possesses vital information to be used by the doctor. The basic outline for the patient-centered model is as follows:

-Accept where the patient is.

-Accept what you do not know.

-Acknowledge that the patient has the answers.

-Build self-efficacy.

-Set realistic expectation for self and patient.

-Share responsibility.

These are two examples of many of the theoretical models available for physicians to use to improve patient compliance. Although useful, these theories are in some way disconnected from the real world of patient compliance. To get a better grasp of the efficacy of these theories, we must examine the literature for studies related to patient compliance.

For example, one physician-centered study28 summarizes the results of 153 studies published between 1977 and 1994 that evaluated the effectiveness of interventions to improve compliance with medical regimens. These studies essentially tested different theoretical models of the physician-patient relationship to find the most effective model. The results were that compliance interventions had a weak to moderate statistical effect on indicators of patient compliance, but represented generally efficacious interventions in practical terms. No single intervention strategy appeared consistently stronger than any other. Direct education, group processes, familiar support, behavioral modalities, and provider interventions showed no advantage over one another. The more comprehensive the program, the more effective the outcome. 28

Conclusions

Currently, the field of medication compliance research is replete with articles on many different aspects of the compliance problem. As summarized in this report, the literature centers on identifying adherence as a problem, identifying adherence solutions, analyzing adherence with respect to specific ailments, and exploring the patient’s role, the pharmacist’s role, and the physician’s role in relation to patient compliance. After studying the

literature, one can only conclude that there is still no real consensus concerning the most effective way to improve patient compliance. The research shows that adherence to medications is not routinely measured in clinical practice and a universal standard that can easily be implemented does not exist. 1-7, 29-32

The vast majority of the compliance literature focuses on patient variables, but since we still do not know a great deal more, perhaps it is reasonable to shift our focuses to the other side of the patient diad: the practitioner. From the literature, we know that the there exists an almost overwhelming amount of information on ways for physicians to improve compliance through establishing better communication techniques. We also know that among the many different communication techniques proposed, none clearly stands out as a clear method for improving patient compliance consistently. We know that the more time physicians give to improving their patients' compliance, the more effective their efforts are. We know that an increase in the role of the pharmacist improves compliance. We know that telephone and mail-card reminders alone show no real significant improvement in patient compliance. Perhaps this is a far more complex construct than is expected. Perhaps the univariate studies in the past are not enough. Even though it is a complex matter, it is still crucial for health care providers to understand compliance triggers and related variables. The cost and trauma are too great without it.