ISSUES IN MEDICATION COMPLIANCE RESEARCH

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Drug noncompliance poses a serious threat to the health of patients and to their financial well-being. Since Schwartz and her colleagues (1962) undertook their classic study of medication compliance among elderly patients, finding that 59% of them were making medication errors, researchers have been interested in studying this problem. A review of the literature indicates that, although there has been a considerable amount of research in this area, the prevalence of noncompliance persists. Estimates of noncompliance range from 15% to 93% (Brand & Smith, 1974; Martin & Coats, 1987; Robertson, 1985).

The consequences of noncompliance are multifaceted. From a research standpoint, noncompliance clouds the efficacy of therapy and compromises the generalizability of clinical studies. For the patients, noncompliance may diminish the benefits of preventive or curative services. Additionally, it may foster both unnecessary diagnostic studies and treatments; this increases the cost and health risks to patients (Becker, 1985; Carey, 1984).

Noncompliance with medical prescriptions has long been a serious problem in the management of both acute and chronic illness. Estimates from the general population suggest that patients fail to have filled one-third of prescriptions written, have filled but do not adequately comply with the dosage regimen for another one-third, and comply with the prescribed medication regimen in one-third of the cases (Robertson, 1985).

Consideration of health care costs alone makes noncompliance a critical issue. In 1965, health care costs in the United States (U.S.) consumed 6.1% of the Gross National Product (GNP); in 1983 that figure rose to 10.8%. Economists predict it will reach 12 to 15% of the GNP by 1990 (Aaron & Schwartz, 1985). From 1970 to 1977, the average number of prescriptions per year for persons over 65 years increased from 13.4 to 17.9 (Lamy, 1984). Snedden and Cadieux (1988) reported a per person average increase in this

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The Canadian Journal of Nursing Research *1989, 21(4), 35-43*

age group from 18 in 1984 to 25 prescriptions a year in 1987. The average cost of a prescription drug increased 4.3% annually from 1970 to 1978, and from 1980 to the present it has increased at an annual rate of 10%. According to the Pharmaceutical Manufacturers' Association the average cost of a prescription drug in 1977 was $5.98, by 1987 it rose to $15.32 (Scripps Howard Service, 1988), a 156% increase.

Persons with a chronic illness (young or old) are likely to find it necessary to follow a multi-drug regimen for long periods of time. Adherence to a medication regimen appears to decrease proportionately after prolonged usage and with an increase in the number of medications prescribed (Baum, Kennedy, Forbes & Jones, 1985; Cooper, Love & Raffoul, 1982; Kendrick & Bayne, 1982; Murray, Darnell, Weinberger & Martz, 1986).

Noncompliance with the drug regimen has magnified the problem of readmission for the medically compromised and the geriatric population. After conducting a six-month post-hospital discharge study of 158 elderly, Brand and Smith (1974) found that 42% of the patients had not adhered to their physician's medication prescriptions and 34% had to be readmitted to the hospital. McKenney and Harrison (1976) studied hospital readmission records and found that 10 to 17% of the readmissions were related to noncompliance. Findings from other studies conducted by Anderson (1974); Levy, Mermelstein and Hemo (1982); Miller (1973); and Wandless, Mucklow, Smith and Prudham (1979) concurred that the incorrect use of medications was a leading cause of hospitalization.

Problems in Designing Research on Noncompliance

Definitions

We know that noncompliance is a problem. A single acceptable definition would be helpful to researchers in measuring noncompliance. A review of the literature quickly points out the difficulty in conducting compliance research: the lack of a single operational definition. Reviews by Marston (1970) and the World Health Organization ([WHO] 1980) found no universally-accepted definition of the term "compliance" existed. Reviewing the literature through 1987 showed the same deficit. The absence of a common operational definition makes it particularly difficult to interpret or compare studies.

Haynes, Taylor and Sackett (1979) defined compliance as, "The extent to which a person's behaviour (in terms of taking medications, following diets or executing life-style changes), coincides with medical or health advice" (p.XV). Complete adherence was also used to define compliance by McDonald and Grimm (1985); Ross and Guggenheim (1983); Ruffalo,

Garabedian-Ruffalo and Pawlson (1985); and Sbarbaro (1985). Complete adherence was implied, but was not defined, in studies by Epstein (1984), Goldoft and Gosky (1981), and Zola (1986).

Other researchers have undertaken the study of levels of compliance. For example, Gordis (1979) divided compliance into three levels: noncompliers, 0-25%, intermediate compliers, 26-74%; compliers, 75-100%. Wandless et al. (1979) used between 90-110% conformity as the boundaries for compliance. Cooper et al. (1982) were more liberal and defined "underuse" if the subject took less than 75% of the prescribed dose and "overuse" as taking more that 125% on a regular basis.

Goldsmith (1979) classified persons as compliant if they took 80-110% of the prescribed medication. This definition has had increasing acceptance amongst researchers in the area of compliance (Cockburn, Gibberd, Reid & Sanson-Fisher, 1987; Garnett, Davis, McKenney and Steiner 1981; Smith and Andrew, 1983).

While one can appreciate the origins of the variance found in the operational definitions of compliance and the unclear relationship of compliance and therapeutic effect, generalizability problems will continue to plague compliance studies unless researchers adopt a definition that can be effectively used to allow valid comparisons across studies (Goldsmith, 1979).

Measurements

Since the reviews by Marston (1970) and WHO (1980), researchers have commonly used several methods to measure and predict noncompliance. Measures are: subjective (physician and patient reports), objective (laboratory tests, pill counts and clinical signs) and predictive (demographics, diagnoses, knowledge, number of medications, information giver and environmental factors).

Subjective measures

Patient report. Hays and DiMatteo (1987) confirm that the patient report is an unsatisfactory measure. They note a 27 to 36% discrepancy between patients' verbal reports and objective measures such as pill counts, urine tests, prescription refills and blood levels. Similar findings of patients' overestimation of compliance were reported by Gordis (1979).

Physician report. Overestimation of compliance levels also are found in studies using physician report (Charney et al., 1967; Davis, 1967; Roth, 1984). In discussing their findings, Gilbert, Evans, Haynes and Tugwell (1980) reported that although 10 family practitioners knew 58 of their

patients for over five years, their ability to predict compliance to digoxin therapy was no greater than chance.

Objective measures

Laboratory tests and clinical signs. Urine and blood analysis have been used to obtain objective data on patients' compliance. Maddock (1967) studied the adherence of 75 pulmonary tuberculosis patients to anti-tuberculosis drugs; three urine assays were performed within a six-month period. Thirty percent of these patients tested negative for one drug, while 42% tested negative for the other drug.

Craig (1985) measured blood pressure levels and urine assays for antihypertensive drugs. The findings showed that 25% of the 40 subjects being treated for hypertension were noncompliant by urine analysis and another 25% by blood pressure levels.

Predictive measures

Demographic variables. So far we have considered factors that answer the question, "Is the patient compliant?" Researchers must also try to predict which patient is likely to be noncompliant. Studies that correlate demographic data with compliance rates have attempted to answer this question.

The most common demographic variables found in correlational studies of compliance include age, sex, marital status and educational levels. However, little evidence supports a consistent correlation of these variables with medication compliance (Craig, 1985; Klein, German, McPhee, Smith & Levine, 1982; Levy et al., 1982; Owen, Friesen, Roberts & Flux, 1985; Schatz, 1988; WHO, 1980). For example, Cooper et al. (1982) interviewed 111 persons, who were taking prescription drugs in their homes and found no correlation between compliance (defined as adherence to prescription directions) and age, race, sex, level of education and income.

Diagnosis. Diagnosis has also been studied as a possible factor influencing compliance. Cooper et al. (1982); and Lundin, Eros, Melloh and Sands (1980) found no correlation between diagnosis and compliance.

Knowledge. Level of a patient's knowledge about medication is another variable that has intuitive appeal for correlating with compliance. While in some instances it has had some correlation, the majority of this research literature indicates that knowledge, of itself, has no significant correlation with compliance (Klein et al., 1982; Lundin et al., 1980).

Information giver. Some researchers have studied the effect of the "information giver" on compliance. Hecht (1974) studied a select group of 45 patients with tuberculosis; he found that adherence significantly improved with several information sessions conducted by nurses in the hospital and in the home after discharge. Benfari, Eaker & Stoll (1981) and Davis (1967) found that a positive relationship between the patient and caregiver improved compliance.

Number of drugs. Most drug compliance studies have been conducted with only one medication (Cockburn et al., 1987; Gilbert et al., 1980; Inui, Carter and Pecoraro, 1981; Rudd et al. (1988); whereas the chronically ill take an average of four medications (Solan, 1987). A study conducted by Ostrom, Hammarlund, Christensen, Plein and Kethley (1985) reported additional factors to be considered. They interviewed 183 persons who lived independently in federally-subsidized, urban housing. They formulated questions to determine the number and type of medications taken, compliance, medication storage and use of pharmacy service. Results showed that 75% used a prescription drug regularly, and 82% used an over-the-counter drug regularly. The average number of drugs (prescription and nonprescription), was 4.5 per person.

Environmental factors. Researchers have also studied environmental variables such as socio-economic status, living arrangements and support systems (Doherty, Schrott, Metcalf & Iasiello-Vailas, 1983; Ryan & Falco, 1985), to determine their effect on compliance. Socio-economic status has not been found to be a predictor for compliance (Cooper et al., 1982; Maddock, 1967). Instead, Benfari et al. (1981) and Davis (1967) found that compliance depended on the degree of congruence between the norms, values and interaction between the patient and the advice given by the doctor.

Levine, Green, Deeds, Chalow, Russell and Finlay (1979) and Miller, Johnson, Garrett, Wickoff and McMahon (1982) found family support to be an important factor for patients to maintain long-term adherence to their medication regimens. Doherty et al. (1983), in a study involving 150 males enrolled in a Coronary Primary Prevention Trial, reported that, in the "high support by wives" group, the adherence to medication averaged 96% - considerably higher than the 70% in the "low-support wives" group.

Several researchers found that noncompliance was related to the complexity of the dosage regimen and the number of pills to be taken daily. Will simplifying the regimen lead to greater compliance?

Discussion and Recommendations

Nursing places a high priority on helping patients adjust to needed changes in their lifestyles as it relates to nutrition, exercise, self-care, etc. The authors

believe that nurses should also place a high priority on working with patients who are on multiple drug therapy. Nurses must accept more responsibility to negotiate the medication regimen with patients so that it causes the least interruption in their lifestyles.

The literature review suggests that Goldsmith's (1979) formula for compliance is acceptable to many investigators because it allows the patient some flexibility. Nurse researchers might use this guideline to study how their interventions can affect this problem. Areas for further research should take into account the finding reviewed in the measurement section, and might include the effect of the following interventions on compliance.

Nurse involvement in drug management

1. Taking responsibility for medication history, including ability to comply (e.g. cost and convenience).
2. Frequently reviewing prescribed and over-the-counter medications, with the goal of reducing the number of drugs and the possibility of incompatibility.
3. Simplifying the drug regimen (e.g. decreasing frequency, use of long acting drugs, etc.).
4. Exploring the effectiveness of various types of patient educational materials.

Involving family, significant others or both

1. Planning a regimen that fits the family's lifestyle.
2. Helping the patient and family to understand and accept the diagnosis and recommendations for treatment.

Nurse involvement in long-term patient compliance

1. Writing down instructions that are easy to read and understandable, (e.g. "blood pressure pill", as well as generic or trade name).
2. Following up on the patient, (e.g. phone call, reminder card, asking patient to bring in all drugs at each visit).
3. Giving out a phone number that the patient or family can feel free to call about problems with taking the medications, (e.g. side effects, new symptoms, etc.).

Nursing has a responsibility in working with the chronically ill and aged in all aspects of their care. Perhaps greater nursing involvement in patient drug management will result in better health and decreased costs. These interventions should be studied in order to determine their feasibility and cost effectiveness.

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This research was supported by the Veterans Administration, HSR & D, the University of Texas Health Science Center School of Nursing San Antonio, and the Veritas Foundation.

RÉSUMÉ

Questions de recherche en observance médicamenteuse

Depuis les années soixante, chercheurs et professionnels de la santé se penchent sur la non observance médicamenteuse. La non adhésion au traitement influe négativement sur la santé du malade et accroît les coûts des soins médicaux. Les questions soulevées par la recherche d'une définition fonctionnelle de l'observance médicamenteuse et la détermination de mesures utiles de non observance sont exposées. D'autres domaines de recherche sont envisagés.

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