REVIEW ARTICLE

Patient compliance—an overview

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SUMMARY

This article reviews the major topic areas of compliance research. Much of the research in the area has focused on measurement, extent, and determinants of non-compliance. Research on the effectiveness of educational and behavioural strategies to improve compliance suggests the need to combine them. While some authors have attempted to model compliance or medication-taking behaviours, these models cannot be applied widely.

After decades of compliance research, very little consistent information is available, except that people do not take their medications as prescribed. The methodological rigour of compliance studies may partially contribute to this situation. Methodological flaws have included design features and study execution. In addition, researchers have proceeded with studies without regard to a theoretical framework.

Many have argued that much of the existing compliance literature also lacks conceptual rigour. Although we know that people do not take their medications consistently, we do not know specifically why they have done so. One reason for this lack of understanding is that compliance research has been dominated by the perspective of the health professional. To better understand medication-taking behaviour, researchers need to examine the patient’s perspective. Consequently, future research needs to investigate a patient’s decision-making process and the reasons for those decisions.

INTRODUCTION

The Office of the Inspector General reported that the consequences of non-compliance among the elderly can include increased morbidity and mortality, in addition to increased cost of treatment (1). Non-compliance has been linked to 23% of nursing home admissions (2) and up to 10% of all hospital admissions (3). Non-compliance with treatment for cardiovascular disease contributes to approximately 125,000 deaths and several thousand hospitalizations per year (4). The annual cost of treatment for moderate to severe hypertension was estimated to be $4,850 if patients purchased all of the medications and were 100% compliant. This annual cost rose to $10,500 when patients purchased the medications but took them irregularly (5). For these reasons, non-compliance has been considered a major public health problem (6).

Compliance research has focused on the extent and determinants of non-compliance, and strategies to improve compliance. The purpose of this article is to summarize and review research on compliance with medications in these areas. In addition, the methodological rigour and conceptual basis of traditional compliance studies will be discussed.

DEFINITION

Compliance has been defined (7) as ‘the extent to which a person’s behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice’. Thus, compliance is viewed as a process. Some researchers have put this definition into operation by dividing their sample populations into compliers and non-compliers based on statistical measures such as the median or mean levels of medicine taken (8). Those who fall below the mean or median are labelled as non-compliant, while those above...
the criteria are compliant. Other researchers have used previously reported levels of medication-taking to distinguish between compliance and non-compliance or relied on their personal belief that a certain level is significant (8).

Compliance can also be viewed in terms of the results of taking medication. Compliance as an outcome is defined as ‘the number of doses not taken or taken incorrectly that jeopardize the therapeutic outcome (6),’ or ‘the point below which the desired preventive or desired therapeutic result is unlikely to be achieved (9).’ Both of these definitions recognize the possibility that taking less than 100% of the medication can result in a desired health outcome. Outcome-oriented definitions differ from the process-oriented definition in their emphasis on the end-result or outcome of the actions taken. For example, Luscher and co-workers (10) reported that 80% compliance to a medication regimen for hypertension lowered blood pressures to a normal level. However, compliance of 50% or less was ineffective in adequately lowering blood pressures. Olson and co-workers (11) reported that a compliance rate of 80% was necessary for therapeutic results in children with streptococcal pharyngitis, but 33% compliance reduced the rate of contracting streptococcus infections in children taking oral penicillin as a prophylactic for rheumatic fever. The absence of a singular conceptual basis of compliance is problematic. Strategies to improve compliance can be evaluated only within the context of a given definition. Furthermore, comparative assessment of the compliance literature cannot be done across studies using different definitions of compliance.

MEASUREMENT

Compliance is measured directly and indirectly. Direct measurements of compliance generally involve the detection of a chemical in a body fluid. Examples of direct measurements include blood levels or urinary excretion of the medication, a metabolite, or a marker. The primary reason for using direct measurements is they are less subject to bias than are indirect measurements (12). They can be misleading, however, if the patient takes the medication prior to testing. Little information can be derived regarding the use of medication over time. Direct measurements do not account for the variability of pharmacokinetic factors of different medications and different individuals. In addition, direct measurements can be quite difficult to perform and costly.

Indirect measurements of compliance are more frequently reported in the literature, possibly due to the relative ease by which these measures are obtained. Examples of indirect measurements of compliance include therapeutic or preventive outcome, impression of the physician or predictability, patient interview, prescription filling dates, and pill counts (13). As with direct measurements, each indirect means of measuring compliance has inherent advantages and disadvantages.

The therapeutic outcome may seem a viable means to assess compliance, however, patients do improve for reasons other than following the prescribed regimen. Epstein and Cluss (14) reported that compliance with either the active product or placebo was associated with an appropriate clinical outcome. In addition, a person’s condition can deteriorate or remain stable even when the medications are taken as prescribed.

The physician’s estimate of patient compliance has been very inadequate. Caron and Roth (15) determined that physicians do not estimate compliance any better than if they simply rely on chance as a predictor. Mushlin and Appel (16) reported that less than one-half of a physician’s predictions correctly discriminated between compliers and non-compliers, while three-quarters of their predictions of non-compliance were inaccurate.

Compliance can also be assessed using a patient interview or self-report. Park and Lipman (17) used both pill counts and patient interviews to assess compliance of psychiatric patients with imipramine. Using interviews, they categorized 100 patients as compliers, but using pill counts only 58 would be compliers. In addition, in only 68 of the patients did both methods lead to the same classification. Gordis et al. (18), interviewing mothers and their children and correlating these with the findings of urine tests, found that both the mother and child overstated compliance and understated non-compliance. Morisky et al. (19) developed a four-item scale for self-report of compliance that demonstrated both concurrent and predictive validity of blood pressure control and supported the use of patient interviews.

Using centralized pharmacy records to check refill dates or the number of pills obtained is another indirect means to measure compliance (20–24). Steiner and co-workers (25) reported that refill records of the managed
care setting under study were valid correlates of medication effects and compliance. The authors believe that this method is useful in detecting non-compliant patients who remain in the health care system but only fill some of the medications prescribed. The validity of this method, however, rests on the completeness of the pharmacy database, usually most complete in institutional settings.

Pill counts have also been used to assess compliance. Roth and co-workers (26) suggested that pill counts often over estimate compliance. Bergman and Werner (27) found that, based on urinalysis, 8% of their study population was compliant, while pill counts showed 18% of the population to be compliant. Rudd and co-workers (28) found that weekly pill counts indicated variability within subjects, between subjects, and among the different regimens.

A recent advance in compliance measurement is electronic monitoring. The prescription vial contains a microprocessor in the lid. This recording device will identify the date and time the prescription vial is opened. Although the device does not verify that the medicine was consumed, it does provide an accurate record of when the vial was opened, supposedly for the purpose of taking the medicine. In this regard, electronic monitoring should be able to identify individuals who falsely claim they are taking medicine as prescribed.

Engstrom (29) reported that five of 19 patients who provided prescription medicine in vials with microprocessors embedded in the caps were non-compliant. None of those five patients claimed to be non-compliant. Four of the five patients did not improve clinically. Cramer et al. (30) used the electronic monitoring system with 24 epileptic patients who consumed 7,413 doses over 3,428 days. A comparison of electronic monitored data and pill counts showed that pill counts overestimated compliance as compliance declined. Furthermore, a clear relationship was established between adherence to the prescribed regimen, as determined by electronic monitoring, and clinical outcome. Five patients reported seizures during monitoring; five of these patients’ seizures could be attributed to missed doses documented by electronic monitoring.

Cramer et al. (30) view electronic monitoring as an additional and needed dimension in measuring patient compliance. Electronic monitoring helps to explain how the total number of doses were taken, if the dosing regimen was followed, and if clinical outcomes can be related to non-compliance. Although not a panacea, electronic monitoring improves clinicians’ and researchers’ understanding of how patients take prescribed medicine.

At this point in time, there is not a consistent measure used to determine compliance. Researchers will often choose a particular method due to ease and convenience. Likewise, it is not known what is the most appropriate means to measure compliance. The use of various measurement techniques makes it very difficult to compare compliance research findings.

**EXTENT OF NON-COMPLIANCE**

Fedder (31) stated that, ‘it seems that a third of patients always comply, a third never comply and a third sometimes comply’. Regardless of the patient population, disease state, or compliance measurement used, the compliance rate is usually well below 100%.

The duration of therapy is a factor which can influence the extent of compliance. Compliance with short-term medications is generally considered to be somewhat higher than for long-term medication regimens. However, rapid declines in compliance occur during even the first 10 days of short-term therapy (32). This suggests that compliance behaviour may be unstable even in short-term therapy.

Generally, the rates of compliance in long-term therapy tend to converge to 50%, regardless of the illness or setting (32). The compliance rate for long-term medications used for prevention, treatment, or cure can range from 33 to 94% (32). Published compliance rates for long-term medication use are shown in Table 1 (32–34).

The extent of compliance in a specific disease population has also been evaluated. Hogarty and co-workers (35) found that only 42% of the 374 schizophrenic patients studied were taking their medications correctly. Young et al. (36) reviewed the literature on non-compliance of schizophrenic out-patients and reported a median compliance rate of 41%, with a range of 10–76%. These findings approach the 50% compliance reported for long-term therapy.

Compliance rates for those with affective disorders are very similar. Johnson and Freeman (37) found that 16% of the 73 patients prescribed medications for depression stopped taking their medication within 1 week of beginning the treatment. Within 30 days of the initiation of the treatment, 68% had stopped taking the prescribed medicine. In three studies that examined compliance with lithium therapy, researchers reported that between 25 and 50% of patients failed to take their medications as prescribed (38), only 47% of the patients were thought to be complying perfectly over the first 2
Table 1 Compliance with long-term medication

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Measure</th>
<th>Definition</th>
<th>Compliance rate%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penicillin prophylaxis for rheumatic fever</td>
<td>Urine assay</td>
<td>Medication in urine</td>
<td>33</td>
</tr>
<tr>
<td>(94)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiolytics in neurotics (95)</td>
<td>Pill counts</td>
<td>Counts within 25% of prescribed amounts</td>
<td>54</td>
</tr>
<tr>
<td>Antipsychotics in schizophrenics (35)</td>
<td>Interview</td>
<td>Taking medications correctly</td>
<td>42</td>
</tr>
<tr>
<td>Tuberculosis medications (96)</td>
<td>Interview and urine</td>
<td>Taking medications throughout follow-up</td>
<td>55</td>
</tr>
<tr>
<td>Tuberculosis medications (97)</td>
<td>Record review</td>
<td>Continuing therapy</td>
<td>63</td>
</tr>
<tr>
<td>Various medications used by the elderly (98)</td>
<td>Interview</td>
<td>Taking medications correctly</td>
<td>41</td>
</tr>
<tr>
<td>Various medications for diabetes or</td>
<td>Interview</td>
<td>Taking medications correctly</td>
<td>42</td>
</tr>
<tr>
<td>congestive heart failure (99, 100)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Various medications used by patients in</td>
<td>Record review</td>
<td>Taking medications correctly</td>
<td>69</td>
</tr>
<tr>
<td>homes for the aged (101)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antihypertensives (102)</td>
<td>Record reviews (same</td>
<td>Remaining in care and on therapy</td>
<td>94, 65, 34</td>
</tr>
<tr>
<td>subjects)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antihypertensives (103, 104)</td>
<td>Pill counts (same</td>
<td>Taking &gt; 80% of medication</td>
<td>53, 53</td>
</tr>
<tr>
<td>subjects)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*This table represents articles that provided demographic descriptions of the subjects and employed statistically rigorous sampling techniques. Examples include the use of random population samples, three or more hospitals/clinics in a geographical area, or a regional programme/referral system.

years of treatment (39), and 24% withdrew from treatment during the first 2 years (40). These studies further support the lack of stability of compliance as a behaviour.

Compliance rates for hypertensive patients are quite similar to rates reported with other conditions. For example, more than 50% of these patients dropped out of therapy within the first year, while of those remaining about 33% did not take enough of their prescribed medications to reduce their blood pressure adequately (41, 42). This finding implies that compliance behaviour is relatively unstable over time. Widmer and associates (43) reported a mean compliance rate of 87% for 291 hypertensive patients in a rural mid-west study. The high rate of compliance may have been partially attributed to the method of measurement and the definition of compliance. Such a conclusion supports the contention that comparability of studies should be done with great caution.

Dodrill and co-workers (44) identified 80 of the 282 adults with epilepsy studied as definitely compliant, while 42 were non-compliant. The remaining subjects fell into the categories between definitely compliant and definitely non-compliant. Eisler and Mattson (45) reported that 40% of patients taking anticonvulsants missed enough doses to affect blood levels. In addition, non-therapeutic serum anticonvulsant levels have been measured in as many as 97% of 34 patients (46) and as low as 26% in 153 cases (47). As with other diseases presented, the extent of compliance with anticonvulsants is quite variable, but still within the range expected for long-term therapy.

The average rate of compliance tends to converge to 50% for long-term therapy, regardless of disease and compliance behaviour tends to decline with time. The increasing prevalence of chronic conditions for which long-term therapy is prescribed suggests that compliance will remain an area of concern.

**DETERMINANTS**

Meichenbaum and Turk (12) identified over 200 variables that have been examined in studying compliance. The majority of these variables are characterized as
demographic variables, such as age, sex, education, and socio-economic factors, or disease-experience variables. In this section, the influence that demographic variables, disease features, and treatment regimen features have on compliance will be presented.

Demographics have been shown to be poor predictors of compliance. Hulka (48) reported that the demographic factors of age, sex, marital status, education, number of people in the household, and social class are not statistically associated with compliance. In a study of hypertensive patients, Widmer et al. (43) found no significant differences between mean compliance rates for males and females. Similarly, Dodrill and co-workers (44) found that the sex and age of the epileptic patients studied did not adequately predict compliance. However, under certain specific conditions, such as a particular disease, demographic variables can predict compliance behaviour (49). Unfortunately, the findings for these specific conditions do not extend to other situations. Such inconsistent results have made it impossible to develop a prototype of the non-compliant individual. Porter (50) summed up the situation well by stating ‘it must be emphasized that it has not proved possible to identify an uncooperative type. Every patient is a potential defaulter. Compliance can never be assumed.’

Features of the disease have also been investigated. In a review of the literature published before 1978, Haynes (51) suggested that disease factors were poor indicators of compliance. Less than half of the studies found any significant correlations between compliance and disease features. In addition, even where significant correlations were noted, the direction of these associations was inconsistent between studies. Only three disease features were found to be determinants of compliance (51). First, psychiatric patients, especially those with schizophrenia, paranoia, or personality disorders, are generally low compliers. Second, when more symptoms are reported by patients, their compliance rate is lower. This finding does not support the assumption that increasing severity of symptoms should encourage compliance, suggesting that as people notice more symptoms they begin to give up on the treatment. In addition, patients with symptomatic illness, such as rheumatoid arthritis, become less compliant. Third, the degree of disability produced by the disease positively influences compliance. The increased compliance could be the result of the severity of the disease or increased supervision due to the disability. The authors felt that increased supervision was the more likely explanation.

Features of the treatment regimen have also been evaluated as possible determinants of compliance. Haynes (51) reported that the duration of treatment, the number of medications, and their cost negatively affected compliance, while parenteral medication administration improved compliance. Sbarbaro (52) suggested that shortening the duration of therapy and reducing the number of times that a medication is taken each day will help to improve patient compliance. Note that while the presence of side effects intuitively seems to decrease compliance, Haynes (51) reported that when patients were asked to give reasons for non-compliance, side-effects were mentioned by only 5–10%. According to Haynes, however, future research in the area of disease features, and to some extent treatment features, should receive low priority because of the inability to increase detection or improve compliance (51).

More than 20 years of research in the area of compliance has produced very little consistent information on the factors which can be correlated with non-compliant behaviour. Most of the variables examined are inconsistently correlated with compliance and thus cannot be used to predict compliant behaviour adequately.

INTERVENTIONS TO IMPROVE COMPLIANCE

Educational strategies

Educational strategies, such as verbal communication or counselling, have been shown to improve compliance (53). Hecht (54) found that counselling provided by registered nurses to patients receiving out-patient chemotherapy decreased drug errors. Nessman et al. (55) developed a programme that combined audiovisual teaching with counselling by a registered nurse which decreased medication errors and diastolic blood pressures. Zismer and associates (56) reported that counselling of hypertensive adults at clinic visits by graduate research assistants produced a substantial decrease in blood pressure. Similarly, counselling by a pharmacist resulted in a significant clinical decrease in the diastolic blood pressures of adults attending a neighbourhood clinic. Based on these studies, one-to-one counselling appears to be an effective means of improving compliance.

Not all research supports the association between educational strategies and compliance. In a review
including only those articles published before 1979, only one of the four studies involving medication instruction found a significant change in compliance due to the intervention (57). In this study of patients being discharged from the hospital, 90% of the patients who received counselling from the pharmacist before discharge were compliant with the prescription orders, but only 24% of those who did not receive counselling were compliant (58). Note that compliance did appear to be positively affected by pharmacy counselling over the short-term of the study. In the other three studies reviewed by Haynes (57), two of which involved pharmacy counselling and one of which involved nursing counselling, these interventions did not produce statistically significant changes in patient compliance.

In their review of the literature on written communication, Morris and Halperin (59) concluded that written information may be effective for short-term medication therapy. Written information alone is not sufficient to increase patient compliance in medication used in long-term therapy. In a meta-analysis of articles written between 1961 and 1984 on intervention strategies, written interventions, except for patient package inserts, were shown to produce increased knowledge and decreased medication utilization errors (60). The studies on patient package inserts resulted in an average effect size value near zero for both knowledge and medication utilization errors (60). This indicates that these inserts have limited ability in improving knowledge or decreasing medication utilization errors. Gibbs et al. (61) found that compliance was not significantly different for those patients who received patient information leaflets, however, their knowledge of the medication was better.

In a meta-analysis of combinations of intervention strategies, one-to-one counselling, group education, and written and/or audiovisual interventions, except patient package inserts, increased knowledge and decreased medication utilization errors (60). Robinson and co-workers (62) found that when written information was combined with verbal reinforcement, compliance was significantly higher than when written information was used alone. In addition, compliance was higher for the intervention groups than for the control. Myers and Calvert (63) found no significant differences in compliance between a group which was told the purpose of the medication but was given no written information, a group which received verbal and written information about the side-effects of the medication, and a group receiving verbal and written information about the beneficial effects of the medication. When the two groups which received both verbal and written information were collapsed into one group, compliance at 3 weeks was significantly higher for this new group than for the group which received no written information and limited verbal information. These results were not sustained over 6 weeks. Myers and Calvert (63) suggested that verbal and written information improves compliance by an attention-placebo effect rather than a cognitive effect. Consequently, it would seem that compliance poses a larger problem in long-term therapy or once the information intervention is removed. Brown et al. (64) found that individuals who receive verbal and written information gain more medical knowledge than those who receive only verbal information, but instruction does not significantly affect compliance.

The use of educational strategies to improve compliance is based on the information model of compliance management (65). The model suggests that patients fail to comply because they do not have sufficient information regarding the risks of the disease, the benefits of treatment, and the details of the treatment. From the studies presented, educational strategies alone may not significantly improve patient compliance. Information may provide its greatest benefit for short-term therapy. Similarly, information is valuable during the early stages of long-term medication regimens. However, in the long-term, once the intervention is removed, information may affect compliance less.

**Behavioural strategies**

Behavioural strategies, such as reminders and special medication containers, have been shown to improve compliance (53, 66). Patients with hypertension who used a medication reminder chart showed improved knowledge of medication use, dose, and frequency of administration after using the chart (67). They presented with fewer incidences of forgetting to take the medication and a lower number of deviations from the prescribed regimen. Another type of reminder is a refill reminder which is generated at the pharmacy level. Sinkins and Wenzloff (68) investigated the use of post-card refill reminders and telephone-call refill reminders. These researchers found that both types of reminders increased refill compliance, but there were no significant differences in compliance between the two types.

Special medication containers are another behavioural intervention. They help the patient to organize medications and monitor self-administration of products on
Patient compliance

**Table 2 Successful compliance interventions**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Strategy</th>
<th>Effect on compliance (%)</th>
<th>Effect on outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension (104)</td>
<td>Self-monitoring + cueing + rewards</td>
<td>+21</td>
<td>Improved</td>
</tr>
<tr>
<td>Hypertension (105)</td>
<td>Nurse management at work + cueing + self-monitoring + rewards</td>
<td>+19</td>
<td>Improved</td>
</tr>
<tr>
<td>Hypertension (55)</td>
<td>Self-monitoring + group discussion + self-management</td>
<td>+19</td>
<td>Improved</td>
</tr>
<tr>
<td>Hypertension (106)</td>
<td>Written instruction + treatment cards + recall of nonattenders</td>
<td>+15</td>
<td>Improved</td>
</tr>
</tbody>
</table>

daily to weekly intervals (53). Special medication packaging has shown to increase compliance (69, 70). Wong and Norman (71) investigated the use of a calendar blister-pak to improve compliance. The average non-compliance index significantly decreased when patients used the blister-pak, indicating that this type of special packaging may be advantageous in improving compliance. Some manufacturers are now selling their products in special packaging. Oral contraceptive packs and the Medrol Dosepak® are two examples of special unit-of-use packaging.

**Educational and behavioural combinations**

Many researchers have evaluated the use of both educational and behavioural strategies in a combined intervention. Combining behavioural and educational strategies is supported by the compliance activity model (65). This model recognizes the relationships between behavioural, cognitive, and social factors in determining compliant behaviour. In a study of patients with epilepsy, the intervention group received patient counselling, a special medication container, mailed reminders to have prescriptions refilled, and they were asked to self-record medication intake and seizure frequency (72). Patient compliance significantly improved in patients receiving this combined intervention. Ascione and Shimp (73) evaluated the effectiveness of oral instructions alone, oral instructions plus a medication reminder calendar, oral instructions plus a medication reminder package, and oral instructions plus written medication information. Interventions including either the medication reminder calendar or package were superior in improving compliance than the other interventions. Swain & Steckel (74) investigated the effects of patient education and contingency contracts on compliance. Patients received routine care only, routine care plus education, or routine care plus education and a contingency contract between the patient and the nurse. This latter group exhibited a decrease in diastolic blood pressures.

Haynes (65) has reported methodologically rigorous studies of compliance interventions. All of the successful interventions, or those which had significantly positive effects on compliance and treatment outcome, involve a combination of interventions. A sample of these interventions can be found in Table 2.

It appears, from the materials presented in this section, that compliance can best be improved by interventions combining educational and behavioural components. The effectiveness of interventions combining educational and behavioural techniques was supported by the findings of a meta-analysis prepared by Mullen et al. (60). Compliance packaging, which incorporates both educational and behavioural components, has been introduced recently by the pharmaceutical industry in an effort to improve compliance. This packaging ideally serves as a patient education tool and makes it easier for the patient to remember to take the medication (75). An example of this is the MACPAC® manufactured by Norwich Eaton Pharmaceuticals, Inc.

**MODELS OF COMPLIANCE**

One of the first models used to explain compliance was the Health Belief Model (76). This model was initially
applied to preventive health behaviour. Becker and Maiman (77) incorporated general health motivations and modifying and enabling factors into the model to provide a focus on sick role behaviour and compliance with medications. While many of the studies that evaluate the Health Belief Model support the components of the model, some studies do not (78). Under certain disease conditions, some of the components of the Health Belief Model do help in the understanding of compliance. However, the entire model has not been supported empirically (79). In response, researchers attempted to improve the model by adding more components.

Ried and Christensen (79) incorporated the Theory of Reasoned Action into the Health Belief Model. In this study, the Health Belief Model explained 10% of the variance in the compliance variable. The inclusion of the Theory of Reasoned Action explained an additional 19% of the variance. The Health Belief Model variables of barriers and benefits and the Theory of Reasoned Action variables of belief strength, outcome evaluation, and behavioural intention were found to be significantly related to compliance. The social influence variables, part of the Theory of Reasoned Action, were able to predict behavioural intention, but not compliance behaviour. The research supported the contention that some of the paths of the models are significant but the models as a whole cannot predict compliance. Even with the combined models, only 29% of the variance was explained. This suggests the possibility of missing paths in the model or the improper measurement of the variables.

The Health Decision Model (80), developed by Eraker et al. incorporates the Health Belief Model and patient preference, including decision analysis and behavioural decision theory. The model is based on the strengths of the Health Belief Model and patient preference models. The model includes bidirectional arrows and feedback loops which suggest that compliance behaviour can also change beliefs. The validity and predictability of this model was not statistically tested by these authors.

Nagy and Wolfe (81) evaluated a model using variables derived from the health locus of control and the Health Belief Model. The demographic variables of age and socio-economic status were also included in the model. Scales to assess Internal Health Locus of Control, chance Health Locus of Control, and powerful others Health Locus of Control were administered. The latter scale evaluated the person's belief that health professionals or family can affect health. The perceived severity of illness, outlook on illness, experienced symptoms, satisfaction with treatment, family support and support of others were used in conjunction with the demographic variables and health locus of control scales to develop an equation to predict compliance. Patient satisfaction was the only significant predictor of medication compliance. The results of this study indicate that either this model or the measurement of the variables is inappropriate. The authors suggest that the limitations of cognitive variables in predicting compliance in patients with chronic diseases can partially explain the results. In addition, subjects in this study had received treatment for an average of 17 years. Because of these characteristics, their health beliefs and health locus of control may differ from patients in other circumstances.

In response to inadequate findings when using the Health Belief Model, Schlenk and Hart (82) investigated the use of Rotter's Social Learning Theory. These authors incorporated health locus of control, health value, and social support in their model. A significant relationship was found between compliance and social support, powerful others health locus of control, and internal health locus of control. In a multiple regression analysis, social support and powerful others health locus of control accounted for 50% of the variance in compliance. Because a non-experimental design with a small number of subjects was used in this study, the results may be different under a more controlled experiment with more subjects.

Stanton (83) proposed a model which included patient–provider communication, knowledge of medication regimen, satisfaction with the provider, internal locus of control, perceived social support, and treatment disruption to lifestyle as variables that directly and indirectly lead to adherence to a medical regimen. The link between adherence to medical regimens and the outcome of blood pressure change were also evaluated. Greater expectancy for internal control over health and hypertension, greater knowledge of the treatment regimen, and stronger social supports were significantly predictive of adherence to medication regimens. In addition, higher levels of adherence were related to blood pressure reduction. Again, several components of the proposed model were statistically significant but the entire model could not predict compliance better than the individual paths in the model.

As with the other areas of compliance research, modelling has produced inconsistent findings. It was intended that these models should serve as data reducers and organizers. However, a strong model of compliance still does not exist. Possibly the problem is that the researchers are examining inappropriate...
paths or relationships. Another problem may be the inconsistency of techniques employed when evaluating the variables in the models and the context may influence the fit of the model, thus limiting wider applications of any model.

**INADEQUACIES OF COMPLIANCE RESEARCH**

The methodological rigour of compliance studies has been questioned. Haynes (65) indicated that the scientific merit of these studies ranged from primitive to exceptionally high. One explanation for this situation may be that health care researchers empirically test potential factors that might overcome low compliance, regardless of any theoretical framework (84). In addition, researchers differ in their ability to recognize and control for design features and execution of the study (85). These flaws in design and execution affect the certainty of the conclusions of the projects.

Haynes and co-workers (65, 85) developed criteria to judge the methodology of 537 original articles on compliance. Bruer (86) combined the results of Haynes bibliography with citation data from the *Science Citation Index* to determine whether methodologically rigorous studies were cited more frequently by compliance researchers than less rigorous articles. The results indicated a statistically significant, but low, correlation between methodological rigour and citation frequency.

Another area of concern is the conceptual rigour of compliance studies. According to Trostle (87), the notion of compliance is dominated by ideological beliefs of the appropriate roles for patients and physicians. The concept of compliance is based on the doctor's perspective and implies that the physician is the benevolent authority and the patients should willingly accept the doctor's word (88). Stimson (89) suggested that researchers have not questioned the assumption that patient's comply with doctor's orders. Consequently, seeing patients as defaulters or deviants has resulted in an unproductive approach to the problem of medication use.

This medically oriented approach to compliance has portrayed the doctor–patient relationship as the key to medication taking behaviour. However, Conrad (90) suggests that this may not adequately reflect the true situation. This view is supported by Trostle (87), who indicates that 'noncompliance is an unavoidable by-product of collisions between the clinical world and other competing worlds of work, play, friendship, and family life'. Stimson (89) points out that people are not taking medicines in a thoughtless vacuum but that they have ideas and attitudes about medicine. These ideas and attitudes are based on their relationships with others and past experiences. Because of the social context of taking medications, researchers should focus on compliance from the patient's perspective rather than from the viewpoint of health professionals (87, 89–92). This approach should focus on the reasons or motivations for the medication-taking behaviour adopted. This type of research has received the lowest priority in much of the previous research (89).

Other problematic assumptions that have prevailed in previous research on compliance have been noted by Gabe and Thorogood (93). First, researchers have assumed that the individual is the methodological unit of analysis. Individuals were treated as though they were members of a single population, rather than as members of many sub-cultures. Second, researchers have attempted to identify causal relationships between variables, assuming that the variables can be treated as independent. However, the phenomenon of medication-taking behaviour involves variables that are inter-related with the possibility of feedback loops. Third, researchers have explained medication use through establishing strong relationships between certain variables and medication use. This approach has neglected to determine how these associations were formed. They have ignored the social contexts which are involved in behaviour. The fourth assumption noted involves the manner in which subjective meanings are gathered. In cases where subjective meanings are introduced as a causal variable, they are obtained through standardized questionnaires. By using these methods, researchers have failed to obtain the social and historical context of medication use in peoples' own words.

The years of research on compliance provide little consistent information other than the fact that people do not always follow the doctor's orders. Unfortunately, we do not know specifically what the patient has done. For example, research has not indicated if individuals consistently take fewer doses or a lower dose. Future research needs to investigate how patients administer their medications and the decision-making process used by the patients. For example, as Trostle (87) suggests, we need to evaluate how patients respond in daily life to the advice and treatment regimens presented by the medical profession. Above all, there appears to be a need to focus on compliance from the patient's perspective.
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