Patient compliance with health care provider advice is a subject of particular importance in developing countries, one that has not been sufficiently studied. This article begins by explaining why this type of research is important and describing the various methodologies used to examine patient compliance in developed nations—notably self-reporting by the patient, collateral reporting by friends or relatives, pill or bottle counting, review of the patient's clinic attendance, review of clinical outcomes, and use of biochemical tracers.

The applicability of each of these methods to scenarios commonly found in developing countries is then considered, and the results of the limited compliance research performed in developing countries are described. In general, it is suggested that self-reporting, collateral reporting, and pill or bottle counting can be employed effectively in many Third World situations. The article also notes the importance of standardizing research procedures, provides logistic advice about applying various compliance research methods in Third World conditions, and points up the need to validate the accuracy of the methods used.

As of 1990 Donovan and Blake (1) had identified at least 8,000 bibliographic entries on the topic of patient compliance with health care providers' advice. In contrast, as of March 1991 we had been able to locate only 37 empirical studies conducted in Third World countries (2).

There are reasons to believe that findings from industrialized nations have limited applicability in the Third World. Furthermore, since many different nations and cultures are included under the headings of “Third World” or “developing areas,” research done in one region may not be directly applicable to others. Among other things, developing nations differ with respect to their health belief systems, health service delivery organizations, health care providers' education, degrees of public education, and availability of modern and traditional health services.

According to studies conducted in developed nations (3-5), patients' compliance with prescribed pharmaceutical regimens depends on how patients perceive their illness and the health care system, their relationship with the health care provider, and their ability to understand and follow instructions. These factors are likely to be different in developing countries, where patients may have less access to information and support services.
provider, their trust of pharmaceuticals, and the type and appearance of the prescribed drug. Therefore, effective patient compliance-enhancing techniques have to be tailored to each particular culture and set of circumstances presented.

More broadly, cultural differences, differences in the definitions and methodologies used in compliance studies, and different orientations of studies dealing with different types of treatments explain the contrasting and at times contradictory results found in the literature. For example, the proportion of good compliers found in the literature ranges from 26% to 100%. Also, some studies have found variables such as age, sex, socioeconomic status, level of education, number of medications prescribed, and the health problem's gravity to be associated with the likelihood of patient compliance, while other studies have not.

Within this wide range of variation, several researchers have identified a core group of issues as key determinants of compliance. For example, a number of authors (2, 6–11) agree that reasons accounting for patient noncompliance include poor communication between practitioners and patients, poorly organized health services, the cost of medicines, the patient's feeling of improvement, and the nature of the treatment (too many drugs, drug side-effects, and lack of trust). Even so, better understanding of the process of compliance is needed in order to identify key issues that can serve as a basis for changing health care delivery systems, improving drug management, and reducing undesirable economic and health effects associated with drug misuse.

The study of patient compliance with medical advice and drug regimens in developing countries is becoming increasingly important for the following reasons:

1. Consumption of pharmaceuticals in developing countries is on the rise due to expansion of health care services and successful marketing of drugs by multinational pharmaceutical companies.

2. Developing countries' health care expenditures are generally insufficient to meet health care needs, and pharmaceuticals represent a large share of the total health care budget. For instance, in comparison to pharmaceutical expenditures typically totaling 5–16% of all health expenditures in developed countries, such outlays typically exceed 30% of all health expenditures in the developing world (12). Therefore, when drugs are misused in developing nations, as compared to developed countries, a larger share of the health care budget and health care system is being inefficiently managed.

3. Patient compliance plays an important role in improving patient health and enabling the overall health care system to be effective (13).

4. Poor medical outcomes resulting from noncompliance may prompt dissatisfaction with the health care delivery system and cause deterioration of the patient-physician relationship (14). Beyond that, patient satisfaction with health provider conduct affects not only patient compliance but also subsequent behavior within the health system, and therefore the overall quality and effectiveness of the health services (15, 16).

5. Lack of compliance with pharmaceutical regimens leads to storage of leftover medicine in people's homes, which in turn increases the chances of accidental poisoning and encourages self-medication and misuse of pharmaceuticals (17–20).

Seen from this perspective, good compliers would appear to be utilizing health
resources adequately. Conversely, those seeking expert advice and then not following it would seem to be demonstrating irrational behavior; and likewise, those receiving or purchasing medicines without using them according to instructions would seem to be economically wasteful.

Despite these appearances, however, there is now growing debate about the desirability of patient compliance. Some authors in developed countries have shown that advantages accrue to some patients who provide self-care and control the management of their illness (1, 21). They argue that the patients should be the ones to assess the advantages and the disadvantages of prescribed therapies. Donovan and Blake conclude: “perhaps the issue should not be compliance, but how medical staff can understand and participate in the decisions that patients already take about their medications!” (1).

Nevertheless, whatever this conclusion’s applicability in developed countries, it is valid to ask whether it applies to the Third World. Obviously, there are substantial differences between health conditions and health care delivery in developed and developing regions. In Third World countries, the bulk of the population with access to “modern medical care” has received such access only recently; and, by and large, the availability of biomedicine is considered an improvement over previous traditional care. Hence, fostering self-care with modern pharmaceuticals among patients with access to professional care for the first time seems to be going backwards.

In this vein, the literature has documented the health risks of self-medication with modern drugs in Third World situations (17–20). Communication between health care providers and users of services is more difficult in Third World countries than in developed societies because of relatively great socioeconomic, educational, cultural, and linguistic differences. Hence, given most patients’ low educational levels and most health care providers’ inability to translate scientific concepts into the culture of their patients, the likelihood of having patients make informed decisions and select appropriate therapies is slim.

In addition, much of the support for illness self-management in industrial nations results from studies of chronic diseases. The applicability of this concept to acute life-threatening conditions or diseases with serious individual and social sequelae for which there is a known cure can be questioned.

Based on the above considerations, one might be tempted to conclude that in the Third World, efforts to improve patients’ compliance with medical regimens should be welcome. Unfortunately, this conclusion needs to be qualified. In many parts of the Third World, basic diagnostic procedures are rarely followed due to lack of equipment, deficient medical training, or an intolerant attitude on the part of middle and upper class urban physicians toward the poor who use their services (22). Hence, while physicians’ diagnostic and prescribing errors are common everywhere, they tend to be more pronounced in the Third World (2).

In sum, advocating patient management of modern drug therapies in the Third World could have undesirable health consequences. On the other hand, enhancing patient compliance can only be strongly recommended if health care providers are in a position to make accurate diagnoses and prescribe appropriate treatment.

Comparing the few studies done on pharmaceutical compliance in the Third World is an almost impossible task, due to different definitions, methodologies, and study populations. Moreover, in contrast to research done in developing nations, there has been hardly any effort to validate the accuracy of the methods.
employed. As a result, there is more than a mere scarcity of information; for the little information that exists presents a real comparability problem; and beyond that there is uncertainty about the validity of the methods used.

RESEARCH METHODS IN DEVELOPED COUNTRIES

When a substantial number of patients are said to be noncompliant, it is important to know the criteria being used to make this determination. Specifically, one must know (1) how compliance is defined and (2) the means used to measure adherence to this defined standard.

Gordis (23) has proposed that minimal adherence be defined as “the point below which the desired preventive or therapeutic result is unlikely to be achieved.” For instance, it has been reported that in using penicillin prophylaxis to prevent streptococcal infections, only one-third of the usually prescribed medication is needed to achieve the desired effects; but high blood pressure is significantly improved only when the subject takes four-fifths of the prescribed medication (24).

The problem in using the Gordis definition is that one must know what percentage of recommended performance is needed to achieve the desired effect. This is often difficult to determine, especially since external factors (environmental, cultural, and socioeconomic) can have a considerable impact on the outcome regardless of the patient's level of compliance. For example, a patient on antihypertensive medication may also be attaining lower blood pressure levels through weight loss, exercise, or even the physician's reassurance. In addition, to complicate matters further, there is increasing awareness that physicians can be wrong and that, on those occasions, noncompliance may have a beneficial effect on patients' health (25).

Behavioral scientists are apt to view as noncompliance any notable deviation from the prescribed course of therapy, even if such deviation has no clinical effect. Certain other researchers have divided their study populations into “compliers” and “noncompliers” on purely statistical grounds (e.g., persons falling above and below median or mean levels of compliance for their group—26).

Traditional methods of assessing compliance include self-reports (interviews, self-monitoring), collateral reports, behavioral methods, biochemical techniques, and review of clinical outcomes. Some of the major limitations and difficulties confronting each of these methods are as follows:

Self-reports

The reliability of the self-report method is limited by three types of errors: (1) deliberate errors in which the respondent adds or omits information in order to make a good impression on the interviewer; (2) memory (recall) errors; and (3) communication errors caused by the investigator not making clear to the patient what is being asked, or by the patient failing to respond clearly to the interviewer, so that the wrong answer is recorded.

The sources of error are also three, these being the characteristics of the interview, the interviewer, and the respondent. Interview characteristics include such things as the type of questions asked, their length and wording, the recall period involved, and the manner of the interview's administration. By and large, interview characteristics are the major source of errors (27), far surpassing the two other sources (interviewer and respondent characteristics).

Some interviewer effects may arise from extra-role characteristics of the interviewer such as sex, race, age, and ethnic, political, or other affiliations. The perception of these other characteristics does not
necessarily mean that they will cause respondents to behave differently, but the potential is there and must be recognized.

Regarding respondent characteristics, some compliance studies have suggested respondents may have a tendency to overreport compliance. Clearly, however, a patient's willingness to report noncompliance is related to the way questions are posed and the skills of the interviewer. Therefore, the interviewer should improve the chances for accuracy by creating an atmosphere in which it is acceptable for the patient to report deviance (28, 29). One questioning technique that can be used to improve accuracy is to ask the questions about compliance in such a way as to show understanding that errors occur (30). In addition, the interviewer who responds to the patient's nonverbal signals and is flexible about pursuing leads the patient may give about following the regimen is more likely to obtain accurate data (31).

There is some evidence that the patient's response is more likely to be accurate if the interviewer is not identified as an employee of the health care delivery system and if the patient likes the interviewer, feels the clinic or research agency involved is a prestigious one, considers himself or herself dutiful, and knows that the reports are periodically checked for accuracy (32). In this vein, Eraker et al. (29) have suggested that the validity of self-reports on compliance may be enhanced by informing those interviewed that other data sources may be used to verify the information they report.

Many studies that have compared self-reporting with other assessment methods have shown substantial correlations (26, 35, 36). Feinstein's research (37) led to a conclusion that the best way of finding out what a patient has done is to ask the patient directly. Carrasco et al. (38) and Homedes,6 using information garnered from self-reports and pill counts in Chile and Costa Rica, respectively, obtained results that supported Feinstein.

Other studies have arrived at the opposite conclusion. A study in India (39), which included self-reporting and biochemical tests, found that self-reports were not reliable. However, there is convincing evidence that a well-designed survey carried out by well-trained interviewers can yield reliable information about patients' perceptions of pharmaceuticals, their level of compliance with instructions, and their reasons for not complying.

Collateral Reports

Collateral reports of medical compliance include reports of physicians, nurses, other health professionals, friends, and family members. The accuracy of collateral reports is a function of the reporter's familiarity with the patient and/or the accuracy of clinical records. Review of clinical records is often used in collateral reporting because it permits retrospective study and is cheap. However, if clinical records are not well kept the data collection becomes cumbersome. In fact, this method is almost exclusively applicable to hospital settings (where notes are kept on all medical recommendations and all drugs administered to the patient) and to special outpatient settings (where the patient needs to go to a clinic to receive the medication).

Studies validating the self-report method (33, 34) suggest that patients can often tell their degree of compliance with a fair degree of accuracy. For instance, Tebbi et al. (35) report that the levels of serum corticosteroids measured by bioassay "corroborated in every case" self-reports of medication compliance by pediatric and adolescent cancer patients.

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6Homedes N. Patients' compliance with physician's advice in Costa Rica. Houston: University of Texas, School of Public Health; 1990. [Doctoral dissertation].
Behavioral Methods

Behavioral methods commonly used to assess compliance include tablet or bottle counts (noting the percentage of medication taken) and review of appointment records.

When the amount of medication used is being employed as a measure of compliance, patients may be provided with an oversupply of their medication and asked to return the unused portion at periodic intervals. The clinician must know how much medication was prescribed, how much was dispensed, and how much was on hand at the time of the assessment. If all goes well, this “pill count” method provides a quantitative assessment of compliance, permitting appraisal of the problem’s magnitude as well as some estimation of the impact varying compliance levels have on therapeutic outcomes and secondary effects.

The method’s main drawback lies in assuming that the missing medication was ingested by the patient. Here the problem of patients not returning all their unused pills is of major importance. The patient who wants to make a good impression but dislikes the medication’s side effects may remove pills from the bottle and throw them in the trash or give them to other people. Other reasons for failure include forgetting or losing pills, dividing the medication between two or more sites and not returning that which is stored at one of them, or putting a few pills in another container or pocket and leaving them there. Some of these problems can be avoided if the pill count is made during an unannounced household visit. However, even under ideal conditions the method does not accurately assess the compliance of an erratic drug taker who fails to follow the prescribed schedule. For example, a patient who takes two pills every 12 hours instead of one every 6 hours will appear to be in perfect compliance because the total amount of medicine taken will be the same as if the recommended schedule had been followed.

Many studies use another behavioral measure, that of clinic attendance, as a proxy to assess compliance. This method assumes that those who do not go to the clinic are not compliers, while those who attend the clinic follow the health professional’s instructions. The approach ignores the fact that some patients may not attend the clinic because they have moved, changed providers, or even died; and that just attending the clinic does not necessarily mean a patient is appropriately following the physician’s instructions.

Biochemical Techniques

This method calls for incorporating chemical markers into the medication. These tracers need to be indiscernible to patients but readily detectable by chemical assays of blood or urine. Such biochemical markers are useful in measuring compliance, largely because they are less subject to bias than self-reports and pill counts.

Unfortunately, not every drug can be readily detected in blood or urine; and some biochemical assays of appropriate markers are quite difficult and costly. Interpretation of biochemical markers as indicators of compliance is also complicated by potential pharmacokinetic differences between different drugs and different patients. Furthermore, the results of accurate and appropriate biochemical assays may be misleading because drug levels primarily reflect medication consumed immediately before sampling, which may not accurately re-
reflect the patient's consumption over the entire treatment period (40).

**Review of Clinical Outcomes**

One cannot assess compliance directly by reviewing clinical outcomes, because adherence to treatment recommendations is only one of a number of factors that could influence those outcomes. Among other things, patients who comply may be less ill or may engage in better health behavior in general. This presumably explains why a review of several studies by Epstein and Cluss (41) showed that adherence per se, whether to a placebo or an active drug, was associated with the best clinical outcome.

More broadly, there is no straightforward relationship between treatment compliance and a successful clinical outcome (42). Sometimes, even if patients do everything the health care professional recommends, they may still get sick, fail to get well, or see their condition worsen because the natural history of a disease and the effectiveness of a treatment regimen is uncertain for any individual patient. Conversely, some people do not become ill or recover in a timely fashion despite risky behavior and poor treatment—as a result of such things as incorrect diagnosis, natural abatement of symptoms, and intercession by a wide array of genetic, physiologic, and environmental factors, many of which are not well understood (36).

Even though clinical outcomes by themselves do not provide a good measure of compliance, the validity of all other methods is also questionable. Therefore, when the resources are available a combination of methods should be used. However, if monetary or other practical limitations preclude gathering of data from multiple sources, Feinstein (37) has concluded that the best way to find out what a patient has done is to ask the patient directly. From the reply, a good investigator can often obtain both qualitative and quantitative information not provided by other methods.

**RESEARCH METHODS IN DEVELOPING COUNTRIES**

A recent review of the literature on compliance studies in developing countries (2) found that the method most commonly used was review of medical records, followed by self-reporting, the pill-count method, and biochemical techniques. Beyond that, however, the studies reviewed were found to define and measure compliance in many different ways.

For example, some researchers defined good compliers as those patients who kept their medical appointments over a specific time period (6, 43–46). Although this is a very indirect way of measuring patient compliance, it is a cheap and suitable way of studying compliance with medications administered at a health center. All the studies depending on this method focused on chronic diseases and were conducted in urban settings. Nevertheless, comparing the results of these studies is still difficult because they used different time periods, some examining patient appointment records over a 3-month period while others followed the patients for over 2 years.

Other studies directed at tuberculous patients (7, 47–50) and one dealing with rheumatic fever prophylaxis (51) defined patients as good compliers if they simply completed the prescribed treatment. For Axton et al. (8), patients whose health status improved were considered good compliers, regardless of how closely they followed the physician's advice, an approach contrasting with that of most other researchers.

Vargas et al. (9) relied on patients' re-
call of the medical consultation plus the pill count method to measure compliance. A good complier was defined as a patient shown by the pill-count method (used during a household interview) to have taken at least 75% of a specified amount of medicine, this specified amount being what the patient said had initially been recommended.

Homedes et al. (52) had observers present during the medical consultation. This permitted self-reporting by the patient about each aspect of treatment (recommended dosage, manner of administration, frequency, duration, and other recommendations) to be compared with the advice written on the medicine labels and with the observer’s notes regarding the advice given by the health provider. In addition, the pill-count method was used to measure compliance in the case of certain drugs that could have iatrogenic effects. In a somewhat similar vein, Carrasco et al. (38) compared medical records with self-report data and pill counts.

In addition, biochemical measurement techniques were used to assess compliance in a few of the studies reviewed, specifically those reported by Taylor et al. (53), Asbeck-Raat et al. (54), Feski et al. (55), and Kumar et al. (39).

In general, the methodology chosen to study patient compliance anywhere must depend first on how compliance is defined. It should also be tailored to the organization of the health care facility involved, the resources available, and the research questions asked. For example, while biochemical analysis could be an appropriate method for overseeing patient compliance with antiepileptic drug regimens at a Danish hospital, it would not be a feasible method in most developing countries, where limitations inherent in the method loom large, and where the necessary economic and institutional resources for such high-tech compliance monitoring are generally lacking.

In contrast, review of medical record data (one form of collateral reporting) offers a cheap and rapid way of studying patient compliance, provided the records are legible and contain the information sought. Unfortunately, most medical records in developing nations do not routinely provide information about how the patient is taking prescribed medicine. At most they indicate the health provider’s prescription, the number of times the patient has been seen at the clinic, and the medicines administered by clinic personnel.

On the other hand, collateral reporting that uses family members as informants is probably more useful in developing than in developed nations. Family relations and housing conditions in most developing nations are such that family members are likely to know if and when the patient has been taking prescribed medication, even though information about specific dosages, frequencies, and side effects may not be very accurate. Moreover, in some societies anthropologic studies have revealed that enlisting family approval is an important factor in achieving patient adherence to prescribed treatments (7, 56). In such cases it becomes worthwhile for health care providers to enlist family

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support when prescribing medications to a patient, a circumstance that increases the accuracy and suitability of collateral reporting by family members.

Family support is especially important when the patient has to purchase the medicine and the family has to allocate part of the household budget for that purpose; or when adherence to the health care provider's instructions entails changes in the patient's behavior; or when the modern medical sector finds itself competing with a large number of traditional health care providers. In these instances, involving the family when discussing the patient's treatment is often a good way of promoting patient compliance and, at the same time, preparing the way for procuring collateral reports on the extent of that compliance.

Regarding use of the "clinical outcome" method in developing countries, this suffers from the same major drawbacks already described with respect to developed countries.

In contrast, self-reporting is an appealing method for compliance monitoring in developing countries. Ideally, compliance studies should measure the medication taken by a patient in terms of dosage, frequency, time, duration, and manner of administration. In this context, good compliers are those who adhere strictly to all dimensions of the medical regimen. The most appropriate way of gathering this information is to interview the patient (or a family member when the study involves children or mentally incompetent people). Experience gained by one of the authors (NH) in Costa Rica, the Dominican Republic, and Mexico indicates that in most cases the respondent being interviewed will be willing to share all the information on hand about how he or she takes the medicine and the reasons for lack of better compliance.

Roth and Caron (57) performed repeated quantitative observations and found that patients admitting to missing occasional dosages tended to miss many dosages and thus had substantial overreporting of their compliance. Presumably, patients tend to remember the days they did well, forgetting the number of times they did poorly. Generally, the reporting errors tend to be greater as patients deviate less from their prescribed regimen, with gross deviations being more accurately reported (58–60). This suggests that one way to improve the accuracy of the data recorded through the self-report method would be to include a question in the interview directed at assessing the frequency of occasional dosages missed.

So far, no study has demonstrated the accuracy of the self-report method in any developing country, although the studies by Homedes et al. (52) and Carrasco et al. (38) found self-reporting to yield results comparable to those obtained with the pill-count method without determining the accuracy of the latter.

Homedes et al. (52), when using the pill-count method, defined a good complier as a patient who, at the time of the interview, had taken at least 80% of the prescribed medicine; and when using the self-report method, defined a good complier as a patient who took the medicine in the amount, frequency, manner, and period of time written on the medicine's label or prescribed by the physician (if the label did not have all the information). Since the two methods used different definitions, comparisons could only be drawn in a very general manner. The authors concluded that the pill-count method, as compared to the self-report method, slightly overestimated the level of compliance with antibiotics and underestimated it with antihypertensive drugs or diuretics. As others have pointed out,
it is likely that variability in daily patient behavior accounts for much of the observed difference in the results obtained with the two methods (31).

Carrasco et al. (38) studied compliance with drug treatments prescribed for upper respiratory infections in children under 6 years of age. When analyzing self-reported information for each drug, they defined a good complier as a patient who had taken the medication following the specifications provided by the physician in terms of dosage, frequency, and duration. If the patient had failed to follow the instructions appropriately with respect to one of the items (dosage, frequency, or duration), compliance was considered average; and if he or she had failed in two or more items, compliance was considered poor. When using the pill-count method, the authors considered compliance good if the patient had taken 85-115% of the prescribed medication. Using this procedure, it was found that both methods indicated exactly the same percentages of compliance with antibiotics and bronchodilators, while the self-report method indicated a higher level of compliance than the pill-count method with mucolytics. The authors concluded that using a combination of methods does not make the study too complex and improves the accuracy of the collected data.

These two studies (38, see footnote 6) suggest that both the self-reporting and pill-count methods yielded good information about compliance but did not indicate exactly how accurate they were. Even though documenting accuracy would require more expensive and intrusive procedures, perhaps it is time for researchers to start thinking about addressing this issue. Meanwhile, the results available lead one to conclude that a combination of the self-reporting and pill-count methods can be used to obtain reliable information.

**ISSUES TO CONSIDER**

The points made here are derived mainly from studies conducted by the authors and their colleagues in Costa Rica, the Dominican Republic, and Mexico. As already noted, the study in Costa Rica (52) involved 404 patients and used a combination of the self-reporting and pill-count methods. The study in the Dominican Republic (61) involved 119 patients; it used household interviews to examine patients' knowledge and recollection of physician advice. The study in Mexico (not yet published) involved 100 patients and employed a combination of the self-reporting and pill-count methods to examine the use of antibiotics by pediatric patients.

In all these studies we used interviewers who were familiar with medical terminology but who were not employed by the health sector. These preselected candidates received a minimum of 4 days' training, including 3 days in the classroom and 1 day of data collection at health centers and patient households. Only those trainees were hired who attended all the training sessions, proved able to collect accurate information, and were willing to work evenings and weekends. During the training, these interviewers became familiar with the objectives of the survey, the survey manual, and the questionnaires. The training methodology included an initial explanation of each interview question, group discussions, role-playing, and field experience with the survey materials. All the training sessions were followed by discussion of errors noted during the training and clarification of points that were not fully understood.

One supervisor was assigned to each group of six or seven interviewers. The supervisor was in the field and accessible to the interviewers at all times while work
was in progress. The data were tallied in
the field in the presence of the inter-
viewer, a procedure that proved useful
because it permitted timely error correc-
tion and identification of doubtful results
at a time when they could be easily clar-
ified. It was also found useful to resurvey
a random sample of the households in-
volved and cross-check the results against
those of the original interviewers. In add-
tion, to enhance rapport between the
respondent and the interviewer, the same
interviewer who observed the physician-
patient encounter was responsible for the
household interview.

The greatest challenge faced by the re-
searchers was obtaining accurate infor-
mation about the health care providers' re-
commendations. To do this a combi-
nation of methods was used including
participant observation, review of medi-
cal records, and collection of drug label
information. It was agreed that the in-
formation written on the labels would be
considered the "norm," against which to
measure patient compliance. If the label
did not include the needed information,
the data gathered by the interviewer dur-
ing the medical encounter was used as
the "norm." The review of medical rec-
ords did not prove useful because most
health care providers recorded only the
name of the drug prescribed.

Contrary to what we had expected, en-
listing physicians' participation did not
present a problem, nor was the partici-
pant observation method perceived as a
threat. All the studies were conducted in
public health clinics; most physicians
chose to participate in the study; and,
although they knew that we intended to
measure patient compliance, they per-
ceived that as an evaluation of patient
behavior rather than a study of their in-
teraction with the patients. We also found
that most patients were willing to collab-
orate, giving us good directions for how
to get to their homes and the best times
to find them there. (By and large, since
they were not informed about the pur-
pose or the day of the visit, finding them
at home required working in the even-
ings and on weekends.)

The pill-count method could not be used
as often as desired for the following rea-
sons: (1) some patients used leftover
medicine; (2) the drug label did not state
the amount of medicine given to the pa-
tient; (3) some patients had changed con-
tainers, so that there was no label avail-
able; (4) some patients finished the
medicine before being interviewed by the
surveyor; and (5) in some cases two or
more medicines had been mixed in one
container and it was impossible to distin-
guish one from the other. It would have
been helpful to instruct the patients to
use the newly obtained package of med-
icine, especially for patients treating
chronic conditions. However, this could
have led them to suspect the purpose of
our visit, possibly leading to behavioral
changes and biasing the results of the
study.

Overall, our experience to date indi-
cates that organization of the health sys-
tem determines how best to measure pa-
tient compliance. If the patients need to
receive their medicine in the clinic, a re-
view of clinic records may be appropri-
ate. However, in most cases the patients
will be taking their medicine at home, in
which case one needs to know if the pa-
tient was given any written information
about how to take the medicine. If the
patient has a written prescription, a good
complier would be one who followed the
prescription's written instructions.

Frequently, the prescription infor-
mat ion is written on the drug label. One has
to be aware that such label prescriptions
may not include all aspects of treatment
that one would like to see (i.e., we found
a tendency to omit the duration of treat-
ment). Also, the patient may have changed containers, losing the label information in the process. If there is no label or the label's information is incomplete, one has to find out if the patient's pharmacy keeps the prescription and who is responsible for advising the patient about how to take the medicine. If a pharmacist keeps the prescription and one knows the pharmacy used by the patient, one can still use the prescription as a reference. Alternatively, when neither the pharmacy nor the patient keep any written information on how the patient should take the medicine, one can consider using medical records.

If there is no written information, there are several other alternatives. One can try to use the patient's memory as the reference point, or one can ask the health care provider about the directions given each particular patient, or one can seek advance permission from health care providers to witness their encounters with the patients. This last "participant observation" method has the advantage of allowing the researcher to study the relationship between the health care provider and the patient; but it must also be realized that the observer may be introducing some distortion into the normal flow of the interaction.

Even participant observation does not solve all the problems. For instance, in some cases the health care provider will not explain the treatment to the patient. He will just say "Take this until you feel better." In that case one has to be sure that the observer will be in a position to identify the type of medicine given, and so can refer to it when doing the household interview. The problem worsens when several medicines are prescribed at the same time and are not properly identified. In such cases it may be useful to examine the patient's medical record in order to identify the particular drugs prescribed.

One should also be aware that observers can make errors while recording the information provided by the physician during the consultation. Ideally, there should be two observers per encounter, at least during part of the study, in order to assess the magnitude of the discrepancies involved. Another possibility is to tape the conversation between the health care provider and the patient.

While it is recommended that researchers avoid using clinic personnel to do the household interviews, it is advantageous to use interviewers who are familiar with medical terminology (52). Medical records personnel or pharmacists' aides who are not currently employed by the clinic where the study is being conducted are appropriate because they can interpret physician's jargon.

An additional problem documented by Homedes et al. (52) is posed by discrepancies between the messages provided during the medical encounter and the messages written by the pharmacist on the customized drug labels. In some countries, the pharmacist may even change the prescription if the prescribed medicine is not in stock. Hence, one needs to decide in advance whether the advice of the pharmacist or that of the health care provider is going to be used as the reference for evaluating patient compliance, and also how one will deal with those aspects of medical treatment that are not addressed in either written or oral form.

Another important issue is the number and types of medications to include in the study. It should be noted that each different medicine adds a considerable number of questions to the survey. On the other hand, including all medicines prescribed during one particular encounter allows the investigator to document the patients' behavior when they have been prescribed a number of different medicines but are unable to purchase all of them or unwilling to take all at the
same time. For example, Ugalde et al. (61) found that patients in the Dominican Republic who were given prescriptions for several items including cough medicine and antibiotic chose to buy the cough medicine but not the antibiotic because the latter was more expensive. In Costa Rica, however, patients complied much better in taking antibiotics and drugs that could cause iatrogenic problems if not taken appropriately than they did in taking symptomatic remedies (52).

By and large, we have found that including all the medicines prescribed during one encounter within the study framework is not the most efficient way to study the clinical implications of patient failure to make appropriate use of the medications. In this case, it is better to concentrate on the medicines that can cause iatrogenic problems if taken inappropriately, or on those medicines that have been proven effective such as antibiotics, antiparasitics, antihypertensives, or corticosteroids.

The type of medicines to be studied will help determine when to do the household interview, which should generally be unannounced. If one is studying compliance with drugs prescribed for an acute health problem, one wants to get to the household late in the treatment period but before the treatment ends. Getting there before treatment ends is especially important if one expects to gather information from the label, because most patients will discard the container once it is empty. If the focus is on treatment for a chronic health problem, however, the timing of the household visit is not so crucial. However, since compliance tends to worsen over time, one might want to make the visit as close to the health worker's follow-up visit as possible.

If one is dealing with chronic disease medication and plans to use the pill-count method, special attention should be paid to the amount of medicine the patient already has on hand. Chronic disease patients may have leftover medicine at home, or they may be inclined to share their medicine with other members of the family or friends. One way of avoiding confusion here is to have the patient bring the leftover medicine to the clinic before getting the new prescription filled and instructing him or her not to share the medicine with anyone.

In addition, the interviewer at the patient's home has to make sure of measuring all the medicine left. It is not uncommon for chronic patients, especially elderly ones, to split the medication among different containers so as to have it more accessible when needed.

Another problem in determining the amount of medication left occurs if the medicine is in liquid form. A minor point is that the interviewer needs to confirm the patient is taking the medicine with a spoon of the appropriate size; the main problem, however, is determining the amount of medicated liquid left. One way to measure the amount of liquid left is to construct a table that takes a standard bottle shape and correlates the volume of medicine left with the height of the liquid in the bottle. Devising such a table is easy when the pharmacists involved are using standard bottles or only a few different types, but it can become very confusing if liquid medicines are sold in many types of containers. In the latter case, it may be more appropriate to have the interviewer get a detailed description of the bottle (height of the column of liquid and diameter of the bottle if it is round or other appropriate measures if it has other shapes) that will permit the researcher to calculate the actual volume of liquid left.

Another alternative is for the researcher to obtain a sample of each type of bottle used before sending the interviewers to the field, and asking the interviewers to identify the type of con-
tainer used in the questionnaire, along with the height of the remaining liquid in the bottle. Having the bottle in the office and knowing the height of the column of liquid left will allow the researcher or the coder to calculate the amount of remaining medication.

Another strategy would be to take measuring cups or other liquid measuring devices to the patient’s home and to pour the remaining medicine into them. However, a researcher choosing to use this tactic needs to ensure that the measuring will be done under hygienic conditions.

Another complication is that some liquid preparations come initially as a powder, to which the patient is instructed to add water. In that case the interviewer has to ask the respondent to indicate the level to where he or she originally filled the bottle. It is not uncommon for patients to ignore the level indicated on the instructions and dilute the powder more than recommended.

Another need that invariably presents a challenge is locating the households of rural Third World patients. Here the use of census maps does not seem to offer a good strategy. Few patients are used to maps, and they have difficulty pointing out their homes. The best thing is to ask the patient for precise directions and specific markers well known by the community that can be identified by the interviewer. Within this context, enlisting the help of a clinic worker to locate addresses on a map or to lead the interviewer to a household is most helpful.

CONCLUSION

In sum, improving patient compliance is an important way of improving the overall effectiveness of any health care system. Most health care professionals underestimate the extent of patient failure to comply with the treatments they prescribe, and so they fail to see compliance as an important aspect of the quality of care provided to their communities. Most training institutions emphasize the importance of making an accurate diagnosis and prescribing the correct treatment; but they neglect to point out that none of the previous steps will have any impact unless the patient is motivated and has the resources to comply with the prescribed treatment.

Considering all this, there is good reason to believe that improving patient compliance, assuming the diagnosis and treatment recommendations are correct, is probably the cheapest and easiest way to improve the overall effectiveness of the health care provided to a community. Hence, getting to know the extent of patient noncompliance and the factors associated with it is a key first step toward getting health administrators, health professionals, and universities interested in the topic and willing to invest in the design and implementation of strategies directed at improving the situation.

This article has outlined the range of methodologies that appear suitable for use in developing nations. Unfortunately, the small amount of published research on this subject and the lack of comparability between studies resulting from use of different definitions and methods adds to the difficulty of understanding the patient compliance process and precludes formulation of strategies aimed at ensuring adequate compliance. It is hoped that the information provided in this article will encourage others to study this problem in their communities. In general, the available information suggests that self-reporting, collateral reporting, and pill-counting would constitute the most adequate methods for measuring compliance in developing nations. Nevertheless, further research under a range of differing circumstances is needed in order to establish the validity and reliability of these methods.
REFERENCES

2. Homedes N, Ugalde A. Patients’ compliance with medical regimens in the Third World: What do we know? Health Pol Plann. [In press].


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**Update on Malaria in Central Haiti**

As this issue of the *Bulletin of PAHO* was going to press, Dr. Heinke Bonnlander provided new information on the status of malaria in the area discussed in the article “Malaria in Central Haiti: A Hospital-based Retrospective Study, 1982–1986 and 1988–1991” (pp. 9–16). She reports that the Artibonite Valley is currently experiencing a malaria epidemic. Hospital Albert Schweitzer is admitting an average of four pediatric cerebral malaria cases per week (personal communication, Dr. Kathy Nelz). No information is available concerning malaria in the adult population, but pregnant women seeking prenatal care have recently been put on prophylactic malaria treatment.