

Executive Summary: Although many different methods have been used to assess patients' compliance with prescribed medications, no single method offers 100% accuracy. The benefits and drawbacks of ten different methods are discussed in detail below. On balance, the best available research methods for measuring medication compliance are either (a) pharmacy records on prescriptions filled and refilled, or (b) data from micro-electronic medication-container monitoring devices. However, these methods can be difficult to implement or costly to use. For routine clinical use, the measure offering the most accuracy without sacrificing cost-effectiveness involves structured clinical interviewing administered by a trained interviewer other than the treating physician. Under certain conditions (discussed below), structured clinical interviews can produce information about medication use that is 80% accurate or more.

Issue: Many different methods have been used to determine whether patients are compliant with their prescribed medication regimens, and each method has its proponents and detractors. What method or methods of assessing compliance should be considered the "gold standard" for determining whether a patient has actually taken his or her medication as prescribed?

Possible Methods for Assessing Compliance: The following methods have been used to assess medication compliance. Each has benefits and limitations, which will be discussed in detail below:

1. Physician judgment (the prescribing physician's rating of patients' compliance)
2. Patient self-report (using a single item, or using a standardized questionnaire)
3. Records regarding the patient's completion of follow-up appointments
4. Pill count calculation (pills dispensed – pills remaining = pills taken)
5. Clinical results that could be expected if the patient had taken the medication
6. Biochemical markers (lab tests to detect serum levels of the drug or its metabolites)
7. Pharmacy records regarding prescriptions filled
8. Microelectronic monitoring devices (MEMS) that record pill-bottle openings over time
9. Clinical interview regarding compliance (structured or unstructured)
10. Direct observation of the patient taking the medication

Findings: Only method #10 (direct observation) establishes that the patient has, in fact, administered his or her medication as prescribed; however, this method does not tell us what the patient's behavior would be in a naturalistic setting, if he or she was not being monitored. Therefore, *no current method for assessing compliance offers 100% accuracy*. However, some methods provide more accurate results than others.

1. Physician Judgment

A. Benefits: This is the simplest method for assessing compliance—ask the prescribing physician whether, in his or her medical opinion, the patient has been compliant with the prescribed treatment. It can be argued that the physician has an ongoing relationship with the patient, as well as access to relevant medical data, and therefore is in the best position to judge whether or not the patient has taken medication as he or she agreed to do.

B. Limitations: Despite many physicians' and some researchers' beliefs to the contrary, physicians are exceptionally poor judges of patient compliance.¹ In one study, physicians "grossly overestimated" their patients' use of prescribed antacid medication, even when they were treating inpatients who were seen every day; in another study, a group of experienced pediatricians in private practice *could not judge with better than chance accuracy* whether children in their practice had taken the penicillin prescribed for them.² Other studies show similar results: In a

¹ Atkin, P. A. & Ogle, S. J. (1996). Issues of medication compliance and the elderly. *Adverse Drug Reactions & Toxicology Review*, 15, 109-118.

² Roth, H. P. (1987). Measurement of compliance. *Patient Education and Counseling*, 10, 107-116.

study of patients with HIV, physicians detected patients' nonadherence to antiretroviral drugs only 59% of the time;³ in a study of patients with hypertension, physicians failed to identify 47% of patients who were not taking their prescribed medication;⁴ and in a study of patients with tuberculosis, 52% of the patients whom physicians judged to be "compliant" were in fact not taking their medication.⁵ Finally, in a study of ophthalmologists' judgment of glaucoma patients' treatment adherence, the physicians' assessments of patient compliance were uniformly inaccurate, *regardless of how well the physician said he or she knew the patient*.⁶ This situation is not entirely the physician's fault: Extensive research shows that patients exaggerate their compliance in reports to their physicians, a phenomenon referred to as the "white-coat" or "toothbrush" effect.⁷

2. *Patient Self-Report*—Note that "self-report" procedures generally involve a patient filling out a questionnaire, providing information on a form, or completing an intake procedure with a receptionist. If the patient provides information through an interview with a clinician or health care professional, the procedure should be considered a "clinical interview" rather than a self-report. Clinical interviews are discussed in point #9, below.

A. Benefits: Again, this is a relatively straightforward method for assessing compliance. Asking people to describe their own behavior is generally the simplest and most intuitive method for gathering this type of information,⁸ as the patient possesses the most detailed information about himself or herself on an ongoing basis. Patients can be asked a single-item assessment question, such as "have you taken your medication in the way that your doctor prescribed it?", or they can be asked to complete a multi-item paper-and-pencil questionnaire about their medication use.

B. Limitations: Patients' self-report may not provide a reliable estimate of patients' true level of medication compliance. In general, researchers have concluded that "when a patient states that the medication is being taken regularly, it often is not. When a patient states that occasional doses are being missed, that is usually an understatement of the extent of deviation from the regimen. However, when a patient states that the drug is not being taken, this is usually corroborated."⁹ One variation on the concept of patient-self report is the "daily diary method," in which patients are asked to keep an ongoing log of their medication use each day. Unfortunately, patients are often noncompliant with the diary-keeping assignment itself, creating a serious logistical concern.¹⁰ Furthermore, diaries seem to have the same drawback as other self-reports, providing overestimates of compliance.¹¹

Often, self-report instruments are designed for specific research projects and little or no information is provided about their reliability or validity.¹² One possible exception to the general weakness of self-report measures is the existence of mixed support for a measure known as the Self-Reported Medication Taking Scale. This four-item (Yes/No) measure seems to be reasonably accurate (75%) when it reports that a patient is *compliant*, which is opposite to the usual bias found in patient self-reports. However, this measure is less accurate when it reports that a patient is *noncompliant*—some of the patients judged to be "noncompliant" are actually compliant,

³ Valenti, W. M. (2001). Treatment adherence improves outcomes and manages costs. *The AIDS Reader*, 11, 77-80.

⁴ Study by Steele et al., 1990, cited in Rand, C. S. & Wise, R. A. (1994). Measuring adherence to asthma medication regimens. *American Journal of Respiratory Critical Care Medicine*, 149, S69-S76.

⁵ Moulding, T., Onstad, G. D., & Sbarbaro, J. A. (1970). Supervision of outpatient drug therapy with the medication monitor. *Annals of Internal Medicine*, 73, 559-564.

⁶ Kass, M. A., Gordon, M., & Meltzer, D. W. (1986). Can ophthalmologists correctly identify patients defaulting from pilocarpine therapy? *American Journal of Ophthalmology*, 101, 524-530.

⁷ Feinstein, A. R. (1990). On white-coat effects and the electronic monitoring of compliance. *Archives of Internal Medicine*, 150, 1377-1378.

⁸ Groth-Marnat, G. (1990). *Handbook of Psychological Assessment*, 2nd Ed. New York: Wiley. p. 20

⁹ Roth, H. P. (1987). *ibid*; see also research indicating that asthmatic patients over-report their own compliance with preventive asthma medications more than 50% of the time: Mawhinney, H., Spector, S. L., Kinsman, R. A., Siegel, S. C., Rachelefsky, G. S., Katz, R. M., & Rohr, A. S. (1991). Compliance in clinical trials of two nonbronchodilator, antiasthma medications. *Annals of Allergy*, 66, 294-299.

¹⁰ Rand, C. S. & Wise, R. A. (1994). *ibid*.

¹¹ Jonasson, G., Carlsen, K. H., Sodal, A., Jonasson, C., & Mowinckel, P. (1999). Patient compliance in a clinical trial with inhaled budesonide in children with mild asthma. *European Respiratory Journal*, 14, 150-154.

¹² See, e.g., Rand, C. S. & Wise, R. A. (1994). *ibid*; Stanton, A. L. (1987). Determinants of adherence to medical regimens by hypertensive patients. *Journal of Behavioral Medicine*, 10, 377-394.

suggesting that this measure is overly sensitive, and may judge patients “noncompliant” based on minor carelessness or regimen deviations that do not actually interfere with treatment.¹³ A modified version of the Self-Reported Medication Taking Scale has demonstrated both retest reliability and construct validity, in terms of its ability to detect the effects of a compliance-enhancing intervention.¹⁴ Therefore, although this scale is not the strongest measure of medication compliance, it may have some utility in some situations, and it provides a starting point for future instrument development efforts in this area.

3. Appointment-Keeping Records

A. Benefits: Patients who miss scheduled follow-up appointments with a physician may be more likely also to stop taking their medication, or to drop out of treatment altogether. Appointment records have the advantage of being readily available as a measure of noncompliance, often requiring minimal data collection (possibly only a report from an existing clinical or administrative database).

B. Limitations: This method is reminiscent of the joke about the man who lost his keys down a dark street, but searched for them under the streetlamp on the corner because “the light was better there.” This method avoids assessing a behavior that is hard to measure—medication compliance—in favor of assessing a behavior that is easier to measure—appointment-keeping. Unfortunately, the two behaviors may not be well correlated with one another. In a study of patients with tuberculosis, 53% of patients no longer had detectable blood levels of their prescribed medication after 1½ years, *even though they continued to see their physician* for routine follow-up care.¹⁵ And in a study of ulcer patients, average medication use was actually *lower* among patients who kept all appointments than among patients who missed at least one appointment!¹⁶ Based on these findings, measures of appointment-keeping are not an appropriate stand-in for measures of medication adherence.¹⁷

4. Pill Count Calculation

A. Benefits: This widely-used method of assessing compliance makes intuitive sense: If the patient is provided with a certain number of pills (or inhaler puffs, injection doses, etc.) at the beginning of the month, and returns to the clinic with a smaller number of pills (puffs, doses, etc.) at the end of the month, then the missing doses must have been taken as prescribed. This method has the benefit of providing more “objective,” quantifiable data than patients’ or physicians’ reports. Research confirms that pill counts provide *more information about deviations* from the medication regimen than self-report,¹⁸ confirming the idea that patients tend to under-report noncompliance.

B. Limitations: First of all, pill counts may be difficult to implement because of difficulty in specifying exactly how much medication *should* have been used. This difficulty occurs whenever one does not have access to information on exact dispensing dates, the amount of medication provided, or the amount of medication remaining—a situation that is more common than one might expect. For example, even when patients are called with reminders to bring medication bottles to their next doctor’s appointment, 20% fail to do so;¹⁹ and in a study where 114 patients brought digoxin pill bottles to clinic appointments, pill counts were impossible (due to missing bottle labels, date on the bottle more than 1 year old, number dispensed not on the label, *more* medication in the bottle than was dispensed, etc.) in 52% of cases.²⁰ In addition, patients often

¹³ Morisky, D. E., Green, L. W., & Levine, D. M. (1986). Concurrent and predictive validity of a self-reported measure of medication adherence. *Medical Care*, 24, 67-74.

¹⁴ Brooks, C. M., Richards, J. M., Kohler, C. L., Soong, S.-J., Martin, B., Windsor, R. A., & Bailey, W. C. (1994). Assessing adherence to asthma medication and inhaler regimens: A psychometric analysis of adult self-report scales. *Medical Care*, 32, 298-307.

¹⁵ Kiley, D. J., Lam, C. S. & Pollak, R. (1993). A study of treatment compliance following kidney transplantation. *Transplantation*, 55, 51-56.

¹⁶ Roth, H. P. (1987). *ibid.*

¹⁷ Stoudemire, A. & Thompson, T. L. II (1983). Medication noncompliance: Systematic approaches to evaluation and intervention. *General Hospital Psychiatry*, 5, 233-239.

¹⁸ Park, L. C. & Lipman, R. S. (1964). A comparison of patient dosage deviation reports with pill counts. *Psychopharmacologia*, 6, 299-302.

¹⁹ Dunbar, J. (1984). Adherence measures and their utility. *Controlled Clinical Trials*, 5, 515-521.

²⁰ Fletcher, S. W., Pappius, E. M., & Harper, S. J. (1979). Measurement of medication compliance in a clinical setting: Comparison of three methods in patients prescribed digoxin. *Archives of Internal Medicine*, 139, 635-638.

store their medications in places other than the original container, share medications with family members or friends, or simply lose their medications. Some of these same logistical issues made it impossible to use a pill-count measure in some of *ScriptAssist*'s own prior research.²¹ Besides these important logistical concerns, it is relatively easy for patients to dispose of extra pills prior to the assessment if they wish to create a false impression that they have been compliant.²² Perhaps because of these factors, one study found that a pill count was *not correlated* with either patient self-report or a biochemical measure, but rather provided relatively random information. However, some researchers *have* found a correlation between pill counts and other measures of compliance,²³ making this measure more reliable than previous approaches despite some random error.

5. *Clinical Results of Treatment*

A. Benefits: As the goal of treatment is to produce some clinical result (e.g., lower blood pressure, reduced frequency of asthma attacks, etc.), it may be reasonable to assume that patients who faithfully take their medication will have better clinical results than those who do not. Again, clinical results are relatively easy to observe, and may require no additional data collection beyond the clinical measurements already included in a patient's medical chart.

B. Limitations: Unfortunately, no medication is 100 percent effective. Patients may routinely take their medication but still not receive clinical benefits, either because the medication is not helpful to them or because they are not receiving an adequate dose.²⁴ For example, in a study of patients with either epilepsy or hypertension, many patients did not show therapeutic benefits even though they were compliant according to other measures.²⁵ And for some conditions or treatments (e.g., blood pressure), the target indicator will tend to fluctuate over time, even when treatment is working. It is likely because of these issues that clinical-result measures generally show *greater* rates of noncompliance than any other measure—suggesting that clinical results tend to *underestimate* patients' true level of medication compliance.

6. *Biochemical Markers*

A. Benefits: Biochemical measures attempt to determine whether the patient has received an appropriate dose of medication by looking at the patient's blood serum level of either the medication or its metabolites. This measure seems to offer one of the most direct indicators of whether or not the medication has actually been received: If the appropriate substance is detected in the patient's system, one can conclude that the medication was taken as prescribed.

B. Limitations: First, it is important to note that this assessment method is not universally available, as some substances are absorbed in such a way that they cannot be detected in the bloodstream, or are detectable for only a very short period of time. A second limitation of the method involves individual variation in the absorption, metabolism, and excretion of drugs—for example, one study found that among patients with low serum digoxin levels, half were fully compliant but had abnormal patterns of drug absorption.²⁶ There are also important logistical considerations, including the fact that the patient must return to the physician's office for assessment of compliance, the fact that this type of measure involves blood draws or other "invasive" tests, the additional costs associated with laboratory work, and the fact that patients can often present false results on this type of test simply by taking a dose of their medication immediately before they arrive at the clinic for assessment.²⁷ Finally, it is important to note that some patients will refuse to participate in this type of laboratory measurement, and this will tend to bias the results: There is

²¹ Cook, P. F., Berdie, M. J., Dubin, M. D. & Wirecki, T. S. (2000). Effect of telephone outreach counseling on patients' adherence to antidepressant medication. Unpublished manuscript, available from *ScriptAssist*, LLC.

²² Roth, H. P. (1987). *ibid.*

²³ Inui, T. S., Carter, W. B., & Pecoraro, R. E. (1981). Screening for noncompliance among patients with hypertension: Is self-report the best available measure? *Medical Care*, 10, 1061-1064; Stewart, M. (1987). The validity of an interview to assess a patient's drug taking. *American Journal of Preventive Medicine*, 3, 95-100.

²⁴ see, e.g., Canaris, G. J., Manowitz, N. R., Mayor, G., & Ridgway, E. C. (2000). The Colorado thyroid disease prevalence study. *Archives of Internal Medicine*, 160, 526-534.

²⁵ Steiner, J. F., Koepsell, T. D., Fihn, S. D., & Inui, T. S. (1988). A general method of compliance assessment using centralized pharmacy records. *Medical Care*, 26, 814-823.

²⁶ Dunbar, J. (1984). *ibid.*

²⁷ Rand, C. S. & Wise, R. A. (1994). *ibid.*

good reason to believe that patients who agree to participate in this type of measure also are more likely to be compliant than those patients who refuse to participate.²⁸ If these limitations somehow can be overcome, then biochemical methods generally correlate well with other measures.²⁹

7. Pharmacy Records

A. Benefits: The greatest benefit of using pharmacy records as a measure of treatment compliance is that they provide an unobtrusive method of measuring this construct. Patients need not be aware that their compliance is being monitored, and therefore there is little risk that the patient will attempt to distort the findings. Additionally, pharmacy databases can provide information about large numbers of patients, allowing researchers to determine patterns of compliance in the overall population. Pharmacy measurements have been used to document patterns of compliance with many common classes of medication, including antihypertensives³⁰ and antidepressants.³¹ There is some evidence that pharmacy records can overcome the limitations associated with self-report measures: They record *all* medications dispensed, while only 60-70% of these medications are reported by patients themselves.³²

B. Limitations: Pharmacy data may be difficult to obtain, although this situation has improved with the advent of large-scale Pharmacy Benefit Management (PBM) companies. However, access to patient-specific data is often still limited due to patient privacy regulations: Most pharmacy-based data provides projections and estimates based on aggregate data, rather than information about how long, on average, each individual patient actually stayed in treatment. In addition, large pharmacy databases may require a great deal of programming work to construct appropriate data queries. An additional concern has to do with the fact that patients may not refill medications on an exact schedule, making it important to determine what decision rule was used for counting a patient as “noncompliant” (e.g., prescription refilled after 35 days, rather than after 30). Finally, pharmacy data can provide little information about compliance with short-term medication regimens, cannot identify those patients who never filled their first prescription, and provide invalid results when a patient refills his or her prescription at a pharmacy outside of the vendor’s database system. Despite these limitations, pharmacy data do provide one of the best sources of information about patients’ compliance with long-term treatments.

8. Micro-electronic Medication Monitors (MEMS)

A. Benefits: MEMS are tiny electronic monitoring devices that are embedded in the lid of a pill bottle, the plunger of an inhaler device, or the dropper of an eye drop bottle. These devices are relatively unobtrusive, and are preferable to pill counts in that they provide exact records of the *dates* and *times* that the medication container was used, rather than merely a count of how much medication remains at the end of the month. MEMS have now been used to assess compliance with a wide variety of medication types, including pills for migraine,³³ epilepsy,³⁴ heart disease,³⁵ and breast cancer,³⁶ inhalers for asthma,³⁷ and eye drops for glaucoma.³⁸ In these studies, the

²⁸ Atkin, P. A. & Ogle, S. J. (1996). *ibid.*

²⁹ see, e.g., Roth, H. P. (1987). *ibid.*; Steiner, J. F. et al. (1988). *ibid.*

³⁰ McCombs, J. S., Nichol, M. B., Newman, C. M., & Sclar, D. A. (1994). The costs of interrupting antihypertensive drug therapy in a Medicaid population. *Medical Care*, 32, 214-226.

³¹ Tierney, R., Melfi, C. A., Signa, W., & Croghan, T. W. (2000). Antidepressant use and use patterns in naturalistic settings. *Drug Benefit Trends*, 12, 7-12.

³² Atkin, P. A. & Ogle, S. J. (1996). *ibid.*

³³ Mulleners, W. M., Whitmarsh, T. E. & Steiner, T. J. (1998). Noncompliance may render migraine prophylaxis useless, but once-daily regimens are better. *Cephalalgia*, 18, 52-56.

³⁴ Cramer, J. A. & Mattson, R. H. (1991). Monitoring compliance with antiepileptic drug therapy. In J. A. Cramer & B. Spilker (Eds.), *Patient Compliance in Medical Practice and Clinical Trials*. New York: Raven Press.

³⁵ Carney, R. M., Freedland, K. E., Eisen, S. A., Rich, M. W., Skala, J. A. & Jaffe, A. S. (1998). Adherence to a prophylactic medication regimen in patients with symptomatic versus asymptomatic ischemic heart disease. *Behavioral Medicine*, 24, 35-39; Straka, R. J., Fish, J. T., Benson, S. R. & Suh, J. T. (1996). Magnitude and nature of noncompliance with treatment using isosorbide dinitrate in patients with ischemic heart disease. *Journal of Clinical Pharmacology*, 36, 587-594.

³⁶ Waterhouse, D. M., Calzone, K. A., Mele, C. & Brenner, D. E. (1993). Adherence to oral tamoxifen: A comparison of patient self-report, pill counts, and microelectronic monitoring. *Journal of Clinical Oncology*, 11, 1189-1197.

³⁷ Mawhinney, H. et al. (1991). *ibid.*

³⁸ Kass, M. A., Meltzer, D. W., Gordon, M., Cooper, D. & Goldberg, J. (1986). Compliance with topical pilocarpine treatment. *American Journal of Ophthalmology*, 101, 515-523.

MEMS devices generally recorded *higher levels of nonadherence* than traditional assessment methods, which suggests that MEMS can detect noncompliance that is otherwise unreported.

B. Limitations: Although MEMS are relatively unobtrusive, they are not completely unobtrusive. In most cases the patient is aware that he or she is being monitored, and it is possible to deceive the monitoring device (although not easy: this would require regularly using the medication container as though one were taking the medication, but not actually taking it). Furthermore, in situations where the patient must agree to the monitoring procedure, those patients who refuse to participate are also likely to be the patients who are noncompliant, and vice versa. This creates a selection bias in the sample, which can lead to inaccurate results. In situations where the patient is not aware of the monitoring device, the patient must still be told to “use this special medication container,” and not to remove any medication unless he or she is going to take it. As noted in the section on pill counts, some patients will choose to remove medication from its original container and keep it elsewhere, which defeats the purpose of the monitoring device. Also as mentioned in the section on pill counts, about 20% of patients will not bring their pill bottle back to the doctor’s office even when reminded to do so. In these situations, it will be impossible to download data from the MEMS device for analysis. A final drawback to the method is that MEMS devices tend to be relatively expensive (e.g., \$50-\$100 per device), and are easily lost, damaged, or destroyed. Therefore, this method for assessing compliance is unlikely to be useful for general practice, only for small-scale clinical trials where more control is possible and more resources are available.

9. Clinical Interview

A. Benefits: “The cheapest and simplest method for determining whether a patient has taken his medicine is to ask him.”³⁹ Like physician judgments and patient self-report data, clinical interviews are relatively simple and inexpensive methods for assessing compliance. But unlike physician ratings or self-reports, *some types of interviews provide relatively accurate measurements of patients’ compliance*: For example, a non-judgmental interview in one study was 87% accurate in detecting noncompliance (i.e., for 87% of patients who said they were taking their medication correctly, this claim was verified by a biochemical measure).⁴⁰ In another study, a single interview question correctly identified 80% of noncompliers (as determined by pill count).⁴¹ Interview measures of compliance have shown good inter-rater reliability ($r = .84$ in one study), as well as significant correlations with ratings of the patient’s compliance by the patient’s spouse or significant other.⁴² One research team found that even psychotic patients receiving inpatient psychiatric treatment were able to give accurate accounts of their own level of medication adherence when they participated in a structured clinical interview.⁴³

B. Limitations: Of course, these impressive results are not obtained in every instance. As noted above, physicians (who presumably rely on interview data as well as medical indicators) are relatively unsuccessful in detecting noncompliance, and patients who are motivated to lie may be able to deceive even a skilled interviewer. However, *in one of the same studies that showed only 59% accuracy for physicians’ ratings of noncompliance, nurses in the same practices were 70% accurate* in their ratings of compliance for the very same patients.⁴⁴ This may reflect patients’ willingness to be more honest with a nurse, who may be perceived as more empathetic and less of an “authority figure” than the physician. The examples cited above show that, when the right conditions are met, interview measures can provide compliance estimates that are relatively accurate in reference to more “objective” indicators.

10. Directly Observed Therapy (DOT)

A. Benefits: DOT is the only method for assessing compliance that allows one to determine for certain whether the patient has actually taken the prescribed medication (but does not allow one to

³⁹ Roth, H. P. (1987). *ibid.* p. 114.

⁴⁰ Fletcher, S. W., Pappius, E. M. & Harper, S. J. (1979). *ibid.*

⁴¹ Stewart, M. (1987). *ibid.*

⁴² Hilbert, G. A. (1985). Accuracy of self-reported measures of compliance. *Nursing Research*, 34, 319-320.

⁴³ Adams, S. G. & Howe, J. T. (1993). Predicting medication compliance in a psychotic population. *Journal of Nervous and Mental Disease*, 181, 558-560.

⁴⁴ Valenti, W. M. (2001). *ibid.*

determine what happens in situations when no observer is present). By having an observer present at the time of administration, it is possible to verify that the amount, dosing, and time of administration are all correct.

B. Limitations: One major problem with this method of assessment is that it is both expensive and time-consuming. It requires having a trustworthy observer present each and every time the medication is taken—something that is very difficult to arrange for medications taken more than once per day in outpatient treatment. But this method has an additional limitation that makes it virtually useless as a valid assessment technique: The presence of an observer creates a “reactive assessment,” in which the patient is likely to behave differently from the way he or she would act if no observer were present. The patient is likely to be much more compliant than usual, for the sake of gaining approval from the observer. In fact, the psychological “demand characteristics” of the DOT situation (i.e., the situation’s ability to “pull for” a particular response) are so powerful that this method has been used *as an intervention to improve compliance* for patients with tuberculosis and with schizophrenia.⁴⁵

Conclusions About Compliance Measures: Overall, the measures with the most consistent evidence for their validity are pharmacy data and MEMS devices. Although either of these measures could be considered a possible “gold standard” against which to validate other measures of compliance, each method is limited in that it does not actually prove that the patient took the medication—only that the medication was appropriately dispensed. As previously stated, pharmacy data may be difficult to access due to patient privacy regulations, do not capture certain types of information, and may be unreliable if data queries are not very carefully specified. The limitations of MEMS are that they are expensive, somewhat more obtrusive, and easily lost or destroyed. Therefore, although both measures are appropriate for a formal research context, neither is necessarily preferable to the other, and it seems unlikely that either will be widely adopted for routine clinical use.

For routine clinical assessment, the most valid measure of compliance is a structured clinical interview, administered by someone other than the treating physician. This method is likely to produce more valid results (with 70-87% accuracy demonstrated in various studies) than either physician ratings or patient self-report. Both physician reports and patient self-reports generally overestimate compliance (although one self-report measure, the Self-Reported Medication Taking Scale, may overcome this bias and therefore should be evaluated in further research).

Of course, interview data still ultimately comes from the patient, and patients may still have some tendency to exaggerate their true level of compliance. In light of the conclusions discussed above, it makes sense to ask whether there are interviewing methods or practices that are more likely to produce accurate data about medication compliance. Therefore, the following section gives recommendations on how to conduct an interview in order to provide the most accurate estimate of compliance.

Recommended Interviewing Techniques: Basic psychological research shows that interviews, which always represent an interaction between two individuals rather than a patient providing self-reports in isolation, can provide the most accurate information if the following conditions are met:

1. Minimize Demand Characteristics of the Assessment Procedure—The concept of “demand characteristics” refers to

“... the influence of the experimenter’s belief and desires about the results on how the subject performs. The effects are considered to be unintentional because the experimenter may not do anything on purpose to influence subjects’ responses. Rather, through tone of voice, posture, facial expressions, and other cues, the experimenter may influence how the subject responds.”⁴⁶

This type of effect may partially account for patients’ unwillingness to communicate information about noncompliance to their physician, who may inadvertently communicate his or her wish that the patient

⁴⁵ McGirr, K. (2001). San Francisco provider follows tuberculosis model in developing medication compliance program. *Mental Health Weekly*, 11/5/01, 4.

⁴⁶ Kazdin, A. E. (1992). *Research Design in Clinical Psychology*, 2nd Ed. New York: Allyn & Bacon. p. 298.

has taken the medication, so that the process of assessment and medical treatment can proceed. (Some physicians very directly communicate this expectation, by “putting the fear of God” into patients regarding what will happen if they do not take their medication. Research suggests that such scare tactics do not improve compliance, and they may in fact make patients less likely to be honest with their physician about their own behavior).⁴⁷ It is possible, however, for the interviewer to minimize demand characteristics and their effect on the patient’s responses. One way to accomplish this is by reducing nonverbal cues (e.g., by using a telephone or Internet-based interviewing format, in which the interviewer’s nonverbal behavior cannot be observed). Another is for the interviewer to carefully monitor his or her own behavior, attempting to eliminate any demand characteristics that might “pull” for a particular answer one way or the other.

2. Maximize the Patient’s Motivation for Honesty—In addition to minimizing demand characteristics, it is helpful to encourage the patient to be honest. It should come as no surprise that patients will provide inaccurate information to the extent that they are motivated to do so, and will provide accurate information to the extent that they are motivated to do that instead. It may help to explicitly communicate the expectation that the patient will be honest, and to enumerate the reasons why honesty is in the patient’s best interest.⁴⁸ For example, the interviewer could say, “it’s important for you to tell me whatever might be going on, because having accurate information allows me to help you better.” The context of the interview is also important—for instance, people are less likely to be honest when they are being evaluated in order to make legal or educational decisions about their future than when they are being evaluated in the context of receiving medical or psychological services.⁴⁹ If the patient feels that he or she is the recipient of a *service* (in other words, feels like the interviewer is there to help him or her in some way), the patient is more likely to provide accurate information than if he or she feels that the purpose of the interview is to judge or condemn the patient, or to pry into the patient’s private affairs. A crucial interviewing skill is the ability to “set the stage,” to structure the interview so that the patient feels that his or her best interests are at heart, and thereby to motivate the patient for honesty rather than for deception.
3. Communicate a Non-Judgmental Attitude—Another important factor in patients’ unwillingness to admit to noncompliance involves a “social desirability bias” that is inherent in the interview situation. Because this type of assessment involves an interaction between two people, the patient may be motivated to avoid being judged unfavorably (“negative social evaluation”). “Blatant dissimulation aside, subjects are likely to alter slightly the image of themselves that they present and to interpret very loosely the meaning of the items so that they appear to place themselves in the best possible light.”⁵⁰ Thus, patients are likely to report that they have taken their medication as prescribed, even when they have not, because this type of “compliant” behavior seems more likely to lead to a favorable evaluation by others. Social desirability bias can be overcome by explicitly communicating the idea that noncompliance is both *normal* and *acceptable*. In addition, patients’ honesty will be greater when the interviewer implicitly communicates an accepting, supportive, non-judgmental attitude.⁵¹ An interview “with an investigator who . . . communicates concern should enable a patient to feel relaxed and trusting. An introductory comment expressing understanding of how difficult it is to comply and that most patients are not completely compliant sets the right atmosphere.”⁵² For example, the interviewer may speak in warm tones of voice, convey interest in what the patient is reporting, and make introductory statements like “many patients have told me that they find it difficult to take all their medicines exactly as the doctor prescribed. Do you find it hard, too?”⁵³
4. Have the Interview Conducted by a Non-Authoritarian Interviewer—In addition to social desirability biases, patients may fall into the “good subject role,” which involves trying to tell the interviewer what the patient thinks the interviewer wants to hear.⁵⁴ Again, this is probably a factor in patients’ reluctance to tell their physicians the true extent of their noncompliance—the patient wants to please

⁴⁷ Meichenbaum, D., & Turk, D. C. (1987). *Facilitating Treatment Adherence : A Practitioner’s Guidebook*. pp. 204-208.

⁴⁸ Kazdin, A. E. (1992). *ibid.* p. 239.

⁴⁹ Groth-Marnat, G. (1990). *ibid.* pp. 31-40.

⁵⁰ Kazdin, A. E. (1992). *ibid.* p. 238.

⁵¹ Groth-Marnat, G. (1990). *ibid.* pp. 61-63.

⁵² Hilbert, G. A. (1985). *ibid.* p. 320

⁵³ Fletcher, S. W. et al. (1979). *ibid.* p. 636.

⁵⁴ Kazdin, A. E. (1992). *ibid.* pp. 313-314.

the physician (whether consciously or not), and therefore tends to exaggerate his or her own level of compliance with treatment. This type of role-related behavior is minimized when the patient is interviewed by someone who is viewed as a peer or a resource person, rather than as a superior. Patients very often fall into a “subordinate/superior” relationship with their physicians, whether or not the physician intends for this to happen; however, patients may not have this type of attitude toward a nurse or other health care professional. This may contribute to the finding that nurses are more accurate than physicians in their judgments of patients’ medication compliance.⁵⁵

5. Provide as Much Anonymity or Confidentiality as Possible—Patients are more likely to provide honest answers to questions under conditions of anonymity, or when confidentiality is guaranteed.⁵⁶ “As part of the informed consent procedure, this assurance should allow subjects to freely discuss their noncompliance.”⁵⁷ Even when feedback is provided to the treating physician, patients are often reassured to know that “only a short written summary will be provided” to the physician, rather than a verbatim transcript of the interview. In addition, patients may be more honest when an interview is conducted by telephone or over the Internet, rather than face-to-face. Some preliminary research has shown that people are more open and honest when using an Internet chat room than when they participate in an in-person support group.⁵⁸
6. Use Structured Questions and Prompts—Structured interviews allow for greater inter-rater reliability and standardization of interview questions,⁵⁹ which has made them the standard of practice for diagnosing “functional” conditions (i.e., conditions for which there is no objective medical test) such as anxiety, depression, or chronic pain.⁶⁰ Structured interviews have also been used successfully to detect drug and alcohol use, which are conditions that inspire a high level of doubt about patients’ willingness to tell the truth.⁶¹ Structured interview measures tend to be more accurate because they “allow for gentle probing if there are discrepancies. For example, the interviewer might say, ‘think back to the last week and tell me how many doses of your medication you think you missed.’”⁶² Questions about very specific details of the patient’s medication use can help to detect any cases in which the patient is not telling the truth. Using specific data (such as information about the patient’s blood pressure, number of days in the last week that medication was used, etc.) to supplement a general question about noncompliance can increase interview measures’ accuracy.⁶³ In addition, specific questions help to overcome the barrier associated with poor memory, as these items may serve as “prompts” to aid in recall of particular details about the patient’s medication use.⁶⁴
7. Attend to Nonverbal Cues in Order to Detect Inaccurate Responses—In psychological studies on deception and lying, researchers have found that nonverbal cues may be more telling than people’s actual words. In this body of research, nonverbal cues have been identified even in spoken language—even though a telephonic interview does not provide access to visual information about a person’s “body language,” it still provides access to the nonverbal aspect of communication. Interviewers can be trained to pay less attention to what people say, and more attention to *the way in which they say it*. By paying attention to cues such as “distancing,” “disqualifying” remarks, or evasiveness in the way a person responds to questions, interviewers can significantly improve the accuracy of their judgments about the interviewee and the truth of his or her statements.⁶⁵

⁵⁵ Valenti, W. M. (2001). *ibid.*

⁵⁶ Kazdin, A. E. (1992). *ibid.* p. 239.

⁵⁷ Hilbert, G. A. (1985). *ibid.* p. 320.

⁵⁸ see, e.g., Rosson, M. B. (1999). I get by with a little help from my cyber-friends. *Journal of Computer-Mediated Communication*, 4.

⁵⁹ Groth-Marnat, G. (1990). *ibid.* p. 62.

⁶⁰ see, e.g., Williams, J. B. et al. (1992). The Structured Clinical Interview for DSM-III-R (SCID): II. Multisite Test-Retest Reliability. *Archives of General Psychiatry*, 49, 630-636.

⁶¹ Del Boca, F. K. & Brown, J. M. (1996). Issues in the development of reliable measures in addictions research: Introduction to Project MATCH assessment strategies. *Psychology of Addictive Behaviors*, 10, 67-74; Hoffman, N. G. & Ninonuevo, F. G. (1994). Concurrent validation of substance abusers’ self-reports against collateral information: Percentage agreement vs. κ vs. Yule’s Y. *Alcoholism: Clinical and Experimental Research*, 18, 231-237.

⁶² Hilbert, G. A. (1985). *ibid.* p. 320.

⁶³ See, e.g., Inui, T. S. et al. (1981). *ibid.*; Stewart, M. (1987). *ibid.*

⁶⁴ Groth-Marnat, G. (1990). *ibid.*; Meichenbaum, D. & Turk, D. C. (1987). *ibid.*

⁶⁵ Mehrabian, A. (1981). *Silent messages: Implicit communication of emotions and attitudes (2nd ed.)*. Wadsworth, Belmont, California; Wiener, M., & Mehrabian, A. (1968). *Language within language: Immediacy, a channel in verbal communication*. Appleton-Century-Crofts, New York.

ScriptAssist uses these research-supported interviewing techniques to obtain the most accurate information available about individual patients' level of medication adherence. *ScriptAssist*'s assessment procedure relies on specially trained nurses who conduct telephonic interviews with patients, using the psychological interviewing methods discussed above to detect any inconsistencies and to improve the accuracy of patients' reports. With these techniques, past research suggests that we will obtain about 80% accurate information about patients' actual level of compliance. Although additional sources of data about compliance (e.g., MEMS or pharmacy records) would be desirable for formal research projects, *ScriptAssist*'s methods for assessing noncompliance provide a simple clinical measurement that achieves the most favorable balance between cost-effectiveness and accurate results.

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