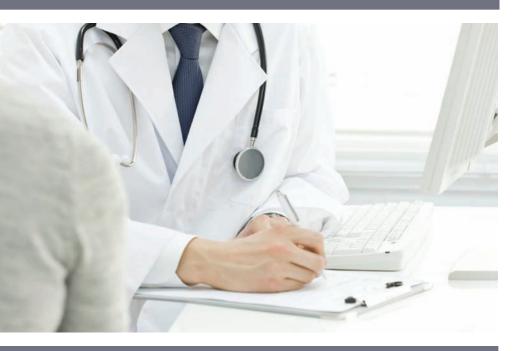
Research to Practice



THE DISTINCTION BETWEEN CLINICAL AND RESEARCH INTERVIEWS IN PSYCHIATRY

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ABSTRACT

Research interviews require a fact-based, neutral inquiry style that contrasts markedly from the empathic style of clinical interviews in psychiatric practice. In fact, the research interview generally seeks to gather information and specifically avoid any therapeutic benefit. This article describes the purpose of these opposing interview styles and provides some guidelines for beginning clinicians conducting research.

KEY WORDS

Research interviews; structured interview guides

INTRODUCTION

Clinical researchers in psychiatry are usually trained as clinicians before they begin to do research. In clinical circles, the oft-cited credo to "do no harm" to the patient also implies some effort to provide some help as well. In contrast, the primary objective of the properly conducted research interview is to

simply get the facts and essentially to "give no help" in order to minimize the placebo response. This distinction between clinical and research interviews reflects the very real difference between psychotherapy that seeks clinical benefit and assessment procedures for conducting research. Research protocols attempt to minimize any extraneous factors that could impact the assessment of an experimental treatment. Clinical improvement gained as a result of the interview process is one possible factor that could obscure the assessment of relevant symptoms or behavior during the course of a clinical trial.

The contrast between seeking hard facts for research versus seeking therapeutic benefit for the patient can be a challenging issue for new research interviewers (raters), who are often trained in a clinical tradition. This article provides a brief review of the rationale and justification underlying the focused, neutral interview style that is required in clinical research.

PSYCHIATRIC INTERVIEWS: THE SETTING DETERMINES THE STYLE

To better understand the marked distinction between psychiatric interviews done in clinical practice and research-specific interviews, it is necessary to review the intended purpose and process of a psychiatric interview that is done in clinical practice.¹

In clinical practice, a psychiatric interview is intended to do more than merely gather information. Generally, the first interview is the beginning of a process meant to engender therapeutic benefit for the patient. The interviewer attempts to establish rapport and trust with the interviewee (patient) in order to put him or her at ease and to facilitate an open and honest communication about psychiatric symptoms and difficulties in living. The initial interview generally proceeds with open- and closedended questions, which are meant to obtain clinical history and current symptoms and to yield a diagnostic formulation and development of a treatment plan. Throughout the interview, the interviewer uses direct questioning, empathic listening, paraphrasing of the patient's words, reflection, interpretation, and summation to clarify the information. Some psychiatric interviews may include positive reinforcement and reassurance to foster the "therapeutic alliance" and sustain the collaboration. Some interviews may even be confrontational in order to get the patient to better examine his or her own ideas or statements.^{1,2}

Harry Stack Sullivan was a brilliant pioneer in the elaboration of the psychiatric interview process. He used an interactive and sometimes confrontational interview style. In fact, he commented, "I do not believe that I have had an interview with anybody in 25 years in which the person to whom I was talking was not annoyed during the early part of the interview by my asking stupid questions."² Sullivan's style was based upon a concept of the expert-client relationship in which the goal was for the patient to leave the interview with some "measure of increased clarity about himself and his living with other people." In contrast to his own interview style, Sullivan described a one-sided interrogation in which questions are asked and answered without any attention given to the subject's insecurities and no clue given to the meaning of the information elicited. Sullivan

opposed this question-and-answer technique and asserted that it cannot work to assess, "a person's assets and liabilities in terms of his future living."² He also noted that the patient comes to the interview with some expectation of improvement or other personal gain from the experience. These high expectations can be useful to motivate the patient toward clinical improvement. An essential part of the interview process according to Sullivan, and many others, is to achieve some therapeutic benefit. Thus, the objectives of the psychiatric interview in clinical practice are to conduct a diagnostic and symptomatic assessment process as well as to seek a therapeutic benefit.

The objective of a psychiatric interview in clinical research is very different from interviews conducted by clinicians in clinical practice.³ The research interviewer still attempts to establish rapport with the patient and to be interactive throughout the interview in order to obtain accurate clinical information. However, the research interviewer intentionally maintains a relatively neutral attitude without making judgments, therapeutic interventions, or offering reassurance or advice. Therapeutic benefit is definitely not an objective of the research interview. It has even been suggested that different interviewers, or even remote interviewers, should be used at each visit to avoid a potential therapeutic alliance that might foster clinical gain. In fact, patients who improve from the interview process are subject to placebo responses that can and do adversely affect clinical trial outcomes. Therefore, the high expectations of the patient that may be useful in clinical practice are not encouraged in a research interview. Consequently, supportive interview

styles that foster empathy and reassurance or interviews that are confrontational or upsetting to the patient are inappropriate in a research setting. Sullivan's goals for patient improvement through the interview process are clearly contradictory to the objective of the research-based interview. Furthermore, Sullivan's reason for opposing the question-and-answer technique for clinical interviews may be exactly why it is useful in research interview settings. Clearly, the question-and-answer interview style is more of an investigative (interrogative) process rather than a therapeutic approach to a psychiatric interview.

The clinical information about symptoms and behavior obtained during the psychiatric interview is often subjective. The clinical information is generally based on the patient's report and cannot always be corroborated. An openended interview style that does not focus on specific questions, and answers may not generate the clinical information necessary to complete an accurate research interview. Therefore, both the validity and reliability of the interview will be at risk.

Validity of the interview refers to whether the data obtained about the illness, the symptoms, and the impact on function appear to be well founded and accurately correspond to how the disorder might present in the real world. There are numerous factors that can influence the validity of the interview.

Some patients may be unable to give a valid interview. They may be uncooperative or defensive, uncomfortable in the interview setting, or too ashamed to be honest in their responses. Some patients may lack awareness of their symptoms, have cognitive deficits, or have distorted views that

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- Interviewer Introduces him/herself to the patient
- Establishes rapport (e.g., trust, engagement)
- Sustains neutrality throughout the interview
- Explains the purpose of the interview
- Obtains verbal consent to proceed
- Explains the need to be as objective as possible
- Indicates the time frame for response to each question (e.g., 7 days)
- Asks concise questions that are related to each item or sub-item a. Uses the structured interview guide
 - b. Asks questions that address anchor points for rating instrument
 - c. Asks additional questions if necessary to get sufficient information for accurate scoring
- Seeks additional clarification whenever necessary
- Avoids leading questions or a rush to judgment
- Summarizes the patient's response to confirm accuracy

influence their responses. There are patients who will intentionally misrepresent their responses in order to inflate or decrease the apparent severity of their symptoms.

Similarly, some interviewers may be unable to conduct a valid interview. The interviewer may have biases about the patient, the research, or the specific treatment intervention that influences their scoring. Other interviewers may simply lack the clinical experience or the interviewing skills necessary to establish rapport with a patient and to elicit accurate information for precise scoring.

Reliability refers to how the clinical data collected about the same patient by different interviewers compare with one another. As noted previously, different interview styles can cause marked variations in the validity and reliability of the collected data. For instance, reliance on open-ended questions alone may lack specificity (e.g., "How have you been feeling lately?") that affects reliability between different raters. Alternatively, closed-ended questions may be able to quantify, but might fail to identify less obvious, or hidden, clinical information (e.g., paranoia).

The use of structured interviews for clinical research purposes has evolved, in part, to respond to the need to improve the validity and reliability of the clinical data obtained.

STRUCTURED CLINICAL INTERVIEWS IN PSYCHIATRIC RESEARCH

Many clinical researchers have contributed to the long history of

the development of structured interviews to improve the precision of psychiatric assessments.^{4,5} Recently, the use of structured clinical interviews for diagnostic assessment as well as for symptomatic measurements have become commonplace in clinical trials as well.^{6–8} The format and specific questions contained in the structured interviews offer a tool to regulate the style of the interview and to assure collection of sufficient information for accurate scoring. The individual items of the interview guides contain fact-based and very concrete queries intended to collect specific clinical data in order to answer very specific questions. The objective, focused nature of the research interview improves the precision of ratings and minimizes the use of a more open-ended or supportive style that could foster therapeutic benefit for the participating patient. The restricted expressive range of the fact-based, structured (question and answer) research interview minimizes the potential placebo responses that could adversely affect signal detection.

Table 1 lists some of the key components necessary for ratings competency when conducting a structured research interview. Similar to clinical practice, it is still necessary to establish rapport and earn trust with the patient in order to conduct a competent research interview. A lack of rapport will diminish the ability of the interviewer to obtain sufficient and honest clinical information to score accurately. As an example, Lipsitz et al³ describe lack of rapport as when the interviewer reads a question that has just been answered in another context without even acknowledging it.

The interviewer needs to sustain a neutral attitude throughout the interview while being an active listener, must not rush judgments, and must avoid asking leading questions to force the response. An interviewer with a neutral attitude can still be engaged in the process of the interview. In fact, maintaining a neutral attitude does not mean that the interviewer is either a disinterested or rigid.

Most structured interview guides anticipate some amount of openended questioning prior to the initiation of the specific probe questions used for each interview item. We recommend that the interviewer explain the purpose of the interview and obtain the patient's consent each time the interview is conducted in order to assure consistency and to confirm that the patient is still willing to participate. It is sometimes helpful to explain that the interview is, in fact, structured by design to ask specific questions and that lengthy responses are not necessary and that unrelated issues may not be addressed.

The ultimate aim of a research interview is to elicit enough information through questioning the patient to accurately identify the presence and rate the severity of symptoms.³ It may sometimes be necessary to go beyond the simple yes or no question and answer format of the structured interview. The interviewer may need to add some additional questions in order to get sufficient clinical information to score the interview item.

Most clinical trials in psychiatry conduct comprehensive ratertraining programs and establish inter-rater reliability using demonstration interviews prior to the initiation of each new study. Obviously, scoring differences could result from variable educational backgrounds, clinical experience, and cultural views. However, the use of the structured interview format improves inter-rater reliability even in multinational studies employing numerous countries and multiple languages.

On the other hand, it is obvious that a lack of ratings competency causing scoring inconsistencies might adversely affect the trial outcome. Ratings competency includes both the demonstrated ability to score accurately (ratings reliability) as well as the possession of adequate interviewing skills to actually conduct the interview. In one study, Kobak et al¹⁰ compared the clinical trial outcome based upon the assessment of ratings competency. There were 34 raters who were distinguished as either good-to-excellent raters or poor-tofair raters based upon the rater applied performance scale (RAPS).³ In a study comparing paroxetine to placebo in patients with major depressive disorder, the overall study failed to separate drug from placebo (t=0.51, df=214, p=0.61). However, when only the good or excellent raters were included in a re-analysis of the data, paroxetine was significantly better than placebo (t=2.612, p=0.017). Although this is only one small study, the results reveal the importance of accurate ratings and competent raters in a clinical trial.

SUMMARY

Experienced clinicians accustomed to facilitating therapeutic interventions may dislike the fact-based, slightly dry question-and-answer interview style that is characteristic of structured psychiatric interviews. However, there is substantial justification for this interview style in clinical research. Clinical research attempts to minimize any extraneous factors that might affect assessments and adversely influence trial outcomes, including the potential for high placebo responses. Most patients enter clinical trials because they have expectations about the benefit they will achieve from their participation. Clinical interviews that foster warmth and reassurance may inadvertently generate clinical improvement related to these expectations that are unrelated to the experimental treatment being studied. The research interview is definitely not a therapeutic interview, and therefore, every effort to restrict clinical benefit accrued during the interview process is warranted. The structured research interview is designed exactly for the singular purpose of collecting the facts. Thus, there is a marked, necessary, and understandable distinction between clinical and research interviews in psychiatry.

REFERENCES

- MacKinnon RA, Michels R, Buckley PJ. The Psychiatric Interview in Clinical Practice. 2nd Edition. Washington, DC: Am Psychiatric Publishing Inc., 2009.
- Sullivan HS. *The Psychiatric Interview*. New York: W.W. Norton and Co; 1970.
- Lipsitz J, Kobak K, Feiger A, et al. The rater applied performance scale: development and reliability. *Psychiatry Res.* 2004;127 (1-2):147–155.
- Spitzer RL, Fleiss JL, Burdock EI, Hardesty AS. The Mental Status Schedule: rationale, reliability, and validity. *Compr Psychiatry*. 1964;10:384–395.
- Kendell RE, EvFlur B, Cooper JE, et al. The reliability of the Present State Examination. Social Psychiat. 1968;3:123–296.
- 6. Williams JB. A structured interview guide for the Hamilton Depression Rating Scale. Arch Gen Psychiatry.

1988;45(8):742-747.

- Shear MK, Vanderbilt J, Rucci P, et al. Reliability and validity of a structured interview guide for the Hamilton Anxiety Rating Scale (SIGH-A). *Depress Anxiety*. 2001;13(4):166–178.
- First MB, Spitzer RL, Gibbon MB, Williams, JB. Structured Clinical Interview for DSM-IV-TR Axis I Disorders, Research Version, Patient Edition (SCID-I/P). New York: Biometrics Research, New York State Psychiatric Institute; November 2002.
- Williams JB, Kobak KA. Development and reliability of a structured interview guide for the Montgomery-Asberg Depression Rating Scale (SIGMA). Br J Psychiatry. 2008;192(1):52–58.

 Kobak KA, Feiger AD, Lipsitz JD. Interview quality and signal detection in clinical trials. Am J Psychiatry. 2005;162(3):628.

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