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Telephone-based Assessments to Minimize Missing Data in Longitudinal Depression Trials: A Project IMPACTS Study Report

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Abstract

Purpose—Missing data in clinical efficacy and effectiveness trials continue to be a major threat to the validity of study findings. The purpose of this report is to describe methods developed to ensure completion of outcome assessments with public mental health sector subjects participating in a longitudinal, repeated measures study for the treatment of major depressive disorder. We developed longitudinal assessment procedures that included telephone-based clinician interviews in order to minimize missing data commonly encountered with face-to-face assessment procedures.

Methods—A pre-planned, multi-step strategy was developed to ensure completeness of data collection. The procedure included obtaining multiple pieces of patient contact information at baseline, careful education of both staff and patients concerning the purpose of assessments, establishing good patient rapport, and finally being flexible and persistent with phone appointments to ensure the completion of telephone-based follow-up assessments. A well-developed administrative and organizational structure was also put in place prior to study implementation.

Results—The assessment completion rate for the primary outcome for 310 of 504 subjects who enrolled and completed 52 weeks (at the time of manuscript) of telephone-based follow-up assessments was 96.8%.

Conclusion—By utilizing telephone-based follow-up procedures and adapting our easy-to-use pre-defined multi-step approach, researchers can maximize patient data retention in longitudinal studies.

Keywords

telephone assessments; follow-up strategies; rapport; longitudinal study; retention; patient contact; appointment adherence; compliance

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Far too often in recent years the scientific usefulness of results from important, high-profile, clinical trials has been compromised by significant amounts of missing data [1]. Inherently, longitudinal research is confronted with the greatest challenges related to patient attrition and the lowest compliance rates with follow-up assessment schedules [1–3]. Concern has specifically mounted in recent years over the amount of missing data associated with longitudinal mental health trials [4].

Two types of missing data jeopardize the significance of longitudinal clinical trials which employ repeated measures: 1) missing data from subjects who dropout prior to trial completion and 2) missing data from those who may miss a particular visit, but remain in the trial. In order to minimize outcome biases associated with subject dropouts, both trial retention protocols and specific statistical techniques are widely employed in clinical trials. However, less attention has been directed toward the bias introduced by missing data points occurring during repeated assessment sessions over time for individuals who remain enrolled in the trial [3]. In fact, no accepted procedures have been evaluated to ensure that all data points are collected during the assessment period. Our purpose in this paper is to describe a longitudinal methodology for minimizing such data loss in a large, ongoing randomized clinical trial for patients with major depressive disorder in the public health sector (Project IMPACTS: Implementation of Algorithms using Computerized Treatment Systems [5]). A primary component of our strategy is a telephone-based longitudinal assessment protocol designed specifically to maximize participant satisfaction with the research process while achieving high rates of completion with repeated measure assessments in a sample of clinically depressed study patients. Telephone follow-up assessments have been previously validated for their accuracy when compared to other follow-up methodologies [6–17], and we believe telephone follow-up may offer further benefits to patients and researchers. The goals of this manuscript are to: 1) describe the study methods that were developed in sufficient detail so that other researchers are able to replicate them in their long term research, and 2) to provide evidence that the telephone-based follow-up techniques described minimize missing data observations.

BACKGROUND

Although multiple approaches have been suggested to help minimize data loss during longitudinal treatment trials, such efforts have historically yielded results that are less than ideal. In their review of the effects of several antidepressants on atypical depression among personality disordered individuals, Agosti and McGrath experienced a 47% missing data rate on primary outcome measures [18]. Lima et al. likewise noted extremely high rates of missing data in their Cochrane review of the use of antidepressants for the treatment of dysthymia [19], and Khan et al.'s meta analysis (even for the highly controlled based on the FDA trial data base) found a mean missing data rate of 37% across short term acute phase antidepressant trials [20], suggesting the need for the development of improved protocols to protect data fidelity in studies addressing the treatment of depression.

Wisniewski et al. have outlined seven domains of preventive measures to be addressed by data fidelity protocols [3]. The domains include use of adequately and comprehensively documented study operations, pre-trial training and pilot testing of data collection and training procedures, an adequate plan for updating protocols as issues arise after startup, the use of multiple strategies to enhance participant engagement, carefully designed data entry and data management systems, and monitoring reports. In addition, prior to data analysis, Wisniewski et al. emphasized the importance of examining patterns and types of missing data as a way to determine how gaps in data will impact statistical analysis.

Similar to other large, prospective multi-center depression treatment trials, Project IMPACTS employed a longitudinal design using a specific treatment algorithm for the care of depressed outpatients [21–24]. Also like Project IMPACTS, two of these prior studies [21, 23] made use of telephone-based assessments to gather the primary outcomes of interest, while Trivedi et al. [22] employed more traditional face-to-face visits. Furthermore, the assessment paradigm utilized by Rush et al. was structured like Project IMPACTS in that the study team was not involved with the implementation of the treatment protocol [21].

A number of studies have employed telephone-based follow-up assessments to achieve higher rates of subject retention, and highlighted the advantages of this technique over face-to-face assessments [7, 13, 15, 17]. Telephone-based assessments have also been validated with other follow-up assessment techniques, such as mail [8–10]. Frequently reported benefits of telephone-based assessment included shorter evaluation time and reduced associated costs [6, 7, 25]. Additionally, while many researchers suggest that the use of telephone-based evaluations produce results that are comparable to face-to-face administration [6, 7, 11–17], others question the reliability and validity of some applications of telephone-based data collection [25]. Senior and colleagues [26] have recently discussed this concern specifically related to patient self-report measures, and found that telephone-administered follow-up does adequately correlate with in-person interviews for two commonly used depression and anxiety self-reports. Furthermore, they surmise that additional benefits provided by telephone assessments include facilitating a more diverse patient population and once again providing a more beneficial cost-effectiveness model for clinical research [26]. We believe that telephone-based assessments provide the best chance for minimizing missing data, a common problem in longitudinal depression studies.

Two common, potentially non-random confounds are frequent in longitudinal depression trials measuring repeated assessments. First, the nature of major depressive disorder is such that patient adherence with complex, study-related treatment and assessment routines may be at its lowest when symptoms are the most severe. This is also the time when patients are most likely to be enrolled in depression treatment studies, leading to a high risk of missing data in these trials. Second, longitudinal trials with subjects in “real world” clinical settings experience considerable difficulties with scheduling face-to-face appointments for the purposes of obtaining outcome assessments. The predictable, non-random nature of these common depression study design issues highlights the need for aggressive treatment engagement and data fidelity protocols during longitudinal outcomes-based research.

METHODS

Project IMPACTS utilizes a combination of easy-to-use techniques developed for the study in conjunction with a telephone-based follow-up assessment procedure and modest monetary (\$25 per assessment) incentives to compensate subjects specifically for the additional time spent performing research activities. Contrary to other longitudinal follow-up studies, IMPACTS does not employ tracking agencies to maximize follow-up and retention. The methods described below present a brief initial overview of the larger study (Project IMPACTS), followed by a detailed description of the study's data fidelity strategies, and lastly a description of our conduct of telephone-based follow-up assessments.

Project IMPACTS Study Description

Study Overview—Project IMPACTS is an NIMH-funded study (RO1 MH MH90003 [5]) designed to test patient outcomes during treatment for major depressive disorder (MDD) informed by use of a treatment algorithm. The study's purpose and methods have been described in detail elsewhere [5]. The study takes place in real-world, public mental healthcare settings and calls for study physicians to be randomized to one of three treatment

cells. A total of 504 subjects with MDD who are being seen by a study physician will be treated in the three treatment cells (n=168/cell).

Assessment Schedule and Patient Contact Registry—The study's assessment protocol consists of one baseline assessment conducted face-to-face, eight telephone-based follow-up evaluations scheduled 6 weeks apart, and an end-of-study evaluation scheduled at week 52. Evaluators utilize an administrative database containing information on demographics, recruitment, and medical history to manage ever-changing information about patient status. The database is stored on a secure, shared drive where it is accessible to all study-related personnel with the appropriate password and clearance levels. The database is used on a daily basis by research evaluators to record patient contact, evaluation dates, and adverse events. Evaluators also maintain spreadsheets for their individual patient loads, monitoring dates/times of follow-up assessments and study reimbursement options chosen by patients in the past. Additionally, a calendar alerts evaluators in advance of approaching follow-up assessments. The calendar specifies which follow-up assessment needs to be administered, as well as when self-report assessment packets need to be mailed.

Data Fidelity Protocol

Pre-enrollment (Staff Training)—We believe an integral component of minimizing missing data observations and ensuring data fidelity relies on a detailed, yet easy to follow protocol for all personnel involved in obtaining follow-up assessments. Below we describe the essential and easily replicable techniques developed for Project IMPACTS. Since start-up, new research staff members have been oriented to the study using a manual that overviews all policies and procedures associated with their particular job functions. Their training is designed as a step-wise experience in which research staff are certified on all instrumentation and procedures first, and then exposed to the project's data fidelity standards. They are monitored closely through their first several assessments to ensure standardized administration techniques. In addition, assessments are routinely conducted in settings where the Project Coordinators are onsite, so that any unique questions or concerns can be addressed in real time.

Standardized training of local site personnel takes place at pre-determined intervals before and during the study. Clinic staff at all remote sites, although not directly involved in the study, are oriented to the project, provided with study rationale and informed about study procedures. Contact numbers for central staff are provided in case these are needed to help study patients treated in their clinics at any point throughout the study.

Telephone Follow-up Assessments

Pre-enrollment (Patient Training and Consent)—After baseline, all patient assessments are conducted by telephone. Project IMPACTS has developed explicit protocols related to the use of telephone-based procedures and these are overviewed next. Multiple techniques are used to establish and maintain patient engagement, minimize data loss throughout the study (for a list of techniques employed throughout the study see Table 1), and maximize patient satisfaction with study protocol. Patient orientation to the study begins during the consenting process when a detailed explanation is given of what the patient can expect throughout their participation. In addition, the baseline evaluator gives numerous opportunities during the consenting process for the patient to ask questions involving procedure or responsibility, and to ensure that the patient is engaged and comfortable with his or her study involvement.

Baseline Assessment (Patient Engagement Protocol)—During study enrollment, we work with study patients to identify a minimum of three, and up to six, pieces of follow-

up contact information, including telephone numbers for at least two friends or relatives and explicit permission to contact these individuals if we are unable to contact the study patient at any point during the study. Unless they become unblinded through some unavoidable accident, the same coordinator contacts the patient each time throughout the study, facilitating rapport, routine, and familiarity. In fact, Ball and colleagues describe rapport building as an integral component to achieving higher retention rates in their 1 year follow-up study also conducted via telephone assessments [30]. To introduce the process used during follow-up telephone interviewing, we “rehearse” during the baseline interview if the assessment site is structured to allow this procedure. Late in the baseline assessment (after rapport has been developed), the examiner explains the process and then administers one clinician-administered rating scale over the telephone (for a complete schedule of follow-up visits with corresponding measures see Table 2). Afterwards, any questions are answered in person, and further patient education about the process (including confidentiality) is provided as needed. Patients are then given a take-home handout that explains key responsibilities for which the patient is accountable, including appointment adherence and providing ongoing, up-to-date contact information. Throughout the course of the study, starting at the baseline visit, evaluators are instructed to maintain a professional tone while interacting with patients, but taking care not to engage in a perfunctory manner.

Three – five weeks post-baseline (Patient Engagement Protocol)—Following study baseline, qualifying patients receive a study “welcome” packet in the mail, which includes some general information about depression and additional study-related materials and instructions. Three weeks after baseline, the study coordinator who will be following the patient initiates the first telephone call to the patient in the patient's home. This week 3 telephone conversation serves as a reminder to patients about upcoming telephone-based assessments. During the week 3 telephone call, patients are told that the first self-report assessment packet will arrive by mail within the next 2–3 weeks (6 weeks after the baseline assessment), and that the evaluator will contact them to schedule the day and hour of their week 6 telephone evaluation. A similar phone call may also be employed at the week 9 mark if the patient still appears unsure of study procedures, or if other disruptions to the patient's routine are known to have arisen.

The self-report assessment packet mailed to the patient before each follow-up contains questionnaires to be filled out by the patient, as well as the expected date of the telephone evaluation. Self-report packets include the following assessments: CAGE Questionnaire (cut-annoyed-guilty-eye), Snaith-Hamilton Pleasure Scale (SHAPS), Utilization and Cost-Questionnaire (UAC-Q), Quality of Life Enjoyment and Satisfaction Questionnaire (QLES-Q), Work and Social Adjustment Scale (WSAS), Social Adjustment Scale-Self Report (SAS-SR), Frequency and Intensity of Side Effects Rating Scale (FISER), Global Rating of Side Effect Burden Scale (GRSEB), Patient Rated Inventory of Side Effects (PRISE), Short Form 36-item (SF-36), Patient Perception of Benefits of Care, Parent Stress Index, Beck Hopelessness Scale, Suicide Cognitions Scale-Revised (SCS-Revised), Anger Attacks Inventory, and the Sheehan Disabilities Scale. Patient self-report instruments have shown to score similarly to clinician-administered versions, while also offering both time and cost benefits [31, 32]. A form in the packet can be used as a reminder card on which the patient can write the time of their telephone evaluation, after scheduling it with the evaluator. At the bottom of this form, in bold print, instructions tell the patient to complete the self-report questionnaires one night before the scheduled telephone evaluation. Finally, telephone numbers for research personnel are included, along with a 30-minute prepaid calling card for patients to use to contact study personnel, if such a call would involve a long distance charge.

One or two days prior to a patient's week 6 evaluation date (the first evaluation conducted by telephone) an evaluator calls the patient to make certain they have received their self-report assessment packet in the mail and to schedule a convenient time for the telephone evaluation, if this has not already been done. Flexibility is a crucial part of scheduling telephone interviews. By allowing the patient to have control over the evaluation time, we hope to communicate that we respect their time and participation, and are working to help them. During this phone call, the evaluator also reminds the patient to complete the self-report assessment packet one night before the telephone evaluation.

Follow-up Assessments—At weeks 6, 12, and 18 (the first three follow-up telephone evaluations), patients receive a personalized letter, once again reinforcing study procedures, and newsletters are mailed four times throughout each patient's 12-month study enrollment period. Even after a follow-up telephone assessment has been scheduled and confirmed, patients do forget the appointment or need to reschedule. Therefore, when evaluators call to administer the evaluation, they first ensure that the time is still convenient. Initial rapport is quickly reestablished by asking a few appropriate, informal questions at the beginning of the conversation which are tailored to the individual subject. This technique is facilitated by remembering appropriate facts about the patient (e.g., non-controversial events, such as upcoming birthdays or topics the patient shared spontaneously during the last telephone assessment). The evaluators are also instructed to keep notes during the evaluations, which are available for future reference. After the evaluation, the research study coordinator makes certain the patient has completed the self-report questionnaires. Page by page, the evaluator instructs the patient to examine the answers to the questionnaires that were completed the night before, making sure each question is answered. Also during this time, the evaluator makes a point to ask study patients about any missing data observations. Study patients are paid \$25 for each follow-up packet, however payment is not contingent upon the completion of the self-report items.

After the patient's last self-report questionnaires have been received, the evaluators mail a final letter and completion certificate. The letter and certificate both express appreciation for the patient's participation, and expresses congratulations for completing the study. Research personnel hope this gesture leaves patients with a positive feeling about their study experience, and enhances their willingness to participate in future studies. We present our unique methods as strategies for other researchers to assist in minimizing missing data, reduce study related costs, and increase the ease of follow-up for both patients and researchers.

RESULTS

Through August 27, 2007 Project IMPACTS enrolled 310 of 504 patients, of whom 83.9% are female, 61.5% are Caucasian, 65.3% are between the ages 40–59, 80.8% are unmarried, 74% have at least a high school diploma/GED, 85.1% are unemployed, and 80% have an annual income below \$20,000 (Table 3). To date, the overall missing data rate for patients that remained in the study, based on the primary depression outcome (Hamilton Rating Scale for Depression [HRSD₁₇] [33]), is 3.2% (1879 follow-up assessments have been completed out of a possible 2395). That is to say that 96.8% of telephone-based HRSD₁₇ assessments were completed for patients that were retained in the study. Furthermore, with 70% of enrollment completed, the average number of phone calls required to schedule a follow-up evaluation is 2.11.

SUMMARY AND CONCLUSIONS

In summary, given the inherent difficulties in attaining longitudinal data for depressed populations, it is vital to establish assessment regimens that sustain long-term data collection. The current study has employed methods that afford higher compliance rates with assessment regimens in a population of depressed patients in real-world, public mental healthcare settings, thereby significantly reducing one type of missing data. Our system employs a telephone-based follow-up methodology that involves multiple techniques to minimize missing data observations for subjects who remain in the study. In accordance with previous longitudinal, multi-center depression treatment trials, we believe that telephone-based follow-up performed by trained coordinators is an integral component of long-term data retention [21–24]. Additionally, our 1-year rates of missing data for those patients remaining in our study are comparable to the 1-year rates reported in a personal communication by J. Unützer (personal communication) (92% for those still enrolled and eligible for data collection) regarding the IMPACT trial [23]. While reporting attrition and missing data related to dropouts is important in clinical trial manuscripts, we believe it is also important to report the percent of all missing data, and more specifically including the missing data from subjects that remain in studies and are eligible for data collection. Making this distinction and relaying the percent of missing data from enrolled subjects is not currently reported in clinical trial data; however, we believe these data points are vital when working to minimize missing data in large, multi-center clinical trials and should always be reported. One potential reason that reporting missing data for those that remain in the study is not standard is due to changes in statistical methods. For example, in traditional multivariate analyses dropout rates were vital because if data were lost at any point that subject could not be included in the analysis. However, the current use of random regression statistical models to analyze data has attempted to overcome this problem, by using all available data [34]. Therefore, we contend that for analyses using random regression models, the percent of data available for analysis is critical and the absolute dropout rate may be less important but that missing data from subjects still in the study continue to threaten the interpretation of results. Table 4 reflects the total number and percent of data observations attained for study participants thus far, and is representative of dropouts as well as missing observations for those retained in the study. The table displays the how the data is obtained – i.e. through telephone assessments or via mailed out packets for all subjects (including dropouts) and more specifically, among those that continue in the study. As such, the primary outcome, measured by the HRSD₁₇, is gathered over telephone, while the majority of secondary outcome measures listed in Table 2 are gathered via mail.

We hypothesize that telephone follow-up is likely to be responsible for the low rates of missing data observations among active study participants. Recent studies indicate that in the United States structural barriers (i.e. financial costs) commonly prevent treatment for patients suffering from mental disorders, especially among the poor [35]. Given the low socioeconomic status/demographics of our sample and the low rates of missing data, telephone follow-up may be a way to facilitate adequate follow-up for poor Americans.

The additional flexibility afforded to both research personnel and study subjects by the telephone-based procedure enhanced convenience in scheduling, avoided transportation issues common among lower-income subjects, and allowed for scheduling after-hours so that ongoing study participation did not compete with day-to-day patient responsibilities. Prior literature suggests that telephone-administered follow-up assessments confer ease of use and reduced study-related costs [6, 7, 25], and the currently reported telephone-based follow-up methodology is also easily replicable.

A limitation of the methodologies presented here are that the population studied were primary English speakers. Many of the assessments evaluated in this study have not been validated in other languages, and thus limit the generalizability of the population to English speakers. Future studies should focus to assess if the methodologies presented here can also be applied to non-English speaking demographic populations. In addition, We look to build upon these results, and will assess the impact of demographic and clinical variables on telephone-based follow-up rates.

Based on our clinical experience, we believe that in addition to telephone follow-up the two most important factors contributing to low rates of missing data were the initial rapport building and obtaining multiple contacts for follow-up assessments. Rapport building is an essential first step in developing a therapeutic relationship with patients and previous research has supported its importance in trial retention [30]. A similar sentiment is true for obtaining multiple points of contact, which is a common strategy used to follow transient populations [36–40]. In conclusion, these processes may be of interest to other researchers concerned with minimizing missing data in studies involving multiple assessment sessions over time, in a difficult-to-reach, depressed population.

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Table 1

Timeline of Techniques Used to Produce High Data Retention and Compliance Rates for Project IMPACTS

Pre-enrollment Period	Baseline Assessment	Prior to First 6-Week Follow-up Assessment	Follow-up Assessments
Prior to Baseline Assessment	Week: 0	Weeks: 3–5	Week: 6, 12, 18, etc.
Staff Training Protocol: <ul style="list-style-type: none"> • Staff manualized orientation and research certifications • Standardized training of local site personnel (including research assessment training) • Contact information for central staff provided to local sites 	<ul style="list-style-type: none"> • 3–6 contact numbers obtained (permission to contact at least 2 of these) • Rapport building—if possible same coordinator contacts patient throughout study • Explain confidentiality 	3 Weeks Prior: <ul style="list-style-type: none"> • Three week phone call • Mail “welcome” packet 	<ul style="list-style-type: none"> • Personalized letter sent to patients reinforcing study procedures; newsletter sent quarterly • Baseline evaluator also conducts follow-up evaluation • Keep personal information notes available for reference.
Patient Training Protocol: <ul style="list-style-type: none"> • Patient Consent and detailed explanation of study procedures • During consent patients encouraged to ask questions to keep them engaged 	<ul style="list-style-type: none"> • Provide take-home handout explaining key study responsibilities • Keep tone professional but not mechanical 	1–2 Days Prior: <ul style="list-style-type: none"> • Schedule time/date of telephone evaluation • Remain flexible when scheduling • Remind patient to complete self-report questionnaires one night before phone evaluation 	<ul style="list-style-type: none"> • Maintain professional, friendly tone • Confirm completion of self-report questionnaires and ask patient to check over self-reports page by page for answers left blank • Coordinate monetary compensation • Letter and research certificate mailed upon study completion

Table 2

Patient assessment schedule by group

WEEK	0 Baseline	6	12	18	24	30	36	42	48	52 or end of trial
PATIENT MEASURES[†]										
Diagnostic Instrument										
SCID-CV	•									
Symptom Severity Measures										
HRSD ₁₇	•	•	•	•	•	•	•	•	•	•
CAGE	•	•	•	•	•	•	•	•	•	•
IDS-C ₃₀	•	•	•	•	•	•	•	•	•	•
Modified Cumulative Illness Rating Scale	•									
SHAPS	•	•	•	•	•	•	•	•	•	•
Utilization & Cost										
UAC-Q	•		•		•		•		•	
Quality of Life/Functional Measures										
QLES-Q short form	•	•	•	•	•	•	•	•	•	•
WSAS/SAS-SR	•	•	•	•	•	•	•	•	•	•
FISER/GRSEB/PRISE	•	•	•	•	•	•	•	•	•	•
SF-36	•	•	•	•	•	•	•	•	•	•
Patient Perception of Care										
CAS	•		•		•		•		•	
CUS [‡]	•		•		•		•		•	
Patient Perception of Benefits of Care	•		•		•		•		•	
Ancillary Scales										
Parent Stress Index	•		•		•		•		•	
Beck Hopelessness Scale	•		•		•		•		•	
Linehan Lifetime Parasuicide Count						•				
MADRS	•	•	•	•	•	•	•	•	•	•
SCS-Revised	•		•		•		•		•	

WEEK	0 Baseline	6	12	18	24	30	36	42	48	52 or end of trial
PATIENT MEASURES†										
Anger Attacks Inventory	•		•		•		•		•	
Sheehan Disabilities	•		•		•		•		•	
Child Trauma History	•									
NEO-FFI	•									

Abbreviations: SCID-CV, Scheduled Clinical Interview for DSM Disorders; HRSD17, 17-item Hamilton Rating Scale for Depression; CAGE, CAGE Questionnaire; IDS-C30, 30-item Inventory of Depressive Symptomatology; SHAPS, Snaith-Hamilton Pleasure Scale; UAC-Q, Utilization and Cost Questionnaire; QLES-Q, Quality of Life Enjoyment and Satisfaction Questionnaire; WSAS, Work and Social Adjustment Scale; SAS-SR, Social Adjustment Scale-Self Report; FISER, Frequency and Intensity of Side Effects Rating Scale; GRSEB, Global Rating of Side Effect Burden Scale; PRISE, Patient Rated Inventory of Side Effects; SF-36, Short Form 36-item; CAS, Computer Attitude Survey; CUS, Computer Use Survey; MADRS, Montgomery Asberg Depression Rating Scale; SCS-Revised, Suicide Cognitions Scale-Revised; NEO-FFI, Neuroticism-Extroversion-Openness Five Factor Inventory

†All three groups (computerized algorithm, paper and pencil algorithm, and treatment as usual) received all measures, except the CUS, which was administered only to computerized algorithm group

Table 3**Patient Demographic Characteristics[#]**

Characteristics	N (%)
Gender	
Male	81 (16.1)
Female	423 (83.9)
Ethnicity	
Caucasian	310 (61.5)
African American	156 (31)
Other	38 (7.5)
Age[†]	
20–39	87 (17.3)
40–59	329 (65.4)
60–79	87 (17.3)
Marital Status	
Unmarried	407 (80.8)
Married	97 (19.2)
Education Level[†]	
No Degree	129 (25.7)
High School Graduate/GED	219 (43.6)
>12 th Grade	154 (30.7)
Employment	
Employed	75 (14.9)
Unemployed	429 (85.1)
Annual Income (in thousands)[†]	
\$0–\$19	403 (83.8)
\$20–\$39	65 (13.5)
\$40+	13 (2.7)

[#]Project IMPACTS patient demographics as of August 27, 2007

[†]Demographic information not complete for these characteristics

Table 4Number and Percent of Completed Data Observations[#]

Type of Data Observation	All Subjects [N (%)]	Subjects Remaining in Study [N (%)]
Total Observations Possible	3100 (100)	1940 (100)
Observations completed by Phone	2395 (77)	1879 (96.8)
Observation completed by Mail	2264 (73)	1799 (92.7)

[#] Project IMPACTS Completed Data Observations for initial 310 subjects