Computerized Adaptive Assessment of Disease Impact (DICAT)
Summary of Study Protocol

PRINCIPAL INVESTIGATOR: John E. Ware, Jr., Ph.D.
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The primary purpose of the DICAT project was to develop and evaluate improved patient-reported measures of disease-specific quality of life impact, which were standardized in content and scoring across diseases. During the DICAT project, a longitudinal Internet-based survey was conducted using Knowledge Networks' (KN) research panel (KnowledgePanel®), which is a probability sample of approximately 50,000 U.S. residents, drawn to represent those in households aged 18 and older. Chronically ill KN research panel members were over-sampled. In this document, summary information is provided about participant recruitment and sampling, survey measures, and survey procedures.

Participant Recruitment and Enrollment

General Recruitment and Eligibility: KnowledgePanel

Participants in the DICAT study were members of Knowledge Networks' online research panel (KnowledgePanel®). Knowledge Networks (KN) was co-founded by two Stanford University professors, one of whom previously had been at the University of Chicago for 30 years and a Senior Study Director at the National Opinion Research Center (NORC). When KN was founded in 1997, its goal was to combine the scientific rigor behind NORC's General Social Survey and similar surveys, with the then-new potential of the Internet for conducting surveys.

In brief, KN initially began recruiting panelists for KnowledgePanel in 1999 using random-digit dialing (RDD) methods[1]. The RDD sampling frame was the U.S. residential landline telephone universe, with oversampling in stratum with high concentrations of African American and Hispanic households. Recruitment was conducted via telephone; if an address match could be made, an advance letter was sent to the household. In the recruitment interview, the household member was informed that they had been selected to join KnowledgePanel, and would be provided with a computer and Internet access if they did not have them. If a household agreed to join KnowledgePanel, initial background information was collected

In 2009, KN began using an address-based sampling (ABS) methodology for panel recruitment. While the RDD frame accessed 96% of U.S. households in 1999, changes in the next decade reduced the validity of this methodology. These changes included declining cooperation in telephone surveys, weakening of the RDD sampling frame as measured by the working telephone number rate, and the growing emergence of cell phone-only households, with the CDC estimating that nearly 30% of U.S. households could not be identified through RDD sampling by 2010[2]. KN conducted an extensive pilot project in 2008, and started using ABS in 2009. ABS uses probability-based sampling of addresses from the U.S. Postal Service's Delivery Sequence File, which covers an estimated 97% of U.S. households, with oversampling of Census blocks within high density minority communities. Households at randomly sampled

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addresses are mailed an invitation to join KnowledgePanel and can indicate their willingness to join by returning a form in a postage-paid envelope, calling a toll-free hotline, or completing an online form on the KN website. Multiple invitations are mailed, and telephone calls are made to non-responders if a telephone number can be matched to an address. As with RDD sampling, households without a computer and Internet service are told that these will be provided. To offset attrition, new samples are recruited evenly throughout the calendar year.

New panelists complete an enrollment survey, to welcome them to KnowledgePanel and to confirm that they can successfully complete an on-line survey. Once enrolled, panelists complete surveys about demographics and other characteristics including health conditions, and are invited to take part in regular surveys via e-mail. To prevent survey fatigue, panelists are not invited to take part in more than one survey per week, with each survey expected to take 10 to 15 minutes. Surveys longer than 20-25 minutes usually provide an additional incentive. KN has a modest general incentive program to encourage survey participation and panelist loyalty.

An important feature of KnowledgePanel is that, unlike convenience ("opt-in") panels that only include people with Internet access who volunteer for research, KnowledgePanel includes people with listed and unlisted telephone numbers, landline and non-landline households and cell-phone-only households, as well as households with and without Internet access. Thus, it is designed to be truly representative of the U.S. general non-institutionalized population. At the time that the DICAT study was conducted, KnowledgePanel had about 50,000 members.

DICAT Sampling and Eligibility

For the DICAT study, KN recruited two types of samples. First, a *general population sample*, consisting of non-institutionalized U.S. residents aged 18 and older, was randomly drawn from KnowledgePanel. Second, an oversample of panelists who were pre-identified with specific conditions (*Pre-ID sample*) was randomly drawn from KnowledgePanel. Pre-ID panelists had previously self-identified with at least one of these nine conditions within five diagnostic areas: arthritis (osteoarthritis or rheumatoid arthritis), cardiovascular disease (myocardial infarction in the past year, angina, and/or congestive heart failure), chronic kidney disease (CKD), diabetes, or respiratory disease (asthma and/or Chronic Obstructive Pulmonary Disease). Panelists were sent a routine survey invitation via e-mail, inviting them to take part in the DICAT survey. An e-mail reminder was sent to non-responders on the third day of the survey, and additional e-mail and telephone reminders were sent to non-responders throughout the survey period.

For Pre-ID sample panelists who consented, screening items were used to confirm that the panelist had one of the nine health conditions listed above. Panelists who self-reported more than one of the nine conditions were assigned to the least prevalent condition as their primary condition. If the panelist did not currently report any of the nine conditions during the DICAT survey (in spite of reporting at least one of the conditions on an earlier KN health profile survey), they were switched to the general population sample and counted toward that target, but also were flagged so they could be identified in later analyses such as the construction of sampling weights. A total of 519 such cases were recorded during data collection. In addition, 33 panelists with heart problems other than angina, a recent myocardial infarction or congestive heart failure were included in the first survey wave.

DICAT surveys were done in three waves: Wave 1 (January-February 2011), Wave 2 (July-September 2011), and Wave 3 (October-December 2011). New general population samples were recruited in all three waves; a subset of these completed follow-up surveys in Waves 2 and 3. New Pre-ID samples were recruited in Waves 1 and 2; a subset completed follow-up surveys in Waves 2 and 3. Sample sizes for the general population and Pre-ID samples are

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summarized across waves in Table 1. This table shows the number completing a baseline survey only (Cross-sectional only row) and the number completing follow-up surveys in addition to a baseline survey (Longitudinal row). Information about sample characteristics is provided in Table 2 (at the end of this document).

Table 1. Sample Sizes for DICAT General Population and Pre-ID Samples (n=10,624)

	General Population	Pre-ID (Total N=5,451)					Total
		Arthritis	Cardiovascular	CKD	Diabetes	Respiratory	
Cross-sectional only	3,873	969	278	118	888	963	7,089
Longitudinal	1,300	605	394	181	438	617	3,535
Total	5,173	1,574	672	299	1,326	1,580	10,624

DICAT Enrollment

All panelists were required to consent to participate in the DICAT study after reading informed consent information at the beginning of the survey. If a panelist did not provide consent, the survey was terminated. After consenting to survey participation, DICAT study participants were assigned to a study arm. All data was collected electronically. Panelists were not compensated for participating in the DICAT study. However, panelists were notified that they would be entered to win a prize through a monthly KN sweepstakes.

Response Rates

Of those panelists selected to participate in the DICAT study, approximately 65% of the general population sample and 76% of the Pre-ID sample responded to the initial survey invitation and reviewed the consent form. Among those who reviewed the consent form, slightly more than 83% (in both samples) consented to take part in the survey; the remainder indicated that they did not consent. Of those who consented, more than 97% (in both samples) completed the survey. Thus, compared to those initially sampled, approximately 53% of the general population sample and 61% of the Pre-ID sample completed a baseline survey.

Of those panelists who completed a baseline survey and were selected for a longitudinal survey, slightly more than 88% (in both samples) opened the survey invitation and read the consent form. Among these, 83% in the general population sample and 90% in the Pre-ID sample consented to complete a longitudinal survey. Of those who consented, slightly more than 98% (in both samples) completed the survey. Thus, compared to those initially sampled for a longitudinal survey, approximately 72% of the general population sample and 78% of the Pre-ID sample completed a longitudinal survey[3].

Panelists with Multiple Conditions

Within the Pre-ID sample, 99.9% of panelists reported 2 or more conditions; among these, 22% reported 3 or 4 conditions, 54% reported 5 to 10 conditions, and 15% reported 11 or more conditions. In the general population sample, 79% reported at least 1 condition. 63% reported 2 or more conditions, including 22% of the total general population sample who reported 3 or 4 conditions, and 26% who reported 5 or more conditions.

Study Measures

DICAT collected a series of generic measures (not pertaining to any age, disease or treatment group) and disease-specific measures, along with other data. To manage respondent burden, panelists were assigned to protocols that assured the sample sizes required for

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analysis of item banks, while also keeping total respondent burden within acceptable limits. Other protocols varied survey lengths to evaluate respondent acceptance and the performance of short- and long-form measures. Study measures are summarized briefly below.

Generic Measures

SF-8™ Health Survey. This instrument includes one global item measuring each of the eight domains in the SF-36® Health Survey[4]. The SF-8 provides Physical (PCS) and Mental (MCS) Component Summary measures and unbiased estimates of the eight SF-36 scales.

SF-36® Health Survey. This instrument includes 35 items measuring eight domains (physical functioning, role limitations due to physical health, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, mental health) and one health transition item[5]. It also can be scored as Physical (PCS) and Mental (MCS) Component Summary measures and eight multi-item scales, along with a utility index (SF-6D).

Item banks. Item banks measuring physical functioning, role functioning, general health, vitality, and mental health were administered. The banks contained a mixture of existing (e.g., PROMIS®) and newly written generic items. Computerized adaptive tests (CATs) based on these banks were administered in Wave 3.

QGEN® measures. DICAT also administered new generic quality of life (QGEN) items that were hypothesized to be useful in improving estimates of specific domains as well as Physical and Emotional Health Summary Measures (PHGS®, EHGS®)[6-8]. Improved estimations of the MOS-based summary measures (PCS, MCS) were also evaluated to maintain comparability with the underlying MOS metrics. The new QGEN items and their respective banks measure 10 generic health domains (those in common with the SF-36 are **bolded**): **physical functioning**, role limitations attributed to general health, **role limitations due to physical health, role limitations due to emotional problems, pain, general health, vitality, social functioning, mental health,** and health distress. For score comparability and to standardize QDIS and QGEN norming samples, all generic summary and profile measures (SF-8, SF-36, PROMIS, QGEN) were scored to have a mean of 50 (SD of 10) in the US general population in 2011.

Disease-specific Measures

Condition checklist. A 35-item condition checklist was administered; a condition of 'current smoker' also was created from items about past and current smoking. For most conditions, panelists were asked to respond yes if they had ever been told by a doctor or other health professional that they had the condition. For nine conditions (e.g., allergies, sensory deficits, skin condition), panelists were asked if they now had the condition. The percent of panelists reporting each condition in the general population and Pre-ID samples is presented in Table 3.

Disease severity items. For each condition (disease) reported, the panelist was asked to rate the severity of that condition using a 5-point scale. A disease severity item was completed for each condition reported, by all panelists (general population and Pre-ID), in all three survey waves.

Global disease QOL impact items. For each condition (disease) reported, the panelist was asked how much that condition limited their everyday activities or quality of life, using a 5-point scale. A global disease impact item was completed for each condition reported, by all panelists (general population and Pre-ID), in all three survey waves.

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Quality of Life Disease Impact Scale (QDIS®) items. In addition to the global disease QOL impact item, panelists answered QDIS items that asked about up to 10 aspects of functioning and well-being that might be affected by a condition[6,9,10]. QDIS items asked about the impact of each specific condition on physical, role and social function, general health, health distress, vitality, mental/emotional health, cognitive function, sleep, and quality of life. All QDIS items used a 5-point rating scale (Very often-Never). Because the primary purpose of the DICAT project was to develop and evaluate patient-reported measures of disease-specific QOL impact, the number of QDIS items that panelists answered varied by protocol. In brief, among the Pre-ID sample, most panelists completed a 49-item bank which contained QDIS items that were specific to the one pre-identified condition (e.g., angina, diabetes) for which the panelist had been sampled. The remaining Pre-ID panelists completed a shorter QDIS form or a CAT (both of which were specific to the one condition for which the panelist had been sampled); these measures were developed from analyses of the 49-item QDIS bank data collected in Wave 1. In addition, general population panelists enrolled in Wave 1 (n=1,930) answered 6 QDIS items for every condition they reported, and 950 of these panelists answered 2 QDIS items at the Wave 2 follow-up for every condition reported. QDIS items also were administered to subsets of panelists in the longitudinal surveys.

Legacy Disease-Specific Measures. Within the Pre-ID sample, a widely-used (legacy) disease-specific measure appropriate for the condition the panelist was sampled to represent was administered to pre-ID samples as follows.

- Seattle Angina Questionnaire[11] - myocardial infarction and angina
- Minnesota Living with Heart Failure® Questionnaire[12] - congestive heart failure
- Diabetes Quality of Life measure (DQOL)[13] - diabetes
- Problem Areas in Diabetes Scale (PAID)[14] - diabetes
- Asthma Control Test™[15] - asthma
- St George's Respiratory Questionnaire[16] - asthma and COPD
- Kidney-Disease Quality of Life 36-item instrument (KDQOL-36™)[17] - CKD
- Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC®)[18] - arthritis

Other disease-specific items. The Pre-ID samples answered other items about specific symptoms for their primary condition (e.g., shortness of breath items for cardiovascular patients).

Vision-specific items. Items from the National Eye Institute Visual Function Questionnaire (VFQ)[19] and other vision questionnaires were administered to subsets of the general population and Pre-ID samples.

Health Risk Assessment

Items were administered to ask about health-related behaviors and lifestyle, including smoking, alcohol consumption, seat belt use, body mass index and weight loss.

Health Care Utilization

Information was collected about recent healthcare utilization and insurance status.

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Self-evaluated transition items

Panelists were asked to rate their health compared to three months ago (in their initial survey) or the time of the previous survey (in follow-up surveys) in various domains, including general health, physical function, role functioning, emotional problems, and quality of life.

Demographics

While most demographic data (e.g., age, gender) was obtained from the KN member profile file, limited demographic items (education, marital status, employment status) were asked in the DICAT survey to obtain the most up-to-date information. Additional items about income and household size were included at the end of the survey, to minimize potential survey non-completion due to the sensitivity of income questions.

Survey Protocols

DICAT was a complex study. Respondents came from 10 different samples (general population and the nine Pre-ID conditions) and surveys were given in three waves. Panelists in each of the nine Pre-ID condition groupings completed a survey that was tailored to their primary sampling condition. Modifications to the surveys were made in Waves 2 and 3, in part based on what was learned from the previous wave (e.g., data from the 49-item disease-specific QDIS item banks administered in Wave 1 were analyzed to produce shorter QDIS forms or to enable QDIS computerized adaptive tests (CATs) in Waves 2 and 3). New panelists were selected in each wave, and subsets of these panelists completed follow-up surveys in Waves 2 and 3. Many different instruments (e.g., SF-8, SF-36, generic item banks, QDIS items, legacy disease-specific surveys) were administered.

In developing the survey protocol, respondent burden was a key consideration, because the median survey time needed to be less than 25 minutes. However, sample sizes also needed to be large enough to calibrate item banks using item response theory (IRT) methods and to conduct head-to-head comparisons of measures for validation purposes. Therefore, a number of survey protocols were developed. All survey protocols included a set of core items, but then varied according to the sample (general population or Pre-ID), survey wave, and whether the panelist was a new enrollee or completing a follow-up survey. Panelists in the general population samples were randomly assigned to 1 of 8 protocols at initial study enrollment; there were 4 protocols for the general population in follow-up surveys. For the Pre-ID sample, panelists could be assigned to 1 of 18 protocols (1 basic protocol for Wave 1 and 1 basic protocol for Wave 2, each of which were customized for the 9 primary conditions) at initial study enrollment. There also were 45 protocols (5 basic protocols, each of which was customized for the 9 conditions) for the Pre-ID sample in follow-up surveys.

All panelists completed the generic SF-8™ Health Survey. About two-thirds of general population panelists also completed the SF-36 Health Survey, which was assigned randomly in addition to the SF-8 to enable more precise estimation of PCS and MCS and to estimate the SF-6D utility index[20]. Another set of panelists was randomized to complete physical function, fatigue, and depression and/or anxiety items included in the PROMIS® 43-item profile form. Some of these latter protocols included conceptually-related legacy tools thought to be useful in validating measures (e.g., PHQ-9 with PROMIS and SF-36 mental health measures).

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Statistical Considerations

Data Quality

The electronic data capture (EDC) method used by this study resulted in a high level of data quality. There was a low rate of missing data (1.5%) across all measures fielded. Per KN's standard procedure, panelists were allowed to skip survey items if they desired.

Sampling Weights

Because KnowledgePanel members were recruited from two different sampling frames (RDD and ABS), KN has implemented technical processes to merge the samples from these frames in a way that preserves the representative structure of the overall panel. KN also constructs a series of weights for each study that uses KnowledgePanel data. Two of these weights are constructed before a sample is drawn for any particular study. A *base weight* is constructed to account for known alterations in the selection process for KnowledgePanel that are a deviation from a pure equal probability sample design. For example, ABS-recruited panelists whose addresses can be matched to a phone number have a slightly higher probability of being recruited, since they can be contacted by phone if they do not respond to mailed invitations. An adjustment is made to the base weight to return the ABS-recruited panel members to the sample's correct national proportion of phone-match and no phone-match households. Second, a *panel demographic post-stratification weight* is constructed to reduce the effects of any non-response and non-coverage bias in KnowledgePanel membership. It is calculated based on the demographic distribution (gender, age, race/Hispanic ethnicity, education, census region, household income, metropolitan area) of KnowledgePanel and the most recent Current Population Survey (CPS) at the time a particular study is conducted. Finally, for each study, a set of *study-specific post-stratification weights* are constructed after the study is completed, to adjust for that particular study's sample design and survey non-response.

Three sets of *study-specific post-stratification weights* were constructed for DICAT. First, weights were constructed for the DICAT general population sample, based on benchmarks from the CPS (gender, age, race/Hispanic ethnicity, education, census region, household income, metropolitan area). Second, weights were constructed for each of the five Pre-ID samples (arthritis, cardiovascular, CKD, diabetes, respiratory) to weight each Pre-ID sample to look like the U.S. population with that condition. Finally, another set of weights were constructed for analysis of all data (general population plus all Pre-ID samples) together. Weights were constructed separately for Waves 1 and 2 and in aggregate across all three waves. Adjustments were made to trim any outliers at the extreme upper and lower tails of the weight distribution, and the weights were scaled to sum to the size of the sample for which the weight was being constructed.

The study-specific post-stratification weights (which incorporated the base weight and panel demographic post-stratification weight) were used to represent the US population as required to estimate means and variances used in norm-based scoring algorithms for the QDIS, QGEN and other measures.

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Table 2. DICAT Demographic Characteristics by Sample (n=10,624)

		General Population (n=5,173)	Pre-identified Sample (n=5,451)	Total (n=10,624)
Gender (%)	Male	49.0	43.0	45.9
Age	Mean (SD)	48.3 (16.5)	59.6 (13.7)	54.1 (16.2)
	Median	49	61	56
	Range	18 - 94	18 - 97	18 - 97
Age Group (%)	Less than 45 years	41.6	13.3	27.1
	45 – 54 years	19.0	17.3	18.1
	55 – 64 years	21.4	31.4	26.5
	65 – 74 years	13.3	25.5	19.6
	75+ years	4.7	12.5	8.7
Race/Ethnicity (%)	White, non-Hispanic	76.0	80.0	78.0
	Black, non-Hispanic	8.7	7.9	8.3
	Hispanic	9.4	5.8	7.6
	Other[a]	5.9	6.3	6.1
Education (%)	Less than high school	6.9	3.3	5.1
	High school	26.9	18.3	22.5
	Some college	31.9	38.0	35.0
	Bachelor's degree or higher	34.2	40.4	37.4
Income (%)	Less than or equal to $20,000	16.8	13.3	15.0
	$20,001 to $30,000	11.2	10.6	10.9
	$30,001 to $60,000	27.4	32.5	30.0
	$60,001 to $100,000	25.9	27.4	26.7
	More than $100,000	18.7	16.1	17.4
Region (%)	Northeast	18.1	16.5	17.3
	Midwest	23.6	27.3	25.5
	South	35.3	30.8	33.0
	West	23.0	25.4	24.2

[a] Other race includes panelists reporting 2+ races.

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Table 3. Percent of Panelists Reporting Each Condition by Sample (n=10,624)

	General Population (n=5,173)	Pre-Identified Sample (n=5,451)
Hypertension	30.6	58.5
Allergies, Seasonal[a]	37.1	50.3
Diabetes[b]	10.1	40.8
Joint problems, Hip or Knee[a]	19.7	40.8
Osteoarthritis[b]	10.4	38.4
Obesity	16.7	34.9
Back problems or sciatica[a]	17.7	33.8
Allergies, Chronic[a]	18.6	33.7
Asthma[b]	10.3	31.2
Deafness or trouble hearing[a]	10.7	20.7
Joint problems, Foot or Ankle[a]	9.4	20.2
Depression (clinical)	11.9	19.4
Migraine headaches	12.9	18.6
Hypothyroidism	8.4	16.9
Rheumatoid arthritis[b]	4.9	16.7
Anemia	9.0	16.5
Vision problems even with corrective lenses[a]	9.2	15.0
Dermatitis/other chronic skin condition[a]	9.2	14.9
Ulcer or other stomach disease	7.5	13.8
Limitation in use of arm or leg[a]	5.5	12.8
Irritable bowel syndrome	7.1	12.8
Erectile dysfunction	5.2	12.6
Chronic obstructive pulmonary disease (COPD)[b]	3.0	11.6
Cancer (except skin cancer)	6.1	11.6
Osteoporosis	5.2	11.5
Enlarged prostate or BPH	5.1	11.3
Congestive heart failure[b]	1.7	8.8
Angina[b]	1.9	7.9
Fibromyalgia	2.7	7.2
Kidney disease[b]	1.5	7.1
Smoker, Current	8.9	6.0
Stroke	2.0	5.2
Chronic fatigue syndrome	2.0	4.3
Liver infection, Hepatitis B or C	1.6	3.1
Myocardial infarction in past year[b]	0.6	2.3
HIV or AIDS	0.5	0.5

[a] Panelist was asked if they now had the condition. For all other conditions, panelist was asked if they had ever been told by a doctor or other health professional that they had the condition.
[b] One of the nine conditions used to select the Pre-identified sample.

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