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Validation of an Internet-based Cohort of Inflammatory Bowel Disease (CCFA Partners)

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Abstract

Background & Aims—As traditional methods have become increasingly difficult, the Internet offers a mechanism for conducting survey research quickly and efficiently. The validity of this research, however, depends on the ability of respondents to accurately report health status. We used a large Internet-based inflammatory bowel disease cohort to validate self-reported IBD against physician reports.

Methods—Between 06/22/2012 and 04/01/13, all CCFA Partners participants (n=6681) were invited to participate and 450 were selected by random stratified sampling. We sent physicians a survey to confirm IBD diagnosis and characteristics. We used descriptive statistics to compare data.

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Author contributions: RLR was involved in all aspects of the study, including study concept and design, data acquisition, analysis and interpretation of data, drafting and critical revision of the manuscript. MDL was involved with study concept and design, analysis and interpretation of the data and critical revision of the manuscript. SFC was involved with study concept and design and critical revision of the manuscript. CEDW was involved with data acquisition and review. WC was involved with computer programming and data acquisition and analysis. CFM was involved with analysis and interpretation of data, statistical analysis and critical revision of the manuscript. KA was involved with study design, data analysis and critical revision of the manuscript. RSS was involved in study concept, critical revision of the manuscript and study supervision and is the principal investigator of CCFA Partners. MDK was involved in all aspects of the study, including study concept and design, analysis and interpretation of data, critical revision of the manuscript and study supervision.

Results—A total of 4423 (66%) participants indicated interest. Of 450 selected, 261 (58%) consented and physician reports were obtained for 184 (71%). Physicians confirmed IBD status in 178 (97%) and type in 171 (97% of confirmed). The matching between patient and physician reports for Crohn’s disease (CD) was 82% for disease location, 89% for presence of perianal disease and 46% for disease behavior. For ulcerative colitis (UC), disease location matched 54% of the time. Physician reports confirmed the status of ever having bowel surgery for 97% of CD and 94% for UC, and confirmed current pouch or ostomy in 84% of CD and 81% of UC.

Discussion—Self-reported IBD in CCFA Partners is highly accurate and participants are willing to release medical records for research. Self-reported phenotypic characteristics were less valid. The validity of IBD diagnoses among CCFA Partners participants supports the use of this cohort for patient centered outcomes research.

Keywords

internet cohort; patient outcomes; inflammatory bowel disease

INTRODUCTION

Health related internet use has become increasingly prevalent. Sixty percent of internet users report searching for health information (1), patient web portals can improve patient outcomes (2), online interventions can promote health behaviors (3) and healthcare information technology can enhance health care quality and efficiency (4). The Internet could also be a valuable tool for medical research.

As traditional methods for survey research such as household and telephone interviews have become increasingly difficult, the Internet offers a mechanism for conducting survey research quickly and efficiently(5, 6). In fact, the Internet has become increasingly popular for symptom reporting for medical research, especially in the past two decades (7, 8). Yet the validity of Internet surveys for health research crucially depends on the ability of patients to accurately report their disease status.

In June, 2011, we launched CCFA Partners, a novel, Internet-based cohort of inflammatory bowel disease (IBD) to facilitate patient centered outcomes research and translational research(9). IBD includes Crohn’s disease (CD) and ulcerative colitis (UC), which are chronic illnesses affecting as many as 1.5 million individuals in the United States (10) with significant medical costs, impact on quality of life (11), and persisting gaps in quality of care (12). Unlike traditional observational studies of IBD, which rely on administrative or medical record data or of patients at tertiary care centers, CCFA Partners collects data on exposures and outcomes directly from the patient. Use of the Internet also allows for a very large, diverse cohort that can prospectively be studied without the high costs typically associated with prospective cohort studies.

While CCFA Partners has the potential to serve as a powerful platform for IBD research, little is known about the validity of self-reported health information collected over the Internet. Here, we sought to determine the feasibility of obtaining clinical data from outside

treating physicians of CCFA Partners participants, and assess the validity of self-reported IBD status by comparing to physician reports.

METHODS

CCFA Partners

The CCFA Partners cohort was established in June 2011 by recruiting through the Crohn's and Colitis Foundation of America (CCFA) email rosters, chapter events and other promotional activities. Inclusion criteria are 18 years of age and Internet access. Participants complete a baseline survey upon registration, which includes questions on demographics, disease type and activity, medications, health behaviors and other topics. Every 6 months, participants receive email reminders to complete follow-up surveys. Details of the CCFA Partners design are described by Long, et al(9).

Validation Study

All CCFA Partners participants completing a survey between June 22, 2012 and April 1, 2013 (n=6681) were invited to participate in a study to validate IBD diagnosis. Of those who indicated interest and provided a mailing address, 450 were selected based on random sampling stratified by disease type, age < or = 50 years and use of IBD medications. Each selected participant was mailed a consent form, Health Insurance Portability and Accountability Act (HIPAA) waiver and request for physician contact information. Selected participants received up to four email reminders as needed. We mailed physicians a 10 question survey to confirm the participant's disease diagnosis, type, location/extent, behavior, surgery, and current pouch or ostomy status. Criteria were developed using the NIDDK IBD Genetics Consortium Phenotype Operating Manual (13) and the Montreal classification (14). The survey could be completed on paper or online using a unique patient identification number. Physicians were compensated \$100 for their effort. Up to two contacts via telephone and fax to physician offices were made if needed.

Data and Statistical Analysis

Comparisons between groups were made using t-tests for normally distributed continuous variables, or equivalent non-parametric tests. All statistics were computed using SAS Version 9.3 (Cary, NC). The study protocol was approved by the Institutional Review Board at the University of North Carolina at Chapel Hill.

RESULTS

A total of 6681 CCFA Partners participants completed any survey between June 22, 2012 and April 1, 2013 and 4423 (66%) indicated interest in sharing medical records. Of 450 selected, 314 (70%) returned documents and 261 (83%) consented to participate in the study. Physician medical record information was obtained for 184 (71% of consented) (Fig 1). The response rate of physicians was 69% for university or academic physicians and 72% for physicians in private practice. Overall, 66% of the cohort considered participating in a study involving medical records, 38% consented and physician reports were obtained for 27%.

The median age of the study population was 46 years, 74% were female and 72% reported taking IBD medications (Table 1). Median disease duration was 16 years. No significant differences were found across sex, disease type, activity or median duration across those who indicated interest in study participation and those who did not indicate interest. Those who indicated interest were slightly younger (43.6 versus 45.0 years) and more likely to report taking IBD medications (86.7% versus 82.1%). Of the participants selected for the study, no significant differences were found across age, sex, medication use, disease type, disease activity or median duration between responders (those from whom physician reports were obtained) and non-responders (those for whom physician reports were not obtained) (Table 1).

Of the 184 responders, physicians confirmed IBD status in 178 (97%) and IBD type in 171 (97% of confirmed IBD). The matching between patient and physician reports for Crohn's disease (CD) was 82% for disease location, 89% for presence of perianal disease and 46% for disease behavior (stricturing or penetrating). For ulcerative colitis (UC), disease location matched 54% of the time. Physician reports confirmed the status of ever having bowel surgery for 97% of CD and 94% for UC, and confirmed current pouch or ostomy in 84% of CD and 81% of UC (Table 2).

DISCUSSION

CCFA Partners has used novel methods to assemble a large cohort of patients with IBD. Self-reported diagnoses of CD and UC appear to be highly valid within the cohort, though self-reported phenotypic characteristics are less valid. The validity of IBD diagnoses in CCFA Partners support the use of this novel, Internet-based cohort to conduct patient centered outcomes research.

A majority of participants were willing to release medical records for research and obtaining reports from community physicians was feasible. Up to 66% of the cohort considered participation in a study involving medical records and consent was obtained for 58% of the random sample of those who considered participating.

Daniels et al. conducted a study to validate diagnosis in a longitudinal Internet-based autism cohort, in which 63% consented and 61% provided documentation of the child's illness (15). The results from the autism study cannot be directly compared to the CCFA Partners sample because Daniels, et al. recruited newly-registered participants who were more likely to participate in the study based on previous findings (16). Furthermore, Daniels, et al. retrieved disease documentation and compensated the participant. Nevertheless, a participation rate of around 60% seems to be consistent for internet survey validation studies. Physician response rates were not significantly different between practitioners in a university or academic center and private practice. These findings demonstrate feasibility of future CCFA Partners studies that require detailed medical history and physician documentation from a diverse community.

Self-reported IBD, type, surgery and pouch/ostomy status was highly valid among those for whom medical records were obtained; IBD diagnosis was confirmed 97% of the time.

Similarly, Daniels, et al. found that 98% of families who provided documentation verified a physician diagnosis. Self-reported phenotypes of IBD, including disease location and behavior, are less valid, which may reflect poor patient understanding of IBD, limited education or study timing.

The generalizability of these findings may be limited by self-selection of participants; however, the similar characteristics across CCFA Partners participants who indicated interest and those who did not support the generalizability of these findings. Although those who indicated interest were slightly younger and more likely to report taking IBD medications, the magnitude of these differences was quite small. Additionally, similar characteristics of responders and non-responders within the study sample support the validity of these findings. A limitation of all Internet-based research is access and literacy. Barriers to Internet use include low income, low education and minority ethnic groups, but these are also the fastest growing groups of Internet users (5, 6). CCFA Partners subjects were enrolled primarily from rosters of an organization dedicated to IBD education (CCFA), so participants may be more educated and motivated than the larger universe of Internet users. In addition, other non-IBD patient populations may differ. Similar findings from an Internet-based autism study (15), however, may support widespread trends. It should also be recognized that, in this study, physicians reported disease characteristics using a standardized case report form, but not source data such as colonoscopy or pathology reports. As we were unable to validate physician reports through source data validation, the survey used may not be a true gold standard, and the possibility of incorrect information provided by physicians remains.

In summary, self-reported IBD in CCFA Partners is valid, while self-reported IBD phenotypes are less valid. Participants are willing to release their medical records for research and obtaining records from a diverse group of outside physicians is feasible. While published data on accuracy of self-reported health information in Internet cohorts remains limited, our findings are similar to an Internet-based autism cohort. In all, the validity of IBD diagnoses in CCFA Partners support the use of this cohort in patient centered outcomes research and show that the Internet can offer a practical, cost-effective strategy to enroll large numbers of subjects for patient-reported outcomes research.

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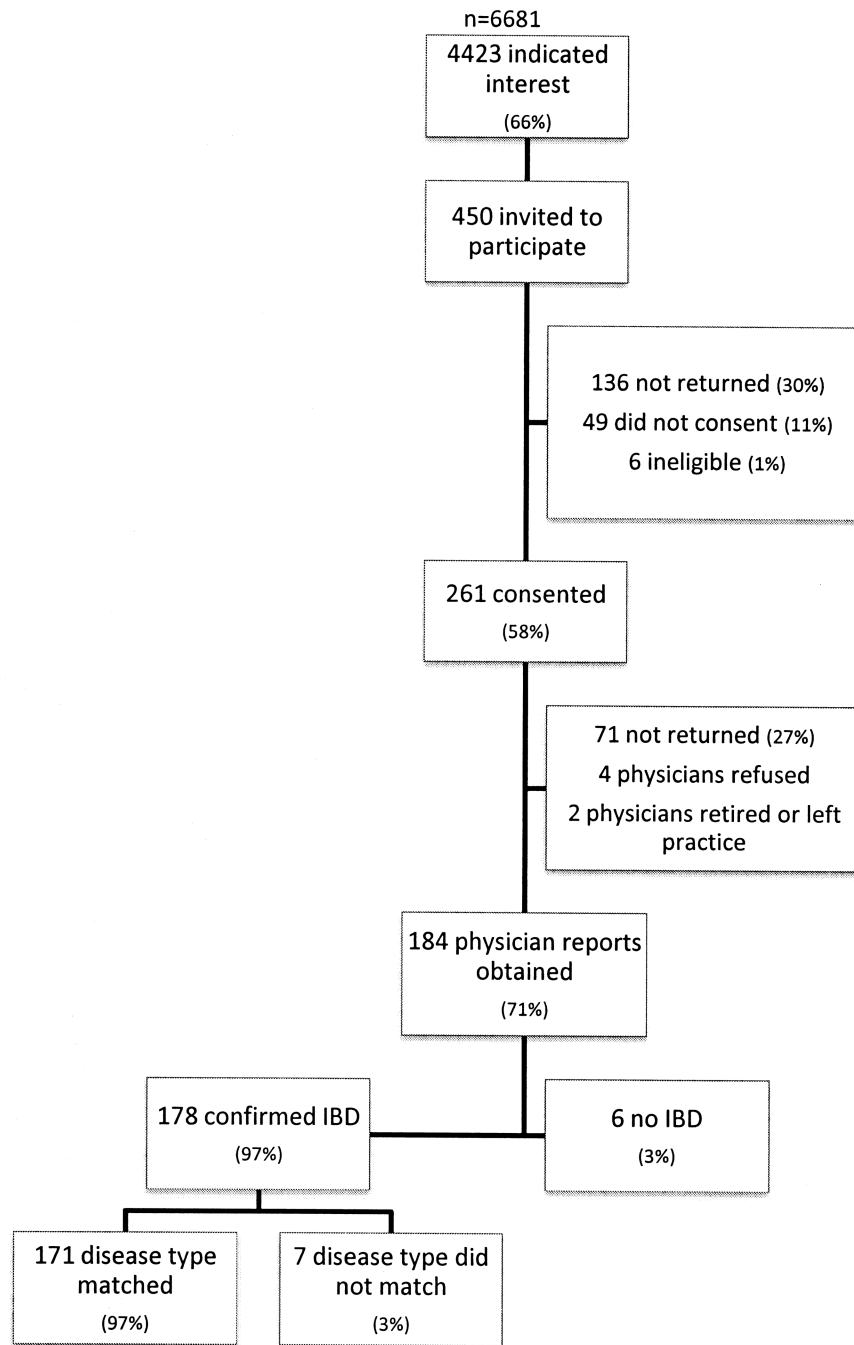


Figure 1.
Validation recruitment and results

Table 1

CCFA Partners Validation Characteristics by Participation Status

	Indicated interest [§] (n=4415)	No interest ^o (n=2249)	P	Responders [†] (n=184)	Non-Responders [‡] (n=260)	P
Median age, years	43.6	45.0	.0002	46	47.5	0.44
Female	3202 (78.7%)	1618 (72.0%)	0.56	136 (74%)	199 (77%)	0.58
CD	2777 (62.9%)	1398 (62.2%)	0.56	97 (53%)	146 (56%)	0.50
UC	1638 (37.1%)	851 (37.8%)	n/a	87 (47%)	114 (44%)	n/a
Median disease duration, years	11.0	11.0	0.82	16.2	16.0	0.83
Reported taking IBD medications	3829 (86.7%)	1847 (82.1%)	<.0001	132 (72%)	185 (71%)	0.92
Disease activity	n=3803	n=1880		n=141	n=202	0.41
Low	996 (26.2%)	501 (26.7%)		49 (35%)	53 (26%)	
Low-Medium	1076 (28.3%)	554 (29.5%)	.22	39 (28%)	65 (32%)	
High-Medium	697 (18.3%)	352 (18.7%)		30 (21%)	40 (20%)	
High	1034 (27.2%)	473 (25.2%)		23 (16%)	44 (22%)	

[§] includes those who indicated interest and provided a mailing address for participation in the study

^o includes those who were not interested in the study

[†] responders are those who indicated interest in study, and from whom consent and validation forms were returned

[‡] non-responders are those who indicated interest in study but whose consent and/or validation forms were never returned.

Table 2

Self-reported IBD confirmed by physician report in CCFA Partners (n=184)

	CD (n=96)	UC (n=87)
IBD	93 (97%)	84 (97%)
Disease location	74/90 (82%)	43/79 (54%)
Disease behavior	41/90 (46%)	n/a
Perianal/perineal disease	97/89 (89%)	n/a
Bowel surgery	56/58 (97%)	15/16 (94%)
Pouch or ostomy	16/19 (84%)	13/16 (81%)