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KD Valentine

Suzanne Brodney

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J. Lee Hargraves

Karen Sepucha

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Authors

KD Valentine, Suzanne Brodney, Carol Cosenza, J. Lee Hargraves, Karen Sepucha, Susan Edgman-Levitan, and Michael Barry

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KD Valentine, *Massachusetts General Hospital, kvalentine2@mgh.harvard.edu*

Suzanne Brodney, *Massachusetts General Hospital, sbrodney@mgh.harvard.edu*

Carol Cosenza, *Center for Survey Research, University of Massachusetts, carol.cosenza@umb.edu*

J. Lee Hargraves, *Center for Survey Research, University of Massachusetts, lee.Hargraves@umb.edu*

Karen Sepucha, *Massachusetts General Hospital, ksepucha@mgh.harvard.edu*

Susan Edgman-Levitan, *Massachusetts General Hospital, Sedgmanlevitan@mgh.harvard.edu*

Abstract

The purpose of this paper was to extend the generalizability of the patient-reported Impact Index by assessing convergent validity in patients with common chronic conditions. We conducted a cross-sectional survey of 1,000 English-speaking patients aged 21 and older who visited their provider in the past 6 months and were included in one or more of a hospital's chronic condition registries. Patients completed a survey that included the Impact Index (4-item measure of how impacted a patient is by their health condition: range 0-12, higher score indicating greater negative impact on quality of life), overall health, and self-report of diagnosis of 8 chronic conditions. Patients were categorized as having symptomatic conditions (one or more symptomatic conditions) or asymptomatic conditions. We hypothesized that Impact Index scores would be negatively correlated with overall health, positively correlated with the number of chronic conditions (using Pearson correlations) and would be higher for symptomatic than asymptomatic conditions (using an independent t-test). Of the 492 respondents (50% response rate), 381/392 eligible respondents completed all Impact Index items. Impact Index scores ranged from 0 to 12 ($M=6$, $SD=4$). As reports of overall health increased (i.e., from poor to excellent), Impact Index scores decreased ($r=-0.59$, $p<.001$). As the number of chronic conditions increased, so did Impact Index scores ($r=0.33$, $p<.001$). Patients with symptomatic conditions reported higher Impact Index scores ($M=6.6$, $SD=3.5$) than those with asymptomatic conditions ($M=4.1$, $SD=3.5$, $p<.001$, $d=.70$). These findings support the validity of the Impact Index for patients with a range of chronic conditions.

Keywords

Chronic condition, validity, Impact Index, measurement, patient reported outcomes.

Introduction

When measuring the impact of a health condition on a person's quality of life (QOL), there has traditionally been a choice between using "generic" measures such as the SF-36 and EQ-5D,¹ or "disease specific" measures such as the Knee Injury and Osteoarthritis Outcome Score (KOOS)² and the Harris Hip Score.³ Both sets are patient-reported outcome measures (PROMS),⁴ but generic measures allow easier comparisons of the impact of different conditions on quality of life. On the other hand, disease-specific measures are able to hone in more specifically on how the condition causes symptoms and alters function, and are generally more responsive to the effect of treatment or time and natural history.⁵

The Impact Index was created as a bridge between generic and disease-specific measures, allowing comparability of the impact of various conditions on QOL, yet maintaining the focus and responsiveness of disease-specific measures.

The original Impact Index, the benign prostatic hyperplasia Impact Index, was developed and validated among men with lower urinary tract symptoms attributed to benign prostatic hyperplasia.⁶ The 4-item scale asked patients, over the past month, how much "any urinary problems" caused you physical discomfort, worry about your health, bother, and interferences with activities. As this is a reflective scale, item scores were summed, equally contributing to the final score. This scale explained significantly more of the variation in overall health than measures of symptom burden, yet unlike the generic measures, maintained the responsiveness to treatment of the symptom scales. In subsequent research, an Impact Index was used that simply substituted the name of a different condition in the same four items, and the response frames were simplified to be the same across the four items (Table 1). The Impact Index was next used to measure the impact of androgen deprivation therapy on patients with prostate cancer recurrence after radical prostatectomy, where the condition was "anything related

Table 1. Generic Impact Index Questions

1.	Over the past 30 days, how much did you worry about your health because of your [name condition]?
2.	Over the past 30 days, how much were you bothered by your [name condition]?
3.	Over the past 30 days how much did your [name condition] limit what you were able to do?
4.	Over the past 30 days, how much pain or physical discomfort did your [name condition] cause you?

Response options: none=0, a little=1, some=2, a lot=3

Total score range 0-12

to your prostate cancer or the effects of its treatment”.⁷

More recently, the Impact Index has been used to measure the impact of hip and knee osteoarthritis on patients’ QOL.⁸ As in previous studies, the Impact Index demonstrated strong evidence of validity, reliability, and responsiveness, combining advantages of generic and disease specific measures. A “common denominator” of these conditions is they largely induce their morbidity through bothersome symptoms.

The purpose of this study was to extend the generalizability of the previously validated Impact Index by evaluating its relationships in patients with a broad range of chronic conditions that differ by symptom severity. We aimed to assess the convergent validity of the Impact Index in this sample by testing if higher Impact Index scores were associated with higher scores on similar scales (e.g. lower overall health, less patient engagement) or with more conditions, and if greater Impact Index scores were found for those with symptomatic conditions compared to those without symptomatic conditions.

Methods

Sample

Patients were chosen from five practices associated with a large academic medical center in the Northeastern United States. Patients were eligible if they were aged 21 and older, able to read and speak English, had an appointment with their clinician in the past 6 months, and were part of the hospital’s chronic condition registries for diabetes, cardiovascular disease, hypertension, or gout. The participating practices included three internal medicine practices, a specialty practice (gout) and a community health center. These five practices represented a convenience sample of practices selected because they were larger and offered a diversity of patient and medical conditions. A random sample was taken by practice, stratified by race and ethnicity (25% Hispanic, 25% African American, 50% non-Hispanic and non-African American). The specialty clinic had fewer patients than the other registries so all patients in that registry were included. For patients who appeared in multiple registries, the patient was only included in the first registry they were selected for. The goal was surveying 1000 patients; with an assumed 50% response rate given similar survey administrations in the past,⁹ we anticipated an effective sample of 500 respondents.

Design

Patients were sent an initial survey packet in the mail that contained a cover letter that described what was involved in participating in the study, instructions on how to opt-out of the study, a fact sheet, and a URL link to an online version of the survey. The packet also contained a paper survey, a return envelope, and a \$2 unconditional incentive. The survey could be completed by mailing back the paper version or completing an electronic version through REDCap. If a response was not received within two weeks, two reminder calls were made. Three weeks after the initial letter was sent, a reminder letter and survey were mailed to all patients who had not yet responded, again with the option to complete the survey via REDCap. A final reminder call was made two weeks after the reminder mailing. The lead physician from each of the five practices co-signed the recruitment letter that was sent to patients.

Measures

Impact Index: 4-item measure of how much a patient is bothered, worried, limited or in pain from ‘any of their health problems or conditions’ in the past 30 days. Although prior use of the scale specified a single problem or condition in each item, we chose to make the scale purposefully broad and generic given the variety of problems and conditions in this sample. Scores range 0-12 with higher scores indicating greater negative impact on quality of life.⁸

Overall health (SF-1): Single item asking patients to rate their general health with response options of excellent, very good, good, fair, or poor.^{10,11} This item was included as we expect that as overall health increases, the impact of a patient’s health problems or conditions should decrease.

SF-ACE: Short-form of the Altarum Consumer Engagement Measure (SF-ACE) – Commitment Subscale measures the extent to which patients are active and engaged in their own health. This subscale was included as we expected that as patient engagement increases, the impact of a patient’s health problems or conditions should decrease. This subscale asked respondents to rate four items using the following response options: strongly disagree, disagree, neither agree nor disagree, agree, strongly agree.¹²

1. I can stick with plans to exercise and eat a healthy diet.
2. Even when life is stressful, I know that I can continue to do the things that keep me healthy.
3. When I work to improve my health, I succeed.
4. I handle my health well.

Self-Ratings: Three items asking about how patients would rate themselves in terms of how well they've been doing in the last 6 months: 1) eating in a way that helps with their health problems or conditions, 2) exercising or doing physical activity to help with their health problems or conditions, and 3) taking their prescription medicines the way they are supposed to. Ordinal response options for each item were on a 5-point Poor (1) to Excellent (5) rating scale. These items are based on those used in work by Wilson and colleagues and were included as we expect that as patients perform these tasks better, the impact of a patient's health problems or conditions should decrease.¹³

Chronic Conditions: Patients were asked to self-report if a doctor, nurse, or other health professional had ever told them they had any of the following chronic conditions: arthritis/gout, angina, heart failure, COPD, depression, diabetes (Type 1 or 2), kidney disease, or high blood pressure. Patients also had the option to indicate if they were diagnosed with other chronic conditions and name them. If patients did not endorse any chronic conditions, they were not included in analyses. We further categorized the diagnoses as generally symptomatic conditions (arthritis or gout, angina or heart disease, congestive heart failure, chronic lung conditions including emphysema or chronic bronchitis, depression) or generally asymptomatic conditions (diabetes, kidney disease, high blood pressure)—if patients had any symptomatic conditions, they were considered symptomatic, even if they also endorsed asymptomatic conditions. We categorized conditions in this way as we expected that symptomatic conditions should be associated with greater impact on a patient's health problems or conditions.

Statistical Analysis

First, we analyzed for differences between responders and non-responders. Chi-square analyses tested for differences in sex, race (Black or African American, White, Other, Unknown), and ethnicity (Hispanic, Non-Hispanic, Unknown); independent t-test tested for differences in ages. We calculated Impact Index scores, explored missing data, and described the data using descriptive statistics. Cronbach's alpha with 95% confidence intervals (CI) were used to evaluate internal consistency. We used the chronic conditions data in two ways: 1) summing the number of chronic conditions patients endorsed as a marker of the number of chronic conditions the patient was facing, 2) categorizing patients as asymptomatic conditions (diabetes, kidney disease, high blood pressure) or having symptomatic conditions (endorsing any one or more of

the following conditions: arthritis/gout, angina, heart failure, COPD, depression).

We tested convergent validity with the following hypotheses:

1. Higher Impact Index scores will be associated with lower overall health, lower engagement, and lower self-ratings.
2. Patients with more chronic conditions will have higher Impact Index scores as will patients with symptomatic conditions versus those with only asymptomatic conditions.

To assess Hypothesis 1, Pearson correlations were used to describe the relationship with overall health and the number of chronic conditions and Spearman correlations were used to test for the relationship with the self-rating items. To test Hypothesis 2, an independent t-test assessed for differences in the mean Impact Index scores of symptomatic and asymptomatic conditions. Cochran-Armitage tests for trend analyzed for differences on individual items between symptomatic and asymptomatic conditions. All analyses were conducted in R version 4.0.3 or higher using base R¹⁴ for descriptives, t-tests and correlations, MOTE¹⁵ for effect sizes, and DescTools¹⁶ for Cochran-Armitage tests for trend. Power analyses were not conducted for this project as it was a secondary analysis of pre-existing data.

Results

Of the 1,000 patients invited, 16 were determined to be ineligible (see Figure 1). Of the 984 eligible, 492 responded (50% response rate). Responders tended to be older than non-responders, and more often identified as White. No differences in sex or ethnicity were found. See Table 2.

Of the 492 respondents, we excluded 99 respondents for reporting no visits during the survey recall period or reporting no chronic conditions. Of these 393, 381 completed all the Impact Index items and were included in our analytic dataset. See Figure 1. Respondents in our analytic data set were 45% women, 69% White, 16% African American, 2% Asian, 15% Hispanic, 48% with at least a college degree or more education, 33% aged 65-74 years and 29% aged 75 or older. Additional characteristics of the sample are described in Table 3.

Impact Index scores ranged from 0 to 12 (M=6, SD=4), with no evidence of skew (skew=0). Cronbach's alpha was 0.89 (95% CI 0.87, 0.90). The four Impact Index items were highly correlated with one another, with correlations ranging from 0.51 to 0.73; see Table 4.

Figure 1. Study Flow Diagram

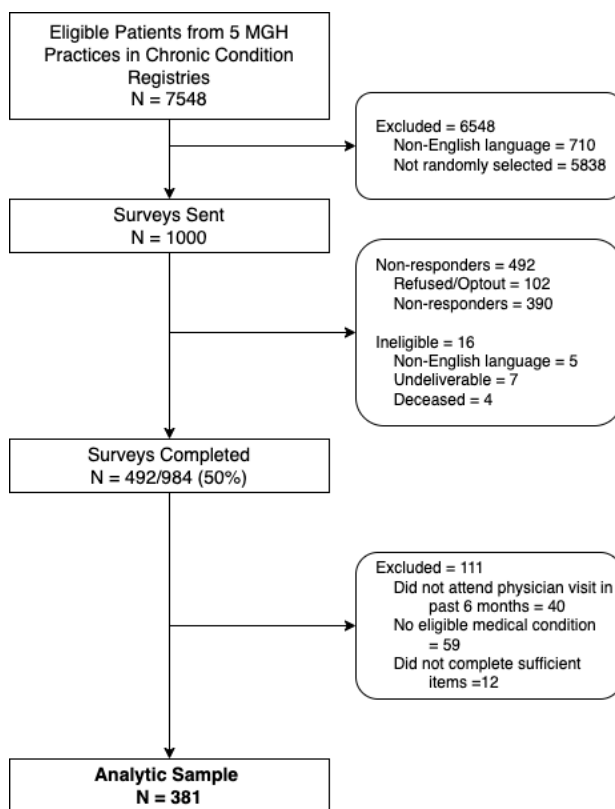


Table 2. Characteristics of Responders and Non-Responders

	Responders	Non-Responders	p
N	492	492	
Age M(SD)	66.8 (12.6)	62 (14.4)	<0.001
Female N(%)	220 (45 %)	237 (48 %)	0.31
Race- Black or African American N(%)	87 (18 %)	149 (30 %)	<0.001
White N(%)	336 (68 %)	262 (53 %)	
Other N(%)	52 (11 %)	67 (14 %)	
Unknown N(%)	17 (3 %)	14 (3 %)	
Ethnicity-Hispanic N(%)	78 (16 %)	86 (17 %)	0.78
Non-Hispanic N(%)	379 (77 %)	373 (76 %)	
Unknown N(%)	35 (7 %)	33 (7 %)	

Note: Those who endorsed ‘Some other way’ to describe their gender were excluded from this analysis (n=1). The ‘Other’ category for race consists of patients who identified as ‘Asian’, ‘Hispanic’, or ‘Other’ in order to have sufficient sample size for analysis.

Hypothesis 1

Impact Index scores showed significant correlations with overall health, engagement, self-rating measures, and number of chronic conditions (see Table 5). Patients who reported higher overall health, doing better at completing diet, exercise, or medications regimes to help with their health problems, or those who reported being more committed all tended to report lower Impact Index scores. Overall, 129 patients reported only one chronic condition and the remaining 252 reported 2 or more chronic

conditions. As the number of chronic conditions patients reported increased, so too did Impact Index scores.

Hypothesis 2

Mean Impact Index scores across the chronic conditions and their standard deviations are reported in Table A in the Appendix. 122 patients indicated only asymptomatic condition(s) and 259 indicated at least one symptomatic condition. Patients with one or more symptomatic conditions reported higher Impact Index scores (M=6.6,

Table 3. Analytic Sample Characteristics

	N (%)
Age Category	
25 to 34	4 (1 %)
35 to 44	15 (4 %)
45 to 54	43 (11 %)
55 to 64	78 (20 %)
65 to 74	126 (33 %)
75 or older	111 (29 %)
Unknown	4 (1 %)
Gender	
Woman	172 (45 %)
Man	202 (53 %)
Some other way	1 (0 %)
Unknown	6 (2 %)
Education	
8th grade or less	11 (3 %)
Some high school, but did not graduate	13 (3 %)
High school graduate or GED	66 (17 %)
Some college or 2-year degree	97 (25 %)
4-year college degree	50 (13 %)
More than 4-year college degree	135 (35 %)
Unknown	9 (2 %)
Ethnicity	
No, not Hispanic or Latino	307 (81 %)
Yes, Hispanic or Latino	57 (15 %)
Unknown	17 (4 %)
Race	
White	263 (69 %)
Black or African American	62 (16 %)
Asian	7 (2 %)
Native Hawaiian or Other Pacific Islander	9 (2 %)
American Indian or Alaska Native	1 (0 %)
Other race	33 (9 %)
None Indicated	1 (0 %)
Multiple	6 (2 %)
Chronic Condition*	
Arthritis/Gout	188 (49 %)
Diabetes	120 (31 %)
CHD/Angina	294 (77 %)
Hypertension	73 (19 %)
Heart Failure	34 (9 %)
COPD	39 (10 %)
Depression	80 (21 %)
Kidney Disease	60 (16 %)

Note: * indicates that participants could endorse multiple chronic conditions

SD=3.5) compared to those who did not report any symptomatic conditions ($M=4.1$, $SD=3.5$, $p<.001$, $d=.70$). This difference was also seen at the level of the individual items. For all four items, patients with symptomatic conditions always endorsed higher scores than patients with asymptomatic conditions (see Table 6).

Discussion

In this diverse sample of patients with a range of symptomatic and asymptomatic chronic conditions, the Impact Index showed scores distributed across its entire range, without evidence of floor or ceiling effects. Internal consistency reliability was high, similar to previous studies

of the Impact Index in people with chronic conditions.^{6,8} All of our hypotheses regarding the convergent validity of the Impact Index were confirmed. We found that scores on the Impact Index increased as the number of patients' chronic conditions increased. Scores on the Impact Index, and each of its four items, were higher in people with symptomatic compared to asymptomatic chronic conditions.

The Impact Index has performed well from a psychometric perspective and has demonstrated validity among patients with a broad range of chronic conditions. We encourage investigators to consider its use when the goal is to understand how one or more chronic conditions

Table 4. Correlations between Impact Index Items and Overall Scores

Variable	Range	Worry	Bother	Limit	Discomfort	Total Score
Worry	0 - 3	1				
Bother	0 - 3	0.72	1			
Limit	0 - 3	0.54	0.72	1		
Discomfort	0 - 3	0.51	0.73	0.73	1	
Total Score	0 - 12	0.79	0.92	0.87	0.86	1

Note: Correlations with total score are not corrected for overlap.

Table 5. Descriptive Statistics for Measures and Correlations with Impact Index

	N	Range	Median (IQR)	r	p
Overall Health	379	1-5	3 (1)	-0.59	<0.001
Self-Rating Diet	291	1-5	3 (2)	-0.23	<0.001
Self-Rating Exercise	291	1-5	3 (2)	-0.33	<0.001
Self-Rating Medicine	364	2-5	5 (1)	-0.12	0.018
	N	Range	Mean (SD)	r	p
SF-ACE (Commitment Subscale)	381	0-25	17.0 (5.0)	-0.29	<0.001
Number of Chronic Conditions	381	1-7	2.3 (1.3)	0.33	<0.001

Table 6. Item-Level Differences for Patients with Symptomatic and Asymptomatic Conditions

Item	Condition Type	Not at all	A little	Some	A lot	p
		N (%)	N (%)	N (%)	N (%)	
Worry	Asymptomatic	30 (25 %)	45 (37 %)	31 (25 %)	16 (13 %)	<.001
	Symptomatic	38 (15 %)	61 (24 %)	98 (38 %)	62 (24 %)	
Bothered	Asymptomatic	39 (32 %)	41 (34 %)	26 (21 %)	16 (13 %)	<.001
	Symptomatic	40 (15 %)	58 (22 %)	94 (36 %)	67 (26 %)	
Limit Activity	Asymptomatic	69 (57 %)	24 (20 %)	18 (15 %)	11 (9 %)	<.001
	Symptomatic	62 (24 %)	62 (24 %)	71 (27 %)	64 (25 %)	
Discomfort	Asymptomatic	53 (43 %)	33 (27 %)	25 (20 %)	11 (9 %)	<.001
	Symptomatic	49 (19 %)	63 (24 %)	87 (34 %)	60 (23 %)	

affects patients’ health and functioning. Further research is needed to assess the sensitivity of the Impact Index to change; however, previous studies in men with benign prostatic hyperplasia and osteoarthritis have demonstrated that Impact Index scores are more responsive to change than non-disease specific measures of general health.^{6,8} Additional research should be carried out to identify functional profiles of conditions and combinations of conditions to better understand how these impact patients. For example, we are not aware if a patient with both hypertension and arthritis would indicate they are more impacted by their chronic conditions than a person who is only diagnosed with arthritis or only diagnosed with hypertension. These functional profiles may help clinicians identify strategies for chronic disease management to help decrease the burden of illness.

Limitations

This research was conducted during the COVID-19 pandemic. The response rate was low at 50%, which is consistent with prior work in this area; however, younger or non-White participants were less likely to complete the survey and may impact the generalizability of the results. This research was conducted at a single academic medical center and only in patients who spoke English which may limit generalizability in terms of geography, language, race, and ethnicity. As all patients were part of chronic condition registries, this may skew our sample toward more committed and engaged individuals, which may not generalize to other samples. Further work is needed to ensure translations of this scale are usable and psychometrically sound for patients speaking other languages and that the discriminate validity and test-retest reliability of the scale are also satisfactory.

Conclusion

These findings extend the generalizability of the Impact Index, which was previously validated among patients living with osteoarthritis or benign prostatic hyperplasia to patients with a range of chronic conditions. The Impact Index was negatively correlated with overall health, positively correlated with the number of chronic conditions, and patients reporting symptomatic conditions had higher scores than those categorized as asymptomatic. This study provides additional evidence that the Impact Index can provide valid information about the impact of a health condition on a person's quality of life.

Statements and Declarations

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Competing Interests

Michael Barry and Suzanne Brodney report a grant from Healthwise, a nonprofit, through Massachusetts General Hospital, outside the submitted article. Dr. Edgman-Levitan received funding from AHRQ as a CAHPS grantee. Drs. Sepucha, Hargraves, and Valentine report no competing interests.

Author Contributions

Michael Barry, Suzanne Brodney, Karen Sepucha, and Susan Edgman-Levitan contributed to the study conception and design. Material preparation, data collection and analysis were performed by Suzanne Brodney, Lee Hargraves, and KD Valentine. The first draft of the manuscript was written by KD Valentine and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Ethics Approval

This study was approved by the Institutional Review Board at Massachusetts General Hospital (#2021P001421).

Consent to Participate

Consent was implied by completion of the survey.

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Appendix

Mean Impact Index scores across the chronic conditions and their standard deviations are reported in Table A. Note that as participants were able to indicate they had multiple chronic conditions that the scores presented are not independent of one another.

Table A. Mean Impact Index Scores for Individuals Endorsing Chronic Conditions

Chronic Condition	M(SD)
Arthritis/Gout	6.71 (3.44)
Diabetes	6.16 (3.6)
CHD/Angina	6.64 (3.39)
Hypertension	7.65 (3.07)
Heart Failure	7.08 (2.82)
COPD	7.8 (3.25)
Depression	7.48 (3.03)
Kidney Disease	5.68 (3.69)