



## Rationale for routine collection of patient reported outcomes during integrative medicine consultation visits

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### ABSTRACT

**Objectives:** Integrative medicine (IM) is whole-person care utilizing complementary health approaches to address numerous physical or emotional influences that can impact an individual's health. Patient-reported outcomes (PRO) are subjective measures that quantify patients' perception of their quality of life. While PRO measures have been routinely assessed in specific oncology clinics, our objective was to assess the ability and utility of routine collection of PRO measures in an IM clinic.

**Design/setting/main outcome:** Patients receiving a clinical consultation in an ambulatory IM clinic completed the PROMIS Global Health Form in the clinic waiting room.

**Results:** From November 2013 through October 2016, the PROMIS Global Health Form (PROMIS-10) was administered during 59% of IM provider consultation visits (7172/12,207), representing 3473 unique patients. Most patients were female (81%), White (93%), middle-aged (49.2; SD 15.4) and had commercial health insurance (66%). Baseline Mental (44.9; SD 9.1) and Physical Health (44.2; SD 8.6) scores were roughly 0.5 standard deviation below the national mean values (50; SD 10). Factors such as age, race and non-commercial insurance were associated with lower PROMIS-10 scores. Patients completing at least two PROMIS-10 questionnaires (n = 1541) exhibited increases of 2.3% and 2.8% from first to last PROMIS-10 assessment in Mental and Physical Health scores respectively.

**Conclusions:** It is possible to routinely collect PRO measures in large IM clinic and longitudinal improvements in Mental and Physical Health scores were observed. Future research should focus on understanding how providers can utilize PRO results in real-time to improve patients' clinical outcomes and potentially decrease healthcare utilization.

### 1. Introduction

According to the 2012 National Health Interview Survey, roughly 1/3 of American adults reported using complementary health approaches in the prior 12 months.<sup>1</sup> The term integrative medicine (IM) has been used to describe whole-person care utilizing complementary health approaches that address a range of physical, emotional, mental, social, and spiritual influences that can impact an individual's health.<sup>2</sup> According to the Academic Consortium for Integrative Medicine & Health,<sup>3</sup> a leading organization of over 70 academic medical centers and health systems in the US, Canada and Mexico, the definition of IM is as follows: "Integrative medicine and health reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate

therapeutic and lifestyle approaches, healthcare professionals and disciplines to achieve optimal health and healing."<sup>3</sup>

Patient-reported outcomes (PRO) are subjective measures reported directly by patients rather than objective measures (e.g., blood pressure) routinely collected by an investigator or clinician, as part of clinical practice. Specifically, PRO measures appraise what patients are able to do and how they feel by asking the patient a set of standardized questions<sup>4</sup> and can be important in evaluating the effectiveness of a treatment in either reducing a patient's perception of the symptoms associated with the condition or improving their perception of their function.<sup>5</sup> The Patient Reported Outcome Measurement Information System (PROMIS) is a suite of PRO questionnaires that were developed as part of a multi-year NIH funded initiative.<sup>6</sup> The PROMIS suite of item banks and short forms provides a brief, precise, and standard process

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for assessing PRO measures<sup>7</sup> with the ability to embed the measures into the electronic health record.

As a result, certain areas within healthcare, particularly oncology,<sup>8,9</sup> have begun to adopt and integrate PRO data collection into routine clinical care as a means of establishing clinical effectiveness for individuals<sup>10–13</sup> and supporting a learning health care environment.<sup>9</sup> Since IM focuses heavily on whole-patient well-being,<sup>14</sup> some have gone as far as suggesting that PRO measures be the *primary* indicator of treatment success and that PRO measures may reflect *the* primary outcome that patients are seeking to address with this line of treatment.<sup>15,16</sup> This movement, paired with the shifting in the health care climate from fee-for-service to value-based reimbursement models, highlights an increasing criticality of exploring routine collection of PRO measures in most clinic settings<sup>17,18</sup> including IM clinics. At present, one small longitudinal study in a naturopathy clinic<sup>19</sup> and one small cross sectional study<sup>47</sup> as well as one large cross sectional study in an integrative oncology clinic<sup>20</sup> have successfully collected PROs as part of routine clinical care. Despite these efforts, there remains a need to test the systematic and longitudinal collection of PRO measures in a large IM clinic with results embedded into the electronic health record so that providers can utilize the PRO results in their discussion with patients during the clinical visit. Furthermore, if mean PRO scores differ by subgroup (e.g., by demographic characteristics), this knowledge may assist the clinical provider with interpreting their patients' PRO outcomes. Finally, it is unclear how patients' perception of their quality of life varies over time as they receive care in an IM clinic.

Accordingly, the purpose of this manuscript is to explore three aims; Aim 1 will assess the feasibility of routinely collecting quality of life levels of PRO measures for patients receiving a consultation in a large IM clinic; Aim 2 will examine if PRO scores vary by patient characteristics, and Aim 3 will evaluate if PRO measures change longitudinally over the course of treatment and to further assess if any such longitudinal changes would be related to patient characteristics.

## 2. Materials and methods

### 2.1. Study design/population/sample

Allina Health is a not-for-profit health system of 13 hospitals, over 100 clinics, and other services in Minnesota and western Wisconsin. Since 2012, as a system-wide measure, the PROMIS global health form (PROMIS-10) was implemented across Allina Health with the two main goals of (1) embedding the PROMIS-10 into the clinical work flow in the ambulatory setting and (2) having clinical providers discuss the PROMIS-10 results with patients during clinic visits. In November 2013, three Penny George Institute for Health and Healing (integrative medicine) outpatient clinics began implementing the questionnaire into clinic flow specifically for patients having consultative office visits with an integrative medicine physician, advance practice nurse, or psychologist.<sup>21</sup> Patients were asked to complete the form on paper and bring the completed form to the exam room for consultation with the provider so the results of the PROMIS-10 could be incorporated into the provider/patient conversation during the visit. Some providers reported that the physical presence of the paper form in the exam room facilitated the discussion of the PROMIS-10 results during the visit. After the clinic visit, a clinical assistant entered the patients' PROMIS-10 responses into a documentation flowsheet within the EPIC electronic health record. In a pilot study of about 100 patients, participants completed the PROMIS-10 on an electronic tablet at visit check-in and the electronic results were immediately available in the EPIC electronic health record during the consultation visit.

Patient data were collected through retrospective review of electronic health records from November 2013 through October 2016. All visits with PROMIS-10 responses for a given patient were included in the analysis. Collected data included visit information (e.g., provider type), patient information (e.g., age, race etc) and PROMIS-10

responses. Specific inclusion criteria for this project required patients to have completed at least one PROMIS-10, to be aged 18 or older, and to not opt out of research in their health record. All protocols and subsequent amendments were approved by the Quorum Institutional Review Board.

### 2.2. Measures

#### 2.2.1. Patient reported outcome- PROMIS-10

The PROMIS-10 was used to measure each patient's health-related quality of life. This tool produces two composite measures of overall health: global mental health (MHS) and global physical health (PHS). The questionnaire is a widely-used and validated 10 item instrument which covers five different areas (physical function, pain, fatigue, emotional distress and social health).<sup>22</sup> The two global health measures are comprised of 4 items each with 2 remaining items scored independently. Each of the 10 questions is scored on a 1–5 Likert scale and scores are calculated and standardized using the national mean values from the 2010 National Health Interview Survey with a mean of 50 (SD 10).<sup>23–25</sup> For patients who completed the PROMIS-10 at more than one visit, a patient average, standard deviation and coefficient of variation across all visits was calculated. The number of visits and the average number of days between visits was also calculated for each patient.

#### 2.2.2. Demographics

Electronic health record data were obtained retrospectively on all eligible patients. Demographic data were collected through patient reported intake forms either in the IM clinics or elsewhere in the health system. Patients may choose not to answer these questions. Age and provider type (physician, nurse or psychologist) were calculated at the time of the first survey administration. Sex was reported binary as either male or female. Both the variables of language and race were analyzed using the patient reported primary selection. Categories of race included: White, American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, or declined/unknown. Primary languages included: English and other. Ethnicity categories included: not Hispanic/not Latino, Hispanic or Latino, and declined/unknown. Marital status was categorized by couple, single, divorced/separated, widowed and other/unknown. Insurance status was categorized into Commercial (e.g., Blue Cross Blue Shield), Medicaid, Medicare, and Other (e.g., worker's compensation, veteran's administration).

### 2.3. Statistical analyses

Descriptive statistics for patient variables and visit variables are presented using means, standard deviations and frequencies. As noted previously, the three aims are as follows; Aim 1 assesses the feasibility of routinely collecting quality of life levels of PRO measures for patients receiving a consultation in a large IM clinic; Aim 2 examines if PRO scores vary by patient characteristics, and Aim 3 evaluates if PRO measures change longitudinally over the course of treatment and to further assess if any such longitudinal changes would be related to patient characteristics.

To evaluate Aim 1, we assessed the feasibility of routinely obtaining the PROMIS-10 scores from patients attending the IM clinic for a physician or mid-level provider visit. The analyses required dividing the number of patients who completed the PROMIS-10 over the number of patients who were eligible to complete it. To evaluate Aim 2, we assessed whether there was an association between demographic characteristics and average PROMIS-10 scores. General linear regression models were used with average standardized scores across all visits as the outcome variable and demographic characteristics as predictors. Interactions between demographic variables were also examined. These models were adjusted for the number for visits and the average length

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