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Design of Study to Assess Impact of Electronic Chronic Pain Questions on Patient-Reported Outcomes and Healthcare Utilization in a US General Practice Setting

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Objective

Describe the design and implementation of a prospective, randomized pragmatic study to evaluate the use of the electronic Chronic Pain Questions (eCPQ) in a primary care practice setting within a large integrated delivery network (Henry Ford Heath System [HFHS]).

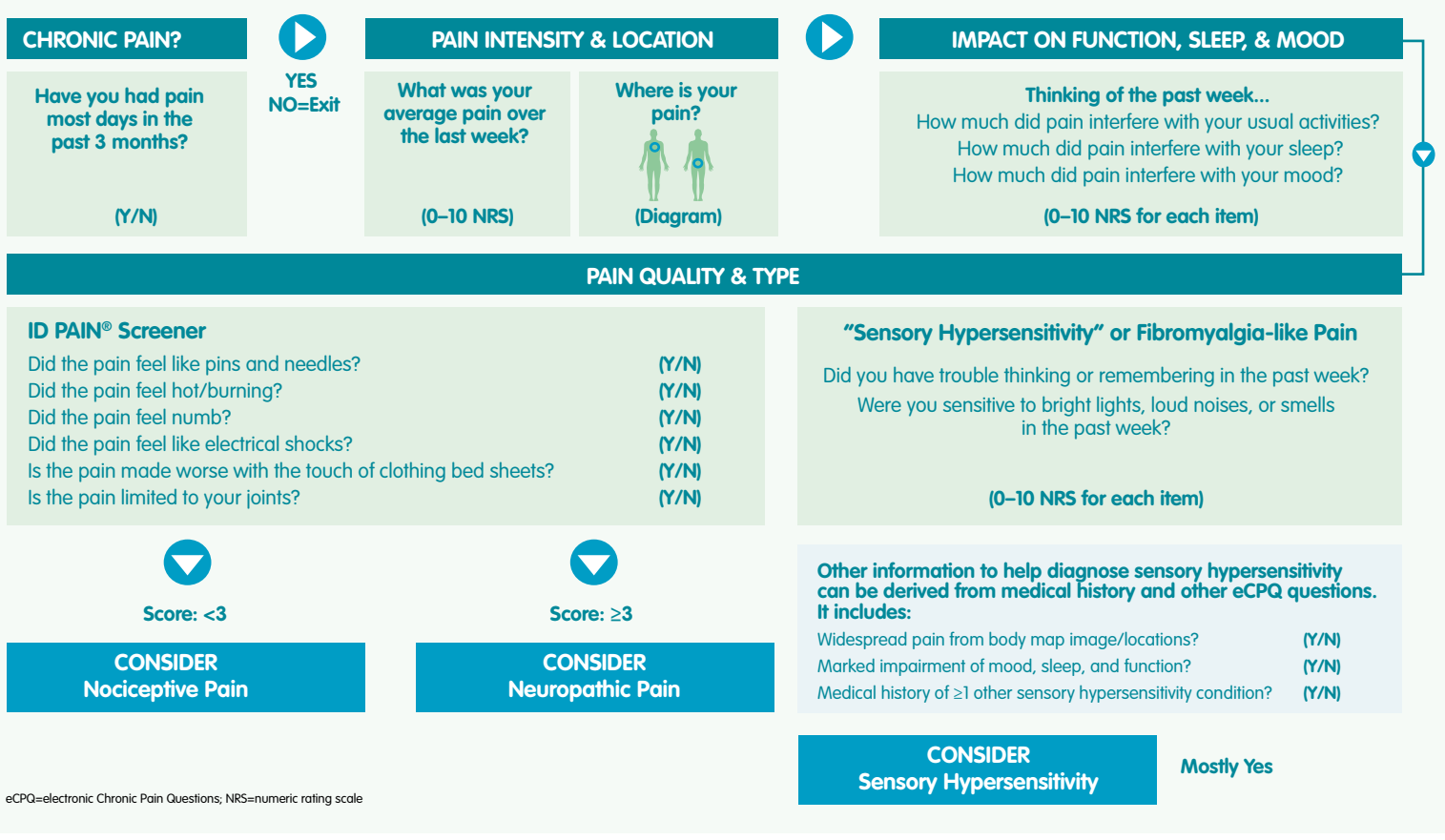
Background

- Chronic pain is common among adults in the United States, with a recent estimate indicating that it affects 20.4% (50 million) of US adults.[1]
- The presence of chronic pain is associated with substantial disability, poor mental health, lower quality of life, and decreased work function.
- Chronic pain also constitutes a significant burden on the healthcare system, resulting in substantial utilization of resources and increased costs.[2]
- There is currently a need for consistent, systematic electronic capture of data for chronic pain, which will allow for better monitoring of patients, more accurate estimation of chronic pain prevalence, and improved guidance with treatment decisions.
- The eCPQ module (**Figure 1**) was developed to help providers capture chronic pain data from their electronic health records.
- Previous studies of the eCPQ demonstrated the validity and reproducibility of this instrument in the primary care setting.[3]
- A paper-administered version of the CPQ was able to help differentiate between patients with neuropathic pain and those with sensory hypersensitivity (nociplastic pain).[4]
- Improved identification of chronic pain types may enable physicians to optimize treatment for maximum effect.

Conclusions

- Outcomes to be assessed include changes in the BPI-sf interference score, PGA, and PHQ from baseline to 6 and 12 months for the Intervention vs Control groups.
- This study aims to determine if the eCPQ will enable physicians to systematically track their patients' progress in terms of chronic pain and help guide their treatment decisions, leading to better clinical outcomes.
- The ability to distinguish between different chronic pain types can assist physicians with selecting the most appropriate treatment based on chronic pain pathophysiology.
- The results from this study will provide a more accurate picture of the prevalence of chronic pain, the associated utilization of healthcare resources, and the impact of diagnosis and treatment.
- Based on these data, healthcare organizations may be able to develop targeted solutions to address the specific issues affecting this patient population.

FIGURE 1. Schematic of the Electronic Chronic Pain Questions



eCPQ=electronic Chronic Pain Questions; NRS=numeric rating scale

Methods

STUDY DESIGN

- This is a prospective, randomized, pragmatic study.
- Patients attending the Academic Internal Medicine (AIM) clinic (Detroit campus) were randomized to receive the eCPQ plus regular care (Intervention Group) or regular care (Control Group).
- Patients attending the North area of the AIM clinic were allocated to the Intervention Group whereas those attending the South area were allocated to the Control Group.
  - There were no differences in procedures, patient flow, physician experience, specialty, or experience between the 2 clinic areas.
  - The recruitment period was from June 2017 to March 2019.
- ~20% of patients and ~10 physicians in the Intervention Group were randomly assigned to complete a qualitative interview halfway through the study.
- As per standard of care, patients were to visit the clinic at least once every 6 months for their chronic pain condition.

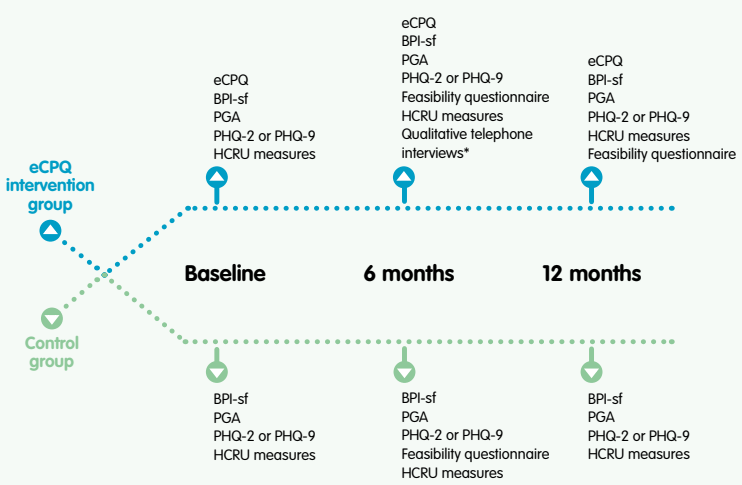
OUTCOMES TO BE ANALYZED

- This study will evaluate changes in the Brief Pain Inventory – Short Form (BPI-sf) scores and the Patient Global Assessment (PGA) from baseline to 6 months for the Intervention vs Control Group.
- The BPI-sf assesses the severity of pain and its impact on daily functions while the PGA assesses the effect of pain on normal activities.
- At their first (baseline, Day 1), second (6 months), and third (12 months) visits to the clinic, patients in the Intervention Group will administer the eCPQ and their answers will be recorded directly into the electronic medical record before their scheduled appointment with the physician; the patient's answers will then be reviewed by the physician.
- The PGA and the BPI-sf will be completed by all patients following their scheduled appointments at baseline, visit 2 (6 months), and visit 3 (12 months) (**Figure 2**).
- The Patient Health Questionnaire (PHQ-2), designed to screen for depression, will be administered to all patients at baseline, visit 2, and visit 3.
- At visits 2 and 3, patients in the Intervention Group and their treating physicians will be asked if they would like to complete a survey, which will assess their perception of the utility, feasibility, and satisfaction with the eCPQ and how the eCPQ impacts patient care.
- A subset of patients in the Intervention Group and a subset of physicians who utilized the eCPQ will complete a qualitative interview on their perceptions of the eCPQ and its value, the impact of the eCPQ on patient care, and any potential areas for improvement (**Figure 2**).

KEY INCLUSION CRITERIA

- Chronic pain as defined via ICD-10 diagnostic criteria.
- Men and women aged ≥18 years.
- Sufficient proficiency with English to complete and self-administer study questionnaires.

FIGURE 2. Schematic of Assessments Performed at Each Study Visit



* ~20% of participants were randomly assigned to the qualitative interview using a 1:5 randomized block design. Randomization was performed at the time of assignment of unique patient ID. Efforts were made to schedule the qualitative interview within 2 weeks of visit 2.

BPI-sf=Brief Pain Inventory–short form; eCPQ=electronic Chronic Pain Questions; HCRU=Healthcare Resource Utilization; PGA=Patient Global Assessment; PHQ=Patient Health Questionnaire

eCPQ MODULE

- The eCPQ consists of 14 items (**Figure 1**) to assess:
  - Does patient have chronic pain?
  - Pain intensity (0–10 on a numeric rating scale [NRS]).
  - Pain location.
  - Does pain interfere with usual daily activities, sleep, and mood (0–10 on NRS).
  - Pain type: nociceptive vs neuropathic pain, using the ID Pain Questionnaire.[5]
  - The presence of sensory hypersensitivity; assessment performed in combination with clinical examination and patient medical history.

STATISTICS

- For a treatment effect on BPI interference score or PGA score where the difference in mean scores on pain (or PGA) between the presence and absence of eCPQ was postulated as 0.5 standard deviation units, 64 subjects per treatment arm were needed in order to have 80% statistical power (0.05 two-tailed test of significance). Assuming 30% attrition, 92 subjects per arm (64/0.7) would need to be enrolled.

Current Status of Study

- Follow-up was completed in April 2020.
- Administrative data will be mined and added to analytic dataset to enable impact analyses to be completed.

References:

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