Case Report

Developing a pediatric pain data repository

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ABSTRACT

The management of pediatric pain typically consists of individualized treatment plans and interventions that have not been systematically evaluated. There is an emerging need to create systems that can support the translation of clinical discoveries, facilitate the assessment of current interventions, and improve the collection of patient-centered data beyond routine clinical information. We present the development of the pediatric pain data repository, a custom-built system developed at Boston Children’s Hospital by a multidisciplinary pain treatment service. The Repository employs a web platform to collect standardized patient-reported outcomes and integrates this with electronic medical record data. To date, we have collected information on 2577 patients and anticipate adding approximately 500 new patients per year. Major strengths of the Repository include collection of extensive longitudinal patient-reported outcomes, automated clinical data abstraction, and integration of the system into clinical workflows to support medical decision making.

Key words: data repository, pain conditions, pediatric populations, patient-reported outcomes, electronic health records

INTRODUCTION

The treatment of pediatric pain has undergone a profound transformation over the past few decades. Pain is increasingly recognized as a complex experience with interactions between biological, cognitive, emotional, behavioral, and social factors. This new perspective has required development of novel treatment avenues and interventions. The standard in pain management now consists of individualized treatment plans that have often not been systematically evaluated, especially in pediatric populations. There is, therefore, an emerging need to create systems that can facilitate assessment of current interventions, support evidence-based translation of clinical discoveries, and improve collection of patient-centered data beyond routine demographic and clinical information.

Prospective randomized controlled trials play a crucial role in establishing efficacy for analgesics and other treatments of pain. However, there are unique ethical and practical challenges in the conduct of pain-related controlled clinical trials in children. These include consenting children to studies and exposing them to risk, small sample sizes and patient heterogeneity, and challenges with blood sampling for pharmacokinetics. Even with Congressional mandates to study and develop drugs for children, the number of analgesics with pediatric labeling remains very low.

The National Academy of Medicine in 2011, in a report on advancing pain research, care, and education, called for the creation of clinical data repositories that collect and curate data for high-quality analyses. The secondary use of rich clinical data contained in the electronic health record (EHR) has become a cost-effective method for performing research on clinical outcomes in a number of fields. These datasets may be particularly advantageous for overcoming many of the barriers encountered with pediatric clinical
trials and may support examination of a wide breadth of clinical interventions.11

However, information available through EHRs consists primarily of demographics, clinical diagnoses, and treatments administered to patients. There are limited data on subjective elements guiding decision making, including patient preferences for certain clinical interventions. Furthermore, there is broad recognition in the clinical environment on the importance of monitoring patients outside of clinical encounters and at specific time points after interventions to enable providers to assess progression and side effects, as well as increase patient involvement in their care.

To address this gap, we created a data repository at Boston Children’s Hospital for patients with pediatric pain conditions, building a system that combines EHR data with extensive patient-reported outcomes.

IMPLEMENTATION EXPERIENCE

Motivation
The pain treatment service at Boston Children’s Hospital, within the Department of Anesthesiology, Critical Care and Pain Medicine, is a multidisciplinary program for pediatric acute and chronic pain management. The patient population consists of multiple subgroups of children and adolescents, including those with chronic musculoskeletal and neuropathic pain conditions, functional abdominal pain, intractable headaches, widespread pain similar to fibromyalgia, and pain associated with severe or life-limiting illnesses. The patient volume consists of approximately 1200 patients with 500 new patients annually, corresponding to 3500 annual outpatient visits. The initial treatment approach typically consists of multidisciplinary outpatient care with medication therapy, physical therapy, cognitive behavioral therapy, and psychosocial restructuring in school and other activities.12,13 For a subgroup of patients, we make selective use of nerve block injections, regional anesthetic infusions, and other invasive treatments.14

Based in an academic institution, the pain treatment service was engaged in research studies involving prospective clinical trials and retrospective studies, since its inception. The latter required chart reviews of medical records, often complemented by prospective data collection. This created a system where redundancies and duplication of efforts were common across different research groups and datasets. Additionally, there were inconsistencies driven by turnover in project managers that left many databases incomplete or with unclear data structures.

In addition to improving our research infrastructure, there was a need to develop a clinical tool that could aggregate and present patient and family information to clinicians. To address these requirements, in 2013, the division developed a web-based platform called WeCOPE, which collects electronic, standardized patient and family information before first-time visits. The data obtained included information on pain locations and characteristics, previous interventions, and responses to a set of validated questionnaires assessing psychosocial constructs associated with pain and maladaptive coping strategies. Clinicians could log into the provider view of the WeCOPE platform to review information submitted by patients, evaluate the patient’s condition and trajectory, anticipate the need for imaging studies or laboratory tests, and plan additional consultations, particularly for patients coming from out of state.

This one-time data feed created a foundation for a registry of patients with pain disorders, but remained disconnected from longitudinal information on the patient’s clinical care, disease course, and patient-reported outcomes.

Establishment of the Pediatric Pain Data Repository
Building on the WeCOPE platform, in 2018 we created the Pediatric Pain Data Repository, augmenting the database with clinical information from patients’ EHR. The aim was to build a centralized data repository to facilitate data use for clinical purposes and increase research collaboration, quality, and scope. Additionally, as part of the standard of care we expanded data collection through WeCOPE to capture patient-reported outcomes longitudinally (Table 1).

EHR data export into the Repository
EHRs are designed primarily to collect data for clinical care and billing. Information collected in the clinical setting may be incomplete, inaccurate, or have insufficient detail to yield useful information for research purposes.15 Additionally, EHR data are typically presented in free text format or may present multiple sources of data for a given measure. We developed a series of extract, transform, and load processes that directly query EHR data and automatically populate a database for the Data Repository. Standard information extracted from EHRs includes patient demographics, dates, and types of encounters (ie, pain clinic visit and emergency room visits), diagnoses (ie, ICD10 codes), medications prescribed, and procedures performed by the pain treatment service. For medications, a script was developed to de-duplicate prescriptions, filter by current status (eg, suspended or active), and parse prescription data into components of dose, frequency, total days prescribed, and number of refills allowed. The Data Repository is continuously working with clinicians and investigators to identify data elements of interest and methods to optimize data quality.

In addition, to supplement standard EHR data with additional patient phenotype information, new clinical variables are developed from the clinical notes using a combination of natural language processing and machine learning algorithms. We use regular-expression matching tools16 to generate labeled datasets in which we train a Support Vector Machine algorithm to identify features of interest for new variables. The Repository also supports statistical learning methodologies such as classification, clustering, and network analysis to analyze patient features, define disease presentation patterns, and identify predictors of disease outcomes. Validated clinical variables can be added to the Repository for use by clinicians and investigators.

Longitudinal patient-reported outcomes in the Data Repository
Patient-reported outcomes describe health-related data provided by patients that facilitate communication and decision making between patients and providers.17 There are 6 core areas recommended by the International Association for the Study of Pain for the assessment of safety and efficacy of interventions in pain management. These are pain characteristics, physical functioning, emotional functioning, participant ratings of global improvement, symptoms and adverse events, and participant disposition.18 These outcomes are rarely systematically collected in clinical notes or outside the clinical encounter, but are captured using the WeCOPE platform. To facilitate ongoing data collection, we expanded the Data Repository to collect longitudinal data, focusing on patient-reported outcomes. Patients now receive validated questionnaires assessing pain charac-
teristics, as well as school, sleep, mood, and physical functioning every month and after all interventions (Figure 1). The data elements collected in these surveys were selected to serve clinicians in ongoing patient monitoring and to allow for rapid adjustments in treatment plans, as needed. Clinicians can review patient responses in the WeCOPE platform prior to or during a clinic visit, including trends over time across specific questions and domains. The platform also includes a “summary view” that presents survey data synthesized into a standardized summary text followed by scores across question types and individual surveys.

Table 1. Information collected in the Pediatric Pain Data Repository

| Type of data                 | Description and examples                                                                 | Source of information                      |
|-----------------------------|------------------------------------------------------------------------------------------|--------------------------------------------|
| Demographics                | • Sex, age, and ethnicity                                                                  | EHR                                        |
| Pain characteristics        | • Body map used to assess pain location                                                  | WeCOPE initial visit questionnaire         |
|                            | • Pain scores and factors associated with the pain per location                           | WeCOPE follow-up questionnaire             |
|                            | • Healthcare utilization                                                                 |                                            |
|                            | • Medication used, including dose and perceived benefits                                 |                                            |
|                            | • Pain at school                                                                         |                                            |
|                            | • Sports and extra-curricular activities participation                                    |                                            |
|                            | • Pain interventions                                                                     |                                            |
| Family information          | • Parental demographic information                                                      | WeCOPE initial visit questionnaire         |
|                            | • Family medical history                                                                  |                                            |
| Patient psychological inventories | Standardized questionnaires assessing: depression, anxiety, quality of life, functional disability, fear of pain, pain catastrophizing | WeCOPE initial visit questionnaire         |
| Caregiver psychological inventories | Standardized questionnaires assessing: adult responses to child’s symptoms, family relationship, pain catastrophizing and pediatric quality of life | WeCOPE initial visit questionnaire         |
| Medical encounters          | • Dates and types of encounters (eg, clinic visit or hospitalization)                     | EHR                                        |
|                            | • Pain and functional scores                                                              |                                            |
|                            | • Diagnoses (based on ICD9 and ICD10 codes)                                               |                                            |
|                            | • Medications prescribed                                                                  |                                            |
|                            | • Interventions performed                                                                 |                                            |

Abbreviations: EHR: Electronic Health Record; ICD: International Classification of Diseases.

Figure 1. WeCOPE data capture. Panel A shows the enrollment rates over the years, and Panel B, the patient survey view including pain locations and functional scores.
Repository governance and management

The Repository is governed by a research protocol approved by the Institutional Review Board (IRB) at Boston Children’s Hospital. Information collected in the WeCOPE system is part of the clinical standard of care, and a waiver of consent was obtained for use of the data in research studies. While patients and families are strongly encouraged to complete the surveys, it is not obligatory and patients receive all indicated medical treatment irrespective of completion status. A committee was created to oversee management and use of the Data Repository, with representation from clinicians and investigators with a wide range of expertise in pediatric pain management. Processes were established to ensure data quality and standardization to facilitate data extraction and visualization, and guiding documents were created to support investigators in the use of this resource. Members of the Data Repository are also available to offer mentorship in the use of the Repository and in development of research projects.

The committee acts as the “honest broker” for data requests for projects using de-identified data and distributes data to investigators after scientific review and approval of the research protocol. Data requests for studies requiring patient identifiers must be accompanied by an IRB-approved protocol justifying the use of identifiable patient data. In all cases, investigators sign a data use agreement committing to use of the data as outlined in the proposal, and a regulatory guidance document is provided to highlight security and confidentiality provisions.

ASSESSMENT

Since the development of the WeCOPE system, 2577 patients have been added to the Repository, with 1993 (77.3%) providing partial or complete data on previsit patient-reported clinical information and psychological surveys. We are currently enrolling approximately 10 new patients per week. Table 2 provides basic demographic and clinical information on patients currently enrolled in the Repository.

In previous pediatric clinical outcome studies of chronic pain, it has become apparent that there are trade-offs between burden on patients and need for data collection at intervals more frequent than what can be derived from follow-up clinic notes. Longitudinal patient data collection in our Repository has been designed to occur once per month and 1 week after any procedure performed by the pain treatment service, with the initial roll-out of the follow-up questionnaires occurring in the second quarter of 2019. This component will be assessed as data become available to optimize the frequency and content of the questionnaires.

Since the implementation of the Data Repository in January 2019, seven research projects have been launched using the Repository. Among these, three are associated with an IRB-approved protocol for use of patient identifiable data and four are exempt from IRB review as they require only de-identified data. Examples of the types of studies underway include an assessment of the emergence of overlapping pain conditions in children and adolescents, examination of the association between patient-reported measures of psychological stress, pain, and pain-related impairment in youth with chronic pain, and characterization of suicidal behaviors (eg, self-harm) associated with the use of gabapentin in children with chronic pain. We have also completed requests for data extraction to assist patient cohort selection and sample estimation in planning prospective studies.

Table 2. Demographic and clinical information of Pediatric Pain

| Outcomes                          | Nationality | Gender | Age groups | School accommodation | Prior pain interventions |
|-----------------------------------|-------------|--------|------------|----------------------|--------------------------|
| Outcomes                          | Nationality | Gender | Age groups | School accommodation | Prior pain interventions |
| Nationality                       | United States | Female | 0–5 years old | 36 | Exercise |
|                                  | Massachusetts | Male | 6–11 years old | 503 | Massage |
|                                  | Out of state | Transgender | 12–17 years old | 1693 | Physical therapy |
|                                  | International | No self defined | 18 years and older | 340 | Psychological treatment or counseling |
| Mean age, years (SD)              | 14.7 | 3.6 | 1.4% | 19.6% | 65.8% |
| Age groups                        | 4.8 | 3.5 | 0.9 | 1.6 | 0.5 |
| Number of visits to a physician, mean (SD) | 3.4 | 4.2 | 7.4 | 1.8 | 16.6 |
| Number of hospital admissions, mean (SD) | 7.4 | 1.8 | 0.9 | 1.6 | 0.5 |
| Mean percentage of school days missed due to pain in 3-month period prior to first clinical visit, mean (SD) | 16.6 | 24.3 | 7.4 | 1.8 | 0.5 |
| Most painful locations            | 100 | 22.5% | 36.9% | 33.5% | 22.5% |
| Multiple/whole body               | 961 | 42.4% | 13.8% | 9.1% | 5.0% |
| Lower extremity                   | 512 | 22.6% | 26.6% | 22.5% | 13.8% |
| Back-hip                          | 312 | 13.8% | 22.5% | 22.5% | 13.8% |
| Abdomen                           | 206 | 9.1% | 9.1% | 9.1% | 9.1% |
| Head                              | 162 | 7.2% | 7.2% | 7.2% | 7.2% |
| Upper extremity                   | 112 | 5.0% | 5.0% | 5.0% | 5.0% |
| Percentage of school days missed due to pain in 3-month period prior to first clinical visit, mean (SD) | 16.6 | 24.3 | 7.4 | 1.8 | 0.5 |
| School accommodation              | 504 plan | 360 | 14.0% | 21.8% |
| Individualized education program  | 360 | 14.0% | 13.5% | 13.5% |
| Other accommodation               | 347 | 13.5% | 13.5% | 13.5% |
| Home tutoring                     | 199 | 7.7% | 7.7% | 7.7% | 7.7% |
| Prior pain interventions          | 1586 | 61.5% | 61.5% | 61.5% | 61.5% |
| Exercise                          | 952 | 36.9% | 36.9% | 36.9% | 36.9% |
| Massage                           | 864 | 33.5% | 33.5% | 33.5% | 33.5% |
| Physical therapy                  | 754 | 29.3% | 29.3% | 29.3% | 29.3% |
| Psychological treatment or counseling | 579 | 22.5% | 22.5% | 22.5% | 22.5% |
| Transcutaneous electrical nerve stimulation (TENS) | 520 | 20.2% | 20.2% | 20.2% | 20.2% |
| Acupuncture                       | 502 | 19.5% | 19.5% | 19.5% | 19.5% |
| Chiropractic                      | 452 | 17.5% | 17.5% | 17.5% | 17.5% |
| Surgery                           | 421 | 16.3% | 16.3% | 16.3% | 16.3% |
| Relaxation training               | 288 | 11.2% | 11.2% | 11.2% | 11.2% |
| Homeopathy                        | 150 | 5.8% | 5.8% | 5.8% | 5.8% |
| Biofeedback training              | 54  | 2.1% | 2.1% | 2.1% | 2.1% |

aData reported are based on the WeCOPE initial visit questionnaire and EHR data.

b504 Plan is a plan developed to ensure that a child who has a disability identified under the law and is attending an elementary/secondary educational institution receives accommodations that will ensure their academic success and access to the learning environment.
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CONFLICT OF INTEREST

None of the authors report conflicts of interest related to this manuscript.

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