CPRN Clinical Registry: Characterizing Patient Populations, Treatments and Outcomes in the Cerebral Palsy Research Network (CPRN) (CPRN Registry) CPRN Protocol Number 001

Cerebral Palsy Research Network

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CPRN Clinical Registry: Characterizing Patient Populations, Interventions and Outcomes in the Cerebral Palsy Research Network (CPRN)

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Executive Summary

The Cerebral Palsy Research Network (CPRN) is a group of clinician-scientists and patient advocates collaborating to improve treatments and outcomes for people with Cerebral Palsy (CP). CPRN's vision is that every clinician caring for persons with CP can offer the best, most current treatment available, proven through high quality research conducted through CPRN. CPRN consists of 20 Clinical Centers and a Data Coordinating Center (DCC). The 20 centers contribute to a clinical data registry. The CPRN Registry is the foundation of a Learning Health System, which seeks to align research and clinical cultures for continuous improvement and clinical innovation and knowledge generation as a by-product of clinical service delivery.

A Common Data Model (CDM) has been developed to obtain data from multiple disciplines that treat cerebral palsy, including pediatrics, physiatry, neurology, orthopedics, neurosurgery, and physical, occupational, and speech therapy. The ongoing maintenance of the CPRN Registry serves two main purposes: (1) it will help investigators understand the variability, progression, and current treatment practices for CP in children and adults, with an ultimate goal of better guiding and assessing therapeutic interventions and providing recommendations on patient care and; (2) it will provide pilot and descriptive data necessary for hypothesis generation and study design (i.e. preliminary power analyses, recruitment projections) for studies under development by the CPRN. This multi-institutional database will be maintained throughout the lifetime of the CPRN or until such time that care is standardized across CPRN network sites, and will be useful for tracking trends in cerebral palsy over time. The CPRN Registry will be an invaluable resource to the CPRN and will help stimulate new research protocols, identify potential need for future expansion of the network to incorporate additional patient populations, and provide a descriptive understanding of children and adults with cerebral palsy cared for within the network.

As basic and translational science networks such as CP Alliance's IMPACT CP or Canada's Childhood Cerebral Palsy Integrated Neuroscience Discovery Network develop new therapeutic interventions, CPRN will provide the clinical trial infrastructure to rapidly and safely test new interventions. The many universities participating in CPRN will enable a new level of collaboration between basic scientists and clinical researchers helping focus research on solving the most important questions for the CP community.

Registry Title	CPRN Registry
Sponsor	Cerebral Palsy Research Network
Subject Selection Criteria	All patients with documented cerebral palsy
Sample Size	Approximately 13,000 clinic visits and 1,500 surgical events
Registry Objectives	1. To describe the number and characteristics of cerebral palsy patient visits and events at CPRN Clinical Centers including demographics, etiology, diagnostic information, surgical and medical management and patient reported outcomes. 2. To provide this data to CPRN investigators to support hypothesis generation, study design development for future studies and practice variation for quality improvement initiatives.
Registry Procedures	Patients will be entered prospectively in the Electronic Data Capture (EDC) or Electronic Health Record system at the time of clinic visits and primary surgical management of their cerebral palsy. Subject data will also include quality of life and follow up information if available. Subjects will be followed prospectively and each cerebral palsy related event or clinic visit will be captured as it occurs. Subjects will also be asked to consent to be contacted for future studies.
Data Management and Statistical Analysis	A web based data capture system or a EHR based capture will be used to collect and report Registry Data. The web based EDC system will be set up for remote data entry. Data extractions from EHR data will be securely transmitted to the DCC for integration in the CPRN Registry database. Reports of specific data points can be requested and statistical analysis generated at the DCC as needed.

Abbreviations

CP: Cerebral Palsy
CPRN: Cerebral Palsy Research Network
CDM: OMOP Common Data Model
CDISC: Clinical Data Interchange Standards Consortium
DCC: Data Coordinating Center
EHR/EMR: Electronic Health Record/Electronic Medical Record
HIPAA: Health Insurance Portability and Accountability Act
IRB: Institutional Review Board
NIH: National Institutes of Health
ODM: CDISC Operational Data Model.
OMOP: Observational Medical Outcomes Partnership
SSL: Secure Socket Layer
REB: Research Ethics Board
VPN: Virtual Private Network

Introduction, Background and Significance

A workshop sponsored by the National Institutes of Health (NIH) in 2014 identified critical advances needed to improve outcomes for cerebral palsy patients.[1] Their recommendations included: (1) the need for a national registry for cerebral palsy; (2) the importance of comparative effectiveness research; and (3) importance of research into long-term outcomes for adults with cerebral palsy. An opportunity to conduct such research is presented through the newly established Cerebral Palsy Research Network (CPRN) infrastructure. CPRN has been established by philanthropic funding to conduct multi-institutional research (clinical trials, observational studies and quality improvement) on cerebral palsy. Multi-institutional longitudinal studies are necessary to generate adequate sample sizes to study clinical problems in cerebral palsy because of the heterogeneity of the population. The success of the CPRN requires expeditious planning, implementation, completion, and publication of research that addresses important issues in the care of children and adult with cerebral palsy. The CPRN currently consists of multiple Clinical Centers and a Data Coordinating Center.

Purpose

In order to engage in collaborative studies within the CPRN, basic epidemiological information about cerebral palsy patients and events is needed from each participating institution. The ongoing maintenance of the CPRN Registry serves two main purposes: (1) it will help investigators understand the variability, progression, and current treatment practices for CP, with an ultimate goal of better guiding and assessing therapeutic intervention and providing recommendations on patient care; and (2) it will provide pilot and descriptive data necessary for hypothesis generation and study design (i.e. preliminary power analyses, recruitment projections) for studies under development by the CPRN. Each Clinical Center will place cerebral palsy patient visit and event information into the centralized CPRN Registry maintained by the Data Coordinating Center (DCC). The DCC will provide access to the database to all CPRN investigators to support CPRN activities. The CPRN Registry supports observational descriptive research within the CPRN network that will be continued throughout the life of the network or until such time that care is standardized across CPRN network sites. It includes ongoing data collection and analysis of CPRN Registry data at each Clinical Center within the network.

Procedures

The overall objective of the CPRN Registry is to establish and maintain a prospective, longitudinal, multi-instutional clinical database for the Clinical Centers of the CPRN, a research network newly established to investigate clinical management of cerebral palsy. The The entire common data model is available here: https://docs.google.com/spreadsheets/d/1p2XkGDOVTfV5VWy0s6CWwsobyAyrvcE16_mx3rfYHaI/edit?usp=sharing.

[1] "Report of a Workshop on Research Gaps in the Treatment of Cerebral Palsy," Codrin Lungu, Deborah G. Hirtz, Diane Damiano, Paul Gross, and Jonathan W. Mink, Neurology, unpublished.

The data collected include range of clinical care data, including the following: non-identifier demographics, birth history, anthropometric data, nutritional plan and history, medical and surgical history (including relevant medical findings from other departments, such de-identified results of imaging, lab results, hospitalizations, emergency room visits, and immunization history), quality of life and other patient-reported outcomes, gross and fine motor function, communication function, sensory difficulties, range of motion, strength, spasticity, timed functional tests, durable medical equipment use, parent-reported academic information, behavioral assessments, use of ancillary services (e.g., participation in rehabilitation therapies), details of surgical procedures, and patient/caregiver reported outcomes. The data collected will include approximately 26,000 clinic visits and 3,000 surgical events, which will support the comparison of surgical treatments with small effect sizes even in relatively small subgroups.

Patient Eligibility

Inclusion Criteria

1. Treatment for CP-related sequelae in a CPRN Clinical Center CP clinic.
2. Assessment or treatment in a CPRN CP clinic in calendar year 2016 and subsequent years, for the duration of the existence of the CPRN.

Exclusion Criteria

1. A co-morbid neurodevelopmental condition that would change the clinical course of CP, including but not limited to the set of syndromes/disorders in Appendix S1 that appears in Smithers-Sheedy, H., Badawi, N., Blair, E., Cans, C., Himmelmann, K., Krägeloh-Mann, I., ... & Wilson, M. (2014). What constitutes cerebral palsy in the twenty-first century?. Developmental Medicine & Child Neurology, 56(4), 323-328.
    a. The kinds of disorders considered here account for only ≈2% of CP cases recorded on/reported to CP registers.

Study Methods

Overview

Each Clinical Center will enroll all persons who are assessed or treated at the Clinical Center and who meet inclusion and exclusion criteria. The enrolling Clinical Center will transfer clinical data to the Data Coordinating Center in one of two ways: (1) via electronic extract from the EHR, or (2) through manual entry into a database via a secure web portal (see Section on Data Security on page 16 for system security information) where the subject will be coded with a unique identifier.

Data Collection Via EHR Extract

The majority of Clinical Centers will collect data to populate the registry in their respective EHR systems in the course of routine care delivery. The data will be extracted using site-specific solutions that reflect whether the sites rely on vendor-provided solutions for extracting data from these EHR systems, whether they have a mature Enterprise Data Warehouse (EDW) or other operational data stores and/or infrastructure like i2b2. The DCC will develop an ETL Virtual Appliance (EVA) solution for common EHRs like Epic, Cerner, and for platforms like i2b2,

available under a limited distribution. EVA will feature workflows to extract data from common EHRs, and to transfer them to the DCC automatically and securely using Secure File Transfer Protocols.

Data Collection Via Manual Entry

Certain sites may not possess the infrastructure or the resources to develop their own mechanisms for point of care structured clinical documentation and would have to rely on alternative approaches. The DCC will offer EDC using Research Electronic Data Capture (REDCap) software to such sites. This approach will require engaging Research Coordinators at the respective sites to perform chart abstraction on consented patients in the CPRN, and enter the various data points using REDCap forms hosted by the DCC. Of note, REDCap is 21 CFR 11 capable when configured and used correctly. The has been certified by the University of Utah Information Security Office has certified the DCC instance of REDCap as 21 CFR 11 compliant and Health Insurance Portability and Accountability Act (HIPAA) compliant.

Protection of Privacy

Data will be acquired from hospital computer systems and medical records, and the primary potential risk to subjects is improper disclosure of medical information. Data collected in this project do not include names, but do include identifying information (such as date of birth, date of visit(s) and date of admission(s)) that project investigators must protect the confidentiality of the research data in accordance with privacy regulations such as HIPAA. This will be accomplished with the following actions:

- All data will be maintained on secure servers.
- The patient log containing the patient's identifying information and unique identifying number produced by the EDC will be stored in a secure locked location. It is recommended that two copies of this record be retained in two different formats in two different physical locations.
- All data transmission will be encrypted, as described in the Data Management Section
- The PI and Research Coordinator at the Clinical Center and the DCC will provide documentation of human subject protection and research ethics prior to enrolling any subjects.
- All DCC staff work under strict confidentiality agreements.
- All analyses and reports will be presented in aggregate fashion.
- No identifiable data, either patient, clinician or site-specific, will be released by the CPRN through the DCC at any time. Requests for data will go through the CPRN and all aggregate data will be de-identified for site, subject and clinician. No collection or submission of data will occur at any specific Clinical Center until IRB/REB review has been completed at that site.

The Clinical Center is responsible for maintaining a log of patient name and medical record (MR) and generating a corresponding subject ID number that will be sent to the DCC. The DCC will at no time have access to the subject's name or MR number.

The DCC will assign each institution a unique Center Identifier so centers will not be identified by name within the database. Each participating center will also keep a log of clinician name and unique identifying number generated at the site. This unique number will be the only clinician identifier throughout the database and neither the DCC nor other CPRN clinical centers will be able to identify the clinician within the database.

Subjects can be entered into the CPRN Registry at several different points of care: at the time of diagnosis, at annual or follow-up clinic visits, during a pre-op clinic visit, or after other medical/surgical procedures for the management of cerebral palsy. A subject can have multiple entries correlated with the procedures performed at each intervention. It is the goal of the CPRN Registry to capture as many CP-related clinical events as possible to provide descriptive information regarding the management of these patients.

Human Subjects

Each of the Clinical Centers with the CPRN network will participate in the CPRN Registry after obtaining Clinical Center Institutional Review Board (IRB) approval or Research Ethics Board (REB) approval for the project. The institution originating the protocol (Nationwide Children's Hospital, Columbus Ohio) will obtain IRB approval at Nationwide Children's Hospital prior to submission of the protocol to the other CPRN clinical centers and the DCC. Other CPRN sites that are part of PEDSNet or the Pediatric Research Alliance will have the option of leveraging Nationwide's IRB approval as the IRB of record for the reliance model.

Recruitment Methods

Waivers of informed consent or parental permission and authorization are being requested to enter participants into the CP Registry. The criteria for waiver of authorization and informed consent and the justification for the waivers are presented below.

HIPAA Privacy Rule Criteria for Waiver of Authorization

1. The use or disclosure involves no more than minimal risk to the privacy of individuals

First, the nature of the research, which is designed to document ongoing care practices in CP clinics around the country, as is done routinely in quality initiatives, poses minimal risk to the welfare or general well being of treated persons and is limited to confidentiality and privacy. The care delivered to persons with CP is in no way linked to study participation.

Second, the registry has an adequate plan to protect identifiers from improper use or disclosure, which significantly reduces the risk to confidentiality and privacy. Key identifiers are maintained exclusively at Clinical Centers and neither reused or disclosed to others, except as required by law, as necessary for the oversight of the research, or as permitted by the Privacy rule for other research.The DCC will at no time have access to the subject's name or MR number.

2. The research cannot practicably be conducted without the waiver

First, requiring prior authorization for entry into the CPRN registry will likely result in selection bias and perhaps other biases in the data obtained, compromising the scientific validity of the study. Studies suggest major differences in care and outcomes between those who are enrolled in consenting registries and those who are not,[2] [3] [4] which results in the gathering of data of limited usefulness, and, consequently, undue burden on those who participate. Inclusivity and universality are key elements of an effective registry.

Second, due to the broad inclusion/exclusion criteria, the multiple potential points of entry into the study, and the variable set of clinical service contacts made by persons with CP, it is challenging to obtain the prior authorization of everyone who may qualify for the study (1) without the nuisance of multiple offers to participate, and (2) in a manner that ensures equitable opportunity to participate. Importantly, the care received by persons with CP is in no way connected with participation in the study.

3. The research cannot be practicably conducted without access to, and use of, the health information

By nature, the research, which is designed to document ongoing care practices in CP clinics around the country, cannot be practicably conducted without access ongoing care practices.

The Common Rule

1. The research involves no more than minimal risk to subjects

Per above, the risk is minimal.

2. The waiver will not adversely affect the rights and welfare of subjects

Per above, the care received by persons with CP is in no way connected with participation in the study.

3. The research cannot practicably be carried out without a waiver

Per above, requiring consent will likely result in selection bias and perhaps other biases in the data obtained, compromising the scientific validity of the study and resulting in undue burden for those who choose to participate.

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[2] Tu, J. V., et al. Impracticability of Informed Consent in the Registry of the Canadian Stroke Network. N Engl J Med 2004;350:1414-21.

[3] Dudeck J. Informed consent for cancer registration. Lancet Oncol 2001;2:8-9.

[4] Chertow GM, Pascual MT, Soroko S, et al. Reasons for nonenrollment in a cohort study of ARF: the Program to Improve Care in Acute Renal Disease (PICARD) experience and implications for a clinical trials network. Am J Kidney Dis 2003;42:507-51.

4. Whenever appropriate, subjects will be provided with additional information after participation

The purposes, procedures, and operations of the CPRN registry and the CPRN network have and will continue to be disclosed publicly.

Risks and Side Effects

This is a minimal risk study without direct patient intervention. The goals of this study are primarily descriptive of the CPRN patient population and internal network capabilities. Data will be acquired from hospital computer systems and medical records, and the primary potential risk to subjects is improper disclosure of medical information. The risk is minimized by the data management steps outlined.

Benefits

There are no direct benefits for study participants. This study will provide previously unavailable epidemiological information about cerebral palsy patients seen throughout CPRN. This information will provide the basis for multi-institutional studies to be carried out by the CPRN that may ultimately improve the clinical care for people with cerebral palsy throughout North America. The continuing collection of such information serves to provide data necessary for hypothesis generation and study design (i.e. preliminary power analyses, sample size determination, recruitment projections and practice variation for quality improvement protocols).

Financial Considerations

Research subjects will not be compensated for their participation, nor will study subjects incur any costs as a result of their inclusion in the study.

Record Retention

Following the guidelines for federally funded studies subject to the Common Rule, records relating to the research conducted shall be retained for at least 3 years after completion of the research. Completion of the research for this protocol should be anticipated to include planned primary and secondary analyses, as well as subsequent derivative analyses. Completion of the research also entails completion of all publications relating to the research. All records shall be accessible for inspection and copying by authorized representatives of the regulatory authorities at reasonable times and in a reasonable manner [45 CFR 46.115(b)].

Health Information Portability and Accountability Act (HIPAA)

A waiver of consent is requested because the data forms a Limited Data Set defined by HIPAA as protected health information in which direct identifiers have been removed but potential identifiers remain such as date of birth, hospitalization dates and relevant medical information. The following direct identifiers will NOT be collected for this study:

- Name
- Street address/postal address information

- Telephone and fax numbers
- Social security numbers
- Medical record numbers, or other account numbers
- Certificate/license numbers
- Vehicle identifiers or serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web universal resource locators (URL's) or Internet protocol address numbers
- Biometric identifiers such as finger and voice prints
- Full face photographic images or any comparable image

The Data Coordinating Center will offer a Business Associate Agreement to each Clinical Center to authorize its creation of a completely de-identified database for use by CPRN investigators.

Data Management

Data Set Description

The entire common data model is available here:
https://docs.google.com/spreadsheets/d/1p2XkGDOVTfV5VWy0s6CWwsobyAyrvcE16_mx3rfYHaI/edit?usp=sharing

Health Information

A range of clinical care data will be collected, including the following: non-identifier demographics, birth history, anthropometric data, nutritional plan and history, medical and surgical history (including relevant medical findings from other departments, such de-identified results of imaging, lab results, hospitalizations, emergency room visits, and immunization history), quality of life and other patient-reported outcomes, gross and fine motor function, communication function, sensory difficulties, range of motion, strength, spasticity, timed functional tests, durable medical equipment use, parent-reported academic information, behavioral assessments, use of ancillary services (e.g., participation in rehabilitation therapies), details of surgical procedures, and patient/caregiver reported outcomes.

Protected Health Information

In addition, 2 of the 18 Health Insurance Portability and Accountability Act (HIPAA) identifiers, birth dates and dates of clinical services, will also be collected.

Data Access

The following data access and security methods will be used to transmit, manage and store the data. For a complete description of the DCC security infrastructure see Section Data Security on page 16.

- The EDC system features 128-bit SSL data encryption to ensure data security over an internet connection.
- The system is configurable for access restrictions by Site and Role base level with an audit trail.

- Hourly incremental backups and full daily backups provide a high level of protection against data loss.

Clinical Site Monitoring

In most multi-institutional studies, the DCC assigns a site monitor to travel to each Clinical Center at times appropriate to the specific study, to ensure that all regulatory requirements are being met and to monitor the quality of the data collected. The CPRN investigators recognize the importance of ensuring data of excellent quality and recognize that site monitoring is critical to this process.

Site monitoring visits are conducted to review compliance with the study methodology and adherence to Good Clinical Practice guidelines. During site monitoring visits patient forms and original source documents will also be inspected. The primary criterion for data element verification is identification in the source document, which is the medical record. Thus, the medical record, either hard copy file or access to the electronic medical record system, must be available for review by the site monitor.

The DCC may supplement on-site monitoring with remote monitoring activities. Remote monitoring involves detailed review of the data entered by the Clinical Center and telephone consultations with the Clinical Center investigator and/or research coordinator to review and verify selected data elements. This requires uploading de-identified copies of specific parts of the medical record to the DCC staff, who review those materials against the data recorded in the EDC system.

The site monitor will provide the study investigator and research coordinator with a written report and Clinical Centers will be required to follow up on any deficiencies.

Data Analysis

Primary Objective

To describe the number and characteristics of cerebral palsy patients and interventions at CPRN Clinical Centers such as patient demographics, etiology of CP, diagnostic information, surgical management decisions, medical management decisions and patient reported outcomes.

Secondary Objective

To provide this data to CPRN investigators to support hypothesis generation and study design development for clinical trials and observational studies to be carried out by the CPRN. It is expected that the CPRN Registry will provide an infrastructure for the execution of future multi-institutional research, such as clinical trials and observational studies, on cerebral palsy within CPRN.

Each Clinical Center will only have access to their Center's data. If a CPRN Investigator requires access to aggregate data across the CPRN, they will need to send a request to a CPRN

investigator committee responsible for the use of aggregate data. The committee will evaluate the project under consideration and will then forward the request to the DCC who will package and export the data as a Limited Data Set to the CPRN Investigator.

All research publications and presentations arising from this study will be presented in aggregate form, and at no time during or after the study will any research data be released by CPRN, DCC, or private funders with patient, surgeon or center identifiable fields.

Accrual Projection and Study Duration

As the primary unit of analysis for this project is the network itself, the entire population of all cerebral palsy clinic and intervention patients is included. It is estimated that there will be approximately 1500 surgical procedures a year within the CPRN. We anticipate open-ended data collection over several years, allowing for analysis over time (Primary Objective). In order to perform preliminary power calculations on diagnostic and therapeutic subsets of patients, it is critical to include the entire population of CPRN cerebral palsy visits and interventions rather than adopting a sampling approach (Secondary Objective).

Data Safety Monitoring Plan

All procedures and interventions are conducted as part of clinical care and the range of possible study events having an important impact on risks and benefits to study participants is limited. The probability and magnitude of harm and/or discomfort anticipated in the research is not greater than that ordinarily encountered in daily life. As such, oversight of an independent Data Safety Monitoring Board is not warranted. Data safety and quality reports will, however, be compiled at the DCC at the University of Utah on a yearly basis and disseminated with the site PIs in the Scientific Steering Committee.

These reports will include: study accruals, unanticipated problems, extraction statistics, the identification of the cause of failed extracts, and any data breaches reported by Clinical Centers. The DCC staff will investigate all breaches and extract failures, collaborate with, and advise Clinical Centers on their findings to formulate appropriate solutions. Reports will be generated by Susan Horn, Jacob Kean, and Vikrant Deshmukh.

Data Security

The Data Coordinating Center (DCC) at the University of Utah relies on the University's existing infrastructure which includes a dedicated hosting all main campus and health sciences servers in a secure facility that conforms to Federal and Utah state standards for security. The DCC has a state-of-the-art server infrastructure, with enterprise high availability features like clustering, load-balancing, transparent failover, etc., and enterprise security features like stateful firewalls, network segmentation, intrusion detection, monitoring, and 24/7/365 support by dedicated Database, Server, Network and Security teams at the University. Communication over public networks is encrypted with using secure socket layer (SSL) or virtual private network (VPN) technologies.

Direct physical access to the DCC server infrastructure is highly restricted, and remote access to most server infrastructure incorporates multi-factor authentication. Additionally, routine vulnerability scanning and patching is performed on a set schedule for servers hosted in DCC, and each server is additionally assigned a technical owner and a business owner, who are personally responsible for ensuring the technical security as well as adherence to University of Utah Information Security Risk Management.

The investigators and staff of the DCC are fully committed to the security and confidentiality of all data collected for CPRN studies. All personnel at the Data Coordinating Center at the University of Utah have signed confidentiality agreements concerning all data encountered in the center. Violation of these agreements may result in termination from employment at the University of Utah. In addition, all personnel involved with the DCC have completed Human Subjects Protection and HIPAA training.