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Principal Investigator	Alyna Chien, MD
Protocol Number	IRB-P00038711
Protocol Title	Health Care Transitions and the Health of Adolescents and Young Adults with Intellectual or Developmental Disabilities
Date:	June 7, 2021

NOTICE OF EXEMPTION

IRB Exemption Date: 6/2/2021

Please Note: The initiation or continuation of clinical research activities must follow the Boston Children's Hospital (BCH) advisories or policies. The IRB is continuing to review protocols; **however, BCH is currently restricting the conduct of clinical research in response to the COVID-19 crisis**. Details of these restrictions and an IRB Q&A document are available at https://www.childrenshospital.org/research/institutional-review-board/latest-resources-and-references and both will be updated as changes are implemented. Please contact the IRB Office with any questions you may have.

The Institutional Review Board (IRB) has reviewed the above referenced protocol and determined that it qualifies as exempt from the requirements of 45 CFR 46.

This protocol was determined to be exempt because it is limited to research activities in which the only involvement of human subjects will be in the following category described in 45 CFR 46.104 (d):

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

> (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b);

Sincerely,

Anna Mitchell, IRB Administrator
For the Institutional Review Board

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RESEARCH STRATEGY

1. SIGNIFICANCE

1.0 Adolescents and young adults with intellectual or developmental disabilities (IDD) are a sizeable and growing population. Intellectual or developmental disabilities are "neurodevelopmental disorders that begin in childhood and are characterized by…difficulties in conceptual, social, and practical areas of living."[46] The prevalence of childhood IDD has tripled over the past 50 years with earlier detection and fewer children dying from previously lethal conditions (e.g., congenital syndromes).[47–50] Currently, between 3–5% of adolescents and 7–10% of young adults have IDD; this totals to 2.6 and 4.8 million in the United States.[2–6]

Although adolescents and young adults with IDD today live longer and with better quality of life than those in prior decades, they still suffer from excess morbidity.[23,24] Common chronic conditions that usually begin in middle-age (e.g., hypertension, hyperlipidemia, diabetes) can present in young adulthood and recommended elements of care (e.g., reproductive health screenings, avoidance of polypharmacy) can be overlooked.[5,6,12,51–53] Youth with IDD are also at-risk for hospital-based services for conditions thought to be avoidable through high-quality ambulatory care (e.g., dehydration, pneumonia, cellulitis); avoidable hospitalization rates rise more for those with IDD during adolescence than those without such that by young adulthood these rates are twice those in childhood or middle-aged adulthood.[54–62]

Maintaining the health of adolescents and young adults with IDD can be complex—certain aspects of care are routine (e.g., immunizations, reproductive health services), but much can be complex. People with IDD frequently have neurologically-based co-morbidities (e.g., epilepsy; cranial anomalies, sleep disorders) and nearly three-quarters have co-impairments (in the realms of mobility, hearing, seeing, and mental health).[63–66] Adolescents and young adults with IDD tend to benefit from primary care and specialist physicians who manage this complexity while also accomplishing basic medical tasks (e.g., oral exams, blood draws) using behavioral or environmental approaches rather invasive tactics (e.g., physical or chemical restraints).[25,67–70]

1.1 Health care transitions (HCTs) have been defined as the, "purposeful, planned movement of adolescents and young adults…from child-centered to adult-oriented health care systems."[14–17] Guidelines for what constitutes a high-quality HCT have been established,[14–17] and several nationally-representative surveys have found that most patients do not receive any HCT or have poor HCT experiences.[20,22,71] Yet several systematic reviews, including a recent systematic review of systematic reviews, find the lack of longitudinal study opportunities to be a major barrier in HCT research.[72] Most studies are cross-sectional and if there is follow-up, that duration ranges from four to 12 months.[72] Basic facts about how HCTs proceed *in vivo* for large populations of adolescents and young adults with IDD have yet to be established and existing paradigms may need to be revisited.

Such investigations are likely to shed light on current guidelines which envision the transfer of care from child-oriented physicians to adult-oriented ones to occur between ages 18 and 21.[14–17] While this paradigm is likely applicable to HCTs involving primary care, it does not appear to fit the realities of how children with complex or disabling health conditions access specialist services currently (**Figure 2** in Approach).[72,73] The pediatric specialist workforce is small—nationally there are 800 developmental/behavioral pediatricians, 2,000 pediatric neurologists, and 8,000 child psychiatrists, compared to 18,000 adult-oriented neurologists and 49,000 general psychiatrists.[74] HCTs for those with IDD will likely need to address the role of adult-oriented specialists in addition to the pediatric specialists.[75–78]

1.2 Quality of clinical care for adolescents and young adults with IDD during HCTs. Many hypothesize that faulty HCTs cause adolescents and young adults with IDD to forgo recommended care (preventative and chronic disease management); health then decompensates until emergency or inpatient treatments become necessary.[18–27] Many have started to assess the quality of care delivered to people with IDD while they are in HCTs using surveys that assess receipt of or satisfaction with HCT planning services, whether care is being delivered within a medical home, or how frequently transitionally-aged people with IDD engage in healthy lifestyles or rate their own health as "excellent."[33,53,79–87] Some of the challenges faced by survey-based studies is that they end or begin at age 18 and cannot observe the full period of interest. One of the advantages of health plan data is that it allows for observation of patients when they may be in HCT from one physician to another. The timings of such transfers can be used to set a beginning and an end to a transitional period, and then investigators will be able to compare how care quality may differ when people with IDD are in HCT versus when they are not.[29,72,88,89]

Recently, several factors have culminated to make a claims-based assessment of care quality during HCTs versus not feasible for adolescents and young adults with IDD. First, the two payers that most frequently insure adolescents and young adults—Medicaid and private health plans—started existing in the same datasets termed "all-payer claims databases." Thereafter, a handful of states developed the ability to track enrollees across health plans and over time (otherwise a state's Medicaid data would just exist side-by-side with its private health plan data and switches from one type of health plan to another was not observable). Second, a conceptually-grounded validated method for identifying people with childhood-onset disabilities the Children with Disabilities Algorithm (CWDA) was created in 2015; tested in Medicaid in 2017; and tested in a commercial health plan in 2019.[5,6,42] Prior to that time, investigators were restricted algorithms that relied on body system counts, adults algorithms, or were designed to predict pediatric spending as opposed to clinical complexity or severity.[90–92] Lastly, concepts and quality measures for pediatric health care began in earnest after the 2009 Children's Health Insurance Program Reauthorization Act established the Pediatric Quality Measures Program through funding from the Agency for Healthcare Research and Quality (AHRQ) and support from the Centers for Medicare and Medicaid Services (CMS).[93,94] Since 2015, over 20 claims-based pediatric measures have become available for use and can be combined with those that have already been developed for adults.[44,95]

1.3 Insurance gaps for adolescents and young adults with IDD. Using survey methods primarily, a handful of studies have assessed if adolescents and young adults with IDD have "any" insurance "in the past year."[5,6,29,33,53,80–85] In addition, most studies could not disentangle the types of payers involved in insurance gaps. The vast majority of youth with IDD are insured by either Medicaid or private insurers, so it is important to study data from these payers.[107,174,183] To our knowledge, none have been able to assess when and how frequently adolescents and young adults with IDD experience insurance gaps (i.e., days for which they lack insurance coverage altogether) or switches (i.e., change from a private health plan to Medicaid or vice versa). (Approximately 1% of the pediatric-aged population is insured via Medicare, so Medicare is not a major source of insurance for adolescents and young adults with disabilities.[96]) it is also important to study the period following the 2010 Patient Protection and Affordable Care Act, when national uninsurance rates fell such that by 2015, less than 10% of the US population lacked health insurance.[97–102]

1.4 Insurance gaps associated with Medicaid's age 19 eligibility rules. Medicaid's eligibility rules center on age 19. This is the age by which those who might not have qualified for Medicaid when they were children can do so as adults meeting its categorical eligibility criteria (e.g., poverty, pregnancy, parenthood, qualifications for the Supplemental Security Income program).[103–105] Age 19 is also the time when childhood beneficiaries of Medicaid "age out" and must re-apply for Medicaid coverage, and only two-thirds will requalify.[104,106] Thus, up to 10% of those insured by Medicaid as adolescents are likely to insurance gap around age 19.[107]

Medicaid's age 19 eligibility rules also affects privately-insured adolescents. Available studies find that 8–10% of privately-insured adolescents with disabling health conditions will switch to Medicaid as young adults, although most will not switch to Medicaid if they are able to maintain dependent coverage on a parent's insurance plan (until the age of 26 for Colorado, Massachusetts, and New York).[24–30,98] A small proportion (5–8%) of Medicaid-insured adolescents with disabling health conditions will change to private insurance as young adults.[30–32,103,107]

2. INNOVATION

The proposed study is innovative in four main ways. First, it combines three newly available claims-based resources to create multi-payer longitudinal datasets of 69,000-217,000 adolescents and young adults with IDD. So 10 to 100 times larger than what has been typically available for study to date,[29] even larger than the Centers for Disease Control's Metropolitan Atlanta Developmental Disabilities Surveillance Program, one of the oldest and longest running cohorts, which totaled 5,590 people after nearly 10 years.[108] These data also allow for multiple measurements of the same person over multiple years as they experience insurance gaps and change.[35,40,41] The combination of three states of all-payer claims databases will also enable us to observe care being delivered in all types of regions within a state (urban, suburban, and rural). Claims data is also constantly being renewed so less susceptible to the inherent challenges created by having to rely upon large-scale surveys that pause their efforts for several years of time.[108–112]

Second, using these novel cohorts of adolescents and young adults with IDD, our research will be the first to contribute *in vivo* information about how adolescents and young adults with IDD proceed through HTCs. While current paradigms have been informed by people with IDD, their families, clinicians, and professional societies,

the field has lacked insights based on the trajectory of large populations of youth with IDD as they move through the real world and obtain insurance and health care in a variety of communities rather than trial settings or the important but rarified environment of a children's hospital. What we learn is likely to shift existing paradigms about the types of physicians caring for people with IDD depend upon and the ages at which ambulatory care transfers of care occur. This descriptive analysis represents a foundation for those interested in developing broader delivery systems, insurance reforms, or design payment policy interventions (e.g., value based purchasing agreements targeting HCTs) to work.

Third, this study will be the first to measure important features of clinical care during HCTs, both in terms of desired and undesired elements of care, but also in how care quality may differ during HCTs and outside of them. Because our study team is expert in clinical care quality measurement (adult and pediatric), we will be able to make quality assessments while taking IDD co-impairments and comorbidities into account.[6,10,13,66,113]

Fourth, by identifying a natural experiment (Medicaid's age-eligibility requirement at 19 years), this study introduces rigorous quasi-experimental methods that can be used broadly in the field of IDD research. As a recent systematic review of systematic reviews surmised, studies specifically focused on the IDD population and those with more rigorous studies are much needed.[72]

In summary, the proposed study overcomes several major challenges facing the field of IDD research—a longitudinal database; a broad range of HCT, clinical care, and insurance gaps measurement approaches; and a quasi-experimental approach—it will substantially advance our understanding of health and HCTs for adolescents and young adults with IDD, and pave the way for future disabilities study approaches. This proposal also addresses two of the Intellectual or Developmental Disabilities Branch priorities to "understand the complexity of comorbid symptoms of IDD" and "translational or implementation research."

3. APPROACH

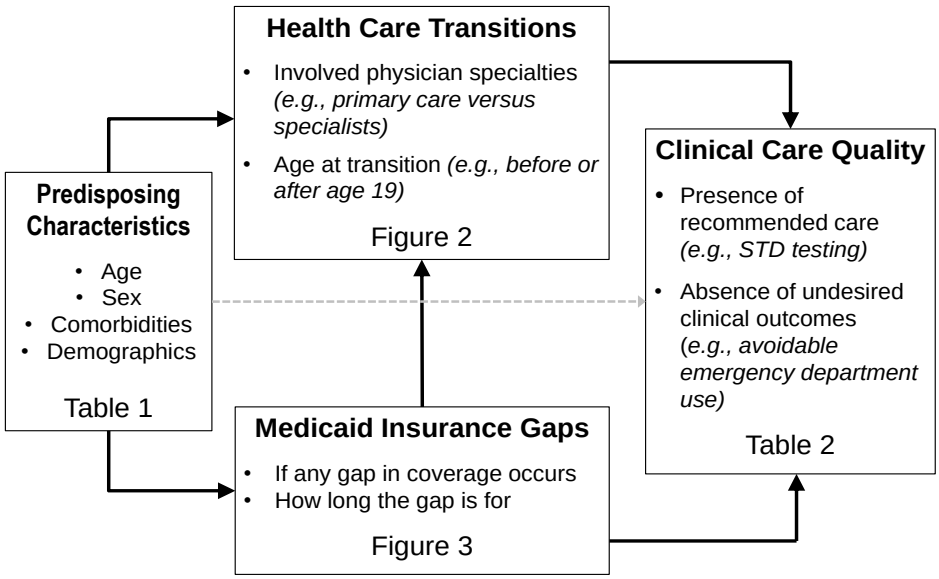
3.0 Research Team. The research team consists of several accomplished, long-time collaborators at Harvard Medical School, Harvard T.H. Chan School of Public Health, and the University of California-San Francisco, each of whom has each been engaged in disabilities-related research for the past 10-20 years.

PI Chien is a physician researcher who is expert on the effect of incentives on care access and quality for medically and socially vulnerable populations.[114–117] **PI Chien** along with several members of the current study team developed the Children with Disabilities Algorithm so that it could be used to assess the health of populations of persons with disabilities within the proliferating number of large administrative databases as the current study proposes.[42] **Senior Co-I Meara** is a PhD economist and Professor of Health Economics and Policy at the Harvard T.H. Chan School of Public Health. She brings extensive expertise modelling the effect of public policies on the use of health care and clinical outcomes for young and older adults with disabilities, and has many published studies of how age-eligibility affects insurance and subsequent health care.[99–102] **Senior Co-I Landrum** is a PhD biostatistician and Professor of Health Care Policy at Harvard Medical School and expert in methods for assessing clinical care quality and outcomes using observational data;[118–125] she has been serving as the chief biostatistician for Dr. Chien's disability-related studies (published[5,6,42] and ongoing). Econometrically-trained analyst **Co-I Dr. Samnaliev** is a PhD economist whose career has focused on implementing comparative effectiveness analyses in large databases.[126–129] He has the track record needed to implement the descriptive longitudinal analyses and also the requisite training to work closely with **Senior Co-I Meara** to execute the regression discontinuity design of Aim 4. **Co-I Okumura** is a dually-boarded general pediatrician and internist health services research who has over 14 years of experience investigating HCTs for adolescents and young adults with IDD and then developing delivery system interventions that improve health care access and health. Co-I Okumura serves on research-oriented HCT organizations nationally and internationally (e.g., Advisory Committee, National Children with Special Health Care Needs Research Network; Scientific Co-Chair, International Health Care Transition Research Consortium). **Co-I Toomey** is PI of Boston Children's Hospital's Pediatric Quality Measures Program Center of Excellence,[130] which initially developed and validated CWDA,[5,6,42] along several other quality measures: a HCT experience survey,[19] Child Hospital Consumer Assessment of Healthcare Providers and Systems survey,[37,39] pediatric hospital readmissions,[59,131] and a pediatric patient safety trigger tool.[132] **PI Chien** continues to be a co-investigator in BCH's Pediatric Quality Measures Program Center of Excellence.

National Advisory Board (NAB). Our NAB is a multi-disciplinary group of adult and pediatric experts in HCTs for adolescents and young adults with IDD. Our national experts represent a variety of backgrounds: research, clinical, delivery system innovation, and advocacy. Easterly is a member of the President's Committee for People with Intellectual Disabilities; Holder is the Chief Executive Officer of Kentucky's first interdisciplinary clinic focused on adults with IDD and Chair of the Medical Advisory Committee for Special Olympics. Houtrow is a member of the National Academies of Medicine; Kuhlthau is PI of the Autism Learning Health Network based at Massachusetts General Hospital; McManus is Co-Director of Got Transition®, a federally-funded resource for delivery system and payment innovation; and Mitra is Director of the Lurie Institute for Disability Policy at Brandeis University.

Expert Panel. Our 13 member Expert Panel contains the clinical experts (physicians and non-physician) important to the care of adolescents and young adults with IDD and their most likely co-morbidities or risks for poor quality clinical care. Our panel members represent primary care (i.e., pediatrics, family medicine, and internal medicine) and specialists (e.g., pediatric neurology, general psychiatry, child protection pediatrics) in community and academic settings. In addition, we can draw on the expertise of the 42 different types of clinical experts involved in the development of CWDA. The investigative team has ample experience conducting observational and quasi-experimental studies using claims data, including the assessment of care quality and insurance coverage.

Figure 1. Conceptual model



3.1 Conceptual model. Our conceptual model (**Figure 1**) is grounded within concepts and definitions of: **A.** disabilities as articulated in the 2006 United Nations' Convention on the Rights of Persons with Disabilities, the 2001 International Classification of Functioning, Disability, and Health; and our own work introducing human development principles to produce functioning expectations appropriate to child, adolescent and young adult periods of life;[42,133-135] **B.** HCTs as outlined by current guidelines, consensus statements, and position papers and the International Health Care Transition Research Consortium;[42,65,136,137] **C.** Evidence-based clinical care and utilization outcomes for adolescents and young adults; and **D.** Our understanding of health insurance policy generally and with respect to Medicaid specifically.

3.2 Overarching study approach and study population. Our overarching study approach will be to conduct descriptive analyses for Aims 1 through 3, and a regression discontinuity analysis for Aim 4. We will identify individuals with IDD aged 10–28 years living in three states between 2014 and 2018 using publicly-available all-payer claims databases (**Table 1**).[41,138–140]

Based on past and ongoing work with these datasets, about 45% of enrollees are continuously insured for 11 months each year, the mean number of years that individuals are present within these datasets is over 3 years, and at least one-third will be able to be observed for four to five years.[141]

For Aims 1 through 3, which uses the entire population of adolescents and young adults with IDD across all data years, we conservatively estimate that we will be able to identify over 69,000 and 85,000 and 217,000 in Colorado, Massachusetts, and New York state, respectively. For Aim 4, we estimate that we will have over 7,800, 5,500, and 18,900 17-21 year olds in each state, respectively.

3.3 All-payer claims databases for Colorado, Massachusetts, and New York. All-payer claims databases are aggregations of health plan claims data from Medicaid and private health plans in each state (50 to 100 plans per state); these are publicly available datasets that anyone can purchase.[41,138–140] Medicaid includes those in Children's Health Insurance Programs; private health plans include all employer-insured plans and most self-insured plans within each state. Colorado, Massachusetts, and New York state databases include health plan enrollment files (e.g., coverage dates and source), claims paid for medical (including mental/behavioral health), pharmacy, and dental services, and provider files (types of entities and personnel delivering services). All three provide the ability to track individuals longitudinally across health insurance plans via state-determined matching processes. For Medicaid and employer-sponsored private health plans, plan participation is 100%. For self-insured private health plans, participation is lower because *2016 Gobeille v. Liberty Mutual Insurance Co., Inc.* eliminated the mandate for database participation, but many self-insured health plans still submit their data voluntarily. Ultimately, we expect 67-75% of privately-insured individuals to be present in each database. The proportion of those dually insured by Medicaid and Medicare is not observable because Medicare is not present within these databases.

Table 1. Study population estimates: unique 10-28 year olds, each all-payer claims databases, 2014-2018

	Colorado	Massachusetts	New York
Per American Community Survey[97]	1,410,330	1,741,100	5,017,291
Less percent uninsured	9.4%	3.0%	7.6%
Portion of self-insured not reported	18.8%	22.5%	26.3%
Expected in all-payer claims dataset	1,013,322	1,297,120	3,318,938
Observed in all-payer claims datasets[138-140]	**1,038,336**	**1,277,759**	**3,245,184**
Mean number of data years per enrollee	3.6 (1.2)	3.8 (1)	3.7 (1.1)
Continuously insured for ≥ 1 month	994,353	1,223,634	3,107,720
For Aims 1 through 3: With intellectual or developmental disability (IDD)[2-6]	**69,605**	**85,654**	**217,540**
By age in years and developmental stage:			
10-13 early adolescence	14,105	15,695	40,219
14-18 middle adolescence	17,274	22,020	53,569
19-21 late adolescence	10,837	14,170	35,255
22-24 young adulthood	11,102	14,468	36,565
25-28 adulthood	16,288	19,303	51,932
By insurance source			
Medicaid	61%	35%	47%
Privately insured[40,41]	39%	65%	53%
For Aim 4: Medicaid-insured 17-21 year olds	**7,855**	**5,546**	**18,915**

3.4 Children with Disabilities Algorithm (CWDA). We will identify adolescents and young adults with IDD using the CWDA tools that we have developed.[42] In 2015, we developed CWDA-9 (i.e., CWDA using the International Classification of Disease-Clinical Modification [ICD] Version 9).[42] As post-2015 data has become increasingly available, we have converted CWDA-9 to CWDA-10 (i.e., CWDA using ICD version 10) and have been using both in ongoing work.[73] CWDA-9 captures the diagnostic codes being used in the United States through September 30, 2015; CWDA-10 does the same for claims generated after October 1st, 2015. **Co-Is** Landrum, Okumura and Toomey**; NAB** members Houtrow and Kuhlthau; and **Expert Panel** members Kuo, Schuster, and Van Cleave were on the team that created CWDA using the International Classification of Disease-Clinical Modification Version 9 and have helped to convert it to Version 10 and test it in national commercial health plan.[42,65,73]

CWDA is unique in its: **a.** conceptual grounding in international concepts and definitions of disability (rather than just from a medical or billing perspective[133,134,184]); **b.** the involvement of 5 nationally-drawn experts on pediatric disability plus 42 pediatric specialists representing all board-certified pediatric specialties and including those most relevant to IDD such as developmental and behavioral pediatricians, child psychiatrists, and pediatric neurologists (most algorithms involve 2-3 clinicians or researchers from the same institution[90-92,113,142,143]); **d.** its validation which comprised parental assessment of their children's types of impairments and functioning plus physician assessment of patients along the same dimensions (not just physicians examining the face validity of codes[92]); and **d**. the application of CWDA in databases covering 3.7 million Medicaid or commercially-insured children in total across 11 states which yielded disability prevalence comparable to that identified via nationally-representative surveys, and thus provides evidence of population level external validity.[5,6]

Beyond its initial development, we have tested CWDA in different countries (i.e., United States, United Kingdom, and Canada) and these tests confirm that outpatient billing in the United States is robust enough to

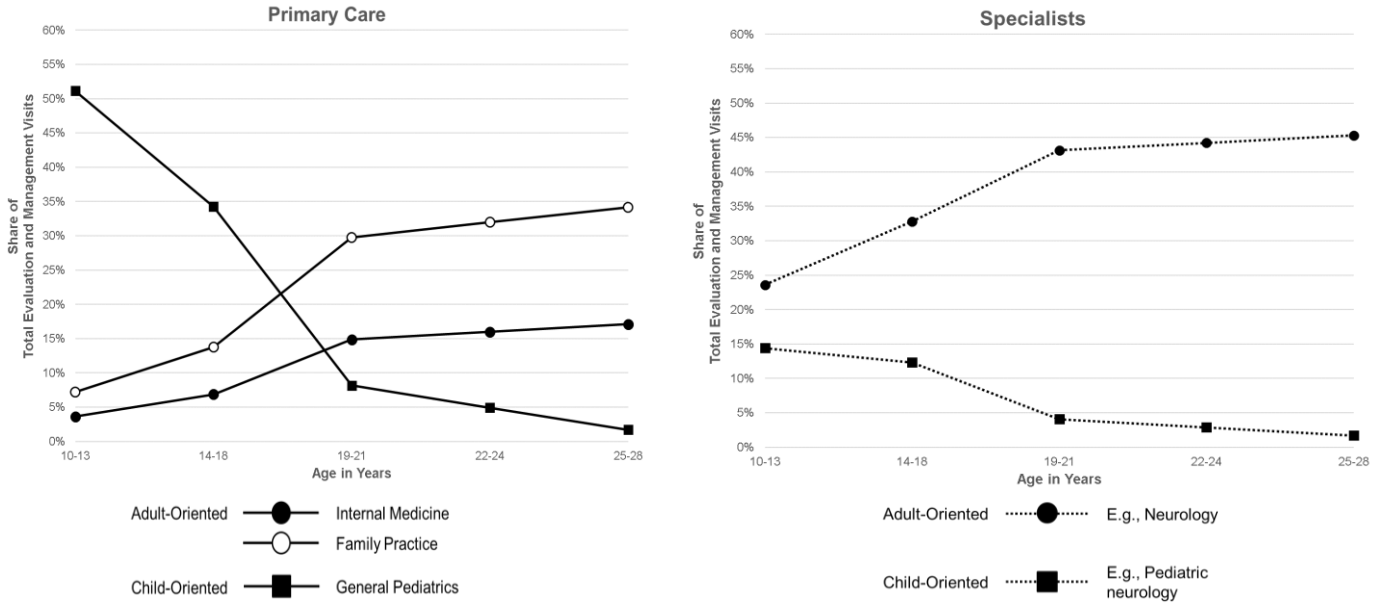
identify those with childhood-onset disability at a prevalence level consistent with nationally-representative surveys.[5,6,42,144] We have also used CWDA in the administrative datasets for which the algorithm was designed (e.g., Medicaid claims, private health plan claims, and electronic health record data) and data years going back to 2008 and through the proposed time period 2018.[5,6,73,141,148] To separate those with childhood-onset IDD from those without IDD impairments, we will use the crosswalk that we have developed to link clinical diagnoses and their corresponding impairments.[65]

3.5 Characterizing child-to-adult HCTs as pediatric-to-adult transfers. For the purposes of these analyses, child-to-adult HCTs will be operationalized as pediatric-to-adult transfers, i.e., for a given youth, a type of pediatric generalist or specialist that stops appearing at a given age while and the adult-oriented counterparts that begins (e.g., claims for general pediatricians stop at age 20 and claims for general internists begin at age 21). In this schema, shifts among adult-trained physicians will not be considered pediatric-to-adult transfers or child-to-adult HCTs. Care delivered by adult-trained physicians, will, however, be quantified because family practitioners and adult-oriented specialists represent an important workforce caring for children with chronic, complex, and disabling health conditions even when these children are very young in age.[73] They do not represent the archetypical pediatric-to-adult transfer that are so concerningly disruptive; in fact, adult-trained physicians that become involved in the care of IDD when they are children might represent a more stable form of child-to-adult HCTs and our characterization approach retains this descriptive possibility.

Non-physicians (e.g., advanced practice nurses, physician assistants) are also designated as providers in claims, but their descriptions typically lack the specificity need to characterize training or orientation as “pediatric” versus “adult,” but we can quantify how frequently services delivered by non-physicians occur during HCTs.

The mechanics by which we classify physician specialty begins with the fact that such information is present in “evaluation and management” claims then connected to taxonomy used by the American Board of Medical Specialties for its 98 unique board-certifications.[149] The mapping procedure was developed by **PI Chien** National Bureau for Economic Research’s Center of Excellence on Comparative Health Systems.[150] Use of this approach is illustrated below **(Figure 2).**[20,77,147,151–154]

Figure 2. Share of ambulatory visits to child- versus adult-oriented physicians



3.6 Clinical care quality during HCTs. We will use National Academies of Medicine (formerly the Institute of Medicine) paradigms and both established and exploratory to assess clinical care quality for young adults with IDD, including detection rates for potentially concerning issues, and avoidance of undesired clinical events such as avoidable emergency or inpatient care (**Table 2**).[155]

Table 2. Clinical care quality measure examples

Recommended clinical care	
General health maintenance	Adolescent well-visit measure (12-21 year olds) Annual influenza immunization At least 1 dental exam annually
Rates of screening for at-risk conditions	Hyperlipidemia testing Hemoglobin A1c testing Pap smears when >21 years Pregnancy screening Sexually transmitted infection testing
Chronic disease management (if condition is present)	Asthma (e.g., controller medications if persistent) Follow-up visits when new psychotropic medications are prescribed (e.g,. ADHD, depression) Diabetes (e.g., hemoglobin A1c testing twice annually) Epilepsy (e.g., annual visit)
Potentially concerning issues	
Rates well above or below average	Abuse, neglect, domestic violence Contraception prescription rates Polypharmacy rates, number of sedative, hypnotic, anti-depressant and anti-psychotic medication classes being filled Sedation for routine dental care, imaging tests or diagnostic procedures
Undesired clinical events	
Emergency and inpatient services	Avoidable emergency department visits Avoidable hospitalizations Hospital 30-day readmission rate

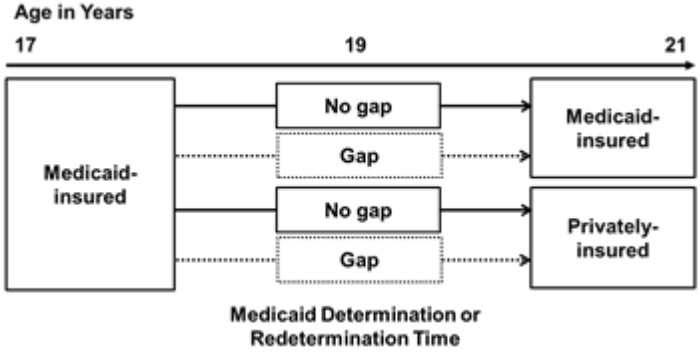
*In the post-October 2015 dates, we may be able to examine body mass index via International Classification of Disease-Version 10.

We will prioritize elements of care that current research or clinical guidelines indicate are important for adolescents and young adults with IDD.[156–167] Reproductive health requires attention because adolescents and young adults with IDD are as sexually active as their counterparts without IDD, but are also at elevated risk for abuse and poor pregnancy outcomes (premature, low birth weight, or stillborn infants).[160–163,168–170] Given how complex medical care for adolescents and young adults can be and how uncomfortable adult primary care physicians have reported feeling when caring for childhood-onset serious medical conditions, it is important to ascertain the degree to which adolescents and young adults with IDD are receiving a comprehensive range of preventive and chronic disease services delivered across outpatient primary care and specialty settings.[164–166] Although quality of life was considered the most important outcome in a Delphi study of 100 experts, health insurance and health services outcomes (e.g., having a medical home), avoiding of unnecessary hospitalizations was also prioritized.[171]

Currently, **Table 2** is restricted to diagnoses, measures and algorithms that can be reliably ascertained in claims data, or occur at frequencies in which change can be measured. However, we will also explore the feasibility of including co-morbidities for which claims have historically been less reliable (e.g., obesity) or for which frequencies may be low (e.g., rates of detecting injury, abuse, or neglect). Where possible, we will draw on established methods endorsed by the Agency for Healthcare Research and Quality (AHRQ), the National Committee for Quality Assurance (aka NCQA), and Healthcare Effectiveness Data and Information Set (aka HEDIS).[172] All members of our study team have substantial experience developing quality measures, and they have experience adapting and applying such measures to health plan claims.[22,25-28,83–102]

3.7 Insurance gaps associated with Medicaid age 19 eligibility rules. To characterize insurance gaps associated with Medicaid's age 19 eligibility rules, in the overall 10-28 year old cohort of individuals with IDD, we will first tabulate the frequency at which enrollees are missing at least one month of insurance (months are the highest level of granularity across the payers in these datasets). We will then examine the number of months for which insurance is missing for both types of insurance (Medicaid versus private) as a function of age. Those disappearing from the data will be presumed to be uninsured while those reappearing will be considered to have experienced a gap. If a gap has been experienced, then we will characterize whether the insurance occurred as a part of staying on the prior source of insurance (i.e., a Medicaid gap or a private insurance gap) or as part of an insurance switch (i.e., a Medicaid-to-private switch

Figure 3. Insurance gap possibilities



gap, a private-to-Medicaid switch gap) (**Figure 3**). In this schema, in APCD data, an adolescent enrolled in Medicaid each month at age 18, but not enrolled in Medicaid upon turning 19 will be classified as having experienced a Medicaid gap.

We will validate this procedure by comparing the rate of Medicaid, private, or no coverage (at ages 18 and 19) to measures for our three states from population-based estimates drawn from the American Community Survey, a household survey of US residents. For Aim 4 and the regression discontinuity analysis, we will pay particular attention to how such gaps and switches proceed for cohorts with Medicaid coverage at 18 in the months before and after their 19th birthday.

In descriptive analyses, we will examine whether the presence or duration of gaps differs according to demographics (e.g., sex, geocoded sociodemographic background, rural residence) or clinical characteristics (e.g., additional co-existing impairments, comorbid complex or straightforward chronic conditions) estimating separate models for Medicaid- and privately-insured individuals. After identifying missing months, we will identify the insurance sources in the months flanking insurance gaps.

3.8 Covariates. In our estimation models of the prevalence of clinical outcomes, health care transitions, and in models relating health insurance gaps to health care transitions, most covariates will relate to a beneficiary's demographics (age, sex, geocoded sociodemographic background based on linking 3 or 5-digit zip codes to the American Community Survey), and clinical background (co-existing non-IDD disability or complex versus straightforward co-morbidities).[5,6,48,49,115] Sex is a biological variable because drivers of IDD, co-impairments, co-morbidities and service use can all vary by sex (e.g., almost all recognized Mendelian intellectual disability is X-linked; males are more likely to be hospitalized than females).

3.9 Analytical approach. To improve the scientific rigor of all our analyses, we will develop a deep descriptive understanding of this longitudinal cohort prior to proceeding to our Aims, examining frequencies of basic demographics and prevalence of key clinical characteristics of adolescents and young adults with and without IDD, and percent Medicaid versus privately-insured. We will verify the degree to which beneficiaries are present in our respective all-payer claims databases across our first year of data (2014) and continuing through our fifth (2018). We will make careful final inclusion/exclusion criteria in order to create our analytic files. We will also examine general utilization patterns across all available benefits and services (outpatient, emergency department, inpatient, and pharmacy).

3.10.1 Aim 1: Characterize health care transitions for adolescents and young adults with IDD with respect to the types of physicians involved and the ages across which shifts occur.

Hypothesis: Child-to-adult HCTs will vary according to patient demographics, clinical characteristics and clinical care context.

First, we will tabulate the volume of health care interactions that our cohort of individuals with IDD made during the study period and percents of total ambulatory visits made to pediatric versus adult-trained primary care physicians and pediatric versus adult-trained specialists (see **Figure 2**) as a function of age. In descriptive analyses, we will also examine whether health care interactions differ according to demographic characteristics (e.g., sex, geocoded sociodemographic background, rural residence) or clinical characteristics (e.g., additional co-existing impairments, comorbid complex or straightforward chronic conditions).

Per section **3.5**, we will create measures of child-to-adult HCTs via pediatric-to-adult health care transfers. For example, a youth with IDD who saw an adult-trained primary care physician in the current year, but a pediatric primary care physician in the prior year will qualify as having experienced an HCT. We will test the sensitivity of transition and transfer definitions based on successive years or longer periods (e.g.. two consecutive years with visits to a pediatric primary care physician followed by two consecutive years with visits to an adult-oriented primary care physician.) Based on these descriptive analyses, we will develop a taxonomy to describe other key features of HCTs. For example, one characteristic of health care transition will be how many non-primary care specialties are involved in the transition (e.g., 0, 1, 2 or more) and whether the specialty being accessed during adolescence was pediatric- or adult-trained.

Finally, we will examine the probability of experiencing an HCT as a function of age. In these models, we will examine the association of demographic, clinical, and contextual factors with health care transitions. We will fit the following set of regression models:

$$h(T_{it}) = \beta_0 + \beta_1 X_{it} + \tau + \alpha + \beta_2 X_{it} * \alpha$$

where T_{it} is a binary variable indicating that individual *i* experienced a health care transition *t*, X_{it} is a vector of patient characteristics, τ is a set of year fixed effects, α is a set of age fixed effects, and $h()$ is a suitable link function (e.g., logit link for binary variables). We will fit separate models for each type of health care transition. In all models, we will cluster at the individual patient level to account for repeated observations within the individual. Our primary coefficients of interest are α and $\beta_1$which describe how the probability of a transition differs by age key patient characteristics (e.g., rural residence and insurance status). We will also explore interactions between key patient characteristics and age (β_2)

3.10.2 Aim 2: Assess the quality of the care received during HCT periods.

Hypothesis: Comparing individuals of the same age and co-morbidity profile, quality of care will be worse for those who are experiencing HCTs versus those not.

First, we will tabulate the prevalence of receipt of recommended care and care utilization (see **Table 2**) as a function of age in the cohort of individuals with IDD. In descriptive analyses, we will also examine whether clinical outcomes differ according to demographic characteristics (i.e., sex, geocoded sociodemographic background, rural residence) or clinical characteristics (i.e., additional co-existing impairments, comorbid complex or straightforward chronic conditions).

To test how HCTs relate to desired and undesired elements of care quality, we will fit the following set of regression models:

$$h(y_{it}) = \beta_0 + \beta_1 T_{ij} + \beta_2 X_{it} + \tau + \alpha$$

where y_{it} is the outcome of interest (e.g., diagnosis of diabetes, avoidable hospitalization), T_{ij} is a binary variable equal to 1 if a health transition occurred in year t, X_{it} is a vector of patient characteristics, τ is a set of year fixed effects, α is a set of age fixed effects, and $h()$ is a suitable link function (e.g., logit link for binary variables). In all models, we will cluster at the individual patient level to account for repeated observations. Our primary coefficient of interest is β_1, which we expect to be negative and statistically significant for recommended care outcomes and positive and statistically significant for utilization outcomes, indicating that individuals with IDD are more less likely to receive recommended care and more likely to experience potentially preventable utilization relative to similar IDD individuals who did not experience a transition. We will also examine models that examine care in years following a health transition. To address the importance of sex as a biological variable in relation to receipt of recommended care and utilization, we will also examine interactions between health care transition status and key clinical variables, including sex, age, and comorbidities.

3.10.3 Aim 3: Characterize insurance gaps associated with Medicaid age 19 eligibility rules.

Hypothesis: Insurance gaps at age 19 are more common than at other ages.

As with heath care transitions, to characterize health insurance changes, we will first tabulate insurance status (Medicaid versus private, number of months uninsured, etc.) as a function of age in the cohort of individuals with IDD. In descriptive analyses, we will also examine whether insurance status differs according to demographics (e.g., sex, geocoded sociodemographic background, rural residence) or clinical characteristics (e.g., additional co-existing impairments, comorbid complex or straightforward chronic conditions).

To examine the association between health insurance transitions and age, we will fit the following set of regression models:

$$h(I_{it}) = \beta_0 + \beta_1 X_i + \tau + \alpha$$

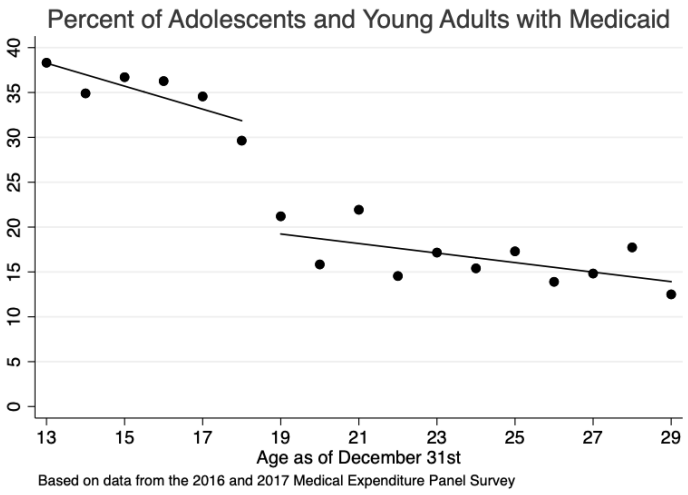
where I_{it}reflects an insurance transition (any gap in Medicaid coverage, change in insurance type, number of months without insurance) X_{it} is a vector of patient characteristics, τ is a set of year fixed effects, α is a set of age fixed effects. In all models, we will cluster at the individual patient level to account for repeated observations within the individual. Our primary coefficients of interest are α which describes how the likelihood of a health care transition differs by age. We will fit these models stratified by insurance type in year t-1. We expect the coefficient associated with age 19 to be positive and statistically different from the other age coefficients in the Medicaid cohort, suggesting that Medicaid enrollees are more likely to have an insurance disruption at age 19 compared to other ages. We do not expect a similar difference at age 19 among individuals with private insurance.

3.10.4 Aim 4: Examine the relationship between insurance gaps following Medicaid's eligibility redetermination at age 19 and service utilization indicating lower quality care using quasi-experimental methods.

Hypotheses: Age-related gaps in Medicaid insurance coverage are associated with lower receipt of recommended care and higher rates of avoidable emergency and inpatient service use.

To study how changes in insurance eligibility cause HCTs and impact subsequent outcomes for adolescents and young adults with IDD, we will exploit the natural experiment created by Medicaid's requirement that individuals newly determine (or redetermine) their Medicaid coverage at the age of 19. This aim will focus on the subset of individuals enrolled in Medicaid at age 18. Based on the general population of adolescents and young adults in the nationally representative Medical Expenditure Panel Survey 2016–2017 (**Figure 4**), we expect a sudden and dramatic drop in prevalence of Medicaid coverage from 30% to 19% in the year that individuals move from 18 to 19 years of age. This sudden drop in proportion of young adults on Medicaid will likely correspond to an abrupt change in the types of physicians caring for adolescents and young adults with IDD, since the networks of healthcare providers participating in Medicaid differ considerably from providers caring for privately-insured individuals. In this setting, young adults who are just before a 19th birthday have very different insurance coverage relative to young adults on or shortly after a 19th birthday. Given the abrupt change in insurance eligibility, it is possible to isolate changes in coverage (and thus health care transitions) that occur abruptly following a 19th birthday. Similarly, we will estimate changes in receipt of care, or hospital-based care utilization (e.g., changes in visits to emergency departments or avoidable hospitalizations) as a function of abrupt changes in Medicaid at age 19. Such designs, called regression discontinuity designs, have been widely used in the health services and social science literature. Authors have used regression discontinuity designs to understand how the length of stay during birth admissions affects health utilization and outcomes for newborns (comparing infants born just before and after midnight, which changes length of stay by 24 hours), how admission to neonatal intensive care units affects health benefits (comparing neonates weighing just under 1,500g to those weighing slightly more than 1,500g, which influences likelihood of admission to a neonatal intensive care unit), and how insurance coverage affects utilization and health outcomes (comparing individuals with unplanned hospitalizations just before and after a 65th birthday, which is when insurance coverage increases abruptly with age-eligibility for Medicare).[175-177]

Figure 4. Determination or redetermination of Medicaid eligibility at age 19 as an instrument for Medicaid coverage and health insurance transitions



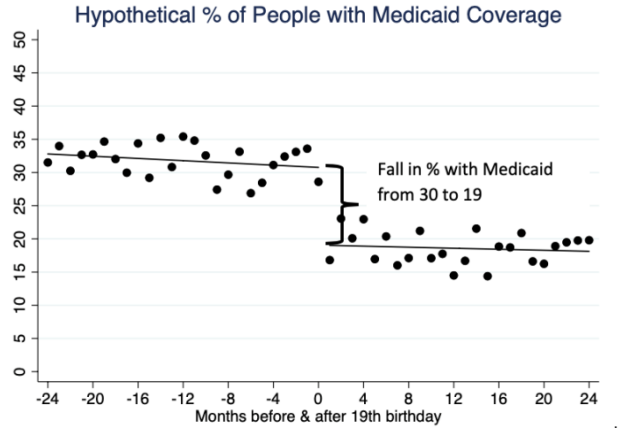
Following the approach of Card, Dobkin and Maestas, our goal in Aim 4 is to estimate models of the form:

$$y_i = f(a_i, \alpha) + Post19_i\beta + \varepsilon_i$$

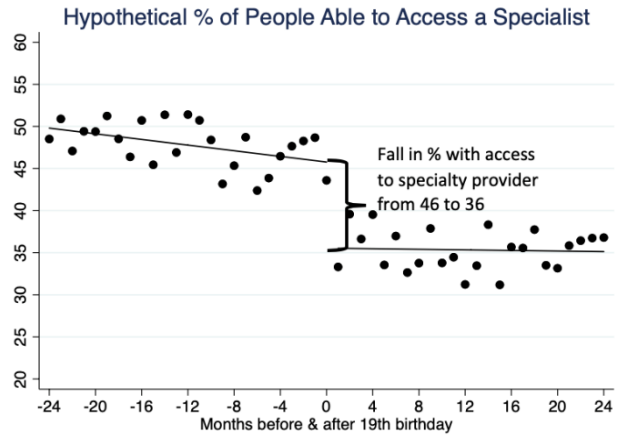
where y_i reflects an outcome (e.g., change in type of physician specialty from pediatric to adult, hospitalization rate, or reproductive health testing frequency) for patient *i*, a_i is the patient's age (measured in months), *f()* is a function that is continuous at age 19 with parameters α (e.g., a flexible polynomial), $Post19_i$ is an indicator for whether individuals have passed their 19th birthday, and ε_i is an error term reflecting the influence of all other factors.[175] If y_i is a measure of an outcome (e.g., percent with emergency department visits), then β is a scaled estimate of the causal effect of changing insurance coverage on emergency department visits. This is a so called "fuzzy" regression discontinuity design, because the changes in insurance coverage (and resulting outcomes) are not complete (i.e., young adults with IDD do not move from 100% to 0% Medicaid coverage at age 19). Thus, the scale factor to determine clinical outcomes (e.g., how Medicaid coverage affects emergency department visits), is the difference in Medicaid coverage just before versus after the 19th birthday.

Figure 5A illustrates the anticipated discontinuity in Medicaid coverage at age 19 due to eligibility requirements and mandatory redetermination. This Medicaid rule, which leads many young adults to lose Medicaid coverage, is the mechanism through which we expect health care transitions (e.g., change in access to specialty care) to occur (**Figure 5B**). Some young adults may transition to private coverage as dependents on parental plans, or they may suffer a gap in health insurance until they requalify for Medicaid. For the latter group, we can observe safety net care in Massachusetts' unique database, which includes encounters with the safety net not reimbursed by Medicaid or private insurance. Furthermore, with the change in insurance coverage, the natural move from pediatric to adult providers and care settings in young adulthood may accelerate.

Figure 5.
A. Age and Medicaid coverage



B. Age and access to specialists



To study examine an outcome of interest (e.g., access to specialists) in the months before and after one's 19th birthday when insurance and health care transitions are expected to occur in relation to Medicaid eligibility redetermination. As seen in **Figure 5B**, if we observe an abrupt decrease in visits to specialists precisely around the 19th birthday, mirroring the change in Medicaid coverage, we will infer that the transitions in coverage (loss of Medicaid) led to reductions in the percent able to access a specialist provider. The magnitude of the change can be measured by the vertical distance between the lines at the 19th birthday (month 0). The coefficient, β, measures this distance for each variable (Medicaid coverage, access to specialist, etc.).

Under the assumption that it is the drop in Medicaid coverage that changes access to specialists, we can estimate how much the ability to access a specialist (measured as prevalence of visits to a specialist) changes with changes in Medicaid. In this hypothetical example, the ratio of the change in the percent of people able to access a specialist (-10 percentage points) to the change in the percent of adolescents and young adults on Medicaid at age 19 (-11 percentage points) is $\frac{-10}{-11} = .91$. We can use a similar calculation to estimate other types of outcomes, like the change in percent of people with emergency department visits in relation to changes in the percent with Medicaid at age 19. Because loss of Medicaid coverage could plausibly affect a range of outcomes directly and indirectly, we will not attempt to attribute changes in emergency department visits directly to a particular mechanism (change in access to specialists).

3.10.5 Rigor and reproducibility. Our study employs the most rigorous methods available to estimate the causal effect of health care transitions and clinical outcomes for adolescents and young adults with IDD that improves upon much of the prior literature on health care transitions. Finally, we will include biological variables such as age and gender in all analyses.

3.11 Power. With approximately 69,000 and 85,000 and 217,000 individuals with IDD in Colorado, Massachusetts and New York, respectively, we are well powered to characterize the physicians and timing of HCTs, changes in care quality of care, and the frequency of insurance gaps across the two major types of payers insuring adolescents and young adults with IDD as spelled out for Aims 1 through 3. In our smallest sample, people with IDD enrolled in Medicaid at age 18, we demonstrate

Table 3. Estimated minimal detectable differences

	N remaining on Medicaid	N with a transition	Rate without transition	Minimal detectable effect of health insurance transition
Avoidable emergency department visit	5,400	600	33%	5.9%
Avoidable hospitalization	5,400	600	18%	5.1%

that we have power to detect modest sized effects even in this, the analyses with the least power to detect effects. For analyses of our Medicaid cohort in Aim 4, we assume a cohort of approximately 6,000 individuals enrolled in Medicaid at 18 and that 10% of these individuals will experience a health insurance transition or gap as they age into young adulthood. **Table 3** displays estimated minimal detectable differences with 80% power for two key outcomes. Based on these analyses we expect to have sufficient power to detect clinical and policy-relevant effects.

3.12 Study limitations. Although this project is novel in that it identifies a longitudinal cohort of adolescents and young adults with IDD that is 10 to 100 times larger than the vast majority of prior studies to date and will deliver information that is far more granular that prior studies have, it is limited in that it relies on administrative data which is weak in its ability to capture the interpersonal dynamics desired in health care interactions (e.g., whether youths and their families are approached in an developmentally appropriate manner). Administrative data does, however, have the advantage of being able to systematically assess whether recommended care is delivered and undesired outcomes are avoided, particularly when assessed over a broad range of measures as we are and we exploit a natural experiment to estimate the causal link between insurance gaps, health care transitions, and desired clinical outcomes.[35,40,41] In this case, we will explore approaches that permit us to combine measures into a continuous index of more versus less desirable outcomes. This method would be less transparent than our current method, but by combining clinical outcomes (**Table 2**) into a continuous index of outcomes that predicts hospitalization, for example, we could increase our power to detect meaningful clinical effects.

Second, even though claims data lack some of the clinical nuance salient for IDD (e.g., the severity of the intellectual disability or the presence of adaptive ability), newly available tools can capture more clinical complexity than previous studies have been able to include.[5,6,10,13,66,113] In future analyses, claims data can be linked to additional data sources such as vital records to capture mortality rates and reasons.

Lastly, although our data are not nationally-representative, they do investigate the two main insurers of adolescents and young adults with IDD; national data would only offer one payer or the other. Our data are also strong in their ability to capture health care transition differences that are likely to exist between rural and populous regions of the United States.

3.13 Summary. In summary, high-quality HCTs are an important health and health care issue for adolescents and young adults with IDD. Put into adult terms, adolescent and young adult IDD prevalence is comparable to that of Type II diabetes (8.6% of adults) and Alzheimer's disease (5 million).[2,4–6,46,49,107,180] People with IDD also experience lifespans that are 20 years shorter than their non-IDD counterparts; this foreshortened life expectancy is comparable to that experienced by adult survivors of childhood cancer.[7,181,182]

By combining three newly available claims-based resources to create one of the largest, longitudinal, and multi-payer datasets of adolescents and young adults with IDD to date, our proposed research will shed new and much needed light on the nature of HCTs for adolescents and young adults with IDD (both which types of physicians are involved as HCTs proceed and care quality during these periods) and how insurance gaps related to Medicaid's age 19 eligibility rules may impede health during HCTs. The proposed methods also represent a new avenue for pursuing disability research more generally—larger scale, continually available, longitudinal rather than cross-sectionally, and more regionally representative than clinic-based.

Specific, effective preventions or treatments for IDD remain elusive, but decades of medical advances have helped newborns at-risk for IDD survive into adulthood and enabled IDD to be identified at earlier stages of life. Until curative therapies can be developed, substantial improvements in the health of youth with IDD may be derived from delivery system and health policy interventions. However, more empirical information is needed so that interventions can better focus, not only in delivery systems, but insurance and payment policies and a wide array of public programs (e.g., Medicaid, supplemental security income [SSI], social security disability income [SSDI], Medicare). This proposal will fill several important gaps in the field of IDD research, but also enable additional research in the disabilities field more generally.