* Protocol Title

Social, Environmental, and Policy Determinants of Acute Care Utilization

* Sponsor/Funding

NIH- National Institute of Allergy and Infectious Disease K01AI168579-01

* Principal Investigator

Alina Schnake-Mahl

* Objectives

To describe the social and environmental determinants of disparities in inpatient and Emergency Department (ED) visits in US metropolitan areas, and to estimate the effects of contextual factors (e.g. policies, environmental exposures, hospital features) on rates and disparities in diagnosis-specific acute care outcomes. The overall goal of this study is to advance our understanding of the social and environmental determinants of acute care disparities and provide a strong evidence-base for policies and interventions that may address these inequities and reduce the overall burden of acute care utilization*.* We will leverage encounter-level healthcare claims data linked to neighborhood (zip code, cross walked to zip code tabulation areas) social and environmental exposures and city and state-level policy factors, as well as hospital characteristics.

Hypothesis:

1. Acute utilization will be strongly spatially and socially patterned revealing large racial-ethnic and socioeconomic disparities
2. Acute utilization will be associated with social and environmental characteristics, and policies measured at the hospital, neighborhood, city, and state levels.
3. The spatial and social patterning of acute utilization will vary over time, including during endemic versus pandemic periods.

* Background

The proposed study will examine social and environmental determinants of acute cate utilization for infectious disease (e.g. influenza, COVID-19), chronic disease (e.g. COPD, heart failure, substance use), injury-related and pregnancy-birth related outcomes in varying contexts. Specifically, we will explore (1) small area (and larger area) variations in all cause and cause specific acute utilization (Emergency Department and Inpatient) and disparities in these outcomes, (2) associations of acute utilization with hospital, neighborhood, city, and state-level indicators and variations in associations over time and under varying contexts, (3) effects of social policies and climate related exposures on acute utilization.

Acute utilization shows clear racial, socioeconomic, and spatial disparities. Research on social determinants of health has primarily focused on chronic diseases, but there has been less investigation of (1) understanding how social and environmental affect acute utilization and disparities in acute utilization, and (2) identifying how policies that address social determinants of health may impact disparities in acute utilization. We will link zip code (and county/state level) emergency department and inpatient data to publicly available data on neighborhood social determinants, including residential segregation, neighborhood poverty, occupational structure, and housing cost burden. The availability of all cause and cause specific utilization over time will also provide a platform to monitor the impact of various policies and interventions through natural experiments.

Our research team has substantial expertise in characterizing and analyzing neighborhood and city-level differences in health, as well as environmental determinants. We also have employed medical claims data to understand neighborhood determinants of health and health disparities, and have expertise with using quasi-experimental methods to examine effects of policies on health. We are well positioned to lead this project.

* Inclusion and Exclusion Criteria

No specific inclusion and exclusion criteria. This study will use secondary data from two deidentified encounter-level national claims datasets, available from the Health Care Cost and Utilization Project (HCUP): The State Inpatient Databases (SID) and the State Emergency Department Databases (SEDD). The databases conform to the definition of a limited data set, are accessible through application, and will be obtained at the encounter level. No new data will be collected. This is a retrospective study that will include a sample of the 100 largest metropolitan statistical areas (MSA), in approximately 20 states across the country, in the years between 2005 to 2023. The study will also use publicly available data at the Zip code level from the American Community Survey (ACS), as well as other publicly available datasets.

* Number of Subjects

This is not a multicenter study. Using two acute utilization outcomes as an example, influenza and COVID: The number of influenza ED and Hospital visits annually ranges from 45,000 to 260,000 during the study period. The number of monthly COVID-19 hospital visits ranged from 20,500 to 53,300 during the first 6 months of the study period. We will avoid publication of values of 1-10 case counts in text and tables. We will not attempt to contact individuals for any purpose, or establishments unless the individual establishment has already consented (as identified in HCUP data sources), including not attempting to verify any information from establishments (other than as available in the AHA linkage).

* Recruitment Methods

This study will use secondary data from deidentified claims records and no new data will be collected. This is a retrospective study. No recruitment is involved.

* Procedures Involved

The study design will involve statistical analyses of de-identified claims records to examine 1) neighborhood and city-level social determinants (e.g. housing crowding, rent/cost burden, racialized segregation, high risk occupations) of acute utilization; 2) effects of policies (rent control, paid sick leave, minimum wage laws, etc) on cause specific acute utilization, 3) impacts of climate related exposures on health outcomes, 4) patterning of acute utilization by hospital characteristics.

This study will not involve recruitment and/or participation of subjects in order to produce new data. There will be no surveys or interaction with participants.

The study will create neighborhood-level (zip code tabulation area) metrics of neighborhood social factors and social policies that will be linked to patient claims records via zip code. Records are deidentified, so Drexel researchers will only interact with deidentified data. No personal information will be available to us in the datasets received.

The database arriving at Drexel from HCUP will not include any identifying information. We will follow the process described for secure use and storage of the data.

The research is expected to continue over 5 years.

* Study Endpoints

The outcomes of interest are all cause and cause specific acute utilization (ED admission, Hospitalization).

* Data and Specimen Management

This study will use de-identified records containing information on: 1) patient demographic information (i.e., age and sex), 2) neighborhood-level social and environmental indicators, 3) city and state policies (paid sick leave, rent control, etc) enacted during the study period), and 4) contextual determinants of acute utilization.

The study design will involve statistical analyses of acute utilization data including: (a) estimation of rates of utilization (and disparities in utilization) for small areas (2) investigation of associations of area and hospital characteristics with acute utilization (and disparities in utilization), and (3) examination of impacts of policies on acute utilization (and disparities in utilization).

All data will be de-identified and analyses will be conducted at the aggregate ZCTA-level (or higher). Data will be managed by Alina Schnake-Mahl. Drexel who will not collect or store names for this project. Drexel will not collect or store HIPAA authorizations and consent documents. As custodian of the data, I will ensure that the data is kept secure, will receive and transmit the data, and only authorized users will have access to the data, and I will not release or disclose information where the number of observations in any given cell of tabulated data is ≤10. Data will be initially accessed through a secure online portal and delivered via a secure digital download.

No specimens will be stored. Data will be securely stored using the procedures listed below. Only de-identified data will be released to investigators for analysis. The data use agreement includes all researchers that will have access to the data. The following precautions will be taken for securing the data:

* Locked office, locked cabinets or storage units;
* Restricted access and restrictions on copying study-related materials;
* Access rights terminated when authorized users leave the project or unit;
* Individual ID plus password protection; all data kept on encrypted as well as password protected devices.
* Routine electronic back up;
* Security software (firewall, anti-virus, anti-intrusion, encryption) is installed and regularly updated on all servers, workstations, laptops, and other devices used in the project;
* Safe disposition/destruction of data or devices, as appropriate (e.g., shredding paper documents, destroying disks or thumb drives, secure erasure of electronic media).
* Provisions to Monitor the Data to Ensure the Safety of Subjects

Not applicable. Drexel will not be collecting data from research subjects and all data have been collected by AHRQ. No personal identifiers will be provided with the dataset. The study involves no more than minimal risk to subjects.

* Withdrawal of Subjects

Not applicable. Drexel will not be collecting data from research subjects.

* Risks to Subjects

Drexel will not be collecting data from research subjects. Data will be obtained from HCUP. The research being done at Drexel will only be secondary data analyses. Drexel will not receive participant names. There is virtually no risk to subjects from participating in their research. No names will be available on any databases Drexel will have access to. These analyses represent no more than minimal risk to participants. All data will be deidentified. The risks from breach of confidentiality and deductive disclosure are minimal.

* Potential Benefits to Subjects

There is no potential benefit to individual subjects. Results from this work will provide information about contextual determinants of acute utilization and effects of policies on disparities. This research may be used to inform interventions and policies and to better focus existing preventive interventions.

* Confidentiality

Data stored at Drexel will be stored on secure password-protected servers maintained by Drexel IRT. Data will be accessed only by investigators associated with the project. Confidentiality will be protected using the procedures outlined in the section on “Provisions to Protect the Privacy Interest of Subjects”.

* Provisions to Protect the Privacy Interests of Subjects

Data has already been collected. The project will not collect any new data from participants.

Drexel will not receive names or any other identifiers. Drexel does not collect or store HIPAA authorizations and consent documents.

* Consent Process

This project involves secondary analyses of this data. Drexel will not have contact with participants and will not have access to personal identifiers linked to clinical information. All datasets containing information derived from clinical records will be deidentified.

* Setting

This is secondary data analysis using claims data. Drexel will not have access to any identifying or clinical information. The final database will be stripped of all identifying information. Describe the sites or locations where your research team will conduct the research.

* Vulnerable Populations

Not applicable. This study does not target vulnerable populations.

* Process to Document Consent in Writing

Not applicable

* Compensation for Research-Related Injury

Not Applicable

* Resources Available

All data was collected by the HCUP and only analyses will be performed. The Drexel University School of Public Health conducts several similar studies each year and is well equipped to do this research.

Data will be managed by Alina Schnake-Mahl.

We anticipate analyses to continue over 5 years (through April 2027).

All personnel involved in the study have completed all of the required trainings.

Alina Schnake-Mahl, ScD, MPH, Postdoctoral Research Fellow, is a health services researcher and social epidemiologist studying the social and political determinants of health inequities. Dr. Schnake-Mahl uses descriptive and quasi-experimental methods to identify the causal and associational relationship between features of places and disparities in chronic and infectious disease outcomes. She also has experience working with large claims datasets, through prior research and evaluation work with health care organizations. Dr. Schnake-Mahl received her ScD and MPH from the Department of Social and Behavioral Sciences at the Harvard T.H. Chan School of Public Health.

* Drugs or Devices

Not Applicable

* Multi-Site Research

Not Applicable

* Research Conducted in a Foreign Country

Not Applicable

* Sharing of Results or Incidental Findings with Subjects

Not applicable. We do not have personal information and cannot identify the individuals in the dataset.

* Community-Based Participatory Research (if applicable)

Not Applicable

**References**