Department of Emergency Medicine Research Committee Meeting

Date:	6/6/2023	**Meeting Lead:** Dr. Andrea Gilmore-Bykovskyi	
Time:	12:30 pm – 01:30pm	**Recorder:** Maria Balbach/Dalton Lee	

	Lead	Length
General Announcements • Learning Plans Welcome!	Dr. Gilmore-Bykovskyi	2 min
Research Administration and Fiscal Updates • Welcome Chelsea McClellan! Chelsea will be working with Dr. Shah. • Welcome Chuck! Chuck is staying on with the Pulia Lab and joining the EDRC team.	Jessie Libber	3 min
EDRC Updates •	Phoebe Natzke	0 min
Items for Approval • Protocol, Patient Flow Optimization (Dr. Patterson) • Protocol, Evaluation of Trends in EMR Note Length (Dr. Patterson) • Protocol, Variability in Clinical Exposure of Diverse Populations (Dr. Schnapp) • Protocol, Person-centered Outcomes for EM Care for PWD (Dr. Gilmore-Bykovskyi)	Dr. Gilmore-Bykovskyi	50 min
Items for Discussion •	Dr. Gilmore-Bykovskyi	0 min

Strategic Plan

1: Implement a pipeline for emergency care researchers that will support our research faculty recruitment efforts.
2: Integrate the DEM Research Enterprise with UW Health/UWSMPH Research in terms of oversight and support of initiatives.
3: Demonstrate the impact of DEM research studies on social emergency medicine topics and expand our portfolio of studies impacting social emergency medicine topics.
4: Expand the number of tenured faculty in DEM.
5: Expand our portfolio of studies with a focus on diversity, equity, and inclusion.

To conduct innovative clinical and translational emergency care research to advance the health of the people of Wisconsin and beyond.

Calendar of Events:

Next EMRC meeting:
June 20, 2023, 12:30-1:30

Attendees:

EM Research Faculty:	EM Staff:		
Gilmore-Bykovskyi, A.	Balbach, M.	Hall, S.	Wood, A.
Hurst, A.	Barton, H.	Hekman, D.	
Jewell, C.	Benson, C.	Kadiyala, S.	
Kim, M.	Block, L.	Laev, L.	**Collaborators:**
Kuttab, H.	Broghammer, C.	Lee, D.	Halfpap, J.
Patterson, B.	Coulson, A.	Libber, J.	Hankwitz, J.
Pulia, M.	Dai, Elena	Maru, A.	Krueger, J.
Shah, M.	Dillon, K.	McClellan, C.	Marr, J.
Spigner, M.	Ebert, L.	Morales, M.	
Tschautscher, C.	Fehland, J.	Oliver, L.	**Guests:**
Tsuchida, R.	Fischer, T.	Natzke, P.	Acosta Perez, F.
	Gifford, A.	Ranade, T.	Schnapp, B.
	Griffin, M.	Schwei, R.	

PROTOCOL TITLE:

Evaluating current state and trends in electronic medical record note length

PRINCIPAL RESEARCHER

Brian Patterson
Department of Emergency Medicine
bpatter@medicine.wisc.edu

Table of Contents

1.0 Study Summary

Study Title	Evaluating current state and trends in electronic medical record note length
Study Design	Health care records research only
Primary Objective	The objective of this study is to quantify and describe temporal trends in the number of clinical notes present for review by clinicians at patient presentation to the emergency department, inpatient admission, and ICU admission
Secondary Objective(s)	N/A
Study Population	Dataset of all patients presenting to the emergency department from 2009 - 2023
Study Specific Abbreviations/ Definitions	Electronic health record (EHR) Natural language processing (NLP) Clinical Research Data Services (CRDS)

2.0 Purpose and Significance

In the modern healthcare system, review of prior records is an important step in the provision of acute care. Prior studies evaluating emergency care document review of previous records as occupying a significant portion of the time clinicians spend during visits. The advent of the Electronic Health Record (EHR) has increased the availability of notes detailing patients' outpatient visits and prior hospitalization. As these notes have become available in real-time during acute care visits, there is an expectation that clinicians familiarize themselves with patients recent course and distant medical history. Given that the EHR has only existed for 10-15 years in most locations, the volume of notes available during this review period has likely grown as more time has elapsed for notes to accrue. Physicians often report stress related to the size and scattered nature of existing records when trying to provide acute care in time-sensitive conditions. However, to our knowledge, the amount of information available in non-discrete and discrete fields has not been quantified over time. This study seeks to evaluate the length, type, and number of notes and other results available for physician review at the time of presentation for acute care, and to evaluate the trend in this amount over time. Significance: Provide any relevant background, evidence, or information that supports the importance or justification and scientific value for creating this database, registry, or repository by describing the unmet need and value of the desired information/specimens.

We will utilize discrete electronic health record (EHR) data and natural language processing (NLP) techniques applied to clinical notes to extract length of notes in words.

We during the study period 2009-2023, we plan to create a dataset of all patients presenting to the emergency department. We will extract both discrete data and metadata surrounding notes from these encounters to generate statistics on volume (i.e. number of notes, number of words, number of different types of notes, as well as number of relevant laboratory tests, radiology studies, and other procedures with reports).

Data will be extracted by Clinical Research Data Services (CRDS) staff through a research data request and delivered to a CHI2 approved computing platform. Initially, MRNs and CSN's will be used to assign patients' study and visit identifiers, but these direct identifiers will then be removed from the dataset. Notes will initially be stored to allow generation of metadata (length, number of words/characters). After initial procession, no note text or direct patient identifiers will be extracted or stored in the dataset used for analysis.

3.0 Subject Identification, Recruitment and Consent

3.1 Method of Subject Identification and Recruitment

Medical records will be used to identify subjects and records. Clinical Research Data Service (CRDS) will be used to identify subjects via these records.

3.2 Process of Consent

The study likely poses minimal risk to subjects because the activities are limited to use of data from medical records (or images created for clinical purposes) and there are sufficient measures in place to protect the data.

The research likely does not adversely affect the subjects' rights and welfare because only those who have valid access to their medical records will collect study data and the use of the data is not expected to affect the patients from whom the data are derived.

The research likely does not adversely affect the subjects' rights and welfare because access to study data will be restricted to the study team and the use of the data is not expected to affect the subjects from whom the data are derived.

It may be impracticable to obtain informed consent from subjects because the study team may not be interacting with the patients and the records may be for patients who are not being currently seen at UWHC or who may no longer be seen at the UW Health clinics.

Identifiable information will be retained for the duration of the study to allow for checking the data as needed.

4.0 Confidentiality of Data and Information Storage

This project will use the minimum amount of data necessary to achieve the aim of the research. Because this is a retrospective records review, study team members will not have direct contact with study subjects. This research does not involve interaction with subjects.

Direct identifiers will initially be used to ensure individuals within the study are not duplicated (i.e. 2 visits made by the same patient are not counted as two separate patients' visits). Also, some identifying data may be within note text.

Direct identifiers (MRN and CSN) will be removed as soon as subjects have been assigned a study id, and note text will be removed as soon as note metadata has been generated.

Clinical notes and EHR data will be extracted by Clinical Research Data Services staff and delivered to a Chi2 approved computing location for dataset creation, storage and analysis.

Individually identifiable or deducible data will not be transmitted by unsecured telecommunications, which include the Internet, email, and non-secure File Transfer Protocol (FTP). No restricted data will be transmitted electronically through unsecured methods such as e-mail, e-mail attachments, or non-secure FTP. No output from the study will contain individual identifiable information. No individual personal health information (PHI) will be released in presentation or publication. No printed materials will contain individual identifiers. Only aggregate statistical output representing groups of subjects will be released.

5.0 Risk/Benefit Assessment

5.1 Potential Benefits to Society

Understanding the amount of data available to physicians at the time of an acute care visit will quantify a serious issue in providing acute care: the growth and fragmentation of text and data in the medical record, leading to an increased burden on providers and increased chance of missing valuable information.

5.2 Potential Psychosocial Risks

The only potential risk to subjects is a loss of confidentiality.

5.3 Procedure to Minimize Risks

We will minimize the risk of loss of confidentiality by protecting the data with IT security best practices, including storing data on secure servers and limiting access to that data to pre-approved personnel.

The identifiable EHR data will be stored on the Research Data Services staff and delivered and delivered to a CHI2 approved computing platform. Following dataset development, the analysis dataset will be stripped of all direct identifiers, but still kept on the a CHI2 approved computing platform, where privacy will be protected by the restriction of access to data to only selected project-specific individuals (need-to-know) and the use of passwords for computer drive and project folder access.

Project Title: Variability in Clinical Exposure to Patients with Diverse Social Identities in Emergency Medicine Residency

1. TITLE PAGE

1.1. PI: Benjamin Schnapp, MD

Key personnel: Dann Hekman
Sponsor/Funder: None
Participating sites: University of Wisconsin, Department of Emergency Medicine

2. PURPOSE OF THE STUDY AND BACKGROUND

2.1. Abstract

Introduction
Experiential learning theory suggests that clinical exposures are key to developing competencies in Patient Care and Interpersonal and Communication Skills. This is likely especially true for developing cultural competency and competency with patients of diverse social identities, including gender identity, sexual orientation identity and socioeconomic backgrounds.
Purpose
The goal of this study is to characterize the variability in EM resident clinical exposure to patients with diverse social identities.
Methods
This study with be a retrospective records review of EHR data at the main residency clinical site at UW. Patient characteristics of patients seen as the first assigned resident will be analyzed with descriptive statistics, including race, sexual orientation, gender identity and care plan status and insurance status as a proxy for socioeconomic status.
Results
We intend to produce box and whisker plots detailing the distribution of patients seen by residents over the course of their entire training for each of the variables of interest.
Conclusions
Based on the results of previous work on clinical variability during training, we anticipate identifying significant variability in resident clinical exposures to diverse patients. This may have multiple implications for residency leadership as they consider how to train residents in cultural competency.

2.2 Purpose of the study & Aims

Previous studies have noted that clinical experiences of emergency medicine residents are highly variable. This could suggest that residents may graduate with relative deficits in exposure, confidence, and competence with caring for patients from different backgrounds. However, to our knowledge, this has never been shown empirically.

The goal of this project is to characterize differences in exposure to patients from different racial, ethnic, and socioeconomic backgrounds, as well as exposure to patients with varied gender identities and sexual orientations during emergency medicine residency training.

Based on previous research showing large variations in clinical exposure variability by ABEM content domain during emergency medicine residency training, we hypothesize that there will be large variability in graduating residents' clinical exposure to patients from a variety of different social, economic, racial, ethnic and gender backgrounds.

2.3 Background

Medical residency training allows physicians to gain the cognitive and procedural skills necessary to practice independently. Based on Kolb's theory of experiential learning, patient encounters form the foundations upon which physicians in training master the practice of medicine (Kolb 1984). Additionally, the development of "illness scripts," or mental models for the classification of patient presentations, is crucial to the development of clinical skills and reasoning during residency training (Bowen 2006). Emergency medicine (EM) trainees must be exposed to a variety of patient chief complaints throughout the course of residency to develop these scripts and become competent clinicians.

Clinical exposure has specifically been shown to be important for the development of competency in the care of diverse patient populations in a variety of medical trainees, including nursing and pharmacy students. Additionally, medical students who cared for more LGBTQ patients reported higher levels of preparedness and knowledge, and provider experience and comfort are noted as a significant factor influencing whether patients with Sickle Cell Disease receive appropriate evidence-based care.

Research Design and Methods

This will be designed as a retrospective analysis utilizing data extracted from the Electronic Medical Record (EHR). Data on resident clinical exposure as the first resident assigned to a visit will be collected at the patient level on diverse social identities, including gender identity, sexual orientation identity and socioeconomic background will be collected; no individually identifying patient information will be collected.

Resident level data will be aggregated for all residents who have completed all 3 years of residency at the UW EMRP consecutively and compared using descriptive statistics.

3. CHARACTERISTICS OF THE RESEARCH POPULATION

3.1 Number of Subjects:

We anticipate approximately 75 residents

3.2 Gender and Age of Subjects:

Male and female, approximately 25 to 40 years old.

3.3 Racial and Ethnic Origin:

Residents of all racial and ethnic origin are eligible

3.4 **Inclusion Criteria:**

All University of Wisconsin Emergency Medicine residents who have completed their residency training are eligible for the study.

4. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT

4.1 Method of Subject Identification and Recruitment

a. **How will subjects be identified and selected for the study? How will privacy of the individuals be maintained? The identification and recruitment of subjects must protect privacy and be free of undue influence.**
All Emegency Medicine residents who worked in the ED from 2016-2023 and completed their residency training are eligible.

b. **How will subjects be identified (e.g. flyers, emails, websites, announcements)?**
EHR (Epic) data review will identify residents who are eligible for the study

c. **Does the study team have routine access to the potential subjects being recruited and/or data being reviewed? If not, how will the study team recruit subjects or obtain the data.** Yes, routine access.

d. **If a secondary analysis of pre-existing data, indicate the database to be used or where the data is coming from and how eligible subjects will be identified from the database.**
EHR (Epic) records will be used, eligible records will be identified if a resident is assigned to the patient. Only non-identifiable demographic data will be collected on patients seen by each resident.

4.2 Process of Consent

Describe who will obtain consent and how the process of informed consent will be structured. Only individuals who have completed the IRB's required human subjects training and are listed on the IRB application are authorized to obtain consent.

N/A – this study is a retrospective records review.

5. METHODS AND STUDY PROCEDURES

5.1 Provide a detailed description of all study activities:

a. **What is the duration of the study (e.g., one semester, one year, until enrollment is reached)?**
The duration of the study will be approximately 1 month while data is collected and analyzed.

b. Who will conduct each activity (e.g., session, focus group, interview, experiment)?
Data from the electronic health records will be collected by Dann Hekman. Review and analysis of data will be completed by Benjamin Schnapp.

c. How long will each activity (e.g., session, focus group, interview, experiment) take?
The retrospective data analysis of the EHR will take approximately 2 weeks to 1 month.

d. Where will the study activities (e.g., session, focus group, interview, experiment) take place?
N/A

e. **If the study involves more than one visit, provide a sequential description of each study visit including what will occur at each visit and how long each visit will take**.
N/A

What type of compensation will be provided to subjects (e.g., class credit, Mechanical Turk payments, or no compensation will be provided)? If using SONA, indicate whether identifier will be used to track payment for class credit and whether or not research data will be linked to payment information/identifiers. N/A

6. RISK/BENEFIT ASSESSMENT

6.1 **Risks:** Possible confidentiality breach of study participants

6.2 **Benefits:** No incentive will be provided to study participants

7. DATA ANALYSIS:

Primary Outcomes of interest: Variability in resident clinical exposure as the first resident assigned to a visit for individual patient demographics such as race, insurance status, sexual orientation, care plan status, and gender identity

8. CONFIDENTIALIATY OF DATA AND INFORMATION STORAGE

Describe where the research data will be stored during the study and how it will be secured. This includes coding data and choosing an appropriate and secure data storage mechanism which will prevent unauthorized access to data.

Data will be stored on a physically secured University of Wisconsin Department of Emergency Medicine computer that is protected by a password. All resident records will be de-identified using a number instead of resident name. Data will be reported in aggregate form only.

Print ☐ Compact Close

University of Wisconsin-Madison MR IRB Application	Study # : 2023-0312 Principal Investigator: Andrea Gilmore Bykovskyi	View: SF: nPBA: Basic Study Information

Basic Study Information

1. Formal Title

This is the title that will appear in correspondence.

* Provide the full, formal study title.

> Development of person-centered outcome measures for emergency care experiences among persons with dementia

2. Transferred Study

Answer Yes to this question only if:

a) the principal investigator (PI) for this application is coming to UW-Madison, UW Health, or the Madison VA from another institution and,

b) they plan to open a study here that is already IRB-approved at their previous institution.

* Is this study being transferred from another institution?

○ Yes ◉ **No**

3. Principal Investigator

* Identify the Principal Investigator.

Andrea Gilmore Bykovskyi

View: SF: nPBA: Type of Research Application

Type of Research Application

1. Type of Research Application

* Select one of the following: Exemption

View: SF: nPBA: PI Appointment

PI Appointment

1. Principal Investigator

PI: Andrea Gilmore Bykovskyi

2. Primary Appointment

* Choose the appointment under which you will be conducting this research.

UW-Madison

3. UW-Madison Appointment

3.1. Appointment Details

* Identify the appointment under which the PI will conduct this research.

	Title	Type	UDDS	Department Combined Name
◉	**Associate Professor**	**FA**	**A534100**	**SMPH/EMERG MED**

3.2. Appointment Not Found

☐ Check if the appointment is not listed above.

4. Investigator-Initiated Study

* Is this an investigator-initiated study?

◉ **Yes** ○ No

View: SF: nPBA: Study Team

Study Team

1. Points of Contact Selection

Points of contact can edit the application and will receive email notifications about this submission.

Please do not use personal email addresses (e.g., Gmail, Hotmail, etc.). A campus business email can be changed following the instructions here.

If the PI is serving as the only study point of contact, indicate that here.

Can't find someone in the chooser? See this FAQ for help.

To register a NetID, click here.

* Identify the points of contact for this study (limit of four).

Name	Email
Clark Benson	cbenson5@wisc.edu
Laura Block	lmblock2@wisc.edu

2. All Other Study Team Personnel

List ONLY UW-Madison, UW Health, or Madison VA personnel. External personnel will be listed elsewhere in the application.

Please do not use personal email addresses (e.g., Gmail, Hotmail, etc.). A campus business email can be changed following the instructions here.

Study team members listed below will have read-access only and will not be able to edit the application. They also will not receive email notifications.

Can't find someone in the chooser? See this FAQ for help.

To register a NetID, click here.

List all the other members of the study team (not including the PI or points of contact).

Name	Email
Alison Coulson	acoulson@wisc.edu
Lucas Ebert	lhebert@medicine.wisc.edu
Jess Fehland	fehland@wisc.edu
Scott Hall	shall@medicine.wisc.edu
Shivani Kadiyala	skadiyala@medicine.wisc.edu
Alden Laev	alaev@medicine.wisc.edu
Maria Mora Pinzon	mmora2@wisc.edu
Phoebe Natzke	pnatzke@medicine.wisc.edu
Lex Oliver	aloliver@medicine.wisc.edu
Natasha Pedone-kahle	pedonekahl@medicine.wisc.edu
Tarjani Ranade	tranade@medicine.wisc.edu
Manish Shah	mnshah@medicine.wisc.edu
Inem Uko	iuko@wisc.edu
Audrey Wood	amwood@medicine.wisc.edu

View: SF: nPBA: Study Team Roles

Study Team Roles

1. Primary POC

If the PI is serving as the primary point of contact, indicate that here.

* Identify the primary point of contact for this study.
Clark Benson

2. Human Subject Involvement

* Does this study involve recruiting, consenting, or interacting with human subjects?
(●) **Yes** ( ) No

2.1. Study Team Details

For each study team member below, click the ✎ button and check the boxes to indicate that study team member's roles for this study. Note: Some study team members may not have any roles listed below.

Tell us which study team members will: recruit human subjects, obtain informed consent from human subjects, interact with human subjects, or perform cognitive assessments on human subjects.

Study Team Member	Recruit Subjects	Obtain Informed Consent	Interact with Subjects
Clark Benson	yes	yes	yes
Laura Block	yes	yes	yes
Alison Coulson	yes	yes	yes
Lucas Ebert			
Jess Fehland	yes	yes	yes
Andrea Gilmore Bykovskyi	yes	yes	yes
Scott Hall			
Shivani Kadiyala			
Alden Laev			
Maria Mora Pinzon	yes	yes	yes
Phoebe Natzke			
Lex Oliver			
Natasha Pedone-kahle			
Tarjani Ranade			
Manish Shah			
Inem Uko	yes	yes	yes
Audrey Wood			

View: SF: nPBA: Funding

Funding

1. Funding Administered by UW Madison

Answer no to this question if this study will only be supported by VA funding; you will have the opportunity to add VA funding later in the application.

* Do you have pending or approved funding administered through Research and Sponsored Programs (RSP) or Business Services to support this project?

(●) **Yes** ( ) No

1.1. Funding Sources

For **federal funds**, pending sources may be listed if the grant has received a highly meritorious score. For example, an impact score of <30 is an indication of a highly meritorious NIH grant proposal. Receipt of a request for Just In Time (JIT) documentation is another indication of a highly meritorious proposal.

For **non-federal funds**, pending sources may be listed if you have confirmation from the sponsor that funding will be awarded due to merit AND the sponsor has a peer-review process.

For **industry**, do not select industry sponsors who are only providing drug/device OR only limited support for the study.

* Use this chooser to select each funding source administered through UW-Madison that will support this study or project.

Funding Source Details

View

PI Name	BYKOVSKYI, ANDREA LEA GILMORE
Proposal ID	MSN270773
Award ID	MSN270773
Funding Title	Person-Centered Outcome Measures for AD Patient Emergency Care Experiences
Project ID	AAL8185
Sponsor Reference Number	
Sponsor (Source)	ALZHEIMER'S ASSOCIATION
Primary Sponsor	*No Value Entered*
Federal	No
Status	Active
Start Date	1/1/2023
End Date	12/31/2024

2. Other Funding

* Do you have pending or approved funding NOT listed on this page?

Yes **No**

View: SF: nPBA: Conflict of Interest

Conflict Of Interest

Please review the study team member Outside Activities Report (OAR) and managed entities data below before answering the questions on this page.

All study team members have completed their Ouside Activities Report for the year.

NOTE: Per campus policy all study team members must submit an OAR every year and keep it up to date.

These study team members have managed entities:

Manish Shah

Exact Sciences Coporation	Advisory Only

1. Sponsorship

* Do any of the managed entities sponsor the study?

○ Yes ◉ **No**

2. Technology

* Do any of the managed entities own or license a technology being used in the study (including any agent, device, or software)?

○ Yes ◉ **No**

3. Irrelevant Management Plans

If any of the management plans identified at the beginning of this page are not relevant to the study please explain why.

> No managed entity has played any role in the conceptualization, design or conduct of this study.

4. Intellectual Property

* Do any study team members involved in the design or conduct of the research (including their spouses and dependent children) own intellectual property that will be used in the study or project?

○ Yes ◉ **No**

5. Other Entities

* Besides the sponsor(s) of this project or entities listed above, do any study team members have a fiduciary or financial relationship with entities that will be involved in this study or that may be significantly affected by it?

○ Yes ◉ **No**

6. Incentives

* Do any of the study team receive any incentives for recruiting human subjects or any other purpose directly related to the study or project?

○ Yes ◉ **No**

View: SF: nPBA: VA Status

VA Status

All studies that fall under Madison VA purview must be reviewed and approved by the VA Research and Development (R&D) Committee in addition to being reviewed by the Health Sciences IRB. For information about the VA R&D Committee review process, please contact **VHAMADRDCoordinator@va.gov**.

1. VA Status

* Does this study involve the Madison VA (Wm. S. Middleton VA Hospital); e.g., funding from the VA, conducted under VA appointment, use of VA facility, recruitment of veterans or use of their data or samples at the Madison VA?

○ Yes ◉ **No**

View: SF: nPBA: PRMC

Scientific Review: Protocol Review Monitoring Committee

1. Cancer Related

* Is the scientific question of the protocol cancer related?

Yes **No**

2. Targeting Cancer Patients

* Are you specifically targeting cancer patients for enrollment in this study?

Yes **No**

3. Use of Cancer Data or Images

* Does this study involve the review and/or use of biological specimens/data/images/records from cancer patients?

Yes **No**

View: SF: nPBA: Exemption

Exemption

1. Exemption Category

If your research does not fit within one of the categories below, please select Full Review on the Type of Research Application page.

* Select the relevant category or categories for which you are requesting an exemption determination.

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2. Research involving the use of educational tests, surveys, interviews.

- Surveys (with adults only)
- Interviews (with adults only)
- Focus groups (with adults only)
- Educational tests
- Observation of public behavior

May NOT involve an intervention (see exemption 3) or linking to additional personally-identifiable data.

View: SF: nPBA: External Collaborations 2

External Collaborations

1. Outside UW Activities

* Will any UW/UW Health or Madison VA personnel conduct any of the following study activities at locations outside the UW/UW Health or Madison VA: subject recruitment, obtaining informed consent, or interacting or intervening with subjects?

○ Yes ◉ **No**

View: SF: nPBA: Sharing Data Outside UW

Sharing Data Outside UW

1. Sharing Data Outside UW Madison

* Will subject data, images, or specimens be shared outside the UW Madison?

Yes **No**

View: SF: nPBA: Study Procedures and Special Populations

Study Procedures and Special Populations

1. Study Procedures Involved

Select "Review or use of information from health care records"

* If your study involves any of the following special procedures or considerations, additional information may be needed. Select all that apply. If none apply, check Not Applicable.

Creation of audio or video recordings or photographs
Interviews, focus groups, surveys, questionnaires, assessments (e.g., QOL, SCID, BDI, etc.)

2. Special Populations

If you will collect data points identifying individuals as any of the following, select the corresponding box(es).

* Is the research designed to include any of the following populations? Select "Not Applicable" if the research will not include any of the populations below. NOTE: If enrolling pregnant women, children, or prisoners, and you can identify them as such, check the box.

Persons with impaired decision-making
Poor/uninsured, elderly/aged, or educationally disadvantaged

View: SF: nPBA: Research Design and Procedures

Research Design and Procedures

1. Overall Purpose

Describe the research questions or gap in knowledge the study proposes to address or contribute to in language that someone who is educated but not an expert in the field can understand.

* What is the overall purpose and aim of this project or study?

> The overarching goals of this study are to determine cross-cultural care priorities of people living with dementia (PLWD) and their caregivers during emergency department (ED) visits and to develop and refine items for a Person-Centered Outcome Measure (PCOM) for use by PLWD to facilitate evaluation of those priorities.

2. Pre-Existing Information/Background Knowledge

* What prior information or knowledge exists to support the conduct of this project or study?

> Over 50% of the more than 6 million people with Alzheimer's Disease and Alzheimer's Disease and Alzheimer's Disease Related Dementia (ADRD) in the US visit an emergency department (ED) annually. The ED often serves as a first layer in supporting people living with dementia (PLWD) experiencing acute exacerbation of underlying chronic illnesses or distressing behavioral and psychological symptoms of dementia, and caregivers without respite who are overburdened or in crisis. Despite the major role the ED plays for PLWD and their care partners, presence of ADRD is often not well-recognized in the ED—and many factors in the ED environment are thought to be detrimental to provision of adequate care and betterment of health outcomes of PLWD. Collectively, the compounding environment of care and situational factors that surround ED visits produces significant distress among PLWD while frequently omitting care approaches that are responsive to the needs of PLWD. Studies suggest that PLWD would benefit considerably from improvements in the ED care experience. Findings from our prior work suggest that commonly used outcome measures which focus predominantly on utilization (e.g., ED revisit) and mortality do not adequately address aspects of the ED care experience or what matters most to PLWD during ED visits. Yet, there is virtually no research identifying specific ED care priorities from the perspectives of PLWD or their caregivers. Because an ED visit is often a marker of advancing illness and for some patients the need to engage palliative care, relying heavily on utilization outcomes to evaluate care quality may be inappropriate in many cases and is globally insufficient, highlighting the need for more sensitive care and outcome measures that capture meaningful indicators of care quality.

3. Study Procedures and Interventions

Provide an overview of the types of records that will be reviewed, what information from these records will be collected, and the kinds of analyses that will be performed on the study data. If data from multiple sources will be used describe this here (e.g., medical record information connected to imaging or billing information or data from multiple institutions collated).

* Briefly describe the procedures and interventions that will be performed for this project or study and all study arms involved. Do not include information on recruitment or consent.

> We will conduct semi-structured interviews with caregivers and individuals with dementia with capacity to share their care experiences from socioculturally diverse backgrounds to identify their ED care priorities. Participants may be interviewed in a private room in the ED or in another place of their choosing after their stay in the ED. This may include their hospital room if they are admitted after their ED visit or

their home, a private room in the Department of Emergency Medicine Offices, or a private room in a public library if they return home. Given the various length of wait times in the ED, participants will have the option to participate in a 10-15 minute interview or a longer 30-60 minute interview.

There are two scenarios under which individuals with dementia will be eligible for participation (explained further in Subject Identification and Recruitment: Subject Population):
1. Individuals with dementia with capacity to share their care experiences who do not currently have an activated power of attorney, legal guardian, or otherwise legal indication of lack of capacity to consent will be included, with the option to complete the interviews individually or with a support person/caregiver based upon their preference. Along with an assessment of capacity to consent from the clinical team and EDRC team, a formal capacity assessment through an Evaluation to Consent will confirm capacity to consent for these individuals just prior to being consented to participate in the study, recognizing this may take place at a timeframe different from clinical staff assessment. Study team members with experience making capacity to consent determinations from a previous study (2018-0101) will conduct the Evaluation to Consent form.

2. Individuals with dementia with capacity to share their experiences but with presence of an activated power of attorney, legal guardian, or otherwise legal indication of lack of capacity to consent will be included if proxy consent from the legally authorized representative can be obtained and the person with dementia provides assent.

Current, former, and/or caregivers providing care to someone with dementia can also complete interviews individually or dyadically.
All participants (caregivers and people living with dementia) will complete demographic questionnaires.

4. Incidental or Adventitious Findings

* Will any study procedures produce incidental or adventitious findings (e.g., imaging scans, laboratory blood tests, depression screening questionnaires, etc.)?

○ Yes ◉ **No**

5. Instruments Involved

This question is intended to identify projects involving the development or use of medical devices. This does not apply to surveys or questionnaires.

* Are there instruments of any kind, including software, tests run on samples, and algorithms, used in the study?

○ Yes ◉ **No**

View: SF: nPBA: Subject Identification Medical Records

Subject Identification: Medical Records

1. Medical Record Use

* Will medical records be used to identify subjects or records?

(●) **Yes** ( ) No

1.1. CRDS Usage

CRDS assists UW investigators with developing data queries and delivering data from the UW Health Enterprise Data Warehouse (EDW) to be used in feasibility assessments, recruitment of participants, pilot studies, and retrospective analyses.

* Will you use the Clinical Research Data Service (CRDS) to identify subjects via these records?

( ) Yes (●) **No**

1.2. Record Identification Details

* Describe how eligible subjects will be identified using medical records, including 1) which records will be accessed and 2) who will identify eligible subjects.

> Medical records will facilitate identification of eligible participants through our recruitment arm at the UW Health University Hospital Emergency Department (ED). ED recruitment will be facilitated through the Emergency Department Research Coordinator (EDRC) Program. EDRC staff are integrated into the ED at UW Health to assist with screening of eligible participants. They regularly interface with ED clinical staff to assess eligibility of potential study participants and determine whether recruitment approaches are appropriate provided patient safety and health.
>
> EDRC staff will examine diagnostic information within the medical record to determine presence of patients with dementia in the ED. EDRC staff will also examine medical records to determine presence of an activated power of attorney, legal guardian, or otherwise legal indication of lack of capacity to consent (referred to hereafter as presence of a legally authorized representative, or LAR) to determine if the person with dementia can legally consent to participation in research.
>
> Subsequent recruitment steps are described in Subject Identification and Recruitment: Recruitment Methods.

View: SF: nPBA: Risks and Benefits

Risks and Benefits

1. Direct Benefits Intended

For this type of research there are generally no direct benefits to subjects. The response to this question, "There are no direct benefits to subjects", would be acceptable.

* Are any of the research activities intended to directly benefit subjects?

○ Yes ◉ **No**

2. Potential Benefits to Society

Describe how the research might help future patients.

* Describe the importance of the knowledge reasonably to be gained from this study and what benefit the research may provide to society.

> The primary benefits of this study are indirect future improvements to ED care for people living with dementia, and evaluation of care quality according to specified person-centered care priorities. Some participants may benefit emotionally from the opportunity to share their experiences and be listened to during interviews.

3. Direct Physical Intervention

A physical intervention refers to study procedures that may pose a risk (however minimal) to a subject's body (e.g., blood draws, MRI scans, drug or device trials, exercise, dietary restrictions/supplements). Examples of activities that are NOT physical intervention include obtaining informed consent and administering surveys.

* Does this study involve direct physical intervention with subjects?

○ Yes ◉ **No**

4. Potential Psychosocial Risks

For this type of research the risks to subjects are generally limited to the risk of breach of confidentiality. The response to this question, "There is a risk of breach of confidentiality", would be acceptable.

* Describe any potential psychosocial risks to subjects, such as psychological stress or confidentiality risks (including risk to reputation, economic risks, and legal risks).

> There is a minimal risk of a breach in confidentiality.
>
> This study involves semi-structured interviews. Some participants may become upset or experience discomfort when speaking of dementia and/or ED care experiences that were traumatic or stressful. Participants, particularly those with dementia, may become fatigued or frustrated throughout the course of the interview or in response to questions that are abstract or complex.
>
> Participants may also reveal personal or identifiable information (e.g. name, names of love ones, location) when responding to questions.

5. Procedures to Minimize Risks

The response to this question should address how the risk of breach of confidentiality will be minimized. For example, it could be described that the study team has several measures in place to protect against a breach of confidentiality, such as limiting the number of people who view identifiable information, coding study instruments, storing study data in restricted areas and on computers that are password-protected, only transmitting coded data outside the institution (if data will be shared), and using a secure web-interface to transmit data off-site (if data will be shared).

* Describe the procedures in place to minimize risks from all interventions performed for research purposes. This should include activities in place to identify, monitor, mitigate, and eliminate risks to the degree possible.

> Confidentiality Risks
> Confidentiality risks will be minimized through use of multiple procedures and processes that maximize anonymity and security in accordance with campus policy. We will assign all participants a study ID number and after interviews, we will only identify participants' data by study ID number.
>
> The study team will minimize the identifiable information collected during the logistical portions of recruitment and scheduling interviews, specifically the study team will only record first names and contact information (phone number and/or email address) during the interview scheduling process (if necessary) which will be deleted 1) upon completion of the interview 2) if the participant(s) decides to no longer participate or 3) after four unreturned contact attempts. Contact information will be stored in a secure folder on the Department of Medicine research data server, with access limited to study members only. This folder location is separate from all other study materials and interview data. Access to the server is restricted to team members with special training on data safety. Access is audited every 6 months, and removed if determined no longer necessary.
>
> Risk of Emotional Upset or Fatigue During Interviews
> The study team is trained in procedures to maximize comfort of the study, including providing the option to skip questions or pause/stop the interview in scenarios of emotional upset or fatigue. This, along with the approximate length of the interview, are covered in informed consent. Interview questions will be modulated based upon the abilities of the participant(s), and the study team is trained to adjust pacing and difficulty of the questions during the interview space. The study team will also ask if participants would like to be referred to resources for dementia caregiving support. Under prior protocols (IRB 2018-0101), the study team has recruited and engaged people living with dementia and their caregivers in interviews in the ED and hospital and offered tailored resources for caregivers nationally and by the state the caregiver resides in.
>
> Risk of Personal or Identifiable Information
> Identifiable information, such as name or location, will be redacted from the interview transcript. Potentially sensitive information, such as experiences with ED care for cognitive needs, is likely to be shared and will not be redacted.
>
> Risk of Loss of Confidentiality due to Mandated Reporting
> If during the interview, participants report situations which may constitute potential abuse of a child or elder, our staff will follow requirements for mandated reporting. This risk will be disclosed to them in the informed consent process and corresponding information sheet.
> If participants disclose care situations which upset or concern them but do not constitute potential abuse of a child or elder, they will be provided with the contact information for UW Hospital Patient Relations: 608-263-8009.

View: SF: nPBA: Subject Population

Subject Population

1. Total Subjects

You must provide an integer. If you are enrolling a range of subjects (e.g., 50 to 100 subjects), enter the larger number.

* Provide the number of subjects that will be enrolled at sites for which UW Madison is serving as the reviewing IRB.

> 30

2. Inclusion Criteria

* Describe the main inclusion criteria.

> Individuals with dementia:
> •Diagnosis of ADRD confirmed via medical record review or by proxy informant such as clinical staff, the participant's activated LAR, caregiver, or family member.
> •For individuals with dementia recruited through community-based recruitment approaches, diagnosis of ADRD as specified through self-report
> •Has had an ED experience
> •Capacity to share their care experience and to consent to participation in research through clinical staff assessment and as measured by the Evaluation to Consent Assessment
> •OR if capacity to share their care experience BUT indication of lacking legal capacity to provide informed consent (i.e. presence of activated power of attorney, legal guardian, or otherwise activated LAR)—proxy consent by the activated LAR and assent by the person with dementia
> •If participating in dyadic nature with caregiver, consent of caregiver
>
> Caregivers:
> •Current or former informal/unpaid caregiver to person with dementia
> •Person with dementia has had an ED experience
> •If participating in a supportive or dyadic nature with person with dementia, consent and/or assent of person with dementia

3. Exclusion Criteria

* Describe the main exclusion criteria.

> Individuals with dementia:
> •Unable to verify diagnosis of ADRD
> •Unable to answer basic questions about their care based on assessment of the clinical team and as verified by EDRC team, or through ongoing assessment by study team
> •Unable to understand and consent to study
> •No relevant ED experience
> •Unable to locate or receive consent from activated LAR (or caregiver if person with dementia prefers dyadic interview)
>
> Caregivers:
> •Paid caregiver
> •Caregiver to person who has condition other than dementia
> •No relevant ED experience
> •Consent/assent not received from person with dementia in context of a supportive or dyadic interview

4. Targeted Populations

Populations could be racial/ethnic, sex, or gender (this also applies to gender identity, or lack thereof).

* Will this study target or exclude specific populations?

(●) **Yes** ( ) No

4.1. Targeted Population Justification

* Describe the population that will be targeted or excluded and provide justification.

> Because our aim is to develop a measure that is responsive socioculturally diverse perspectives on ED care among people with dementia, we will endeavor to include individuals from racially/ethnically diverse groups, with a familial history of immigration for different cultural perspectives, and socioeconomically diverse groups. These groups are underrepresented in research on dementia and ED care despite experiencing poorer outcomes.

View: SF: nPBA: Special Populations Justification

Special Populations Justification

1. Justification

If more than one special population is enrolled, separate justifications should be provided for each unique population.

* What is the justification for the inclusion of these subjects?

> This study aims to understand ED care priorities for people with dementia by including and interviewing people living with dementia themselves. Most existing measures to assess care rely on caregiver reports, and have been developed through caregiver interviews. While these measures may accurately capture some of what matters to people with dementia, there is evidence of a lack of perfect alignment between the perspectives of people with dementia themselves and caregivers. Therefore, it is critical that we include people with dementia in this study so that we can integrate their perspectives into future measure development. Considerable research demonstrates that individuals living with dementia have capacity to participate in research, particularly in interviews, and as a result considerable resources have been developed and disseminated to support their inclusion.
>
> Moreover, we plan to include people with dementia who do not have legal decision-making capacity as these individuals are even more under-included in research. Lack of legal decision-making capacity does not always equate to a lack of ability to participate in research procedures or decisions about research which we recognize as necessitating a situationally specific assessment. In other words, many people with dementia who do not have legal decision-making capacity may still be able to share details on their care experiences and preferences, and therefore we wish to ensure their perspectives are not systematically under-included. They may also have unique experiences on care in the context of fluctuating cognition.
>
> Moreover, we plan to include diverse participants, including those who are potentially socio-economically disadvantaged. This is critical because those who are socio-economically disadvantaged often rely on the ED as a more accessible point of care, and therefore findings around ED care priorities and corresponding measurement must be responsive to their perspectives.

2. Safeguards

Include the measures that will be taken to minimize any potential coercion or undue influence in recruitment and ongoing participation in the study.

* Describe the additional safeguards that have been included in this study to protect the rights and welfare of these subjects.

> Our team has extensive training and experience in working with individuals with dementia, and procedures for ensuring supported decision-making and tailoring and pacing of study activities. Throughout the study process, we will assess legal capacity to consent and capacity to share care experiences, ability to answer study questions comfortably, involve activated LARs and engage established protocols to ascertain and confirm assent in situations where the individual with ADRD lacks the legal capacity to consent.
>
> We will ensure study materials and activities can be accessed by individuals with varying abilities. We will do this by building rapport with the participant prior to the interview, giving the participant the option to conduct the interview in a familiar place, providing cues to skip questions, giving ample time to respond, restructuring interview questions to be familiar and comfortable to the participant, and offering to stop the interview if the participant appears to be fatigued or distressed.

View: SF: nPBA: Recruitment Methods

Recruitment Methods

1. Recruitment Plan

This description should address what methods will be used, when and how often they will be used, and how many times potential subjects will be contacted.

* Describe the recruitment plan for this study.

Recruitment Mechanism: Emergency Department
Emergency Department Research Coordinator (EDRC) Program staff will monitor medical records to determine presence of potentially eligible patients in the ED who have a diagnosis of ADRD. EDRC staff will engage the clinical team (ED nurse) to complete initial screener questions to determine if the patient is appropriate to approach to ascertain interest. Screener questions will confirm a) appropriateness to approach based on patient stability/safety, b) patient capacity to communicate and answer questions, and c) legal decision-making capacity/presence of an activated LAR.

After identification of potentially eligible participants, EDRC staff will approach the patient and/or their activated LAR as well as any caregivers present (who may or may not be the patient's activated LAR but are otherwise involved in their care) to determine their interest in learning about the study.

EDRC staff will ask the potential participant(s) if the study team can visit them in the ED (or hospital if admitted) or call them at their preferred phone number. If the potential participant(s) authorizes an ED/hospital visit or a phone call, EDRC staff will call the study team to securely relay contact and contextual information. The study team will store contact information in a secure Department of Medicine server folder. If the potential participant(s) prefers, they can contact the study team themselves.

The study team will further assess the potential participants' interest in the study and eligibility, and determine the participant with dementia's capacity to consent and to participate in a brief interview. The study team will proceed to obtaining informed consent and/or assent dependent upon the individual with dementia's legal decisional capacity—using procedures outlined in Informed Consent: General and Informed Consent: Impaired Consent. Upon obtaining informed consent and/or assent, interviews will either take place a) in the ED/hospital, or b) be scheduled for a future date and/or a means for follow-up contact will be collected for the interview to be scheduled at a future time.

The study team may contact caregivers and activated LARs if the person with dementia grants permission for the study team to contact them over the phone.

If the patient, caregiver, and/or activated LAR are willing to discuss the study with a research staff member but are busy with a member of the clinical team, or are busy with another matter and cannot discuss the study at length at that time, a recruitment brochure will be offered and distributed. The brochure contains a brief description of the study and instructions that the patient, caregiver, and/or activated LAR can follow to contact the lead researcher if they are interested in the study.

Recruitment Mechanism: IRB-Approved Registry
The use of one IRB-approved registry will occur for recruitment of people living with dementia and caregivers. Dr. Gilmore-Bykovskyi has an IRB-approved registry (2019-1148) of older adults with and without changes in memory and caregivers who are interested in brain health related research.

Recruitment Mechanism: Community-Based Organizations
We will conduct recruitment in partnership with community-based organizations, by collaborating with each organization to distribute information on the study and how to contact the study team if interest through the community organizations' regularly scheduled newsletters (online or print) and/or posted flyers. Organizations include:
•Madison Senior Center
•Madison School and Community Recreation – East
•Madison Public Library- Central Library
•New Bridge

Newspaper, radio and social media advertisements will contain Information about the study, eligibility for details on how interested participants can contact the study team members. Outlets are listed below:

•Madison 365
•La Comunidad
•WIBA-FM 101.5
•WORT 89.9
•WZEE 101.4
•Facebook
•Twitter
•Gilmore-Bykovskyi Lab Website: https://gilmorebykovskyilab.org/

2. Recruitment Material Upload

Upload recruitment materials such as recruitment emails, letters, phone scripts, brochures, or advertisements.

Brochure ARCOM_03.02.2023.tif

3. Approved Recruitment Database Usage

* Are you using an IRB approved recruitment database to disseminate recruitment materials or to contact subjects?

(●) **Yes** ( ) No

3.1. Recruitment Database Details

Provide the IRB protocol number of the recruitment database.

2019-1148

3.2. Database Usage Approval Documentation

If the recruitment database is not the investigator's own, upload a letter of support for the use of the database.

There are no items to display

View: SF: nPBA: Subject Screening

Subject Screening

1. Preliminary Eligibility Screen

* Will subjects undergo a preliminary screen to determine basic eligibility?

(●) **Yes** ( ) No

1.1. Screening Materials

* Upload a copy of the screening questionnaire.

↔ ARCOM Screener Questions_05.04.docx

1.2. Data Retention

If you are retaining screen data, the previously uploaded questionnaire/script should address this and include authorization language for maintaining PHI if HIPAA applies.

* Will you be retaining screen data from subjects who do not enroll in the study?

( ) Yes (●) **No**

2. Planned Study Procedures Before Obtaining Consent

Examples include fasting, discontinuing medications, etc.

* Will there be any procedures performed before informed consent is obtained from subjects (apart from screening)?

( ) Yes (●) **No**

View: SF: nPBA: Remuneration and Costs

Remuneration and Costs

1. Payment

* Will subjects be compensated to participate in the study?
(●) **Yes** ( ) No

1.1. Travel and Other Expenses

* Is payment limited to covering travel expenses and other costs incurred by subjects as a result of study participation?
( ) Yes (●) **No**

1.2. Payment Plan

Include the amount of payment(s), proration, multiple payment schedules, etc.

* Describe the payment plan.

> $30 if an individual starts the interview; whether or not the interview is fully completed

1.3. Child/Parent Payment

* Are any payments being offered to child subjects?
( ) Yes (●) **No**

1.4. Nonmonetary Compensation

* Will nonmonetary compensation be offered?
( ) Yes (●) **No**

2. Costs

* Will subjects incur any costs as a result of study participation (pharmacy preparation fees, payment for a device, billing of study procedures to subjects insurance)?
( ) Yes (●) **No**

View: SF: nPBA: Privacy and Confidentiality

Privacy and Confidentiality

1. Privacy Plan

Privacy is defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. In the context of research, this primarily pertains to methods used to obtain information about subjects or the setting in which research takes place.

* Explain how the subjects' privacy will be protected. (e.g., research intervention is conducted in a private room).

> Interviews will take place by phone, UW-Madison Zoom, Cisco Webex web conferencing or in a private room in the ED, hospital, or their home, a private room in the Department of Emergency Medicine Offices, or a private room in a public library. Interview mode and location will be determined based on participant preference, including ED/hospital, which was successful in a previous study (IRB 2018-0101). Data collection will be limited to the amount necessary to achieve the aims of the research. In the event that unnecessary personal or identifiable information is provided by the participant(s), it will either not be recorded or removed from the research record as soon as possible. Only research staff will have access to individually identifiable private information about human subjects. No direct participant identifiers will be used to label interview data files, de-identified transcripts, or stored questionnaire data. All data will be labeled by assigned study ID numbers. No identifiable data will be kept from those subjects who were ineligible for the study or chose not to enroll. Data will be reported as group data, or deidentified participant quotes, so that no individual could be identified. All members of the research team and study staff will complete HIPAA and research ethics training and have certification thereof. Any member of the research team who knows or has a personal relationship with any participants will recuse himself or herself from further study activity with the identified participants, and will not have access to those participants' data. Contact information from participants will be stored to facilitate conduct of the study (e.g. scheduling) and separately from data. It will be deleted after sharing of the study findings, unless the participant(s) indicates preference for it to be deleted immediately after participation. Fully de-identified interview data will be kept indefinitely.

2. Level of Identifiability

* Select how subjects are identified in the data. Check all that apply.

No Identifiers (De-identified, Anonymous, or Anonymized): stored data is stripped of all identifiers

3. Data Protection Plan

Records and data include informed consent documents, case report forms or study flow sheets, survey instruments, database or spreadsheet, screening logs or telephone eligibility sheets, web based information gathering tool, audio/video/photo recordings of subjects, labeled specimens, data about subjects, subject identifiers, etc.

The study team should describe how data confidentiality will be protected. Some measures that are often used and acceptable to the IRB are: using codes so that no direct subject identifiers are recorded on data collection sheets; creating codes for data that are not based on subject identifiers (i.e., avoiding codes that include subject initials or are based on birth dates); and destroying the link to the code as soon as possible.

* How will the study team protect research records, data, and/or specimens against inappropriate use or disclosure, or malicious or accidental loss, or destruction? Include how and where the data and/or

specimens will be stored.

Data collected from this study will come from participant interviews and sociodemographic questionnaires.

All electronic records and data related to the study protocol will be kept on password-secure Department of Medicine (DOM) servers with limited access to Study Team members.

Contact information necessary for recruitment and scheduling of interviews will be stored in a folder on the DOM server separate from the parent study folder. This contact information will not be linked to the participant's study data whatsoever and will be destroyed immediately after all necessary contact with the individual has ceased (e.g. scheduling, sharing of study findings) or at the end of the study.

Original recordings will be rapidly transferred to the DOM server and destroyed from their original platform after completion of the interview. Original recordings stored on the UW-Madison Zoom or Cisco Webex secure platform if interviews are completed remotely or temporarily on an encrypted audio recording device in a locked cabinet in the PI's locked office located at 800 University Bay Dr. if performed in person. Only the PI and study team members will have access to this locked drawer. Recordings on Zoom or Cisco Webex will be destroyed immediately after secure transfer to the DOM server, and likewise recordings on the audio recording device will be destroyed immediately after secure transfer to the DOM server. Audio recordings on the DOM server will be destroyed promptly after successful transcription and de-identification.

Questionnaire data (e.g. demographic questionnaires) will be provided directly to study team members conducting interviews and stored on the password-secure DOM servers.

De-identified transcripts will be stored electronically on the password-secure DOM servers. Hard copies of de-identified transcripts will be used in team meetings for data analysis and will be stored in a locked cabinet in the PI's locked office. Only the PI and study team members will have access to this locked drawer. When these transcripts are used for analysis, it will take place in a private room at 800 University Bay Dr. and then returned to the locked drawer.

No identifiable data will be kept from those subjects who were ineligible for the study or chose not to enroll. In coordination with EDRC staff, we will be maintaining a general tabulation of how many patients were approached, but screened ineligible or chose not to enroll in the study. This tabulation will include reason for ineligibility/non enrollment. This general tabulation will not be linked in any way to the individuals approached for the study.

At no point in study procedures will participants be identified by name or other identifiable information. All participants will be identified via a study ID number that will be associated with their transcripts.

Depending on the nature of the event, the study team will report events such as noncompliance, new information, and potential unanticipated problems in accordance with the IRB's posted guidance.

4. Certificate of Confidentiality

If NIH, CDC, FDA, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award, answer "Yes".

* Is there a Certificate of Confidentiality (CoC), or will one be obtained, for this research?

○ Yes ◉ **No**

View: SF: nPBA: Retention of Data and/or Specimens

Retention of Data and or Specimens

1. Future Research Plans

* Will data and/or specimens collected for this study be banked for future research outside the scope of the current project?

Yes **No**

View: SF: nPBA: Exemption Consent

Exemption Consent

1. Upload Exemption Consent

- The exemption consent template is available here.
- For educational and social-behavioral studies, you can use the Consent Form Wizard. The Wizard does not include HIPAA authorization language.

Upload all consent materials (scripts, information sheet, etc.).

Information Sheet_Exempt_04.12.2023.docx

2. Exemption Consent Process

* Please describe the consent process.

> Information sheet will be provided to subjects and, if applicable, their activated LAR prior to starting in-person interviews/focus groups.

View: SF: nPBA: Impaired Decision-Making Capacity

Impaired Consent

1. Capacity Assessment Method

* Describe how capacity to consent will be assessed.

> Formal capacity assessment will follow the Evaluation to Consent measure – a widely used reliable/valid procedure. The study team member will clearly explain the study and will use the teach-back method to confirm understanding of the study purpose and interview procedures.
>
> This method utilizes a series of open-ended questions throughout the process to confirm that the participant understands the study and their involvement. These questions include: 1. What is the potential risk of your participation? 2. What will happen in this study? 3. What if you don't want to continue the interview? 4. What if you experience discomfort during the interview?

2. Schedule for Capacity Assessment

* Describe when capacity to consent will be assessed, noting specifically if there is a need to reassess consent capacity during the course of the study.

> Capacity to consent will be performed as a part of the Informed Consent process, prior to commencing study procedures.
>
> We will engage robust procedures to obtain informed consent and assent, and continually re-evaluate capacity to consent as well as assent across study procedures.
>
> Re-assessment of capacity and/or assessment will be triggered by statements from participants indicating they are confused or do not understand study procedures, and /or responses that indicate they do not understand the study procedures or questions or may not want to participate.

3. Who Assesses Capacity

* Describe who will assess consent capacity.

> Study team members will complete the formal Evaluation to Consent measure. These individuals are trained in dementia assessment, teach-back method, and interviewing techniques.
>
> EDRC staff will only preliminarily assess consent capacity through chart review and confirmation with clinical staff on the patient’s ability to answer questions about their care.

4. Subject Involvement in Consent

If you plan to enroll only those subjects who are able to provide informed consent (for example, early-stage Alzheimer's Disease subjects), state this here.

* Describe the extent to which (if any) the subject will be included in the consent process.

> Individuals who do not have an activated LAR, who can answer questions about their care, and who can complete the Evaluation to Consent measure will complete informed consent on their own behalf, as will caregiver participants.
>
> Individuals who have an activated LAR will be assented in an ongoing manner; this participant's activated LAR will complete consent on behalf of the participant.
>
> A participant's preference not to participate in the study will operate as a veto to their participation, even if their representative consents to the research.

5. Surrogate Consent Necessary

* Will there be a need for surrogate consent?

(●) **Yes** ( ) No

5.1. Who Provides Surrogate Consent

* From whom will surrogate consent be obtained?

> Activated legally authorized representatives that may provide informed consent on behalf of participants with dementia in this study will follow established priorities for surrogate decision-making according to the following priority list, in accordance with institutional policy and state law:
>
> 1) A research power of attorney may consent to a potential participant's participation in research, if the agent's decision is not inconsistent with the wishes and preferences of the potential participant expressed in the power of attorney instrument.
> 2) A court-appointed guardian of the person may consent to a ward's participation in research if the court order includes the power to consent to research. NOTE: A guardian of the estate or guardian ad litem cannot provide surrogate consent.
> 3) A power of attorney for healthcare may consent to a potential participant's participation in research, if the agent's decision is not inconsistent with the wishes and preferences of the potential participant expressed in the power of attorney for health care instrument.
> 4) If the potential participant has no research power of attorney, guardian, or healthcare power of attorney, then the potential participant's "next of kin" may consent on behalf of the potential participant.
> 5) "Next of kin" can provide surrogate consent in the following order: the spouse or registered domestic partner, adult child, parent, adult sibling, grandparent, adult grandchild, or a close friend of the potential participant.
>
> If the individual is interested in participating and can answer questions about their care, but has presence of an activated LAR and the activated LAR cannot be identified, the study team will thank them for their time and interest, end the recruitment process, and destroy any identifiable information about the person.

6. Consent Plan for Reassessing Capacity

* Is there a plan for obtaining consent if a subject regains capacity?

(●) **Yes** ( ) No

6.1. Reassessing Capacity

* Describe the plan to obtain consent from the subject should they regain the ability to provide informed consent on their own

behalf.

> While this is a single interview study and reassessment is unlikely to be formally needed, we recognize consent assessment as an ongoing process and interviewers will be mindful of communication or changes that indicate the need to reassess capacity.
> Formal capacity re-assessment will be triggered by disclosed concerns about memory or cognition, observed challenges following the consent process, and/or demonstrated lack of recollection or comprehension of key study details.
> Ongoing assessment of assent will also be performed. The research team will closely monitor the patient throughout all study procedures to ensure they are not uncomfortable or indicating dissent related to study procedures. If the patient indicates they dissent from participating in the study procedures, study activities will cease immediately.
> In addition to verbal assent, research staff will look for non-verbal cues indicating assent and dissent:
> Assent: Nodding head, smiling, engaging in conversation
> Dissent: Fidgeting, frowning, crossing arms, withdrawing or turning away in space

View: SF: nPBA: HIPAA General

HIPAA

1. Identifiable Information

* Will the research involve identifiable health information for any reason?

(●) **Yes** ( ) No

1.1. UW Madison Health Care Component or Madison VA

The HCC of the UW-Madison currently includes SMPH clinical departments; School of Pharmacy (clinical units only); School of Nursing; University Health Services (non-student records only); State Laboratory of Hygiene; and Waisman Center (clinical units only). Ensure the PI or any study team members are covered under HIPAA Privacy Rule regulations as part of their appointment.

* Are you or any member of the study team conducting the study under an appointment that is within the UW-Madison Health Care Component (HCC) and/or Affiliated Covered Entity (ACE) or the Madison VA?

(●) **Yes** ( ) No

1.2. HIPAA Authorization

* Will HIPAA authorization for access to the PHI be obtained for all or some subjects, or for only some uses?

( ) Yes, always: HIPAA authorization will be obtained from all subjects with signed documentation.

(●) **Yes, sometimes or without signed documentation: HIPAA authorization will not be obtained from some subjects/uses or may be obtained without a signature.**

( ) No: HIPAA authorization will not be obtained from any subjects.

1.3. External PHI Access

* Will you access or obtain fully identifiable health information from a health care provider that is not UW or UW Health, such as Meriter or ACHC, without first obtaining patient permission or authorization?

( ) Yes (●) **No**

View: SF: nPBA: HIPAA Waivers Sometimes

Authorization and Waivers

When sharing fully identifiable health information outside of UW or UW Health or obtaining it from a covered entity that is not UW or UW Health (e.g. bringing PHI from Meriter to a UW workstation to contact for phone screening or to recruit), you may need a partial waiver of authorization and accounting for disclosures may be required. Please consult with the **HIPAA Privacy Officer** and consult the Accounting for Disclosures Guidance found **here**.

1. HIPAA Requirement Fulfillment

* Please select which option(s) will be applied to fulfill HIPAA requirements.

Request Partial Waiver or Altered Authorization

2. Applicable HIPAA Identifiers

Select which of following identifiers will be associated with the health information you propose to collect for study purposes. Check all that apply to your study. If none of these identifiers will be collected for you study, select 'None of the Above'.

None of the Above

View: SF: nPBA: HIPAA Waivers/Authorization Request

Request for Authorization/Waivers

When sharing fully identifiable health information outside of UW or UW Health or obtaining it from a covered entity that is not UW or UW Health (e.g. bringing PHI from Meriter to a UW workstation to contact for phone screening or to recruit), you may need a partial waiver of authorization and accounting for disclosures may be required. Please consult with the **HIPAA Privacy Officer** and consult the Accounting for Disclosures Guidance found **here**.

1. Altered Authorization

HIPAA authorization for research must be project-specific. Standard clinical consent and authorization does not cover research use. If you will not obtain authorization in writing or seek to significantly modify the standard HIPAA authorization language, an altered authorization is necessary.

* Are you requesting an altered authorization?

(●) **Yes** ( ) No

1.1. Waiver Details

HIPAA authorization for research must be project-specific. Standard clinical consent and authorization does not cover research use. If you will not obtain authorization in writing or seek to significantly modify the standard HIPAA authorization language, a waiver of altered authorization is necessary.

Please describe how authorization will be altered.

> As the health information collected only includes diagnostic information regarding dementia status to screen for eligibility which will not be linked to any identifiable data within the study and will only be reported in the aggregate, we request verbal HIPAA authorization only.

2. Partial Waiver of Authorization

If you will not obtain authorization from any subjects, a full waiver is required.

* Are you requesting a partial waiver of authorization?

( ) Yes (●) **No**

3. Type of Records

* Identify the PHI to be used. Select all that apply.

Hospital/doctor records, including test results and dental records

4. Confirm Policy for Sharing PHI Externally

For help, see https://compliance.wisc.edu/hipaa/coordinators/

If you disclose PHI outside the HIPAA covered entity under which you are conducting the study, confirm you will contact the UW Madison HIPAA Privacy Officer or the Madison VA Privacy Officer.

(●) **Yes** ( ) No

5. PHI Protection Plan

* Describe your plan to protect PHI form unauthorized use or disclosure.

> Health information collected only includes diagnostic information regarding dementia status to screen for eligibility. This information will be stored in a secure Department of Medicine server folder, and will not be linked to any identifiable data and will only be reported in the aggregate. Only approved personnel will have access to study data.

6. PHI Destruction Plan

* Describe your plan for destroying identifiers at the earliest possible opportunity.

> No identifiers will be collected in association with PHI. Contact information will be destroyed after all necessary contact with participants is completed.

7. Waiver/Alteration Justification

* Explain why the study cannot practicably be conducted without the waiver of authorization or altered authorization.

> We are not obtaining signed consent given the minimum risk nature of the study and in the interest of limiting the number of study documents with the participant's name. Participation in the interview indicates consent and authorization. HIPAA language will be included in the information sheet.

8. Limitations Confirmation

* Federal law prohibits the re-use or disclosure of PHI in connection with this research to any person or entity other than those authorized to receive it, except: (1) as required by law; (2) for authorized oversight of the research; or (3) in connection with other research for which the HIPAA Privacy Rule permits the PHI to be used or disclosed. Do you agree to abide by these limitations in order to obtain a waiver of authorization?

(●) **Yes** ( ) No

View: SF: nPBA: Recordings and Photographs

Audio/Video Recordings and Photographs

1. Recordings Collected

* Select which of the following will be collected for this study. Check all that apply.

- [x] **Audio recordings**
- [ ] Video recordings
- [ ] Photographs

2. Identifiable Recordings

E.g., full face photo/video, audio recording of first and last name, or other individually identifiable information.

* Will the subject be identifiable in the audio/video recording or photograph?

○ Yes ◉ **No**

3. Retain Recordings

* Will the audio/video recordings or photographs be retained beyond the conclusion of this study?

○ Yes ◉ **No**

4. External Transcription

* Will anyone outside the study team transcribe audio recordings?

◉ **Yes** ○ No

4.1. Transcriber Details

* Indicate who will perform the transcription.

> Recordings include health information covered by HIPAA, transcription will be done by a professional transcription service covered by a BAA with the UW.

View: SF: nPBA: Interviews, Focus Groups, Surveys, Questionnaires

Interviews, Focus Groups, Surveys, Questionnaires

1. Tool Details

* Describe the interview tools, questionnaires, or surveys that will be used. Click the add button to provide information about each tool to be used.

View

Tool Description	Person with Dementia Demographic Questionnaire
Tool Standardized	No
File name	Demographic Questionnaire_PLWD_02.03.2023.docx
Tool Manner	Telephone In-person Internet
Tool Manner Other	In-person at ED, hospital, home, private room in public library or Department of Emergency Medicine, or other private location preferred by participation. Phone or Internet over Zoom or WebEx
Date Modified	3/29/2023

View

Tool Description	Interview Guide - Abbreviated Version for ED/Hospital Use
Tool Standardized	No
File name	Interview Questions Short Version_02.03.2023.docx
Tool Manner	In-person
Tool Manner Other	In-person at ED or hospital.
Date Modified	3/6/2023

View

Tool Description	Interview Guide - Full Version
Tool Standardized	No
File name	Interview Question Domains_02.03.2023.docx
Tool Manner	Telephone In-person Internet
Tool Manner Other	In-person at home, private room in public library or Department of Emergency Medicine, or other private location preferred by participation. Phone or Internet over Zoom or WebEx
Date Modified	3/6/2023

View

Tool Description	Caregiver Demographic Questionnaire

Tool Standardized	No
File name	Demographic Questionnaire_Caregiver_02.03.2023.docx
Tool Manner	Telephone In-person Internet
Tool Manner Other	In-person at ED, hospital, home, private room in public library or Department of Emergency Medicine, or other private location preferred by participation. Phone or Internet over Zoom or WebEx
Date Modified	3/6/2023

2. Cognitive or Psychological Assessment

* Are any of the uploaded instruments used to assess cognitive or psychological status or function?

○ Yes ◉ **No**

View: SF: nPBA: Supplemental Information

Supplemental Information

1. Additional Documents

Provide any additional relevant documents (e.g., data sharing agreements, letters of support, MOUs, site permission letters), if applicable.

There are no items to display

View: SF: nPBA: Final Page

Final Page

1. Assurance

The information presented in this application is accurate;
If the application is being submitted on behalf of the Principal Investigator (PI) rather than by the PI, the information presented was done so with the PI's agreement; and
The specific aims and description of research (including subject population, subject interventions, collaborators, performance sites, and general scope of work) in this IRB application are consistent with those described in the sources of support listed as providing financial and/or material resources to conduct this study.

* Do you certify the above statements?

(●) **Yes** ( ) No

2. Complete and Submit Application Instructions

To complete and submit this application to the IRB office, please follow the steps below:

1. Select Ready to Submit or Exit on this page to be directed to the application workspace.
2. In the application workspace, click the Submit activity to send the application to the IRB office. NOTE: The Submit activity is only available to certain study team members.

Department of Emergency Medicine Research Committee Meeting

Date:	6/6/2023	**Meeting Lead:** Dr. Andrea Gilmore-Bykovskyi	
Time:	12:30 pm – 01:30pm	**Recorder:** Maria Balbach/Dalton Lee	

	Lead	Length
General Announcements • Learning Plans Welcome!	Dr. Gilmore-Bykovskyi	2 min
Research Administration and Fiscal Updates • Welcome Chelsea McClellan! Chelsea will be working with Dr. Shah. • Welcome Chuck! Chuck is staying on with the Pulia Lab and joining the EDRC team.	Jessie Libber	3 min
EDRC Updates •	Phoebe Natzke	0 min
Items for Approval • Protocol, Patient Flow Optimization (Dr. Patterson) • Protocol, Evaluation of Trends in EMR Note Length (Dr. Patterson) • Protocol, Variability in Clinical Exposure of Diverse Populations (Dr. Schnapp) • Protocol, Person-centered Outcomes for EM Care for PWD (Dr. Gilmore-Bykovskyi)	Dr. Gilmore-Bykovskyi	50 min
Items for Discussion •	Dr. Gilmore-Bykovskyi	0 min

Strategic Plan

1: Implement a pipeline for emergency care researchers that will support our research faculty recruitment efforts.
2: Integrate the DEM Research Enterprise with UW Health/UWSMPH Research in terms of oversight and support of initiatives.
3: Demonstrate the impact of DEM research studies on social emergency medicine topics and expand our portfolio of studies impacting social emergency medicine topics.
4: Expand the number of tenured faculty in DEM.
5: Expand our portfolio of studies with a focus on diversity, equity, and inclusion.

To conduct innovative clinical and translational emergency care research to advance the health of the people of Wisconsin and beyond.

Calendar of Events:

Next EMRC meeting:
June 20, 2023, 12:30-1:30

Attendees:

EM Research Faculty:	EM Staff:		
Gilmore-Bykovskyi, A.	Balbach, M.	Hall, S.	Wood, A.
Hurst, A.	Barton, H.	Hekman, D.	
Jewell, C.	Benson, C.	Kadiyala, S.	
Kim, M.	Block, L.	Laev, L.	**Collaborators:**
Kuttab, H.	Broghammer, C.	Lee, D.	Halfpap, J.
Patterson, B.	Coulson, A.	Libber, J.	Hankwitz, J.
Pulia, M.	Dai, Elena	Maru, A.	Krueger, J.
Shah, M.	Dillon, K.	McClellan, C.	Marr, J.
Spigner, M.	Ebert, L.	Morales, M.	
Tschautscher, C.	Fehland, J.	Oliver, L.	**Guests:**
Tsuchida, R.	Fischer, T.	Natzke, P.	Acosta Perez, F.
	Gifford, A.	Ranade, T.	Schnapp, B.
	Griffin, M.	Schwei, R.	

PROTOCOL TITLE:

Evaluating current state and trends in electronic medical record note length

PRINCIPAL RESEARCHER

Brian Patterson
Department of Emergency Medicine
bpatter@medicine.wisc.edu

Table of Contents

1.0 Study Summary

Study Title	Evaluating current state and trends in electronic medical record note length
Study Design	Health care records research only
Primary Objective	The objective of this study is to quantify and describe temporal trends in the number of clinical notes present for review by clinicians at patient presentation to the emergency department, inpatient admission, and ICU admission
Secondary Objective(s)	N/A
Study Population	Dataset of all patients presenting to the emergency department from 2009 - 2023
Study Specific Abbreviations/ Definitions	Electronic health record (EHR) Natural language processing (NLP) Clinical Research Data Services (CRDS)

2.0 Purpose and Significance

In the modern healthcare system, review of prior records is an important step in the provision of acute care. Prior studies evaluating emergency care document review of previous records as occupying a significant portion of the time clinicians spend during visits. The advent of the Electronic Health Record (EHR) has increased the availability of notes detailing patients' outpatient visits and prior hospitalization. As these notes have become available in real-time during acute care visits, there is an expectation that clinicians familiarize themselves with patients recent course and distant medical history. Given that the EHR has only existed for 10-15 years in most locations, the volume of notes available during this review period has likely grown as more time has elapsed for notes to accrue. Physicians often report stress related to the size and scattered nature of existing records when trying to provide acute care in time-sensitive conditions. However, to our knowledge, the amount of information available in non-discrete and discrete fields has not been quantified over time. This study seeks to evaluate the length, type, and number of notes and other results available for physician review at the time of presentation for acute care, and to evaluate the trend in this amount over time. Significance: Provide any relevant background, evidence, or information that supports the importance or justification and scientific value for creating this database, registry, or repository by describing the unmet need and value of the desired information/specimens.

We will utilize discrete electronic health record (EHR) data and natural language processing (NLP) techniques applied to clinical notes to extract length of notes in words.

We during the study period 2009-2023, we plan to create a dataset of all patients presenting to the emergency department. We will extract both discrete data and metadata surrounding notes from these encounters to generate statistics on volume (i.e. number of notes, number of words, number of different types of notes, as well as number of relevant laboratory tests, radiology studies, and other procedures with reports).

Data will be extracted by Clinical Research Data Services (CRDS) staff through a research data request and delivered to a CHI2 approved computing platform. Initially, MRNs and CSN's will be used to assign patients' study and visit identifiers, but these direct identifiers will then be removed from the dataset. Notes will initially be stored to allow generation of metadata (length, number of words/characters). After initial procession, no note text or direct patient identifiers will be extracted or stored in the dataset used for analysis.

3.0 Subject Identification, Recruitment and Consent

3.1 Method of Subject Identification and Recruitment

Medical records will be used to identify subjects and records. Clinical Research Data Service (CRDS) will be used to identify subjects via these records.

3.2 Process of Consent

The study likely poses minimal risk to subjects because the activities are limited to use of data from medical records (or images created for clinical purposes) and there are sufficient measures in place to protect the data.

The research likely does not adversely affect the subjects' rights and welfare because only those who have valid access to their medical records will collect study data and the use of the data is not expected to affect the patients from whom the data are derived.

The research likely does not adversely affect the subjects' rights and welfare because access to study data will be restricted to the study team and the use of the data is not expected to affect the subjects from whom the data are derived.

It may be impracticable to obtain informed consent from subjects because the study team may not be interacting with the patients and the records may be for patients who are not being currently seen at UWHC or who may no longer be seen at the UW Health clinics.

Identifiable information will be retained for the duration of the study to allow for checking the data as needed.

4.0 Confidentiality of Data and Information Storage

This project will use the minimum amount of data necessary to achieve the aim of the research. Because this is a retrospective records review, study team members will not have direct contact with study subjects. This research does not involve interaction with subjects.

Direct identifiers will initially be used to ensure individuals within the study are not duplicated (i.e. 2 visits made by the same patient are not counted as two separate patients' visits). Also, some identifying data may be within note text.

Direct identifiers (MRN and CSN) will be removed as soon as subjects have been assigned a study id, and note text will be removed as soon as note metadata has been generated.

Clinical notes and EHR data will be extracted by Clinical Research Data Services staff and delivered to a Chi2 approved computing location for dataset creation, storage and analysis.

Individually identifiable or deducible data will not be transmitted by unsecured telecommunications, which include the Internet, email, and non-secure File Transfer Protocol (FTP). No restricted data will be transmitted electronically through unsecured methods such as e-mail, e-mail attachments, or non-secure FTP. No output from the study will contain individual identifiable information. No individual personal health information (PHI) will be released in presentation or publication. No printed materials will contain individual identifiers. Only aggregate statistical output representing groups of subjects will be released.

5.0 Risk/Benefit Assessment

5.1 Potential Benefits to Society

Understanding the amount of data available to physicians at the time of an acute care visit will quantify a serious issue in providing acute care: the growth and fragmentation of text and data in the medical record, leading to an increased burden on providers and increased chance of missing valuable information.

5.2 Potential Psychosocial Risks

The only potential risk to subjects is a loss of confidentiality.

5.3 Procedure to Minimize Risks

We will minimize the risk of loss of confidentiality by protecting the data with IT security best practices, including storing data on secure servers and limiting access to that data to pre-approved personnel.

The identifiable EHR data will be stored on the Research Data Services staff and delivered and delivered to a CHI2 approved computing platform. Following dataset development, the analysis dataset will be stripped of all direct identifiers, but still kept on the a CHI2 approved computing platform, where privacy will be protected by the restriction of access to data to only selected project-specific individuals (need-to-know) and the use of passwords for computer drive and project folder access.

Project Title: Variability in Clinical Exposure to Patients with Diverse Social Identities in Emergency Medicine Residency

1. TITLE PAGE

1.1. PI: Benjamin Schnapp, MD

Key personnel: Dann Hekman
Sponsor/Funder: None
Participating sites: University of Wisconsin, Department of Emergency Medicine

2. PURPOSE OF THE STUDY AND BACKGROUND

2.1. Abstract

Introduction
Experiential learning theory suggests that clinical exposures are key to developing competencies in Patient Care and Interpersonal and Communication Skills. This is likely especially true for developing cultural competency and competency with patients of diverse social identities, including gender identity, sexual orientation identity and socioeconomic backgrounds.
Purpose
The goal of this study is to characterize the variability in EM resident clinical exposure to patients with diverse social identities.
Methods
This study with be a retrospective records review of EHR data at the main residency clinical site at UW. Patient characteristics of patients seen as the first assigned resident will be analyzed with descriptive statistics, including race, sexual orientation, gender identity and care plan status and insurance status as a proxy for socioeconomic status.
Results
We intend to produce box and whisker plots detailing the distribution of patients seen by residents over the course of their entire training for each of the variables of interest.
Conclusions
Based on the results of previous work on clinical variability during training, we anticipate identifying significant variability in resident clinical exposures to diverse patients. This may have multiple implications for residency leadership as they consider how to train residents in cultural competency.

2.2 Purpose of the study & Aims

Previous studies have noted that clinical experiences of emergency medicine residents are highly variable. This could suggest that residents may graduate with relative deficits in exposure, confidence, and competence with caring for patients from different backgrounds. However, to our knowledge, this has never been shown empirically.

The goal of this project is to characterize differences in exposure to patients from different racial, ethnic, and socioeconomic backgrounds, as well as exposure to patients with varied gender identities and sexual orientations during emergency medicine residency training.

Based on previous research showing large variations in clinical exposure variability by ABEM content domain during emergency medicine residency training, we hypothesize that there will be large variability in graduating residents' clinical exposure to patients from a variety of different social, economic, racial, ethnic and gender backgrounds.

2.3 Background

Medical residency training allows physicians to gain the cognitive and procedural skills necessary to practice independently. Based on Kolb's theory of experiential learning, patient encounters form the foundations upon which physicians in training master the practice of medicine (Kolb 1984). Additionally, the development of "illness scripts," or mental models for the classification of patient presentations, is crucial to the development of clinical skills and reasoning during residency training (Bowen 2006). Emergency medicine (EM) trainees must be exposed to a variety of patient chief complaints throughout the course of residency to develop these scripts and become competent clinicians.

Clinical exposure has specifically been shown to be important for the development of competency in the care of diverse patient populations in a variety of medical trainees, including nursing and pharmacy students. Additionally, medical students who cared for more LGBTQ patients reported higher levels of preparedness and knowledge, and provider experience and comfort are noted as a significant factor influencing whether patients with Sickle Cell Disease receive appropriate evidence-based care.

Research Design and Methods

This will be designed as a retrospective analysis utilizing data extracted from the Electronic Medical Record (EHR). Data on resident clinical exposure as the first resident assigned to a visit will be collected at the patient level on diverse social identities, including gender identity, sexual orientation identity and socioeconomic background will be collected; no individually identifying patient information will be collected.

Resident level data will be aggregated for all residents who have completed all 3 years of residency at the UW EMRP consecutively and compared using descriptive statistics.

3. CHARACTERISTICS OF THE RESEARCH POPULATION

3.1 Number of Subjects:

We anticipate approximately 75 residents

3.2 Gender and Age of Subjects:

Male and female, approximately 25 to 40 years old.

3.3 Racial and Ethnic Origin:

Residents of all racial and ethnic origin are eligible

3.4 **Inclusion Criteria:**

All University of Wisconsin Emergency Medicine residents who have completed their residency training are eligible for the study.

4. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT

4.1 Method of Subject Identification and Recruitment

a. **How will subjects be identified and selected for the study? How will privacy of the individuals be maintained? The identification and recruitment of subjects must protect privacy and be free of undue influence.**
All Emegency Medicine residents who worked in the ED from 2016-2023 and completed their residency training are eligible.

b. **How will subjects be identified (e.g. flyers, emails, websites, announcements)?**
EHR (Epic) data review will identify residents who are eligible for the study

c. **Does the study team have routine access to the potential subjects being recruited and/or data being reviewed? If not, how will the study team recruit subjects or obtain the data.** Yes, routine access.

d. **If a secondary analysis of pre-existing data, indicate the database to be used or where the data is coming from and how eligible subjects will be identified from the database.**
EHR (Epic) records will be used, eligible records will be identified if a resident is assigned to the patient. Only non-identifiable demographic data will be collected on patients seen by each resident.

4.2 Process of Consent

Describe who will obtain consent and how the process of informed consent will be structured. Only individuals who have completed the IRB's required human subjects training and are listed on the IRB application are authorized to obtain consent.

N/A – this study is a retrospective records review.

5. METHODS AND STUDY PROCEDURES

5.1 Provide a detailed description of all study activities:

a. **What is the duration of the study (e.g., one semester, one year, until enrollment is reached)?**
The duration of the study will be approximately 1 month while data is collected and analyzed.

b. Who will conduct each activity (e.g., session, focus group, interview, experiment)?
Data from the electronic health records will be collected by Dann Hekman. Review and analysis of data will be completed by Benjamin Schnapp.

c. How long will each activity (e.g., session, focus group, interview, experiment) take?
The retrospective data analysis of the EHR will take approximately 2 weeks to 1 month.

d. Where will the study activities (e.g., session, focus group, interview, experiment) take place?
N/A

e. **If the study involves more than one visit, provide a sequential description of each study visit including what will occur at each visit and how long each visit will take**.
N/A

What type of compensation will be provided to subjects (e.g., class credit, Mechanical Turk payments, or no compensation will be provided)? If using SONA, indicate whether identifier will be used to track payment for class credit and whether or not research data will be linked to payment information/identifiers. N/A

6. RISK/BENEFIT ASSESSMENT

6.1 **Risks:** Possible confidentiality breach of study participants

6.2 **Benefits:** No incentive will be provided to study participants

7. DATA ANALYSIS:

Primary Outcomes of interest: Variability in resident clinical exposure as the first resident assigned to a visit for individual patient demographics such as race, insurance status, sexual orientation, care plan status, and gender identity

8. CONFIDENTIALIATY OF DATA AND INFORMATION STORAGE

Describe where the research data will be stored during the study and how it will be secured. This includes coding data and choosing an appropriate and secure data storage mechanism which will prevent unauthorized access to data.

Data will be stored on a physically secured University of Wisconsin Department of Emergency Medicine computer that is protected by a password. All resident records will be de-identified using a number instead of resident name. Data will be reported in aggregate form only.

Print ☐ Compact Close

University of Wisconsin-Madison MR IRB Application	Study # : 2023-0312 Principal Investigator: Andrea Gilmore Bykovskyi	View: SF: nPBA: Basic Study Information

Basic Study Information

1. Formal Title

This is the title that will appear in correspondence.

* Provide the full, formal study title.

> Development of person-centered outcome measures for emergency care experiences among persons with dementia

2. Transferred Study

Answer Yes to this question only if:

a) the principal investigator (PI) for this application is coming to UW-Madison, UW Health, or the Madison VA from another institution and,

b) they plan to open a study here that is already IRB-approved at their previous institution.

* Is this study being transferred from another institution?

○ Yes ◉ **No**

3. Principal Investigator

* Identify the Principal Investigator.

Andrea Gilmore Bykovskyi

View: SF: nPBA: Type of Research Application

Type of Research Application

1. Type of Research Application

* Select one of the following: Exemption

View: SF: nPBA: PI Appointment

PI Appointment

1. Principal Investigator

PI: Andrea Gilmore Bykovskyi

2. Primary Appointment

* Choose the appointment under which you will be conducting this research.

UW-Madison

3. UW-Madison Appointment

3.1. Appointment Details

* Identify the appointment under which the PI will conduct this research.

	Title	Type	UDDS	Department Combined Name
◉	**Associate Professor**	**FA**	**A534100**	**SMPH/EMERG MED**

3.2. Appointment Not Found

☐ Check if the appointment is not listed above.

4. Investigator-Initiated Study

* Is this an investigator-initiated study?

◉ **Yes** ○ No

View: SF: nPBA: Study Team

Study Team

1. Points of Contact Selection

Points of contact can edit the application and will receive email notifications about this submission.

Please do not use personal email addresses (e.g., Gmail, Hotmail, etc.). A campus business email can be changed following the instructions here.

If the PI is serving as the only study point of contact, indicate that here.

Can't find someone in the chooser? See this FAQ for help.

To register a NetID, click here.

* Identify the points of contact for this study (limit of four).

Name	Email
Clark Benson	cbenson5@wisc.edu
Laura Block	lmblock2@wisc.edu

2. All Other Study Team Personnel

List ONLY UW-Madison, UW Health, or Madison VA personnel. External personnel will be listed elsewhere in the application.

Please do not use personal email addresses (e.g., Gmail, Hotmail, etc.). A campus business email can be changed following the instructions here.

Study team members listed below will have read-access only and will not be able to edit the application. They also will not receive email notifications.

Can't find someone in the chooser? See this FAQ for help.

To register a NetID, click here.

List all the other members of the study team (not including the PI or points of contact).

Name	Email
Alison Coulson	acoulson@wisc.edu
Lucas Ebert	lhebert@medicine.wisc.edu
Jess Fehland	fehland@wisc.edu
Scott Hall	shall@medicine.wisc.edu
Shivani Kadiyala	skadiyala@medicine.wisc.edu
Alden Laev	alaev@medicine.wisc.edu
Maria Mora Pinzon	mmora2@wisc.edu
Phoebe Natzke	pnatzke@medicine.wisc.edu
Lex Oliver	aloliver@medicine.wisc.edu
Natasha Pedone-kahle	pedonekahl@medicine.wisc.edu
Tarjani Ranade	tranade@medicine.wisc.edu
Manish Shah	mnshah@medicine.wisc.edu
Inem Uko	iuko@wisc.edu
Audrey Wood	amwood@medicine.wisc.edu

View: SF: nPBA: Study Team Roles

Study Team Roles

1. Primary POC

If the PI is serving as the primary point of contact, indicate that here.

* Identify the primary point of contact for this study.
Clark Benson

2. Human Subject Involvement

* Does this study involve recruiting, consenting, or interacting with human subjects?
(●) **Yes** ( ) No

2.1. Study Team Details

For each study team member below, click the ✎ button and check the boxes to indicate that study team member's roles for this study. Note: Some study team members may not have any roles listed below.

Tell us which study team members will: recruit human subjects, obtain informed consent from human subjects, interact with human subjects, or perform cognitive assessments on human subjects.

Study Team Member	Recruit Subjects	Obtain Informed Consent	Interact with Subjects
Clark Benson	yes	yes	yes
Laura Block	yes	yes	yes
Alison Coulson	yes	yes	yes
Lucas Ebert			
Jess Fehland	yes	yes	yes
Andrea Gilmore Bykovskyi	yes	yes	yes
Scott Hall			
Shivani Kadiyala			
Alden Laev			
Maria Mora Pinzon	yes	yes	yes
Phoebe Natzke			
Lex Oliver			
Natasha Pedone-kahle			
Tarjani Ranade			
Manish Shah			
Inem Uko	yes	yes	yes
Audrey Wood			

View: SF: nPBA: Funding

Funding

1. Funding Administered by UW Madison

Answer no to this question if this study will only be supported by VA funding; you will have the opportunity to add VA funding later in the application.

* Do you have pending or approved funding administered through Research and Sponsored Programs (RSP) or Business Services to support this project?

(●) **Yes** ( ) No

1.1. Funding Sources

For **federal funds**, pending sources may be listed if the grant has received a highly meritorious score. For example, an impact score of <30 is an indication of a highly meritorious NIH grant proposal. Receipt of a request for Just In Time (JIT) documentation is another indication of a highly meritorious proposal.

For **non-federal funds**, pending sources may be listed if you have confirmation from the sponsor that funding will be awarded due to merit AND the sponsor has a peer-review process.

For **industry**, do not select industry sponsors who are only providing drug/device OR only limited support for the study.

* Use this chooser to select each funding source administered through UW-Madison that will support this study or project.

Funding Source Details

View

PI Name	BYKOVSKYI, ANDREA LEA GILMORE
Proposal ID	MSN270773
Award ID	MSN270773
Funding Title	Person-Centered Outcome Measures for AD Patient Emergency Care Experiences
Project ID	AAL8185
Sponsor Reference Number	
Sponsor (Source)	ALZHEIMER'S ASSOCIATION
Primary Sponsor	*No Value Entered*
Federal	No
Status	Active
Start Date	1/1/2023
End Date	12/31/2024

2. Other Funding

* Do you have pending or approved funding NOT listed on this page?

Yes **No**

View: SF: nPBA: Conflict of Interest

Conflict Of Interest

Please review the study team member Outside Activities Report (OAR) and managed entities data below before answering the questions on this page.

All study team members have completed their Ouside Activities Report for the year.

NOTE: Per campus policy all study team members must submit an OAR every year and keep it up to date.

These study team members have managed entities:

Manish Shah

Exact Sciences Coporation	Advisory Only

1. Sponsorship

* Do any of the managed entities sponsor the study?

○ Yes ◉ **No**

2. Technology

* Do any of the managed entities own or license a technology being used in the study (including any agent, device, or software)?

○ Yes ◉ **No**

3. Irrelevant Management Plans

If any of the management plans identified at the beginning of this page are not relevant to the study please explain why.

> No managed entity has played any role in the conceptualization, design or conduct of this study.

4. Intellectual Property

* Do any study team members involved in the design or conduct of the research (including their spouses and dependent children) own intellectual property that will be used in the study or project?

○ Yes ◉ **No**

5. Other Entities

* Besides the sponsor(s) of this project or entities listed above, do any study team members have a fiduciary or financial relationship with entities that will be involved in this study or that may be significantly affected by it?

○ Yes ◉ **No**

6. Incentives

* Do any of the study team receive any incentives for recruiting human subjects or any other purpose directly related to the study or project?

○ Yes ◉ **No**

View: SF: nPBA: VA Status

VA Status

All studies that fall under Madison VA purview must be reviewed and approved by the VA Research and Development (R&D) Committee in addition to being reviewed by the Health Sciences IRB. For information about the VA R&D Committee review process, please contact **VHAMADRDCoordinator@va.gov**.

1. VA Status

* Does this study involve the Madison VA (Wm. S. Middleton VA Hospital); e.g., funding from the VA, conducted under VA appointment, use of VA facility, recruitment of veterans or use of their data or samples at the Madison VA?

○ Yes ◉ **No**

View: SF: nPBA: PRMC

Scientific Review: Protocol Review Monitoring Committee

1. Cancer Related

* Is the scientific question of the protocol cancer related?

Yes **No**

2. Targeting Cancer Patients

* Are you specifically targeting cancer patients for enrollment in this study?

Yes **No**

3. Use of Cancer Data or Images

* Does this study involve the review and/or use of biological specimens/data/images/records from cancer patients?

Yes **No**

View: SF: nPBA: Exemption

Exemption

1. Exemption Category

If your research does not fit within one of the categories below, please select Full Review on the Type of Research Application page.

* Select the relevant category or categories for which you are requesting an exemption determination.

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2. Research involving the use of educational tests, surveys, interviews.

- Surveys (with adults only)
- Interviews (with adults only)
- Focus groups (with adults only)
- Educational tests
- Observation of public behavior

May NOT involve an intervention (see exemption 3) or linking to additional personally-identifiable data.

View: SF: nPBA: External Collaborations 2

External Collaborations

1. Outside UW Activities

* Will any UW/UW Health or Madison VA personnel conduct any of the following study activities at locations outside the UW/UW Health or Madison VA: subject recruitment, obtaining informed consent, or interacting or intervening with subjects?

○ Yes ◉ **No**

View: SF: nPBA: Sharing Data Outside UW

Sharing Data Outside UW

1. Sharing Data Outside UW Madison

* Will subject data, images, or specimens be shared outside the UW Madison?

Yes **No**

View: SF: nPBA: Study Procedures and Special Populations

Study Procedures and Special Populations

1. Study Procedures Involved

Select "Review or use of information from health care records"

* If your study involves any of the following special procedures or considerations, additional information may be needed. Select all that apply. If none apply, check Not Applicable.

Creation of audio or video recordings or photographs
Interviews, focus groups, surveys, questionnaires, assessments (e.g., QOL, SCID, BDI, etc.)

2. Special Populations

If you will collect data points identifying individuals as any of the following, select the corresponding box(es).

* Is the research designed to include any of the following populations? Select "Not Applicable" if the research will not include any of the populations below. NOTE: If enrolling pregnant women, children, or prisoners, and you can identify them as such, check the box.

Persons with impaired decision-making
Poor/uninsured, elderly/aged, or educationally disadvantaged

View: SF: nPBA: Research Design and Procedures

Research Design and Procedures

1. Overall Purpose

Describe the research questions or gap in knowledge the study proposes to address or contribute to in language that someone who is educated but not an expert in the field can understand.

* What is the overall purpose and aim of this project or study?

> The overarching goals of this study are to determine cross-cultural care priorities of people living with dementia (PLWD) and their caregivers during emergency department (ED) visits and to develop and refine items for a Person-Centered Outcome Measure (PCOM) for use by PLWD to facilitate evaluation of those priorities.

2. Pre-Existing Information/Background Knowledge

* What prior information or knowledge exists to support the conduct of this project or study?

> Over 50% of the more than 6 million people with Alzheimer's Disease and Alzheimer's Disease and Alzheimer's Disease Related Dementia (ADRD) in the US visit an emergency department (ED) annually. The ED often serves as a first layer in supporting people living with dementia (PLWD) experiencing acute exacerbation of underlying chronic illnesses or distressing behavioral and psychological symptoms of dementia, and caregivers without respite who are overburdened or in crisis. Despite the major role the ED plays for PLWD and their care partners, presence of ADRD is often not well-recognized in the ED—and many factors in the ED environment are thought to be detrimental to provision of adequate care and betterment of health outcomes of PLWD. Collectively, the compounding environment of care and situational factors that surround ED visits produces significant distress among PLWD while frequently omitting care approaches that are responsive to the needs of PLWD. Studies suggest that PLWD would benefit considerably from improvements in the ED care experience. Findings from our prior work suggest that commonly used outcome measures which focus predominantly on utilization (e.g., ED revisit) and mortality do not adequately address aspects of the ED care experience or what matters most to PLWD during ED visits. Yet, there is virtually no research identifying specific ED care priorities from the perspectives of PLWD or their caregivers. Because an ED visit is often a marker of advancing illness and for some patients the need to engage palliative care, relying heavily on utilization outcomes to evaluate care quality may be inappropriate in many cases and is globally insufficient, highlighting the need for more sensitive care and outcome measures that capture meaningful indicators of care quality.

3. Study Procedures and Interventions

Provide an overview of the types of records that will be reviewed, what information from these records will be collected, and the kinds of analyses that will be performed on the study data. If data from multiple sources will be used describe this here (e.g., medical record information connected to imaging or billing information or data from multiple institutions collated).

* Briefly describe the procedures and interventions that will be performed for this project or study and all study arms involved. Do not include information on recruitment or consent.

> We will conduct semi-structured interviews with caregivers and individuals with dementia with capacity to share their care experiences from socioculturally diverse backgrounds to identify their ED care priorities. Participants may be interviewed in a private room in the ED or in another place of their choosing after their stay in the ED. This may include their hospital room if they are admitted after their ED visit or

their home, a private room in the Department of Emergency Medicine Offices, or a private room in a public library if they return home. Given the various length of wait times in the ED, participants will have the option to participate in a 10-15 minute interview or a longer 30-60 minute interview.

There are two scenarios under which individuals with dementia will be eligible for participation (explained further in Subject Identification and Recruitment: Subject Population):
1. Individuals with dementia with capacity to share their care experiences who do not currently have an activated power of attorney, legal guardian, or otherwise legal indication of lack of capacity to consent will be included, with the option to complete the interviews individually or with a support person/caregiver based upon their preference. Along with an assessment of capacity to consent from the clinical team and EDRC team, a formal capacity assessment through an Evaluation to Consent will confirm capacity to consent for these individuals just prior to being consented to participate in the study, recognizing this may take place at a timeframe different from clinical staff assessment. Study team members with experience making capacity to consent determinations from a previous study (2018-0101) will conduct the Evaluation to Consent form.

2. Individuals with dementia with capacity to share their experiences but with presence of an activated power of attorney, legal guardian, or otherwise legal indication of lack of capacity to consent will be included if proxy consent from the legally authorized representative can be obtained and the person with dementia provides assent.

Current, former, and/or caregivers providing care to someone with dementia can also complete interviews individually or dyadically.
All participants (caregivers and people living with dementia) will complete demographic questionnaires.

4. Incidental or Adventitious Findings

* Will any study procedures produce incidental or adventitious findings (e.g., imaging scans, laboratory blood tests, depression screening questionnaires, etc.)?

○ Yes ◉ **No**

5. Instruments Involved

This question is intended to identify projects involving the development or use of medical devices. This does not apply to surveys or questionnaires.

* Are there instruments of any kind, including software, tests run on samples, and algorithms, used in the study?

○ Yes ◉ **No**

View: SF: nPBA: Subject Identification Medical Records

Subject Identification: Medical Records

1. Medical Record Use

* Will medical records be used to identify subjects or records?

(●) **Yes** ( ) No

1.1. CRDS Usage

CRDS assists UW investigators with developing data queries and delivering data from the UW Health Enterprise Data Warehouse (EDW) to be used in feasibility assessments, recruitment of participants, pilot studies, and retrospective analyses.

* Will you use the Clinical Research Data Service (CRDS) to identify subjects via these records?

( ) Yes (●) **No**

1.2. Record Identification Details

* Describe how eligible subjects will be identified using medical records, including 1) which records will be accessed and 2) who will identify eligible subjects.

> Medical records will facilitate identification of eligible participants through our recruitment arm at the UW Health University Hospital Emergency Department (ED). ED recruitment will be facilitated through the Emergency Department Research Coordinator (EDRC) Program. EDRC staff are integrated into the ED at UW Health to assist with screening of eligible participants. They regularly interface with ED clinical staff to assess eligibility of potential study participants and determine whether recruitment approaches are appropriate provided patient safety and health.
>
> EDRC staff will examine diagnostic information within the medical record to determine presence of patients with dementia in the ED. EDRC staff will also examine medical records to determine presence of an activated power of attorney, legal guardian, or otherwise legal indication of lack of capacity to consent (referred to hereafter as presence of a legally authorized representative, or LAR) to determine if the person with dementia can legally consent to participation in research.
>
> Subsequent recruitment steps are described in Subject Identification and Recruitment: Recruitment Methods.

View: SF: nPBA: Risks and Benefits

Risks and Benefits

1. Direct Benefits Intended

For this type of research there are generally no direct benefits to subjects. The response to this question, "There are no direct benefits to subjects", would be acceptable.

* Are any of the research activities intended to directly benefit subjects?

○ Yes ◉ **No**

2. Potential Benefits to Society

Describe how the research might help future patients.

* Describe the importance of the knowledge reasonably to be gained from this study and what benefit the research may provide to society.

> The primary benefits of this study are indirect future improvements to ED care for people living with dementia, and evaluation of care quality according to specified person-centered care priorities. Some participants may benefit emotionally from the opportunity to share their experiences and be listened to during interviews.

3. Direct Physical Intervention

A physical intervention refers to study procedures that may pose a risk (however minimal) to a subject's body (e.g., blood draws, MRI scans, drug or device trials, exercise, dietary restrictions/supplements). Examples of activities that are NOT physical intervention include obtaining informed consent and administering surveys.

* Does this study involve direct physical intervention with subjects?

○ Yes ◉ **No**

4. Potential Psychosocial Risks

For this type of research the risks to subjects are generally limited to the risk of breach of confidentiality. The response to this question, "There is a risk of breach of confidentiality", would be acceptable.

* Describe any potential psychosocial risks to subjects, such as psychological stress or confidentiality risks (including risk to reputation, economic risks, and legal risks).

> There is a minimal risk of a breach in confidentiality.
>
> This study involves semi-structured interviews. Some participants may become upset or experience discomfort when speaking of dementia and/or ED care experiences that were traumatic or stressful. Participants, particularly those with dementia, may become fatigued or frustrated throughout the course of the interview or in response to questions that are abstract or complex.
>
> Participants may also reveal personal or identifiable information (e.g. name, names of love ones, location) when responding to questions.

5. Procedures to Minimize Risks

The response to this question should address how the risk of breach of confidentiality will be minimized. For example, it could be described that the study team has several measures in place to protect against a breach of confidentiality, such as limiting the number of people who view identifiable information, coding study instruments, storing study data in restricted areas and on computers that are password-protected, only transmitting coded data outside the institution (if data will be shared), and using a secure web-interface to transmit data off-site (if data will be shared).

* Describe the procedures in place to minimize risks from all interventions performed for research purposes. This should include activities in place to identify, monitor, mitigate, and eliminate risks to the degree possible.

> Confidentiality Risks
> Confidentiality risks will be minimized through use of multiple procedures and processes that maximize anonymity and security in accordance with campus policy. We will assign all participants a study ID number and after interviews, we will only identify participants' data by study ID number.
>
> The study team will minimize the identifiable information collected during the logistical portions of recruitment and scheduling interviews, specifically the study team will only record first names and contact information (phone number and/or email address) during the interview scheduling process (if necessary) which will be deleted 1) upon completion of the interview 2) if the participant(s) decides to no longer participate or 3) after four unreturned contact attempts. Contact information will be stored in a secure folder on the Department of Medicine research data server, with access limited to study members only. This folder location is separate from all other study materials and interview data. Access to the server is restricted to team members with special training on data safety. Access is audited every 6 months, and removed if determined no longer necessary.
>
> Risk of Emotional Upset or Fatigue During Interviews
> The study team is trained in procedures to maximize comfort of the study, including providing the option to skip questions or pause/stop the interview in scenarios of emotional upset or fatigue. This, along with the approximate length of the interview, are covered in informed consent. Interview questions will be modulated based upon the abilities of the participant(s), and the study team is trained to adjust pacing and difficulty of the questions during the interview space. The study team will also ask if participants would like to be referred to resources for dementia caregiving support. Under prior protocols (IRB 2018-0101), the study team has recruited and engaged people living with dementia and their caregivers in interviews in the ED and hospital and offered tailored resources for caregivers nationally and by the state the caregiver resides in.
>
> Risk of Personal or Identifiable Information
> Identifiable information, such as name or location, will be redacted from the interview transcript. Potentially sensitive information, such as experiences with ED care for cognitive needs, is likely to be shared and will not be redacted.
>
> Risk of Loss of Confidentiality due to Mandated Reporting
> If during the interview, participants report situations which may constitute potential abuse of a child or elder, our staff will follow requirements for mandated reporting. This risk will be disclosed to them in the informed consent process and corresponding information sheet.
> If participants disclose care situations which upset or concern them but do not constitute potential abuse of a child or elder, they will be provided with the contact information for UW Hospital Patient Relations: 608-263-8009.

View: SF: nPBA: Subject Population

Subject Population

1. Total Subjects

You must provide an integer. If you are enrolling a range of subjects (e.g., 50 to 100 subjects), enter the larger number.

* Provide the number of subjects that will be enrolled at sites for which UW Madison is serving as the reviewing IRB.

> 30

2. Inclusion Criteria

* Describe the main inclusion criteria.

> Individuals with dementia:
> •Diagnosis of ADRD confirmed via medical record review or by proxy informant such as clinical staff, the participant's activated LAR, caregiver, or family member.
> •For individuals with dementia recruited through community-based recruitment approaches, diagnosis of ADRD as specified through self-report
> •Has had an ED experience
> •Capacity to share their care experience and to consent to participation in research through clinical staff assessment and as measured by the Evaluation to Consent Assessment
> •OR if capacity to share their care experience BUT indication of lacking legal capacity to provide informed consent (i.e. presence of activated power of attorney, legal guardian, or otherwise activated LAR)—proxy consent by the activated LAR and assent by the person with dementia
> •If participating in dyadic nature with caregiver, consent of caregiver
>
> Caregivers:
> •Current or former informal/unpaid caregiver to person with dementia
> •Person with dementia has had an ED experience
> •If participating in a supportive or dyadic nature with person with dementia, consent and/or assent of person with dementia

3. Exclusion Criteria

* Describe the main exclusion criteria.

> Individuals with dementia:
> •Unable to verify diagnosis of ADRD
> •Unable to answer basic questions about their care based on assessment of the clinical team and as verified by EDRC team, or through ongoing assessment by study team
> •Unable to understand and consent to study
> •No relevant ED experience
> •Unable to locate or receive consent from activated LAR (or caregiver if person with dementia prefers dyadic interview)
>
> Caregivers:
> •Paid caregiver
> •Caregiver to person who has condition other than dementia
> •No relevant ED experience
> •Consent/assent not received from person with dementia in context of a supportive or dyadic interview

4. Targeted Populations

Populations could be racial/ethnic, sex, or gender (this also applies to gender identity, or lack thereof).

* Will this study target or exclude specific populations?

(●) **Yes** ( ) No

4.1. Targeted Population Justification

* Describe the population that will be targeted or excluded and provide justification.

> Because our aim is to develop a measure that is responsive socioculturally diverse perspectives on ED care among people with dementia, we will endeavor to include individuals from racially/ethnically diverse groups, with a familial history of immigration for different cultural perspectives, and socioeconomically diverse groups. These groups are underrepresented in research on dementia and ED care despite experiencing poorer outcomes.

View: SF: nPBA: Special Populations Justification

Special Populations Justification

1. Justification

If more than one special population is enrolled, separate justifications should be provided for each unique population.

* What is the justification for the inclusion of these subjects?

> This study aims to understand ED care priorities for people with dementia by including and interviewing people living with dementia themselves. Most existing measures to assess care rely on caregiver reports, and have been developed through caregiver interviews. While these measures may accurately capture some of what matters to people with dementia, there is evidence of a lack of perfect alignment between the perspectives of people with dementia themselves and caregivers. Therefore, it is critical that we include people with dementia in this study so that we can integrate their perspectives into future measure development. Considerable research demonstrates that individuals living with dementia have capacity to participate in research, particularly in interviews, and as a result considerable resources have been developed and disseminated to support their inclusion.
>
> Moreover, we plan to include people with dementia who do not have legal decision-making capacity as these individuals are even more under-included in research. Lack of legal decision-making capacity does not always equate to a lack of ability to participate in research procedures or decisions about research which we recognize as necessitating a situationally specific assessment. In other words, many people with dementia who do not have legal decision-making capacity may still be able to share details on their care experiences and preferences, and therefore we wish to ensure their perspectives are not systematically under-included. They may also have unique experiences on care in the context of fluctuating cognition.
>
> Moreover, we plan to include diverse participants, including those who are potentially socio-economically disadvantaged. This is critical because those who are socio-economically disadvantaged often rely on the ED as a more accessible point of care, and therefore findings around ED care priorities and corresponding measurement must be responsive to their perspectives.

2. Safeguards

Include the measures that will be taken to minimize any potential coercion or undue influence in recruitment and ongoing participation in the study.

* Describe the additional safeguards that have been included in this study to protect the rights and welfare of these subjects.

> Our team has extensive training and experience in working with individuals with dementia, and procedures for ensuring supported decision-making and tailoring and pacing of study activities. Throughout the study process, we will assess legal capacity to consent and capacity to share care experiences, ability to answer study questions comfortably, involve activated LARs and engage established protocols to ascertain and confirm assent in situations where the individual with ADRD lacks the legal capacity to consent.
>
> We will ensure study materials and activities can be accessed by individuals with varying abilities. We will do this by building rapport with the participant prior to the interview, giving the participant the option to conduct the interview in a familiar place, providing cues to skip questions, giving ample time to respond, restructuring interview questions to be familiar and comfortable to the participant, and offering to stop the interview if the participant appears to be fatigued or distressed.

View: SF: nPBA: Recruitment Methods

Recruitment Methods

1. Recruitment Plan

This description should address what methods will be used, when and how often they will be used, and how many times potential subjects will be contacted.

* Describe the recruitment plan for this study.

Recruitment Mechanism: Emergency Department
Emergency Department Research Coordinator (EDRC) Program staff will monitor medical records to determine presence of potentially eligible patients in the ED who have a diagnosis of ADRD. EDRC staff will engage the clinical team (ED nurse) to complete initial screener questions to determine if the patient is appropriate to approach to ascertain interest. Screener questions will confirm a) appropriateness to approach based on patient stability/safety, b) patient capacity to communicate and answer questions, and c) legal decision-making capacity/presence of an activated LAR.

After identification of potentially eligible participants, EDRC staff will approach the patient and/or their activated LAR as well as any caregivers present (who may or may not be the patient's activated LAR but are otherwise involved in their care) to determine their interest in learning about the study.

EDRC staff will ask the potential participant(s) if the study team can visit them in the ED (or hospital if admitted) or call them at their preferred phone number. If the potential participant(s) authorizes an ED/hospital visit or a phone call, EDRC staff will call the study team to securely relay contact and contextual information. The study team will store contact information in a secure Department of Medicine server folder. If the potential participant(s) prefers, they can contact the study team themselves.

The study team will further assess the potential participants' interest in the study and eligibility, and determine the participant with dementia's capacity to consent and to participate in a brief interview. The study team will proceed to obtaining informed consent and/or assent dependent upon the individual with dementia's legal decisional capacity—using procedures outlined in Informed Consent: General and Informed Consent: Impaired Consent. Upon obtaining informed consent and/or assent, interviews will either take place a) in the ED/hospital, or b) be scheduled for a future date and/or a means for follow-up contact will be collected for the interview to be scheduled at a future time.

The study team may contact caregivers and activated LARs if the person with dementia grants permission for the study team to contact them over the phone.

If the patient, caregiver, and/or activated LAR are willing to discuss the study with a research staff member but are busy with a member of the clinical team, or are busy with another matter and cannot discuss the study at length at that time, a recruitment brochure will be offered and distributed. The brochure contains a brief description of the study and instructions that the patient, caregiver, and/or activated LAR can follow to contact the lead researcher if they are interested in the study.

Recruitment Mechanism: IRB-Approved Registry
The use of one IRB-approved registry will occur for recruitment of people living with dementia and caregivers. Dr. Gilmore-Bykovskyi has an IRB-approved registry (2019-1148) of older adults with and without changes in memory and caregivers who are interested in brain health related research.

Recruitment Mechanism: Community-Based Organizations
We will conduct recruitment in partnership with community-based organizations, by collaborating with each organization to distribute information on the study and how to contact the study team if interest through the community organizations' regularly scheduled newsletters (online or print) and/or posted flyers. Organizations include:
•Madison Senior Center
•Madison School and Community Recreation – East
•Madison Public Library- Central Library
•New Bridge

Newspaper, radio and social media advertisements will contain Information about the study, eligibility for details on how interested participants can contact the study team members. Outlets are listed below:

•Madison 365
•La Comunidad
•WIBA-FM 101.5
•WORT 89.9
•WZEE 101.4
•Facebook
•Twitter
•Gilmore-Bykovskyi Lab Website: https://gilmorebykovskyilab.org/

2. Recruitment Material Upload

Upload recruitment materials such as recruitment emails, letters, phone scripts, brochures, or advertisements.

Brochure ARCOM_03.02.2023.tif

3. Approved Recruitment Database Usage

* Are you using an IRB approved recruitment database to disseminate recruitment materials or to contact subjects?

(●) **Yes** ( ) No

3.1. Recruitment Database Details

Provide the IRB protocol number of the recruitment database.

2019-1148

3.2. Database Usage Approval Documentation

If the recruitment database is not the investigator's own, upload a letter of support for the use of the database.

There are no items to display

View: SF: nPBA: Subject Screening

Subject Screening

1. Preliminary Eligibility Screen

* Will subjects undergo a preliminary screen to determine basic eligibility?

(●) **Yes** ( ) No

1.1. Screening Materials

* Upload a copy of the screening questionnaire.

↔ ARCOM Screener Questions_05.04.docx

1.2. Data Retention

If you are retaining screen data, the previously uploaded questionnaire/script should address this and include authorization language for maintaining PHI if HIPAA applies.

* Will you be retaining screen data from subjects who do not enroll in the study?

( ) Yes (●) **No**

2. Planned Study Procedures Before Obtaining Consent

Examples include fasting, discontinuing medications, etc.

* Will there be any procedures performed before informed consent is obtained from subjects (apart from screening)?

( ) Yes (●) **No**

View: SF: nPBA: Remuneration and Costs

Remuneration and Costs

1. Payment

* Will subjects be compensated to participate in the study?
(●) **Yes** ( ) No

1.1. Travel and Other Expenses

* Is payment limited to covering travel expenses and other costs incurred by subjects as a result of study participation?
( ) Yes (●) **No**

1.2. Payment Plan

Include the amount of payment(s), proration, multiple payment schedules, etc.

* Describe the payment plan.

> $30 if an individual starts the interview; whether or not the interview is fully completed

1.3. Child/Parent Payment

* Are any payments being offered to child subjects?
( ) Yes (●) **No**

1.4. Nonmonetary Compensation

* Will nonmonetary compensation be offered?
( ) Yes (●) **No**

2. Costs

* Will subjects incur any costs as a result of study participation (pharmacy preparation fees, payment for a device, billing of study procedures to subjects insurance)?
( ) Yes (●) **No**

View: SF: nPBA: Privacy and Confidentiality

Privacy and Confidentiality

1. Privacy Plan

Privacy is defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. In the context of research, this primarily pertains to methods used to obtain information about subjects or the setting in which research takes place.

* Explain how the subjects' privacy will be protected. (e.g., research intervention is conducted in a private room).

> Interviews will take place by phone, UW-Madison Zoom, Cisco Webex web conferencing or in a private room in the ED, hospital, or their home, a private room in the Department of Emergency Medicine Offices, or a private room in a public library. Interview mode and location will be determined based on participant preference, including ED/hospital, which was successful in a previous study (IRB 2018-0101). Data collection will be limited to the amount necessary to achieve the aims of the research. In the event that unnecessary personal or identifiable information is provided by the participant(s), it will either not be recorded or removed from the research record as soon as possible. Only research staff will have access to individually identifiable private information about human subjects. No direct participant identifiers will be used to label interview data files, de-identified transcripts, or stored questionnaire data. All data will be labeled by assigned study ID numbers. No identifiable data will be kept from those subjects who were ineligible for the study or chose not to enroll. Data will be reported as group data, or deidentified participant quotes, so that no individual could be identified. All members of the research team and study staff will complete HIPAA and research ethics training and have certification thereof. Any member of the research team who knows or has a personal relationship with any participants will recuse himself or herself from further study activity with the identified participants, and will not have access to those participants' data. Contact information from participants will be stored to facilitate conduct of the study (e.g. scheduling) and separately from data. It will be deleted after sharing of the study findings, unless the participant(s) indicates preference for it to be deleted immediately after participation. Fully de-identified interview data will be kept indefinitely.

2. Level of Identifiability

* Select how subjects are identified in the data. Check all that apply.

No Identifiers (De-identified, Anonymous, or Anonymized): stored data is stripped of all identifiers

3. Data Protection Plan

Records and data include informed consent documents, case report forms or study flow sheets, survey instruments, database or spreadsheet, screening logs or telephone eligibility sheets, web based information gathering tool, audio/video/photo recordings of subjects, labeled specimens, data about subjects, subject identifiers, etc.

The study team should describe how data confidentiality will be protected. Some measures that are often used and acceptable to the IRB are: using codes so that no direct subject identifiers are recorded on data collection sheets; creating codes for data that are not based on subject identifiers (i.e., avoiding codes that include subject initials or are based on birth dates); and destroying the link to the code as soon as possible.

* How will the study team protect research records, data, and/or specimens against inappropriate use or disclosure, or malicious or accidental loss, or destruction? Include how and where the data and/or

specimens will be stored.

Data collected from this study will come from participant interviews and sociodemographic questionnaires.

All electronic records and data related to the study protocol will be kept on password-secure Department of Medicine (DOM) servers with limited access to Study Team members.

Contact information necessary for recruitment and scheduling of interviews will be stored in a folder on the DOM server separate from the parent study folder. This contact information will not be linked to the participant's study data whatsoever and will be destroyed immediately after all necessary contact with the individual has ceased (e.g. scheduling, sharing of study findings) or at the end of the study.

Original recordings will be rapidly transferred to the DOM server and destroyed from their original platform after completion of the interview. Original recordings stored on the UW-Madison Zoom or Cisco Webex secure platform if interviews are completed remotely or temporarily on an encrypted audio recording device in a locked cabinet in the PI's locked office located at 800 University Bay Dr. if performed in person. Only the PI and study team members will have access to this locked drawer. Recordings on Zoom or Cisco Webex will be destroyed immediately after secure transfer to the DOM server, and likewise recordings on the audio recording device will be destroyed immediately after secure transfer to the DOM server. Audio recordings on the DOM server will be destroyed promptly after successful transcription and de-identification.

Questionnaire data (e.g. demographic questionnaires) will be provided directly to study team members conducting interviews and stored on the password-secure DOM servers.

De-identified transcripts will be stored electronically on the password-secure DOM servers. Hard copies of de-identified transcripts will be used in team meetings for data analysis and will be stored in a locked cabinet in the PI's locked office. Only the PI and study team members will have access to this locked drawer. When these transcripts are used for analysis, it will take place in a private room at 800 University Bay Dr. and then returned to the locked drawer.

No identifiable data will be kept from those subjects who were ineligible for the study or chose not to enroll. In coordination with EDRC staff, we will be maintaining a general tabulation of how many patients were approached, but screened ineligible or chose not to enroll in the study. This tabulation will include reason for ineligibility/non enrollment. This general tabulation will not be linked in any way to the individuals approached for the study.

At no point in study procedures will participants be identified by name or other identifiable information. All participants will be identified via a study ID number that will be associated with their transcripts.

Depending on the nature of the event, the study team will report events such as noncompliance, new information, and potential unanticipated problems in accordance with the IRB's posted guidance.

4. Certificate of Confidentiality

If NIH, CDC, FDA, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award, answer "Yes".

* Is there a Certificate of Confidentiality (CoC), or will one be obtained, for this research?

○ Yes ◉ **No**

View: SF: nPBA: Retention of Data and/or Specimens

Retention of Data and or Specimens

1. Future Research Plans

* Will data and/or specimens collected for this study be banked for future research outside the scope of the current project?

Yes **No**

View: SF: nPBA: Exemption Consent

Exemption Consent

1. Upload Exemption Consent

- The exemption consent template is available here.
- For educational and social-behavioral studies, you can use the Consent Form Wizard. The Wizard does not include HIPAA authorization language.

Upload all consent materials (scripts, information sheet, etc.).

Information Sheet_Exempt_04.12.2023.docx

2. Exemption Consent Process

* Please describe the consent process.

> Information sheet will be provided to subjects and, if applicable, their activated LAR prior to starting in-person interviews/focus groups.

View: SF: nPBA: Impaired Decision-Making Capacity

Impaired Consent

1. Capacity Assessment Method

* Describe how capacity to consent will be assessed.

> Formal capacity assessment will follow the Evaluation to Consent measure – a widely used reliable/valid procedure. The study team member will clearly explain the study and will use the teach-back method to confirm understanding of the study purpose and interview procedures.
>
> This method utilizes a series of open-ended questions throughout the process to confirm that the participant understands the study and their involvement. These questions include: 1. What is the potential risk of your participation? 2. What will happen in this study? 3. What if you don't want to continue the interview? 4. What if you experience discomfort during the interview?

2. Schedule for Capacity Assessment

* Describe when capacity to consent will be assessed, noting specifically if there is a need to reassess consent capacity during the course of the study.

> Capacity to consent will be performed as a part of the Informed Consent process, prior to commencing study procedures.
>
> We will engage robust procedures to obtain informed consent and assent, and continually re-evaluate capacity to consent as well as assent across study procedures.
>
> Re-assessment of capacity and/or assessment will be triggered by statements from participants indicating they are confused or do not understand study procedures, and /or responses that indicate they do not understand the study procedures or questions or may not want to participate.

3. Who Assesses Capacity

* Describe who will assess consent capacity.

> Study team members will complete the formal Evaluation to Consent measure. These individuals are trained in dementia assessment, teach-back method, and interviewing techniques.
>
> EDRC staff will only preliminarily assess consent capacity through chart review and confirmation with clinical staff on the patient’s ability to answer questions about their care.

4. Subject Involvement in Consent

If you plan to enroll only those subjects who are able to provide informed consent (for example, early-stage Alzheimer's Disease subjects), state this here.

* Describe the extent to which (if any) the subject will be included in the consent process.

> Individuals who do not have an activated LAR, who can answer questions about their care, and who can complete the Evaluation to Consent measure will complete informed consent on their own behalf, as will caregiver participants.
>
> Individuals who have an activated LAR will be assented in an ongoing manner; this participant's activated LAR will complete consent on behalf of the participant.
>
> A participant's preference not to participate in the study will operate as a veto to their participation, even if their representative consents to the research.

5. Surrogate Consent Necessary

* Will there be a need for surrogate consent?

(●) **Yes** ( ) No

5.1. Who Provides Surrogate Consent

* From whom will surrogate consent be obtained?

> Activated legally authorized representatives that may provide informed consent on behalf of participants with dementia in this study will follow established priorities for surrogate decision-making according to the following priority list, in accordance with institutional policy and state law:
>
> 1) A research power of attorney may consent to a potential participant's participation in research, if the agent's decision is not inconsistent with the wishes and preferences of the potential participant expressed in the power of attorney instrument.
> 2) A court-appointed guardian of the person may consent to a ward's participation in research if the court order includes the power to consent to research. NOTE: A guardian of the estate or guardian ad litem cannot provide surrogate consent.
> 3) A power of attorney for healthcare may consent to a potential participant's participation in research, if the agent's decision is not inconsistent with the wishes and preferences of the potential participant expressed in the power of attorney for health care instrument.
> 4) If the potential participant has no research power of attorney, guardian, or healthcare power of attorney, then the potential participant's "next of kin" may consent on behalf of the potential participant.
> 5) "Next of kin" can provide surrogate consent in the following order: the spouse or registered domestic partner, adult child, parent, adult sibling, grandparent, adult grandchild, or a close friend of the potential participant.
>
> If the individual is interested in participating and can answer questions about their care, but has presence of an activated LAR and the activated LAR cannot be identified, the study team will thank them for their time and interest, end the recruitment process, and destroy any identifiable information about the person.

6. Consent Plan for Reassessing Capacity

* Is there a plan for obtaining consent if a subject regains capacity?

(●) **Yes** ( ) No

6.1. Reassessing Capacity

* Describe the plan to obtain consent from the subject should they regain the ability to provide informed consent on their own

behalf.

> While this is a single interview study and reassessment is unlikely to be formally needed, we recognize consent assessment as an ongoing process and interviewers will be mindful of communication or changes that indicate the need to reassess capacity.
> Formal capacity re-assessment will be triggered by disclosed concerns about memory or cognition, observed challenges following the consent process, and/or demonstrated lack of recollection or comprehension of key study details.
> Ongoing assessment of assent will also be performed. The research team will closely monitor the patient throughout all study procedures to ensure they are not uncomfortable or indicating dissent related to study procedures. If the patient indicates they dissent from participating in the study procedures, study activities will cease immediately.
> In addition to verbal assent, research staff will look for non-verbal cues indicating assent and dissent:
> Assent: Nodding head, smiling, engaging in conversation
> Dissent: Fidgeting, frowning, crossing arms, withdrawing or turning away in space

View: SF: nPBA: HIPAA General

HIPAA

1. Identifiable Information

* Will the research involve identifiable health information for any reason?

(●) **Yes** ( ) No

1.1. UW Madison Health Care Component or Madison VA

The HCC of the UW-Madison currently includes SMPH clinical departments; School of Pharmacy (clinical units only); School of Nursing; University Health Services (non-student records only); State Laboratory of Hygiene; and Waisman Center (clinical units only). Ensure the PI or any study team members are covered under HIPAA Privacy Rule regulations as part of their appointment.

* Are you or any member of the study team conducting the study under an appointment that is within the UW-Madison Health Care Component (HCC) and/or Affiliated Covered Entity (ACE) or the Madison VA?

(●) **Yes** ( ) No

1.2. HIPAA Authorization

* Will HIPAA authorization for access to the PHI be obtained for all or some subjects, or for only some uses?

( ) Yes, always: HIPAA authorization will be obtained from all subjects with signed documentation.

(●) **Yes, sometimes or without signed documentation: HIPAA authorization will not be obtained from some subjects/uses or may be obtained without a signature.**

( ) No: HIPAA authorization will not be obtained from any subjects.

1.3. External PHI Access

* Will you access or obtain fully identifiable health information from a health care provider that is not UW or UW Health, such as Meriter or ACHC, without first obtaining patient permission or authorization?

( ) Yes (●) **No**

View: SF: nPBA: HIPAA Waivers Sometimes

Authorization and Waivers

When sharing fully identifiable health information outside of UW or UW Health or obtaining it from a covered entity that is not UW or UW Health (e.g. bringing PHI from Meriter to a UW workstation to contact for phone screening or to recruit), you may need a partial waiver of authorization and accounting for disclosures may be required. Please consult with the **HIPAA Privacy Officer** and consult the Accounting for Disclosures Guidance found **here**.

1. HIPAA Requirement Fulfillment

* Please select which option(s) will be applied to fulfill HIPAA requirements.

Request Partial Waiver or Altered Authorization

2. Applicable HIPAA Identifiers

Select which of following identifiers will be associated with the health information you propose to collect for study purposes. Check all that apply to your study. If none of these identifiers will be collected for you study, select 'None of the Above'.

None of the Above

View: SF: nPBA: HIPAA Waivers/Authorization Request

Request for Authorization/Waivers

When sharing fully identifiable health information outside of UW or UW Health or obtaining it from a covered entity that is not UW or UW Health (e.g. bringing PHI from Meriter to a UW workstation to contact for phone screening or to recruit), you may need a partial waiver of authorization and accounting for disclosures may be required. Please consult with the **HIPAA Privacy Officer** and consult the Accounting for Disclosures Guidance found **here**.

1. Altered Authorization

HIPAA authorization for research must be project-specific. Standard clinical consent and authorization does not cover research use. If you will not obtain authorization in writing or seek to significantly modify the standard HIPAA authorization language, an altered authorization is necessary.

* Are you requesting an altered authorization?

(●) **Yes** ( ) No

1.1. Waiver Details

HIPAA authorization for research must be project-specific. Standard clinical consent and authorization does not cover research use. If you will not obtain authorization in writing or seek to significantly modify the standard HIPAA authorization language, a waiver of altered authorization is necessary.

Please describe how authorization will be altered.

> As the health information collected only includes diagnostic information regarding dementia status to screen for eligibility which will not be linked to any identifiable data within the study and will only be reported in the aggregate, we request verbal HIPAA authorization only.

2. Partial Waiver of Authorization

If you will not obtain authorization from any subjects, a full waiver is required.

* Are you requesting a partial waiver of authorization?

( ) Yes (●) **No**

3. Type of Records

* Identify the PHI to be used. Select all that apply.

Hospital/doctor records, including test results and dental records

4. Confirm Policy for Sharing PHI Externally

For help, see https://compliance.wisc.edu/hipaa/coordinators/

If you disclose PHI outside the HIPAA covered entity under which you are conducting the study, confirm you will contact the UW Madison HIPAA Privacy Officer or the Madison VA Privacy Officer.

(●) **Yes** ( ) No

5. PHI Protection Plan

* Describe your plan to protect PHI form unauthorized use or disclosure.

> Health information collected only includes diagnostic information regarding dementia status to screen for eligibility. This information will be stored in a secure Department of Medicine server folder, and will not be linked to any identifiable data and will only be reported in the aggregate. Only approved personnel will have access to study data.

6. PHI Destruction Plan

* Describe your plan for destroying identifiers at the earliest possible opportunity.

> No identifiers will be collected in association with PHI. Contact information will be destroyed after all necessary contact with participants is completed.

7. Waiver/Alteration Justification

* Explain why the study cannot practicably be conducted without the waiver of authorization or altered authorization.

> We are not obtaining signed consent given the minimum risk nature of the study and in the interest of limiting the number of study documents with the participant's name. Participation in the interview indicates consent and authorization. HIPAA language will be included in the information sheet.

8. Limitations Confirmation

* Federal law prohibits the re-use or disclosure of PHI in connection with this research to any person or entity other than those authorized to receive it, except: (1) as required by law; (2) for authorized oversight of the research; or (3) in connection with other research for which the HIPAA Privacy Rule permits the PHI to be used or disclosed. Do you agree to abide by these limitations in order to obtain a waiver of authorization?

(●) **Yes** ( ) No

View: SF: nPBA: Recordings and Photographs

Audio/Video Recordings and Photographs

1. Recordings Collected

* Select which of the following will be collected for this study. Check all that apply.

- [x] **Audio recordings**
- [ ] Video recordings
- [ ] Photographs

2. Identifiable Recordings

E.g., full face photo/video, audio recording of first and last name, or other individually identifiable information.

* Will the subject be identifiable in the audio/video recording or photograph?

○ Yes ◉ **No**

3. Retain Recordings

* Will the audio/video recordings or photographs be retained beyond the conclusion of this study?

○ Yes ◉ **No**

4. External Transcription

* Will anyone outside the study team transcribe audio recordings?

◉ **Yes** ○ No

4.1. Transcriber Details

* Indicate who will perform the transcription.

> Recordings include health information covered by HIPAA, transcription will be done by a professional transcription service covered by a BAA with the UW.

View: SF: nPBA: Interviews, Focus Groups, Surveys, Questionnaires

Interviews, Focus Groups, Surveys, Questionnaires

1. Tool Details

* Describe the interview tools, questionnaires, or surveys that will be used. Click the add button to provide information about each tool to be used.

View

Tool Description	Person with Dementia Demographic Questionnaire
Tool Standardized	No
File name	Demographic Questionnaire_PLWD_02.03.2023.docx
Tool Manner	Telephone In-person Internet
Tool Manner Other	In-person at ED, hospital, home, private room in public library or Department of Emergency Medicine, or other private location preferred by participation. Phone or Internet over Zoom or WebEx
Date Modified	3/29/2023

View

Tool Description	Interview Guide - Abbreviated Version for ED/Hospital Use
Tool Standardized	No
File name	Interview Questions Short Version_02.03.2023.docx
Tool Manner	In-person
Tool Manner Other	In-person at ED or hospital.
Date Modified	3/6/2023

View

Tool Description	Interview Guide - Full Version
Tool Standardized	No
File name	Interview Question Domains_02.03.2023.docx
Tool Manner	Telephone In-person Internet
Tool Manner Other	In-person at home, private room in public library or Department of Emergency Medicine, or other private location preferred by participation. Phone or Internet over Zoom or WebEx
Date Modified	3/6/2023

View

Tool Description	Caregiver Demographic Questionnaire

Tool Standardized	No
File name	Demographic Questionnaire_Caregiver_02.03.2023.docx
Tool Manner	Telephone In-person Internet
Tool Manner Other	In-person at ED, hospital, home, private room in public library or Department of Emergency Medicine, or other private location preferred by participation. Phone or Internet over Zoom or WebEx
Date Modified	3/6/2023

2. Cognitive or Psychological Assessment

* Are any of the uploaded instruments used to assess cognitive or psychological status or function?

○ Yes ◉ **No**

View: SF: nPBA: Supplemental Information

Supplemental Information

1. Additional Documents

Provide any additional relevant documents (e.g., data sharing agreements, letters of support, MOUs, site permission letters), if applicable.

There are no items to display

View: SF: nPBA: Final Page

Final Page

1. Assurance

The information presented in this application is accurate;
If the application is being submitted on behalf of the Principal Investigator (PI) rather than by the PI, the information presented was done so with the PI's agreement; and
The specific aims and description of research (including subject population, subject interventions, collaborators, performance sites, and general scope of work) in this IRB application are consistent with those described in the sources of support listed as providing financial and/or material resources to conduct this study.

* Do you certify the above statements?

(●) **Yes** ( ) No

2. Complete and Submit Application Instructions

To complete and submit this application to the IRB office, please follow the steps below:

1. Select Ready to Submit or Exit on this page to be directed to the application workspace.
2. In the application workspace, click the Submit activity to send the application to the IRB office. NOTE: The Submit activity is only available to certain study team members.

Department of Emergency Medicine Research Committee Meeting

Date:	6/6/2023	**Meeting Lead:** Dr. Andrea Gilmore-Bykovskyi	
Time:	12:30 pm – 01:30pm	**Recorder:** Maria Balbach/Dalton Lee	

	Lead	Length
General Announcements • Learning Plans Welcome!	Dr. Gilmore-Bykovskyi	2 min
Research Administration and Fiscal Updates • Welcome Chelsea McClellan! Chelsea will be working with Dr. Shah. • Welcome Chuck! Chuck is staying on with the Pulia Lab and joining the EDRC team.	Jessie Libber	3 min
EDRC Updates •	Phoebe Natzke	0 min
Items for Approval • Protocol, Patient Flow Optimization (Dr. Patterson) • Protocol, Evaluation of Trends in EMR Note Length (Dr. Patterson) • Protocol, Variability in Clinical Exposure of Diverse Populations (Dr. Schnapp) • Protocol, Person-centered Outcomes for EM Care for PWD (Dr. Gilmore-Bykovskyi)	Dr. Gilmore-Bykovskyi	50 min
Items for Discussion •	Dr. Gilmore-Bykovskyi	0 min

Strategic Plan

1: Implement a pipeline for emergency care researchers that will support our research faculty recruitment efforts.
2: Integrate the DEM Research Enterprise with UW Health/UWSMPH Research in terms of oversight and support of initiatives.
3: Demonstrate the impact of DEM research studies on social emergency medicine topics and expand our portfolio of studies impacting social emergency medicine topics.
4: Expand the number of tenured faculty in DEM.
5: Expand our portfolio of studies with a focus on diversity, equity, and inclusion.

To conduct innovative clinical and translational emergency care research to advance the health of the people of Wisconsin and beyond.

Calendar of Events:

Next EMRC meeting:
June 20, 2023, 12:30-1:30

Attendees:

EM Research Faculty:	EM Staff:		
Gilmore-Bykovskyi, A.	Balbach, M.	Hall, S.	Wood, A.
Hurst, A.	Barton, H.	Hekman, D.	
Jewell, C.	Benson, C.	Kadiyala, S.	
Kim, M.	Block, L.	Laev, L.	**Collaborators:**
Kuttab, H.	Broghammer, C.	Lee, D.	Halfpap, J.
Patterson, B.	Coulson, A.	Libber, J.	Hankwitz, J.
Pulia, M.	Dai, Elena	Maru, A.	Krueger, J.
Shah, M.	Dillon, K.	McClellan, C.	Marr, J.
Spigner, M.	Ebert, L.	Morales, M.	
Tschautscher, C.	Fehland, J.	Oliver, L.	**Guests:**
Tsuchida, R.	Fischer, T.	Natzke, P.	Acosta Perez, F.
	Gifford, A.	Ranade, T.	Schnapp, B.
	Griffin, M.	Schwei, R.	

PROTOCOL TITLE:

Evaluating current state and trends in electronic medical record note length

PRINCIPAL RESEARCHER

Brian Patterson
Department of Emergency Medicine
bpatter@medicine.wisc.edu

Table of Contents

1.0 Study Summary

Study Title	Evaluating current state and trends in electronic medical record note length
Study Design	Health care records research only
Primary Objective	The objective of this study is to quantify and describe temporal trends in the number of clinical notes present for review by clinicians at patient presentation to the emergency department, inpatient admission, and ICU admission
Secondary Objective(s)	N/A
Study Population	Dataset of all patients presenting to the emergency department from 2009 - 2023
Study Specific Abbreviations/ Definitions	Electronic health record (EHR) Natural language processing (NLP) Clinical Research Data Services (CRDS)

2.0 Purpose and Significance

In the modern healthcare system, review of prior records is an important step in the provision of acute care. Prior studies evaluating emergency care document review of previous records as occupying a significant portion of the time clinicians spend during visits. The advent of the Electronic Health Record (EHR) has increased the availability of notes detailing patients' outpatient visits and prior hospitalization. As these notes have become available in real-time during acute care visits, there is an expectation that clinicians familiarize themselves with patients recent course and distant medical history. Given that the EHR has only existed for 10-15 years in most locations, the volume of notes available during this review period has likely grown as more time has elapsed for notes to accrue. Physicians often report stress related to the size and scattered nature of existing records when trying to provide acute care in time-sensitive conditions. However, to our knowledge, the amount of information available in non-discrete and discrete fields has not been quantified over time. This study seeks to evaluate the length, type, and number of notes and other results available for physician review at the time of presentation for acute care, and to evaluate the trend in this amount over time. Significance: Provide any relevant background, evidence, or information that supports the importance or justification and scientific value for creating this database, registry, or repository by describing the unmet need and value of the desired information/specimens.

We will utilize discrete electronic health record (EHR) data and natural language processing (NLP) techniques applied to clinical notes to extract length of notes in words.

We during the study period 2009-2023, we plan to create a dataset of all patients presenting to the emergency department. We will extract both discrete data and metadata surrounding notes from these encounters to generate statistics on volume (i.e. number of notes, number of words, number of different types of notes, as well as number of relevant laboratory tests, radiology studies, and other procedures with reports).

Data will be extracted by Clinical Research Data Services (CRDS) staff through a research data request and delivered to a CHI2 approved computing platform. Initially, MRNs and CSN's will be used to assign patients' study and visit identifiers, but these direct identifiers will then be removed from the dataset. Notes will initially be stored to allow generation of metadata (length, number of words/characters). After initial procession, no note text or direct patient identifiers will be extracted or stored in the dataset used for analysis.

3.0 Subject Identification, Recruitment and Consent

3.1 Method of Subject Identification and Recruitment

Medical records will be used to identify subjects and records. Clinical Research Data Service (CRDS) will be used to identify subjects via these records.

3.2 Process of Consent

The study likely poses minimal risk to subjects because the activities are limited to use of data from medical records (or images created for clinical purposes) and there are sufficient measures in place to protect the data.

The research likely does not adversely affect the subjects' rights and welfare because only those who have valid access to their medical records will collect study data and the use of the data is not expected to affect the patients from whom the data are derived.

The research likely does not adversely affect the subjects' rights and welfare because access to study data will be restricted to the study team and the use of the data is not expected to affect the subjects from whom the data are derived.

It may be impracticable to obtain informed consent from subjects because the study team may not be interacting with the patients and the records may be for patients who are not being currently seen at UWHC or who may no longer be seen at the UW Health clinics.

Identifiable information will be retained for the duration of the study to allow for checking the data as needed.

4.0 Confidentiality of Data and Information Storage

This project will use the minimum amount of data necessary to achieve the aim of the research. Because this is a retrospective records review, study team members will not have direct contact with study subjects. This research does not involve interaction with subjects.

Direct identifiers will initially be used to ensure individuals within the study are not duplicated (i.e. 2 visits made by the same patient are not counted as two separate patients' visits). Also, some identifying data may be within note text.

Direct identifiers (MRN and CSN) will be removed as soon as subjects have been assigned a study id, and note text will be removed as soon as note metadata has been generated.

Clinical notes and EHR data will be extracted by Clinical Research Data Services staff and delivered to a Chi2 approved computing location for dataset creation, storage and analysis.

Individually identifiable or deducible data will not be transmitted by unsecured telecommunications, which include the Internet, email, and non-secure File Transfer Protocol (FTP). No restricted data will be transmitted electronically through unsecured methods such as e-mail, e-mail attachments, or non-secure FTP. No output from the study will contain individual identifiable information. No individual personal health information (PHI) will be released in presentation or publication. No printed materials will contain individual identifiers. Only aggregate statistical output representing groups of subjects will be released.

5.0 Risk/Benefit Assessment

5.1 Potential Benefits to Society

Understanding the amount of data available to physicians at the time of an acute care visit will quantify a serious issue in providing acute care: the growth and fragmentation of text and data in the medical record, leading to an increased burden on providers and increased chance of missing valuable information.

5.2 Potential Psychosocial Risks

The only potential risk to subjects is a loss of confidentiality.

5.3 Procedure to Minimize Risks

We will minimize the risk of loss of confidentiality by protecting the data with IT security best practices, including storing data on secure servers and limiting access to that data to pre-approved personnel.

The identifiable EHR data will be stored on the Research Data Services staff and delivered and delivered to a CHI2 approved computing platform. Following dataset development, the analysis dataset will be stripped of all direct identifiers, but still kept on the a CHI2 approved computing platform, where privacy will be protected by the restriction of access to data to only selected project-specific individuals (need-to-know) and the use of passwords for computer drive and project folder access.

Project Title: Variability in Clinical Exposure to Patients with Diverse Social Identities in Emergency Medicine Residency

1. TITLE PAGE

1.1. PI: Benjamin Schnapp, MD

Key personnel: Dann Hekman
Sponsor/Funder: None
Participating sites: University of Wisconsin, Department of Emergency Medicine

2. PURPOSE OF THE STUDY AND BACKGROUND

2.1. Abstract

Introduction
Experiential learning theory suggests that clinical exposures are key to developing competencies in Patient Care and Interpersonal and Communication Skills. This is likely especially true for developing cultural competency and competency with patients of diverse social identities, including gender identity, sexual orientation identity and socioeconomic backgrounds.
Purpose
The goal of this study is to characterize the variability in EM resident clinical exposure to patients with diverse social identities.
Methods
This study with be a retrospective records review of EHR data at the main residency clinical site at UW. Patient characteristics of patients seen as the first assigned resident will be analyzed with descriptive statistics, including race, sexual orientation, gender identity and care plan status and insurance status as a proxy for socioeconomic status.
Results
We intend to produce box and whisker plots detailing the distribution of patients seen by residents over the course of their entire training for each of the variables of interest.
Conclusions
Based on the results of previous work on clinical variability during training, we anticipate identifying significant variability in resident clinical exposures to diverse patients. This may have multiple implications for residency leadership as they consider how to train residents in cultural competency.

2.2 Purpose of the study & Aims

Previous studies have noted that clinical experiences of emergency medicine residents are highly variable. This could suggest that residents may graduate with relative deficits in exposure, confidence, and competence with caring for patients from different backgrounds. However, to our knowledge, this has never been shown empirically.

The goal of this project is to characterize differences in exposure to patients from different racial, ethnic, and socioeconomic backgrounds, as well as exposure to patients with varied gender identities and sexual orientations during emergency medicine residency training.

Based on previous research showing large variations in clinical exposure variability by ABEM content domain during emergency medicine residency training, we hypothesize that there will be large variability in graduating residents' clinical exposure to patients from a variety of different social, economic, racial, ethnic and gender backgrounds.

2.3 Background

Medical residency training allows physicians to gain the cognitive and procedural skills necessary to practice independently. Based on Kolb's theory of experiential learning, patient encounters form the foundations upon which physicians in training master the practice of medicine (Kolb 1984). Additionally, the development of "illness scripts," or mental models for the classification of patient presentations, is crucial to the development of clinical skills and reasoning during residency training (Bowen 2006). Emergency medicine (EM) trainees must be exposed to a variety of patient chief complaints throughout the course of residency to develop these scripts and become competent clinicians.

Clinical exposure has specifically been shown to be important for the development of competency in the care of diverse patient populations in a variety of medical trainees, including nursing and pharmacy students. Additionally, medical students who cared for more LGBTQ patients reported higher levels of preparedness and knowledge, and provider experience and comfort are noted as a significant factor influencing whether patients with Sickle Cell Disease receive appropriate evidence-based care.

Research Design and Methods

This will be designed as a retrospective analysis utilizing data extracted from the Electronic Medical Record (EHR). Data on resident clinical exposure as the first resident assigned to a visit will be collected at the patient level on diverse social identities, including gender identity, sexual orientation identity and socioeconomic background will be collected; no individually identifying patient information will be collected.

Resident level data will be aggregated for all residents who have completed all 3 years of residency at the UW EMRP consecutively and compared using descriptive statistics.

3. CHARACTERISTICS OF THE RESEARCH POPULATION

3.1 Number of Subjects:

We anticipate approximately 75 residents

3.2 Gender and Age of Subjects:

Male and female, approximately 25 to 40 years old.

3.3 Racial and Ethnic Origin:

Residents of all racial and ethnic origin are eligible

3.4 **Inclusion Criteria:**

All University of Wisconsin Emergency Medicine residents who have completed their residency training are eligible for the study.

4. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT

4.1 Method of Subject Identification and Recruitment

a. **How will subjects be identified and selected for the study? How will privacy of the individuals be maintained? The identification and recruitment of subjects must protect privacy and be free of undue influence.**
All Emegency Medicine residents who worked in the ED from 2016-2023 and completed their residency training are eligible.

b. **How will subjects be identified (e.g. flyers, emails, websites, announcements)?**
EHR (Epic) data review will identify residents who are eligible for the study

c. **Does the study team have routine access to the potential subjects being recruited and/or data being reviewed? If not, how will the study team recruit subjects or obtain the data.** Yes, routine access.

d. **If a secondary analysis of pre-existing data, indicate the database to be used or where the data is coming from and how eligible subjects will be identified from the database.**
EHR (Epic) records will be used, eligible records will be identified if a resident is assigned to the patient. Only non-identifiable demographic data will be collected on patients seen by each resident.

4.2 Process of Consent

Describe who will obtain consent and how the process of informed consent will be structured. Only individuals who have completed the IRB's required human subjects training and are listed on the IRB application are authorized to obtain consent.

N/A – this study is a retrospective records review.

5. METHODS AND STUDY PROCEDURES

5.1 Provide a detailed description of all study activities:

a. **What is the duration of the study (e.g., one semester, one year, until enrollment is reached)?**
The duration of the study will be approximately 1 month while data is collected and analyzed.

b. Who will conduct each activity (e.g., session, focus group, interview, experiment)?
Data from the electronic health records will be collected by Dann Hekman. Review and analysis of data will be completed by Benjamin Schnapp.

c. How long will each activity (e.g., session, focus group, interview, experiment) take?
The retrospective data analysis of the EHR will take approximately 2 weeks to 1 month.

d. Where will the study activities (e.g., session, focus group, interview, experiment) take place?
N/A

e. **If the study involves more than one visit, provide a sequential description of each study visit including what will occur at each visit and how long each visit will take**.
N/A

What type of compensation will be provided to subjects (e.g., class credit, Mechanical Turk payments, or no compensation will be provided)? If using SONA, indicate whether identifier will be used to track payment for class credit and whether or not research data will be linked to payment information/identifiers. N/A

6. RISK/BENEFIT ASSESSMENT

6.1 **Risks:** Possible confidentiality breach of study participants

6.2 **Benefits:** No incentive will be provided to study participants

7. DATA ANALYSIS:

Primary Outcomes of interest: Variability in resident clinical exposure as the first resident assigned to a visit for individual patient demographics such as race, insurance status, sexual orientation, care plan status, and gender identity

8. CONFIDENTIALIATY OF DATA AND INFORMATION STORAGE

Describe where the research data will be stored during the study and how it will be secured. This includes coding data and choosing an appropriate and secure data storage mechanism which will prevent unauthorized access to data.

Data will be stored on a physically secured University of Wisconsin Department of Emergency Medicine computer that is protected by a password. All resident records will be de-identified using a number instead of resident name. Data will be reported in aggregate form only.

Print ☐ Compact Close

University of Wisconsin-Madison MR IRB Application	Study # : 2023-0312 Principal Investigator: Andrea Gilmore Bykovskyi	View: SF: nPBA: Basic Study Information

Basic Study Information

1. Formal Title

This is the title that will appear in correspondence.

* Provide the full, formal study title.

> Development of person-centered outcome measures for emergency care experiences among persons with dementia

2. Transferred Study

Answer Yes to this question only if:

a) the principal investigator (PI) for this application is coming to UW-Madison, UW Health, or the Madison VA from another institution and,

b) they plan to open a study here that is already IRB-approved at their previous institution.

* Is this study being transferred from another institution?

○ Yes ◉ **No**

3. Principal Investigator

* Identify the Principal Investigator.

Andrea Gilmore Bykovskyi

View: SF: nPBA: Type of Research Application

Type of Research Application

1. Type of Research Application

* Select one of the following: Exemption

View: SF: nPBA: PI Appointment

PI Appointment

1. Principal Investigator

PI: Andrea Gilmore Bykovskyi

2. Primary Appointment

* Choose the appointment under which you will be conducting this research.

UW-Madison

3. UW-Madison Appointment

3.1. Appointment Details

* Identify the appointment under which the PI will conduct this research.

	Title	Type	UDDS	Department Combined Name
◉	**Associate Professor**	**FA**	**A534100**	**SMPH/EMERG MED**

3.2. Appointment Not Found

☐ Check if the appointment is not listed above.

4. Investigator-Initiated Study

* Is this an investigator-initiated study?

◉ **Yes** ○ No

View: SF: nPBA: Study Team

Study Team

1. Points of Contact Selection

Points of contact can edit the application and will receive email notifications about this submission.

Please do not use personal email addresses (e.g., Gmail, Hotmail, etc.). A campus business email can be changed following the instructions here.

If the PI is serving as the only study point of contact, indicate that here.

Can't find someone in the chooser? See this FAQ for help.

To register a NetID, click here.

* Identify the points of contact for this study (limit of four).

Name	Email
Clark Benson	cbenson5@wisc.edu
Laura Block	lmblock2@wisc.edu

2. All Other Study Team Personnel

List ONLY UW-Madison, UW Health, or Madison VA personnel. External personnel will be listed elsewhere in the application.

Please do not use personal email addresses (e.g., Gmail, Hotmail, etc.). A campus business email can be changed following the instructions here.

Study team members listed below will have read-access only and will not be able to edit the application. They also will not receive email notifications.

Can't find someone in the chooser? See this FAQ for help.

To register a NetID, click here.

List all the other members of the study team (not including the PI or points of contact).

Name	Email
Alison Coulson	acoulson@wisc.edu
Lucas Ebert	lhebert@medicine.wisc.edu
Jess Fehland	fehland@wisc.edu
Scott Hall	shall@medicine.wisc.edu
Shivani Kadiyala	skadiyala@medicine.wisc.edu
Alden Laev	alaev@medicine.wisc.edu
Maria Mora Pinzon	mmora2@wisc.edu
Phoebe Natzke	pnatzke@medicine.wisc.edu
Lex Oliver	aloliver@medicine.wisc.edu
Natasha Pedone-kahle	pedonekahl@medicine.wisc.edu
Tarjani Ranade	tranade@medicine.wisc.edu
Manish Shah	mnshah@medicine.wisc.edu
Inem Uko	iuko@wisc.edu
Audrey Wood	amwood@medicine.wisc.edu

View: SF: nPBA: Study Team Roles

Study Team Roles

1. Primary POC

If the PI is serving as the primary point of contact, indicate that here.

* Identify the primary point of contact for this study.
Clark Benson

2. Human Subject Involvement

* Does this study involve recruiting, consenting, or interacting with human subjects?
(●) **Yes** ( ) No

2.1. Study Team Details

For each study team member below, click the ✎ button and check the boxes to indicate that study team member's roles for this study. Note: Some study team members may not have any roles listed below.

Tell us which study team members will: recruit human subjects, obtain informed consent from human subjects, interact with human subjects, or perform cognitive assessments on human subjects.

Study Team Member	Recruit Subjects	Obtain Informed Consent	Interact with Subjects
Clark Benson	yes	yes	yes
Laura Block	yes	yes	yes
Alison Coulson	yes	yes	yes
Lucas Ebert			
Jess Fehland	yes	yes	yes
Andrea Gilmore Bykovskyi	yes	yes	yes
Scott Hall			
Shivani Kadiyala			
Alden Laev			
Maria Mora Pinzon	yes	yes	yes
Phoebe Natzke			
Lex Oliver			
Natasha Pedone-kahle			
Tarjani Ranade			
Manish Shah			
Inem Uko	yes	yes	yes
Audrey Wood			

View: SF: nPBA: Funding

Funding

1. Funding Administered by UW Madison

Answer no to this question if this study will only be supported by VA funding; you will have the opportunity to add VA funding later in the application.

* Do you have pending or approved funding administered through Research and Sponsored Programs (RSP) or Business Services to support this project?

(●) **Yes** ( ) No

1.1. Funding Sources

For **federal funds**, pending sources may be listed if the grant has received a highly meritorious score. For example, an impact score of <30 is an indication of a highly meritorious NIH grant proposal. Receipt of a request for Just In Time (JIT) documentation is another indication of a highly meritorious proposal.

For **non-federal funds**, pending sources may be listed if you have confirmation from the sponsor that funding will be awarded due to merit AND the sponsor has a peer-review process.

For **industry**, do not select industry sponsors who are only providing drug/device OR only limited support for the study.

* Use this chooser to select each funding source administered through UW-Madison that will support this study or project.

Funding Source Details

View

PI Name	BYKOVSKYI, ANDREA LEA GILMORE
Proposal ID	MSN270773
Award ID	MSN270773
Funding Title	Person-Centered Outcome Measures for AD Patient Emergency Care Experiences
Project ID	AAL8185
Sponsor Reference Number	
Sponsor (Source)	ALZHEIMER'S ASSOCIATION
Primary Sponsor	*No Value Entered*
Federal	No
Status	Active
Start Date	1/1/2023
End Date	12/31/2024

2. Other Funding

* Do you have pending or approved funding NOT listed on this page?

Yes **No**

View: SF: nPBA: Conflict of Interest

Conflict Of Interest

Please review the study team member Outside Activities Report (OAR) and managed entities data below before answering the questions on this page.

All study team members have completed their Ouside Activities Report for the year.

NOTE: Per campus policy all study team members must submit an OAR every year and keep it up to date.

These study team members have managed entities:

Manish Shah

Exact Sciences Coporation	Advisory Only

1. Sponsorship

* Do any of the managed entities sponsor the study?

○ Yes ◉ **No**

2. Technology

* Do any of the managed entities own or license a technology being used in the study (including any agent, device, or software)?

○ Yes ◉ **No**

3. Irrelevant Management Plans

If any of the management plans identified at the beginning of this page are not relevant to the study please explain why.

> No managed entity has played any role in the conceptualization, design or conduct of this study.

4. Intellectual Property

* Do any study team members involved in the design or conduct of the research (including their spouses and dependent children) own intellectual property that will be used in the study or project?

○ Yes ◉ **No**

5. Other Entities

* Besides the sponsor(s) of this project or entities listed above, do any study team members have a fiduciary or financial relationship with entities that will be involved in this study or that may be significantly affected by it?

○ Yes ◉ **No**

6. Incentives

* Do any of the study team receive any incentives for recruiting human subjects or any other purpose directly related to the study or project?

○ Yes ◉ **No**

View: SF: nPBA: VA Status

VA Status

All studies that fall under Madison VA purview must be reviewed and approved by the VA Research and Development (R&D) Committee in addition to being reviewed by the Health Sciences IRB. For information about the VA R&D Committee review process, please contact **VHAMADRDCoordinator@va.gov**.

1. VA Status

* Does this study involve the Madison VA (Wm. S. Middleton VA Hospital); e.g., funding from the VA, conducted under VA appointment, use of VA facility, recruitment of veterans or use of their data or samples at the Madison VA?

○ Yes ◉ **No**

View: SF: nPBA: PRMC

Scientific Review: Protocol Review Monitoring Committee

1. Cancer Related

* Is the scientific question of the protocol cancer related?

Yes **No**

2. Targeting Cancer Patients

* Are you specifically targeting cancer patients for enrollment in this study?

Yes **No**

3. Use of Cancer Data or Images

* Does this study involve the review and/or use of biological specimens/data/images/records from cancer patients?

Yes **No**

View: SF: nPBA: Exemption

Exemption

1. Exemption Category

If your research does not fit within one of the categories below, please select Full Review on the Type of Research Application page.

* Select the relevant category or categories for which you are requesting an exemption determination.

---

2. Research involving the use of educational tests, surveys, interviews.

- Surveys (with adults only)
- Interviews (with adults only)
- Focus groups (with adults only)
- Educational tests
- Observation of public behavior

May NOT involve an intervention (see exemption 3) or linking to additional personally-identifiable data.

View: SF: nPBA: External Collaborations 2

External Collaborations

1. Outside UW Activities

* Will any UW/UW Health or Madison VA personnel conduct any of the following study activities at locations outside the UW/UW Health or Madison VA: subject recruitment, obtaining informed consent, or interacting or intervening with subjects?

○ Yes ◉ **No**

View: SF: nPBA: Sharing Data Outside UW

Sharing Data Outside UW

1. Sharing Data Outside UW Madison

* Will subject data, images, or specimens be shared outside the UW Madison?

Yes **No**

View: SF: nPBA: Study Procedures and Special Populations

Study Procedures and Special Populations

1. Study Procedures Involved

Select "Review or use of information from health care records"

* If your study involves any of the following special procedures or considerations, additional information may be needed. Select all that apply. If none apply, check Not Applicable.

Creation of audio or video recordings or photographs
Interviews, focus groups, surveys, questionnaires, assessments (e.g., QOL, SCID, BDI, etc.)

2. Special Populations

If you will collect data points identifying individuals as any of the following, select the corresponding box(es).

* Is the research designed to include any of the following populations? Select "Not Applicable" if the research will not include any of the populations below. NOTE: If enrolling pregnant women, children, or prisoners, and you can identify them as such, check the box.

Persons with impaired decision-making
Poor/uninsured, elderly/aged, or educationally disadvantaged

View: SF: nPBA: Research Design and Procedures

Research Design and Procedures

1. Overall Purpose

Describe the research questions or gap in knowledge the study proposes to address or contribute to in language that someone who is educated but not an expert in the field can understand.

* What is the overall purpose and aim of this project or study?

> The overarching goals of this study are to determine cross-cultural care priorities of people living with dementia (PLWD) and their caregivers during emergency department (ED) visits and to develop and refine items for a Person-Centered Outcome Measure (PCOM) for use by PLWD to facilitate evaluation of those priorities.

2. Pre-Existing Information/Background Knowledge

* What prior information or knowledge exists to support the conduct of this project or study?

> Over 50% of the more than 6 million people with Alzheimer's Disease and Alzheimer's Disease and Alzheimer's Disease Related Dementia (ADRD) in the US visit an emergency department (ED) annually. The ED often serves as a first layer in supporting people living with dementia (PLWD) experiencing acute exacerbation of underlying chronic illnesses or distressing behavioral and psychological symptoms of dementia, and caregivers without respite who are overburdened or in crisis. Despite the major role the ED plays for PLWD and their care partners, presence of ADRD is often not well-recognized in the ED—and many factors in the ED environment are thought to be detrimental to provision of adequate care and betterment of health outcomes of PLWD. Collectively, the compounding environment of care and situational factors that surround ED visits produces significant distress among PLWD while frequently omitting care approaches that are responsive to the needs of PLWD. Studies suggest that PLWD would benefit considerably from improvements in the ED care experience. Findings from our prior work suggest that commonly used outcome measures which focus predominantly on utilization (e.g., ED revisit) and mortality do not adequately address aspects of the ED care experience or what matters most to PLWD during ED visits. Yet, there is virtually no research identifying specific ED care priorities from the perspectives of PLWD or their caregivers. Because an ED visit is often a marker of advancing illness and for some patients the need to engage palliative care, relying heavily on utilization outcomes to evaluate care quality may be inappropriate in many cases and is globally insufficient, highlighting the need for more sensitive care and outcome measures that capture meaningful indicators of care quality.

3. Study Procedures and Interventions

Provide an overview of the types of records that will be reviewed, what information from these records will be collected, and the kinds of analyses that will be performed on the study data. If data from multiple sources will be used describe this here (e.g., medical record information connected to imaging or billing information or data from multiple institutions collated).

* Briefly describe the procedures and interventions that will be performed for this project or study and all study arms involved. Do not include information on recruitment or consent.

> We will conduct semi-structured interviews with caregivers and individuals with dementia with capacity to share their care experiences from socioculturally diverse backgrounds to identify their ED care priorities. Participants may be interviewed in a private room in the ED or in another place of their choosing after their stay in the ED. This may include their hospital room if they are admitted after their ED visit or

their home, a private room in the Department of Emergency Medicine Offices, or a private room in a public library if they return home. Given the various length of wait times in the ED, participants will have the option to participate in a 10-15 minute interview or a longer 30-60 minute interview.

There are two scenarios under which individuals with dementia will be eligible for participation (explained further in Subject Identification and Recruitment: Subject Population):
1. Individuals with dementia with capacity to share their care experiences who do not currently have an activated power of attorney, legal guardian, or otherwise legal indication of lack of capacity to consent will be included, with the option to complete the interviews individually or with a support person/caregiver based upon their preference. Along with an assessment of capacity to consent from the clinical team and EDRC team, a formal capacity assessment through an Evaluation to Consent will confirm capacity to consent for these individuals just prior to being consented to participate in the study, recognizing this may take place at a timeframe different from clinical staff assessment. Study team members with experience making capacity to consent determinations from a previous study (2018-0101) will conduct the Evaluation to Consent form.

2. Individuals with dementia with capacity to share their experiences but with presence of an activated power of attorney, legal guardian, or otherwise legal indication of lack of capacity to consent will be included if proxy consent from the legally authorized representative can be obtained and the person with dementia provides assent.

Current, former, and/or caregivers providing care to someone with dementia can also complete interviews individually or dyadically.
All participants (caregivers and people living with dementia) will complete demographic questionnaires.

4. Incidental or Adventitious Findings

* Will any study procedures produce incidental or adventitious findings (e.g., imaging scans, laboratory blood tests, depression screening questionnaires, etc.)?

○ Yes ◉ **No**

5. Instruments Involved

This question is intended to identify projects involving the development or use of medical devices. This does not apply to surveys or questionnaires.

* Are there instruments of any kind, including software, tests run on samples, and algorithms, used in the study?

○ Yes ◉ **No**

View: SF: nPBA: Subject Identification Medical Records

Subject Identification: Medical Records

1. Medical Record Use

* Will medical records be used to identify subjects or records?

(●) **Yes** ( ) No

1.1. CRDS Usage

CRDS assists UW investigators with developing data queries and delivering data from the UW Health Enterprise Data Warehouse (EDW) to be used in feasibility assessments, recruitment of participants, pilot studies, and retrospective analyses.

* Will you use the Clinical Research Data Service (CRDS) to identify subjects via these records?

( ) Yes (●) **No**

1.2. Record Identification Details

* Describe how eligible subjects will be identified using medical records, including 1) which records will be accessed and 2) who will identify eligible subjects.

> Medical records will facilitate identification of eligible participants through our recruitment arm at the UW Health University Hospital Emergency Department (ED). ED recruitment will be facilitated through the Emergency Department Research Coordinator (EDRC) Program. EDRC staff are integrated into the ED at UW Health to assist with screening of eligible participants. They regularly interface with ED clinical staff to assess eligibility of potential study participants and determine whether recruitment approaches are appropriate provided patient safety and health.
>
> EDRC staff will examine diagnostic information within the medical record to determine presence of patients with dementia in the ED. EDRC staff will also examine medical records to determine presence of an activated power of attorney, legal guardian, or otherwise legal indication of lack of capacity to consent (referred to hereafter as presence of a legally authorized representative, or LAR) to determine if the person with dementia can legally consent to participation in research.
>
> Subsequent recruitment steps are described in Subject Identification and Recruitment: Recruitment Methods.

View: SF: nPBA: Risks and Benefits

Risks and Benefits

1. Direct Benefits Intended

For this type of research there are generally no direct benefits to subjects. The response to this question, "There are no direct benefits to subjects", would be acceptable.

* Are any of the research activities intended to directly benefit subjects?

○ Yes ◉ **No**

2. Potential Benefits to Society

Describe how the research might help future patients.

* Describe the importance of the knowledge reasonably to be gained from this study and what benefit the research may provide to society.

> The primary benefits of this study are indirect future improvements to ED care for people living with dementia, and evaluation of care quality according to specified person-centered care priorities. Some participants may benefit emotionally from the opportunity to share their experiences and be listened to during interviews.

3. Direct Physical Intervention

A physical intervention refers to study procedures that may pose a risk (however minimal) to a subject's body (e.g., blood draws, MRI scans, drug or device trials, exercise, dietary restrictions/supplements). Examples of activities that are NOT physical intervention include obtaining informed consent and administering surveys.

* Does this study involve direct physical intervention with subjects?

○ Yes ◉ **No**

4. Potential Psychosocial Risks

For this type of research the risks to subjects are generally limited to the risk of breach of confidentiality. The response to this question, "There is a risk of breach of confidentiality", would be acceptable.

* Describe any potential psychosocial risks to subjects, such as psychological stress or confidentiality risks (including risk to reputation, economic risks, and legal risks).

> There is a minimal risk of a breach in confidentiality.
>
> This study involves semi-structured interviews. Some participants may become upset or experience discomfort when speaking of dementia and/or ED care experiences that were traumatic or stressful. Participants, particularly those with dementia, may become fatigued or frustrated throughout the course of the interview or in response to questions that are abstract or complex.
>
> Participants may also reveal personal or identifiable information (e.g. name, names of love ones, location) when responding to questions.

5. Procedures to Minimize Risks

The response to this question should address how the risk of breach of confidentiality will be minimized. For example, it could be described that the study team has several measures in place to protect against a breach of confidentiality, such as limiting the number of people who view identifiable information, coding study instruments, storing study data in restricted areas and on computers that are password-protected, only transmitting coded data outside the institution (if data will be shared), and using a secure web-interface to transmit data off-site (if data will be shared).

* Describe the procedures in place to minimize risks from all interventions performed for research purposes. This should include activities in place to identify, monitor, mitigate, and eliminate risks to the degree possible.

> Confidentiality Risks
> Confidentiality risks will be minimized through use of multiple procedures and processes that maximize anonymity and security in accordance with campus policy. We will assign all participants a study ID number and after interviews, we will only identify participants' data by study ID number.
>
> The study team will minimize the identifiable information collected during the logistical portions of recruitment and scheduling interviews, specifically the study team will only record first names and contact information (phone number and/or email address) during the interview scheduling process (if necessary) which will be deleted 1) upon completion of the interview 2) if the participant(s) decides to no longer participate or 3) after four unreturned contact attempts. Contact information will be stored in a secure folder on the Department of Medicine research data server, with access limited to study members only. This folder location is separate from all other study materials and interview data. Access to the server is restricted to team members with special training on data safety. Access is audited every 6 months, and removed if determined no longer necessary.
>
> Risk of Emotional Upset or Fatigue During Interviews
> The study team is trained in procedures to maximize comfort of the study, including providing the option to skip questions or pause/stop the interview in scenarios of emotional upset or fatigue. This, along with the approximate length of the interview, are covered in informed consent. Interview questions will be modulated based upon the abilities of the participant(s), and the study team is trained to adjust pacing and difficulty of the questions during the interview space. The study team will also ask if participants would like to be referred to resources for dementia caregiving support. Under prior protocols (IRB 2018-0101), the study team has recruited and engaged people living with dementia and their caregivers in interviews in the ED and hospital and offered tailored resources for caregivers nationally and by the state the caregiver resides in.
>
> Risk of Personal or Identifiable Information
> Identifiable information, such as name or location, will be redacted from the interview transcript. Potentially sensitive information, such as experiences with ED care for cognitive needs, is likely to be shared and will not be redacted.
>
> Risk of Loss of Confidentiality due to Mandated Reporting
> If during the interview, participants report situations which may constitute potential abuse of a child or elder, our staff will follow requirements for mandated reporting. This risk will be disclosed to them in the informed consent process and corresponding information sheet.
> If participants disclose care situations which upset or concern them but do not constitute potential abuse of a child or elder, they will be provided with the contact information for UW Hospital Patient Relations: 608-263-8009.

View: SF: nPBA: Subject Population

Subject Population

1. Total Subjects

You must provide an integer. If you are enrolling a range of subjects (e.g., 50 to 100 subjects), enter the larger number.

* Provide the number of subjects that will be enrolled at sites for which UW Madison is serving as the reviewing IRB.

> 30

2. Inclusion Criteria

* Describe the main inclusion criteria.

> Individuals with dementia:
> •Diagnosis of ADRD confirmed via medical record review or by proxy informant such as clinical staff, the participant's activated LAR, caregiver, or family member.
> •For individuals with dementia recruited through community-based recruitment approaches, diagnosis of ADRD as specified through self-report
> •Has had an ED experience
> •Capacity to share their care experience and to consent to participation in research through clinical staff assessment and as measured by the Evaluation to Consent Assessment
> •OR if capacity to share their care experience BUT indication of lacking legal capacity to provide informed consent (i.e. presence of activated power of attorney, legal guardian, or otherwise activated LAR)—proxy consent by the activated LAR and assent by the person with dementia
> •If participating in dyadic nature with caregiver, consent of caregiver
>
> Caregivers:
> •Current or former informal/unpaid caregiver to person with dementia
> •Person with dementia has had an ED experience
> •If participating in a supportive or dyadic nature with person with dementia, consent and/or assent of person with dementia

3. Exclusion Criteria

* Describe the main exclusion criteria.

> Individuals with dementia:
> •Unable to verify diagnosis of ADRD
> •Unable to answer basic questions about their care based on assessment of the clinical team and as verified by EDRC team, or through ongoing assessment by study team
> •Unable to understand and consent to study
> •No relevant ED experience
> •Unable to locate or receive consent from activated LAR (or caregiver if person with dementia prefers dyadic interview)
>
> Caregivers:
> •Paid caregiver
> •Caregiver to person who has condition other than dementia
> •No relevant ED experience
> •Consent/assent not received from person with dementia in context of a supportive or dyadic interview

4. Targeted Populations

Populations could be racial/ethnic, sex, or gender (this also applies to gender identity, or lack thereof).

* Will this study target or exclude specific populations?

(●) **Yes** ( ) No

4.1. Targeted Population Justification

* Describe the population that will be targeted or excluded and provide justification.

> Because our aim is to develop a measure that is responsive socioculturally diverse perspectives on ED care among people with dementia, we will endeavor to include individuals from racially/ethnically diverse groups, with a familial history of immigration for different cultural perspectives, and socioeconomically diverse groups. These groups are underrepresented in research on dementia and ED care despite experiencing poorer outcomes.

View: SF: nPBA: Special Populations Justification

Special Populations Justification

1. Justification

If more than one special population is enrolled, separate justifications should be provided for each unique population.

* What is the justification for the inclusion of these subjects?

> This study aims to understand ED care priorities for people with dementia by including and interviewing people living with dementia themselves. Most existing measures to assess care rely on caregiver reports, and have been developed through caregiver interviews. While these measures may accurately capture some of what matters to people with dementia, there is evidence of a lack of perfect alignment between the perspectives of people with dementia themselves and caregivers. Therefore, it is critical that we include people with dementia in this study so that we can integrate their perspectives into future measure development. Considerable research demonstrates that individuals living with dementia have capacity to participate in research, particularly in interviews, and as a result considerable resources have been developed and disseminated to support their inclusion.
>
> Moreover, we plan to include people with dementia who do not have legal decision-making capacity as these individuals are even more under-included in research. Lack of legal decision-making capacity does not always equate to a lack of ability to participate in research procedures or decisions about research which we recognize as necessitating a situationally specific assessment. In other words, many people with dementia who do not have legal decision-making capacity may still be able to share details on their care experiences and preferences, and therefore we wish to ensure their perspectives are not systematically under-included. They may also have unique experiences on care in the context of fluctuating cognition.
>
> Moreover, we plan to include diverse participants, including those who are potentially socio-economically disadvantaged. This is critical because those who are socio-economically disadvantaged often rely on the ED as a more accessible point of care, and therefore findings around ED care priorities and corresponding measurement must be responsive to their perspectives.

2. Safeguards

Include the measures that will be taken to minimize any potential coercion or undue influence in recruitment and ongoing participation in the study.

* Describe the additional safeguards that have been included in this study to protect the rights and welfare of these subjects.

> Our team has extensive training and experience in working with individuals with dementia, and procedures for ensuring supported decision-making and tailoring and pacing of study activities. Throughout the study process, we will assess legal capacity to consent and capacity to share care experiences, ability to answer study questions comfortably, involve activated LARs and engage established protocols to ascertain and confirm assent in situations where the individual with ADRD lacks the legal capacity to consent.
>
> We will ensure study materials and activities can be accessed by individuals with varying abilities. We will do this by building rapport with the participant prior to the interview, giving the participant the option to conduct the interview in a familiar place, providing cues to skip questions, giving ample time to respond, restructuring interview questions to be familiar and comfortable to the participant, and offering to stop the interview if the participant appears to be fatigued or distressed.

View: SF: nPBA: Recruitment Methods

Recruitment Methods

1. Recruitment Plan

This description should address what methods will be used, when and how often they will be used, and how many times potential subjects will be contacted.

* Describe the recruitment plan for this study.

Recruitment Mechanism: Emergency Department
Emergency Department Research Coordinator (EDRC) Program staff will monitor medical records to determine presence of potentially eligible patients in the ED who have a diagnosis of ADRD. EDRC staff will engage the clinical team (ED nurse) to complete initial screener questions to determine if the patient is appropriate to approach to ascertain interest. Screener questions will confirm a) appropriateness to approach based on patient stability/safety, b) patient capacity to communicate and answer questions, and c) legal decision-making capacity/presence of an activated LAR.

After identification of potentially eligible participants, EDRC staff will approach the patient and/or their activated LAR as well as any caregivers present (who may or may not be the patient's activated LAR but are otherwise involved in their care) to determine their interest in learning about the study.

EDRC staff will ask the potential participant(s) if the study team can visit them in the ED (or hospital if admitted) or call them at their preferred phone number. If the potential participant(s) authorizes an ED/hospital visit or a phone call, EDRC staff will call the study team to securely relay contact and contextual information. The study team will store contact information in a secure Department of Medicine server folder. If the potential participant(s) prefers, they can contact the study team themselves.

The study team will further assess the potential participants' interest in the study and eligibility, and determine the participant with dementia's capacity to consent and to participate in a brief interview. The study team will proceed to obtaining informed consent and/or assent dependent upon the individual with dementia's legal decisional capacity—using procedures outlined in Informed Consent: General and Informed Consent: Impaired Consent. Upon obtaining informed consent and/or assent, interviews will either take place a) in the ED/hospital, or b) be scheduled for a future date and/or a means for follow-up contact will be collected for the interview to be scheduled at a future time.

The study team may contact caregivers and activated LARs if the person with dementia grants permission for the study team to contact them over the phone.

If the patient, caregiver, and/or activated LAR are willing to discuss the study with a research staff member but are busy with a member of the clinical team, or are busy with another matter and cannot discuss the study at length at that time, a recruitment brochure will be offered and distributed. The brochure contains a brief description of the study and instructions that the patient, caregiver, and/or activated LAR can follow to contact the lead researcher if they are interested in the study.

Recruitment Mechanism: IRB-Approved Registry
The use of one IRB-approved registry will occur for recruitment of people living with dementia and caregivers. Dr. Gilmore-Bykovskyi has an IRB-approved registry (2019-1148) of older adults with and without changes in memory and caregivers who are interested in brain health related research.

Recruitment Mechanism: Community-Based Organizations
We will conduct recruitment in partnership with community-based organizations, by collaborating with each organization to distribute information on the study and how to contact the study team if interest through the community organizations' regularly scheduled newsletters (online or print) and/or posted flyers. Organizations include:
•Madison Senior Center
•Madison School and Community Recreation – East
•Madison Public Library- Central Library
•New Bridge

Newspaper, radio and social media advertisements will contain Information about the study, eligibility for details on how interested participants can contact the study team members. Outlets are listed below:

•Madison 365
•La Comunidad
•WIBA-FM 101.5
•WORT 89.9
•WZEE 101.4
•Facebook
•Twitter
•Gilmore-Bykovskyi Lab Website: https://gilmorebykovskyilab.org/

2. Recruitment Material Upload

Upload recruitment materials such as recruitment emails, letters, phone scripts, brochures, or advertisements.

Brochure ARCOM_03.02.2023.tif

3. Approved Recruitment Database Usage

* Are you using an IRB approved recruitment database to disseminate recruitment materials or to contact subjects?

(●) **Yes** ( ) No

3.1. Recruitment Database Details

Provide the IRB protocol number of the recruitment database.

2019-1148

3.2. Database Usage Approval Documentation

If the recruitment database is not the investigator's own, upload a letter of support for the use of the database.

There are no items to display

View: SF: nPBA: Subject Screening

Subject Screening

1. Preliminary Eligibility Screen

* Will subjects undergo a preliminary screen to determine basic eligibility?

(•) **Yes** ( ) No

1.1. Screening Materials

* Upload a copy of the screening questionnaire.

↔ ARCOM Screener Questions_05.04.docx

1.2. Data Retention

If you are retaining screen data, the previously uploaded questionnaire/script should address this and include authorization language for maintaining PHI if HIPAA applies.

* Will you be retaining screen data from subjects who do not enroll in the study?

( ) Yes (•) **No**

2. Planned Study Procedures Before Obtaining Consent

Examples include fasting, discontinuing medications, etc.

* Will there be any procedures performed before informed consent is obtained from subjects (apart from screening)?

( ) Yes (•) **No**

View: SF: nPBA: Remuneration and Costs

Remuneration and Costs

1. Payment

* Will subjects be compensated to participate in the study?
(●) **Yes** ( ) No

1.1. Travel and Other Expenses

* Is payment limited to covering travel expenses and other costs incurred by subjects as a result of study participation?
( ) Yes (●) **No**

1.2. Payment Plan

Include the amount of payment(s), proration, multiple payment schedules, etc.

* Describe the payment plan.

> $30 if an individual starts the interview; whether or not the interview is fully completed

1.3. Child/Parent Payment

* Are any payments being offered to child subjects?
( ) Yes (●) **No**

1.4. Nonmonetary Compensation

* Will nonmonetary compensation be offered?
( ) Yes (●) **No**

2. Costs

* Will subjects incur any costs as a result of study participation (pharmacy preparation fees, payment for a device, billing of study procedures to subjects insurance)?
( ) Yes (●) **No**

View: SF: nPBA: Privacy and Confidentiality

Privacy and Confidentiality

1. Privacy Plan

Privacy is defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. In the context of research, this primarily pertains to methods used to obtain information about subjects or the setting in which research takes place.

* Explain how the subjects' privacy will be protected. (e.g., research intervention is conducted in a private room).

> Interviews will take place by phone, UW-Madison Zoom, Cisco Webex web conferencing or in a private room in the ED, hospital, or their home, a private room in the Department of Emergency Medicine Offices, or a private room in a public library. Interview mode and location will be determined based on participant preference, including ED/hospital, which was successful in a previous study (IRB 2018-0101). Data collection will be limited to the amount necessary to achieve the aims of the research. In the event that unnecessary personal or identifiable information is provided by the participant(s), it will either not be recorded or removed from the research record as soon as possible. Only research staff will have access to individually identifiable private information about human subjects. No direct participant identifiers will be used to label interview data files, de-identified transcripts, or stored questionnaire data. All data will be labeled by assigned study ID numbers. No identifiable data will be kept from those subjects who were ineligible for the study or chose not to enroll. Data will be reported as group data, or deidentified participant quotes, so that no individual could be identified. All members of the research team and study staff will complete HIPAA and research ethics training and have certification thereof. Any member of the research team who knows or has a personal relationship with any participants will recuse himself or herself from further study activity with the identified participants, and will not have access to those participants' data. Contact information from participants will be stored to facilitate conduct of the study (e.g. scheduling) and separately from data. It will be deleted after sharing of the study findings, unless the participant(s) indicates preference for it to be deleted immediately after participation. Fully de-identified interview data will be kept indefinitely.

2. Level of Identifiability

* Select how subjects are identified in the data. Check all that apply.

No Identifiers (De-identified, Anonymous, or Anonymized): stored data is stripped of all identifiers

3. Data Protection Plan

Records and data include informed consent documents, case report forms or study flow sheets, survey instruments, database or spreadsheet, screening logs or telephone eligibility sheets, web based information gathering tool, audio/video/photo recordings of subjects, labeled specimens, data about subjects, subject identifiers, etc.

The study team should describe how data confidentiality will be protected. Some measures that are often used and acceptable to the IRB are: using codes so that no direct subject identifiers are recorded on data collection sheets; creating codes for data that are not based on subject identifiers (i.e., avoiding codes that include subject initials or are based on birth dates); and destroying the link to the code as soon as possible.

* How will the study team protect research records, data, and/or specimens against inappropriate use or disclosure, or malicious or accidental loss, or destruction? Include how and where the data and/or

specimens will be stored.

Data collected from this study will come from participant interviews and sociodemographic questionnaires.

All electronic records and data related to the study protocol will be kept on password-secure Department of Medicine (DOM) servers with limited access to Study Team members.

Contact information necessary for recruitment and scheduling of interviews will be stored in a folder on the DOM server separate from the parent study folder. This contact information will not be linked to the participant's study data whatsoever and will be destroyed immediately after all necessary contact with the individual has ceased (e.g. scheduling, sharing of study findings) or at the end of the study.

Original recordings will be rapidly transferred to the DOM server and destroyed from their original platform after completion of the interview. Original recordings stored on the UW-Madison Zoom or Cisco Webex secure platform if interviews are completed remotely or temporarily on an encrypted audio recording device in a locked cabinet in the PI's locked office located at 800 University Bay Dr. if performed in person. Only the PI and study team members will have access to this locked drawer. Recordings on Zoom or Cisco Webex will be destroyed immediately after secure transfer to the DOM server, and likewise recordings on the audio recording device will be destroyed immediately after secure transfer to the DOM server. Audio recordings on the DOM server will be destroyed promptly after successful transcription and de-identification.

Questionnaire data (e.g. demographic questionnaires) will be provided directly to study team members conducting interviews and stored on the password-secure DOM servers.

De-identified transcripts will be stored electronically on the password-secure DOM servers. Hard copies of de-identified transcripts will be used in team meetings for data analysis and will be stored in a locked cabinet in the PI's locked office. Only the PI and study team members will have access to this locked drawer. When these transcripts are used for analysis, it will take place in a private room at 800 University Bay Dr. and then returned to the locked drawer.

No identifiable data will be kept from those subjects who were ineligible for the study or chose not to enroll. In coordination with EDRC staff, we will be maintaining a general tabulation of how many patients were approached, but screened ineligible or chose not to enroll in the study. This tabulation will include reason for ineligibility/non enrollment. This general tabulation will not be linked in any way to the individuals approached for the study.

At no point in study procedures will participants be identified by name or other identifiable information. All participants will be identified via a study ID number that will be associated with their transcripts.

Depending on the nature of the event, the study team will report events such as noncompliance, new information, and potential unanticipated problems in accordance with the IRB's posted guidance.

4. Certificate of Confidentiality

If NIH, CDC, FDA, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award, answer "Yes".

* Is there a Certificate of Confidentiality (CoC), or will one be obtained, for this research?

○ Yes ◉ **No**

View: SF: nPBA: Retention of Data and/or Specimens

Retention of Data and or Specimens

1. Future Research Plans

* Will data and/or specimens collected for this study be banked for future research outside the scope of the current project?

Yes **No**

View: SF: nPBA: Exemption Consent

Exemption Consent

1. Upload Exemption Consent

- The exemption consent template is available here.
- For educational and social-behavioral studies, you can use the Consent Form Wizard. The Wizard does not include HIPAA authorization language.

Upload all consent materials (scripts, information sheet, etc.).

Information Sheet_Exempt_04.12.2023.docx

2. Exemption Consent Process

* Please describe the consent process.

> Information sheet will be provided to subjects and, if applicable, their activated LAR prior to starting in-person interviews/focus groups.

View: SF: nPBA: Impaired Decision-Making Capacity

Impaired Consent

1. Capacity Assessment Method

* Describe how capacity to consent will be assessed.

> Formal capacity assessment will follow the Evaluation to Consent measure – a widely used reliable/valid procedure. The study team member will clearly explain the study and will use the teach-back method to confirm understanding of the study purpose and interview procedures.
>
> This method utilizes a series of open-ended questions throughout the process to confirm that the participant understands the study and their involvement. These questions include: 1. What is the potential risk of your participation? 2. What will happen in this study? 3. What if you don't want to continue the interview? 4. What if you experience discomfort during the interview?

2. Schedule for Capacity Assessment

* Describe when capacity to consent will be assessed, noting specifically if there is a need to reassess consent capacity during the course of the study.

> Capacity to consent will be performed as a part of the Informed Consent process, prior to commencing study procedures.
>
> We will engage robust procedures to obtain informed consent and assent, and continually re-evaluate capacity to consent as well as assent across study procedures.
>
> Re-assessment of capacity and/or assessment will be triggered by statements from participants indicating they are confused or do not understand study procedures, and /or responses that indicate they do not understand the study procedures or questions or may not want to participate.

3. Who Assesses Capacity

* Describe who will assess consent capacity.

> Study team members will complete the formal Evaluation to Consent measure. These individuals are trained in dementia assessment, teach-back method, and interviewing techniques.
>
> EDRC staff will only preliminarily assess consent capacity through chart review and confirmation with clinical staff on the patient’s ability to answer questions about their care.

4. Subject Involvement in Consent

If you plan to enroll only those subjects who are able to provide informed consent (for example, early-stage Alzheimer's Disease subjects), state this here.

* Describe the extent to which (if any) the subject will be included in the consent process.

> Individuals who do not have an activated LAR, who can answer questions about their care, and who can complete the Evaluation to Consent measure will complete informed consent on their own behalf, as will caregiver participants.
>
> Individuals who have an activated LAR will be assented in an ongoing manner; this participant's activated LAR will complete consent on behalf of the participant.
>
> A participant's preference not to participate in the study will operate as a veto to their participation, even if their representative consents to the research.

5. Surrogate Consent Necessary

* Will there be a need for surrogate consent?

(●) **Yes** ( ) No

5.1. Who Provides Surrogate Consent

* From whom will surrogate consent be obtained?

> Activated legally authorized representatives that may provide informed consent on behalf of participants with dementia in this study will follow established priorities for surrogate decision-making according to the following priority list, in accordance with institutional policy and state law:
>
> 1) A research power of attorney may consent to a potential participant's participation in research, if the agent's decision is not inconsistent with the wishes and preferences of the potential participant expressed in the power of attorney instrument.
> 2) A court-appointed guardian of the person may consent to a ward's participation in research if the court order includes the power to consent to research. NOTE: A guardian of the estate or guardian ad litem cannot provide surrogate consent.
> 3) A power of attorney for healthcare may consent to a potential participant's participation in research, if the agent's decision is not inconsistent with the wishes and preferences of the potential participant expressed in the power of attorney for health care instrument.
> 4) If the potential participant has no research power of attorney, guardian, or healthcare power of attorney, then the potential participant's "next of kin" may consent on behalf of the potential participant.
> 5) "Next of kin" can provide surrogate consent in the following order: the spouse or registered domestic partner, adult child, parent, adult sibling, grandparent, adult grandchild, or a close friend of the potential participant.
>
> If the individual is interested in participating and can answer questions about their care, but has presence of an activated LAR and the activated LAR cannot be identified, the study team will thank them for their time and interest, end the recruitment process, and destroy any identifiable information about the person.

6. Consent Plan for Reassessing Capacity

* Is there a plan for obtaining consent if a subject regains capacity?

(●) **Yes** ( ) No

6.1. Reassessing Capacity

* Describe the plan to obtain consent from the subject should they regain the ability to provide informed consent on their own

behalf.

> While this is a single interview study and reassessment is unlikely to be formally needed, we recognize consent assessment as an ongoing process and interviewers will be mindful of communication or changes that indicate the need to reassess capacity.
> Formal capacity re-assessment will be triggered by disclosed concerns about memory or cognition, observed challenges following the consent process, and/or demonstrated lack of recollection or comprehension of key study details.
> Ongoing assessment of assent will also be performed. The research team will closely monitor the patient throughout all study procedures to ensure they are not uncomfortable or indicating dissent related to study procedures. If the patient indicates they dissent from participating in the study procedures, study activities will cease immediately.
> In addition to verbal assent, research staff will look for non-verbal cues indicating assent and dissent:
> Assent: Nodding head, smiling, engaging in conversation
> Dissent: Fidgeting, frowning, crossing arms, withdrawing or turning away in space

View: SF: nPBA: HIPAA General

HIPAA

1. Identifiable Information

* Will the research involve identifiable health information for any reason?

(●) **Yes** ( ) No

1.1. UW Madison Health Care Component or Madison VA

The HCC of the UW-Madison currently includes SMPH clinical departments; School of Pharmacy (clinical units only); School of Nursing; University Health Services (non-student records only); State Laboratory of Hygiene; and Waisman Center (clinical units only). Ensure the PI or any study team members are covered under HIPAA Privacy Rule regulations as part of their appointment.

* Are you or any member of the study team conducting the study under an appointment that is within the UW-Madison Health Care Component (HCC) and/or Affiliated Covered Entity (ACE) or the Madison VA?

(●) **Yes** ( ) No

1.2. HIPAA Authorization

* Will HIPAA authorization for access to the PHI be obtained for all or some subjects, or for only some uses?

( ) Yes, always: HIPAA authorization will be obtained from all subjects with signed documentation.

(●) **Yes, sometimes or without signed documentation: HIPAA authorization will not be obtained from some subjects/uses or may be obtained without a signature.**

( ) No: HIPAA authorization will not be obtained from any subjects.

1.3. External PHI Access

* Will you access or obtain fully identifiable health information from a health care provider that is not UW or UW Health, such as Meriter or ACHC, without first obtaining patient permission or authorization?

( ) Yes (●) **No**

View: SF: nPBA: HIPAA Waivers Sometimes

Authorization and Waivers

When sharing fully identifiable health information outside of UW or UW Health or obtaining it from a covered entity that is not UW or UW Health (e.g. bringing PHI from Meriter to a UW workstation to contact for phone screening or to recruit), you may need a partial waiver of authorization and accounting for disclosures may be required. Please consult with the **HIPAA Privacy Officer** and consult the Accounting for Disclosures Guidance found **here**.

1. HIPAA Requirement Fulfillment

* Please select which option(s) will be applied to fulfill HIPAA requirements.

Request Partial Waiver or Altered Authorization

2. Applicable HIPAA Identifiers

Select which of following identifiers will be associated with the health information you propose to collect for study purposes. Check all that apply to your study. If none of these identifiers will be collected for you study, select 'None of the Above'.

None of the Above

View: SF: nPBA: HIPAA Waivers/Authorization Request

Request for Authorization/Waivers

When sharing fully identifiable health information outside of UW or UW Health or obtaining it from a covered entity that is not UW or UW Health (e.g. bringing PHI from Meriter to a UW workstation to contact for phone screening or to recruit), you may need a partial waiver of authorization and accounting for disclosures may be required. Please consult with the **HIPAA Privacy Officer** and consult the Accounting for Disclosures Guidance found **here**.

1. Altered Authorization

HIPAA authorization for research must be project-specific. Standard clinical consent and authorization does not cover research use. If you will not obtain authorization in writing or seek to significantly modify the standard HIPAA authorization language, an altered authorization is necessary.

* Are you requesting an altered authorization?

(●) **Yes** ( ) No

1.1. Waiver Details

HIPAA authorization for research must be project-specific. Standard clinical consent and authorization does not cover research use. If you will not obtain authorization in writing or seek to significantly modify the standard HIPAA authorization language, a waiver of altered authorization is necessary.

Please describe how authorization will be altered.

> As the health information collected only includes diagnostic information regarding dementia status to screen for eligibility which will not be linked to any identifiable data within the study and will only be reported in the aggregate, we request verbal HIPAA authorization only.

2. Partial Waiver of Authorization

If you will not obtain authorization from any subjects, a full waiver is required.

* Are you requesting a partial waiver of authorization?

( ) Yes (●) **No**

3. Type of Records

* Identify the PHI to be used. Select all that apply.

Hospital/doctor records, including test results and dental records

4. Confirm Policy for Sharing PHI Externally

For help, see https://compliance.wisc.edu/hipaa/coordinators/

If you disclose PHI outside the HIPAA covered entity under which you are conducting the study, confirm you will contact the UW Madison HIPAA Privacy Officer or the Madison VA Privacy Officer.

(●) **Yes** ( ) No

5. PHI Protection Plan

* Describe your plan to protect PHI form unauthorized use or disclosure.

> Health information collected only includes diagnostic information regarding dementia status to screen for eligibility. This information will be stored in a secure Department of Medicine server folder, and will not be linked to any identifiable data and will only be reported in the aggregate. Only approved personnel will have access to study data.

6. PHI Destruction Plan

* Describe your plan for destroying identifiers at the earliest possible opportunity.

> No identifiers will be collected in association with PHI. Contact information will be destroyed after all necessary contact with participants is completed.

7. Waiver/Alteration Justification

* Explain why the study cannot practicably be conducted without the waiver of authorization or altered authorization.

> We are not obtaining signed consent given the minimum risk nature of the study and in the interest of limiting the number of study documents with the participant's name. Participation in the interview indicates consent and authorization. HIPAA language will be included in the information sheet.

8. Limitations Confirmation

* Federal law prohibits the re-use or disclosure of PHI in connection with this research to any person or entity other than those authorized to receive it, except: (1) as required by law; (2) for authorized oversight of the research; or (3) in connection with other research for which the HIPAA Privacy Rule permits the PHI to be used or disclosed. Do you agree to abide by these limitations in order to obtain a waiver of authorization?

(●) **Yes** ( ) No

View: SF: nPBA: Recordings and Photographs

Audio/Video Recordings and Photographs

1. Recordings Collected

* Select which of the following will be collected for this study. Check all that apply.

- [x] **Audio recordings**
- [ ] Video recordings
- [ ] Photographs

2. Identifiable Recordings

E.g., full face photo/video, audio recording of first and last name, or other individually identifiable information.

* Will the subject be identifiable in the audio/video recording or photograph?

○ Yes ◉ **No**

3. Retain Recordings

* Will the audio/video recordings or photographs be retained beyond the conclusion of this study?

○ Yes ◉ **No**

4. External Transcription

* Will anyone outside the study team transcribe audio recordings?

◉ **Yes** ○ No

4.1. Transcriber Details

* Indicate who will perform the transcription.

> Recordings include health information covered by HIPAA, transcription will be done by a professional transcription service covered by a BAA with the UW.

View: SF: nPBA: Interviews, Focus Groups, Surveys, Questionnaires

Interviews, Focus Groups, Surveys, Questionnaires

1. Tool Details

* Describe the interview tools, questionnaires, or surveys that will be used. Click the add button to provide information about each tool to be used.

View

Tool Description	Person with Dementia Demographic Questionnaire
Tool Standardized	No
File name	Demographic Questionnaire_PLWD_02.03.2023.docx
Tool Manner	Telephone In-person Internet
Tool Manner Other	In-person at ED, hospital, home, private room in public library or Department of Emergency Medicine, or other private location preferred by participation. Phone or Internet over Zoom or WebEx
Date Modified	3/29/2023

View

Tool Description	Interview Guide - Abbreviated Version for ED/Hospital Use
Tool Standardized	No
File name	Interview Questions Short Version_02.03.2023.docx
Tool Manner	In-person
Tool Manner Other	In-person at ED or hospital.
Date Modified	3/6/2023

View

Tool Description	Interview Guide - Full Version
Tool Standardized	No
File name	Interview Question Domains_02.03.2023.docx
Tool Manner	Telephone In-person Internet
Tool Manner Other	In-person at home, private room in public library or Department of Emergency Medicine, or other private location preferred by participation. Phone or Internet over Zoom or WebEx
Date Modified	3/6/2023

View

Tool Description	Caregiver Demographic Questionnaire

Tool Standardized	No
File name	Demographic Questionnaire_Caregiver_02.03.2023.docx
Tool Manner	Telephone In-person Internet
Tool Manner Other	In-person at ED, hospital, home, private room in public library or Department of Emergency Medicine, or other private location preferred by participation. Phone or Internet over Zoom or WebEx
Date Modified	3/6/2023

2. Cognitive or Psychological Assessment

* Are any of the uploaded instruments used to assess cognitive or psychological status or function?

○ Yes ◉ **No**

View: SF: nPBA: Supplemental Information

Supplemental Information

1. Additional Documents

Provide any additional relevant documents (e.g., data sharing agreements, letters of support, MOUs, site permission letters), if applicable.

There are no items to display

View: SF: nPBA: Final Page

Final Page

1. Assurance

The information presented in this application is accurate;
If the application is being submitted on behalf of the Principal Investigator (PI) rather than by the PI, the information presented was done so with the PI's agreement; and
The specific aims and description of research (including subject population, subject interventions, collaborators, performance sites, and general scope of work) in this IRB application are consistent with those described in the sources of support listed as providing financial and/or material resources to conduct this study.

* Do you certify the above statements?

(●) **Yes** ( ) No

2. Complete and Submit Application Instructions

To complete and submit this application to the IRB office, please follow the steps below:

1. Select Ready to Submit or Exit on this page to be directed to the application workspace.
2. In the application workspace, click the Submit activity to send the application to the IRB office. NOTE: The Submit activity is only available to certain study team members.