

AWARD NUMBER: W81XWH-21-1-0009

TITLE: Using Machine Learning to Identify, Risk Stratify, and Guide Personalized Treatment of COVID-19 Patients

PRINCIPAL INVESTIGATOR: Matthew M. Churpek, MD, MPH, PhD

CONTRACTING ORGANIZATION: The Board of Regents of the University of Wisconsin System

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14. ABSTRACT

Coronavirus disease 2019 (COVID-19) has spread rapidly in countries around the world, including the United States, where over 2 million cases have been reported to date. COVID-19 is highly contagious and deadly, with up to 11% of patients requiring intensive care unit (ICU) admission and a case-fatality rate between 1% and 3% according to a recent report by the Centers for Disease Control and Prevention. The rapid spread, high severity, limited testing availability, ICU resource limitations, and lack of evidence regarding how to best treat hospitalized patients has hampered progress on limiting the morbidity and mortality from this pandemic. The objective of this proposal is to develop a novel clinical decision support (CDS) tool to detect, risk stratify, and recommend personalized treatments of COVID-19 patients using machine learning and electronic health record (EHR) integrated clinical workflows. We will combine granular multicenter data with artificial intelligence methods and human factors approaches to address several important challenges. The first challenge is that the early identification of COVID-19 relies on clinician intuition, screening guidelines that vary across sites, and testing that can be delayed or falsely negative. This results in missed diagnoses and unnecessary resource use in COVID-19 negative cases. This is especially important considering that the pandemic will likely span many months before a vaccine becomes available, thereby making continual resource-intensive manual screening impractical. A second challenge is the lack of accurate bedside tools to risk-stratify patients with COVID-19. Earlier identification and treatment of high-risk patients, such as patients with sepsis and respiratory failure, is known to improve patient outcomes, and risk stratification tools may better allocate ICU resource needs. Therefore, a major goal of this work is to improve both the early identification and risk stratification of patients with COVID-19 to provide life-saving interventions. A third challenge is the lack of data on providing personalized treatment recommendations for patients with COVID-19. Variability in the host response to infection leads to wide variations in clinical presentations and outcomes.

15. SUBJECT TERMS

NONE LISTED

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1. INTRODUCTION: *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

The objective of this project is to develop a novel clinical decision support tool to detect, risk stratify, and recommend personalized treatments of COVID-19 patients using machine learning and electronic health record (EHR) integrated clinical workflows.

2. KEYWORDS: *Provide a brief list of keywords (limit to 20 words).*

COVID-19; machine learning; clinical decision support; Veterans Affairs; hospital admissions; multicenter; personalized treatment; risk stratification; diagnosis; deep learning

3. ACCOMPLISHMENTS: *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Major Task 1: Research Set Up

- Subtask 1. Local and Human Research Protection Office (HRPO) institutional review board (IRB) review and approval
 - Subtask 1a: Human Research Protection Office (HRPO) institutional review board (IRB) review and approval for Aim 1.
 - Subtask 1b: Local and Human Research Protection Office (HRPO) institutional review board (IRB) review and approval for Aim 2.

Major Task 2: Aim 1: Develop novel machine learning models to identify, risk stratify, and provide personalized treatment recommendations for patients with COVID-19. We will utilize a multicenter dataset of hospitalized adult patients from the national Veterans Affairs (VA) health system and nine non-VA health systems (approximately 10,000 COVID-19 admissions). Machine learning algorithms, such as gradient boosted machines and deep learning, will be used to develop models to predict which patients will test positive and which patients will develop critical illness. Causal forests, which provide patient-specific treatment effect estimates based on their characteristics, will be used to make treatment recommendations.

- Subtask 1: Data cleaning and formatting for analysis
- Subtask 2: Aim 1a: Derive and validate diagnostic models
- Subtask 3: Aim 1b: Derive and validate risk stratification model
- Subtask 4: Aim 1c: Derive and validate treatment recommendation models
- Subtask 5: Disseminate research findings

Major Task 3: Aim 2: Develop a clinical decision support (CDS) tool graphical user interface (GUI) and test it in a simulation study. We will develop a CDS GUI incorporating the models from Aim 1 through stakeholder engagement, user-centered design principles, and human factors methods. We will then compare the developed CDS tool to the native EHR environment for the identification, risk stratification, and treatment of patients with COVID-19 in a case scenario-based simulation study to test effectiveness, efficiency, and user satisfaction.

- Subtask 1: Develop graphical user interface (GUI) with Small virtual interviews
- Subtask 2: Pilot testing of final CDS tool and case scenarios
- Subtask 3: Simulation study evaluating the clinical decision support tool
- Subtask 4: Disseminate research findings

Major Task 4: Research Close Out

Subtask 1. Local and Human Research Protection Office (HRPO) institutional review board (IRB) closure report submission

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Major Task 1: Research Set Up

- Subtask 1. Local and Human Research Protection Office (HRPO) institutional review board (IRB) review and approval
 - Subtask 1a: Human Research Protection Office (HRPO) institutional review board (IRB) review and approval for Aim 1

We completed HRPO institutional review board review and approval for Aim 1.

Major Task 2: Aim 1: Develop novel machine learning models to identify, risk stratify, and provide personalized treatment recommendations for patients with COVID-19.

- Subtask 1: Data cleaning and formatting for analysis

To date, the cleaning and formatting of electronic health record (EHR) datasets for all adult patients hospitalized in 8 non-VA health systems (University of Wisconsin-Madison (UW), Washington University-St. Louis, Cleveland Clinic, NorthShore University HealthSystem, Loyola University Medical Center, Northwestern University, Medical College of Wisconsin, and the University of Chicago Medicine (UCM)) is 90% complete. Data from a ninth health system (Rush University) has been delayed, so it will not be used for the initial phases of this project until it is received. We are still working to clean and format the EHR data for all adult patients hospitalized in the national VA

health system (75% complete). Thus, the cleaning and formatting will be delayed one quarter longer than anticipated due to challenges outlined in #5 below.

These highly granular datasets include: Laboratory Values, Vital Signs, Ventilator/O2 Device, Medications, Orders, Admission-discharge-transfer (ADT) system data, Patient Demographics, Nursing Assessments, Cultures, and Diagnosis Codes. Our cleaning pipelines have harmonized these variables across sites such that they are comparable at all hospitals. This required an enormous amount of effort to align tens of thousands of fields at each site, including the fact that the same variable may have different names at different sites. These final datasets will be formatted such that they can be used for all models in Aim 1 seamlessly.

- Subtask 2: Aim 1a: Derive diagnostic models

We have also created modeling pipelines for diagnostic, prognostic, and causal machine learning models. For example, we have completed an automated pipeline that can optimize, fit, and then compare several state-of-the-art deep learning models to each other, which can be used for the models in Aim 1. Furthermore, we have developed a pipeline to automatically tune and validate the causal forest algorithm for Aim 1. These accomplishments will allow us to rapidly complete all models for Aim 1 once data cleaning is completed in Quarter 1 of Year 2. Therefore, because of this pipeline development we will be able to complete two of the three models in Year 2 as originally planned.

What opportunities for training and professional development has the project provided?

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. “Training” activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. “Professional development” activities result in increased knowledge or skill in one’s area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

This DOD award has provided protected time so that I can focus on research efforts, which also allows for opportunities to mentor staff and trainees in research methods and advanced machine learning techniques. My DOD, other awards, and departmental support allow over 80% of my effort to be directed towards research activities.

I am training and professionally developing my Postdoctoral Research Associate mentee, Fereshteh Bashiri, PhD, who is a computer scientist. Together, she and I had created an Individual Development Plan (IDP) to assess her current skills, interests, and strengths; maintain a plan for developing her skills to meet academic and professional goals; and communicate with me about evolving goals and related skills. The IDP was revisited periodically to update and refine as goals change or come into focus and to record progress and accomplishments. For this project, Fereshteh

has been working on comparing different types of machine learning algorithms for our project, and she has built a deep learning pipeline that allows for the rapid optimization and comparison of different models. I am also training Alex Spicer, MS, a staff data scientist in our lab. We created a similar IDP, with a focus on data cleaning as well as developing models for individual treatment effects prediction using causal forests. For this project, she has been cleaning the national VA data and completed a pipeline for causal forests that will allow for the rapid completion of Aim 1c.

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

If this is the final report, state “Nothing to Report.”

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

During Year 2, we will complete the data cleaning and formatting for analysis in Quarter 1. Next, we will complete the work on the derivation and validation of our Aim 1 Diagnostic COVID-19 models. We will then work to derive and validate our Risk Stratification model, and we will derive our Treatment Recommendation model (Aims 1b and 1c). Throughout the year we will work to disseminate research findings from these models. As noted above, we have already developed the pipelines for these models, which will be applied to the datasets once cleaning is complete. Therefore, we will be able to complete all the originally proposed Year 2 activities on time.

4. **IMPACT:** *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report

- 5. CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:*

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

The data cleaning and formatting has taken longer than expected for several reasons. First, the national VA data encompasses more than 2.7 million acute hospital admissions, with over 560 million rows of vital signs alone. The enormous size of this dataset caused significant issues with memory and space related to opening and cleaning the EHR datasets in the VA VINCI environment, which caused significant delays. To address this, we have partnered with the VA ARCHES Enterprise Cloud computing environment, which will allow us to finish cleaning and formatting the VA data much more efficiently and effectively. Second, vital signs in the ICU in the VA system are mostly stored in PDF files, while mental status and ventilator use are documented in free text. Therefore, the time and complexity of extraction was increased. We are finalizing the development of a novel REST API interface extracting PDF files containing the relevant discrete data and pipelines extracting, standardizing, and storing these data. Third, we were unable to rely on standard terminologies, such as LOINC for laboratory values, because manual review discovered significant errors in these mappings, including in the VA national dataset. Therefore, we have had to manually review and map laboratory values at each site, which significantly increased the time required to complete data cleaning (e.g., there are >90,000 unique lab names in the national VA system alone, and there are different variable names for the same concept in the VA vs. non-VA systems). We have completed this manual review and are in the process of coding all these mappings to the final variables (e.g., there are hundreds of possible fields for hemoglobin, only some of which are the specific hemoglobin concept for the models (e.g., hemoglobin vs. hemoglobin A1C vs. Hemoglobin F, etc.)). Finally, some of the health systems had delays in transferring data due to staffing shortages related to the COVID-19 pandemic.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. **PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”*

- **Publications, conference papers, and presentations**

Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume; year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to Report

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change”.

Example:

Name:

Mary Smith

Project Role:

Graduate Student

Researcher Identifier (e.g. ORCID ID): 1234567

Nearest person month worked: 5

Contribution to Project:

Ms. Smith has performed work in the area of combined error-control and constrained coding.

Funding Support:

The Ford Foundation (Complete only if the funding support is provided from other than this award.)

Name:	Matthew M. Churpek MD, MPH, PhD
Project Role:	PI
Researcher Identifier (e.g. ORCID ID):	eRA Commons MCHURPEK
Nearest person month worked:	4
Contribution to Project:	Dr. Churpek oversaw all aspects of the proposed research grant, including overseeing electronic data collection and transfers, directing data cleaning and analysis, implementing the research plan, and supervising staff. He also led scientific discussions about study design and methodology with CO-Is.
Funding Support:	N/A

Name:	Mark W. Craven, PhD
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	eRA Commons MARKWCRAVEN
Nearest person month worked:	1
Contribution to Project:	Dr. Craven contributed to scientific discussions about methodology for explaining and understanding models and their predictions (i.e., explainable artificial intelligence).
Funding Support:	N/A

Name:	Madeline Oguss, MS
Project Role:	Project Manager
Researcher Identifier (e.g. ORCID ID):	eRA Commons MKOGUSS
Nearest person month worked:	2

Contribution to Project:	Ms. Oguss led study protocol administration, HRPO IRB and Data Use Agreement approvals, data analyst (Xu) recruitment and hiring, budget and subaward administration, coordination of meetings, communication, and research activities across sites.
Funding Support:	N/A

Name:	Alex Spicer MS
Project Role:	Data Analyst
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	10
Contribution to Project:	Ms. Spicer compiled and cleaned data from the National VA dataset for use in model building. Developing pipelines for effectively optimizing causal forest models for Aim 1c.
Funding Support:	N/A

Name:	John Caskey PhD
Project Role:	Data Analyst
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1
Contribution to Project:	Dr. Caskey coordinated data transfers and computing technical support, including downloading of packages and troubleshooting technical difficulties. He also helped develop deep learning pipelines for model development.
Funding Support:	N/A

Name:	Clark Xu BS
Project Role:	Data Analyst
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Mr. Xu compiled and cleaned data (Non-VA) from all participating sites for use in model building.

Funding Support:	N/A
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Name:	Fereshteh Sadat Bashiri, PhD
Project Role:	Post Doctoral Research Associate/ Data Scientist
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	3
Contribution to Project:	Dr. Bashiri developed pipelines for deep learning model building, including optimizing and comparing different algorithms.
Funding Support:	N/A

Name:	Dana Edelson, MD, MS
Project Role:	Co-Investigator, Site PI
Researcher Identifier (e.g. ORCID ID):	eRA Commons EDELSON
Nearest person month worked:	2
Contribution to Project:	Dr. Edelson met regularly with the UW-Madison research team to advise on the study design and to lend her expertise in data prediction and modeling. Scientific discussions were about methodology and prioritizing models for greatest impact. She also oversaw all data sharing and transmission between the two institutions.
Funding Support:	N/A

Name:	Mary Akel, MPH
Project Role:	Project Manager
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1
Contribution to Project:	Ms. Akel worked to ensure approval of regulatory protocols and data sharing documentation for this project through the University of Chicago Biological Sciences Division Institutional Review Board (IRB16-0608). We also executed a subcontract for this award with UW-Madison.

Funding Support:	N/A
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Name:	Sushant Govidian, MD
Project Role:	Co-Investigator, Site PI
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	3
Contribution to Project:	Dr. Govidian has been responsible for oversight of all processes at the Kansas City VA Site, including ensuring completion of all needed regulatory and IRB documents. He provided clinical expertise related to caring for critically ill patients at the VA, as well as consultation and collaboration with VA “eHRM,” academic and industry partners. Finally, he contributed to scientific discussions about methodology and prioritizing models for greatest impact.
Funding Support:	Salary support from the Kansas City VA Medical Center: Dr. Govidian has protected time for this research, and other related projects due to his appointment as the Kansas City VA Associate Chief of Staff Quality.

Name:	R. Spencer Schaefer, PharmD
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	As CO-I and analyst, Dr. Schaefer worked and advocated to help create and expand our VA analytic infrastructure and pipelines for clinical decision support tools, and pull + troubleshoot extraction of sources of VA data and software for our research. This includes but is not limited to collaborations with Office of Enterprise Integration (OEI), VA Arches, VINCI and other industry and academic consultants to develop a novel NLP extraction standardization and storage Common Operating Platform (COP). In addition, he participated as a subject matter expert on the joint

	DOD and VA “eHRM” Clinical Deterioration and Sepsis workgroups to provide expertise for analysis of methodologies. Additionally, he compiled and assisted with cleaning VA data for use in model building for this study. Finally, he contributed to scientific discussions about methodology and prioritizing models for greatest impact.
Funding Support:	Salary support from the from the Kansas City VA Medical Center: As Dr. Schaefer’s position as the Chief Health Informatics Officer, his effort related to this project is also supported by the Kansas City VA and the expansion of organizational related initiatives.

Name:	Andrea Uhl
Project Role:	Project Manager
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	5
Contribution to Project:	As the Project Manager for the Kansas City VA Site, Ms. Uhl has been responsible for coordinated project timeline efforts, meetings and information as related to the collaborations and work with our academic and industry partners. I have also tracked, managed and provided information for regulatory, reporting, academic output and administrative requirements as related to the KCVA Site work for this project.
Funding Support:	N/A

Name:	Melanie Wright, PhD
Project Role:	Co-Investigator, Site PI
Researcher Identifier (e.g. ORCID ID):	eRA Commons MELANIE.WRIGHT
Nearest person month worked:	1
Contribution to Project:	Dr. Wright contributed to scientific discussions about methodology and prioritizing models for greatest impact.
Funding Support:	N/A

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Yes, updates in our PCPs are shown in yellow.

PI Dr. Churpek has received two new grants as PI in 2021 (which include his Co-Is Dr. Edelson, Dr. Craven, and eventually Dr. Wright), as shown below and in Other Support documentation included:

- NIH/NHLBI R01-HL157262-01 (Churpek), 08/01/2021 - 07/31/2025, Title: Developing a clinical decision support tool for the identification, diagnosis, and treatment of critical illness in hospitalized patients
- NIH/NIDDK R01-DK126933-01 (Koyner/ Churpek), 08/01/21 - 07/31/26, Title: Using Machine Learning for Early Recognition and Personalized Treatment of Acute Kidney Injury

All three investigators have maintained effort required for this grant, without decreasing more than 25% than the effort originally committed. Dr. Churpek’s effort will remain at 26%/ 3.12 CM from 35%/4.2 CM committed through year 2 to accommodate effort needed on his two new grants.

Co-I Dr. Craven also has active support on three new grants that were awarded in 2021 (UW WARF MSN254443 (A. Gasch), NIH/NIAID UM1AI160050 (D. Jackson), NIH/NHGRI U01HG0120339 (M. Craven), as shown in his Other Support documentation. This does not change his 0.6 CM effort devoted to this project.

CO-I Dr. Edelson has active support on three new grants that were awarded or began in 2021 (NIH-NIGMS R01-GM137083 (Wright), US HHS/ASPR-BARDA 21-00592 (Edelson), NIH SBIR R44-EB030955 (Edelson)), as shown in her Other Support documentation. This does not change her 1.5 CM effort devoted to this project.

CO-I Dr. Wright has a new FDA Contract # 75F40121C00130 that started in 2021. This does not change her 0.6 CM effort devoted to this project.

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or

domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name:

Location of Organization: (if foreign location list country)

Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

The University of Chicago/ The University of Chicago Medicine (UCM)

Location: 5841 S. Maryland, Chicago, IL 60637-1447

- **Collaboration** Scientific discussions about methodology, data contribution

Midwest Veterans' Biomedical Research Foundation/

Kansas City VA Medical Center (KCVAMC)

Location: 4801 E. Linwood Blvd, Kansas City, MO 64128-2295

- **Collaboration** Scientific discussions about methodology, VA infrastructure set up, Data cleaning and formatting for analysis
- **In-kind support** for Dr. Govidian's full salary and part of Dr. Schaefer's salary and VA infrastructure

Idaho State University

Location: 921 S. 8th Ave., Pocatello, ID 83209-8046

- **Collaboration** Scientific discussions about methodology

AgileMD, Inc

Location: 301 Howard St, Suite 950, San Francisco, CA 94105 US

- **Other:** Development of the project's clinical decision support tool's graphical user interface
- **Other:** Coordination of compliance and security certification attestation

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ebrap.org/eBRAP/public/index.htm> for each unique award.*

N/A

QUAD CHARTS: *If applicable, the Quad Chart (available on <https://www.usamraa.army.mil/Pages/Resources.aspx>) should be updated and submitted with attachments.*

Attached

- 9. APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*

N/A

Project Title: Using Machine Learning to Identify, Risk Stratify, and Guide Personalized Treatment of COVID-19 Patients

ERMS/Log Number: PR202571

Award Number: W81XWH2110009

PI: Matthew M. Churpek, MD, MPH, PhD **Org:** The Board of Regents of the University of Wisconsin System **Award Amount:** \$2,284,257

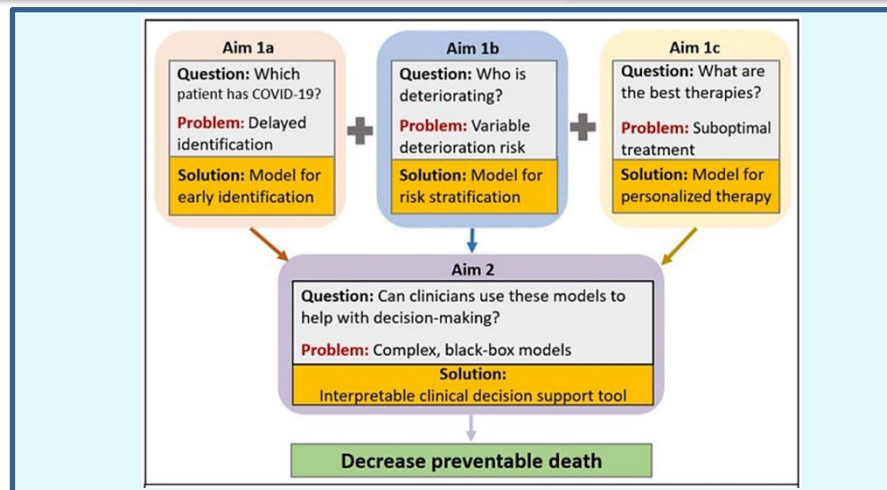


Study/Product Aim(s)

- Aim 1: Develop novel machine learning models to identify, risk stratify, and provide personalized treatment recommendations for patients with COVID-19.
- Aim 2: Develop a CDS tool graphical user interface (GUI) and test it in a simulation study.

Approach

The objective of this proposal is to develop a novel CDS tool to detect, risk stratify, and recommend personalized treatments of COVID-19 patients using machine learning and electronic health record (EHR) integrated clinical workflows. We hypothesize that using granular EHR data and machine learning will produce accurate algorithms for early detection, risk stratification, and treatment recommendations in patients with COVID-19. We further hypothesize that incorporating these models into a CDS tool using human factors principles will result in an effective, efficient, and highly usable tool.



Accomplishment: We have completed data collection from the national VA and non-VA hospitals, and data cleaning is 90% complete. Coding pipelines have been developed for all models for application to the cleaned data once completed.

Timeline and Cost

CY 2022 2023 2024 2025

Table 2. Timeline	Year 1	Year 2	Year 3	Year 4
Aim 1: Develop novel machine learning models to identify, risk stratify, and provide personalized treatment recommendations for patients with COVID-19.				
Local and HRPO IRB review				
Data cleaning and formatting for analysis				
Derive and validate diagnostic models				
Derive and validate risk stratification model				
Derive and validate treatment recommendation models				
Disseminate research findings				
Aim 2: Develop a CDS tool graphical user interface (GUI) and test it in a simulation study.				
Develop graphical user interface				
Simulation study evaluating the clinical decision support tool				
Disseminate research findings				

Estimated Budget \$2,284,257

\$583,064

\$552,167

\$579,693

\$569,333

Updated: 01/18/2021

Goals/Milestones

CY21 Goal—Data Cleaning and beginning of model derivation Aim 1a

- ☒ Local and HRPO IRB Review
- ☒ Data Cleaning and formatting for analysis
- ☐ Derive diagnostic models

CY22 Goals – Complete Aims 1a and 1b, begin Aim 1c

- ☐ Validate diagnostic models
- ☐ Data Cleaning and formatting for analysis
- ☐ Derive and validate risk stratification models
- ☐ Derive treatment recommendation models
- ☐ Disseminate research findings

CY23 Goal – Complete 1c, begin Aim 2 GUI development

- ☐ Derive and validate treatment recommendation models
- ☐ Develop graphical user interface
- ☐ Disseminate research findings

CY24 Goal – Finalize GUI and test final CDS tool in simulation study

- ☐ Finalize graphical interface
- ☐ Simulation study evaluating the clinical decision support tool
- ☐ Disseminate research findings

Comments/Challenges/Issues/Concerns

- The data cleaning will take an extra quarter due to several challenges.

Budget Expenditure to Date: Projected Expenditure: **\$583,064**

Actual Expenditure: **\$505,749**

OTHER SUPPORT

CHURPEK, MATTHEW M.

ACTIVE

R01GM123193-05 (Churpek) 08/01/2019 - 03/31/2022 2.84 CM
NIH/NIGMS total costs
45 Center Drive MSC 6200
Bethesda, MD 20892-6200
Program Official: Sarah Dunsmore, dunsmores@nigms.nih.gov
Grants Management Specialist: Christina M Rinaldi, christina.rinaldi@nih.gov, 301-827-8287
Sepsis Early Prediction and Subphenotype Illumination Study (SEPSIS)
Goal: The purpose of this proposal is to use data from the electronic health record to identify high-risk infected patients on the hospital wards. We will develop a novel algorithm for identifying ward patients with infection and then derive a severity of illness score in ward patients with infection. We will then utilize these scores to determine which subgroups may benefit from early intervention.
Specific Aims: 1) Develop a tool for identifying infected patients outside the ICU using machine learning. 2) Develop a tool for risk stratifying infected patients outside the ICU using machine learning. 3) Determine whether the benefit of early interventions varies based on clinical phenotype.
Role: Principal Investigator

W81XWH-21-1-0009 (Churpek) 01/01/2021 - 12/31/2024 3.12 CM
DOD COVID-19 TTDA PRMRP PR202571 total costs
820 Chandler Street
Fort Detrick, MD 21702-5014
Science Officer: Robin Walker robin.k.walker5.ctr@mail.mil
Grants Officer Representative: Julia M Huiberts, julia.m.huiberts.ctr@mail.mil
Using Machine Learning to Identify, Risk Stratify, and Guide Personalized Treatment of COVID-19 Patients
Goal: The objective of this proposal is to develop a novel clinical decision support (CDS) tool to detect, risk stratify, and recommend personalized treatments of COVID-19 patients using machine learning and electronic health record (EHR) integrated clinical workflows. We will combine granular multicenter data with artificial intelligence methods and human factors approaches to address several important challenges.
Specific Aims: 1) Develop novel machine learning models to identify, risk stratify, and provide personalized treatment recommendations for patients with COVID-19. 2) Develop a CDS tool graphical user interface (GUI) and test it in a simulation study.
Role: Principal Investigator

R01-DK126933-01 (Koyner/ Churpek) 08/01/2021 - 07/31/2026 1.92 CM
NIH/NIDDK total costs
31 Center Drive, MSC 2560
Bethesda, MD 20892
Program Officer: Ivonne Hernandez Schulman ivonne.schulman@nih.gov
Grants Management Specialist: Charlette Kenley kenleyc@extra.niddk.nih.gov (301) 594-8847
Using Machine Learning for Early Recognition and Personalized Treatment of Acute Kidney Injury
Goal: Up to 20% of hospitalized patients develop acute kidney injury, which is associated with increased risk of readmission, morbidity, and mortality. This project will use advanced machine learning methods and biomarkers to improve the identification and treatment of patients at risk of acute kidney injury. This project will result in novel tools and personalized treatment algorithms that can be implemented to improve patient outcomes.
Specific Aims: In Aim 1, we will use NLP and deep learning algorithms to develop a model to predict severe AKI across four health systems. In Aim 2, we will silently run the best performing model developed in Aim 1 in

real-time to identify high-risk patients. Manual retrospective chart review will be performed on a cohort of the highest risk patients to determine both the proportion of patients who receive guideline-based care as well as the association between receipt of guideline-based care and outcomes. We will also identify novel phenotypes of patients who are particularly helped or harmed by specific guideline-based interventions. Finally, in Aim 3, we will collect kidney injury biomarkers in the highest-risk patients to determine the added value of biomarkers to EHR-based models alone.

Role: Principal Investigator

R01-HL157262-01 (Churpek) 08/01/2021 - 07/31/2025 2.4 CM

NIH/NHLBI total costs

Building 31, 31 Center Drive

Bethesda, MD 20892

Program Officer: Jared P. Reis, jared.reis@nih.gov

Grants Management Specialist: Judy Sint, sintj@mail.nih.gov

Developing a clinical decision support tool for the identification, diagnosis, and treatment of critical illness in hospitalized patients

Goal: The objective of this project is to develop a clinical decision support (CDS) system incorporating novel models that identify, diagnose, and provide treatment recommendations for ward patients at high risk of clinical deterioration.

Specific Aims: 1) Develop machine learning models to identify patients at high risk of deterioration using both structured data and unstructured clinical notes; 2) Develop models to predict the diagnosis that is causing the deterioration event and the potentially life-saving treatments that should be provided to high-risk patients; 3) Develop a clinical decision support tool with a graphical user interface incorporating the models from Aims 1 and 2 via user-centered design principles and then test its effectiveness, efficiency, and user satisfaction in a case-based simulation study.

Role: Principal Investigator

PENDING

R35-13362546 (Churpek) 04/01/2022 - 03/31/2027 5.2 CM

NIH/NIGMS total costs

45 Center Drive MSC 6200

Bethesda, MD 20892-6200

Sepsis Early Prediction and Subphenotype Illumination Study (SEPSIS)

Goal: The overall vision of the PI's research program is to address these knowledge gaps by utilizing detailed multicenter electronic health record (EHR), clinical trial, and biomarker data combined with machine learning approaches to improve the identification, risk stratification, and discover important subphenotypes of sepsis to decrease preventable death from infection.

Role: PI

PREVIOUS

R21 AG068720-01 (Schwarze) 07/01/2020 – 08/01/2021 0.36 CM NIH/

NIA total costs

Building 31, Room 5C27, 31 Center Drive, MSC 2292

Bethesda, MD 20892

Characterization and Identification of Markers of Clinical Momentum in the Care of Older Adults with Advanced Dementia

This is a two-year observational study for an exploratory or developmental research proposal to develop new tools, methods and models focused on palliative care in geriatric populations.

Role: Co-Investigator

R01 DA051464-01 (Afshar) 09/30/2020 – 08/01/2021 1.2 CM

NIH/ NIDA total costs

6001 Executive Blvd

Rockville, Maryland 20852

Program Officer: Shelley Su Email: shelly.su@nih.gov, Phone: (301) 402-3869

Grants Management Officer: Jennifer J. Cho, jennifer.cho@nih.gov, (301) 827-0019

Data-Driven Strategies for Substance Misuse Identification in Hospitalized Patients

Goal: The research proposed will provide novel and critically important tools in artificial intelligence for the detection of substance misuse from the electronic health record (EHR). Development and validation of the substance misuse classifier would enable a standardized approach to perform screening on *all* patient encounters on a *daily* basis in health systems.

Specific Aims: 1) Using clinical notes from the EHR, we will train and test an NLP substance misuse classifier in a cohort of adult hospitalized patients. 2) Externally validate our NLP substance misuse classifier from Aim 1 in an independent cohort of hospitalized patients at a separate health system without current screening for substance misuse. 3) Evaluate the effectiveness of the substance misuse classifier in increasing the proportion of patients who receive an intervention compared to usual care, which involves interviewer administered screening.

Role: Co-Investigator

R21DK113420-01A1 (Koyner)

08/01/2018 - 07/31/2020

0.36 CM NIH/

NIDDK

total costs

9000 Rockville Pike

Bethesda, MD 20892

Program Official: SCHULMAN, IVONNE HERNANDEZ, ivonne.schulman@nih.gov

Grants Management Specialist: Charlette Kenley, kenleyc@extra.niddk.nih.gov, (301) 594-8847

An Early Real-Time Electronic Health Record Risk Algorithm for the Prevention and Treatment of Acute Kidney Injury: A Randomized Trial of an Early Standardized, Personalized Nephrology Intervention

Goal: Acute Kidney Injury (AKI) is a common complication in hospitalized patients and is associated with increased morbidity and mortality. My objective is to transform the medical care of hospitalized patients at risk for the development of AKI through the utilization of an automated, real-time, electronic health record risk assessment score allowing for early standardized nephrology intervention.

Role: Collaborator

No number (Edelson)

06/01/2018 - 05/31/2020

0.36 CM

NIH

total costs

9000 Rockville Pike

Bethesda, MD 20892

301-496-4000

eCART Lite: Detecting Clinical Deterioration in the Hospital Using Limited Clinical Variables and Continuous Monitoring Data

Goal: To assess clinical deterioration in hospital in-patients.

Specific Aims: The aims of this grant proposal are to derive and validate a risk prediction model that uses only a limited number of clinical variables in both a multicenter database of inpatient EHR data as well as in a retrospective dataset of variables obtained via automated vital sign sensors.

Role: Co-Investigator

5K08 HL121080 (Churpek)

01/01/2014 –

9.0 CM

NIH/NHLBI,

12/31/2018 total costs

Building 31, 31 Center Drive

Bethesda, MD 20892

877-645-2448

Program Officer: Li-Shin Huang li-shin.huang@nih.gov

Predicting In-Hospital Cardiac Arrest Using Electronic Health Record Data

Goal: The aims of this grant proposal are to develop and validate prediction models to detect in-hospital cardiac arrest using vital signs and laboratory values in a multicenter dataset.

Role: Principal Investigator

OVERLAP

While there is no current scientific, budgetary, or commitment overlap, in the event that multiple pending awards are funded, Dr. Churpek will make **modest** modifications to his effort on these projects, and prior approval will be requested where applicable.

OTHER SUPPORT

CRAVEN, MARK

ACTIVE

UH3 OD023282 (J. Gern) 09/01/2016 - 8/31/2023 2.4 CM
NIH/NHLBI
Building 31, 31 Center Drive
Bethesda, MD 20892
877-645-2448
PO: HANSPAL, MANJIT, hanspalm@nhlbi.nih.gov
Children's Respiratory and Environmental Workgroup (CREW)
This consortium is focused on identifying specific types of childhood asthma, developing an understanding of what early life environmental influences cause these different types of asthma, and identifying targets for future efforts aimed at preventing childhood asthma. My role in the project is to lead the development of computational methods to characterize asthma phenotypes.
Role: Investigator and Lead of the Biostatistics and Bioinformatics Core

P30 CA14520 (H. Bailey) 04/01/2007 - 03/31/2023 1.2 CM
NIH/NCI
31 Center Drive, Building 31
Bethesda, Maryland, 20814
PO: SHAFIK, HASNAA, shafikh@mail.nih.gov
UWCCC Cancer Informatics Shared Resources
I serve as a member of the Biomedical Informatics Core for the Carbone Cancer Center. This core provides informatics support to basic-science and clinical investigators in the center.
Role: Investigator

T15 LM07359 (M. Craven) 07/12/2012 - 6/30/2022 0.6 CM
NIH/NLM
8600 Rockville Pike
Bethesda, MD 20894
PO: FLORANCE, VALERIE, florancev@mail.nih.gov
Computation and Informatics in Biology and Medicine Training Grant
This training grant supports predoctoral and postdoctoral trainees conducting research in biomedical informatics.
Role: Principal Investigator

UL1 TR002372 (A. Brasier) 09/21/2017 - 6/30/2022 0.6 CM
NIH/NCATS
Institutional Clinical and Translational Science Award (UW-Madison)
I serve as a member of the Biomedical Informatics Core for the University of Wisconsin's CTSI, and lead a project focused on predictive modeling from electronic health record data.
Role: Investigator

(C. Dewey and M. Craven, Co-PIs) 09/01/2020 - 08/31/2022 0.6 CM
American Family Insurance
Machine-learning Approaches for Metadata Standardization
This project is focused on developing automated approaches for mapping unstructured metadata to structured, ontology-based metadata.
Role: Co-Principal Investigator

R01-DK126933-01 (Koyner/ Churpek) 08/01/2021 - 07/31/2026 0.6 CM

NIH/NIDDK total costs

31 Center Drive, MSC 2560

Bethesda, MD 20892

Program Officer: Ivonne Hernandez Schulman ivonne.schulman@nih.gov

Grants Management Specialist: Charlette Kenley kenleyc@extra.niddk.nih.gov (301) 594-8847

Using Machine Learning for Early Recognition and Personalized Treatment of Acute Kidney Injury

Goal: Up to 20% of hospitalized patients develop acute kidney injury, which is associated with increased risk of readmission, morbidity, and mortality. This project will use advanced machine learning methods and biomarkers to improve the identification and treatment of patients at risk of acute kidney injury. This project will result in novel tools and personalized treatment algorithms that can be implemented to improve patient outcomes.

Specific Aims: In Aim 1, we will use NLP and deep learning algorithms to develop a model to predict severe AKI across four health systems. In Aim 2, we will silently run the best performing model developed in Aim 1 in real-time to identify high-risk patients. Manual retrospective chart review will be performed on a cohort of the highest risk patients to determine both the proportion of patients who receive guideline-based care as well as the association between receipt of guideline-based care and outcomes. We will also identify novel phenotypes of patients who are particularly helped or harmed by specific guideline-based interventions. Finally, in Aim 3, we will collect kidney injury biomarkers in the highest-risk patients to determine the added value of biomarkers to EHR-based models alone.

Role: Investigator

R01-HL157262-01 (Churpek) 08/01/2021 - 07/31/2025 0.6 CM

NIH/NHLBI total costs

Building 31, 31 Center Drive

Bethesda, MD 20892

Program Officer: Jared P. Reis, jared.reis@nih.gov

Grants Management Specialist: Judy Sint, sintj@mail.nih.gov

Developing a Clinical Decision Support Tool for the Identification, Diagnosis, and Treatment of Critical Illness in Hospitalized Patients

Goal: The objective of this project is to develop a clinical decision support (CDS) system incorporating novel models that identify, diagnose, and provide treatment recommendations for ward patients at high risk of clinical deterioration.

Specific Aims: 1) Develop machine learning models to identify patients at high risk of deterioration using both structured data and unstructured clinical notes; 2) Develop models to predict the diagnosis that is causing the deterioration event and the potentially life-saving treatments that should be provided to high-risk patients; 3) Develop a clinical decision support tool with a graphical user interface incorporating the models from Aims 1 and 2 via user-centered design principles and then test its effectiveness, efficiency, and user satisfaction in a case-based simulation study.

Role: Investigator

W81XWH-21-1-0009 (Churpek) 01/01/2021 - 12/31/2024 0.6 CM

DOD COVID-19 TTDA PRMRP total costs

820 Chandler Street

Fort Detrick, MD 21702-5014

Science Officer: Swapna Sista, swapna.sista.ctr@mail.mil

Grants Officer Representative: Julia M Huiberts, julia.m.huiberts.ctr@mail.mil

Using Machine Learning to Identify, Risk Stratify, and Guide Personalized Treatment of COVID-19 Patients

The objective of this proposal is to develop a novel clinical decision support (CDS) tool to detect, risk stratify, and recommend personalized treatments of COVID-19 patients using machine learning and electronic health record (EHR) integrated clinical workflows. We will combine granular multicenter data with artificial intelligence

methods and human factors approaches to address several important challenges.

Specific Aims: 1) Develop novel machine learning models to identify, risk stratify, and provide personalized treatment recommendations for patients with COVID-19. 2) Develop a CDS tool graphical user interface (GUI) and test it in a simulation study.

Role: Investigator

MSN254443 (A. Gasch) 06/01/2021-06/30/2023 0.12 CM

Research Forward-

Wisconsin Alumni Research Foundation

An Integrative Computational and Experimental System for Interpreting Genomic Variation

The objective of this project is to develop a clinical decision support system incorporating novel models that identify, diagnose, and provide treatment recommendations for ward patients at high risk of clinical deterioration. My role in this project is to provide expertise in interpretable machine learning.

Role: Investigator

UM1AI160050 (D. Jackson) 04/12/2021-03/31/2028 1.20 CM

NIH/NIAID

5601 Fishers Lane

Rockville, MD 20852

Program Officer: Gang Dong, gdong@niaid.nih.gov

Grants Management Specialist: Shaun W. Gratton, Shaun.Gratton@nih.gov

Childhood Asthma in Urban Settings (CAUSE) – Leadership Center

This network will conduct observational studies and clinical trials to further improve our understanding of asthma and to develop effective interventions and asthma prevention approaches tailored to children living in urban communities. My role is to develop computational models of respiratory allergy and asthma phenotypes/endotypes, and to identify biomarkers that are predictive these phenotypes.

Role: Co-Investigator

U01HG0120339 (M. Craven) 09/01/2021-05/31/2026 3.0 CM

NIH/NHGRI

31 Center Drive

Bethesda, MD 20894

Program Officer: Daniel A. Gilchrist, Daniel.Gilchrist@nih.gov

Grants Management Specialist: Natalie Danielle Linear, Natalie.Linear@nih.gov

Linking Variants to Multi-scale Phenotypes via a Synthesis of Subnetwork Inference and Deep Learning

This project is focused on advancing our ability to predict the impact of genetic variants thereby boosting the effectiveness of genomic analyses ranging from genome-wide association studies for common diseases to diagnostic odysseys searching for genetic causes of rare diseases

Role: Principal Investigator

PENDING

R01 (M. Craven) 12/01/2020 - 11/31/2024 4.2 CM

NIH/NLM

8600 Rockville Pike

Bethesda, MD 20894

Interpreting Learned Black-Box Models for Biomedicine

The objective of this project is to develop methods for increasing our understanding and trust of “black-box” models inferred by machine-learning in a broad range of biomedical domains.

Role: Principal Investigator

(C. Brandt) 11/20/2020 - 10/31/2025 1.2 CM

Wisconsin Partnership Program

Genetic Drivers of Alzheimer's Disease in Herpes simplex Virus Type 1

This project is focused on assessing role of HSV-1 infections on early biomarkers of Alzheimer's Disease, determining the effect of HSV-1 genetic variation on these biomarkers and potential mechanisms linking them. My role in this project is to lead the efforts to model disease phenotypes in terms of viral genotypes.

Role: Investigator

(O. Alagoz and N. Safdar)

08/01/2020 - 07/31/2025

1.2 CM

CDC

1600 Clifton Rd.

Atlanta, GA 30329-4027

888-232-6348

Innovative Modeling Paradigms to Combat Antimicrobial Resistant Infection Threats

My role in this project is to develop and apply active, multitask machine-learning methods for calibrate agent-based simulation models of healthcare-associated infections.

Role: Investigator

PREVIOUS

U54 AI117924 (Craven)

09/29/2014 - 08/31/2019

NIH/NIAID

5601 Fishers Ln

Rockville, MD 20852

PO: MATHUR, PUNAM, mathurpu@mail.nih.gov

The Center for Predictive Computational Phenotyping

I served as the Director of this Center, which is one of the NIH Centers of Excellence for Big Data Computing in the Biomedical Sciences. The Center is developing innovative computational and statistical methods and software for a broad range of problems that involve transforming large, heterogeneous, high-dimensional data sources into predictive models for biomedicine.

No number (Craven, subcontract PI)

08/01/2014 - 06/30/2018

DARPA

675 North Randolph St.

Arlington, VA 22203-2114

(703) 526-6630

Pathway Logic Extended with Information Assembled from Data Extracted Selectively (PLEIADES)

This project was focused on developing interactive, natural-language-processing methods to help automate the conversion of the scientific literature on molecular biology into executable pathway models.

Role: PI of subcontract to University of Wisconsin from SRI

IIS-1218880 (Craven)

09/10/2012 - 08/31/2016

NSF

2415 Eisenhower Avenue

Alexandria, Virginia 22314.

Active Learning with Rich Query Types on Networks and Trees

The major goal of this project was to develop a new class of algorithms for active learning that (i) address complex learning tasks such as biological network reconstruction and event extraction from natural language, (ii) assemble batches of queries when it is cost effective to do so, (iii) are able to employ a variety of query types, and (iv) reason about the costs incurred for various queries.

Role: Principal Investigator

R01 EY023292 (Brandt)

03/01/2013 - 02/29/2016

NIH/NEI

31 Center Drive MSC 2510

Bethesda, MD 20892-2510

301-496-5248

PO: MCKIE, GEORGE ANN, mckiegeo@mail.nih.gov

Virulence Genes in Herpes Simplex Virus Ocular Infection

The goal of this project was to uncover the sequence features that are implicated in HSV virulence. My role in this project was to lead the efforts to model disease phenotypes in terms of viral genotypes.

Role: Investigator

R01GM115591 (D. Pagliarini, PI) 04/01/2016-03/31/2021

NIH/NIGMS

Systematic Functional Annotation of the Mitochondria Proteome

My role in this project is to help develop machine learning approaches to predicting orphan mitochondrial protein functions.

Role: Investigator

OVERLAP

None

OTHER SUPPORT

EDELSON, DANA

ACTIVE

R01GM123193-04 (Churpek) 08/01/2019 - 03/31/2022 0.9 CM
NIH/NIGMS total costs
45 Center Drive MSC 6200
Bethesda, MD 20892-6200
Program Official: DUNSMORE, SARAH, dunsmares@nigms.nih.gov
Grants Management Specialist: Christina M Rinaldi, christina.rinaldi@nih.gov, 301-827-8287
Sepsis Early Prediction and Subphenotype Illumination Study (SEPSIS)
Goal: The purpose of this proposal is to use data from the electronic health record to identify high risk infected patients on the hospital wards. We will develop a novel algorithm for identifying ward patients with infection and then derive a severity of illness score in ward patients with infection. We will then utilize these scores to determine which subgroups may benefit from early intervention.
Specific Aims: 1) Develop a tool for identifying infected patients outside the ICU using machine learning. 2) Develop a tool for risk stratifying infected patients outside the ICU using machine learning. 3) Determine whether the benefit of early interventions varies based on clinical phenotype.
Role: Co-Investigator

R01-DK126933-01 (Koyner/Churpek) 08/01/2021 - 07/31/2026 0.0 CM
NIH/NIDDK total costs
31 Center Drive, MSC 2560
Bethesda, MD 20892
Program Officer: Ivonne Hernandez Schulman ivonne.schulman@nih.gov
Grants Management Specialist: Charlette Kenley kenleyc@extra.niddk.nih.gov (301) 594-8847
Using Machine Learning for Early Recognition and Personalized Treatment of Acute Kidney Injury
Goal: Up to 20% of hospitalized patients develop acute kidney injury, which is associated with increased risk of readmission, morbidity, and mortality. This project will use advanced machine learning methods and biomarkers to improve the identification and treatment of patients at risk of acute kidney injury. This project will result in novel tools and personalized treatment algorithms that can be implemented to improve patient outcomes.
Specific Aims: In Aim 1, we will use NLP and deep learning algorithms to develop a model to predict severe AKI across four health systems. In Aim 2, we will silently run the best performing model developed in Aim 1 in real-time to identify high-risk patients. Manual retrospective chart review will be performed on a cohort of the highest risk patients to determine both the proportion of patients who receive guideline-based care as well as the association between receipt of guideline-based care and outcomes. We will also identify novel phenotypes of patients who are particularly helped or harmed by specific guideline-based interventions. Finally, in Aim 3, we will collect kidney injury biomarkers in the highest-risk patients to determine the added value of biomarkers to EHR-based models alone.
Role: Co-Investigator

R01-HL157262-01 (Churpek) 08/01/2021 - 07/31/2025 0.6 CM
NIH/NHLBI total costs
Building 31, 31 Center Drive
Bethesda, MD 20892
Program Officer: Jared P. Reis, jared.reis@nih.gov
Grants Management Specialist: Judy Sint, sintj@mail.nih.gov
Developing a clinical decision support tool for the identification, diagnosis, and treatment of critical illness in hospitalized patients

Goal: The objective of this project is to develop a clinical decision support (CDS) system incorporating novel models that identify, diagnose, and provide treatment recommendations for ward patients at high risk of clinical deterioration.

Specific Aims: 1) Develop machine learning models to identify patients at high risk of deterioration using both structured data and unstructured clinical notes; 2) Develop models to predict the diagnosis that is causing the deterioration event and the potentially life-saving treatments that should be provided to high-risk patients; 3) Develop a clinical decision support tool with a graphical user interface incorporating the models from Aims 1 and 2 via user-centered design principles and then test its effectiveness, efficiency, and user satisfaction in a case-based simulation study.

Role: Co-Investigator

W81XWH-21-1-0009 (Churpek) 01/01/2021 - 12/31/2024 1.5 CM

DOD COVID-19 TTDA PRMRP

total costs

820 Chandler Street

Fort Detrick, MD 21702-5014

Science Officer: Robin Walker robin.k.walker5.ctr@mail.mil

Grants Officer Representative: Julia M Huiberts, julia.m.huiberts.ctr@mail.mil

Using Machine Learning to Identify, Risk Stratify, and Guide Personalized Treatment of COVID-19 Patients

The objective of this proposal is to develop a novel clinical decision support (CDS) tool to detect, risk stratify, and recommend personalized treatments of COVID-19 patients using machine learning and electronic health record (EHR) integrated clinical workflows. We will combine granular multicenter data with artificial intelligence methods and human factors approaches to address several important challenges.

Specific Aims: 1) Develop novel machine learning models to identify, risk stratify, and provide personalized treatment recommendations for patients with COVID-19. 2) Develop a CDS tool graphical user interface (GUI) and test it in a simulation study.

Role: Co-Investigator

R01-GM137083 (Wright) 07/15/20 - 06/30/24 0.06 CM

NIH-NIGMS

45 Center Drive MSC 6200

Bethesda, MD 20892-6200

Program Official: Xiaoli Zhao, xiaoli.zhao@nih.gov

Timely Response to In-Hospital Deterioration Through Design of Actionable Augmented Intelligence

UChicago's primary role in the project will be to support qualitative and quantitative research activities that engage clinicians who will use AI-informed risk prediction algorithms in evaluations of the usefulness and design of user experiences. UChicago will assist Dr. Wright and other team members in selecting representative and boundary patient cases and providing relevant data that can be used to simulate the representation of those patients to clinicians in their workflow, that will serve as context for interviews and experiments to evaluate different aspects of user experience design.

Role: Co-Investigator

ASPR-BARDA 21-00592 (Edelson) 04/30/21 - 12/30/22 3.0 CM

US HHS/AgileMD Inc

total costs

200 Independence Avenue, S.W.

Washington, D.C. 20201

Grants Officer: Kimberly Sciarretta, kimberly.sciarretta@hhs.gov

A Rapid Diagnostic of Risk in COVID-19 Patients to Improve Outcomes and Critical Resources Allocation Using Machine Learning

The overall objective of this contract is to fast track the development and deployment of eCART, a clinical

decision support tool that combines a real-time machine learning algorithm, within the electronic health record of ten initial partner hospitals for identifying need for mechanical ventilation or hemodynamic support with specific COVID-19 treatment algorithms to standardize care of these patients based on a real-time, quantitative assessment of patient risk.

Role: Principal Investigator

R44-EB030955 (Edelson) 07/01/2021 - 06/30/2023 3.0 CM

NIH-SBIR total costs

9000 Rockville Pike

Building 31 Room 1C14

Bethesda, MD 20892

Program Officer: Behrouz Shabestari, shabestb@mail.nih.gov

Opening the Black Box: Enhancing Machine Learning Interpretability to Optimize Clinical Response to Sudden Deterioration In COVID-19 Patients

The goals of this project are to a) upgrade the existing AgileMD platform to support eCARTv4 and overhaul the human-machine interface for an advanced user experience (UX) that provides interpretable insight into a real-time EHR-embedded advanced ML analytic, and b) measure the impact of the new tool on HCP effectiveness, efficiency, and satisfaction.

Role: Principal Investigator

AgileMD 01/01/2019 – present 0.0 CM
annual salary

Dr. Edelson is President and Co-Founder of AgileMD. AgileMD acquired the UCM license to eCART when it acquired QuantHC. AgileMD markets a clinical decision support platform and sells eCART licenses to hospitals for use on that platform. QuantHC was converted into 8,035,414 shares AgileMD common stock, of which I own 97%, and the University owns the remaining. QuantHC is now a wholly owned subsidiary of AgileMD. I own equity in AgileMD stock, I serve as the President and Co-Founder of AgileMD and a portion of my salary is paid by the company, and I own Intellectual Property Rights (ARCD.P0535US.P2) for a risk prediction algorithm that I developed at the University of Chicago; AgileMD acquired the exclusive licensing rights to eCART when it acquired QuantHC. This role supports her research endeavors.

PENDING

NONE

PREVIOUS

No Number (Edelson) 06/01/2018 – 05/31/2020 1.2 CM

NIH

9000 Rockville Pike

Bethesda, MD 20892

301-496-4000

eCART Lite: Detecting Clinical Deterioration in the Hospital Using Limited Clinical Variables and Continuous Monitoring Data

Goal: To assess clinical deterioration in hospital in-patients.

The aims of this grant proposal are to derive and validate a risk prediction model that uses only a limited number of clinical variables in both a multicenter database of inpatient EHR data as well as in a retrospective dataset of variables obtained via automated vital sign sensors.

Role: Principal Investigator

21 DK 113420-01 A1 (Koyner)

09/01/2017- 08/31/2019

3.6 CM

IH/NIDDK,

9000 Rockville Pike

Bethesda, MD 20892

Program Official: SCHULMAN, IVONNE HERNANDEZ, ivonne.schulman@nih.gov

Grants Management Specialist: Charlette Kenley, kenleyc@extra.niddk.nih.go, (301) 594-8847

An Early Real-Time Electronic Health Record Risk Algorithm for the Prevention and Treatment of Acute Kidney Injury: A Randomized Trial of an Early Standardized, Personalized Nephrology Intervention

Goal: To perform a prospective randomized clinical trial utilizing the ESTOP- AKI risk assessment model prior to measurable loss of kidney function ("pre-AKI") to determine if potential benefit (defined as lower peak SCr, lower AKI stage, shorter LOS and less morbidity and mortality) of ENC exists as compared to usual care.

Role: Co-Investigator

No Number (Edelson)

04/11/2016 - 09/10/2017

1.2 CM

EarlySense

12 Tzvi Street

Ramat Gan 52504, Israel

Contracting/Grants Officer: Avner Halperin

Identifying At-Risk Patients and Predicting Deterioration of In-Patients Using Continuous Heart Rate, Respiratory Rate and Movement Monitoring

Specific Aims: 1) to determine the correlation between subjective and objective sleep quality measures; 2) to compare the objective and subjective measures of sleep quality and satisfaction between the interventional group and the control group; 3) to compare the adverse event rates in the interventional group and the control group, defined as ICU transfer or cardiac arrest occurring within 24 hours of risk stratification.

Role: Principal Investigator

OVERLAP

None

OTHER SUPPORT

GOVINDAN, SUSHANT

ACTIVE

Department of Veterans Affairs (Govindan)
Office of Academic Affiliations
810 Vermont Ave NW
Washington, DC 20420

11/2018 - Present
total costs

1.2 CM

Program Officer: Christyann Clary

Goal: Grant that funds a Chief Resident in Quality and Safety at the KCVA and provides support for curriculum development on quality improvement as well as running projects locally, regionally, and nationally. This is an ongoing grant without a term limit.

Specific Aims: 1) To increase house officer involvement in quality improvement and patient safety initiatives at the KCVA. 2) To increase curriculum development and teaching of quality improvement and patient safety principles at the KCVA.

Role: Principal Investigator

W81XWH-21-1-0009 (Churpek)

01/01/2021 - 12/31/2024

3.0 CM

DOD COVID-19 TTDA PRMRP

total costs

820 Chandler Street

Fort Detrick, MD 21702-5014

Science Officer: Robin Walker robin.k.walker5.ctr@mail.mil

Grants Management Specialist: Julia M Huiberts, julia.m.huiberts.ctr@mail.mil

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Specific Aims: 1) Develop novel machine learning models to identify, risk stratify, and provide personalized treatment recommendations for patients with COVID-19. 2) Develop a CDS tool graphical user interface (GUI) and test it in a simulation study.

Role: Site PI/ Co-Investigator

PREVIOUS

Blue Cross/Blue Shield Foundation of Michigan (Govindan) 05/2018 - 05/2019

1.2 CM

BCBSFM

total costs

600 E. Lafayette Blvd.

Detroit, MI 48226

Program Officer: Kelly Brittain

Goal: Foundation grant investigating vascular access practices in the ICU

Specific Aims: 1) To characterize vascular access practices, knowledge, and perceptions of critical care practitioners in the state of Michigan (utilization rates, indications, preferences, and knowledge of complications). We will do this by surveying practitioners in the Michigan Hospital Medicine Safety (HMS) Consortium. 2) Compare and contrast vascular access practices in Michigan to that of critical care practitioners across the United States. We will assess usage, indications, preferences, and knowledge of vascular complications, and we will do this by surveying practitioners through the Society of Critical Care Medicine (SCCM).

T32 HL007749 (Standiford)

07/01/2016 - 2018

9.0 CM

NIH/NHLBI

total costs

31 Center Drive

Bethesda, MD 20892

Program Officer: Roya Kalantari, roya.kalantari@nih.gov

Multidisciplinary Training Program in Lung Disease

Training grant dedicated to providing support and protected time for early career investigators.

Goal: provide early career investigators with protected time to pursue investigational work.

Specific Aim: Fund MD and PhD early career scientists on investigational studies regarding pulmonary and critical care medicine.

Role: Awardee

OVERLAP

None

OTHER SUPPORT

SCHAEFER, RICHARD SPENCER

ACTIVE

W81XWH-21-1-0009 (Churpek)	01/01/2021 - 12/31/2024	1.2 CM
DOD COVID-19 TTDA PRMRP	total costs	

820 Chandler Street

Fort Detrick, MD 21702-5014

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Grants Management Specialist: Julia M Huiberts, julia.m.huiberts.ctr@mail.mil

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Role: Co-Investigator

PREVIOUS

None

OVERLAP

None

OTHER SUPPORT

WRIGHT, MELANIE C.

ACTIVE

R01-GM137083 (Wright)

07/01/2020 - 06/30/2024

2.8 CM

NIH-NIGMS

annual total costs

9000 Rockville Pike

Bethesda, MD 20892

301-496-4000

PO: Sarah Dunsmore dunsmores@nigms.nih.gov

Timely Response to In-Hospital Deterioration Through Design of Actionable Augmented Intelligence

The primary objectives are to: identify factors that influence clinicians' perceptions of augmented intelligence (AI) usefulness, generate design principles for effective health risk surveillance human-AI interaction, and design human-AI user interfaces that meaningfully improve human-AI performance when responding to sepsis and acute kidney injury.

Specific Aims: 1) We will develop a temporal reasoning AI model for predicting in-hospital development of sepsis and AKI. 2) We will interview clinicians while reviewing temporal progression of a patient's change in condition over their stay, including AI generated risk information. 3) We will conduct participatory design activities with clinicians to design effective human-centered AI display and interaction to support early response to in-hospital sepsis and AKI. 4) Using simulated realistic patient care tasks and comparing to traditional patient information technologies, we will evaluate the impact of human-centered AI designs on human-AI performance.

Role: Principal Investigator

Contract # 75F40121C00130

2.2 CM

FDA

4041 Powder Mill Rd

Beltsville MD 20705

COR: Piya Sawhney piya.sawhney@fda.hhs.gov

Artificial intelligence in healthcare: Understanding patient information needs and designing comprehensible transparency

The primary aims of this project are to understand factors that influence patients perceived value and trust of healthcare AI applications and their related information needs and to develop guidance for the FDA and device manufacturers to ensure appropriate transparency and safe use of AI-enabled devices and applications.

Role: Principal Investigator

W81XWH-21-1-0009 (Churpek)

01/01/2021 - 12/31/2024

0.6 CM

DOD COVID-19 TTDA PRMRP

total costs

820 Chandler Street

Fort Detrick, MD 21702-5014

Science Officer: Robin Walker robin.k.walker5.ctr@mail.mil

Grants Management Specialist: Julia M Huiberts, julia.m.huiberts.ctr@mail.mil

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Role: Investigator

PENDING

R44-EB030955 (Edelson)

04/01/2022 – 03/31/2024

1.72 CM

NIH-SBIR

Opening the Black Box: Enhancing Machine Learning Interpretability to Optimize Clinical Response To Sudden Deterioration In COVID-19 Patients

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Role: Investigator

R01HL157262 (Churpek)

8/1/2023 – 7/31/2025

0.30 CM

NIH-NHLBI

Building 31, 31 Center Drive

Bethesda, MD 20892

Program Officer: Jared P. Reis, jared.reis@nih.gov

Grants Management Specialist: Judy Sint, sintj@mail.nih.gov

Developing a clinical decision support tool for the identification, diagnosis, and treatment of critical illness in hospitalized patients

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Role: Co-Investigator

PREVIOUS

No number (Robinson)

01/10/2021 – 12/31/2021

0.48 CM

Merck Investigator Studies Program

Identification of and solutions to VAccination Challenges through Community-Identified Needs of Elders (VACCINE): a mixed-methods study

Identify barriers and facilitators, including underlying patient and family attitudes, that contribute to low-vaccine uptake in high-risk elders. Co-develop an evidence-based intervention plan, in partnership with AB members, to address vaccine hesitancy, improve vaccine confidence, and increase COVID-19 vaccination rates (once available) in high-risk elders.

Role: Investigator

5R01-HS023387-05 (Segall)

04/01/2015 – 03/31/2021

0.2 CM

Agency for Healthcare Research and Quality

annual total costs

(Years 1-5)

5600 Fishers Lane, 7th Floor

Rockville, MD 20857

301-427-1104

PO: GRAY, DARRYL T

Effect of monitoring system design on response time to cardiac arrhythmias

Our overarching aim is to improve survival after life-threatening arrhythmias by speeding detection of these events. The objective of the proposed research is to identify and test determinants of efficient cardiac monitoring

systems. We hypothesize that response times to cardiac events can be reduced by ensuring direct communication about arrhythmias to the bedside nurse.

Role: Investigator

FY19 01-02556 (Wright)	07/01/2019 – 06/30/2020	0.1 CM
Saint Alphonsus Foundation	total costs	
<i>Coronary artery disease assessment screening and long-term follow-up for firefighters and police officers</i>		
The purpose of this study is to conduct quantitative analysis of four years of cardiac risk data for firefighters and police. We will also conduct qualitative interviews to provide insight into how risk information sharing may be linked to positive behavior change to reduce risk among firefighters and police involved in this longitudinal study.		
Role: Principal Investigator		

061219-003 (Wright)	07/01/2019 –	1.2 CM
06/30/2021 Trinity Assurance Limited	total costs	(Year 1)
<i>Spreading empathy and interpersonal skills: Developing novel approaches to prevent patient violence</i>		
The objective of this project is to develop brief micro-learning videos and validate evaluation metrics toward future development and evaluation of novel approaches to reduce colleague harm, change colleague perceptions, and improve patient outcomes in response to patient-staff conflict and aggression.		
Role: Principal Investigator		

R56LM011925-01 (Wright)	08/01/2015 – 7/31/2018	2.8 CM
National Library of Medicine	Total costs	
8600 Rockville Pike		
Bethesda, MD 20892		
301-496-4000		
PO: SIM, HUA-CHUAN, simh@mail.nih.gov		
<i>Right place, right time: Information design to support decisions in acute care</i>		
This project proposes a user-centered approach to support the development of design guidelines and design concepts to better organize, prioritize, and present acute care electronic patient information.		
Role: Principal Investigator		

No number (Wright)	09/01/2017 – 06/30/2018	0.6 CM
American Association for Advancement of Medical Instrumentation (AAMI)	total costs	
901 N. Glebe Road, Suite 300		
Arlington, VA 22203		
703-525-4890		
<i>Organizing Audible Alarms in Hospitals: Expert Knowledge Elicitation to Develop Useful Alarm Categories</i>		
The primary objective of this project is to understand what information is important to discern from an auditory alarm and to determine what categories and sub-categories of alarms will ensure that a standardized and integrated solution is comprehensive and useful to hospital staff.		
Role: Principal Investigator		

1 R21 LM 010700-01 (Segall)	09/01/2011 – 08/31/2015	3.2 CM
National Institutes of Health	total costs	
National Library of Medicine Grant		
8600 Rockville Pike		
Bethesda, MD 20892		
301-496-4000		
PO: VANBIERVLIET, ALAN, alan.vanbiervliet@nih.gov		
<i>Toward intelligent display of health data: a qualitative study of use patterns</i>		

The primary goal of this effort was to, through qualitative observational research in the context of critical care, generate principles to improve the organization and prioritization of data in electronic health records.

OVERLAP

None