SUMMARY STATEMENT

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(Privileged Communication) ***Release Date:*** **02/28/2014**

Application Number: **2 R01 AG034676-50**

Principal Investigators (Listed Alphabetically):
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ST SAUVER, JENNIFER LYNN PHD

Applicant Organization: MAYO CLINIC ROCHESTER

Review Group: **CASE**
Cardiovascular and Sleep Epidemiology Study Section

Meeting Date: **02/04/2014** ***RFA/PA:*** **PA13-302**
Council: **MAY 2014** ***PCC:*** **4BCLGCD**
Requested Start: **07/01/2015**

Project Title: **Multimorbidity and Aging: Rochester Epidemiology Project**

SRG Action: **Impact Score: 36 Percentile: 25**
Next Steps: **Visit http://grants.nih.gov/grants/next_steps.htm**
Human Subjects: **30-Human subjects involved - Certified, no SRG concerns**
Animal Subjects: **10-No live vertebrate animals involved for competing appl.**
Gender: **1A-Both genders, scientifically acceptable**
Minority: **1U-Minorities and non-minorities, scientifically unacceptable**
Children: **1A-Both Children and Adults, scientifically acceptable**
Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
50	948,084	1,465,202
51	948,077	1,465,191
52	948,077	1,465,191
53	948,077	1,465,191
54	948,077	1,465,191
TOTAL	4,740,392	7,325,965

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

2R01AG034676-50 ROCCA, WALTER

INCLUSION OF MINORITIES PLAN UNACCEPTABLE

RESUME AND SUMMARY OF DISCUSSION: This renewal application proposes to examine the causes and consequences of multi-morbidity using the records-linkage system of the Rochester Epidemiology Project (REP). The investigators plan to identify groups of people with different levels of multi-morbidity, to study interactions across specific conditions, to identify the causes and the long-term consequences of multi-morbidity, and to share the Rochester Epidemiology Project data via the internet-based Data Exploration Portal. During the discussion, the committee disagreed about the impact of the proposed study. Some reviewers argued that this study will have a high impact because it continues the study of a unique population-based dataset with long term follow-up, and that the study of multi-morbidity has high significance and is understudied. Other reviewers suggested that this study will have only a moderate impact because of several concerns about the proposed approach. The committee agreed that this application has multiple strengths, noting that this study is requesting support for years 50-54 of an important unique longitudinal cohort which has led to many ancillary studies. They commented that the investigators have demonstrated very high levels of prior research productivity. Other strengths include an excellent team of investigators who have extensive experience with the proposed dataset, a very carefully developed analysis plan, plans for community engagement, established linkages of electronic data, and a strong plan for data sharing. The reviewers also commented that the application has a number of weaknesses, noting that the study of multi-morbidity is not uniquely novel and that the cohort has low socio-economic and racial/ethnic diversity. They also expressed a concern that the study does not characterize most known cardiovascular risk factors, does not consider phychiatric disease, has only limited information on cigarette smoking, does not include information on air pollution, and that the study results may not be generalizable to younger subjects. They commented that only one investigator has experience with multi-morbidity. The reviewers disagreed about the importance of these weaknesses. Some committee members considered these weaknesses to be negligible and to be outweighed by the strengths of the proposed study and by the uniqueness of the study cohort, whereas other reviewers considered these weaknesses to be moderate and to diminish the impact of the study.

DESCRIPTION (provided by applicant): The unifying theme of this application is multi-morbidity and its causes and consequences. Growth of the elderly population and changes in disease dynamics predict major increases in the prevalence of chronic diseases, other chronic conditions, and combinations of chronic conditions (multi-morbidity). Greater life expectancy associated with advances in public health and clinical medicine, and the persistently high prevalence of some risk factors (e.g., obesity), pose unique challenges. These trends threaten both the public health and the financial health of the United States. Traditionally, preventive programs have focused on individual chronic diseases without considering the broader context of multiple risk factors and multiple chronic conditions. Because the nation is facing a high prevalence of multiple chronic conditions, there is an urgent need for prevention, treatment, and planning. In response to this health crisis, the US Department of Health and Human Services (US DHHS) developed a strategic framework for optimizing health and quality of life for individuals with multiple chronic conditions. The US DHHS also developed a list of 20 selected conditions considered to be a public health priority for the nation. The Rochester Epidemiology Project (REP) is an ideal environment to study multi-morbidity and its causes and consequences because it includes information for all ages, from newborns to the elderly, regardless of insurance status or health care setting (both inpatient and outpatient care), and it has accumulated almost half a century of data on local residents. In this renewal application, we propose to identify groups of people with different levels of multi-morbidity across 7 age cohorts spanning the entire population, and to study possible interactions across specific conditions (Aim 1). In addition, we will identify the causes (Aim 2) and the long- term adverse health outcomes of multi-morbidity (Aim 3). This knowledge will inform earlier and more integrated interventions to prevent multi-morbidity and to improve its outcomes, as recommended

by the US DHHS. Finally, we will develop an innovative approach to data sharing by making REP data electronically accessible to users worldwide through a Data Exploration Portal accessible on the internet (Aim 4). Broad sharing of the comprehensive and longitudinal REP data to the wider scientific community will allow investigators worldwide to rapidly explore patterns of diseases, procedures, and drug prescriptions and their associations at no cost. In summary, the studies proposed here are novel, can be efficiently conducted using the REP, and are urgently needed.

PUBLIC HEALTH RELEVANCE: We propose to study the causes and consequences of multi-morbidity using the records-linkage system of the unique Rochester Epidemiology Project, which has captured comprehensive information about the medical care delivered to local residents since the 1960s. Our ultimate goal is to provide evidence to guide the prevention of multi-morbidity, and to improve health outcomes for those already affected. The studies proposed here are novel, can be efficiently conducted using the Rochester Epidemiology Project, and are urgently needed.

CRITIQUE 1:

Significance: 1
Investigator(s): 1
Innovation: 1
Approach: 2
Environment: 1

Overall Impact: This renewal application for years 50-54 of this award seeks support to continue the Rochester Epidemiology Project (REP), conducted in Olmstead County, MN. The focus, or theme, of the research is multi-morbidity (multiple chronic conditions), which increasingly characterizes the aging U.S. population. The aims are (1) to identify and characterize people with differing levels of multi-morbidity using 7 cohorts defined by age across the life span; (2) to identify causes; and (3) outcomes of multi-morbidity; and (4) to make REP data available for sharing. The REP, which was begun in the 1960s, exploits the very high quality of the medical record system at the Mayo Clinic and other providers in Olmstead County, their linkage, and the low mobility and high level of willingness of the population to participate in clinical research. The REP has >6.8 million person years of observation and >525,000 individuals from a population-based sampling frame. This application has a number of important strengths, including an experienced multidisciplinary group of investigators, the importance both of multi-morbidity and of the unique data set for epidemiological research, strong publication record during the prior funding cycle, the size and longitudinality of the data set, its population-based sampling frame, a thoughtful data analysis plan, and a strong research environment. Minor limitations in the approach include a low level of race/ethnic diversity in the population and the lack of specific attention to psychiatric diseases as a cause of medical multi-morbidity. The overall impact of the proposed research is judged to be high.

1. Significance:

Strengths

- Uniqueness of the archival and current population data in the REP.
- Importance of multi-morbidity in the population.
- Ability of the REP to be used as a platform for studies not directly related to multi-morbidity.

Weaknesses

- None noted.

2. Investigator(s):

Strengths

- The principal investigator is Professor of Epidemiology and Neurology at the Mayo Clinic School of Medicine and a highly experienced investigator. He has been Director of the REP since 2006. He is very well qualified to lead the proposed research.
- The co-investigators are multi-disciplinary including clinical medicine, medical informatics, epidemiology, pharmacoepidemiology, biostatistics, and health services research. The investigator team is well qualified to conduct the proposed studies.

Weaknesses

- None noted.

3. Innovation:

Strengths

- The uniqueness of the REP makes epidemiological research in this setting innovative by its nature.
- Multi-morbidity is not a completely novel focus, but it is timely, important, and, because of the uniqueness of the REP, the proposed studies are innovative.
- The specific hypotheses regarding risk factors for multi-morbidity (e.g., obesity, smoking, alcohol) are not novel but are nonetheless appropriate in this context. As the investigators point out, no other comprehensive population-based data sets to address their hypotheses are available across age groups in the U.S.

Weaknesses

- None noted.

4. Approach:

Strengths

- Extensive experience with the data and the medical informatics and analytic methods by the investigator team.
- Very high level of research productivity in the REP (>2,300 publications since 1966).
- Very large data set with consequent statistical power.
- Population based sampling frame.
- Long term follow up on most people in the sample.
- Successful linkage of records into working analytic data structures.
- Addition of electronic drug prescribing data into the analytic database during the last funding cycle.
- Expansion of the included population to 11 counties during the last funding cycle.
- Availability and inclusion of health care utilization and expenditure data.

- Progress report indicates that the previous cycle supported publication of 261 papers and provided infrastructure for 23 other federally grants – a high level of productivity by any standard.
- A carefully thought out data analysis plan that takes into account limitations in some elements of the data set.
- Community engagement in governance and oversight of research uses of individually identifiable medical data.

Weaknesses

- Low level of race/ethnic and socioeconomic diversity in the REP. However, the investigators are aware of this limitation and describe studies previously reported by the REP addressing generalizability of findings.
- The investigators could consider psychiatric diseases as contributors to multi-morbidity both in terms of hypotheses and covariates, to a greater extent than they have in the application.
- With regard to aim 4, it is not entirely clear how outside users of the data will be able to conduct analyses if the data are available only at the level of clusters of n=30 or greater (a limitation necessary to protect confidentiality of individuals).

5. Environment:

Strengths

- The research environment is strong, well developed, and highly appropriate to the proposed research.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M1A - Minority and Non-minority, Acceptable

C1A - Children and Adults, Acceptable

Vertebrate Animals:

Not Applicable

Biohazards
Not Applicable

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2:

Significance: 1
Investigator(s): 1
Innovation: 3
Approach: 3
Environment: 2

Overall Impact: This is a renewal application requesting support for the Rochester Epidemiology Project (REP) that has supported the medical records-linkage system for residents of Olmsted County, MN, since 1966. The REP is an ideal environment to investigate multiple chronic illnesses as well as their causes and consequences; it captures varying information for all ages regardless of insurance status or health care setting (both inpatient and outpatient care). The investigative team proposes to identify groups of people with different levels of multi-morbidity across 7 age cohorts spanning the entire population and to study interactions across specific conditions (Aim 1). They will identify the causes (Aim 2) and the associated long-term adverse health outcomes (Aim 3). They also plan to develop an internet-based data sharing approach, thus making REP data electronically accessible to users worldwide through a Data Exploration Portal (Aim 4). This project has the potential to facilitate access to comprehensive and longitudinal REP data to the wider scientific community, enhancing ability of investigators worldwide to explore patterns of diseases, procedures, and drug prescriptions and their associations. Lack of well-developed engagement plan to ensure patients and stakeholders are involved in varying aspects of the project from conceptualization to dissemination of study findings.

1. Significance:

Strengths

- Investigators propose to utilize a comprehensive research infrastructure to define patterns of multi-morbidity and to study related causes and consequences in a well-characterized population.
- Investigators propose to develop an internet-based data exploration portal to allow clinicians and researchers to examine incidence of diagnoses, procedures, and drug prescriptions and to explore their interrelationships.

Weaknesses

- No significant weaknesses are noted.

2. Investigator(s):

Strengths

- A well-experienced team in the proposed area of study would work collaboratively to achieve project aims in an excellent research environment. The team has great access to population-based data to test proposed aims and adequate resources to support data analysis as well as tools to provide worldwide access to the REP data.

Weaknesses

- No significant concerns.

3. Innovation:

Strengths

- Description of patterns of prevalent multi-morbidity in a defined US population.
- Systematic study ofthe incidence and the severity of multi-morbidity across all ages.
- Identification of risk factors or predictors for incident multi-morbidity obtained from medical records using up to 20 years of follow-up data.
- Providing internet-based access to population-based, aggregated medical record.

Weaknesses

- No major weaknesses are noted.

4. Approach:

Strengths

- REP investigators who were supported in the previous cycle have produced 261 peer-reviewed publications and received 23 federally-funded grants.
- Use of cross-sectional analyses to assess prevalence and severity of multi-morbidity and discover possible interactions by identifying dyads and triads of conditions.
- Use longitudinal analyses to assess incidence and severity of multi-morbidity over 20 years of follow-up among adults with no baseline multi-morbidity and determination of whether multi-morbidity and specific disease combinations can predict long-term outcomes.
- Strong pilot results supporting testable hypotheses and adequate power estimations.
- Consideration of alternative approaches and limitations of proposed analytic methods.

Weaknesses

- Insufficient details regarding engagement plan to maximize dissemination of important findings in ‘hard-to-reach’ or vulnerable populations, where multi-morbidity is a significant concern.

5. Environment:

Strengths

- The environment is suitable to achieve the proposed aims.

Weaknesses

- No significant weaknesses are noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M1A - Minority and Non-minority, Acceptable

C1A - Children and Adults, Acceptable

Vertebrate Animals:

Not Applicable

Biohazards:

Acceptable

Budget and Period of Support:

Recommend as requested

CRITIQUE 3:

Significance: 7
Investigator(s): 3
Innovation: 8
Approach: 6
Environment: 3

Overall Impact: This group of experienced investigators proposes extension of the Rochester Epidemiology Project to explore multi-morbidity in terms of prevalence, risks factors/causes, and outcomes. The project has a number of strengths related to the ongoing REP database and the multiple cohorts it entails in terms of data collection, coverage, and breath for measures. The research team is strong but do not seem to have many, if any, publications directly addressing multi-morbidity risk or causes. However, it is likely the investigators will achieve their stated aims and make significant contributions to the literature given their history of productivity. However it is not clear whether the contributions will be in terms of understanding the ultimate causes that distinguish various patterns of multi-morbidity in their Rochester New York sample. In addition, there are a number of weaknesses not the least of which is the narrow scientific breadth of their aims. First, the unifying theme for collecting the breath of measures in the REP for the research is database seems to be the epidemiology of multi-morbidity. It is not clear why so much medical record data is required given the limited breadth of the aims in terms of describing multi-morbidity in terms of broad risk factos (e.g., obesity). In addition, the weakness of this theme is that it seems to be restricted itself to epidemiologic analysis (e.g., multi-morbidity survival analysis by well-studied risk factors). There is nothing scientifically nuanced in the approach with regard to understanding various mechanisms of causation both in measures described or analyses proposed, if any. Including study hypotheses linked to a mechanistic conceptual model would have been helpful in this R01 research proposal to provide discipline in terms of design and statistical analyses and hypothesis testing. Second, they fail to take advantage of the fact the REP is geographically well described and circumscribed. While they mention linking address data to census housing measures for SES characterization, these measures are appropriate from pediatric asthma but have questionable value for a multi-morbidity study where other more relevant social determinants associated with health disparities in CVD, diabetes, and HTN would be appropriate. There is an entire literature on this topic which is not considered. Third, only one of the listed principal and co-investigators has any claimed or listed experience in studying multi-morbidity causes and predictors in their biosketches. The majority describe their involvement as contributing to the development of the database. The application lists a number of “nonpaid” consultants who do have experience related to the study area. It is not clear what experts in psychiatry, dentistry, and pediatrics contribute given the

study described in the application. Finally, the homogeneity of population (i.e.,90% white) is a major weakness if the goal as it is described in the application is to be the authority on multi-morbidity of aging. Alternatively, justifying the use of this population because of interesting findings regarding the identification of new biologic mechanisms or potential causes that transcend race would have been helpful.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- Secondary data analysis

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Acceptable

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M1U - Minority and Non-minority, Unacceptable

C1A - Children and Adults, Acceptable

- Despite the inclusion of additional counties in the sample described the project failed to include sufficient minority participants to be generalizable to the US population.

Budget and Period of Support:

Recommend as requested

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

INCLUSION OF MINORITIES PLAN (Resume): UNACCEPTABLE
The committee suggested that low ethnic and racial diversity of the cohort limits generalizability of the study results.

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

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Population Sciences and Epidemiology Integrated Review Group
CENTER FOR SCIENTIFIC REVIEW
CASE
February 04, 2014

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* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.