Putting together the pieces of a Career Development Award

Allan J. Walkey, MD, MSc

Career Development Awards (CDA)

- NIH K series: K01, K08, K23
- AHRQ
- Foundation: RWJ, Doris Duke, AHA, ATS…
- Institutional: KL2

Start from the End

- How are “they” judging your application?

CRITIQUE 1:

Candidate: 1
Career Development Plan/Career Goals /Plan to Provide Mentoring: 1
Research Plan: 2
Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 1
Environment Commitment to the Candidate: 1

First, Readability

Additional Comments to Applicant:

- This application was truly a pleasure to read. Thank you.

- Grant reviewers will be reading many applications
- Make yours Easy, Simple and Clear!
- If they don't understand it…they won't fund it

When will you do it?

Table 2: Timeline

Activity	Year 1	Year 2	Year 3	Year 4	Year 5
Coursework	20%	20%	20%	10%	10%
Tutorial workshops/Seminars	3%	3%	3%	3%	3%
Mentor/Advisor Meetings (weekly, monthly)	10%	10%	10%	10%	10%
Local, National, International Scientific Meetings	2%	2%	2%	2%	2%
Aim 1					
Construct longitudinal Medicare 5% data set	20%				
Data analysis	20%	15%			
Prepare Manuscripts: e.g., [4]Long-term outcomes associated with new-onset atrial fibrillation during sepsis[2]		15%			
Aim 2					
Construct sepsis hospitalization practice pattern data sets		10%	20%		
Data analysis			10%	20%	
Prepare Manuscripts: e.g., [5]Practice patterns associated with the management of atrial fibrillation during sepsis[2]				15%	
Aim 3					
Data analysis				5%	20%
Prepare Manuscripts: e.g., [6]Outcomes associated with anticoagulation of atrial fibrillation during sepsis[2]					20%
R03 Submission, e.g., [3]Creation of a novel longitudinal critical care database[2]			10%	10%	
R01 Preparation, [1]Longitudinal Cohort Study of Risk factors for Cardiovascular Complications of Sepsis [2]					10%
Non K-Award Activities* (e.g., Clinical Service in the Medical Intensive Care Unit)	25%	25%	25%	25%	25%

■ = activity pending, □ = activity completed

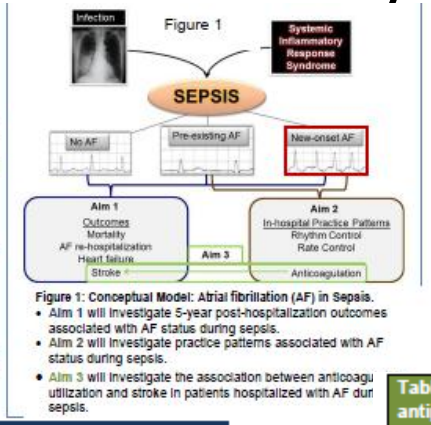
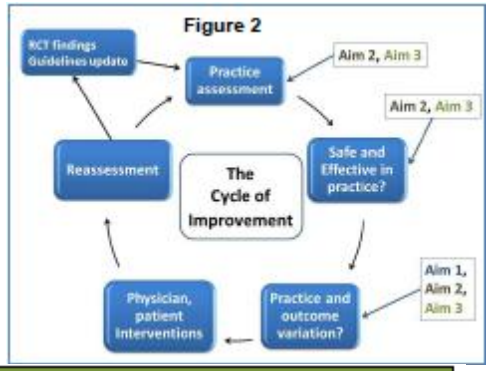


Figure 1: Conceptual Model: Atrial fibrillation (AF) in Sepsis.

- Aim 1 will investigate 5-year post-hospitalization outcomes associated with AF status during sepsis.
- Aim 2 will investigate practice patterns associated with AF status during sepsis.
- Aim 3 will investigate the association between anticoagu utilization and stroke in patients hospitalized with AF dur sepsis.



1.1. Significance: Aim 1

Large knowledge gaps exist regarding prognosis of patients with AF that occurs during sepsis. The long-term

1.2. Significance: Aim 2

1.3. Significance: Aim 3

The risk of developing a new stroke during sepsis appears to be elevated after new-onset AF[3] and systemic anticoagulation reduces the stroke risk in chronic AF in the community setting.[31] Thus, *we hypothesize that*

Table 6: Power calculations in Aim 3: Anticoagulation and antiplatelet agent as risk modifiers for In-hospital stroke during in patients with AF sepsis

Risk for In-hospital stroke in reference population	% Power to detect odds ratio of : 0.6	0.7	0.8
0.5%	89	64	32
1%	>99	90	56
2%	>99	>99	85

The 5 Judging Criteria

1. The Candidate
2. Career Development/Mentoring Plan
3. The Team: Mentors, Co-mentors, collaborators
4. Research Plan
5. Environment

1. The Candidate (you!)

- *Who are you* and *why do you want to do this*?

- There are 3 sections devoted to this ?
  1. Candidate Background
  2. NIH Biosketch
  3. Career Goals and Objectives

Candidate Background

- One page to summarize your past:
  - Why are you interested in this topic?

"I became interested in investigating AF during sepsis after observing…"

  - Key events on road leading to this moment

"My interest in epidemiology and comparative effectiveness research began soon after college…."

  - Why you can be successful

"…our multidisciplinary team has already produced high quality, novel investigations with direct clinical relevance…."

NIH Biosketch

- You will need one of these for any grant

NIH BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Allan J Walkey, MD, MSc	
eRA COMMONS USER NAME	Assistant Professor of Medicine
ALLAN.WALKEY@BMC.ORG	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(If applicable)*	YEAR(s)	FIELD OF STUDY
Tufts University	BA	1997	Psychology
University of Massachusetts Medical School	MD	2002	Medicine
Boston University School of Public Health	MSc	2010	Epidemiology
Beth Israel-Deaconess Medical Center, Harvard Medical School	-	2002-2005	Internal Medicine Internship and Residency
Boston Medical Center, Boston University School of Medicine	-	2006-2010	Pulmonary and Critical Care Medicine Fellowship
American Board of Internal Medicine Certifications	-	2006 2008 2009	Internal Medicine Pulmonary Medicine Critical Care Medicine

A. Personal Statement

I am a patient-oriented investigator with a deep commitment to improving outcomes of the critically ill. I have received prior training in the conduct of clinical research and clinical epidemiology through the Boston University Clinical Research Training Fellowship (CREST) and the Boston University School of Public Health. I have published 11 first-author manuscripts investigating methods to reduce complications associated with critical illness. In order to more fully reach my career goals of establishing an independent research program in critical care epidemiology and comparative effectiveness research, I seek new training in outcomes, health services, and observational comparative effectiveness research methods through a K01 Mentored Career Development Award. The goal of the proposed project is to continue to develop a research program investigating atrial fibrillation in sepsis under the mentorship of Drs. Emelia Benjamin and Lesley Curtis. As demonstrated with our manuscript "Incident Stroke and Mortality Associated with New-onset Atrial Fibrillation in Patients Hospitalized with Severe Sepsis" - which was recently published in *JAMA* - our research team has been productive. With the addition of Drs. Lindenauer and Nelson to the research team as sepsis outcomes research and statistical advisors, respectively, we seek to investigate long-term outcomes and compare effectiveness of treatment strategies for atrial fibrillation that occurs during sepsis. By the end of the Award period I will have gained skills necessary to achieve research independence and will have produced data that addresses large knowledge gaps in the care of patients with atrial fibrillation during sepsis.

B. Positions and Honors

Employment

Career Goals and Objectives

- Candidate background looks to the past…
- Career Goals and Objectives to the future
- One paragraph

"My career objective is to use specific skills gained through the K01 Mentored Career Development Award to …"

"The training and mentorship gained through conduct of my research proposal will provide me with…"

"as part of a future R01 application, I plan to…"

2. Mentoring/Career Development Plan

Career Development and Training During the Award Period

WHAT Will you be doing?

Table 1. Subject Domains in Relation to Training Objectives, Mechanisms, and Mentors

Subject domain	Training Objectives	Training Mechanisms	Relationship to Research	Mentors and Advisors
1. Advanced epidemiology training	+ Epidemiology of AF + Epidemiology of sepsis + Observational study design + Advanced methods of confounding adjustment + Study logistics	**Boston University School of Public Health (BUSPH)** • *EP 830 Drug epidemiology (fall Year 1)* • *EP 815 Epidemiologic Modeling (fall year 4)* **Boston University AF Affiliate Research Collaborative** • *Monthly multidisciplinary AF research meetings*	**Aim 1:** Appropriate design long-term outcomes of AF in sepsis **Aim3:** Appropriate confounding adjustment investigating association of anticoagulation to outcomes during sepsis	•EJB primary mentor •LHC co-mentor •PKL advisor
2. Advanced outcomes and health services research training	+ Expertise in strengths, weaknesses and management of large healthcare databases. + Methodology for using administrative data in outcomes, comparative effectiveness and health services research	**BUSPH** • *PM 821 Advanced Health Services Research Methods (summer Year 1)* • *PM 814 Contemporary Theoretical & Empirical Issues in Health Services (fall Year 2)* • *PM 855 Cost effectiveness and decision analysis (spring year 2)* **Center for Quality Care Research-Baystate Health Center** • *Quarterly outcomes and health services research meetings* **American Thoracic Society** • *Assembly on Behavioral Science yearly meetings* **American Heart Association** • *Quality of Care and Outcomes Research yearly Sessions* **PATH/AF** • *Bimonthly AF outcomes and health services research conference calls*	**Aim 1-3:** Appropriate selection and use of administrative claims data in evaluating outcomes and practice patterns associated with AF during sepsis.	•LC primary mentor, outcomes training •LHC, EJB co-mentors •PKL advisor for sepsis outcomes training
3. Advanced Biostatistical training	+ Data management + Advanced biostatistics	**BUSPH** • *BS 805 Intermediate Statistical Computing and Applied Regression Analysis(fall year 3)* • *BS 820 - Logistic Regression and Survival Analysis (spring year 3)* **US Critical Care and Injury Trials Group** • *Critical Care Informatics Working Group, yearly meetings*	**Aims 1-3:** Expand SAS programming skills to manage and merge large administrative datasets. Skills to appropriately select and carry out statistical analyses	•KPN primary advisor
4. Development	+ Leadership + Manuscript writing + Grant-writing + Mentoring network	**Boston University School of Medicine** • *Bimonthly Faculty Development Seminars* • *Early Career Faculty Development Program* • *Research Faculty retreat* • *Pulmonary Critical Care Clinical Epidemiology and Outcomes Group meetings* **American Thoracic Society** • *Young Academicians Committee*	**Aims 1-3:** Obtain skills to disseminate findings, obtain further funding, and collaborate in order to expand upon results of research program	•EJB primary mentor •LHC co-mentor

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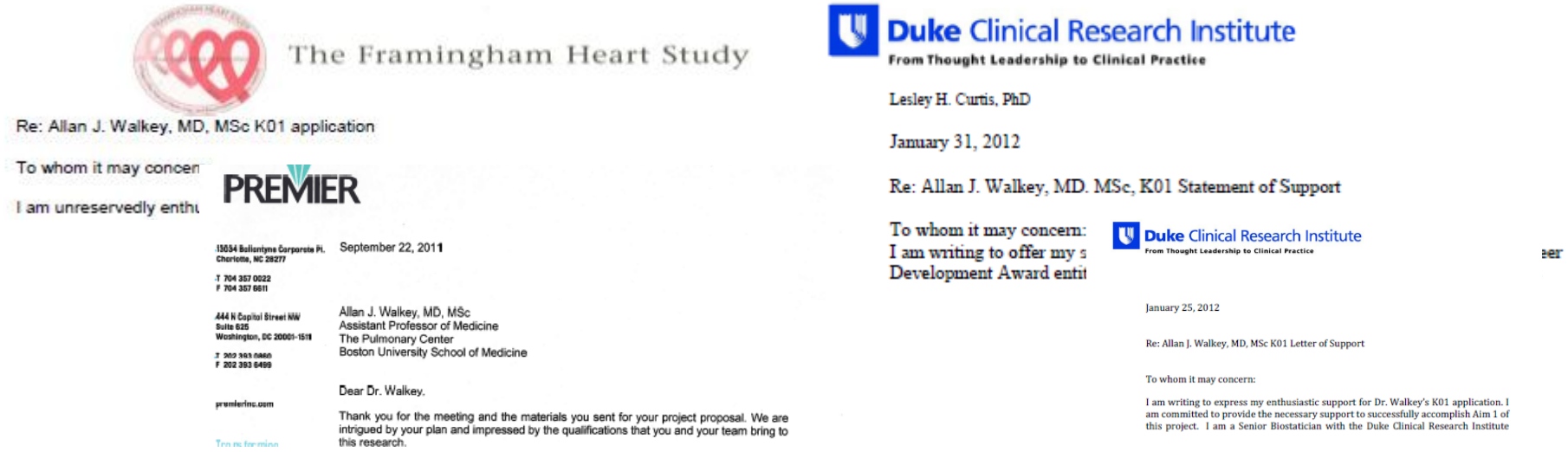
3. The Team

- A different criterion from mentorship plan!
- Thus **choice of your mentor(s) is the most important part of the K**: it's scored *twice*
- Mentors and collaborators need to write statements of support



The Framingham Heart Study

Re: Allan J. Walkey, MD, MSc K01 application

To whom it may concer

I am unreservedly enthu

PREMIER

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F 202 393 6499

premierinc.com

September 22, 2011

Allan J. Walkey, MD, MSc
Assistant Professor of Medicine
The Pulmonary Center
Boston University School of Medicine

Dear Dr. Walkey,

Thank you for the meeting and the materials you sent for your project proposal. We are intrigued by your plan and impressed by the qualifications that you and your team bring to this research.

Duke Clinical Research Institute
From Thought Leadership to Clinical Practice

Lesley H. Curtis, PhD

January 31, 2012

Re: Allan J. Walkey, MD. MSc, K01 Statement of Support

To whom it may concern:
I am writing to offer my s
Development Award entit

Duke Clinical Research Institute
From Thought Leadership to Clinical Practice

January 25, 2012

Re: Allan J. Walkey, MD, MSc K01 Letter of Support

To whom it may concern:

I am writing to express my enthusiastic support for Dr. Walkey's K01 application. I am committed to provide the necessary support to successfully accomplish Aim 1 of this project. I am a Senior Biostatician with the Duke Clinical Research Institute

Specific Aims

- The introduction to your Research Plan
- Paragraph to introduce your plan
- Bullets for each Aim

Aim 1: Determine 5-year post-hospitalization outcomes associated with new-onset AF during sepsis.
Hypothesis: Compared to patients with sepsis and no AF, sepsis survivors with new-onset AF are at increased long-term risk for AF re-hospitalization, heart failure, stroke, death, and increased healthcare costs.

We will use the Medicare 5% sample to characterize a cohort of patients hospitalized with sepsis and follow this cohort longitudinally for adjusted outcomes after a sepsis hospitalization, stratified by AF status.

- Paragraph to conclude
  - Why you can do this, where it lead

4. Research Plan

- What you will spend the most time on
- Remember, weighted same as other parts!
- Three Sections to Research Plan
  1. Significance
  2. Innovation
  3. Approach

Readability II

- Figures, Graphs, Tables are always better than Words

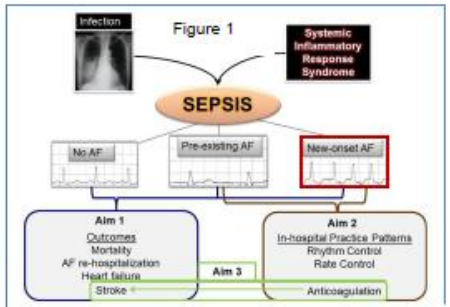
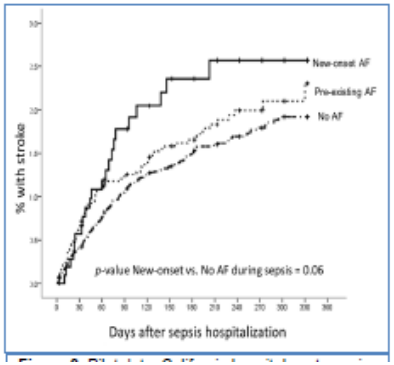


Figure 1: Conceptual Model: Atrial fibrillation (AF) in Sepsis.

- **Aim 1** will investigate 5-year post-hospitalization outcomes associated with AF status during sepsis.
- **Aim 2** will investigate practice patterns associated with AF status during sepsis.
- **Aim 3** will investigate the association between anticoagulation utilization and stroke in patients hospitalized with AF during sepsis.

- Have a Conceptual Model

- Use Figures from your past work to illustrate where you need to go next



Significance

- Why is your proposal important?

"The proposed research plan directly addresses the goals of the National Institutes of Health, National Heart Lung and Blood Institute Workshop on Research Directions…"

- This is where you put the basic epi/stats
- This is where you explain the knowledge gap you will address

"Projects such as ours that seek to decrease knowledge gaps regarding AF in sepsis have the potential for substantial public health impact. "

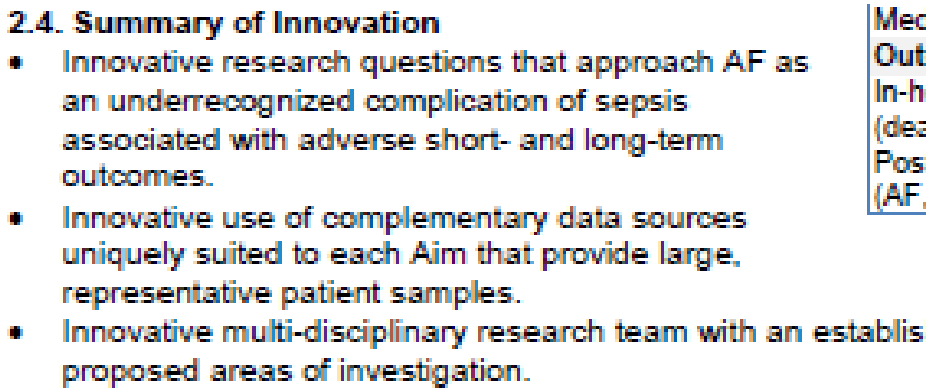
1.4. Summary of Significance:

- The proposed project addresses goals of the National Institutes of Health, National Heart Lung and Blood Institute Workshop on Research Directions on the Prevention of AF
- New-onset AF occurs in greater than 120,000 patients with sepsis/year
- New-onset AF during sepsis is likely associated with increased short-term mortality, stroke, hospital length of stay, and healthcare costs
- Large knowledge gaps exist regarding epidemiology, long-term prognosis and practice patterns associated with AF during sepsis
- Comparative effectiveness analyses of the association between practice patterns and prognosis in sepsis-associated AF will inform the design of clinical trials to improve prognosis of new-onset AF during sepsis.

Innovation

- Why is your proposal different?

"Our innovative proposal brings together a multi-disciplinary team with diverse clinical and research backgrounds to investigate novel questions using complementary data sources."



2.4. Summary of Innovation

- Innovative research questions that approach AF as an underrecognized complication of sepsis associated with adverse short- and long-term outcomes.
- Innovative use of complementary data sources uniquely suited to each Aim that provide large, representative patient samples.
- Innovative multi-disciplinary research team with an establis proposed areas of investigation.

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Approach

- What you **specifically** will be doing with the $
- For eac
  - Data
  - Hypo
  - How
  - POW

istical Plan

scenarios

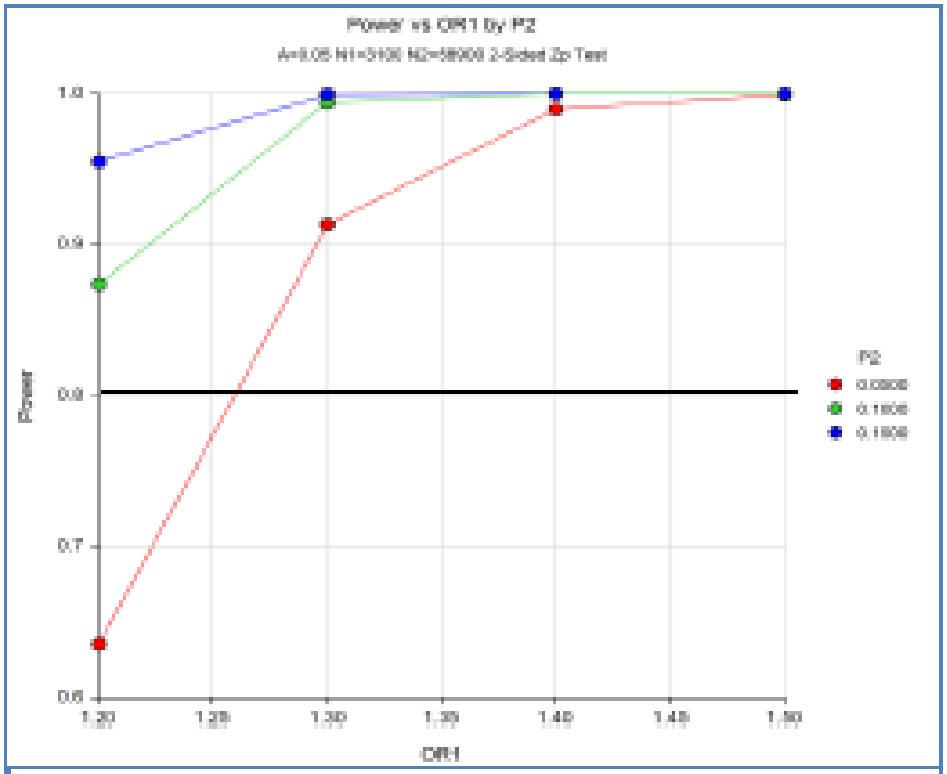

Figure 4: Power Aim 1, Red line = power at various odds ratios for stroke (~5% 5-year incidence), green= CHF and AF (~10% 5-year incidence), blue =death (~15% 5-year incidence)

Strengths and Limitations

- It is better that you, and not the Reviewer, identify the limitations
- Describe how you will address the limitations

"Confounding by indication: *we will pursue multiple methods to address confounding, but residual confounding by indication, unmeasured covariates, or unclear severity of measured covariates may be present. In manuscripts we will acknowledge that residual confounding cannot be excluded."*

Future Directions

- Where will the CDA take you?

"At the end of the 5-year Career Development Award, Dr. Walkey will have established a clinical epidemiology and observational comparative effectiveness research program investigating AF during sepsis."

- Be specific

"In order to further expand the research program, Dr. Walkey will also apply for R03 funding through the National Institute on Aging in year 3…"

"…data generated from the current proposal will lead to additional R01 applications in Year 5 to initiate…"

5. Environment

- Where will you be working?

10. Facilities & Other Resources

The facilities and resources of the Boston University School of Medicine Pulmonary Center will allow for successful completion of the proposed project. The Pulmonary

- Do your bosses support you!?

Boston University School of Medicine
The Pulmonary Center

Medical Campus
Housman Building
72 East Concord Street, R-304
Boston, Massachusetts 02118-2526
T 617-638-4860 F 617-536-8093

David M. Center, M.D.
Associate Provost,
Translational Research
Director, Boston University
Translational Science Institute
Gordon and Ruth Snider
Professor of Pulmonary Medicine
Chief, Pulmonary, Allergy,
and Critical Care Medicine

BOSTON UNIVERSITY

9. Institutional Commitment:

As Division Chairman, I will guarantee that over 75% of Dr. Allan Walkey's time will be protected

Conclusion

- CDAs are a microcosm of your future as a scientist:
  - Difficult, iterative work
  - Team-Building
  - Introspection
  - Organization
  - Clear presentation of ideas

Good Luck!

- alwalkey@bu.edu if you have questions