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

- 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?
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
Allan J. Walkay, MD, MSc

eRA COMMONS USER NAME
ALLAN.WALKAY@BMC.ORG

POSITION TITLE
Assistant Professor of Medicine

EDUCATION/TRAINING

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>YEAR(s)</th>
<th>FIELD OF STUDY</th>
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<tr>
<td>Tufts University</td>
<td>BA</td>
<td>1997</td>
<td>Psychology</td>
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<td>University of Massachusetts Medical School</td>
<td>MD</td>
<td>2002</td>
<td>Medicine</td>
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<tr>
<td>Boston University School of Public Health</td>
<td>MSc</td>
<td>2010</td>
<td>Epidemiology</td>
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<td>Beth Israel-Deaconess Medical Center, Harvard Medical School</td>
<td>-</td>
<td>2002-2005</td>
<td>Internal Medicine, Residency and Internship</td>
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<tr>
<td>Boston Medical Center, Boston University School of Medicine</td>
<td>-</td>
<td>2006-2010</td>
<td>Pulmonary and Critical Care Medicine, Fellowship</td>
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<tr>
<td>American Board of Internal Medicine Certifications</td>
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<td>2008</td>
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<td></td>
<td>-</td>
<td>2009</td>
<td>Critical Care Medicine</td>
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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. Emelie Benjamin and Leslie 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. Lindenauber 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
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>
<thead>
<tr>
<th>Subject domain</th>
<th>Training Objectives</th>
<th>Training Mechanisms</th>
<th>Relationship to Research</th>
<th>Mentors and Advisors</th>
</tr>
</thead>
</table>
| 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 80: 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  
Aim 2: Appropriate confounding adjustment investigating association of antibiotic use and outcomes during sepsis | EJS 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, computative 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 Research (Fall Year 2), PM 855 Cost effectiveness and decision analysis (Spring Year 3) | Aim 1: 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, EJS co-mentor, PKL advisor for sepsis outcomes training |
| 3. Advanced Biostatistical training        | Data management, Advanced biostatistics, Boston University School of Public Health | BS 805 Intermediate Statistical Computing and Applied Regression Analysis (Fall Year 3), BS 820: Logistic Regression and Survival Analysis (Spring Year 4), US Critical Care and Injury Trials Group, Critical Care Informatics Workshop, yearly meetings | Aim 1: Expand SAS programming skills to manage and merge large administrative datasets, Skills to appropriately select and carry out statistical analyses | KPIH primary advisor |
| 4. Development                              | Leadership, Manuscript editing, 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 | Aim 1: Obtain skills to disseminate findings, obtain further funding, and collaborate in order to expand upon results of research program | EJS primary mentor, LHC co-mentor |

**When will you do it?**

Table 2: Timeline

<table>
<thead>
<tr>
<th>Activity</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coursework</td>
<td>20%</td>
<td>20%</td>
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<td>20%</td>
<td>20%</td>
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<tr>
<td>Tutor workshops/Seminars</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
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<tr>
<td>Mentor/Advisor Meetings (weekly, monthly)</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>RAND, National, International Scientific Meetings</td>
<td>10%</td>
<td>20%</td>
<td>20%</td>
<td>20%</td>
<td>20%</td>
</tr>
<tr>
<td>Conduct longitudinal Medicare 5% data set</td>
<td>10%</td>
<td>20%</td>
<td>10%</td>
<td>20%</td>
<td>10%</td>
</tr>
<tr>
<td>Data analysis</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>Prepare Manuscript: e.g., Long-term outcomes associated with new-or old atrial fibrillation during sepsis</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>Conduct sepsis hospitalization practice pattern data sets</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
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<tr>
<td>Data analysis</td>
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<tr>
<td>Prepare Manuscript: e.g., Practice patterns associated with the management of sepsis and associated with the management of sepsis</td>
<td>10%</td>
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</tr>
</tbody>
</table>
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
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

- 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. “
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 established proposed areas of investigation.
Approach

- What you **specifically** will be doing with the $\$
- For each Aim, Describe in detail:
  - Data Sources
  - Hypotheses
  - How you will test the hypotheses/Statistical Plan
  - POWER CALCULATIONS under various scenarios
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 Center is located in the

• Do your bosses support you!?
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