

Non-Government Application for Re-Use of Massachusetts All-Payer Claims Data Extract [Exhibit A: Data Application]

I. INSTRUCTIONS

This form is required for all Applicants, except Government Agencies as defined in <u>957 CMR 5.02</u>, who wish to re-use Data received pursuant to a previously approved Data Application ("Extract"). If the applicant requires data not presently held by its Organization the applicant should not use this form. Re-use of All-Payer Claims Database data is limited to data released in Limited Data Set format (i.e., Release Versions 4.0 and later).

All attachments must be uploaded to IRBNet with your Application. All Application documents can be found on the <u>CHIA website</u> in Word and in PDF format or on <u>IRBNet</u> in Word format. If you submit a PDF document, please also include a Word version in order to facilitate edits that may be needed.

Applications will not be reviewed until the Application and all supporting documents are complete and the required application fee is submitted. A Fee Remittance Form with instructions for submitting the application fee is available on the CHIA website and IRBNet. A copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet.

II. ALL-PAYER CLAIMS DATABASE EXTRACT TO BE RE-USED			
Project Title: Evaluation of Massachusetts Medicaid ACO Program			
Extract Number:	301_HMS_Beaulieu		
IRBNet Number:	1197741-1		
Date of Data Use Agreement	Feb. 5, 2019		

III. ORGANIZATION AND INVESTIGATOR INFORMATION			
Project Title:	Risk Aversion, Fear of Malpractice, and Medical Decision Making in the		
	Emergency Department		
IRBNet Number:			
Organization Name:	Harvard Medical School		
Organization Website:	www.hms.harvard.edu		
Authorized Signatory for Organization Jonathan Eaton			
Title:	Senior Grants & Contracts Officer		
E-mail Address:			
Address, City/Town, State, Zip Code			
Primary Investigator:	Bruce Landon		
Title:	Professor of Medicine and Health Care Policy		
E-mail Address:	landon@hcp.med.harvard.edu		
Telephone Number:	617-432-3456		
Names of Co-Investigators:	Peter Smulowitz, Victor Novack, Linda Isbell		
E-mail Address of Co-Investigators:	psmulowi@bidmc.harvard.edu / victorno@clalit.org.il / lisbell@umass.edu		

January:	2017	v.1.	0
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IV. FEE INFORMATION	
IV. FEE INFORMATION	
1. Consult the Fee Schedule for All-Payer Claims Database data and select from the following options:	
⊠ Researcher	
□ Other	
□ Reseller	
2. Are you requesting a fee waiver?	
□ Yes	
□ Tes	
ino ino	
3. Compete and submit the <u>Fee Remittance Form</u> . If requesting a fee waiver, submit a letter stating the basis request (if required). Please refer to the <u>Fee Schedule</u> (effective Feb 1, 2017) for fee waiver criteria. (Please refee must be paid in order to re-use the Data, even if no new extract of data is required upon application approximately.	note that
V. PROJECT INFORMATION	
1. What will be the use of the CHIA Data requested? [Check all that apply]	
\square Epidemiological \square Health planning/resource allocation \square Cost trends	
·	
☐ Reference tool ☐ Research studies ☐ Severity index tool ☐ Control ☐ Contr	
☐ Surveillance ☐ Student research ☐ Utilization review of resources	
\square Inclusion in a product \square Other (describe in box below)	
 Provide a summary of the specific purpose and objectives of your Project. This may include research quest business use Projects. 	ons and/or
The proposed study will combine survey data from emergency medicine physicians and Advanced Practice EPs across Massachusetts with utilization data from an all payer claims database (which we will concombining Medicare claims data and the Massachusetts All Payer Claims Database) to determine the rebetween provider personality traits (risk aversion and Need for Cognitive Closure) and practice intensity (the of laboratory tests, imaging studies, and the frequency of hospital admission) for key clinical conditions. Finally, we will examine the relationship between practice intensity and patient harm, leveraging the fact the are randomly assigned to EPs. In addition to shedding light on a largely unexplored area of medical decision our findings will serve as the foundation for the development and implementation of behavioral interventiat guiding providers with different levels of risk tolerance to more standard management decisions or to the interface between risk aversion and the cognitive bias that may result.	elationship de number in the ED. at patients on-making, ons aimed

- 4. <u>Research Methodology</u>: Applicants must provide either the IRB protocol or a written description of the Project methodology (typically 1-2 pages), which should state the Project objectives and/or identify relevant research questions. This document must be included with the Application package on IRBNet and must provide sufficient detail to allow CHIA to understand how the Data will be used to meet objectives or address research questions.

VI. PUBLIC INTEREST

1. Briefly explain why completing your Project is in the public interest. Uses that serve the public interest under CHIA regulation include, but are not limited to: health cost and utilization analysis to formulate public policy; studies that promote improvement in population health, health care quality or access; and health planning tied to evaluation or improvement of Massachusetts state government initiatives.

This research will help untangle the reasons why different physicians/Advance Practice Providers in the ED have different practice styles, and to set the table for interventions aimed at reducing excessive variation in practice. This may have profound implications on both the cost and quality of healthcare delivered in Massachusetts EDs. Our proposed work focuses on risk aversion and the need for closure (NFC), two main personality traits that we suspect influences emergency physician practice styles. Our findings will help us develop key interventions to reduce the impact of these traits on medical decision-making. We also will be able to link patterns of testing to patient outcomes. From a larger policy perspective, untangling the relationship between risk aversion/NFC and practice intensity may help to support or refute the notion that large scale policy changes to reduce the exposure of emergency physicians to malpractice risk would result in substantial reduction in "defensive medicine" and health care spending. We plan to publish our results and share them broadly with state and federal health policy makers and healthcare organizations.

VII. DATASETS REQUESTED

The Recipient will use Data included in the Extract referenced above for use in this Project; no new Data will be released under this Application.

1. Specify below the dataset(s) and year(s) of data requested for this Project, and provide your justification for requesting *each* dataset.

⋈ Medical Claims

 \square 2011 \square 2012 \boxtimes 2013 \boxtimes 2014 \boxtimes 2015 \boxtimes 2016 \boxtimes 2017

Datasets → 2013-2017when available

Longitudinal medical claims data are needed to compute measures of utilization and outcomes at the patient level. These measures will be used to determine the association between provider personality traits and practice intensity, as well as between practice intensity and outcomes. Claims will be used to identify emergency room visits, the outcomes of visits, and for risk adjustment.

Exhibit A: CHIA Non-Government Application to Re-Use APCD Data	January 2017 v.1.0
☐ Pharmacy Claims	
Describer how your research objectives require Pharmacy Claims data:	
☐ Dental Claims	
□2011 □2012 □2013 □2014 □2015	
Describer how your research objectives require Dental Claims data:	
Describer how your research objectives require Member Eligibility data:	
, , , , , , , , , , , , , , , , , , , ,	
Member eligibility data will be crucial in identifying those who have been conti	nuously enrolled. Demographic data will
be important in controlling for patient characteristics.	
□ Provider □ Provider	
□2011 □2012 ⊠2013 ⊠2014 ⊠2015 ⊠2016 ⊠2017	
Describer how your research objectives require Provider data:	
Markill be achine as an add and the second and actions are second at the second at the second at the second at	ti Duraidan data (NDI asserbas and
We will be relying on provider data as a major component of our research q other identifiers) will be needed to link the survey results to the individual eme	•
other identifiers) will be fleeded to link the survey results to the marviadal effic	ergency provider's practice patterns.
⊠ Product	
□2011 □2012 ⊠2013 ⊠2014 ⊠2015 ⊠2016 ⊠2017	
Describer how your research objectives require Product data:	
•	
Product file will be used to control for insurance benefit design.	

Exhibit A: CHIA Non-Government APCD Data		January 2017 v.1.0			
2. If there are datasets that are included in the Extract that <u>are not</u> required for this Project indicate below.					
☐ Medical Claims☐ Provider	☐ Pharmacy Clai	ms 🗆 Denta	l Claims	☐ Member Eligibility	
3. If there are datasets will be segregated and			· · · · · · · · · · · · · · · · · · ·	r this Project, describe below how those datase	ets
VIII. DATA ELEMENTS F	REQUESTED				
State and federal privace specific Project objective	-	lease and use of	Data to the n	minimum amount of data needed to accomplis	h a
All-Payer Claims Database data is released in Limited Data Sets (LDS). Applicants receive the "Core" LDS, but may also request additional elements listed below for inclusion in their analyses. Requests for additional elements will be reviewed by CHIA to determine whether each represents the minimum data necessary to complete the specific Project objective.					
1. Specify below which elements you are requesting in addition to the "Core" LDS and provide your justification for requesting <u>each</u> element.					
Geographic Data					
The geographic sub-divisions listed below are available for Massachusetts residents and providers only. Choose <u>one</u> of the following geographic options. [Extracts with 5 digit zip code, have been filter to remove all claims that include a substance abuse diagnosis or treatment.]					
☐ 3-Digit Zip Code (sta	ndard)		⊠ 5-Digit 7	Zip Code***	
		uesting 5-Digit Zip	Code. Refer t	to specifics in your methodology:	
Dates Choose <u>one</u> option from	n the following opt	ions for dates:			
☐ Year (YYYY) (Standar	rd)	☐ Month (YYYYI	ММ) ***	□ Day (YYYYMMDD) *** [for selected data elements only]	
*** If requested, provide	justification for req	uesting Month or	Day. Refer to	o specifics in your methodology:	

Exhibit A: CHIA Non-Government Appli	cation to Re-Use APCD Data	January 2017 v.1.0
Day will be required to determine utiliz visit, and to adequately track 7 and 30 (nstream outpatient testing done after an ED
National Provider Identifier (NPI)		
Choose <u>one</u> of the following options for	National Provider Identifier(s):	
☐ Encrypted National Provider Identifi	er(s) (standard) 🗵 Decrypt	ed National Provider Identifier(s)***
*** If requested, provide justification for methodology:		
We need decrypted National Provider NPI number) with the actual provider u		urvey data (which will have the unique provider
2. If there are data elements that are ir	icluded in the Extract that <u>are not</u>	required for this Project indicate below.
☐ 5-Digit Zip Code ☐ Month (YYY	YMM) 🗆 Day (YYYYMMDD)	☐ Decrypted National Provider Identifier(s)
3. If there are data elements included in elements will be segregated and protection	-	d for this Project, describe below how the data
IX. MEDICAID DATA		
1. Is Medicaid Data included in the Extr	act?	
2. Indicate whether you are seeking to	use Medicaid Data for this Project	t:

3. Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are directly connected to the administration of the Medicaid program. If you are requesting Medicaid Data, please describe, in the space below, why your use of the data meets this requirement. Requests for Medicaid data will be forwarded to MassHealth for a determination as to whether the proposed use of the data is directly connected to the

and the purpose for each linkage.

administration of the Medicaid program. This may introduce significant delays in the receipt of Medicaid Data. *Recipient may not use the Medicaid data for the new Project until Recipient is notified of MassHealth approval.*

Medicaid data are essential for the evaluation of patterns of health care utilization and for generalizability of our results. It will be important to determine if patterns of utilization or outcomes differ for Medicaid patients. Our study will assess the relationship between key physician personality traits of ED physicians and their practice patterns in the ED. We will identify whether personality traits are associated with the propensity to admit patients and, in future work, will develop interventions to address such unwarranted variation. Decreasing unnecessary admissions from the ED could be useful to the state Medicaid program and to ACOs participating in Medicaid that are looking to identify opportunities for savings that will not have negative consequences for outcomes.
4. If the Extract contains Medicaid Data and you are not seeking to use Medicaid Data for this Project, or this Application is not approved by MassHealth, describe below how Medicaid Data will be segregated and protected from use in this Project.
X. DATA LINKAGE AND FURTHER DATA ABSTRACTION
A. DATA LINKAGE AND FORTHER DATA ADSTRACTION
Data linkage involves combining CHIA Data with other data to create a more extensive database for analysis. Data linkage is typically used to link multiple events or characteristics within one database that refer to a single person within CHIA Data.
1. Do you intend to link or merge CHIA Data to other data? ☑ Yes
\square No linkage or merger with any other data will occur
 2. If yes, please indicate below the types of data to which CHIA Data will be linked. [Check all that apply]
3. If yes, describe the dataset(s) to which the CHIA Data will be linked, indicate which CHIA data elements will be linked.

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Providers and facilities will be linked to the NPPES (NPI), Medicare's Physician Compare National Downloadable File (provider gender, years since medical school graduation, specialty, academic degree, foreign vs U.S. medical graduate, and graduation from a medical school ranked among the top 20 research schools in US News and World Report in 2013), and to AHA survey data (for hospital characteristics). The purpose of linking these files is to obtain characteristics of providers (both individual and institutional) that may influence patterns of health care utilization. We also will link patient zip codes to census data to obtain aggregated socio-economic characteristics of individuals living in the zip code. Finally, we will be linking data from our survey on physician personality traits to individual providers using NPI number. We will not identify individual physicians in any analysis.

4. If yes, for each proposed linkage above, please describe your method or selected algorithm (e.g., deterministic or probabilistic) for linking each dataset. If you intend to develop a unique algorithm, please describe how it will link each dataset.

We will first attempt to link providers and facilities using government IDs (deterministic). In cases where this linkage fails, we will use fuzzy matching techniques to match on names and addresses (probabilistic). We will map zip codes directly to Census data (deterministic).

5. If yes, please identify the specific steps you will take to prevent the identification of individual patients in the linked dataset.

Identification of individual patients may occur at two junctures. First, in the context of the analyses, in very sparsely populated zip codes, it may be possible to use the linked data in combination with additional data available on the web to identify individual patients. Investigators have been trained and certified in human subjects research and ethics and understand this is a violation of patient privacy. The second juncture is at the presentation and publication of research results. All research results will be aggregated to a level that would make it impossible to identify individual patients. No ZIP code data will be display or published and will be stripped from analytic file after linkage with census data and computation of travel distance calculations. A randomly-assigned ID will be used in place of zip codes for fixed-effect estimations.

XI. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from CHIA Data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting. Any and all publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how

formulas that will result in the display of a cell less than 11.
We have no plans to use or otherwise disclose CHIA data directly other than those noted above.
2. Do you anticipate that the results of your analysis will be published and/or made publically available? If yes, describe how an interested party will obtain your analysis and, if applicable, the amount of the fee, that the third party must pay.
3. Will you use CHIA Data for consulting purposes?☐ Yes☒ No
 4. Will you be selling standard report products using CHIA Data? ☐ Yes ☒ No
5. Will you be selling a software product using CHIA Data? ☐ Yes ☑ No
6. Will you be reselling CHIA Data in any format? ☐ Yes ☑ No
If yes, in what format will you be reselling CHIA Data (e.g., as a standalone product, incorporated with a software product, by a subscription, etc.)?
7. If you have answered "yes" to questions 4, 5 or 6, please describe the types of products, services or studies.

you will ensure that any publications will not disclose a cell less than 11, and percentages or other mathematical

Exhibit A: CHIA Non-Government Application to Re-Use APCD Data	January 2017 v.1.0
8. If you have answered "yes" to questions 4, 5, or 6, what is the fee you will charstudies?	ge for such products, services or
XII. APPLICANT QUALIFICATIONS	
1. Describe your previous experience using claims data. This question should be	answered by the primary investigator
and any co-investigators who will be using the Data.	
Investigators Landon, Smulowitz, and Novack each have years of experience wo	rking with claims data., including many
years of working with similar claims data from the Medicare program and privat	
Dr. Landon and Dr. Smulowitz are currently working on an AHRQ funded study (predictors of variation in admission rates from the ED and the extent to which t matters as a determinant of variation.	-
Dr. Landon has extensive experience working with claims datasets, including the Massachusetts APCD to study the consequences of insurance switching on care insurance design on referral use.	
Dr. Smulowitz has current experience with Medicare claims and previously work data to explore the impact of Massachusetts health reform on ED use.	ked with Massachusetts administrative
Dr. Novack's main clinical and research interest is clinical epidemiology and adm published extensively in the area of clinical epidemiology utilizing a number of la Clalit Health Services (Israel; the second largest HMO in the world), MIMIC data hospital claims data.	arge administrative databases such
Dr. Isbell is mainly supporing this work with her expertise is social psychology a the claims data.	nd will not be working directly with

2. <u>Resumes/CVs</u>: If not submitted with a prior approved Application, when submitting your Application package on IRBNet, include résumés or curricula vitae of the principal investigator and co-investigators. (These attachments will not be posted on the internet.)

XIII. USE OF AGENTS AND/OR CONTRACTORS

AGENT/CONTRACTOR #2

Please note: By signing this Application, the Organization assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors.

Provide the following information for all agents and contractors who will have access to the CHIA Data. [Add agents or contractors as needed.]

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	
Company Website:	
Contact Person:	
Title:	
E-mail Address:	
Address, City/Town, State, Zip Code:	
Telephone Number:	
Term of Contract:	
1. Describe the tasks and products assignated completing the tasks.	ed to the agent or contractor for this Project and their qualifications for
	and monitoring of the activities and actions of the agent or contractor for this vill ensure the security of the CHIA Data to which the agent or contractor has
3. Will the agent or contractor have accesoff-site server and/or database? ☐ Yes ☐ No	ss to or store the CHIA Data at a location other than the Organization's location,
4. If yes and a Data Management Plan for Data Management Plan <u>must</u> be complet	this agent or contractor is not part of the Data Use Agreement, a separate ed by the agent or contractor.

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INFORMATION	
Company Name:	
Company Website:	
Contact Person:	
Title:	
E-mail Address:	
Address, City/Town, State, Zip Code:	
Telephone Number:	
Term of Contract:	
 Describe the tasks and products assign completing the tasks. 	ed to the agent or contractor for this Project and their qualifications for
_	and monitoring of the activities and actions of the agent or contractor for this vill ensure the security of the CHIA Data to which the agent or contractor has
off-site server and/or database?	ss to or store the CHIA Data at a location other than the Applicant's location,
☐ Yes	
□ No	
4. If yes and a Data Management Plan for	this agent or contractor is not part of the Data Use Agreement, a separate

XIV. ATTESTATION

By submitting this Application, the Organization attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* confirms that it is compliant with such use, privacy and security standards. The Organization further agrees and understands that it is solely responsible for any breaches or unauthorized access, disclosure or use of CHIA Data, including, but not limited to, any breach or unauthorized access, disclosure or use by its agents.

The Organization's use of the Data for this Project will be governed by the executed Data Management Plan(s), Data Use Agreement, and any Amendment thereto.

By my signature below, I attest: (1) to the accuracy of the information provided herein; (2) that the requested Data is the minimum necessary to accomplish the purposes described herein; (3) that the Organization will meet the data privacy and security requirements described in this Application and supporting documents, and will ensure that any third party with access to the Data meets the data use, privacy and security requirements; and (4) to my authority to bind the Organization.

Signature: (Authorized Signatory for Organization)		
Printed Name :		
<u>Attachments</u>		
A completed Application must have the fo	ollowing documents attached to the Application:	
\square 1. IRB approval letter and protocol (if a	applicable)	
\square 2. Research Methodology (if protocol i	s not attached)	
\square 3. CVs of Investigators (if not submitted	ed previously)	
□ 5. Data Use Agreement		

Applications will not be reviewed until they are complete, including all attachments. Applicant may not use the Extract for this Project until CHIA approval and the execution of an amendment to the Recipient's Data Use Agreement.

TRACKING TABLE (to be completed by CHIA staff only)		
Complete Application Received		
Application Fee Received		
Data Privacy Committee Review		
Data Release Committee Review		
Linkages Approved (as described)		
Executive Director Approval		
Data Fee Received		
Data of First Audit		
IT Extract #		



Application for Massachusetts Case Mix and Charge Data (Non-Government) [Exhibit A – Data Application]

I. INSTRUCTIONS

This form is required for all Applicants, Agencies, or Organizations, hereinafter referred to as "Organization", except Government Agencies as defined in <u>957 CMR 5.02</u>, requesting protected health information. All Organizations must also complete the <u>Data Management Plan</u>, and attach it to this Application. The Application and the Data Management Plan must be signed by an authorized signatory. This Application and the Data Management Plan will be used by CHIA to determine whether the request meets the criteria for data release, pursuant to 957 CMR 5.00. Please complete the Application documents fully and accurately. Prior to receiving CHIA Data, the Organization must execute CHIA's <u>Data Use Agreement</u>. Organizations may wish to review that document prior to submitting this Application.

Before completing this Application, please review the data request information on CHIA's website:

- Data Availability
- Fee Schedule
- Data Request Process

After reviewing the information on the website and this Application, please contact CHIA at <u>casemix.data@state.ma.us</u> if you have additional questions about how to complete this form.

The Application and all attachments must be uploaded to <u>IRBNet</u>. All Application documents can be found on the <u>CHIA</u> website.

Information submitted as part of the Application may be subject to verification during the review process or during any audit review conducted at CHIA's discretion.

Applications will not be reviewed until the Application and all supporting documents are complete and the required application fee is received.

A <u>Fee Remittance Form</u> with instructions for submitting the application fee is available on the CHIA website. If you are requesting a fee waiver, a copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet. Please be aware that if your research is funded and under that funding you are required to release raw data to the funding source, you may not receive CHIA Data.

II. FEE INFORMATION

- 1. Consult the most current Fee Schedule for Case Mix and Charge Data.
- 2. After reviewing the Fee Schedule, if you have any questions about the application or data fees, contact casemix.data@state.ma.us.
- 3. If you believe that you qualify for a fee waiver, complete and submit the <u>Fee Remittance Form</u> and attach it and all required supporting documentation with your application. Refer to the <u>Fee Schedule</u> (effective Feb 1, 2017) for fee waiver criteria.
- 4. Applications will not be reviewed until the application fee is received.
- 5. Data for approved Applications will not be released until the payment for the Data is received.

III. ORGANIZATION & INVESTIGATOR INFORMATION

Project Title:	Risk Aversion, Fear of Malpractice, and Medical Decision Making in the Emergency Department
IRBNet Number:	Need this
Organization Requesting Data (Recipient):	Harvard Medical School
Organization Website:	www.hms.harvard.edu
Authorized Signatory for Organization:	Jonathan Eaton
Title:	Senior Grants & Contracts Officer
E-Mail Address:	jonathan_eaton@hms.harvard.edu
Telephone Number:	617 432-1596
Address, City/Town, State, Zip Code:	25 Shattuck Street, Boston, MA 02115
Data Custodian:	Laurence Zaborski
(individual responsible for organizing, storing, and archiving	
Data)	
Title:	Senior Programmer
E-Mail Address:	zaborski@hcp.med.harvard.edu
Telephone Number:	617-432-4904
Address, City/Town, State, Zip Code:	180A Longwood Avenue, Boston, MA 02115
Primary Investigator (Applicant):	Bruce Landon
(individual responsible for the research team using the Data)	
Title:	Professor of Medicine and Health Care Policy
E-Mail Address:	landon@hcp.med.harvard.edu
Telephone Number:	617-432-3456
Address, City/Town, State, Zip Code:	Peter Smulowitz, Victor Novack, Linda Isbell
Names of Co-Investigators:	psmulowi@bidmc.harvard.edu
	victorno@clalit.org.il
	lisbell@umass.edu
E-Mail Addresses of Co-Investigators:	psmulowi@bidmc.harvard.edu
	victorno@clalit.org.il
	lisbell@umass.edu
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IV. PROJECT INFORMATION

IMPORTANT NOTE: Organization represents that the statements made below as well as in any study or research protocol or project plan, or other documents submitted to CHIA in support of the Data Application are complete and accurate and represent the total use of the CHIA Data requested. Any and all CHIA Data released to the Organization under an approved application may ONLY be used for the express purposes identified in this section by the Organization, and for <u>no</u> other purposes. Use of CHIA Data for other purposes requires a separate Data Application to CHIA written request to CHIA, with approval being subject to CHIA's regulatory restrictions and approval process. Unauthorized use is a material violation of your institution's Data Use Agreement with CHIA.

1. What will be the use of the CHIA Data requested? [Check all that apply]		
	☐ Health planning/resource allocation	□Cost trends

Exhibit A: CHIA Non-Government Case Mix and Charge Data Application March 2020			March 2020
☑ Longitudinal Research☐ Reference tool☐ Surveillance☐ Inclusion in a product	 ☐ Quality of care assessment ☑ Research studies ☐ Student research ☐ Other (describe in box below) 	☐ Rate setting ☐ Severity index tool (or other d ☐ Utilization review of resource	* /
Click here to enter text.			
include the research questions a report that will be derived from pertinent literature with citation. The proposed study will construct by Database) as well as the "between provider personal intensity (the number of lal for key clinical conditions in intensity and patient harm, to shedding light on a large the foundation for the development of the devel	ammary of the specific purpose and objud/or hypotheses the Project will attem the requested data and how this products, if applicable. In the survey data from emerge ross Massachusetts with utilization combining Medicare claims data casemix" data on emergency rocality traits (risk aversion and Need boratory tests, imaging studies, and the ED. Finally, we will examinately unexplored area of medical delopment and implementation of less of risk tolerance to more stantween risk aversion and the cognitive stantage.	pt to address, or describe the intend t will be used. Include a brief summer or many medicine physicians and a property of the Massachusetts All Form utilization to determine the for Cognitive Closure) and property of hospital are the relationship between property are randomly assigned to EP ecision-making, our findings woo behavioral interventions aimed dard management decisions of the summer of the summ	Advanced ns database Payer Claims relationship ractice admission) actice s. In addition will serve as d at guiding
⊠ Yes [If yes, a copy of the app	Board (IRB) reviewed your Project? Proval letter and protocol <u>must</u> be inclused subject research and does not require I		n IRBNet.]
methodology (typically 1-2 pag This document must be included	plicantions must include either the IRB es), which should state the Project object with the Application package on IRB ata will be used to meet objectives or act	ctives and/or identify relevant resea Net and must provide sufficient deta	rch questions.

V. PUBLIC INTEREST

1. Briefly explain why completing this Project is in the public interest. Use quantitative indicators of public health importance where possible, for example, numbers of deaths or incident cases; age-adjusted, age-specific, or crude rates; or years of potential life lost. Uses that serve the public interest under CHIA regulations include, but are not limited to: health cost and utilization analysis to formulate public policy; studies that promote improvement in population health, health care quality or access; and health planning tied to evaluation or improvement of Massachusetts state government initiatives.

This research will help untangle the reasons why different physicians/Advance Practice Providers in the ED have different practice styles, and to set the table for interventions aimed at reducing excessive variation in practice. This may have profound implications on both the cost and quality of healthcare delivered in Massachusetts EDs. Our proposed work focuses on risk aversion and the need for closure (NFC), two main personality traits that we suspect influences emergency physician practice styles. Our findings will help us develop key interventions to reduce the impact of these traits on medical decision-making. We also will be able

to link patterns of testing to patient outcomes. From a larger policy perspective, untangling the relationship between risk aversion/NFC and practice intensity may help to support or refute the notion that large scale policy changes to reduce the exposure of emergency physicians to malpractice risk would result in substantial reduction in "defensive medicine" and health care spending. We plan to publish our results and share them broadly with state and federal health policy makers and healthcare organizations.

VI. DATASETS REQUESTED

The Massachusetts Case Mix ("Case Mix") are comprised of Hospital Inpatient Discharge, Emergency Department and Outpatient Hospital Observation Stay Data collected from Massachusetts' acute care hospitals, and satellite emergency facilities. Case Mix Data are updated each fiscal year (October 1 – September 30) and made available to approved data users. For more information about Case Mix Data, including a full list of available elements in the datasets please refer to release layouts, data dictionaries and similar documentation included on CHIA's website.

Data requests are typically fulfilled on a one time basis, however; certain Projects may require years of data not yet available. Applicants who anticipate a need for future years of data may request to be considered for a subscription. Approved subscriptions will receive, upon request, the <u>same data files and data elements</u> included in the initial release annually or as available. Please note that approved subscription request will be subject to the Data Use Agreement, will require payment of fees for additional Data, and subject to the limitation that the Data can be used only in support of the approved Project.

1. Please indicate below whether this is a one-time request, or if the described Project will require a

subscription.
oximes One-Time Request OR $oximes$ Subscription
2. Specify below the dataset(s) and year(s) of data requested for this Project, and your justification for requesting <i>each</i> dataset. Data prior to 2004 is not available.
☐ Hospital Inpatient Discharge Data
2017 ⊠2018 ⊠2019
Describe how your research objectives require Inpatient Discharge data:
Click here to enter text.
☐ Outpatient Hospital Observation Stay Data
2017 ⊠2018 ⊠2019
Describe how your research objectives require Outpatient Hospital Observation Stay data:
Click here to enter text.
Emergency Department Data
2017 ⊠2018 ⊠2019
Describe how your research objectives require Emergency Department data:

The primary focus of our research is to study the relationship between physician personality traits (that we are collecting via survey) and management decisions (specifically the decision to admit a patient) in the ED. We thus require ED data for this research proposal.

VII. DATA ENHANCEMENTS REQUESTED

State and federal privacy laws limit the release and use of Data to the minimum amount of data needed to accomplish a specific Project objective.

Case Mix Data are released in Limited Data Sets (LDS). All applicants receive the "Core" LDS, but may also request the data enhancements listed below for inclusion in their analyses. Requests for enhancements will be reviewed by CHIA to determine whether each represents the minimum data necessary to complete the specific Project objective.

For a full list of elements in the release (i.e., the "Core" elements and enhancements), please refer to <u>release layouts</u>, <u>data dictionaries</u> and similar documentation included on CHIA's website.

Please note that CHIA Case Mix Data contain reports produced using proprietary computer software created, owned, and licensed by the 3M Company. All Copyrights in and to the 3M APRTM Software, and to the 3M APRTM DRG classification system(s) (including the selection, coordination and arrangement of all codes) are owned by 3M. All rights reserved.

1. Specify below which enhancements you are requesting in addition to the "Core" LDS. CHIA will use this information to determine what Level of data is needed for pre-FY 2015 data requests.

Geographic Subdivisions

State, five-digit zip code, and 3-digit code are available for patients residing in CT, MA, ME, NH, RI, VT, and NY. City or Town of residence is available for residents of MA only. States outside of this region will be coded as XX ("Other").

Select *one* of the following options:

☐ 3-Digit Zip Code	☐ 3-Digit Zip Code &	⊠ 5-Digit Zip Code	☐ 5-Digit Zip Code &
(Standard)	City/Town ***	***	City/Town ***
***If requested, pro	vide justification for reque	sting 5-Digit Zip Code o	or City/Town. Refer to specifics
in your methodology	7:		
We will be using 5-di	git zip code to impute socio-	demographic characteris	tics (using census data).
Demographic Data			
Selcect <u>one</u> of the follo	wing options:		
☐ Not Requested (Sta	andard)	□ Race & Ethnicity**	**
** If requested, prov	vide justification for reques	ting Race and Ethnicity	. Refer to specifics in your
methodology:			
We plan to include ra	ce/ethnicity in statistical mod	dels as there is a relations	ship between race/ethnicity and the
likelihood of admission. We also will perform stratified analyses by race.			

Date Resolution			
Select <u>one</u> of the following option	s for dates of admission	ns, discharges,	, and significant procedures.
☐ Year (YYYY)(Standard)	☐ Month (YYYYMN	M) ***	☐ Day (YYYYMMDD)***
***If requested, provide justifi	cation for requesting	Month or Da	y. Refer to specifics in your
methodology:			
		n the ED (by n	natching to the other files) as well as 7
and 30 day outcome measures su	ich as ED revisits.		
D C X1 CC CIDY			
Practioner Identifiers (UPN)			
Select <u>one</u> of the following option	S.		
☐ Not Requested (Standard)	⊠ Hashed ID ***		⊠ Board of Registration in Medicine
			Number(BORIM) ***
***If requested, provide justif	ication for requesting	Hashed ID o	or BORIM Number. Refer to specifics
in your methodology:			
	dentifiers (that we can l	ink to NPI) in	order to link our survey data with the
provider utilization data.			
Unique Health Information Numb	er (UHIN)		
Select one of the following option	S.		
☐ Not Requested (Standard)		UHIN Reques	
			r to specifics in your methodology: nk patients among the 3 datasets we are
requesting access to.	inne ii mere were ED revisii	is as well as to in	nk patients among the 3 datasets we are
1 0			
II 1 1 1 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2	NT 1		
Hashed Mother's Social Security Select <i>one</i> of the following option			
Select <u>one</u> of the following option			
□ Not Requested (Standard)		Hashed Mothe	er's SSN Requested ***
	ication for requesting	Hashed Mot	her's SSN. Refer to specifics in your
methodology:			
Click here to enter text.			

VIII. DATA LINKAGE

Data linkage involves combining CHIA Data with other data to create a more extensive database for analysis. Data linkage is typically used to link multiple events or characteristics within one database that refer to a single person within CHIA Data.

1. Do you intend to link or merge CHIA Data to other data?	
⊠ Yes	
☐ No linkage or merger with any other data will occur	
2. If yes, please indicate below the types of data to which CHIA Data will be linked. [Check all that apply]	
☐ Individual Patient Level Data (e.g. disease registries, death data)	
☐ Individual Provider Level Data (e.g., American Medical Association Physician Masterfile)	
☐ Individual Facility Level Data (e.g., American Hospital Association data)	
⋈ Aggregate Data (e.g., Census data)	
☐ Other (please describe):	

3. If yes, describe the dataset(s) to which the CHIA Data will be linked, indicate which CHIA Data elements will be linked and the purpose for each linkage.

Providers and facilities will be linked to the NPPES (NPI), Medicare's Physician Compare National Downloadable File (provider gender, years since medical school graduation, specialty, academic degree, foreign vs U.S. medical graduate, and graduation from a medical school ranked among the top 20 research schools in US News and World Report in 2013), and to AHA survey data (for hospital characteristics). The purpose of linking these files is to obtain characteristics of providers (both individual and institutional) that may influence patterns of health care utilization. We also will link patient zip codes to census data to obtain aggregated socioeconomic characteristics of individuals living in the zip code. Finally, we will be linking data from our survey on physician personality traits to individual providers using NPI number. We will not identify individual physicians in any analysis.

4. If yes, for each proposed linkage above, please describe your method or selected algorithm (e.g., deterministic or probabilistic) for linking each dataset. If you intend to develop a unique algorithm, please describe how it will link each dataset.

We will first attempt to link providers and facilities using government IDs (deterministic). In cases where this linkage fails, we will use fuzzy matching techniques to match on names and addresses (probabilistic). We will map zip codes directly to Census data (deterministic).

5. If yes, attach or provide below a complete listing of the variables from <u>all sources</u> to be included in the final linked analytic file.

NPI: will link to the original survey data to measure personality traits (including scales for risk aversion, fear of malpractice, and need for closure); from physician compare includes provider gender, years since medical school graduation, specialty, academic degree, foreign vs U.S. medical graduate, and graduation from a medical school ranked among the top 20 research schools in US News and World Report in 2013.. Hospitals: number of beds (< 100, 100-199, 200-499, ≥ 500), ownership (public/municipal, for-profit, non-profit), teaching status (major teaching, minor teaching, non-teaching), urban/rural (urban, large rural, small rural), quartiles of Medicare and Medicaid admissions, ED volume, and technology index.

County (ARF) or Area level (HRR): acute care hospital bed supply per 1,000 residents, per capita income, primary care physicians per 100,000 residents, percentage of persons less than age 65 without health insurance, and percentage of Medicare beneficiaries who are dual eligible.

6. If yes, please identify the specific steps you will take to prevent the identification of individual patients in the linked dataset.

Identification of individual patients may occur at two junctures. First, in the context of the analyses, in very sparsely populated zip codes, it may be possible to use the linked data in combination with additional data available on the web to identify individual patients. Investigators have been trained and certified in human subjects research and ethics and understand this is a violation of patient privacy. The second juncture is at the presentation and publication of research results. All research results will be aggregated to a level that would make it impossible to identify individual patients. No ZIP code data will be display or published and will be stripped from analytic file after linkage with census data and computation of travel distance calculations. A randomly-assigned ID will be used in place of zip codes for fixed-effect estimations.

IX. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Do you anticipate that the results of your analysis will be published or made publically available? If so, how do you intend to disseminate the results of the study (e.g.; publication in professional journal, poster presentation, newsletter, web page, seminar, conference, statistical tabulation)? Any and all publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications *will not disclose a cell less than 11*, and percentages or other mathematical formulas that result in the display of a cell less than 11.

We expect to produce at least 4 manuscripts. With input from project collaborators we will further develop the clinical and policy implications of the research findings by writing related perspective pieces and meeting directly with policy makers. We will target major general medicine and emergency medicine clinical journals and health policy specific journals and will pursue a strategy of wide dissemination of published findings with the assistance of the Harvard Medical School Communications Group, the Beth Israel Deaconess Medical Center Office of Communications and External Relations, as well as the American College of Emergency Physicians. In addition, we will present project findings annually at national research meetings such as AcademyHealth and the Society for Academic Emergency Medicine. All tables and figures will be reviewed by investigators and research compliance officers in our department to ensure that no results with a cell size less than 11 are divulged.

We expect to produce at least 4 manuscripts. With input from project collaborators we will further develop the clinical and policy implications of the research findings by writing related perspective pieces and meeting directly with policy makers. We will target major general medicine and emergency medicine clinical journals and health policy specific journals and will pursue a strategy of wide dissemination of published findings with the assistance of the Harvard Medical School Communications Group, the Beth Israel Deaconess Medical Center Office of Communications and External Relations, as well as the American College of Emergency Physicians. In addition, we will present project findings annually at national research meetings such as AcademyHealth and the Society for Academic Emergency Medicine. All tables and figures will be reviewed by investigators and research compliance officers in our department to ensure that no results with a cell size less than 11 are divulged.

Data, in any paper, report, website, statistical tabulation, seminar, or other setting that is not disseminated to public.	
We have no plans to use or otherwise disclose CHIA data directly other than those noted above.	
3. What will be the lowest geographical level of analysis of data you expect to present for publication or presentation (e.g., state level, city/town level, zip code level, etc.)? Will maps be presented? If so, what me will be used to ensure that individuals cannot be identified?	ethods
The lowest geographical level of data analysis we might to present is the county. There is sufficient large populations in Massachusetts counties that it will not be possible to identify individuals from the results.	
4. Will you be using CHIA Data for consulting purposes?☐ Yes☒ No	
5. Will you be selling standard report products using CHIA Data?☐ Yes☒ No	
6. Will you be selling a software product using CHIA Data?☐ Yes☒ No	
7. Will you be using CHIA Data as in input to develop a product (i.e., severity index took, risk adjustment	t tool,

If yes, in what format will you be reselling CHIA Data?

8. Will you be reselling CHIA Data in any format not noted above?

Click here to enter text.

reference tool, etc.)

☐ Yes

☒ No

☐ Yes ☐ No

9. If you have answered "yes" to questions 5, 6, 7 or 8, please provide the name and a description of the products, software, services, or tools.

Click here to enter text.

10. If you have answered "yes" to questions 5, 6, 7 or 8, what is the fee you will charge for such products, software, services or tools?

Click here to enter text.

X. APPLICANT QUALIFICATIONS

1. Describe your previous experience using hospital data. This question should be answered by the primary investigator and any co-investigators who will be using the Data.

Investigators Landon, Smulowitz, and Novack each have years of experience working with claims data., including many years of working with similar claims data from the Medicare program and private insurers.

Dr. Landon and Dr. Smulowitz are currently working on an AHRQ funded study (using Medicare data) to determine the predictors of variation in admission rates from the ED and the extent to which the physician (vs the hospital or region) matters as a determinant of variation.

Dr. Landon has extensive experience working with claims datasets, including the Massachusetts APCD. He used the Massachusetts APCD to study the consequences of insurance switching on care continuity and the influence of insurance design on referral use.

Dr. Smulowitz has current experience with Medicare claims and previously worked with Massachusetts administrative data to explore the impact of Massachusetts health reform on ED use.

Dr. Novack'smain clinical and research interest is clinical epidemiology and administrative data analysis. He has published extensively in the area of clinical epidemiology utilizing a number of large administrative databases such Clalit Health Services (Israel; the second largest HMO in the world), MIMIC database, NIS database, and BIDMC hospital claims data.

Dr. Isbell is mainly supporing this work with her expertise is social psychology and will not be working directly with the claims data.

2. <u>Resumes/CVs</u>: When submitting your Application package on IRBNet, include résumés or curricula vitae of the principal investigator and co-investigators. (These attachments will not be posted on the internet.)

XI. USE OF AGENTS AND/OR CONTRACTORS

By signing this Application, the Organization assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors. The Organization must have a written agreement with the agent of contractor limiting the use of CHIA Data to the use approved under this Application as well as the privacy and security standards set forth in the Data Use Agreement. CHIA Data may not be shared with any third party without prior written consent from CHIA, or an amendment to this Application. CHIA may audit any entity with access to CHIA Data.

Provide the following information for <u>all</u> agents and contractors who will have access to the CHIA Data. [Add agents or contractors as needed.]

AGENT/CONTRACTOR #1 INFORMATION		
Company Name:	Click here to enter text.	
Company Website	Click here to enter text.	
Contact Person:	Click here to enter text.	
Title:	Click here to enter text.	
E-mail Address:	Click here to enter text.	
Address, City/Town, State, Zip Code:	Click here to enter text.	
Telephone Number:	Click here to enter text.	
Term of Contract:	Click here to enter text.	

1. Describe the tasks and	products assigned to	the agent or contracte	or for this Project and	d their qualifications for
completing the tasks.				

Click here to enter text.

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor
for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or
contractor has access.

Click here to enter text.

3.	Will the agent or contractor have access to and store the CHIA Data at a location	other	than t	he
O	rganization's location, off-site server and/or database?			

☐ Yes

 \square No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

AGENT/CONTRACTOR #2 INFORMATION		
Company Name:	Click here to enter text.	
Company Website	Click here to enter text.	
Contact Person:	Click here to enter text.	
Title:	Click here to enter text.	
E-mail Address:	Click here to enter text.	
Address, City/Town, State, Zip Code:	Click here to enter text.	
Telephone Number:	Click here to enter text.	
Term of Contract:	Click here to enter text.	

1. Describe the tasks and products assigned to	the agent or contractor for this	s Project and their qualifications:	for
completing the tasks.			

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2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.
Click here to enter text.

3. Will the agent or contractor have access to and store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

Yes

No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

[INSERT A NEW SECTION FOR ADDITIONAL AGENTS/CONTRACTORS AS NEEDED]

XII. ATTESTATION

By submitting this Application, the Organization attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* confirms that it is compliant with such use, privacy and security standards. The Organization further agrees and understands that it is solely responsible for any breaches or unauthorized access, disclosure or use of CHIA Data, including, but not limited to, any breach or unauthorized access, disclosure or use by any third party to which it grants access.

Organizations approved to receive CHIA Data will be provided with Data following the payment of applicable fees and upon the execution of a Data Use Agreement requiring the Organization to adhere to processes and procedures designed to prevent unauthorized access, disclosure or use of data.

By my signature below, I attest: (1) to the accuracy of the information provided herein; (2) this research is not funded by a source requiring the release of raw data to that source; (3) that the requested Data is the minimum necessary to accomplish the purposes described herein; (4) that the Organization will meet the data privacy and security requirements described in this Application and supporting documents, and will ensure that any third party with access to the Data meets the data use, privacy and security requirements; and (5) to my authority to bind the Organization.

Signature: (Authorized Signatory for Organization)	Drag signature image here or delete and physically sign
Printed Name:	Jonathan Eaton
Title:	Senior Grants & Contracts Officer
Date:	November 12, 2020

Attachments:

A completed Application must have the following documents attached to the Application or uploaded separately to IRBNet:

- □ 1. IRB approval letter and protocol (if applicable), or research methodology (if protocol is not attached)
- ☐ 2. Data Management Plan (including one for each agent or contractor that will have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database);
- ☐ 3. CVs of Investigators (upload to IRBNet)

APPLICATIONS WILL NOT BE REVIEWED UNTIL THEY ARE COMPLETE, INCLUDING ALL ATTACHMENTS.

RESEARCH STRATEGY

A. Significance

A.1 Scientific premise. The concept that variation in health care practices without concomitant variation in outcomes is prima facie evidence that much of the care provided in high spending areas is of low value. Indeed, this is well established and suggests that care can be reduced without impacting health outcomes. Within emergency care, studies thus far reveal substantial differences in admission rates and practice patterns across regions, hospitals, and diagnoses. Although physicians are responsible for most medical decisions and thus most health care spending, the extent, drivers, and outcomes of variation amongst individual physicians is less well understood. It follows that a better understanding of the causes and consequences of variation in care practices at the level of the individual physician is paramount to devising interventions to reduce unwarranted variation and improve the value of care.

The emergency department (ED) is a high-risk environment with heterogeneous patient presentations, which makes it uniquely suited for studying variation in care practices. In this environment, both *extrinsic* challenges (e.g., unpredictable patient presentations, high decision density, diagnostic uncertainty) and *intrinsic* personality traits of emergency physicians (EPs) relate to the intensity of workups, and potentially to suboptimal decisions.^{2,3} It also is likely that an EP's personality traits affect her response to static or changing extrinsic circumstances in the ED.

Risk aversion is a personality trait fundamental to decision-making. The relevance of this concept to decision-making was introduced first in the context of *prospect theory* by Kahneman and Tversky, which suggests that people are particularly risk averse with respect to negative experiences (losses) as opposed to positive experiences (gains).^{4,21} The potential relevance of risk aversion and aversion to loss – as in missed diagnoses or adverse outcomes – in medicine is clear, and its influence on EP decision-making may be especially strong because of the high stakes and uncertain nature of emergency care. EPs face time-sensitive and critical decisions in caring for patients with potentially serious causes of their symptoms, and it has been widely discussed that EPs often make decisions to over-test or admit because the concern over a bad outcome (the perceived loss) far outweighs the perception of long-term risk of an additional test or admission.²²

The potential impact of risk aversion on decision-making in the ED has been studied to a limited degree with each sharing the fundamental limitation of including physicians only in a single ED. These studies, however, build a foundation for the use of risk preference surveys, which is key to our work. We will utilize four survey instruments to assess risk aversion: the Risk Taking Scale (RTS), the Stress from Uncertainty Scale (SUS); the Fear of Malpractice Scale (FMS); and the Need for (Cognitive) Closure (NFC). The RTS is adapted from the Jackson Personality Inventory (JPI), an assessment of personality widely used in business and industrial settings and for psychological research.²³⁻²⁶ The risk-taking component is a subscale of the JPI that asks respondents to rate their agreement with 6 statements about general risk taking behavior (unrelated to medical care; e.g., "I enjoy taking risks"). The JPI subscales have been validated with behaviors in a wide range of situations and occupations. The Jackson Personality Index (of which the Risk Taking Scale (RTS) is a component) has been shown to be a stable personality measure over time. The SUS measures a similar construct but is specific to the medical setting; it quantifies a physician's discomfort when confronted by diagnostic uncertainty (e.g., "The uncertainty of patient care often troubles me"). Unlike the RTS, the SUS pertains specifically to uncertainty in medical decision-making and taps a physician's level of comfort with an inability to pinpoint a specific diagnosis. This scale assesses a key aspect of the EP's daily responsibility, which is to make management decisions under varying degrees of uncertainty. The FMS addresses the physician's concerns related to medical malpractice rather than general risk aversion or uncertainty. The scale includes a series of statements about how malpractice fear influences a physician's practice of medicine (e.g., "I feel pressured in my day-to-day practice by the threat of malpractice litigation"), Finally, Need for (Cognitive) Closure (NFC) is a related construct that taps one's need for a concrete answer, which may or may not be correct, so that one can come to a conclusion and terminate cognitive processing (e.g., "When I am confronted with a problem, I'm dying to reach a solution very quickly"). 5,6 Individuals differ in their inherent dispositional levels of NFC, which is manifested by "a preference for order and predictability, a need for decisiveness, discomfort with ambiguity, and closed-mindedness," each of which is addressed by the NFC scale. 5 The NFC demonstrates stability over time, with high a test-retest reliability (r=0.87) at 12-13 weeks. ²⁷ An abridged 15 item version of the full NFC was developed and validated by Roets et al.⁶

Pearson et al. first applied the Risk Taking Scale (RTS) to physician decision-making at a single site with 119 physicians and demonstrated that greater risk tolerance was associated with lower rates of admission for patients presenting to the ED with chest pain. In later work Fiscella et al. surveyed 61 family physicians and

112 internists and found differences in the overall risk aversion profile between the two groups, with greater risk aversion amongst internists related to measurable increases in case-mix adjusted expenditures. Franks et al. surveyed 182 physicians in a single managed care organization and found that greater risk aversion (using the RTS, SUS, and FMS scales) was associated with greater specialty referrals. The NFC also was studied in a small group of medical students at a single site, where greater NFC led to greater premature closure and anchoring on an incorrect diagnosis in students with less clinical experience, suggesting that experience may diminish the impact of NFC. NFC has not been well studied with respect to practice intensity. Figure 12.

Within emergency medicine Pines at al – in two single site studies with 29 and 31 physicians respectively – studied the association between the RTS, SUS, and FMS and the use of an observation unit for chest pain and the use of imaging for patients with abdominal pain. In these studies only the RTS was associated with the outcomes of interest. Finally, Katz et al studied 33 physicians at two academic hospitals and found that greater fear of malpractice was associated with increased rates of hospitalization for patients presenting with low-risk chest pain and increased use of diagnostic tests. In both of these studies the surveys were administered at time points substantially after the period of data collection on practice intensity, supporting that these traits are stable enough to be measured at a time point separate from the actual practice data.

These prior studies suggest that risk aversion (RTS, SUS, and FMS) and NFC translate into different levels of clinical compulsiveness amongst EPs, but leave many questions unanswered. The distribution of these traits amongst a representative sample of EPs is unclear, as is the potential impact on patients. It is likely that a particularly anxious or compulsive EP will be vulnerable to over-testing (errors of commission), and that this over-testing results in harmful downstream outcomes. Yet, in the ED setting the opposite also might be true. It is possible that for some clinical conditions, over-testing in the ED setting might be protective by minimizing missed diagnoses and picking up on potentially critical diagnoses. It simply is unknown and critical to define for most ED conditions whether higher or lower rates of testing is better, or if a range of testing is associated with better outcomes. It might be that greater risk aversion and clinical compulsiveness is protective by minimizing errors of omission. It is equally reasonable that there is a level of testing and admission above which harm is more likely to occur. In addition, given the cost pressures of our health care system, workups that yield little clinical benefit constitute low value care, which presents an opportunity for improving value by cutting costs without impacting outcomes.

A.2 Significance of the Expected Research Contribution. As noted above, prior research studies within emergency care are limited in number and scope. However, robust experience from other industries and limited studies from other areas of medicine cumulatively suggests that risk aversion and NFC are related traits that might have a profound impact on decision-making in the ED. In this proposal, we seek to define the basic prevalence of risk aversion and NFC among a representative sample of EPs and delineate the relationship of these related traits to practice variation. The results of this study will establish a strong foundation for later behavioral interventions intended to guide physicians with different levels of risk tolerance to more standard management decisions (e.g. admissions for chest pain) or to manage the interface between risk aversion and the cognitive biases that may result. Such interventions may improve a physician's ability to use metacognitive strategies to reduce any negative impact of the decisions that result from their risk preferences, or may support the adoption of standardized pathways to mitigate the impact of risk aversion on decision-making. Our study also may help to support or refute the notion that large scale policy changes to reduce the exposure of EPs to malpractice risk would result in substantial reduction in "defensive medicine" and health care spending. Our proposed work will provide the first measures of the prevalence of risk aversion and NFC among EPs – and the relationship between them and decision-making – which currently remains unknown.

B. INNOVATION

By using a comprehensive all payer claims database, we will have the most complete and representative study of this relationship reported in the literature to date. While the hypotheses are driven from validated instruments and a solid theoretical framework outside of medicine, our study will be the first to explore these relationships with such scope and detail within medicine. While focused on emergency medicine for its unique practice setting and pressures, our findings will also be suggestive about behavior in other areas of medicine. As described, this project's innovation lies in the following features:

We intend for the first time to delineate the prevalence of several related personality traits that together
comprehensively assess EP risk aversion and tolerance of uncertainty. Our data will represent the first time
that these traits are measured in a large and representative sample including all EPs in a single state.

- The breadth of our survey population in combination with clinical data from both the Massachusetts APCD and Medicare claims permits us to comprehensively evaluate the association between risk aversion and practice intensity for key clinical conditions.
- We will evaluate whether our findings differ between EPs and emergency department APPs, a group of providers responsible for a growing role in the provision of emergency care.
- We will further extend our investigation by leveraging the fact that patients are randomly assigned to EPs within a single ED to assess any association between levels of EP risk aversion, practice intensity, and measures of patient harm.
- Our results will allow us to ascertain whether defensive medicine and fear of malpractice drive over-testing, as opposed to overall levels of risk aversion.
- We will use our empirical results to set a foundation for the development of key behavioral interventions to reduce variation in care practices, avoid suboptimal decision-making that stems from certain cognitive biases (e.g., premature closure), and improve the value of care delivered in the ED.

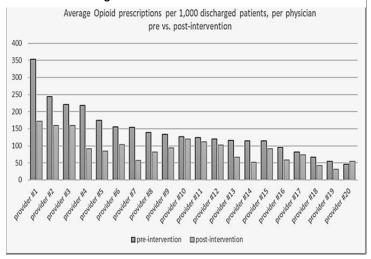
C. APPROACH

C.1 Preliminary Studies

C.1.1 Previous work detailing individual provider practice variation in the ED. This study is in part motivated by work by Dr. Smulowitz and Dr. Novack that first examined variation in individual EP practice patterns within our own institution and then tested interventions designed to mitigate this variation. They first demonstrated wide variation across physicians within a single ED group in the rate of admission (including use of an ED observation unit) for patients presenting with chest pain, with an average admission rate of 74% and rates of admission ranging from 54% to 96%. Greater physician experience was associated with a higher admission probability. Based on this work, they designed an intervention using the electronic medical record to implement the HEART chest pain pathway in one community hospital ED. This intervention resulted in a 12% overall reduction in the rate of hospital admission. Since most of this reduction occurred in the group of physicians whose pre-intervention rates of admission were above the group median, the results suggested the intervention reduced potentially unnecessary admissions with no demonstrated adverse outcomes.

They showed similar results in studying the rate of opioid prescribing in a single community hospital ED. In that study there was wide variation among individual providers, with rates ranging from 33 to 332 prescriptions per 1,000 visits. 32 Dr. Smulowitz and Dr. Novack then implemented a behavioral intervention that involved sharing with each provider their individual prescribing pattern (and the group's for comparison) in the same ED where earlier variation in prescribing was demonstrated. This intervention resulted in a 57% reduction in opioid prescribing (176 prescriptions per 1,000 patient discharges in the pre-intervention group (IQR 169 - 180) compared to 76 (IQR 64 - 115) in the post-intervention period (p = 0.028)). The results also demonstrated consistent decreases in opioid prescribing at the individual level, with the greatest decreases in those with the

Figure 1: The impact of an intervention on opioid prescribing at the individual physician level. This is representative of the potential impact of behavioral interventions in altering practice variation across a wide range of clinical conditions.



highest initial rates of prescribing (Figure 1).33

In ongoing work funded by AHRQ, we are evaluating the extent to which physicians contribute to observed variation in rates of admission from the ED for Medicare patients presenting with a heterogeneous set of medical conditions. In work submitted for presentation, we found considerable variation at the physician level – the overall rate of admissions was 10.9% at the 10th percentile and 57.1% at the 90th percentile. In adjusted models, the probability of admission changed by 13.3% (95% CI 13.2% -13.4%) if a patient visited a physician at the 90th versus the 10th percentile of admission propensity. After adjusting for patient level variation, we found that physician, hospital, and area levels accounted for 13.3%, 64.3%, and 22.4% of the remaining variation, respectively. Notably, unmeasured variation at the patient or physician level might

contribute to unexplained variation at the hospital or area level. Additionally, observable EP factors (e.g., age, gender, years of practice) explained little of the physician level variation. That study further sets the stage for

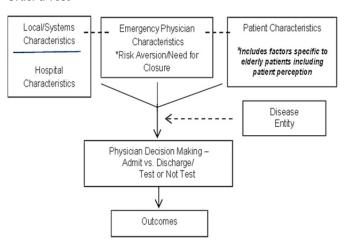
this current study; while greater variation is attributed to the hospital level, there remain substantial differences in the likelihood of admission across EPs that is only minimally explained by the physician characteristics we measured. This physician level variation may be partly explained by the personality traits we intend to study.

C.1.2 Evaluation of the risk aversion and NFC scales. In preparation for this study, we developed and pilot tested separately in the U.S. and Israel an internet enabled survey instrument that included previously validated measures of the four constructs we plan to measure in our proposed study. We first administered the survey to physicians at two hospitals within our system (one academic and one community hospital), receiving responses from 43 of 50 physicians (86%) over a relatively accelerated time-period and without the use of any participation incentives. We found only moderate correlation across all four scales (NFC: to SUS = 0.51, to RTS 0.60, to FMS 0.24 RTS: to SUS 0.50; to FMS 0.39. SUS: to FMS 0.58), suggesting that we are capturing related but distinct traits with each scale and supports the inclusion of all four scales in this proposed project. The scales also showed good internal consistency reliability (Cronbach's alpha: RTS = 0.83, SUS = 0.89, NFC = 0.84, FMS = 0.82). Additional pilot work was completed by Dr. Novack in Israel, where the RTS, FMS, and SUS scales were tested in a sample of 72 physicians. This work demonstrated substantial variation in the scores across the survey participants, with median scores (IQR) of: RTS 21.0 (18-23), SUS 37.0 (33-44.3), and FMS 17.5 (14-20). This pilot work also generally confirmed the correlation across these scores (RTS to SUS 0.25, RTS to FMS 0.06, SUS to FMS 0.45). Both analyses also support the construct validity of the instrument. For instance, we found a generally linear relationship between EP risk aversion and years of experience.

C.1.3 Evaluation of the role of affective factors in medical decision-making and the contribution to diagnostic errors. In an AHRQ-funded study investigating the role of affective factors on medical decision-making and diagnostic error, Dr. Isbell conducted qualitative interviews with EPs at four academic medical institutions and four community hospitals. Interviews completed with 45 attending EPs suggest some common themes (using grounded theory): (1) provider anxiety or worry about diagnostic and other errors is believed to drive decision-making, including decisions about testing; (2) following a diagnostic or medical error, EPs describe a tendency to be overly conservative in their decision-making, particularly for clinical presentations similar to the one in which the error was made; and (3) this tendency is believed to be especially pronounced in the time immediately following the error, but may last long beyond this. Such findings are consistent with Dr. Isbell's prior experimental research, which demonstrate that anxiety, worry, and fear can lead to more careful and thorough information processing in a variety of non-medical contexts. ³⁴⁻³⁷ This and other research on the influence of affect on cognition strongly supports the prediction that increased fear of malpractice and anxiety about making errors will increase testing in a medical context and foster more conservative decision-making, providing strong theoretical support for the quantitative assessment of the hypotheses in this proposal.

C.1.4 Previous research using large datasets. Our research team also has extensive experience using large datasets to evaluate utilization, including of the ED. In work recently funded by AHRQ, we are using Medicare claims data to study variation in and predictors of rates of admission to the hospital from the ED among elderly

Figure 2: Conceptual Framework for the ED Decision to Admit or Order a Test



patients. In developing that project we noted that the decision to admit a patient from the ED generally rests with the individual EP, and that beyond the clinical presentation this decision also is influenced by a variety of situational and time invariant features of both the physician and the system within which the physician is embedded. Our conceptual framework (Figure 2) demonstrates the levels of factors that play a role in physician decision making with respect to the decision to admit, with identical factors involved with the decision to order a particular lab or imaging test. The interconnectedness of the factors is represented by the dashed lines at the top level; specific physicians and hospitals will develop practice patterns that are at least in part responsive to characteristics of the patients they serve. For every physician these decisions are likely to vary depending on the clinical condition, since most

physicians have clinical areas in which they are more or less knowledgeable or comfortable. This in turn is highly likely to influence their rate of admission or test ordering. This framework informs our current proposal in which we focus on defining characteristics of individual physicians that influence these decisions.

That project also increased our familiarity and capability with Medicare datasets, in particular with refining a strategy for identification of all ED visits including those resulting in observation status. We first identified ED visits from the Carrier files by identifying claims with the following Healthcare Common Procedure Coding System (HCPCS) codes: 99281 – 99285, 99291, 99292, 99235, 99236, 99217 – 99220, 99224 – 99226 and ED place of service coded "23". We limited the beneficiaries to those who had Medicare Parts A and B in the 12 months prior to the ED visit and no history of Medicare Advantage enrollment in that same time period. A single beneficiary could have multiple ED events in our dataset, but we required at least a 30 day period without an ED visit to define a new episode of care. We then matched these Carrier defined events to the Inpatient and Outpatient files, using the revenue center codes 0981 or 0450 – 0459. We defined a case as having been admitted (full or observation) if there was a respective record within two days of the Carrier-defined ED event. Those cases having neither (approximately 5%) were excluded from the final analysis set after closely examining sequences of claims for a sample of patients to verify that these claims were not associated with an identifiable ED visit in either the inpatient or outpatient hospital setting.

We also refined a strategy for delineating categories of conditions, including categories of conditions frequently admitted, frequently discharged, and those where there is significantly more discretion in the rate of admission and discharge. We first grouped diagnoses into clinically meaningful categories using the Clinical Classifications Software (CCS) available from AHRQ, first using ICD-9 codes and then with ICD-10 codes starting on October 1, 2015. We excluded surgical and trauma related conditions and any condition with fewer than 30,000 total visits over our study period. We used conditions either from level 2 or level 3 classifications where appropriate, and combined conditions that were clinically related into larger meaningful groupings. Our list of conditions and associated admission rates extracted from Medicare claims data in 2012 to 2015 contains 27 categories (with admission rates ranging from 8.5% to 89.4%) and 6 larger subgroups (cardiovascular, gastrointestinal, pulmonary, neurologic, genitourinary, and other).

In related work, Drs. Smulowitz and Landon conducted an analysis of the 2006 Massachusetts health reform's impact on ED use.³⁸ Because health reform was implemented across the entire state at the same time, there was no clear in-state control group that we could use. We therefore employed a quasi-experimental design that leveraged the differential area-level impact of health reform to provide estimates of the impact of the health reform on ED utilization. We found the implementation of health care reform was estimated to result in a 1.1%-1.9% increase in ED visits per year when compared to the pre-reform period, and that this increase was not seen in the over-65 population who were covered by Medicare for the entire study period.

Dr. Landon has extensive experience working with large datasets, including both the Massachusetts APCD and Medicare data being proposed for this application. Previously, he compared utilization and quality of care between Medicare's managed care program (Medicare Advantage (MA)) and traditional Medicare.³⁹⁻⁴² This work shows that matched MA enrollees generally use fewer services, including ~40% fewer visits to the ED and lower rates of hospitalization, while receiving care of equal or higher quality. Dr. Landon also studied the relationship between physician financial incentives and the costs and quality of care for Medicare patients and published the first national study of the use of low value services based on the Choosing Wisely list among Medicare beneficiaries.⁴³⁻⁴⁷ Dr. Landon also has used Medicare data to study physician social networks and care patterns and used the Massachusetts APCD to study the consequences of insurance switching on care continuity and the influence of insurance design on referral use.⁴⁸⁻⁵³

C.2 Overview of approach. Our proposed project will begin with the administration of a survey consisting of the four validated scales described earlier to measure the prevalence and distribution of risk aversion and NFC in the entire population of Massachusetts EPs and APPs. Based on our pilot survey, we anticipate this survey should take under 10 minutes to complete. Nevertheless, recognizing the rigors and challenges of a study relying on survey completion, we will leverage a strong relationship with the Massachusetts College of Emergency Physicians (MACEP) and a multi-pronged approach to encourage completion of the survey. In Aim 2, we will link these data with clinical data from Medicare claims and the Massachusetts APCD using the physician's NPI number to study the association between the two measured personality traits and clinical decision-making in the ED, both overall and for key clinical conditions for which discretion plays a larger role in decisions to test or admit. In Aim 3 we will rely on the fact that patients are randomly allocated to physicians within a single ED to examine the relationship between practice intensity and measures of patient harm.

C.3 Survey Development and Administration

C.3.1 Survey Instrument. We previously developed and pilot tested the survey instrument, achieving a high response rate with minimal item non-response. Administration took less than 10 minutes. We will use the four

previously validated scales introduced earlier, followed by questions assessing demographic information including age, gender, and years since graduating residency. The questions from the survey scales will be asked in the same order as our pilot study (RTS, SUS, NFC, then FMS; starting from most general and ending with the most focused scale). The survey is in **Table 1**, with headings and Likert scales only shown here for illustrative purpose. To encourage honest responding, we will assure participants of the confidentiality of their responses and will have participants provide their identifying information separate from their responses to the questionnaire. This information will be linked only via a unique alphanumeric code. We will add questions about experience (number of shifts per month, percent of night shifts, and number of years practicing) and method of reimbursement (salary, salary plus bonus, pure productivity). We will be parsimonious as our goal is to balance the breadth of variables measured with survey length to maximize the rate of completion.

Table 1: Final survey format (headings and Likert scales shown here for descriptive purposes)

RTS:

Based on 6-point Likert scale (1 – Strongly Disagree; 2- Moderately Disagree; 3 – Slightly Disagree; 4 – Slightly Agree; 5 – Moderately Agree; 6 – Strongly Agree. Scores range from 6 to 30. We will invert the numeric answers for questions 1, 3, 5.

- 1. I enjoy taking risks.
- 2. I try to avoid situations that have uncertain outcomes.
- 3. Taking risks does not bother me if the gains involved are high.
- 4. I consider security an important element in every aspect of my life.
- 5. People have told me that I seem to enjoy taking chances.
- 6. I rarely, if ever, take risks when there is another alternative.

Need for Cognitive Closure scale:

Based on 6-point Likert scale (1 – Strongly Disagree; 2- Moderately Disagree; 3 – Slightly Disagree; 4 – Slightly Agree; 5 – Moderately Agree; 6 – Strongly Agree). Scores range from 15 to 90.

- 7. I don't like situations that are uncertain.
- 8. I dislike questions which could be answered in many different ways.
- 9. I find that a well ordered life with regular hours suits my temperament.
- 10. I feel uncomfortable when I don't understand the reason why an event occurred in my life.
- 11. I feel irritated when one person disagrees with what everyone else in a group believes.
- 12. I don't like to go into a situation without knowing what I can expect from it
- 13. When I have made a decision, I feel relieved.
- 14. When I am confronted with a problem, I'm dying to reach a solution very quickly.
- 15. I would quickly become impatient and irritated if I would not find a solution to a problem immediately.
- 16. I don't like to be with people who are capable of unexpected actions.
- 17. I dislike it when a person's statement could mean many different things.
- 18. I find that establishing a consistent routine enables me to enjoy life more.
- 19. I enjoy having a clear and structured mode of life.
- 20. I do not usually consult many different opinions before forming my own view.
- 21. I dislike unpredictable situations.

Stress from Uncertainty scale:

Based on 6-point Likert scale (1 – Strongly Disagree; 2- Moderately Disagree; 3 – Slightly Disagree; 4 – Slightly Agree; 5 – Moderately Agree; 6 – Strongly Agree). Scores range from 13 to 78. We will invert order of answers to question 24 and 34.

- 22. The uncertainty of patient care often troubles me.
- 23. Not being sure of what is best for a patient is one of the most stressful parts of being a physician.
- 24. I am tolerant of the uncertainties present in patient care.
- 25. I find the uncertainty involved in patient care disconcerting.
- 26. I usually feel anxious when I am not sure of a diagnosis.
- 27. When I am uncertain of a diagnosis, I imagine all sorts of bad scenarios patient dies, patient sues, etc.
- 28. I am frustrated when I do not know a patient's diagnosis.
- 29. I fear being held accountable for the limits of my knowledge.
- 30. Uncertainty in patient care makes me uneasy.
- 31. I worry about malpractice when I do not know a patient's diagnosis.
- 32. The vastness of the information that physicians are expected to know overwhelms me.
- 33. I frequently wish I had gone into a specialty or subspecialty that would minimize the uncertainties of patient care.
- 34. I am quite comfortable with the uncertainty in patient care make a diagnosis is becoming riskier from a medicolegal perspective

<u>Fear of malpractice scale</u>. Based on 5-point Likert Scale: (1 – Strongly Disagree; 2 – Disagree; 3 – Not sure; 4 – Agree; 5 – Strongly Agree). Scores range from 6 to 30.

- 35. I have had to make significant changes in my practice pattern because of recent legal developments concerning medical delivery.
- 36. I am concerned that I will be involved in a malpractice case sometime in the next 10 years.
- 37. I feel pressured in my day-to-day practice by the threat of malpractice litigation.
- 38. I order some tests or consultations simply to avoid the appearance of malpractice.
- 39. Sometimes I ask for consultant opinions primarily to reduce my risk of being sued.
- 40. Relying on clinical judgment rather than on technology to

Demographics: Age; years since graduating residency, number of shifts per month, % of night shifts per month, number of years of practice, method of reimbursement.

C.3.2 Survey Population. Our plan is to perform a statewide survey of all Massachusetts EPs and APPs, which currently includes 623 attending physicians, 31 fellows, approximately 250 APPs, and excludes resident physicians. To identify the sample, we will use a database that includes name, address, telephone number, hospital affiliation(s), and email address of all practicing EPs in the state of Massachusetts that is maintained by the Massachusetts College of Emergency Medicine (MACEP). MACEP continuously updates the data and includes both members and non-members. Dr. Smulowitz has secured the support of the MACEP (see letter) to aid in administration and achieving a high response rate. He is a recent President and current board member, and will coordinate the survey with the executive director of MACEP using MACEP's e-mail list for distribution. At the onset of the study we will also query each individual ED director for the names and contact information of each of their full time APPs, since these are not provided by MACEP.

C.3.3 Survey Administration Procedures. As tested in our pilot, the survey will be administered online using REDCap. We will send an invitation to all eligible subjects and to each ED director to notify them of the purpose of the study. We will assure all invited participants that no individual responses will be shared but that aggregate results will be made public. The initial e-mail, as well as follow-up e-mails to non-responders, will include a uniquely coded hyperlink to the online survey. Subjects will have the option to decline participation and be removed from the e-mail list at any time. To maximize our response rate, we will offer a \$50 Amazon on-line gift card for those who complete the survey. Dr. Smulowitz will further work with a group of survey "coordinators" that we have already recruited (selected from the major hospital networks, please see attached letters), each of whom will paid \$1,000 as a project consultant to facilitate physician enrollment at hospitals in their network in order to maximize the response rate. We will follow the same process for maximizing survey completion for the EPs and APPs, ensuring a robust sample from both populations. Finally, our research assistant (in daily contact with Dr. Smulowitz) will coordinate survey distribution, monitor response rates, and along with Dr. Smulowitz make site visits for survey completion on paper for EDs with lower response rates.

C.4 Administrative Data sources.

C.4.1 Medicare Part A and B Claims. Medicare Part A provides coverage for inpatient care in acute care hospitals and skilled nursing facilities, home health care, and hospice care. Medicare Part B covers services rendered by physicians and other medical providers, and outpatient facilities. Although beneficiaries are automatically entitled to services provided under Part A, they must purchase Part B coverage voluntarily. Approximately 97% of persons aged 65 and older are covered by Medicare and most beneficiaries (95%) carry Part B coverage. CMS collects and maintains health care claims for all services billed to and paid for under Medicare's fee-for-service (FFS) payment system, but does not have claims data available for those enrolled in Medicare Advantage (MA), Medicare's managed care program. MA enrollment in Massachusetts (21%) is lower than the national rate. We will use the following sources: 1) The Master Beneficiary Summary File contains demographic, vital status, and enrollment data for each enrolled Medicare beneficiary as well as indicators of whether the beneficiary has been diagnosed during the past year or ever with one of 27 chronic clinical conditions including stroke, myocardial infarction, and diabetes (the Chronic Conditions Warehouse); 2) The Inpatient File contains inpatient discharges from acute care hospitals; 3) The Carrier File contains one claim for each service covered by Part B; and 4) The Outpatient File contains claims for Part B services provided by outpatient institutional providers (e.g., hospital outpatient departments where imaging studies often occur). Each of these files can now be obtained in a timely and cost efficient manner through the CMS Virtual Research Data Center (VRDC). Currently the VRDC contains access to the data files noted above through calendar year 2017, and 2018 data are expected to be available in the VRDC by January 2020. We will utilize Medicare data from 2015 through the most recent year available to identify all ED visits and admissions from the ED using the methods detailed above. Since claims data do not allow for the determination of which facility claims (e.g. labs, imaging, procedures) for admitted patients originated in the ED, our analysis involving measures of practice intensity (excluding the rate of admissions) will be limited to patients discharged from the ED. This is a limitation of all extant claims databases (including the APCD).

C.4.2 Massachusetts All Payer Claims Database (MA APCD). The APCD is available from the MA Center for Healthcare Information and Analysis, an agency of the Commonwealth of Massachusetts. The APCD collects information from over 120 private payers and all public payers in the state, including medical, dental and pharmacy claims as well as files with provider, member and insurance product information. The only payers not included in the APCD are self-pay, worker's compensation, Veterans Affairs, Federal Employees Health Benefit Plan, and some small private insurers. The APCD includes paid amounts for all claims. The APCD also has a wealth of descriptive data on patients, physicians, and organizations. At the patient level, the member eligibility file combined with the product file of the APCD provides data on patient demographics (age, gender, race, zip code), as well as detailed information on insurance status throughout the study period. The member eligibility file describes which insurance product a patient has at any time in the eligibility period. This information can be merged with the product file, which describes the benefit arrangements associated with each insurance product, including copayment levels for primary care, specialty care, emergency care, and drugs as well as deductible levels and coinsurance. For individual providers, the provider data file has identifying information for providers such as name and practice location as well as the National Provider Identification (NPI) in some cases, and provides demographic information (age, gender, specialty, practice location), as well as organizational affiliation, which could span multiple organizations. We will use data from 2015 through the most recent data to match the Medicare data sets. The currently available version APCD 7.0 includes claims data from 2012 through 2017, with anticipated release of data through 2018 available in 2020.

For both databases there will be a time lag between the survey administration and the data availability, particularly in the early years of the study. Using the VRDC, Medicare data are available with a one-year time lag and the APCD is available with a two-year time lag. As we complete our models we will be able to add additional years when available, such that we anticipate having claims data concurrent with the survey by the end of the study. Moreover, as noted in our preliminary studies and from our review of the literature, the scales we will be using demonstrate test-retest reliability (NFC), measure stable personality characteristics (RTS), and already have been shown to relate to provider decisions in the ED assessed at different times (RTS, FMS, SUS). Thus, we expect the time lag to have a relatively minimal impact on our ability to perform the specified analyses. Further, we will be able to assess this given the longitudinal nature of the study.

C.5 Study Measures. Our analytic model will require us to control for factors at the patient and ED/hospital level to determine the association between physician risk tolerance, NFC, and practice intensity. The outcomes of interest in Aim 2 are practice intensity (e.g., lab tests/imaging studies) and admission. The outcomes of interest in Aim 3 are repeat ED visit, hospitalizations, and death (the latter is only available for Medicare data). Consistent with our conceptual framework (see section C.1.4) the independent variables of interest are physician risk tolerance and NFC, and the control variables will include patient level (discharge diagnosis, comorbidities, prior utilization, demographics), other provider level (age, gender, years of experience, shift distribution), ED/hospital level (crowding, ED volume, teaching status), and additional market level measures either at the county (Area Resource File) or Hospital Referral Region (Dartmouth Atlas) level. **Table 2** demonstrates the levels of variables and the data source for each that are to be included in the analytic model.

<u>Identifying Emergency Department Visits and Hospitalizations.</u> In our ongoing AHRQ-funded work, we refined a method for identification of ED visits starting with the Carrier file, which allows for identification of the individual emergency physician or APP and corresponding NPI number associated with the visit. This method is described in detail in the "Preliminary Studies" section above.

	Patient Level (Medicare claims, All Payer Claims Database)	ED/Hospital (Medicare claims, American Hospital Association survey)	Market (Area Resource File, Dartmouth Atlast)	Provider Level (Physician and APP survey)
Independent variables				Risk aversion/NFC scores
Dependent or Control variables	Sociodemographic: age, gender, race, insurance	Daily hospital census	Quartiles of Medicare and Medicaid admissions	Demographics: age, gender
	Primary and secondary ICD-9 or 10 codes (secondary to control for comorbidities)	Quartiles of total daily ED volume	Acute care hospital bed supply per 1,000 residents	Years since graduating residency program
	Laboratory tests	Teaching Status (major teaching, minor teaching, non-teachin)	Per capita income	Board certification status
	Imaging studies (plain radiographs, CT, ultrasound, MRI)	Hospital size (<100, 100-100, 200-499, ≥ 500 beds)	Primary care physicians per 100,000 residents	Shift distribution: number of shifts per month, percent night shifts
	Disposition at time of ED visit (admit, discharge)	Ownership (for-profit, non-profit, government)	Percentage of persons < 65 in the county without health insurance	Number of years practicing in the same state
		Urban/rural (urban, large rural, small rural)	Percent of Medicare beneficiaries who are dual eligible	

Identification of APP claims. Both Medicare claims and the APCD contain a field that allows for identification of the type of provider submitting the claim for the ED professional fee. This field permits identification of physicians and APPs. One limitation is that both Medicare and the APCD allow for identification of patients seen by an APP only where there is no physician claim. If there is a corresponding physician claim for the same visit then there is no recorded APP claim, so it is not feasible to determine "shared" visits seen by an APP and directly supervised by an EP. In our ongoing AHRQ-funded work we found that 15% of ED visits are attributed to an APP only, which is a sufficient number of visits per year even accounting for this limitation.

<u>Identification of Clinical Condition.</u> We will group diagnoses into clinically meaningful categories in order to identify discretionary conditions. These are conditions where there is substantial judgment involved in the decision to utilize test or to admit, and thus more apt to demonstrate variation in practice patterns. Our approach is described in the "Preliminary studies" section above.

<u>Measures of patient harm.</u> We will use accepted measures of patient harm for studies of the ED. Our main focus will be on mortality and unplanned ED revisits, with a focus on those resulting in hospitalization. We also will examine hospital LOS and 30-day utilization/spending after an index ED visit.

Comorbidities. We will calculate hierarchical condition category (HCC) risk scores from the claims over the 12-month period preceding the enrollee's ED visit using a publically available program that is downloadable from CMS. HCC risk scores are derived from demographic and diagnostic data in enrollment and claims files and higher scores are indicative of higher predicted spending. We will complement this with data on prior outpatient care, hospitalizations, and ED visits by each individual patient in order to develop measures of prior utilization. In addition, for the Medicare sample, we also will use the chronic conditions warehouse (CCW), which contains markers for the presence of 27 coexisting conditions as well as an indicator of whether these were diagnosed in the past year or ever (since entering the Medicare program) and thus can be used as a measure of disease burden and to control for comorbid conditions. Using the CCW we will assess whether the Medicare enrollee has any of the 27 conditions and create binary markers to indicate the presence or absence of each of these, as Dr. Landon has done in prior work.

C.6 Analysis Plan

Aim 1: To measure the distribution of risk aversion and NFC in the population of Massachusetts EPs and APPs. We will accomplish this using four validated scales (the Risk Taking Scale (RTS), the Stress from Uncertainty Scale (SUS), the Fear of Malpractice Scale (FMS), and the Need for Closure scale (NFC)). We will survey all practicing EPs and APPs in Massachusetts (MA). We will measure each scale separately and. depending on the results of exploratory factor analyses, we will create and use composite scores. The scores will be ranked consistently from low (lowest risk aversion or highest risk tolerance; lowest NFC) to high (highest risk aversion or lowest risk tolerance; highest NFC). We will examine the range and distribution of responses. correlations among the scales, and perform exploratory factor analysis to empirically identify constructs from the data. The goal will be to use the survey results to develop a parsimonious set of measures of risk tolerance for use in subsequent analyses. Following the descriptive analyses of the scores, we will analyze the association between the scales and provider demographic characteristics, place of practice and experience level. Assuming non-linearity of some of the associations, we will explore the trends by Locally Weighted Scatterplot Smoothing (LOWESS) approach with different smoothing parameter (a). To ascertain the factors associated with the composite score in the adjusted analysis, we will utilize generalized linear mixed models (GLMM) where the hospital will be treated as a random effect. The models will include the physician characteristics. The general approach in the analysis can be captured by the following regression expression:

$$E(Risk\ Aversion) = (\alpha_0 + \alpha_{hospital}) + \sum_{i=1}^{d} \beta_i X_i + \sum_{j=1}^{p} \gamma_j Z_j,$$

where $Risk\ Aversion$ stands for one of the four risk aversion/NFC scales, $\alpha_{hospital}$ is the random intercept for hospitals, $\beta_i X_i$ are the d coefficients and EP's demographic characteristics and $\gamma_j Z_j$ are the p coefficients for practice characteristics. Non-responders will be tracked and their practice data will be compared to the practice data of responders to investigate if there are systematic differences between responders and non-responders.

Aim 2: To determine the relationship between risk aversion and NFC scores and overall practice intensity (the number of laboratory tests, imaging studies, and the frequency of hospital admission) for key clinical conditions in the ED. For this aim a provider-patient encounter will be the unit of analysis. We hypothesize that practice intensity will be positively correlated with risk aversion scores, and similarly for NFC we hypothesize that higher NFC scores will indicate less tolerance of uncertainty. However, it is also possible that higher NFC scores will be negatively correlated with practice intensity given that NFC is associated with a strong motivation to reach a decision quickly. We will evaluate these competing possibilities. Descriptive statistics will include data summaries of main health care system variables as well as patient and provider characteristics. Results will be presented as percentages for categorical variables, with median and range for non-normally distributed variables and mean ± SD for continuous, normally distributed variables. The relationship between a provider's personal risk tolerance and the outcomes of interest, in this case the decision to perform a test or procedure or total number of the tests/procedures will be assessed by using generalized linear mixed model (GLMM), with random and fixed effects to account for the same patient visiting the ED more than once. Case-mix adjustment including patient, hospital and ED (e.g. crowding) and provider covariates will be included in the regression. Next, the models will include the physicians' risk (RTS, SUS, FMS) and NFC scores. We will use logistic regression, Poisson regression and negative binomial regression

as a link functions according to the observed distribution of the outcome. For these analyses an incidence rate ratio (IRR) and odds ratio (OR) and 95% confidence interval (CI) will be reported. Specifically, the main approach in this analysis can be described as follows:

$$E(Practice\ Intensity) = \left(\alpha_0 + \alpha_{patient}\right) + \beta_1 Risk\ Aversion\ scale + \beta_2 NFC + \sum_{j=1}^p \gamma_j X_j + \sum_{k=1}^{ph} \delta_k Z_k,$$

where $Risk\ Aversion\ scale\$ will include RTS, SUS, FMS, and NFC, $\gamma_j X_j$ are the p coefficients for demographic and clinical characteristics of patients and $\delta_k Z_k$ are the ph coefficients for physicians and APP demographic characteristics. Lastly, we will assess the intra-provider variation in decision making comparing both between different conditions (e.g. decision making process for pneumonia and acute MI) and time periods, assuming the variation in time and between the conditions. Non-linearity of the associations between the scales and measures of the practice intensity will be explored by fitting generalized additive mixed models (GAMM).

Aim 3: To examine the relationship between practice intensity (average number of laboratory tests, imaging tests and rate of admission per individual physician) and patient harm, as defined by repeat ED visits, hospitalizations, and deaths within 7 and 30 days. For this aim, the physician/APP will be the unit of analysis. We hypothesize that the association between practice intensity and patient harm will have a U-shape (i.e., patient harm might result from too much testing/admissions and not enough testing/admissions), but we will also explore other functional firms. We will stratify the physician and APP population by dividing into the quartiles of the practice intensity markers for each marker and will compare providers in the top quartile and bottom quartile with those in the middle two quartiles.

The key assumption underlying the analyses for this aim is that patients effectively are randomized to EPs within an institution. To test this, we will construct a series of hierarchical linear or logistic regression models with key patient attributes such as age, HCC score, sex, race, etc. as the dependent variables that include random effects for each physician and each institution. These models will account for the random variation from sampling error. We will look for the random effects on physician to be non-significant, suggesting that the key patient attributes are essentially randomized across physicians within an institution. This approach builds off the approach taken by Barnett et al to examine the effect of opioid prescribing in the ED, but we will explicitly use these additional models to test the key assumption underlying these analyses. 54 In case of systematic assignment of lower acuity cases to APPs in some EDs, we will perform this as a stratified analysis including both EPs and APPs then each separately. The relationship between practice intensity and the outcomes of interest, ED visits, hospitalizations, and deaths within 7 and 30 days (binary variables) will be assessed by using generalized linear mixed model (GLMM), with random and fixed effects. Case-mix adjustment including patient, hospital and ED (e.g. crowding) and physician covariates will be included in the regression. We will use logistic regression as a link functions according to the observed distribution of the outcome. We will further evaluate this association for key conditions where delays in diagnosis or suboptimal management decisions are high risk for EPs, including acute myocardial infarction (MI), pulmonary embolus (PE), aortic dissection, stroke, and sepsis. Specifically, the model will be of the form:

 $E(Patient\ harm) = (\alpha_0 + \alpha_{patient}) + \beta_1 Practice\ Intesity\ + \sum_{j=1}^p \gamma_j X_j + \sum_{k=1}^{ph} \delta_k Z_k$, where $\gamma_j X_j$ are the p coefficients for demographic and clinical characteristics of the patients and $\delta_k Z_k$ are the ph coefficients for physicians' demographic characteristics.

- **C.4** <u>Power Analysis.</u> We plan to approach approximately 650 physicians and 250 APPs and expect the response rate based on our previous experience to be between 60% and 80%. Therefore, we can estimate the sample size as being between 350 and 490 physicians, and 150 and 200 APPs. We estimate the number of total patient encounters over the time period per provider will be 2,000. As suggested by Moineddin et al a minimum group size of 50 with at least 50 groups produces valid estimates for multi-level logistic regression models. Moreover, this sample size is favorably comparable to that in the previous studies dealing with the issue of the risk aversion and physicians' behavior, as described in the scientific premise section.
- **C.5 Potential Problems and Alternative Approaches.** There several potential challenges we will face. First, a key to our grant is achieving a high response rate on the survey. Our team is quite familiar with research using surveys and is cognizant of the challenges inherent in maximizing survey response rate. Based on our experience, close relationship with the Massachusetts EP community, and multi-pronged strategy, we are confident in our ability to achieve a high response rate to the survey. Massachusetts has a high density of EDs in a relatively small geographic area, which should further facilitate data collection to the extent this requires

individual site visits. Finally, the 654 total attending physicians and fellows plus additional APPs is more than sufficient to allow for meaningful comparisons, but in a range where we believe a high rate of survey response is certainly realistic. Despite these points, we anticipate that some regions and individual hospitals will be more difficult to obtain maximal cooperation with survey responses. If this turns out to be the case, we will focus on obtaining as close to 100% response rate in the majority of hospitals as opposed to less consistent responses at a greater number of hospitals. Since there is apt to be significant within hospital variation in survey responses, this strategy should ensure we obtain a representative sampling of the personality traits.

As noted above, claims data do not allow for distinguishing ED labs or imaging for admitted patients. Thus, we are not able to distinguish the extent of labs and imaging ordered in the ED for admitted patients. We recognize the possibility of endogeneity in the use of only discharged patients for analysis in that discharging some types of patients might require a more intensive ED workup. Nonetheless, we anticipate that physicians who demonstrate high utilization of tests/imaging for discharged patients will demonstrate a similar pattern of utilization for admitted patients, and will also tend to be high admitters. We intend to evaluate this relationship using the claims data and to evaluate labs/imaging and admission rates as separate measures.

Our survey is also subject to social desirability response bias. We will minimize this concern by reassuring EPs that their responses will only be connected to a unique identifying number (whether completed electronically or on paper), which will be connected to their name in a separately stored file. These codes (and not names) will be used to connect individual EP's individual responses to their practice data. That is, at no time will names be directly connected to scale responses. In our pilot study utilizing these scales we did not follow this procedure (i.e., physicians provided their names on their surveys) and even so, we still found considerable variation among EPs' responses. The response scores were distributed across a range of risk aversion and NFC, suggesting the responses were not highly susceptible to social desirability bias. This suggests that biased responses are not likely to be a limiting concern, especially given our use of more confidential procedures. This study has the added advantage of a sample size of close to 1,000 providers, and all providers will be reminded that we are not interested in their specific response but only in the aggregate.

Given the use of large observational databases, we are not able to explore all potentially relevant factors that may be associated with rates of testing or admission. For example, the datasets do not allow for inclusion of potentially important factors such as vital signs and presenting symptoms, access to follow-up, or qualitative components of socioeconomic status or social supports, all of which undoubtedly factor into a clinician's decision making. Nevertheless, the use of large observational datasets carries strengths particularly in terms of the ability to study large numbers of patients, hospitals, and EPs, and provides the best available large scale data measuring these constructs that we are aware of. In addition, in contrast to studies involving surveys or prospective data collection, biases related to missing data are minimized. While we recognize we cannot measure every variable of interest, the relationships we are examining are potentially major contributors to excess testing or admissions, are important to quantify, and have essential practical relevance.

C5. Future research. We anticipate this work will lead to additional projects within and after the proposed timeline. While additional insights will undoubtedly come from our work, we anticipate interventions will include the following: 1) providing feedback to physicians, highlighting their individual risk tolerance, practice intensity, and measurable outcomes; 2) employing clinical decision tools targeted at those clinical conditions in which decision-making is most impacted by risk aversion; 3) promoting changes within the health care system and at the policy level aimed at reducing the burden of medical liability on providers, particularly if the fear of malpractice and intolerance of uncertainty is associated with lower value care (either excessive testing, worse outcomes, or both); 4) providing education and strategies aimed at improving awareness of the effects of these traits on clinical decisions, the cognitive biases to which they predispose, and metacognitive strategies that may facilitate bias reduction; 5) implementing technology-based solutions such as machine learning to monitor patterns of physician practice while incorporating data on personality traits, with the intent of guiding physicians towards more standard practice patterns; and 6) improving the environment of care in the ED aimed at curtailing the impact of extrinsic factors on physician personality traits and decision-making. We plan to submit additional R01 proposals to accomplish these goals following the successful completion of our current aims.

C.6 Policy Implications and Dissemination Plans. Within emergency medicine training and clinical practice, there is potentially undue attention paid to the influence of an adverse outcome or medical malpractice case. While some of the "over-testing" that occurs in emergency medicine may be warranted given the factors discussed in this proposal, over-testing should not be the inevitable default. If we can determine that this heightened focus is resulting in patient harm, we may begin to shift the discussion to focus on ways to reduce

variation in testing towards some ideal level for specific clinical conditions. Furthermore, our results with respect to the FMS will have a potentially significant impact on the policy discussions related to malpractice reform, either by supporting or refuting the notion that large scale policy changes to reduce the exposure of EPs to risk would result in substantial reduction in "defensive medicine" and health care spending.

We expect to produce at least 4 manuscripts (see timeline). With input from project collaborators we will further develop the clinical and policy implications of the research findings by writing related perspective pieces and meeting directly with policy makers. We will target major general medicine and emergency medicine clinical journals and health policy specific journals and will pursue a strategy of wide dissemination of published findings with the assistance of the Harvard Medical School Communications Group, the Beth Israel Deaconess Medical Center Office of Communications and External Relations, as well as the American College of Emergency Physicians. In addition, we will present project findings annually at national research meetings such as AcademyHealth and the Society for Academic Emergency Medicine.

C.7 Study Team

Bruce Landon, M.D., M.B.A., M.Sc. is Professor of Health Care Policy and Medicine at Harvard Medical School and a practicing general internist at Beth Israel Deaconess Medical Center. Dr. Landon's primary research interest has been assessing the impact of various policy interventions to improve the delivery of care. In particular he has been interested in the impact of different characteristics of physicians and health care organizations, ranging from health plans to physician group practices, on the provision of health care services. In his current research, he is leading a project comparing utilization of services and quality care delivered to enrollees of Medicare's managed care program (Medicare Advantage) with care in the traditional Medicare program. Dr. Landon has extensive experience performing studies of the type proposed using observational data, including the use of the Massachusetts APCD. Dr. Landon completed a term as a member of the Health Services Organization and Delivery (HSOD) Study Section at NIH and is an elected member of both the American Society of Clinical Investigation and the Association of American Professors. He was named one of Thomson Reuters most highly cited researchers over the last decade.

<u>Peter Smulowitz, M.D., M.P.H.</u> is Assistant Professor in Emergency Medicine at Harvard Medical School, an attending physician in Emergency Medicine at Beth Israel Deaconess Medical Center, and Past President of the Massachusetts College of Emergency Physicians. He and Dr. Landon are currently collaborating on AHRQ-funded work detailing the variation in and predictors of admission to the hospital among elderly patients. He has experience using health services research methods to study the impact of various policies on ED utilization, has recent work highlighting the implications of individual physician variation in practice patterns and, along with Dr. Landon, has studied the impact of health care reform in Massachusetts on ED use and on cost reduction in emergency care.^{38,56-61}

<u>Linda Isbell, Ph.D.</u> is a Professor of Psychological and Brain Sciences at the University of Massachusetts Amherst. Dr. Isbell's primary research interests focus on the influence of emotions on social cognitive processing in a variety of real-world contexts.^{34-37,62-64} She has been the PI on two NSF grants and is currently the PI on an AHRQ-funded grant investigating the role of emotions on clinical decision-making by Emergency Physicians when evaluating simulated patients presenting with medical complaints either with or without comorbid mental illness. This work aims to identify how emotions influence clinical reasoning and information processing, focusing especially on emotional influences on diagnostic errors. This work also tests cognitive interventions aimed at mitigating adverse influences of emotion on diagnostic reasoning. Dr. Isbell has been awarded fellow status for the Society for Experimental Social Psychology and the Society for Personality and Social Psychology. She serves as Associate Editor of *Emotion*, a leading journal in her field.

<u>Victor Novack, M.D. PhD</u> is Professor of Medicine in the Faculty of Health Sciences, Ben Gurion University of the Negev, Beer-Sheva, Israel, Head of the Clinical Research Center and Research Authority, Soroka Medical Center, Beer-Sheva, Israel, and Senior Statistical Adviser to the Departments of Emergency Medicine; Anesthesia, Critical Care & Pain Medicine and Center for Health Care Delivery Science, Beth Israel Deaconess Medical Center. His background includes training in internal medicine and PhD in epidemiology. Dr. Novack has published more than 200 original articles in different aspects of the clinical epidemiology. For the last 5 years he serves as a Statistical Editor for the European Journal of Internal Medicine and statistical reviewer for the Lancet Respiratory Medicine.