A. Title. System Alignment for VaccinE Delivery (SAVED): Improving rates of influenza and pneumococcal vaccination through patient outreach, improved medical record accuracy and targeted physician alerts.

B. Goal. To improve the rates of appropriate influenza and pneumococcal vaccination among 140,000 adults in central Massachusetts.

C. Objectives
I. To improve rates of influenza and pneumococcal vaccination in eligible populations via patient-directed messages targeted at unvaccinated patients.
II. To improve the capture of vaccinations administered to Reliant Medical Group (RMG) patients in the community, hospitals and nursing facilities via electronic Health Information Exchange (HIE).
III. To improve rates of influenza and pneumococcal vaccination in eligible populations via provider and staff-directed educational interventions and system support.

D. Assessment of Need. Reliant Medical Group (RMG), a large multispecialty group practice with an electronic health record (EHR) cares for approximately 140,000 adults age 18 and older at more than 20 clinical locations throughout Central Massachusetts; approximately 30,000 are aged 65 or older. For the 2011-2012 influenza season, 55% of these adults had EHR documentation of influenza vaccination. Assuming similar rates of vaccination in 2013, there will be just over 63,000 undocumented or unvaccinated adults who could benefit from targeted influenza vaccine interventions. Similarly, 76% of RMG patients aged 65 or older have EHR documentation of pneumococcal vaccination. Even more notable is that only 31% of RMG patients between the ages of 18 and 64 who have conditions qualifying them for a pneumococcal vaccination had EHR documentation of having received one. This gap exists despite EHR alerts reminding providers and clinical staff that these immunizations are due at the time of visits. Approximately 29,000 adults age 18 and older could benefit from our targeted pneumococcal vaccine interventions to patients, providers and their staff.

E. Intervention Design and Methods. We propose a multifaceted intervention with patient-provider- and system-level components. In Year 1, we will interview patients, providers and clinical staff to elicit barriers and elucidate optimal messaging (Birmingham 2011, Chen 2007, Koch 2012,). Informed by these interviews and by RMG EHR data indicating that 25% of ignored EHR vaccination alerts are seen by providers, while 75% are seen by their support staff, we plan to develop targeted educational materials for physicians and their staff regarding the risks and benefits of influenza and pneumococcal vaccination, by the middle of Year 1.

At the end of Year 1 (several months after the start of the 2014-2015 influenza immunization season) we will implement patient outreach, providing tailored messages to address attitudinal, informational, and logistical barriers to vaccination. This outreach will take advantage of two cost-effective and generalizable electronic technologies (e.g. MyChart, RMG’s electronic patient portal, and ELIZA, an Interactive Voice Recognition (IVR) system) to deliver targeted pneumococcal and influenza education as well as information on times and locations of RMG influenza vaccination clinics and in-office immunization opportunities. These two modes will also include components that will enable patients to automatically update their own EHR records to reflect vaccination receipt at external locations (e.g. pharmacies and senior centers), allowing for system-level improvement in vaccination record accuracy.
In Year 2, after the 2014-2015 flu season, we will evaluate and refine our Year 1 interventions by interviewing patients who failed to respond to our electronic outreach, and providers and staff who most frequently continue to ignore alerts. Based on this feedback, we will modify our Year 1 interventions and redeploy them, with repeat provider and staff education in the middle of Year 2 and the electronic patient outreach towards the end of Year 2 for the 2015-2016 influenza immunization season.

In Year 2 we will also implement a system-level intervention, centralizing and updating vaccination records so that providers will have greater confidence in patient records and reduce inappropriate alerts. Building on existing state-wide HIE initiatives, we will implement electronic transmission of vaccination administration histories from 3 central Massachusetts hospitals and 8 skilled nursing facilities (SNFs) directly into the RMG EHR.

**F. Innovation.** This proposal builds upon innovative technologies already implemented at RMG and the unique strengths of our multidisciplinary research team to create and test patient, provider and system-level interventions that will be generalizable to practices across the country. RMG won the prestigious 2011 HIMSS Davies Award for exemplary implementation of their EHR. Through work done by Dr. Fisher, RMG’s EHR currently alerts providers, their staff, and the 30% of their patients who use MyChart when they are overdue for immunizations. Dr. Garber led the implementation of an interface from a payer that automatically loads immunization claims on 60% of our patients back into the EHR. However despite these efforts and the ability to manually enter immunization history into our EHR, RMG still suffers from a significant gap in immunization completion and documentation.

Our proposal to combine tailored messages with access-enhancing information, delivered via electronic patient portals and two-way Interactive Voice Recognition systems that automatically update the EHR involves technologies that are becoming more common, but using them in innovative ways that efficiently fit into the busy healthcare system. Similarly, HIEs are rapidly being deployed around the country, but the ability to automatically load immunization data and resolve potential duplicate entries based on RMG’s prior work with claims data will make immunization data conveyed by these HIEs more useful.

We also recognize the importance of effective evidence-based messaging in the success of our interventions. A clinician-researcher, Dr. Cutrona, is well positioned to lead this team, building on her previous work exploring adherence both to medications and to preventive behaviors including cancer screening. Dr. Mazor is a nationally-recognized expert in patient-provider communication and brings her wisdom to support this project. And Dr. Goff’s previous work exploring HPV vaccines using qualitative methods will contribute important vaccine-specific expertise to the success of this project.

**G. Design of Outcomes Evaluation.** We will test the effectiveness of physician and clinical staff education and system support comparing the response rates to EHR alerts for the 12 months prior to the Year 1 intervention to the 12 months after the Year 1 intervention and the 12 months after the Year 2 intervention. We will break these into monthly analyses for comparison to both the prior month and prior year to look for seasonal variations as well as to identify any decay in the interventions’ effectiveness.

In Years 1 and 2 we will test the effectiveness of electronic patient outreach efforts through a non-blinded randomized design. We will test two modes of outreach: (1) the electronic patient portal (MyChart) and (2) phone calls via IVR. For the 2014-15 flu season and
again for the 2015-16 flu season, we expect ~90,000 adults will have no evidence for appropriate influenza or pneumococcal immunizations, with ~30,000 of them being MyChart users. The ~60,000 potentially unvaccinated patients who do not use MyChart will be randomized into 2 groups of ~30,000 adults each for either usual care vs. IVR outreach. The ~30,000 potentially unvaccinated adults who do use MyChart will be randomized to 3 groups of ~10,000: Usual care vs. IVR outreach vs. MyChart outreach. Use of these randomized control groups will allow us to identify the impact of each intervention.

We will track and conduct secondary analyses stratifying by source of vaccination information (e.g. administered by RMG vs. administered outside clinic and either manually entered by RMG, loaded from payer claims, loaded via MyChart, loaded via IVR outreach, or loaded from hospital or nursing facility via HIE) (Rolnick 2013, Zimmerman 2009), and all comparisons will be conducted using an intent-to-treat analysis.

All messages, texts for alerts and algorithms will be made freely available through presentations, publications and posting on the Meyers Primary Care Institute website.

### H. Timeline

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### I. Requested Budget.
We plan to request $635,104 across the 2 ½ years, inclusive of indirect costs.
Organizational Detail. Three institutions will support and facilitate the proposed study: the Meyers Primary Care Institute (MPCI), University of Massachusetts Medical School (UMMS) and Reliant Medical Group (RMG). MPCI is a joint endeavor of UMMS, RMG and Fallon Community Health Plan. MPCI’s mission is to improve the health and healthcare of populations through innovative research and educational endeavors. Direct linkages with major clinical systems enable MPCI’s investigators to track treatment and outcomes in defined populations, assess the effectiveness of changes in the health care system, and develop and test innovations in care delivery. Drs. Cutrona and Mazor are MPCI investigators and UMMS faculty members. UMMS is the only public academic health sciences center in Massachusetts and is dedicated to advancing the health and well-being of the population through pioneering education, research, and health care delivery. UMMS is consistently ranked as a national leader in primary care research and education in the U.S. News & World Report. RMG (formerly Fallon Clinic) was founded in 1929 as the first group medical practice in Central Massachusetts. RMG offers a full range of primary and specialty care with over 260 physicians, 1,700 employees and 20+ clinical locations throughout Central Massachusetts. In 2012 RMG served approximately 200,000 patients in approximately 2,000,000 encounters. RMG’s collaborative group practice model encourages primary care physicians and specialists to work together to deliver the highest level of care to each patient. RMG has played a leading role in health information technology utilizing Epic Care, a comprehensive electronic health record, and MyChart, a secure online portal that provides patients electronic access to their healthcare team and to portions of their medical record. RMG has had a long standing commitment to medical education and research, serving as a site for training of medical students and residents and as the location of large population-based studies with the potential to make an impact on the health care of the nation. Dr. Sarah L. Cutrona will lead the multidisciplinary research team. Dr. Cutrona is a general internist whose research has examined the influence of providers and caregivers on patient adherence to medications and preventive behaviors. She is currently investigating the role of social networks and e-messaging in encouraging preventive health behaviors. Dr. Lloyd D. Fisher is a general pediatrician and a pediatric site chief. He has built complex decision support algorithms into the Epic EHR to guide providers’ administration of vaccines. Dr. Fisher is on RMG immunization committees, is a member of the Epic optimization team and Assistant Medical Director for Informatics at RMG. Dr. Lawrence Garber is a general internist and Medical Director for Informatics at RMG. He has extensive experience designing and implementing EHR-based interventions and led the creation of electronic interfaces between RMG’s EHR and 6 regional hospitals. Dr. Garber is Vice Chair of the Massachusetts eHealth Collaborative’s Executive Committee, a member of the Massachusetts State Health Information Technology and Health Information Exchange Advisory Committee, and a member of ONC Policy Committee’s Health Information Exchange Workgroup. Dr. Sarah Goff is a health services researcher with clinical specialties in general pediatrics and internal medicine whose research focuses on health care quality and safety. Her work includes numerous applications of qualitative methods, including a mixed-methods content analysis of patient-provider discussions about human papilloma vaccine, with Dr. Mazor. Dr. Kathleen M. Mazor is a Professor of Medicine at UMMS and a highly experienced researcher; she brings expertise in developing and testing health-related messages for patients and providers. She has led and collaborated on over 30 qualitative studies using in-depth interview methods.
References


System Alignment for VaccinE Delivery (SAVED): Improving rates of influenza and pneumococcal vaccination through patient outreach, improved medical record accuracy and targeted physician alerts.

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C. MAIN SECTION OF THE PROPOSAL
C1. Overall Goals and Objectives

The goal of the SAVED study is to improve the rates of appropriate influenza and pneumococcal vaccination among adults enrolled in a large multi-specialty group practice in central Massachusetts.

C1a. Key Objectives.

I. To improve rates of influenza and pneumococcal vaccination in eligible patient populations via:
   a. **Patient-level messages** targeted at unvaccinated patients;
   b. **Provider- and staff-level educational interventions** and system support.

II. To improve the capture of vaccinations administered to Reliant Medical Group (RMG) patients in the community, hospitals and nursing facilities via **system-level electronic Health Information Exchange (HIE)**.

C1b. Overview. Influenza and pneumococcal vaccines are beneficial but underutilized\(^1\text{-}\text{5}\). Working with a large multi-specialty group practice in central Massachusetts, we propose to develop, implement, and evaluate a multi-faceted vaccine promotion program with **patient-, provider-, and system-level components**. Patient-level components will include tailored outreach to patients who are not up-to-date on either their influenza or on both influenza and pneumococcal vaccines. We will evaluate the relative effectiveness of two generalizable electronic technologies - MyChart, RMG’s electronic patient portal with secure email, and Eliza, an Interactive Voice Recognition (IVR) system – for providing tailored messages for patients that **address local barriers**\(^6\text{-}\text{8}\) to vaccination. Both systems will also allow patients to **provide data**, for instance to indicate that they have been vaccinated at another location, or to report reasons for not receiving a vaccination. Provider-level components will include **targeted and recurring educational materials for providers and their staff** regarding the indications, risks and benefits of influenza and pneumococcal vaccination, and suggesting strategies for overcoming local barriers to vaccination. Beginning in year 2, providers will also receive individualized report cards providing feedback on their immunization rates. Inaccuracy of vaccine records is a commonly cited reason for failure of provider reminder systems\(^9\text{-}\text{16}\). System-level components will include both the capability to capture patient reported vaccinations, and **automatic updating of EHR vaccination records** with pneumococcal and influenza immunizations given at local hospitals and skilled nursing facilities. These system-level components will reduce inappropriate alerts and improve provider confidence in patient records\(^9\text{-}\text{16}\).

Figure 1. Study Overview
The project will have 2 outreach cycles with an interim period for evaluation and refinement, so that lessons learned during the first cycle can be used to enhance the educational materials and messaging, and optimize effectiveness of the most costly components during the second cycle. These outreach cycles will address the 2014-2015 flu season (Cycle 1) and the 2015-2016 flu season (Cycle 2). After Cycle 1, quantitative data collection and analysis will allow us to evaluate the effectiveness of the intervention, and determine whether one or more components are differentially effective in increasing vaccination rates in certain patient groups. We will: 1) identify any patient factors which moderate the impact of the patient outreach in order to increase the cost effectiveness of the outreach; 2) identify patients who received the electronic outreach, but did not subsequently receive the vaccinations which they were eligible for; and 3) identify providers and staff who frequently ignored electronic alerts. Qualitative interviews with patients, staff, and providers will inform initial development during Cycle 1 and later refinement of educational materials and messages. After our evaluation and refinement period, we will initiate Outreach Cycle 2. In the last 4-6 months of the study we will evaluate the impact of our multi-faceted intervention on vaccination rates across the RMG population.

C2. Technical Approach

C2ai. Baseline data, methods of collection and analysis. Baseline data collection has been conducted at Reliant Medical Group (RMG), the clinical setting for the intervention and evaluation. RMG is a large multi-specialty group which employs 217 outpatient physicians at more than 15 clinical locations throughout Central Massachusetts. RMG physicians and providers care for approximately 140,000 adults age 18 and older of whom approximately 30,000 are aged 65 or older. Of those RMG patients for whom information on race was available in 2012, whites represented 73.3%, blacks represented 3.7% and other races represented 23.1%.

Reliant Medical Group’s EHR: All RMG providers and staff use an electronic health record system (EHR) made by Epic Systems Corporation. Epic EHRs store information on more than half of all US patients. Epic is highly configurable to meet the specific needs of local clinical sites and has a customer portal to encourage sharing of local adaptations to numerous clinical sites across the nation. We will take advantage of this customer portal to disseminate our vaccine-related adaptations at the close of this project. RMG’s EHR is designed to record vaccine administrations performed at RMG as well as outside of RMG. The EHR also displays if the patient refuses an immunization or is allergic to an immunization. Consistent with studies showing that Clinical Decision Support can improve rates of indicated vaccines, the RMG EHR is configured to flag a patient’s record when they are due or overdue for an immunization based on the patient’s age, immunization history, medical history, surgical history, and social history. When patients call or are seen at RMG, physicians and staff accessing the patient’s record are alerted to immunizations that are due or overdue. Using a Microsoft SQL Server database which is updated nightly with data from all of the EHRs, we are able to identify patients who are eligible and in need of immunizations, identify users (e.g., physicians or staff) alerted to immunization deficiencies, and understand whether immunizations were given.

Baseline Vaccination Data: We used EHR-derived data to calculate the percent of RMG patients aged 18 and older who received vaccination for influenza between August 1, 2011 and
March 30, 2012 (i.e. the 2011-2012 flu season). Similarly, we used EHR-derived data to examine percent completion of pneumococcal vaccination among eligible adults. To be considered eligible for the pneumococcal vaccine, an RMG patient needed to be either (a) aged 65 or older or (b) between the ages of 18 and 64 years with a qualifying chronic condition.

We found that vaccination rates for RMG patients were suboptimal. During the 2011-2012 influenza season, 55% of RMG’s adults over age 18 had EHR documentation of influenza vaccination. Similarly, 76% of RMG patients aged 65 or older had EHR documentation of pneumococcal vaccination. Even more notable, only 31% of RMG patients between the ages of 18 and 64 who have conditions qualifying them for a pneumococcal vaccination had EHR documentation of having received one. This gap in vaccination rates exists despite EHR alerts already in place at RMG reminding providers and clinical staff that these immunizations are indicated and due at the time of patient encounters. We found that 25% of ignored EHR alerts were seen by providers, while 75% were seen by their support staff, highlighting the importance of targeting an intervention to both providers and staff.

**C2aii. Primary audience and expected beneficiaries of intervention.** There are two primary audiences for our interventions. The primary audience for our patient-level outreach will be RMG patients eligible for the influenza vaccine, the pneumococcal vaccine or both. The primary audience for our provider- and system-level interventions will be RMG providers and staff who interact with these eligible patients. RMG has multiple points of clinical interaction with patients. Patients who call or send secure messages through MyChart are triaged by secretaries, medical assistants or nurses. Patients who come for office visits are roomed by medical assistants and may have visits with nurses, nurse practitioners, nurse midwives, physician assistants, or physicians. All of these providers and clinical staff have the opportunity to discuss immunizations with the patient and so will be targeted in this intervention.

**Overall, we anticipate that approximately 63,000 RMG adult patients could benefit from targeted interventions focused on influenza vaccination, and approximately 29,000 could benefit from targeted interventions focused on pneumococcal vaccination.**

**C2b. Intervention Design and Methods.** Our multifaceted approach will address the gap between current and optimal vaccination rates via patient-, provider- and system-level interventions intended to target local barriers. We will conduct qualitative interviews with patients, providers and staff, design targeted messages and educational materials, then implement these in a health care system in Central Massachusetts.

**C2bi. The Communication Human Information Processing Model: Theoretical Framework.** The Communication Human Information Processing (CHIP) model\(^{20-21}\) will provide the overarching framework for the design and implementation of the intervention components. Growing out of extensive research on effective communication of safety information, this model includes the core concepts of communication theory (i.e., message source, channel and receiver) while highlighting the need to enhance effective information processing. Effective information processing requires attention to and comprehension of the message (e.g., that a vaccine is needed); these processes are influenced by attitudes and beliefs, and motivation. In the context of vaccination, beliefs about susceptibility, severity, disease likelihood and vaccine effectiveness are likely to be important\(^{22}\). All of these processes in turn influence behavior (i.e,
vaccination). Therefore we will develop interventions that garner attention, are easily understood, address critical beliefs, and motivate vaccination.

**C2bii. RMG patient & provider/staff interviews: Understanding barriers to vaccination.** Our first step in intervention design will be to interview patients, providers and staff in order to tailor intervention components to target local barriers, and inform message design.

**Patient and Provider/Staff Sample.** A total of 20 RMG patients will be recruited to participate in interviews. Using electronic medical records at RMG, we will identify patients aged ≥18 who are not up-to-date on influenza vaccination, pneumococcal vaccination or both (i.e., per RMG EHR data, were eligible but were not vaccinated against influenza during the most recent flu season and/or were eligible but never vaccinated for pneumococcal vaccine). Candidates will be sent a letter of invitation to participate in interviews; those who express interest will be screened to confirm unvaccinated status. Sampling will be purposeful to ensure that interviewees are diverse in terms of age, gender, which vaccination(s) is/are needed, and personal risk factors (e.g. underlying respiratory disease). Providers and staff (10 total) will be selected in order to represent a range of clinic sites, provider types (e.g. family practice, internal medicine, geriatrics), and role (e.g. physician, nurse practitioner; nurse, medical assistant). Interviews will be offered in-person and via telephone, to minimize barriers such as transportation constraints, frailty or busy clinical schedules.

**Interview Procedures.** All interviews will be conducted by a trained interviewer, supervised by Dr. Mazor. The interviewer will explore possible barriers to vaccination, first using open-ended questions, then probing for specific barriers using the CHIP framework (e.g., understanding of vaccine indications, risks and benefits, lack of information regarding access, motivational factors, etc.). The interviewer will present sample patient or provider/staff messages intended to address the barriers raised by the interviewee, and will solicit his/her reactions to those messages and recommendations for modifications to increase effectiveness. Interviewees will be asked to paraphrase the main points of the messages to assess comprehension. They will also be asked whether they found the messages persuasive and motivating; patients will be asked whether they would be likely to get vaccinated after hearing the messages. All interviewees will be asked to listen and respond to IVR messages; those with portal access will also be asked to respond to sample portal messages. Informed consent will be confirmed prior to the start of the interview. Interviews will be audio-recorded and professionally transcribed.

**Analysis of Interview Data.** Interview data will be analyzed using qualitative methods which Drs. Mazor, Cutrona and Goff have used in prior studies. Using an iterative process, Drs. Mazor and Goff will each read 2 transcripts and together will generate a preliminary list of content
codes that capture the themes and subthemes identified in those transcripts. They will then apply the coding scheme to 2 additional transcripts, adding codes if needed to ensure that all relevant content is captured. When they are satisfied that the coding scheme captures all relevant themes and subthemes, Dr. Mazor will train the Research Assistant to apply the coding scheme to the full set of transcripts. Drs. Mazor and Goff will prepare a summary for the full investigative team to inform design of the final patient messages and educational materials.

**C2bii. Development of Messages and Educational Material.**

*C2bii(1) Creation of patient outreach messages.* As noted above, patients will be asked to react to draft messages during the interviews. Content for these initial drafts will be drawn from 1) existing sample scripts used by Eliza corporation; 2) the CDC website ([http://www.cdc.gov/vaccines/](http://www.cdc.gov/vaccines/)); 3) existing RMG Epic alerts developed by Dr. Fisher; as well as the clinical and communication expertise of the study team. Using the CHIP model as our guide (see figure), we will take into account (1) a patient’s expected level of attention to information delivered via various channels (e.g. in-person from a provider, or via IVR or e-portal), (2) likely level of comprehension and (3) pre-existing attitudes and beliefs and we will seek to develop a message that (4) maximizes patient motivation and leads to vaccine completion. We will also include information on upcoming RMG flu clinics in order to provide access-enhancing information to facilitate completion of the desired behavior.

*C2biii(2) Designing provider/staff educational material.* Using the same techniques described above for patient interviews, we will identify and interview 10 RMG providers and staff (6 providers; 4 staff members). Information gained through our interviews will inform educational material targeted to providers and staff. We will again be guided by the CHIP model, considering the impact of available channels of communication with providers (in person and e-messages and alerts) as well as accounting for expected level of attention and comprehension. We will use interview results to identify effective ways to motivate providers to attend to alerts and encourage vaccination.

**C2biv. Provider/Staff Outreach.**

*C2biv(1) Education.*

**Educational Focus and Content.** Ninety-two percent of RMG providers and clinical staff received an influenza vaccine in the 2012-2013 flu season, reflecting widespread personal acceptance of its benefits. We therefore anticipate that focusing our provider and staff education efforts on the pneumococcal vaccine will provide the highest yield. Our educational material will review in detail the patient populations for whom this vaccine is recommended before age 65 and will also highlight select populations requiring more complex pneumococcal vaccination regimens. If our provider and staff interviews indicate a need for influenza vaccination education we will expand our focus to include this as well. Possible topics for influenza vaccine education would include information on options for people who don't like needles and options for egg-allergic individuals.

**Education Format/Venue.** Providers and staff at each RMG site meet monthly for lunch to discuss clinical and administrative updates. These meetings are well attended and are an important communication venue for RMG. We will design 10 minute presentations to be delivered by Drs. Fisher and Garber, respected practicing clinicians within RMG. These
presentations will be delivered at all of the 15 physician sites during year 1. Subsequently, bi-monthly reminder emails will be sent to providers and clinical staff, reinforcing the educational message presented at the lunch meetings. In year 2, Drs. Fisher and Garber will repeat their 10-minute lunchtime presentations to providers and staff at the 15 clinical sites.

C2bv(2) Provider report cards. An important component of the provider and staff education will be “report cards” distributed to user-specific Epic “dashboards” which are visible when logging into the Epic EHR. Report cards will provide individualized feedback with comparative data on pneumococcal and influenza vaccination completion rates. We will begin distribution in June of Year 2; these will continue monthly throughout the remainder of the study period.

C2bv. Patient outreach via electronic portal with secure email and Interactive Voice Recognition (IVR). We will test the effectiveness of electronic patient outreach efforts through a non-blinded randomized design. We will test two outreach channels: (1) the electronic patient portal (MyChart) with secure email and (2) phone calls via IVR. Use of randomized control groups will allow us to identify the impact of each intervention. Messages will have 2 goals: (1) vaccine promotion and (2) improve the accuracy of the patient record.

C2bv(1) Outreach via electronic patient portal with secure email.
Current E-portal use in RMG. All RMG patients are given the option to sign up for MyChart, an electronic patient portal with secure email that is offered to patients free of cost. Over 30% of RMG patients use MyChart. MyChart provides patients personalized, secure online access to portions of their medical record. They can view their immunization history as well as alerts for immunizations that are due or overdue. Patients can securely send and receive messages with their RMG providers, and complete questionnaires sent to them by their providers.

Description of e-portal intervention. We will design an outgoing secure email message to be sent via MyChart to patients who are due or overdue for influenza according to the RMG EHR (among these patients, those due or overdue for pneumococcal vaccination will receive additional messaging addressing this vaccine). Messages will include information on upcoming flu clinics as well as opportunities to receive immunizations at RMG offices or pharmacies. Patients will also receive an attached online questionnaire enabling online self-reporting of vaccine completion if they were vaccinated outside of RMG, as well as reporting other barriers to vaccination (e.g., misconceptions related to need or eligibility, beliefs about vulnerability, etc.). Receipt of completed online questionnaires will trigger automated updating of immunization types and dates in the Epic EHR by a process that extracts questionnaire responses each night and resubmits them through Epic’s Inbound Immunization interface. Also, all of the questionnaire data, including information on patient barriers, will automatically be stored and available to the project team for analysis.

C2bv(2) IVR outreach.
Current IVR use in RMG. RMG currently uses IVR to notify patients of upcoming scheduled appointments. Three days in advance of a scheduled appointment, RMG’s Epic EHR automatically sends a list of patients and their phone numbers to Eliza which tries calling each patient up to 3 times in the evening to make a successful connection. Patients respond to the IVR calls by voice, affirming that they will keep their appointment, or cancelling the
appointment. Each night, Eliza automatically sends a file back to the EHR which cancels any appointment that was so indicated by the patient.

**Description of IVR intervention.** Using information gained through our interviews and building on the expertise of the Eliza interactive design team, we will develop a script similar to the message used in the e-portal intervention but uniquely suited for telephone communication. The IVR message will promote completion of influenza vaccines by providing education as well as information on upcoming flu clinics. In addition, the IVR call will gather information on potential barriers and will provide patients the opportunity to report the date they had already completed their vaccinations outside of the RMG system, or to provide their reason for not being up-to-date with vaccinations (i.e. patients will be invited to identify barriers or to report reasons for not wanting to be immunized). Having completed just over 1 billion outreaches, the Eliza interactive voice recognition system has extensive experience working with health systems and has developed effective approaches to validation of phone numbers, identification of optimal times for reaching patients and patient-centered scripts that are able to keep patients engaged and achieve stated goals.

Patient-entered immunization type (mapped to “Codes for Vaccine Administered” (CVX code)) and date, and reasons for not being immunized will be sent nightly by Eliza to the Epic EHR where the patient’s immunization history will automatically be updated via Epic’s Inbound Immunization interface, and all IVR responses will be stored for analysis by the project team.

**C2bv(3)Programming.** An established RMG Application Development Team will be responsible for programming the components of the intervention. Each team member has extensive experience developing and introducing technology to the clinical environment and has close working relationships with key stakeholders within the organization (see Organizational Details for further information).

All of the described interfaces will have **audit trails that will allow the project team to understand where each record of immunization came from** (see Table 1. Data Sources for EHR-documented Vaccinations) as well as assisting in debugging any errors.

**Healthcare Information Technology Standards:** Healthcare Information Technology Standards Panel (HITSP) approved standards will be used in the development of the proposed intervention. Vaccine information received from Eliza will use CVX codes. Patient summaries containing administered immunization history from other facilities will use CVX codes within HL7 Consolidated CDA documents.

**Privacy and security related to the exchange of protected health information (PHI):** RMG information technology policies will serve as the basis for the privacy and security procedures governing the use of sensitive health information in the development of the proposed intervention. These policies have been vetted within the RMG enterprise, were prepared by their HIPAA Security Officer, issued by their IT Business Office, and approved by their Chief Information Officer. These policies comply with good information security practice and regulations set forth by the Health Insurance Portability and Accountability (HIPAA) Act of 1996.

**C2bv(4) Implementation of patient outreach.**

**Outreach Cycle 1: Nonblinded Randomized Controlled Trial.**
In Outreach Cycle 1, we will randomize 20,000 e-portal users and 10,000 non e-portal users who are identified in the RMG EHR as not being up-to-date on their influenza vaccines (Figure 3). The RCT approach was chosen because it minimizes selection bias and confounding that might limit interpretation of the study findings. As a group, patients who take initiative to sign up for E-portals may differ from people who do not, possibly demonstrating more health-conscious or adherent behaviors. For this reason, we will treat e-portal and non-eportal users separately. We will randomize e-portal users to: (1) E-portal message with IVR call; (2) E-portal message with no IVR call; (3) No e-portal message with IVR call; or (4) No E-portal message with no IVR call. Non e-portal users will be randomized to either (1) IVR call or (2) no IVR call. We will conduct analyses stratified by e-portal use and examine the effect of IVR calls in both users and non-users of e-portals.

**Evaluation & Intervention Refinement.** In addition to the quantitative analyses of Cycle 1 data, we will conduct a second round of qualitative interviews in order to identify areas where the messaging and educational materials can be improved. We will use the methods described under *C2bii* above; but will focus recruitment on “unresponsive” patients, providers and staff. We will define as unresponsive those patients who received a message (via IVR, e-portal or both) but did not subsequently receive a vaccination or report having received one elsewhere. We will define as unresponsive those providers and staff who have high rates of ignoring alerts. The interview content will specifically explore reactions to the messaging and educational materials, and will seek to identify specific areas of resistance and continuing barriers.

**Outreach Cycle 2. Cost-conscious Targeted Intervention.** In order to implement our cost-conscious targeted intervention, we will carry out stratified analyses (detailed below) of patients’ responses to the Cycle 1 IVR intervention and will identify those patients most likely to benefit from the IVR intervention. We will then implement a cost-efficient outreach effort in which vaccination messages are sent to all e-portal users (because...
e-portal messages are free once developed) and IVR messages are sent to those patients identified as most likely to benefit from targeted IVR calls (i.e. most likely to get vaccinated). As in Outreach Cycle 1, we will make a total of 15,000 IVR calls in Cycle 2. The important difference is that in Cycle 2 those IVR calls will be allocated to those patients who our analyses suggest will be most likely to respond positively to the IVR intervention (i.e., to get vaccinated).

C2bvi. Electronic import of vaccine completion reports from hospitals & nursing facilities.

We will address incomplete adult vaccination histories through electronic import of influenza and pneumococcal vaccinations performed at 3 Worcester hospitals and 8 skilled nursing facilities into the RMG EHR.

Every hospital in the country is developing the ability to transmit electronic summary documents, such as an HL7 Consolidated CDA Continuity of Care Document (CCD), at time of discharge to the primary care physician in order to satisfy “Meaningful Use” of EHRs. To support this, each state is building a Health Information Exchange (HIE) to support transmissions. Within 2 years, transmission of e-summary documents is expected to be implemented nationally; the target date for central Massachusetts is 2014. RMG is leading an ONC-sponsored project known as IMPACT: Improving Massachusetts Post-Acute Care Transfers. This project is interconnecting 2 hospitals, 8 nursing facilities, 2 home health agencies, and 2 large group practices; connection to a third hospital is also underway.

For the SAVED project, starting in June of 2015, RMG will take the immunization history received from these facilities and automatically load them into the Epic EHR via Epic’s Inbound Immunization Interface. Patient-matching will be performed using a technique currently in place at RMG, where the received patient demographics (i.e. name, date of birth, and gender) are first loaded using Epic’s Inbound Registration Interface along with the sending facility’s Medical Record Number (MRN) so that Epic’s “Bridges” Master Patient Index will attach that MRN to the correct patient. Subsequently, when the MRN-linked immunization is passed through Epic’s Inbound Immunization Interface, it will be added to the correct patient’s record.

C2c. Evaluation Design
In our initial needs assessment we described the percent of eligible RMG patients who had EHR documentation of completed influenza and pneumococcal vaccines. In our evaluation, we will determine whether our multi-faceted intervention effectively closed the gap between patient eligibility for vaccination and documented vaccine completion. We will systematically analyze each intervention component to determine its value, both to increase external capture rates as well as to promote vaccination rates at RMG.

C2ci. Data sources and data collection for year 1 RCT analysis. We will draw on data from EHR records, brought into the EHR via several pathways that are clearly traceable via audit trails (see Table 1). Determining which intervention resulted in the greatest capture of external immunizations will be relatively straightforward. However, determining which intervention caused the greatest increase in immunizations rates is more complex. Since the control groups will not be given the opportunity to self-report, immunizations recorded via the MyChart questionnaire or the Eliza IVR will be excluded from the immunization rate analysis. Similarly, only a subset of patients will be hospitalized or require skilled nursing facility stays during the
study period and the electronic import of these records may be somewhat erratic, so these will be excluded as well.

Thus, when assessing the impact of our Outreach Cycle 1 Randomized Controlled Trial (analysis described below) we will include only vaccines directly administered or documented in an RMG facility for our primary analysis.

Separately, we will calculate (a) the percent of patients self-reporting vaccine completion at the end of Outreach Cycle 1 and at the end of Outreach Cycle 2; (b) the percent of patients for whom documentation of vaccination in a hospital or skilled nursing facility is electronically imported by the end of the 2015-2016 influenza season.

Table 1. Data Sources for EHR-documented Vaccinations (influenza and pneumococcus)

<table>
<thead>
<tr>
<th>Directly Documented by RMG Staff</th>
<th>Patient Self-reported</th>
<th>Electronically Imported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccinated at RMG or report entered manually into the Epic EHR by staff or provider.</td>
<td>Vaccinated outside of RMG with report received from a MyChart questionnaire or received via the Eliza IVR.</td>
<td>Vaccinated at hospital or long-term care facility with report received from a Health Information Exchange.</td>
</tr>
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C2cii. Determination of intervention impact on vaccination rates: Outreach Cycle 1 RCT. To determine the impact of our Cycle 1 Randomized Controlled Trial on RMG vaccination rates for the 2014-15 flu season, we will perform unadjusted and adjusted analyses of the overall group of randomized patients (30,000 patients) and will also carry out several stratified analyses.

Table 2. Year 1 RCT: Patients in Need of Influenza Vaccine (Subset Will Also Need Pneumococcal Vaccine)

<table>
<thead>
<tr>
<th></th>
<th>E-portal Users</th>
<th>Non E-portal Users</th>
<th>Total</th>
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<tr>
<td>E-portal only</td>
<td>5,000</td>
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<td>5,000</td>
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<tr>
<td>IVR only</td>
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<td><strong>Total</strong></td>
<td><strong>20,000</strong></td>
<td><strong>10,000</strong></td>
<td><strong>30,000</strong></td>
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Unadjusted Analyses Overall Group. With the goal of understanding whether IVR call receipt increased likelihood of vaccine completion across both e-portal users and nonusers, we will conduct an intention-to-treat(ITT) analysis using a Chi-square test to compare vaccine completion rates among those randomized to receiving IVR calls vs. those randomized to not receive calls. In order to isolate the effect of the IVR call, the denominator for this analysis will exclude the 10,000 e-portal users randomized to receipt of an e-portal message (either alone or in combination with IVR call) but will include all other randomized patients (final N=20,000).

E-portal Users. Using a factorial design, we will conduct unadjusted Chi-square tests focused only on e-portal users, again using an ITT approach. Our goal will be to understand (a) whether e-portal message receipt increased likelihood of vaccine completion compared to control; (b) whether an IVR call increased likelihood of vaccine completion compared to control; and (c) whether receiving an IVR call plus e-portal message improved likelihood of vaccine completion compared to e-portal message alone.
**Non-E-portal Users.** In an analysis focused only on those who do not have an e-portal, we will assess whether those receiving IVR calls displayed increased vaccination rates.

| Through these analyses, we will determine whether e-portal messages and IVR calls are effective and, for e-portal users, whether there is incremental value attained through the added expense of the IVR call (in addition to or in place of an e-portal message). |

**Amount of Change Expected.** With our proposed sample size and using a factorial design as described, we will be powered to detect a 2-3% difference in vaccination rates between any two randomized groups. Based on previous studies, we expect a 10-20% improvement in vaccination rates for either intervention compared to control.

**Adjusted Analyses**

**Overall Group and Stratified by E-portal Use.** We will examine the adequacy of randomization in the overall group and separately among e-portal users and non e-portal users by assessing whether there was differential representation in intervention vs. control groups by (a) age group; (b) race/ethnicity; (c) gender; (d) influenza vaccination in previous year; and (e) level of healthcare utilization; if differences are found we will carry out adjusted analyses using logistic regression to control for significant differences, modeling odds of receiving (a) influenza vaccine and (b) pneumococcal vaccine.

**Stratified Analyses: Identifying Subgroups for Whom Intervention Was Effective.** Our large sample size will allow us to stratify by 5 patient characteristics (listed above) readily identifiable in the EHR. These analyses will help us carefully target the more costly IVR intervention in Cycle 2. We will carry out analyses stratified by these five patient characteristics, using (a) the overall group excluding e-portal message recipients, and (b) e-portal users only. As above, we will seek to understand the incremental value attained for a given subgroup through the added expense of the IVR call, and will target those subgroups for whom the IVR yields the greatest benefit.

| Through these analyses, we will identify optimal targets for IVR calls in Cycle 2, both for e-portal users (all of whom will also receive e-portal messages) and for non e-portal users. |

**C2ciii. Determination of impact: Outreach Cycle 2 cost-conscious targeted intervention.** With the goal of understanding whether our multipronged intervention improved overall RMG vaccination rates by the end of the 2015-2016 influenza season, we will compare the overall percent of RMG patients with EHR documentation of vaccine completion at baseline and at the end of Flu seasons 2014-2015 and 2015-2016. In order to capture the impact of provider education and system updates as well as the impact of the Cycle 2 targeted intervention, this analysis will include all RMG patients; those who were randomized and those who were not. We will examine both (a) the rate of direct documentation and (b) the rate of combined documentation (e.g. direct, self-report or e-import).

**Physician Response to Vaccine Alerts: Secondary Outcome.** We will test the effectiveness of physician and staff education and system support comparing the response rates to EHR pneumococcal vaccine alerts for June 1 2013-May 31 2014 (baseline) to rates for June 1 2014-May 31, 2015 (exposed to provider education alone) and for June 1, 2015-May 31, 2016 (exposed to provider education plus report card and e-import from hospitals and nursing
homes). We will break these into monthly analyses for comparison to the prior month and to the same month in the prior year, assessing for seasonal variations and decay in effectiveness.

**Determination of Engagement by Target Audience.** We will assess percent of patients reached in Outreach Cycles 1 and 2 (i.e. percent engaged with the IVR, percent opening and percent responding to e-portal messages). We will measure attendance at provider/staff educational sessions, rates of response to vaccine alerts and of progress report opening among providers.

**Dissemination.** We will publish findings through presentations at scientific meetings and in peer reviewed journals and will present them to RMG leadership for possible long-term implementation. Patient messages and educational materials will be available on our website. SmartTool adaptations to the Epic system will be published on the Epic UserWeb portal.

**C3. Detailed Workplan and Deliverables Schedule**

Year 1 will include four main steps: (1) **preparation**, (2) **interviews**, (3) **message & educational material development**, and (4) **Outreach Cycle 1 to providers and patients**. In the first 6 months, we will prepare for provider, staff and patient interviews; months 4-11 will be devoted to preparation and development of the IT architecture needed to (a) identify unvaccinated patients and send them outgoing messages (e-portal and IVR calls) and (b) capture and upload into the EHR incoming patient-reported data on vaccine completion barriers and preferences. Preparation for EHR capture of vaccinations from hospitals and long-term care facilities will be ongoing during this entire year. In months 4-9 we will recruit and interview patients, providers and staff regarding influenza and pneumococcal vaccine attitudes, beliefs, and comprehension of risks/benefits, as well as regarding perceived barriers to vaccine completion. Interview findings will inform **development of messages & educational material** for providers, staff and patients which will be completed by month 9 (provider/staff) and by month 11 (patient messages). Educational **outreach to providers** will take place between months 7 and 12; randomized **outreach to patients** via MyChart and IVR will take place in month 12 of year 1.

Year 2 will include three main steps: (1) **evaluation and refinement** of Cycle 1 interventions, (2) **Cycle 2 targeted outreach to providers and patients** and (3) **EHR import of vaccination reports originating from hospitals and nursing facilities**. Months 13 through 19 will be spent evaluating the impact of the intervention and identifying patient subgroups who benefited most from the more costly IVR outreach. Included in this evaluation will be targeted interviews (months 16-18) with patients who received the outreach but did not get vaccinated. We will refine patient messages, outreach strategy and provider/staff education based on results from analyses and interviews. **Targeted outreach to providers** will begin in month 18 via provider provider immunization ‘report cards’ which will continue for the duration of the study, accompanied by additional educational presentations. **Targeted patient outreach** in month 24 will involve secure e-portal messages to all e-portal users and IVR calls to patients identified as standing to gain the greatest benefit. **EHR import of vaccination reports** from outside facilities will begin in month 18 and will be ongoing for the duration of the study.

Year 3 will be devoted to (1) **evaluation** of impact and (2) **dissemination**. Evaluation will require retrieval, review and analysis of data on vaccination rates and on provider response to alerts. Dissemination will include manuscript preparation, presentation of findings at national meetings, communication of findings to RMG leadership, and website posting of materials.
C3. Detailed Workplan and Deliverables Schedule (see also Figure 1)

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**Preparation**

- IRB approval
- Preparation for provider and staff interviews
  - Deliverable: Provider/Staff interview script
- Preparation for Year 1 patient interviews
  - Deliverable: Patient interview script
- IT Development of architecture for outgoing secure e-portal message and IVR call
- IT Development of architecture for incoming data on vaccine completion, barriers and preferences.
  - Deliverable: Itemized ‘Lessons Learned’ addressing
    1) RMG EHR architecture required to identify eligible patients and send outgoing secure e-portal messages and IVR calls
    2) RMG EHR architecture required to incorporate incoming data on vaccine receipt, preferences and barriers

**Interviews, Year 1**

- Provider and staff interviews
- Patient interviews
- Analysis of interviews
  - Deliverable: Findings from qualitative analysis of interviews (main themes, information to inform development of message and educational material)
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**Outreach Cycle 1:** Months 1-12 (2014-2015 influenza season)

**Evaluation & Refinement:** Months 13-21 (2015-2016 influenza season)

**Outreach Cycle 2:** Months 22-30 (2015-2016 influenza season)

### Development of messages and educational material

**Development of provider and staff education**

**Development of patient outreach messages for e-portal and IVR**

**Provider/Staff Outreach Year 1**

**Provider and staff education**

*Deliverable: draft and final PowerPoint educational presentation for providers & staff addressing indications for pneumococcal vaccination (and influenza if needed)*

**Patient Outreach, Year 1**

**MyChart & IVR messages sent to Intervention group patients in Year 1 RCT**

*Deliverable: Patient outreach messages*

*Deliverable: Description of Cycle 1 Patient Outreach RCT Methods*

### Evaluation and Refinement

**Analysis of impact**

*Deliverable: ITT Comparison of vaccine completion rates in Intervention (E-portal & IVR) vs. Control*

**Analysis of impact in subgroups**

*Deliverable: Identification of which RMG patients will most benefit from targeted IVR messages in Outreach Cycle 2*

**Preparation for Year 2 patient, provider and staff interviews**

*Deliverable: Revised Patient, Provider and Staff Interview scripts*

**Year 2 Patient, Provider and Staff Interviews**
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Outreach Cycle 1: Months 1-12 (2014-2015 influenza season)

- Analysis of Year 2 Patient, Provider and Staff Interviews
- Evaluation and Refinement of Patient and Provider Outreach interventions
  - Deliverable: Revised Outreach messages and Revised Provider/Staff educational powerpoint

Provider/Staff Outreach Year 2

- Provider and Staff Education
- Provider Report Cards
  - Deliverable: Description of Provider Report Card methods

Patient Outreach Year 2

- MyChart & IVR messages sent to targeted patients in Year 2 Targeted Cost-conscious Intervention
  - Deliverable: Description of Cycle 2 Patient Outreach Targeted Intervention Methods

E-import of vaccine completion (from hospitals & nursing facilities)

- Preparation: EHR capture of vaccinations from outside sites
- Implementation: EHR capture of vaccinations from outside sites
  - Deliverable: Description of methodology for e-import of vaccination reports from hospitals and nursing facilities into RMG EHR.

Evaluation

- Retrieval and review of data on vaccination rates across baseline and 2 years
- Retrieval and review of data on provider response to alerts
- Analysis of impact
  - Deliverable: Calculation of % of patients with EHR documentation of vaccine completion (direct
|------------------------------------------------------------|--------------------------------------|------------------------------------------------------------|

*documentation AND combined)*

Manuscript preparation

*Deliverable: Published report of study outcome in medical literature*

**Dissemination**

*Deliverable: Presentations at national meetings, result communication to RMG leadership*
C4. References

D. ORGANIZATIONAL DETAIL

| Three institutions will support and facilitate the proposed study: the University of Massachusetts Medical School (UMMS), the Meyers Primary Care Institute (MPCI), and Reliant Medical Group (RMG). |

UMMS and MPCI Organizational Capacity: UMMS is the only public academic health sciences center in Massachusetts and is dedicated to advancing the health and well-being of the population through pioneering education, research, and health care delivery. UMMS is consistently ranked as a national leader in primary care research and education in the *U.S. News & World Report*. Drs. Cutrona and Mazor are UMMS faculty members as well as MPCI investigators.

MPCI is a joint endeavor of UMMS, RMG and Fallon Community Health Plan. MPCI’s mission is to improve the health and healthcare of populations through innovative research and educational endeavors. Direct linkages with major clinical systems enable MPCI’s investigators to track treatment and outcomes in defined populations, assess the effectiveness of changes in the health care system, and develop and test innovations in care delivery.

UMMS and MPCI Leadership: Dr. Sarah L. Cutrona will lead the multidisciplinary research team. Dr. Cutrona is a general internist whose research has examined the influence of providers and caregivers on patient adherence to medications and preventive behaviors. She is currently investigating the role of social networks and e-messaging in encouraging preventive health behaviors. Dr. Cutrona has collaborated successfully with numerous members of the proposed study team in the past on NIH-funded research projects. Drs. Cutrona and Mazor have both past and ongoing research collaborations, including shared work focused on health literacy and adherence to preventive screening. Dr. Cutrona has worked with Ms. Preusse and Dr. Garber along with MPCI staff members Hassan Fouayzi and Shawn Gagne on a study examining adverse events following hospital discharge, leading to publications both in print and in press. Dr. Cutrona’s combined research and clinical expertise, as well as her close working relationship with the proposed study team, places her in an ideal position to successfully lead this project.

Dr. Kathleen M. Mazor is Professor of Medicine at UMMS and a highly experienced researcher with expertise in developing and testing health-related messages for patients and providers. She has led and collaborated on over 30 qualitative studies using in-depth interview methods.

UMMS and MPCI Staff Capacity: MPCI will provide primary staff support. Meera Sreedhara, MPH is an experienced Project Manager at the Meyers Primary Care Institute. Meera’s Masters degree in public health, her experience assessing community and neighborhood health and assisting with educational sessions within the Worcester Division of Public Health and her seven years of project coordination both at UMMS and at other medical institutions have provided her with the skill set and knowledge base necessary to oversee this project. Hassan Fouayzi is an experienced programmer and Shawn Gagne is a highly skilled research assistant. Both Mr. Gagne and Mr. Fouayzi have multiple years’ experience collaborating with Dr. Cutrona and with the RMG team on study implementation, RMG data management and analysis. For further detail on the roles played by MPCI staff, please see the budget justification. From UMMS, the Quantitative Methods Core (QMC), in the Division of Biostatistics and Health...
Sciences Research in the Department of Quantitative Health Sciences will provide clinical research support in biostatistics, experimental design, and data management. QMC is led by Director Bruce Barton, PhD who has contributed to this study design and who will personally provide input on the proposed project if funded. In addition, we will seek input throughout the study from our consultant, Dr. Sarah Goff, a health services researcher with clinical specialties in general pediatrics and internal medicine whose research focuses on health care quality and safety. Her work includes numerous applications of qualitative methods, including a mixed-methods content analysis of patient-provider discussions about human papilloma vaccine.

**RMG Organizational Capacity:** The clinical site for this work will be RMG. RMG (formerly Fallon Clinic) was founded in 1929 as the first group medical practice in Central Massachusetts. RMG offers a full range of primary and specialty care with 217 outpatient physicians, 1,700 employees and over 15 clinical locations throughout Central Massachusetts. RMG’s collaborative group practice model encourages primary care physicians, specialists and clinical staff to work together to deliver the highest level of care to each patient. RMG has played a leading role in health information technology utilizing **Epic, a comprehensive electronic health record (EHR),** and **MyChart, a secure online portal** that provides patients electronic access to their healthcare team and to portions of their medical record. RMG has had a long standing commitment to medical education and research, serving as a site for training of medical students and residents and as the location of large population-based studies with the potential to make an impact on the health care of the nation.

**Vaccination-Promoting Practices Already in Place at RMG.** We will build on several initiatives already in place at RMG. Epic records all vaccinations administered at RMG as well as those that are administered externally and manually entered by providers or staff. Epic also records patient refusals or contraindications for vaccination. A healthcare provider viewing the Epic record of an influenza vaccine-eligible adult (i.e. anyone over 18 without contraindications who has not been vaccinated during the current season) sees a ‘Health Maintenance alert’ in the corner of his or her screen. This alert is a flag icon which, if clicked on, will provide information on all immunizations due and is turned on October through March for influenza. In provider routine physical order sets during flu season, if a patient has not yet received their flu vaccine, there is a notification in the Order Set that one is due and the order can be placed directly from this screen. Similar health maintenance alerts are also constantly available for pneumococcal polysaccharide vaccine (PPV23) and pneumococcal conjugate vaccine (PCV13), taking into account patient-specific risk factors. RMG has already created electronic architecture optimizing identification of patients in need of vaccine and has also allowed those patients who have set up online patient portals (MyChart) to view the Health Maintenance alerts as well.

Thus, RMG has already invested considerable resources into healthcare provider prompts and supporting electronic architecture in an effort to identify eligible unvaccinated patients and promote vaccination. In addition, RMG has taken the first steps toward activating patients by providing them with access to their own immunization records through e-portals.

**RMG Leadership.** Dr. Lawrence Garber will oversee all RMG activities, with the assistance of Peggy Preusse, RN, an experienced research nurse coordinator who has skillfully led health information exchange (HIE) and remote home blood pressure monitoring projects. Dr.
Lawrence Garber is Medical Director for Informatics at RMG and a general internist. He has extensive experience designing and implementing EHR-based interventions and led the creation of electronic interfaces between RMG’s EHR and 6 regional hospitals. Dr. Garber is Chair of the Massachusetts eHealth Collaborative’s Executive Committee, a member of the Massachusetts State Health Information Technology Council and Health Information Exchange Advisory Committee, and a member of ONC Policy Committee’s Health Information Exchange Workgroup and Privacy and Security Tiger Team. Dr. Garber has architected several HIEs (e.g. wwwSAFEHealth.org) and will lead the integration of immunizations received from HIEs into Epic’s Inbound Immunization interface. Dr. Lloyd D. Fisher is a general pediatrician and a pediatric site chief. He has built complex decision support algorithms into the Epic EHR to guide providers’ administration of vaccines. Dr. Fisher is on RMG immunization committees, is a member of the Epic optimization team and Assistant Medical Director for Informatics at RMG. He has written Reporting Workbench queries in Epic, so will be responsible for writing the queries that generate the MyChart messages with Questionnaires.

**RMG Staff Capacity.** Peggy Preusse, RN, will coordinate study activities on site, submit IRB materials, assist with interviews and education, as well as data collection and analysis. Once EHR components are programmed, the RMG Application Development Team will carry out unit and integrated testing. Carlo Vivenzio wrote the current bidirectional Eliza/Epic interfaces and has worked with the Epic immunization interface; he will be responsible for creating the new interfaces to support this project. Donna Curboy has written Epic EHR database extraction routines that feed synthesized data back into the Epic EHR; she will be responsible for extracting immunization data from the online questionnaires and passing them to Epic’s Inbound Immunization interface. Ms. Curboy will develop Epic Clarity database queries to identify patients that need IVR immunization messaging, as well as provider and staff immunization Report Cards. She will also develop and manage the ongoing distribution of immunization Report Cards to the appropriate Epic Radar Dashboards. Devi Sundaresan, MS, an experienced data analyst who has done numerous sophisticated data extracts from Epic’s audit trails, will develop study data bases and perform data extractions and some analyses.

**Eliza Corporation.** Interactive Voice Recognition calls will be managed by the Eliza Corporation, a company already working closely with RMG on patient outreach related to office scheduling. For over 13 years Eliza has been a leader in providing strategic member engagement solutions to the healthcare industry. They have conducted over 1 billion interactions on behalf of 90 + clients encompassing Health Plans, Pharmacy Benefit Managers, Pharmaceutical companies, Disease Management vendors and large employers. They maintain a database of over 1 billion individual interactions, yielding unique, actionable insights on consumer attitudes toward health and wellness. Eliza Corporation was chosen by 20 of the top 25 Health Plans and the top four Pharmacy Benefit Managers (by membership) to be the provider of choice for strategic multi-modal engagement and data capture solutions. Eliza brings deep experience in health engagement to bear on population segmentation and targeting, customer experience design, campaign design, message and content tailoring. A communications framework that specifies tailoring (message, tone, call to action) as well as frequency and timing (who gets what touches, how often, and when) reinforces and optimizes response, avoids confusion and redundancy and coordinates across constituencies (individuals receive appropriate messaging).
E. DETAILED BUDGET

E1. Budget Template
See enclosed budget for both University of Massachusetts Medical School and Reliant Medical Group.

E2. Budget Narrative
See enclosed budget justifications for both University of Massachusetts Medical School and Reliant Medical Group.
### 2013 BUDGET - UMASS Medical School

#### Itemized Budget (please complete in US $)

#### Year 1  01/01/14-12/31/2014

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#### Deliverables - Direct Labor & Initiative Costs

- **1** RMG EHR architecture required to identify eligible patients and send outgoing secure e-portal messages and IVR calls
- **2** RMG EHR architecture required to incorporate incoming data on vaccine receipt, preferences and barriers

#### Notes

- Itemized ‘Lessons Learned’ addressing findings from qualitative analysis of interviews
- Draft and final powerpoint educational presentation for providers & staff addressing pneumococcal vaccination (and influenza if needed)
- Patient Outreach Messages
- Description of Cycle 1 Patient outreach RCT methods
## Year 2 01/01/15-12/31/2015

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**Total Initiative Budget** $635,102.00

**Total Funding Requested** $635,102.00
UMASS MEDICAL SCHOOL
BUDGET JUSTIFICATION

Project Title: System Alignment for VaccinE Delivery (SAVED): Improving rates of influenza and pneumococcal vaccination through patient outreach, improved medical record accuracy and targeted physician alerts.

Project Dates for Activities: January 1, 2014 - June 30, 2016

PERSONNEL

Sarah L. Cutrona, MD, MPH (Principal Investigator): Dr. Cutrona is an Assistant Professor of Medicine at University of Massachusetts Medical School and a Research Scientist at Meyers Primary Care Institute. A clinician-investigator and population health researcher, Dr. Cutrona has prior research experience in adherent behaviors and has studied patient’s views and patterns of family communication regarding prevention and routine screening. Dr. Cutrona will assume primary responsibility for overseeing all aspects of this study. She will provide input regarding the development of study materials, including the interview guides and data collection materials, as well as analyzing and interpreting data. As a practicing inpatient and outpatient general internist, she will contribute insights as a clinician stakeholder. Dr. Cutrona will oversee and supervise personnel in conducting the randomized controlled trial in Year 1, the cost-conscious targeted intervention in year 2, the data gathering and analysis and will lead manuscript development. She will ensure that all human subjects review requirements are met. Dr. Cutrona will devote 20% effort to the project each year during the 2 ½-year study period.

Kathleen M. Mazor, EdD (Co-Investigator): Dr. Mazor is Professor of Medicine at the University of Massachusetts Medical School, and Assistant Director of the Meyers Primary Care Institute. She will assume primary responsibility for tasks related to patient, provider and staff interviews, and will work closely with Dr. Cutrona and the study team on all study activities. Dr. Mazor is a psychometrician with extensive research experience, who has led several multi-site studies focused on healthcare communication. Dr. Mazor has expertise in health literacy, physician-patient communication, psychometric analysis, instrument development, survey methods and qualitative methods. She will oversee the overall conduct of the qualitative interviews and will ensure the timely and reliable completion of related project tasks. Dr. Mazor will lead the development of all related interview materials, including the interview guides and all data collection materials. She will have primary oversight of study personnel conducting interviews. She will oversee interviewer training, participant recruitment, conduct of the interviews, analyses of the interview data and reporting of interview results. Dr. Mazor will oversee the execution of qualitative study analyses, reporting of qualitative study results, and development of manuscripts. Dr. Mazor will also participate in the message development for patient-directed messages, and in the development of educational materials for providers. Dr. Mazor will devote 10% effort to the project each year during the 2 ½-year study period.
**Hassan Fouayzi, MS (Programmer):** Mr. Fouayzi will work closely with the research team. He will work under the direction of Dr. Cutrona with guidance from Dr. Garber and from the Quantitative Methods Core Biostatistical team. Mr. Fouayzi will be involved in data management and will assist the Reliant Medical Group (RMG) staff in writing programs to identify appropriate populations. He will abstract automated data, and conduct data analysis under the guidance of the biostatistician and the study team. **Mr. Fouayzi will devote 5% effort to the project in year 1, 10% effort in year 2, and 15% effort in the last 6 months of the study period.**

**Meera Sreedhara, MPH (Project Manager):** Ms. Sreedhara is an experienced Project Manager at the Meyers Primary Care Institute. Under the direction of Dr. Cutrona, Ms. Sreedhara will be responsible for day-to-day coordination and oversight of this project at MPCI, including: developing timelines, work allocation, workflow plans, monitoring project progress and task completion, monitoring spending and effort allocation, and managing correspondence and administrative tasks. She will monitor/manage ethics and regulatory approvals (IRB, HIPAA/DUA) at MPCI and the University of Massachusetts Medical School. She will attend and plan for all project-related meetings as needed. She will work under the direction of Dr. Mazor to assist with all interview-related study activities at the MPCI site, including overseeing the research assistant, preparing IRB submissions and reports, developing study materials such as interview guides and consent forms, managing recruitment, and interfacing with clinic staff. **Ms. Sreedhara will commit 25% effort to the project each year during the 2 ½-year study period.**

**Shawn Gagne, BA (Research Assistant):** Mr. Gagne is an experienced Research Assistant at the Meyers Primary Care Institute and will assist Drs. Cutrona and Mazor and the Project Manager throughout the study. He will be responsible for the day-to-day project activities including organizing study documentation and IRB application submissions, and performing other general project coordination activities. Mr. Gagne will assist in the development and submission of IRB and HIPAA materials, and will assist in all IRB reporting over the course of the project. He will coordinate all meetings related to the study, record meeting minutes and products, and send agendas and reminders prior to each meeting. He will assist with development of interview materials, recruitment efforts, coordination of interviews, consent subjects and conduct in-person interviews, perform data collection and organization. He will help coordinate data entry and analysis, and help in coding and summarizing qualitative data. **Mr. Gagne will commit 30% effort to the project each year during the 2 ½-year study period.**

**Fringe Benefits:** Fringe benefits are calculated at **29.16%** of requested salary.

**OTHER**

**Indirect Costs:** Indirect costs are calculated at **28%.**

**Note:** The University of Massachusetts Medical School calculates indirect costs on salaries, fringe benefits, materials, supplies, services, travel and subcontracts up to the first $25,000.
**Sarah Goff, MD (Consultant):** Dr. Sarah Goff is a board-certified pediatrician and internist and Assistant Professor at the Tufts University School of Medicine. She is a health services researcher whose research interests include maternal-child healthcare quality and safety with a particular interest in healthcare-associated infections related to obstetric care and public reporting of perinatal quality measures. Additional interests include qualitative methodology and how communication impacts health outcomes. Her work includes numerous applications of qualitative methods, including a mixed-methods content analysis of patient-provider discussions about human papilloma vaccine, with Dr. Mazor. Dr. Goff will provide input on development of all study materials, including interview guides and scripts. She will work closely with Dr. Mazor and other team members to develop and implement coding schemes for all qualitative data. She will participate in qualitative and quantitative data analyses, and interpretation, and will provide input on message development and educational materials for providers and staff, drawing on her prior experience in developing education materials for physicians and residents. She will contribute to development of final project deliverables and manuscript writing. **Dr. Goff will be funded for 4 days during year one of the study at a rate of $500 per day, for a total of $2,000; 4 days during year two of the study at a rate of $500 per day, for a total of $2,000; and 2 days during the final six months of the study at a rate of $500 per day, for a total of $1,000 (project period total $5,000).**

**Biostatistical Services:** Biostatistical services will be provided by the Quantitative Methods Core (QMC), under the leadership of Dr. Bruce Barton. The QMC is a service unit for methodological research support and data management at the University of Massachusetts Medical School. QMC will assist the research team with designing and implementing our approach to randomization, defining and measuring appropriate outcome measures, outlining appropriate data-analytic strategies and tests, and assisting in interpreting statistical results. Biostatistical services are budgeted at **$7,200** during year one, **$7,200** during year two, and **$3,600** during the final six months of the project period (project period total $18,000).

**Incentives for Interview Participants:** Incentives will be utilized for in-person interview sessions in order to maximize participation rates. **$750** is budgeted in year one, and **$750** is budgeted in year two for 20 patient interviews and 10 provider/staff incentives (30 interviews X $25 incentive = $750) (project period total $1,500).

**Transcription:** **$1,800** is budgeted in year one, and **$1,800** is budgeted in year two for transcription services at an estimated cost of $45/hour (40 hours X $45 rate = $1,800) (project period total $3,600).

**Subcontract:** See Budget Justification for Reliant Medical Group.
PERSONNEL

Lawrence Garber, MD, [Site Principal Investigator]: is Medical Director for Informatics for Reliant Medical Group in Worcester, Massachusetts. He will be architecting and overseeing the integration of the ELIZA Interactive Voice Response (IVR) and Health Information Exchange (HIE) applications with Reliant’s Epic Electronic Health Record (EHR), drawing on his extensive knowledge of the EHRs and HIEs. He will also assist with patient, staff and provider immunization message development and communication. Programming/system development tasks are anticipated to be most intense in the start-up period, while data analysis and manuscript development will require the most work during the final 6 months of the study. Dr. Garber’s commitment is for 7.5% effort during year 1, 5% effort during year 2 and 10% in the first six months of year 3.

Lloyd Fisher, MD, [Site Co-investigator]: is Assistant Medical Director for Informatics for Reliant Medical Group in Worcester, Massachusetts. He will be managing the use of Epic’s Personal Health Record (PHR) to engage patients, drawing on his extensive knowledge of the EHRs, PHRs and immunizations. He will develop the Reporting Workbench queries that identify PHR patients in need of immunization messaging, as well as overseeing integrating the patient-entered responses back into the EHR. He will also assist with patient, staff and provider immunization message development and communication. Programming/system development tasks are anticipated to be most intense in the start-up and wrap-up period, while data analysis and manuscript development will require the most work during the final 6 months of the study. Dr. Fisher’s commitment is for 7.5% effort during year 1, 5% effort during year 2 and 10% in the first six months of year 3.

Peggy Preusse, RN – Research Nurse Coordinator: under the supervision and direction of Drs. Cutrona, Garber and Fisher, the research nurse coordinator will be responsible for coordinating study activities on site, submitting IRB materials, assisting with patient, provider and staff interviews and education, data collection and analysis. The research nurse coordinator will devote 15% effort during year 1, 10% effort during year 2, and 10% effort during the first 6 months of year 3.

Devi Sundaresan, MS – Data Analyst: will develop study data bases and perform data extractions from the Epic EHR and some analyses with Drs. Cutrona, Garber and Fisher’s guidance. The data analyst will devote 10% effort during each of years 1 & 2 and 20% in the first six months of Year 3.

Carlo Vivenzio – Interface Developer: will develop the interfaces between the ELIZA IVR application and the Epic EHR, as well as the interface from the HIE into Epic. The Interface Developer will also be responsible for supporting and modifying the program as necessary. The Interface Developer will devote 15% effort during year 1, 7.5% effort during year 2, and 5% effort during the first six months of year 3.
**Donna Curboy – Database Report Writer:** will develop Epic Clarity database queries to identify patients that need IVR immunization messaging, as well as provider and staff immunization Report Cards. The Database Report Writer will also develop and manage the ongoing distribution of immunization Report Cards to the appropriate Epic Radar Dashboards. The Database Report Writer will devote 5% effort during year 1, 10% effort during year 2, and 5% effort during the first six months of year 3.

**Fringe Benefits:** the fringe benefit rate is calculated at 23.11% for all study personnel.

**OTHER**

**Subcontracts:** the ELIZA IVR system will make outgoing calls to patients to educate them regarding immunizations, record prior immunization dates, and record reasons for not being immunized. This service will cost $5,000 to implement and $6,885 for calls in Year 1, and $2,230 to change the messaging and $6,885 for calls in Year 2.

**Indirect Costs:** Indirect costs are budgeted at 28%.
F. REQUIRED DOCUMENTATION

No additional documentation applicable.
G. STAFF BIOSKETCHES

Please see enclosed biographical sketches for the following personnel:

Sarah L. Cutrona, MD, MPH  Principle Investigator
Kathleen M. Mazor, EdD  Co-Investigator
Lawrence Garber, MD  Co-Investigator
Lloyd D. Fisher, MD  Co-Investigator
Sarah L. Goff, MD  Consultant
Bruce Barton, PhD, MS, MA  Director of the Quantitative Methods Core, UMMS
BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. DO NOT EXCEED FOUR PAGES.

<table>
<thead>
<tr>
<th>NAME</th>
<th>POSITION TITLE</th>
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</thead>
<tbody>
<tr>
<td>Sarah LeLeiko Cutrona</td>
<td>Assistant Professor of Medicine, University of Massachusetts Medical School</td>
</tr>
</tbody>
</table>

eRA COMMONS USER NAME (credential, e.g., agency login)

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

<table>
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<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
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<td>Yale University</td>
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<td>1997</td>
<td>English Literature</td>
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<tr>
<td>Columbia College of Physicians and Surgeons</td>
<td>M.D.</td>
<td>2001</td>
<td>Medicine</td>
</tr>
<tr>
<td>Harvard School of Public Health</td>
<td>MPH</td>
<td>2007</td>
<td>Public Health</td>
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A. Personal Statement

My current research examines adherence to routine screening and preventive behavior, with a focus on the ways in which communication between members of a patient’s social network can impact preventive screening decisions. I led a pilot study through the NCI-funded Cancer Research Network on this subject, building on the work done by Dr. Mazor and her team in their study of health literacy, cancer prevention and patient understanding of oral messages. I have also been awarded a K12 career development grant, through which I am exploring the characteristics of a message promoting colon cancer screening that would make it acceptable for email transmission between members of a social network. In 2012, I was awarded an Early Career Investigator Award from the HMO Research Network. Through this work I have collaborated closely with Dr. Mazor and have worked extensively with staff members from the Meyers Primary Care Institute.

As a practicing general internist, I am also acutely aware of the risks of poor communication at times of care transitions, such as when patients are discharged from the hospital into the community. I worked with Dr. Garber to study risks associated with adverse drug events post-hospital discharge and my work studying communication patterns at hospital discharge places me in an excellent position to lead our proposed study in which we facilitate communication between hospitals, nursing facilities and primary care EHRs regarding administered vaccines.

My past research has examined the influence of physicians, pharmacists and caregivers on patient adherence to cardiovascular medications and has described distribution patterns and potential safety concerns for free pharmaceutical drug samples in adult and pediatric populations. I then focused further on interventions to improve medication adherence. I worked with the Division of Pharmacoepidemiology and Pharmacoeconomics at the Brigham and Women’s Hospital, earning a nomination for the Milton W. Hamolsky Award for Outstanding Scientific Presentation (Junior Faculty) from the Society of General Internal Medicine for my work on the role of physicians in improving cardiovascular medication adherence.

Health communication is a topic on which I have both expertise and great interest through my roles as a general internist, researcher, and teacher in an academic medical setting. Improving communication and outreach to support patients in efforts toward disease prevention activities can have a vital impact on the health of individuals as well as communities at-large. My research and clinical experience have aptly prepared me to lead a project such as the one we have proposed.

B. Positions and Honors

Positions and Employment

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<th>Year</th>
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<tr>
<td>2001-2004</td>
<td>Internship and Residency, Internal Medicine – Brown University/Rhode Island Hospital, Providence, RI</td>
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<tr>
<td>2001-2004</td>
<td>Instructor of Medicine, Brown University School of Medicine, Providence, RI</td>
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</table>
2004-2005  Hospitalist, Internal Medicine, Kent Hospital, Warwick, RI
2005-2007  Clinical and Research Fellow in Medicine, Harvard Medical School Program in General Internal Medicine, Cambridge Hospital, Cambridge, MA
2005-2008  Hospitalist, Department of Medicine, Cambridge and Somerville Hospitals, Massachusetts
2007-2008  Instructor of Medicine, Harvard Medical School, Cambridge, MA
2007-2010  Research Associate, Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women’s Hospital, Boston, MA
2008-2010  Hospitalist, Internal Medicine, Tri-County Medical Associates, Milford Regional Medical Center, Milford, MA
2009-present  Assistant Professor of Medicine, University of Massachusetts Medical School, Worcester, MA
2010-present  Internist, Division of General Medicine and Primary Care, UMass Memorial Medical Center, Worcester, MA

Honors
1997   Elmore A. Willets Prize for Fiction Writing, Yale University
1997   Ralph Paine Memorial Prize (First Place for English Senior Thesis), Yale University
1997   English Department Honors, Yale University, cum laude, Yale University
2006   Mack Lipkin, Sr. Research Award for Outstanding Scientific Presentation (Fellow), Society of General Internal Medicine Annual Meeting
2009   Nominated for Milton W. Hamolsky Award for Outstanding Scientific Presentation (Junior faculty), Society of General Internal Medicine Meeting
2012   Early Career Investigator Award, HMO Research Network

Other Experience and Professional Memberships
2004-2005  Member, Kent Hospital Pharmaceutical Committee, Kent Hospital, Warwick, Rhode Island
2005-present  Member, Society for General Internal Medicine
2006-present  Member, American Public Health Association
2007-2008  Board member, Cambridge Health Alliance Institutional Review Board; Cambridge, MA
2008   Interview, National Public Radio discussing physician use of free drug samples
2009   Invited written testimony on disclosure of free samples, Vermont Attorney General & Commission on Health Care Reform
2009   Invited oral testimony on use of free samples, National Legislative Association on Prescription Drug Prices: Meeting of state legislators
2009   Invited participant, National Public Radio, All Things Considered. Discussion of free antibiotics.
2013-present  Pharmacy& Therapeutics Committee, U. of Massachusetts Medical Center; Worcester, MA
2010-2011  Transitions of Care Committee, U. of Massachusetts Medical Center; Worcester, MA
2007-present  AcademyHealth member
2011-2013  Reviewer of abstracts, SGIM Regional New England Meeting.
2011-2013  Reviewer, Health Policy Abstract Committee, SGIM Annual Meeting
2013-present  Editor, Connections. National Newsletter, American Medical Women’s Association
2013-present  Co-faculty advisor, American Medical Women’s Association (AMWA) UMass student chapter

C. Selected Peer-reviewed Publications

Papers


D. Selected Abstracts and Non-Peer Reviewed Publications


E. Research Support

**Ongoing support**

KL2RR031981 (Sullivan) 12/1/10-11/30/15

UMMS Clinical Scholar Award, Center for Clinical and Translational Science

**Electronic Message Transmission between Members of a Social Network to Improve Screening for Cancer: Colorectal Cancer Screening as a Model.**

The goal of this study is to gather information on current patterns in friend-to-friend and within-family discussion of colorectal cancer screening, then to conduct a pilot study of an electronic message transmission system, asking patients who have recently completed normal screening colonoscopies to transmit messages to friends and family encouraging screening completion.

Role: Project Leader
Patient Centered Outcomes Research Institute (PCORI) Pilot Grant
**Influence & Evidence: Understanding Consumer Choices in Preventive Care**
Grant to develop interventions to help patients make more evidence-based cancer screening decisions through use of a “beneficent advocacy” approach and evaluate ability of community health workers to deliver these novel interventions.
Role: Co-Investigator

(Tjia)

2011-2014
**Patient Centered Prescribing for Medically Complex Older Adults with Cancer**
American Cancer Society/National Palliative Care Resource Center- Pilot Grant
The overarching goal of the pilot/exploratory ACS/NPCRC proposal is to inform the development of a patient-centered approach for managing the medication regimens of complex older adults with advanced cancer. In particular, we propose to assess the feasibility of using a paper-based, medication assessment instrument to incorporate patient-centered goals into prescribing at the end-of-life.
Role: Co-Investigator

**Selected Completed Research**

CRN Pilot U19 CA79689-13. 05/01/11-04/30/12
**Friend to Friend: Colorectal Cancer Screening Discussions among Members of Social Networks.**
The aims of this study were to: describe current practices and identify potential barriers to communication about colorectal cancer screening in friend-to-friend and within-family networks, and to determine participant’s preferences for message content and mode of transmission regarding colorectal cancer screening.
Role: PI

HHSF223200910006I (Platt) 07/01/11-03/31/12
**FDA- Mini-Sentinel Project Foundational Elements: Anaphylaxis Case Identification and Validation**
The primary goals of this project are to develop algorithm for identifying anaphylaxis cases in the mini-sentinel, develop a sampling strategy to identify and retrieve medical records of likely anaphylaxis cases, and a Protocol for evaluating the positive predictive value of the algorithm.
Role: Co-Investigator

HHSF2232009100061(Platt) 08/01/10-02/28/11
**Design and Test a Case Identification and Validation/Adjudication Process for AMI**
The major goal of this project is to design and test a case definition and validation/adjudication process for acute myocardial infarction (AMI).
Role: Co-Investigator
BIOGRAPHICAL SKETCH

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<table>
<thead>
<tr>
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<th>POSITION TITLE</th>
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<tbody>
<tr>
<td>Kathleen Mazor</td>
<td>Professor of Medicine</td>
</tr>
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</table>

| eRA COMMONS USER NAME (credential, e.g., agency login) | Mazork |

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

<table>
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<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>YEAR</th>
<th>FIELD OF STUDY</th>
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<tr>
<td>University of Massachusetts Amherst</td>
<td>B.A.</td>
<td>1979</td>
<td>Psychology</td>
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<tr>
<td>Eastern Washington University</td>
<td>M.S.</td>
<td>1985</td>
<td>Psychology</td>
</tr>
<tr>
<td>University of Massachusetts Amherst</td>
<td>Ed.D.</td>
<td>1993</td>
<td>Psychometrics</td>
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A. Personal Statement

My training and expertise as a psychometrician, and my skills and experience in qualitative data collection methods and coding, health literacy, communicating medical information to patients, instrument development and validity studies make me an ideal collaborator on this project. My training in psychometrics provided me a strong foundation for test development and validation, and over the past 20 years I have continued to develop my expertise in this area. I have led and collaborated on numerous studies examining the psychometric properties of the items and scales used to measure knowledge, skills, beliefs and attitudes in a variety of stakeholder groups, including patients, medical students, residents, practicing physicians, nurses, and others. Examples of my research into psychometric issues include studies of differential item functioning, response bias, and generalizability. I have also led a number of validity studies; examples of my research in this area are studies examining missing values and score validity, and in using think aloud interviews to explore validity issues. I have led or collaborated on over 30 instrument development efforts, and have expertise in instrument conception and planning, item writing, validity and reliability studies. While I have a strong appreciation of the value of tests, scales and other quantitative measures, my research has also caused me to appreciate the value of qualitative methods. Such methods are often a necessary first step in understanding the phenomenon under study, and are essential to generating meaningful questions and testable hypotheses. This appreciation has led me to develop expertise in qualitative methods, and I have gained expertise in developing interview protocols, in training and supervising interviewers, and in qualitative data analysis. I have published over 30 studies reporting the results of qualitative interviews and focus groups, involving stakeholders from a variety of backgrounds. I have collaborated with Dr. Cutrona for the past 3 years, and I am confident that she will be a highly effective leader for this study. I am excited about working on this innovative project, and I look forward to working with this team of skilled, experienced researchers and clinicians should we receive funding.

B. Positions and Honors

Employment

1984-1993  Psychologist; Massachusetts Department of Mental Retardation
1993-1996  Research Analyst; Smith College, Northampton, Massachusetts
1996-1999  Co-Director, Research and Evaluation Division, Office of Medical Education, University of Massachusetts Medical School
1999-2000  Director, Research and Evaluation Division, Office of Medical Education, University of Massachusetts Medical School
1999-2011  Research Associate; Meyers Primary Care Institute
1999-2006  Assistant Professor of Medicine, University of Massachusetts Medical School
2006-2013  Associate Professor of Medicine, University of Massachusetts Medical School
2013-present  Professor of Medicine, University of Massachusetts Medical School
2011-present  Assistant Director, Meyers Primary Care Institute
Other Experiences and Professional Memberships
1992-present  Member, National Council on Measurement in Education
2006-2008  Member, Professional Behaviors Advisory Group, National Board of Medical Examiners
2007-present  Member, Communication Task Force, National Board of Medical Examiners
2007-2011  Member, Clinician-Consumer Health Advisory Information Network (CHAIN) Editorial Board
2008-2012  Member, Drug Safety and Risk Management Advisory Committee, Center for Drug Evaluation and Research, the Food and Drug Administration
2011-present  Co-Director, CRN Cancer Communication Research Center

C. Selected Peer-Reviewed Publications (selected from over 100 publications as relevant)


D. Research Support

**ACTIVE**

5 R01 CA136888-05 (Ockene, J) 07/06/09-05/31/14

NCI

**RCT for Smoking Cessation in Medical Schools**
The goal of this study is to compare two methods of teaching brief, physician-delivered tobacco cessation counseling to (the 5As) to medical students: 1) traditional medical education, and 2) multi-modal education that includes a web-based instructional program and preceptor training as well as traditional medical education. Using a pair-matched, randomized group-controlled design (implemented in 10 medical schools), this study will examine the impact of the two teaching methods on students' tobacco counseling skills.

Role: Co-Investigator

PEP-11-263-01PCSM (Tjia) 07/01/11-06/30/14

American Cancer Society

**Patient Centered Prescribing for Medically Complex Older Adults with Cancer**
The overarching goal of the pilot/exploratory ACS/NPCRC proposal is to inform the development of a patient-centered approach for managing the medication regimens of complex older adults with advanced cancer. In particular, we propose to assess the feasibility of using a paper-based, medication assessment instrument to incorporate patient-centered goals into prescribing at the end-of-life.

Role: Co-Investigator

1 IP2 PI000633-02 (Saver) 07/01/12-06/30/14

PCORI

**Influence & Evidence: Understanding Consumer Choices in Preventive Care**
This project will study consumers’ and Community Health Workers’ reactions to the recent United States Preventive Services Task force recommendations which promote a patient-centered discussion and decision regarding mammography for women aged 40-49 and contain a draft recommendation against routine prostate cancer screening using the PSA test.

Role: Co-Investigator

1 R18 HS20831-01 (Gurwitz) 07/01/12-06/30/15

AHRQ

**Improving Indwelling Catheter Use to Study CAUTI in the Nursing Home**
The overarching goal of our project is to develop a toolkit that is effective in increasing performance of evidence-based clinical practices relevant to reducing the use of urethral catheters and the risk of CAUTI in the NH setting. Our project will be performed in three phases. In the first phase, which comprises Aims 1-3, we will focus on developing a deep understanding of the factors that are associated with indwelling urethral catheter use in the NH setting. Understanding NH resident population and organizational level factors, as well as current catheter management practices, will guide the development and evaluation of an adaptable toolkit, encompassing the second and third phase of the project.

Role: Co-Investigator

1R21HS021864-01 (Goff) 10/15/12-08/31/15

AHRQ

**Reducing Disparities in the Use of Publicly Reported Quality Measures**
In the proposed randomized controlled trial we will evaluate the impact of providing assistance in the use and interpretation of information about the quality of pediatric care on the Massachusetts Health Quality Partners Quality Insights website among a population of low-income pregnant women. Results of the study will advance our understanding of effective strategies for overcoming barriers to using publicly reported information among vulnerable populations.

Role: Co-Investigator
NIH/NHLBI
**Implementation and Outcomes of Non-Invasive Ventilation in COPD**
The goal of this project is to conduct a multi-center intervention to implement a COPD bundle to improve the treatment and outcomes of patients hospitalized with acute COPD.
Role: Co-Investigator

U24 CA171524-01(Kushi) 09/01/12-08/31/17
NCI
**CRN4: Cancer Research Resources and Collaboration in Integrated Health Care Systems**
The Cancer Research Network (CRN) is a scientific and research resource to support population sciences cancer research in integrated health care delivery systems. Continuously funded by the National Cancer Institute since 1999, the CRN brings together epidemiologists, biostatisticians and health services researchers from 15 research organizations affiliated with not-for-profit health maintenance organizations. The CRN provides a platform for conducting collaborative studies among these researchers, and with researchers at other entities, including academic health centers, cancer centers, schools of medicine and public health, government agencies, and independent research organizations.
Role: Site Principal Investigator

1 R18 HS022757-01 (Mazor) 09/30/13-07/31/18
AHRQ
**Detecting, Addressing and Learning from Patient-Perceived Breakdowns in Care**
Building on our prior work, and in partnership with MedStar Health (MSH), a national leader in patient safety, we will develop, implement, disseminate and evaluate a program for detecting, addressing and preventing patient-perceived breakdowns in care, a program we call “We Want to Know”.
Role: Principal Investigator
A. Personal Statement

The goal of this project is to increase immunization rates in adults, facilitated by an Electronic Health Record (EHR). I have extensive experience and expertise in designing and implementing such systems. Over the past several years I have led the implementation of our Electronic Health Record (EHR) from Epic, along with its “MyChart” Personal Health Record. During this process I became an Epic Certified Analyst. I have architected and led the implementation of an interface that loads immunizations into Epic from claims data, and loads home blood pressure readings via Microsoft HealthVault into the Epic EHR. I was also the PI and principal architect for SAFEHealth, an AHRQ-funded federated Health Information Exchange that is currently live in central Massachusetts.

As a practicing primary care physician, I am also keenly aware of the importance of immunizations, as well as the numerous obstacles in the way of their successful completion and documentation. I have led multiple patient-safety initiatives geared towards alerting patients and physicians of near-due or overdue Health Maintenance tests and procedures, appointment reminders, automated no-show letters to patients, and closed-loop order reports that look for orders that were never resulted back to the ordering physician.

In summary, I have demonstrated that I possess the clinical, technical, and managerial skills necessary to ensure that Reliant Medical Group’s participation in this project will be successful and fruitful.

B. Positions and Honors

Positions and Employment

1986-present Reliant Medical Group (formerly Fallon Clinic) – Worcester, Massachusetts
Office practice in Internal Medicine
In-hospital care as attending physician at University of Massachusetts Medical Center and Saint Vincent Hospital in Worcester.

1998-present Medical Director for Informatics, Reliant Medical Group
Professional Organizations/Workgroups

2012-present  Office of the National Coordinator (ONC) Health IT Policy Committee’s Health Information Exchange Workgroup member and co-chair of the Care Coordination Sub-workgroup
2011-present  CMS Continuity Assessment Record & Evaluation (CARE) Technical Expert Panel (CARE TEP)
2011-2013  Epic Care Everywhere Governing Council member
2010-present  Massachusetts Health Information Technology Council Member and Health Information Exchange Ad Hoc Workgroup and Advisory Committee member
2004-present  Massachusetts eHealth Collaborative (MAeHC) Board, acting Chair of Executive Committee, and past Chair of “Clinical Functional Requirements” working group
2003-present  Health Level Seven (HL7)
2001-present  Massachusetts Medical Society’s Information Technology Executive Council and Clinical Data Repository Task Force since 2008.
1987-present  Massachusetts Medical Society
1999-present  Association of Medical Directors for Information Systems (AMDIS)
1998-present  American Society for Testing Materials (ASTM) E31 Committee on Health Care Informatics
1992-present  American Medical Informatics Association (AMIA)
1987-present  Worcester District Medical Society since 1987, including membership on the Technology Task Force for Emergency Email Notification, and Worcester E-Mail Collaborative (WEC) Chairman since 2009.

Honors

Rutgers University Graduated with Highest Honors in Biochemistry
Henry Rutgers Scholar
Member of Phi Beta Kappa
Reliant Medical Group (formerly Fallon Clinic) Innovator of the Year – 2000
Reliant Medical Group (formerly Fallon Clinic) Physician Manager of the Year – 2008
Reliant Medical Group (formerly Fallon Clinic) Researcher of the Year – 2009, 2012
2009 Association of Medical Directors of Information Systems (AMDIS) Award
2009 Massachusetts Health Data Consortium Investing in Information Award
2010 eHealth Initiative eHealth Advocate Award
2010 Massachusetts Medical Law Report Rx for Excellence Award
2011 Health Data Management EHR Game Changer Award
Office of the National Coordinator Fall 2013 Health IT Vanguard Fellow
C. Peer-Reviewed Publications

Publications


Presentations

“No LTPAC, No ACO” - AHIMA LTPAC HIT Summit, June 18th, 2013.

“LTPAC Informatics: Creating Organizational Readiness” - AHIMA LTPAC HIT Summit, June 18th, 2013.

“Maximizing the Value of an EHR: Beyond Meaningful Use Stage 1” – Institute for Health Technology Transformation HIT Summit, May 7th, 2013.


“HCC Coding Using the Easy Button” - Epic Physician Advisory Council Meeting, April 25th, 2013.


“Clinical Documentation for Care Coordination” - Testimony before the Health IT Policy Committee Clinical Documentation Hearing, February 13th, 2013.


“Making an IMPACT on Care Transitions in Central Massachusetts” – Healthbridge Care Manager Continuing Education seminar, January 16th, 2013.


“Engaging Patients Online with Electronic Medical Records” – American College of Rheumatology’s Annual Scientific Meeting, November 9th, 2012.


“How To Do Better With Your Electronic Medical Record” – Tufts Medical Center Ob/Gyn Grand Rounds, September 4th, 2012.


“Longitudinal Care Planning and Meaningful Use” – Office of the National Coordinator’s Health Information Technology Policy Committee Meaningful Use Workgroup on Care Coordination, May 17th, 2012, and Epic Longitudinal Plan of Care Brain Trust June 21st, 2012.

“Plans for the Massachusetts Statewide Health Information Exchange” – Massachusetts Medical Society Committee on Information Technology, November 22nd, 2011.


“Clinical Practice Redesign with IT: Examples from the Fallon Clinic Experience” – Leadership Strategies for Information Technology in Health Care – Harvard School of Public Health, May 19th, 2011.


“Streamlining Pre-Physical Lab Orders and Test Results with Best Practice Advisories” – Epic Physicians Advisory Council, April 7th, 2011.


“Transforming Health Information Technology into Improved Healthcare Delivery” – Testimony to the Massachusetts State Congressional Joint Committee on Healthcare Financing, July 20th, 2010.


“How to Change an Airplane Into a Jet in Midair – The Role of Research in EHR Implementations” – Boston College Conference on Using IT to Improve Outcomes in Healthcare Delivery, October 6th, 2006

“Privacy issues related to the advent of a National Health Information Network” – Testimony to the National Committee on Vital and Health Statistics (NCVHS) Privacy and Confidentiality Subcommittee, June 7th, 2005

D. Research Support

Ongoing Research Support

90HT0038/01 Shoup (PI) 07/01/2011-01/31/2014
IMPACT: Improving Massachusetts Post-Acute Care Transfers.
Purpose is to improve long-term and post-acute care transitions within the Commonwealth.
Role: Investigator

R18HS017817 Field (PI) 09/30/2008-09/29/2012
Using HIT to Improve Transitions of Complex Elderly Patients from SNF to Home
The specific aims are to evaluate, among a population of older adults with multiple co morbid conditions, the impact of an HIT-based transitional care intervention upon discharge from sub acute care in a skilled nursing facility to the ambulatory setting.
Role: Investigator

R18HS017906 Field (PI) 09/30/2008-09/29/2012
Risk Informed Intervention to Improve Ambulatory Drug Monitoring and Safety
Our overall goal is to improve patient safety by implementing an intervention directed at improving the rate of ordering and completion of therapeutic laboratory monitoring of high-risk medications in the ambulatory setting.
Role: Investigator
Health Information Technology as an Agent of Change for Improving Health Care Delivery Processes

The goal is to examine the effects of the EHR system on the care delivery process. Investigators will study process and productivity changes and their implications on service quality and physician/staff and patient satisfaction.

Role: Investigator

Completed Research Support

UC1 HS015220 (PI) 09/30/2004-09/29/2009
SAFEHealth – Secure Architecture For Exchanging Health Information
The primary goal of this project is to enable patient information to flow among these three organizations, following the patients as they traverse the healthcare systems, in order to enhance quality of care, patient safety and efficiency of healthcare delivery.

Role: PI

P20 HS017109 Field (PI) 09/01/2007-08/31/2008
Proactive Risk Reduction in Medication Prescribing in the Ambulatory Setting
The goal is to examine the underlying processes leading to serious medical errors, identify potential intervention points and prepare action plans for implementation.

Role: Investigator

R18 HS017203 Gurwitz (PI) 09/01/2007-08/31/2010
Improving Posthospital Medication Management of Older Adults Through Health IT
The goal is to determine the effects of a post-discharge medication reconciliation intervention, including the use of information technology, on serious medication errors and on the use of the ED and hospital readmissions.

Role: Investigator
BIOGRAPHICAL SKETCH
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<table>
<thead>
<tr>
<th>NAME</th>
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<tbody>
<tr>
<td>Lloyd D. Fisher</td>
<td>Assistant Medical Director for Informatics, Reliant Medical Group</td>
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**EDUCATION/TRAINING** (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

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<td>Biology</td>
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<td>University of Massachusetts Medical School</td>
<td>MD</td>
<td>1998-2003</td>
<td>Medicine</td>
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<tr>
<td>University of Massachusetts Medical School</td>
<td></td>
<td>2003-2006</td>
<td>Residency in Pediatrics</td>
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</table>

A. Personal Statement
This research project will investigate methods to improve compliance with influenza and pneumococcal vaccine administration through both provider education and patient outreach. I have extensive experience and expertise in designing, building, and implementing clinical decision supports within an Electronic Health Records (EHR) system of a large multispecialty medical group. As a primary care pediatrician and Assistant Medical Director for Informatics at Reliant Medical Group, I am responsible for creating alerts in our EHR. Through various projects we have managed to reduce the time providers must spend determining which vaccines are due and encourage them to order all needed vaccines at each patient interaction. Point of care reminders have been employed to ensure accurate and on time administration of all appropriate immunizations for both children and adult patients. Through my involvement in local, state, and national committees and organizations I have disseminated our techniques to others and participated in work groups to share best practices widely among other medical groups and hospital systems. This proposed research will build upon the skills I have developed over the years and allow me to successfully build easy to use and understand clinical decision tools to facilitate appropriate and on time ordering and administration of both the influenza and pneumococcal vaccines in our adult population.

B. Positions and Honors

**Positions and Employment**
2010-present  May Street Pediatrics Site Chief, Reliant Medical Group
2009-present  Assistant Medical Director for Informatics, Reliant Medical Group
2012-present  Division Chief of Community Pediatrics, UMass Memorial Healthcare

**Other Experience and Professional Memberships**
2011-present  Member of the Epic Governance Committee, Reliant Medical Group
2011-2012    Member of Department of Pediatrics Compensation Revision Subcommittee, Reliant Medical Group
2009-2011    Member of Branding Committee, Reliant Medical Group
2006-2009    Member of EMR Implementation Committee, Reliant Medical Group
2007-2008    Member of Process Improvement Committee, Reliant Medical Group
2008         Member of Strategic Planning Committee, Reliant Medical Group
2006-2011    Editor, Massachusetts Chapter of the AAP (MCAAP) Forum
C. Selected Peer-reviewed Publications

Most relevant to the current application


2. Innovation with Information Technologies in Healthcare
"Logic Rules" Springer, 2013

Recent presentations

1. Epic 2013 User Group Meeting
   September 18, 2013, Verona, WI
   “2013: A Vaccine Odyssey”

2. Massachusetts Society of Medical Assistance
   January 9, 2013 West Boylston, MA
   “The Medical Professional and Social Media: The Good, the Bad, and the Scary”

3. Atrius Healthcare Leadership Academy
   June 20, 2012 and November 7, 2012, Waltham, MA
   “Health Care Professionals and Social Media”

4. Advanced Faculty Development Retreat
   May 5, 2012, South Yarmouth, MA
   “Physicians and Social Media”

5. Epic 2011 User Group Meeting
   September 21, 2011, Verona, WI
   “Efficiency from Smarter Order, Best Practice Advisories, and Documentation”

6. University of Massachusetts Medical School, Pediatric Grand Rounds
   June 24, 2011, Worcester, MA
   “How Can Pediatricians Find Meaning in Meaningful Use”

7. Epic 2011 Spring Physicians Advisory Council
   April 6, 2011, Verona, WI
   “Advanced SmartTools Tips and Tricks”

8. Epic 2010 User Group Meeting
   September 21, 2010, Verona, WI
   “The Complete Well Child Visit in Under 525,600 Minutes”

9. Epic 2010 Spring Physicians Advisory Council
   April 28, 2010, Verona Wisconsin
   “Using SmartPhrases to Offload Physician Work”

10. MMS Resident and Fellows Section Annual Meeting
    April 24, 2010, Waltham, MA
    “What to Look for When Finding a Practice”
11. MMS Career Day  
   February 6, 2010, Waltham, MA  
   "Different Practice Models"

12. Epic 2009 Fall Physicians Advisory Council  
   September 22, 2009, Verona, WI  
   "Smarter SmartTools - Making Smarter Providers"

13. Epic 2009 Spring Physicians Advisory Council  
   March 12, 2009, Verona, WI  
   "Smart SmartTools - Guidelines for Success"

14. Northeast Pediatric Resident Advocacy Conference  
   September 30, 2005, Providence, RI  
   Poster Presentation: “A Health Policy Curriculum in a Pediatrics Residency Program.”

15. Society for Adolescent Medicine Annual Meeting  
   March 13-16, 2002, Boston, MA.  
   Poster Presentation: “Predicting who is at risk for pelvic infection based upon symptom history at time of presentation.”

   Guest appearance on local cable television show designed to address common health concerns for the general public. Show topic: adolescent health and sexuality.
A. Personal Statement
I am a pediatrician and internist trained as a health services researcher. My research focuses on health care quality and safety. I have led or participated in twelve studies (nine publications) using qualitative methods to date. In these studies, I have led in-depth interviews and focus groups with subsequent analysis of the data and have performed content analysis on transcripts of patient-provider conversations. I have used innovative qualitative data collection techniques such as photo-elicitation, in which participants take photographs of the subject at hand and use the photos to stimulate discussion during an in-depth interview. My previous work exploring HPV vaccines using qualitative methods will contribute important vaccine-specific expertise to the success of this project. Additionally, I bring experience in designing and implementing educational programs for healthcare providers. These skills make me well-suited to my role in this proposed study.

B. Employment
7/00-1/01 Primary Care Internist/Pediatrician, Locum tenens
2/01-1/02 Primary Care Internist/Pediatrician, Community Health Center of Franklin County, Turners Falls, MA
2/02-6/03 Internist/Pediatrician, Asst. Medical Director and School Based Clinic Medical Director, Hilltown Community Health Centers, Huntington, MA
8/05-12/06 Assistant Professor, General Internal Medicine and Meyers Primary Care Institute (MPCI), University of Massachusetts Medical School, Worcester, MA
1/07-Present: Assistant Professor, General Pediatrics and Internal Medicine, Baystate Medical Center, Springfield, MA, Tufts University School of Medicine Affiliate
C. Honors
1991   BS awarded *cum laude*
1999   ACP-ASIM State Chapter Clinical Vignette Finalist
2003   Robert Wood Johnson Clinical Scholar Fellowship
2007   Children’s Miracle Network Research Grant
2008   Baystate Medical Center Incubator Fund Grant
2008   Tufts School of Medicine Innovations in Medical Education Research Grant
2008   Tufts Medical Student Teaching Award
2009   Baystate Medical Center Incubator Fund Grant
2009   AAMC Early-Career Women Professional Development Seminar
2010   Tufts School of Medicine Natalie Zucker Award
2010   Baystate Health Insurance Company Research Grant
2011   Baystate Medical Center-University of Massachusetts Collaborative Biomedical Research Grant
2011   KL-2 Career Development Award Recipient Tufts University School of Medicine
2012   AHRQ R21 “IDEAS for a Healthy Baby”
2013   Baystate Medical Center Incubator Fund Grant

D. Professional Societies and Public Advisory Committees
2010 -   AcademyHealth
2011 -    Society for General Internal Medicine
2009 - 12  Ambulatory Pediatric Association
2006 - 10   NAASO (Obesity) Society
2004 - 07   American Academy of Pediatrics Med/Peds Executive Committee
1996 - 08   Fellow of the American Academy of Pediatrics
2002 - 08   Massachusetts Medical Society
1999 - 03   American College of Physicians-American Society of Internal Medicine

E. Selected Publications


F. Research Support

Current

NIDDK 1R01DK097011 - 01A1 Chasan-Taber (PI) 09/01/13-06/30/18
University of Massachusetts, Amherst

Randomized Lifestyle Intervention in Overweight and Obese Pregnant Hispanic Women
This study tests the impact of a lifestyle intervention on weight and metabolic outcomes for pregnant Hispanic women at high risk for gestational diabetes and their offspring.
Role: Co-investigator

PCORI Communication and Dissemination Research Award Unruh (PI) 09/01/13-08/31/16

Shared Decision Making - Renal Palliative Care
This study will assess the impact of an intervention to enhance shared decision making for end-of-life care for renal dialysis patients.
Role: Co-investigator

AHRQ 1 R21 HS021864-01 Goff (PI) 09/01/12-08/31/15
Baystate Medical Center

IDEAS for a Healthy Baby: Reducing Disparities in use of Publicly Reported Quality Data
This study will test the efficacy of an intervention to increase low income pregnant women’s use of publicly reported quality data for Massachusetts pediatric practices.

Baystate Incubator Fund Goff (PI) 01/31/13-12/31/14
Baystate Medical Center

Page 58 of 67
Evaluating the Impact of an Enhanced Primary Care Program at a Health Center Serving a Low Income Hispanic Population

This study will assess the effectiveness of an enhanced primary program as measured by patient outcomes and adherence to treatment guidelines for patients with type II diabetes as well as compliance with preventive care for all adult patients.

Completed

Tufts University School of Medicine
KL-2 Career Development Award
Selker (PI) 07/01/11-06/30/13

Clinical Practices and Hospital Characteristics Associated With Health Care Associated Obstetric Infection Rates in US Hospitals

This two year career development award provides additional training in methods of clinical research and mentored research, serving as a bridge to obtaining additional career development award funding through NIH. Role: Scholar

Baystate Health Insurance Company
Baystate Medical Center
Goff (Co-PI) 10/01/10-02/28/13

Obstetric Hand-offs: Identifying and Implementing Best Practices

This study will describe current practices for transferring patient care between nurses, physicians, and resident physicians and incorporate national best practices into re-design of current practices.

Baystate Medical Center/University of Massachusetts Collaborative Biomedical Research Grants
Goff (Co-PI) 06/01/10-12/31/12

The Massachusetts BMI Letter: How Are Parents Responding?

This study evaluated the literacy level of a letter sent home from schools regarding children’s body mass index and qualitatively assessed parents’ response to these mandatory letters. Role: Co-PI

Department of Internal Medicine
Baystate Medical Center
Rothberg (PI) 06/01/10-12/31/12

Medical Waste: A Photo-elicitation Study of Wasted Resources in a Tertiary Care Hospital

This study is designed to qualitatively explore areas of wasted resources as perceived by health care providers. Role: Co-investigator

Foundation for Informed Medical Decision Making
Rothberg (PI) 09/01/11-12/31/12

Informed Consent Discussions About Angioplasty for Chronic Stable Angina: Why Do Patients Perceive Mortality Benefit?

This study employs content analysis techniques to assess the quality of informed decision making that occurs between cardiologists and patients prior to undergoing cardiac catheterization for angina. Role: Co-investigator

Department of Pediatrics
Baystate Medical Center
Goff (PI) 06/01/10-12/31/12

Palliative Care Training in Pediatric Residency Programs

This national survey seeks to describe the state of pediatric palliative care resident education.

Baystate Medical Center Incubator Fund.
Goff (PI) 01/01/09-12/31/11

Identifying Predictors of Variation in Obstetric Complication Rates Across US Hospitals: Preliminary Studies to Improve Obstetric Quality of Care

In this project, we assessed the validity of ICD-CM coding for obstetric complications and developed detailed analytic models for examining factors associated with obstetric outcomes.
BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.

Follow this format for each person.  DO NOT EXCEED FOUR PAGES.

NAME
Bruce A. Barton

POSITION TITLE
Research Professor of Quantitative Health Sciences

eRA COMMONS USER NAME (credential, e.g., agency login)
bbarton (PI/IAR)

EDUCATION/TRAINING  (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training and residency training if applicable.)

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>MM/YY</th>
<th>FIELD OF STUDY</th>
</tr>
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<tr>
<td>Dickinson College, Carlisle, PA</td>
<td>B.A.</td>
<td>06/1970</td>
<td>Latin</td>
</tr>
<tr>
<td>Pennsylvania State University, State College, PA</td>
<td>M.A.</td>
<td>09/1971</td>
<td>Classical Languages</td>
</tr>
<tr>
<td>University of Pittsburgh Graduate School of Public Health</td>
<td>M.S.(Hyg.)</td>
<td>12/1974</td>
<td>Biostatistics</td>
</tr>
<tr>
<td></td>
<td>Ph.D.</td>
<td>08/1982</td>
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</tr>
</tbody>
</table>

A. Personal Statement

This application is to investigate the use of reminders, both electronic and telephonic, to patients to receive a flu shot and a pneumonia vaccine shot. I am a Ph.D. biostatistician with over thirty years of experience in randomized clinical trials. I have been the primary/lead statistician/statistical PI on over 35 NIH- and industry-sponsored trials in the past 10 years. My current position as the Director of the Quantitative Methods Core at the University of Massachusetts Medical School put me in a position to provide the input on the required data that are needed to provide the high-level statistical input that will allow this study to be analyzed in such a way as to provide the optimal results. My background and decades of experience in medical research studies, in particular, will be an important resource for this study and for providing Dr. Cutrona with the senior statistical support for the successful, insightful analysis of the data. The publications and studies cited below illustrate that depth of my experience as well as specifically referenced relevant work in this area.

B. Positions and Honors

1979-1984 Statistician/Study Mgr Maryland Medical Research Institute, Baltimore, MD
1984-1998 Senior Statistician Maryland Medical Research Institute, Baltimore, MD
1998-2009 Principal Statistician Maryland Medical Research Institute, Baltimore, MD
1999-present Lecturer (Biostatistics) Johns Hopkins University Advanced Academic Program (Biotech)
2010-present Research Professor Department of Quantitative Health Sciences (QHS), University of Massachusetts Medical School (UMMS), Worcester, MA
2010-present Director Quantitative Methods Core, QHS, UMMS, Worcester, MA
2010-present Team Leader Research Methods Unit, Center for Health Policy and Research, UMMS, Worcester, MA
2012-present Adjunct Professor Department of Clinical Sciences, Cumming School of Veterinary Medicine, Tufts University, North Grafton, MA

Other Experience (of 35 studies either as PI or Director of Data Coordinating Center [DCC]) and Professional Memberships

1988-2004 Principal Investigator, DCC NHLBI Growth and Health Study (NGHS)
1988-2004 Principal Investigator, DCC Dietary Intervention Study in Children (DISC)
1998-2006 Principal Investigator, DCC Neurological Outcomes and Pre-Emptive Analgesia in Neonates (NEOPAIN)
2000-2006 Director, DCC Longitudinal LDL-C Studies in Black and White Families
2001-2006 Director, DCC Warfarin vs. Aspirin in Reduced Cardiac Ejection Fraction

Page 60 of 67
2001-2008 Director, DCC Hip Impact Protection Program (HIP PRO)
2003-2010 Principal Investigator, DCC Silent Infarct Transfusion Trial (SITT)
2004-2008 Principal Investigator, DCC Multicenter Study of Hydroxyurea (MSH) Patients Follow-up
2004-2010 Principal Investigator, DCC Pegylated Interferon ± Ribavirin for Children with HCV (PEDS-C)
2007-2010 Principal Investigator, DCC Occluded Artery Trial (OAT)
2006-2010 Director, DCC Low Magnitude Mechanical Stimulation to Improve Bone Mass Density (VIBES)

Professional Memberships (current): American Statistical Association, Biometric Society, Society for Clinical Trials

C. Selected peer-reviewed publications (in chronological order - selected from 119 publications):


D. Research Support

Current Research Support

1 UL1RR031982-01; Sullivan; NIH/NCRR 07/01/2010-03/31/2015
University of Massachusetts Center for Clinical and Translational Science
Biostatistics, Epidemiology & Research Design Component (BERD)
To transform the conduct of clinical and translational research by providing an “academic home” for all university clinical investigators at UMass. The UMCCTS will provide robust pilot grant programs, comprehensive education and career development programs, and innovative core facilities to support and nurture clinical investigators.
Role: Director, Quantitative Methods Core

1R01ADA029741-01; Clark; NIH/NIDA 09/15/10-08/31/2013
Cost, Benefit & Regulation of Buprenorphine Treatment for Medicaid Beneficiaries
The proposed study has two primary aims: (1) to study the impact of a 2008 Medicaid policy change in Massachusetts that introduced a prior authorization requirement related to buprenorphine dose levels, and (2) to compare costs and outcomes of Medicaid funded treatments for opioid dependence, including buprenorphine, methadone maintenance and outpatient drug free treatment as well as no treatment.
Role: Lead statistician

Subcontract to Hebrew SeniorLife, Kiel (PI); NIA/NIAMS 10/01/06-10/30/2014
Low Magnitude Mechanical Stimulation to Improve Bone Mass Density (VIBES)
This study is a randomized clinical trial to study the effect of low magnitude mechanical stimulation (vibrating platforms) to improve the bone mass density in residents of independent living facilities. A total of 200 residents were recruited for a three-year study using vibrating platforms at 36 independent living facilities.
Former Role: Director/Lead Statistician, DCC; Current Role: Lead Statistician

1 P50 HS018910-01; Franklin; NIH/AHRQ 09/30/2010 – 09/29/2014
Improving TJR outcomes through a national orthopedic registry
This research will collect patient, surgical, and care delivery metrics on a national sample of patients (N=33,000) to determine the relative contributions of patient factors, technology use, and delivery factors to (1) early functional failure and (2) adverse post-arthroplasty events; (3) examine disparities in TJR use and outcome, seeking to elucidate root causes; and (4) conduct economic analyses to determine the personal and societal value of TJR in working aged adults.
Role: Director, DCC

1R21 HL110208-01A1 (Pbert); NHLBI 08/18/11-07/31/13
School Nurse Intervention and after School Exercise Program for Overweight Teens
The major goal of this study is to evaluate the effectiveness of a school-based weight reduction program compared to an information only control condition in reducing BMI.
Role: Co-I; Lead Statistician
A Mobile, Personalized Intervention with Real-Time Adaptation to HAART Adherence

Goals: iHAART ("i♥"), is an adaptive, personalized, mobile technology designed to maximize HAART adherence in stimulant users. The goal is to design and deploy an adaptive, personalized, mobile technology (smartphone app) to improve HAART adherence in patients with HIV/AIDS and to evaluate participant experience with the developed technology to understand the barriers and facilitators of technology utilization. The specific focus is on usability and mechanisms of action that might underlie the potential effectiveness of the interventions and quality of the patient-technology relationship.

Role: Co-I; Lead Statistician

Novel Therapies in Alcoholic Hepatitis

Goals: The aims of this U01 application are to 1) evaluate novel therapeutic targets to attenuate inflammation in AH using bench-to-bedside approaches, and to 2) identify unique biomarkers for diagnostic and therapeutic decisions in AH. This is a multi-center project that will include laboratory/cellular level investigation, animal (mouse) studies, and clinical trial in humans.

Role: Director, DCC

MAP Kinase Signaling in Lymphoma: A Novel Therapeutic Paradigm

Goals: The goal of this proposed project is to investigate the biology and clinical efficacy of targeting the MAP Kinase MEK/ERK pathway in lymphoma through in vitro and in vivo mouse models as well as through early-phase clinical trials in relapsed/refractory non-Hodgkin’s lymphoma.

Role: Lead Statistician

Completed Research Support

N01 (HB-67129) McCarthy (PI); NHLBI

The objective of this project is to establish a follow-up study of adult patients who participated in the Multicenter Study of Hydroxyurea in Sickle Cell Disease (MSH) in order to ascertain whether there are any long-term toxic effects of hydroxyurea in this patient population.

Role: Previous Principal Investigator/Lead Statistician, DCC

1U01 NS42940 Barton (PI): NINDS

The objective of this study is to determine whether blood transfusion therapy will limit strokes or new or progressive MRI lesions in children with silent cerebral infarcts.

Role: Principal Investigator/Lead Statistician, DCC
H. LETTERS OF COMMITMENT

Please see enclosed letters of commitment from the following:

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jerry H. Gurwitz, MD</td>
<td>Executive Director</td>
<td>Meyers Primary Care Institute</td>
</tr>
<tr>
<td>Armin Ernst, MD</td>
<td>President/CEO</td>
<td>Reliant Medical Group</td>
</tr>
<tr>
<td>Terrence R. Flotte, MD</td>
<td>Dean, Provost, Chancellor</td>
<td>U. of Massachusetts Medical School</td>
</tr>
</tbody>
</table>
October 16, 2013


Dear Dr. Cutrona,

I am pleased to write this letter on behalf of the Meyers Primary Care Institute in support of your proposed study “System Alignment for VaccinE Delivery (SAVED): Improving rates of influenza and pneumococcal vaccination through patient outreach, improved medical record accuracy and targeted physician alerts” being submitted to Pfizer.

As a geriatrician, I very much appreciate the importance of annual flu vaccinations. Up to 90% of flu-related deaths each year claim our older adult patients. With the advent of the influenza vaccination, these deaths may be largely preventable. As a health services researcher, I am excited by your plan to utilize modern technology to improve care in a real world setting.

The Meyers Primary Care Institute, a joint endeavor of the University of Massachusetts Medical School, Reliant Medical Group, and Fallon Community Health Plan, is committed to research across the lifespan, from childhood to advanced age. We conduct population-based research to inform policy and practice, promoting evidence-based care for the benefit of our community, and beyond. This important research endeavor is entirely consistent with our mission. As Executive Director of Meyers Primary Care Institute, I assure the commitment of the necessary resources to complete your project. Specifically, we will allocate space and equipment, faculty effort commitment, and administrative and research staff support to this project.

The outcomes of this study will have a positive impact on the quality of care provided to our patients. I wish you the best of luck in your effort to secure funding for this very important work.

Sincerely,

Jerry H. Gurwitz, MD
Executive Director, Meyers Primary Care Institute
Chief, Division of Geriatric Medicine
The Dr. John Meyers Professor of Primary Care Medicine
University of Massachusetts Medical School
October 15th, 2013

Sarah L. Cutrona, MD, MPH
Assistant Professor
University of Massachusetts Medical School
377 Plantation Street, Biotech 4, Suite 315
Worcester, MA 01605

Re: System Alignment for VaccinE Delivery (SAVED): Improving rates of influenza and pneumococcal vaccination through patient outreach, improved medical record accuracy and targeted physician alerts.

Dear Dr. Cutrona,

I am writing on behalf of Reliant Medical Group to express our complete and enthusiastic support for your grant application “System Alignment for VaccinE Delivery (SAVED): Improving rates of influenza and pneumococcal vaccination through patient outreach, improved medical record accuracy and targeted physician alerts” being submitted to Pfizer.

Today's vaccines are among the most successful and cost-effective public health tools for preventing disease and death. The mission of Reliant Medical Group is to maximize the health of our patients and the community through expert medical care, compassion, innovative delivery models, medical research and education, and the appropriate use of health care resources. The aims of the proposed research project SAVED are thoroughly aligned with our mission.

Reliant Medical Group is willing to commit the resources necessary to ensure successful completion of your project. Specifically, Dr. Lawrence Garber (Medical Director for Informatics) and Dr. Lloyd Fisher (Assistant Medical Director for Informatics) will both devote the time necessary for successful implementation. Additionally, allocation of appropriate support personnel, space, equipment, and logistics will be devoted to this project.

This study’s outcomes will elucidate the most cost-effective interventions to maximize immunization rates. Reliant Medical Group is committed to improving and maintaining the health of those we serve in our communities. If the interventions developed by this project are successful, Reliant Medical Group intends to continue to use such systems for the benefit of our patients.

We hope that Pfizer recognizes the science and innovation in your proposal and provides funding for this very important proposed work.

Sincerely,

Armin Ernst, M.D.
President and Chief Executive Officer
Reliant Medical Group
100 Front Street
Worcester, MA 01608
Sarah L. Cutrona, MD, MPH  
Assistant Professor  
University of Massachusetts Medical School  
377 Plantation Street  
Biotech 4 Suite 315  
Worcester, MA 01605  

October 16, 2013  

Dear Dr. Cutrona,  

On behalf of the University of Massachusetts Medical School (UMMS) I am writing in support of your grant application to Pfizer entitled “System Alignment for VaccinE Delivery (SAVED): Improving rates of influenza and pneumococcal vaccination through patient outreach, improved medical record accuracy and targeted physician alerts.”  

The research plan and intervention that you propose is both important and feasible. Immunization is one of the easiest and most effective disease prevention activities to employ. The mission of the University of Massachusetts Medical School is to advance the health and well-being of the people of the commonwealth and the world through pioneering advances in education, research and health care delivery. Your proposed research aligns well with this mission.  

As the Chief Research Officer and Dean, I can assure you that the University will provide the infrastructure to facilitate this research at UMMS. Specifically, the University has designated existing resources including space and equipment in order to accomplish the objectives of this grant. Faculty effort, as described in the proposal, will be devoted to this project. Lastly, administrative research staff within the Meyers Primary Care Institute will be available to provide support to the investigators conducting research in this project.  

I am highly supportive of your efforts as outlined in this proposal, and if there is anything more I can do to assist this effort, please let me know.  

Sincerely,  

Terence R. Flotte, MD  
Chief Research Officer  
Celia and Isaac Haidak Professor of Medical Education  
Dean, Provost and Executive Deputy Chancellor  
University of Massachusetts Medical School