

A. COVER PAGE

Advancing RA Disease Activity Management Using Principles of Design Thinking (ADAPT)

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Abstract:

Goal: The goal of the ADAPT (Advancing RA Disease Activity Management Using Principles of Design Thinking) project is to create a novel method to facilitate a treat-to-target strategy for RA patients in clinical practice.

Target Population: Short term, the target population includes rheumatologists at an academic and safety-net hospital and their RA patients. The tools developed as part of this project will be broadly applicable and will be disseminated to improve the implementation of T2T approaches nationally.

Project: The project entails (1) implementing an electronic-record-based tool that will record tender and swollen joint counts and automatically calculate disease activity measure scores; (2) developing a user-friendly interface for presenting disease activity data and targets to patients and clinicians in collaboration with a professional design team; (3) testing the combination of these improvements in data entry, management, and presentation in a interrupted-time-series trial in two rheumatology clinics.

Evaluation: The success of the overall (combination) intervention will be evaluated based on the proportion of RA patient visits in which disease activity and target information were provided to the patient. Additional outcomes will include the proportion of visits where disease activity score was documented in the electronic health record (performance on a nationally endorsed quality measure) and the proportion of visits in which patients had disease activity scores of “low” or “remission” (achievement of T2T).

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C. REVIEW COMMENTS AND RESPONSE. We appreciate the opportunity to respond to reviewer comments, and are glad to see that our proposal was felt to be “well-written, clear, concise, detailed and impactful” and that there were “positive comments to the degree that this project could truly impact practice.” Below, we respond to each point in the review.

1. While the panel clearly understood the need for this project, one panel member noted the professional practice gap was not described but could be inferred from the statement in the project design about the cumbersome situation ("what is") and aims #1 and #2 ("what should be").

We have now provided detailed information about baseline performance on RA quality measures in clinical practices, both nationally and in our local clinics. Major gaps in quality based on our data analyses include 1) disease activity measurements that facilitate T2T not being performed consistently (gap in national quality measure), and 2) Even when these measurements are performed, they are not consistently used by clinicians to discuss progress with patients or to facilitate clinical decision making that achieves remission or low disease activity in RA.

2. It was also noted that while the educational model cited suggests that practice and feedback will be used, the panel requests more detail regarding this in your full proposal.

The full proposal includes details regarding specific practice and feedback sessions that we will create to refine and implement novel health information technology (HIT)-enabled tools deriving from Aims 1 and 2.

3. One panel member requests your full proposal to include concrete details on the project design and outcomes evaluation. It was noted that these were presented broadly in the LOI, without sufficient detail to truly know how the proposed aims would be implemented and tested. Some examples of unanswered questions include the number of clinicians, the number of patients with RA; the existence or not of a comparison arm, etc.

We have added details about the precise outcomes evaluation, including the primary and secondary outcomes included in our intervention. We also include information on the number of clinicians and patients involved in each phase of the study (see preliminary data section), including the interrupted time series trial for Aim 3. Our statistical approach, including a power calculation, is also included.

4. Two panelists noted the outcomes evaluation addressed the anticipated benefit to quality measure collection and use, but did not specifically relate this to a direct impact on patient care metrics or achievement of T2T.

Achievement of T2T is an explicit outcome in our study and we will evaluate whether our intervention improves this outcome in Aim 3 by performing an interrupted time series trial.

D. RESEARCH PROPOSAL

1. Overall Goal and Objectives. Bringing together national leaders in quality measurement, reliability science, and design thinking, the Advancing RA Disease Activity Management Using Principles of Design Thinking (ADAPT) study aims to create novel approaches to facilitate a treat-to-target strategy (T2T) for RA in clinical practice.

Despite evidence that treat-to-target improves outcomes in RA, this strategy is not used regularly in clinical practice.¹ Documentation of key patient outcomes, including disease activity and patient functional status, occur inconsistently.^{1,2} Even when these outcome measures are documented, clinicians may not act on this information to set goals with patients or to achieve tighter disease control. Two important reasons for this gap in care include 1) burdensome workflows to collect patient-centric RA measures, and 2) lack of tools to present data to patients and clinicians in an intuitive, actionable format. *It is clear that a new approach is needed to address these barriers, one that brings principles of human-centered design thinking to the problem of implementing treat-to-target for RA.*

In 2014, the National Quality Forum endorsed new quality measures that require EHR documentation of standardized RA disease activity and functional status scores (via “eMeasures,” which are automatically extracted quality measures from information in the EHR).³ However, for these measures to effectively facilitate health care improvement, performance data must be seamlessly integrated into clinical workflows in a way that is meaningful to clinicians and impactful for patients. *This step is often overlooked in performance reporting and quality improvement, and is ripe for innovation.*

Our overarching goal is to address the critical usability and workflow challenges of implementing and effectively using treat-to-target strategies in clinical practice by designing and developing novel health information technology (HIT)-enabled performance feedback tools. These tools will be tailored separately to both clinicians and patients to guide clinical decisions and improve quality. To develop these tools, we propose novel partnerships with industry leaders in human-centered design thinking, leaders in implementation science and quality measurement, patients, and clinicians.

We propose three aims:

Aim 1: To design and develop a HIT-enabled solution that resides *within* the EHR to facilitate clinical documentation of disease activity and functional status for RA. Gaps in quality of care for RA, including around the use of disease activity measurement and T2T, has been documented in research led by the investigators and others.^{2,4-10} To scale tools for quality measurement and improvement, we must adapt measure collection to the EHR environment. We propose to leverage existing technology (SmartForms and Templates) in two of the most commonly used EHR systems in the United States (Epic and eClinicalWorks) to ease documentation of RA quality measures and facilitate T2T strategies. *Because these two EHR systems cover over 100 million Americans, and because our methods will leverage existing*

software capability in many EHRs, our approach is pragmatic and will facilitate rapid dissemination to other institutions nationwide.

Aim 2: To use principles of human-centered design thinking to develop, test and iterate new approaches to the feedback of RA disease activity and functional status data to both patients and clinicians. Validated tools to measure RA disease activity and functional status exist, but are underutilized.¹ Even when these outcome measures are collected, they are insufficiently used to guide clinical decisions because the information is not presented in a timely, efficient, visually compelling or actionable manner. To address this important gap, we propose a novel collaboration with design experts outside of healthcare. We will partner with a leading design and innovation consultancy, GravityTank, to tackle this issue.

Aim 3: To evaluate whether implementation of a newly designed performance feedback system is effective in improving eMeasure performance and facilitating treat-to-target using an interrupted time-series (ITS) trial. We will use the products from Aim 1 and Aim 2 in an ITS trial to test their effect on the use of treat-to-target strategies in rheumatology clinics. ITS is a strong quasi-experimental study design and useful when evaluating new health system interventions. The approach is both feasible and rigorous, allowing us to evaluate the impact of our intervention. *The study will test the hypothesis that providing easy-to-use, customized RA disease activity and outcome education and feedback to providers and patients will improve performance on quality measures and achieving T2T in our health system.*

2. Technical Approach

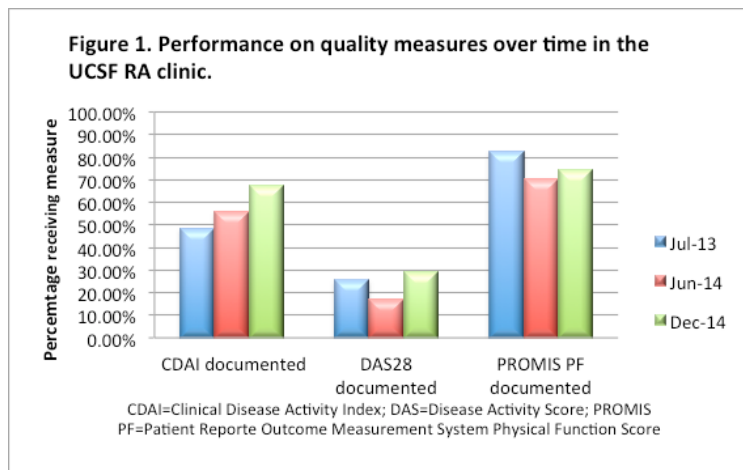
2a. Background and Assessment of Need for the Project. For the last decade, our investigative team has worked at the local and national levels to advance quality measurement in RA. We performed the first national investigation of disease-modifying anti-rheumatic drug (DMARD) use in RA, published in *JAMA*, demonstrating significant sociodemographic disparities in care.⁴ We have performed numerous other investigations of quality of care in RA, using diverse data sources.^{2,4-7,10-12} As co-Chair of the American College of Rheumatology's Quality Measures Committee, Dr. Yazdany created new infrastructure to develop and test quality measures, and served as the principal investigator for the ACR's RA quality measure development program. This project resulted in the first eMeasures, or EHR-enabled quality measures, to achieve National Quality Forum endorsement in rheumatology.³ One of the measures explicitly calls for routine assessment of RA disease activity. Currently, as Chair of Research for the ACR's EHR-enabled registry, the Rheumatology Informatics System for Effectiveness (RISE), Dr. Yazdany is working to evaluate eMeasure performance nationwide. In all of these roles, our investigative team has worked to build a robust quality measurement infrastructure for RA. *The next step in advancing quality measurement in RA must address the human-technology interface.* Clinicians need easy-to-use tools to collect measures efficiently in practice (Aim 1), and there is a critical need to apply design thinking to feed this information back to clinicians and patients in a way that is visually appealing and actionable to guide management (Aims 2) and to document the efficacy of this approach in facilitating T2T (Aim 3).

Preliminary data.

Data sources and research infrastructure. To scale quality improvement efforts, it is increasingly important to leverage the EHR, where most clinical documentation and clinical decision support currently resides in the United States. The proposed ADAPT project will leverage robust and established data systems already available to our investigative team, greatly enhancing the feasibility of the proposed Aims. *Through prior work using EHR-based patient cohorts, Dr. Yazdany's team has the technical ability and administrative permissions to access the EHR data warehouses for two health systems (a university-based system, UCSF, and a public health system, SFGH).* Our highly experienced staff has been trained to work with this data (e.g. learning the data warehousing process for specific data elements, learning Microsoft SQL), and to extract information on RA disease activity measurement and medication management at each institution. We have used this data analytic capacity to create performance dashboards for quality improvement in our local clinics and for clinical research. Funding for these efforts has come from the National Institutes of Health (NIH), Rheumatology Research Foundation (RRF) and the UCSF Foundation; the current project will be able to draw on these unique resources.

Preliminary data on RA measures and T2T. We have performed initial EHR-based analyses to determine (1) the number of unique, ambulatory patients with RA in our health systems and (2) baseline performance on the outcome measures of interest. At UCSF, the rheumatology clinic has 15 providers and cares for approximately 600 RA patients.

At SFGH, the rheumatology clinic has 9 providers and cares for approximately 500 RA patients.



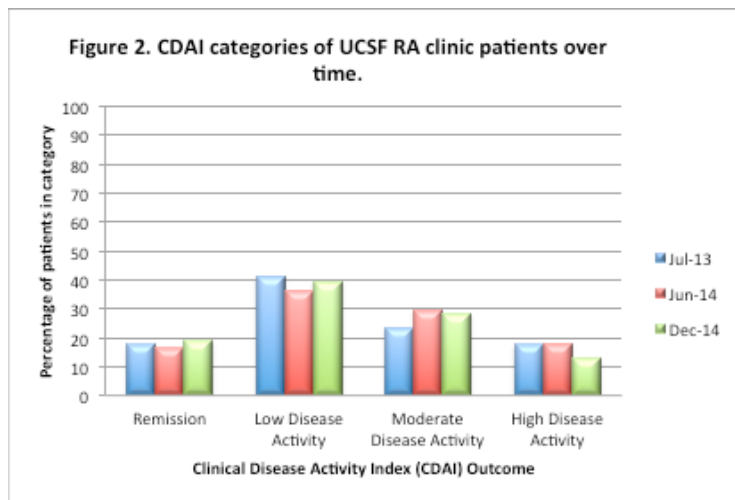
RA disease activity and functional status measures are collected routinely at both institutions' rheumatology clinics, although the workflow is cumbersome and results in substantial burdens on physicians for data entry. At UCSF, the existing workflow solution is inefficient, leading to disease activity measures being collected inconsistently; Figure 1 illustrates infrequent collection of the Disease Activity Score (DAS), moderate collection of the Clinical Disease Activity Index (CDAI) and higher levels of collection of a patient-reported functional status measure (the PROMIS PF 10a). Performance on collection of these scores, now nationally endorsed quality measures, has been relatively stable over time but physician satisfaction is low because of cumbersome workflows.

At SFGH, disease activity and functional status information makes it into the EHR even less consistently, with disease activity scores recorded in a minority of patients. *Most importantly,*

at both sites, even though quality measure information may be recorded, information regarding outcomes (RA disease activity state or functional status) is not displayed in an easy-to-interpret or actionable manner, which hinders achieving T2T in practice. Figure 2 illustrates this point; data from the UCSF practice shows that a substantial number of patients still have moderate or high disease activity at their most recent clinic visit and that these outcomes have been stagnant over time. Importantly, outcome measures are rarely shared with patients to help them track their progress and participate in goal-setting. This indicates that a T2T strategy is not being implemented effectively and is not reaching its full potential. Our preliminary data therefore justifies the need for the intervention proposed here.

Data on clinical populations.

Both UCSF and SFGH serve very diverse patient populations, which is important for the eventual generalizability of our findings. Specifically, SFGH serves a population that is 17% African-American, 23% Asian/Pacific Islander, 23% Caucasian, and 31% Hispanic. Fifty-five percent of patients are under 45 years old and 36% are age 45-64 years old. Functional status outcomes for RA patients are collected in multiple languages, including Spanish and Chinese. UCSF health system serves a population that is approximately 56% Caucasian, 13% Asian, 11% Hispanic, 6% African-American, 18% other (e.g. either mixed race or other race), and 3% Native American. Drawing on these diverse patient populations is a unique strength of the proposed project.

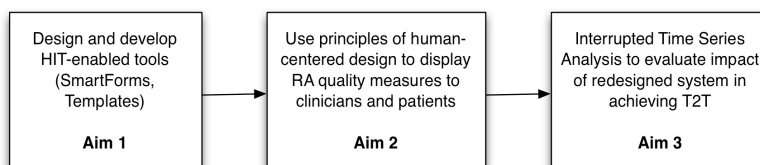


Primary audience for ADAPT project. Short-term, the ADAPT project aims to improve quality of care and achievement of T2T in our two health systems, UCSF and SFGH. The primary audience of the intervention is rheumatologists working in our clinics and RA patients seen in these healthcare systems. Long-term, we plan to share our specific workflows in our Epic and eClinicalWorks EHRs with other users of these EHRs (Aims 1 and 2), and to broadly disseminate our intervention through peer-reviewed publications, presentations at national meetings, and through our work with national stakeholders on quality measurement and improvement strategies.

2b. PROJECT DESIGN AND METHODS.

The overall project design and methods are presented in Figure 3. The study will address the key barriers to

Figure 3. ADAPT study flow and Aims.



achieving T2T in real-world clinical practice, including barriers to efficiently recording information (Aim 1) and to receiving that information back in an actionable format (Aim 2). Importantly, ADAPT will evaluate the effectiveness of the redesigned system of care on performance on RA quality measures and achieving T2T (Aim 3).

Aim 1 Design and Methods. *The goal of this aim is to develop scalable HIT-enabled tools to simplify the collection of disease activity and functional status measures in routine clinical practice.* Existing workflows for collecting RA outcomes in our two health systems, UCSF (university-based system) and SFGH (safety-net system), are cumbersome. For example, to calculate a Clinical Disease Activity Index (CDAI) or Disease Activity Score (DAS), clinicians must enter information into a desktop computer program outside of the EHR, and then manually re-enter this information into an EHR flowsheet. Similar workflow challenges exist for collecting functional status outcomes. *Current processes are inefficient, disrupt clinical workflow and decrease provider buy-in, leading to suboptimal performance scores on RA quality measures and inadequate implementation of T2T.* We plan to work iteratively with clinical teams, using principles of quality improvement, including the Institute for Health Care Improvement's (IHI) Model for Improvement, to increase the efficiency of these processes. Our approach will include:

1) Changes to the HIT environment. At UCSF, we will leverage technology available in Epic, SmartForms, to integrate disease activity and functional status documentation more seamlessly into clinician notes. This approach is appealing because it allows the clinician to maintain documentation in a single place (the clinical note) and standardizes a complex workflow. At SFGH, we will leverage existing functionality in eClinicalWorks (templates), to create a more efficient workflow. *We chose these approaches because they leverage capacity that is already available in the EHR and that can be shared across institutions, increasing potential for future dissemination.* Our investigative team has a successful track record in quality improvement, building HIT-enabled tools, and engaging stakeholders in process redesign, greatly increasing the feasibility of this Aim.

Epic SmartForms and eClinicalWorks Templates will be designed and implemented to give providers a way to document disease activity and functional status easily and efficiently. Changes will include: 1) including check boxes organized around a homunculus to allow for the fast documentation of tender and swollen joint counts; 2) automatic conversion of checked boxes into text that will populate the clinic note; 3) Automatic population of fields for inflammatory markers from most recent lab draw, if applicable; 4) Automatic calculation of disease activity score and category (remission, mild, moderate, severe).

2) Clinician education. We will use well-accepted instructional design to train clinicians in the use of these new HIT tools, including (1) web-based help modules within the EHR at the point of care; (2) using "worked" examples and demonstrations to show learners new systems; (3) providing opportunities to practice inputting data in a setting that resembles the learners' clinical practice; (4) giving learners feedback highlighting the difference between what they are doing and what they are expected to do.¹³

Specifically, after the new SmartForms and Templates are available in the respective EHRs, investigators will hold two training sessions for providers at each clinic site. These will be approximately 30-minute-long and occur just prior to the beginning of clinic to maximize attendance. The goal will be for 100% of providers to attend at least one session. These sessions will be done in a conference room with a computer for each provider and will include (1) Brief introduction for rationale; (2) walk through by investigators of how to use the new tool to document disease activity; (3) allowing providers to test and practice inputting data for a mock patient in the EHR; (4) using the investigators as “super users,” providing feedback and guidance on the use of the new HIT tools in the practice session. Investigators will then stay in the clinic for the remainder of the session in order to assist with data entry and training as clinicians apply the tools to real patients.

Aim 1 Outcome measures: We will use specific outcome measures to analyze the success of this Aim 1 system redesign.

Before implementation of the SmartForms and Templates, we will assess:

1. *Baseline performance on quality measure documentation* will be assessed by calculating the proportion of patients with RA disease activity and functional status documented in the clinical note over the 6-month period preceding the availability of SmartForms and Templates. This will be done via automated EHR queries of all RA clinic patients.
2. *Baseline provider satisfaction* will be assessed by administering a short (3 question) survey to each provider in both clinics to assess satisfaction with existing workflows for documenting RA disease activity and functional status using a 1-10 Likert scale.

After implementation of the SmartForms and Templates, we will allow a 4-week ramp-up period. At the end of this period, we will begin a “post-intervention assessment period” lasting 6 months. During this time, we will assess:

1. Proportion of RA encounters in which SmartForms or Templates are utilized.
2. Change in proportion of patients with RA disease activity and functional status measures documented (provider performance before and after implementation).
3. Change in provider satisfaction with workflow and documentation tools (1-10 Likert scale before and after implementation).

Aim 2 Design and Methods. *The goal of this aim is to use design thinking to address clinician and patient informational needs about RA outcomes in a way that facilitates patient-centered decision-making and T2T.* Collecting quality measures efficiently (Aim 1) is important, but insufficient for effective treat-to-target implementation. To make a greater impact, we need to fundamentally re-think the way that information is fed back to clinicians, providing intuitive, actionable data that supports goal setting and RA disease control, especially in low-literacy and non-English speaking populations. We propose a novel partnership with a design and innovation consultancy, GravityTank (<http://www.gravitytank.com>), to design both clinician and patient dashboards of RA outcome measures. GravityTank is an award winning firm and well known for their innovative design work in healthcare. They have won numerous awards,

including the Best Overall Design in the national Health Design Challenge for work on the Blue Button medical record. Our approach for Aim 2 will include:

1) Designing prototype dashboards to facilitate T2T. Working with a design team at GravityTank, we will develop initial prototype dashboards to display RA outcomes (disease activity and functional status) to both clinicians and patients using data automatically extracted from the EHR. Specifically, GravityTank consultants will work with our investigative team using techniques such as brainstorming, living in the future, storyboarding and mock-ups to design these dashboards. This collaboration will build on our previously successful collaboration with the firm to develop dashboards for an AHRQ-funded project at San Francisco General Hospital to improve patient safety.

2) Tool revision, refinement and acceptability assessment. Following this initial prototyping, we will work with our clinical teams and with patients to develop and iterate prototype dashboards for reporting RA disease activity and functional status data during routine clinical care. Specifically, we plan to conduct 4 focus groups with the help of a trained facilitator. Design consultants from GravityTank will also attend these sessions to help us iterate the dashboard prototypes. Separate focus groups will include 1) Rheumatologists at UCSF (target n=8); 2) Rheumatologists at SFGH (target n=8); 3) RA patients at UCSF (target n=8); 4) RA patients at SFGH (target n=8). Our investigators will draw on the extensive qualitative work already done with patients in both settings to develop materials for RA medication choices for low-health literacy, diverse populations.^{14,15} *The goal of the focus groups will be to receive specific qualitative feedback and suggestions for RA outcome performance feedback prototypes developed during the initial design work. The information gained from these groups will inform final versions and specific implementation of the new performance dashboards.*

Aim 3 Design and Methods. *The goal of this Aim is to test whether the newly designed system of care (including SmartForms, Templates and performance dashboards) is effective in improving RA quality measure performance and facilitating treat-to-target using an interrupted time-series (ITS) analysis. ITS is a strong quasi-experimental study design and useful when evaluating new health system interventions. The approach is feasible to implement within the timeframe of the proposed work, particularly given the robust EHR data analytic capacity already in place in our investigative group.*

We plan to test the hypothesis that our redesigned system of care (including improved workflows for collecting RA quality measures, Aim 1, and more thoughtfully designed approaches to feeding back performance data to clinicians and patients, Aim 2) will improve performance on quality measures and achieving T2T in RA.

Setting and study subjects

Our study will take place at two San Francisco rheumatology clinics – UCSF hospital clinic and the SFGH hospital clinic. Both hospitals are part of the UCSF training program in rheumatology.

The study cohort will include all adult patients seen between September 2015 and September 2017 at one of these two rheumatology clinics who have a physician-confirmed diagnosis of rheumatoid arthritis based on EHR problem list and confirmed through chart review. Included patients will be followed for at least 6 months following their last visit to the clinic in order to obtain baseline data and information on change in disease activity scores over time.

Data sources

Clinical data will be retrieved, as described above, from the outpatient electronic health record for UCSF (Epic) and SFGH (eClinicalWorks), respectively. Through chart review, we will assess whether disease activity was adequately documented in the EHR, what the disease activity score was, and whether medication changes were made in response to the disease activity score or category. With this information, we will be able to classify all RA patient encounters according to the outcomes described below.

Outcomes

Our primary outcome for the ITS trial is the proportion of RA patient visits in which information about progress in achieving T2T outcomes (disease activity score and target, and functional status score) were provided to the patient in the clinic's After Visit Summary (AVS) *before and after the proposed interventions*. The AVS is a document generated by the provider via the EHR that is handed to the patient at the end of the visit. Typically, it contains information about important changes to the patient's medication regimen and tasks (labs or radiology studies). To calculate performance on this metric, we will develop and periodically update an automated query that determines whether the AVS was printed and whether it contained T2T information (i.e., current disease activity category, goal disease activity category, changes to medications or other strategies to achieve this goal).

Additional outcomes will include the proportion of visits in which disease activity scores were documented appropriately in the EHR and the proportion of visits in which patients achieved T2T (i.e. disease activity scores of "low" or "remission").

We will calculate two balancing measures¹⁶ to assess for potential negative or unintended consequences of the intervention on provider burden or patient satisfaction: (1) For a sample of visits before and after the intervention, we will measure "face-to-face time" in minutes, defined as the number of minutes patients spent in the room with the providers; (2) For a sample of visits before and after the intervention, we will administer a short exit questionnaire to patients assessing satisfaction with the visit and whether they felt their visit included shared-decision making with their provider. For the latter, we will use a validated subscale from the Interpersonal Processes of Care (IPC) survey designed to measure specific components of doctor-patient communication in diverse populations.¹⁷ This subscale of the IPC is the calculated mean score for two questions: "If there were treatment choices, how often did you and your doctors work out a treatment plan together?" and "If there were treatment choices, how often did doctors ask if you would like to help decide your treatment?"; each has a five-item response ranging from 1 "never" to 5 "always."

Pre-post and interrupted time series analysis.

We will use pre-post and interrupted time series (ITS) analytical approaches to assess the impact of the combined intervention (HIT and disease activity presentation tool) on the primary and secondary outcomes. For the pre-post analyses, to determine whether differences in outcome measures between the two time periods were statistically significant, the outcomes will be modeled using a dichotomous “intervention” predictor variable in multiple logistic regression models. Regression models to adjust for potential confounders will be built using manual backward-stepwise variable selection. Variables that will be considered include: patient variables (age, sex, race, body mass index, education, insurance type) and physician variables (years in practice, sex, race). The “intervention” variable will be locked in the model *a priori*, while all other variables will be retained at $p < 0.20$ to reduce the risk of over-fitting.

In addition, we will use an ITS design to evaluate the longitudinal effects of the intervention on the outcomes of interest.¹⁸ While pre-post analyses effectively compare average rates before and after the intervention, the ITS approach allows more formal conclusions about the impact of an intervention on the outcome and is able to control for secular trends.¹⁸ *We will use ITS logistic modeling to examine the proportion of patient visits in which disease activity and target information were provided to the patient (primary outcome), the proportion meeting quality measures, and the proportion achieving T2T (additional outcomes) and will adjust for the variables found to be associated with these outcomes.* Because analyses will be done on a per-visit basis, we will use generalized estimating equations with robust variances to account for repeated visits by the same patient and for clustering by physician.

In order to strengthen the validity of our results, we will include a non-equivalent control group that will not be exposed to the intervention in our analysis. For the control group, we will use a rheumatology clinic from the third hospital within our healthcare system (San Francisco VA). We have access to clinical data from this clinical site and collect data on performance to quality measures (proportion of visits with disease activity score recorded and functional status score recorded) routinely. This will help us to assess for secular trends in disease activity scores and achievement of T2T that are not related to our intervention.

Sample size estimates

From our baseline data, we anticipate that we will have an adequate sample size for the ITS trial. All power calculations were based on 80% power and a two-tailed $\alpha=0.05$. After accounting for the design effect related to multivariable modeling, clustering by physician and repeated measures for patients, the study will be adequately powered to detect an improvement of 15% or more in either quality measure performance (disease activity measure recorded) or achievement of T2T.

Dissemination strategy

We aim to publish at least 2 peer-reviewed manuscripts related to this project and to present our findings at regional and national meetings including the American College of Rheumatology meeting. We plan to make the SmartForms and Templates created through this project

publically available and free-of-charge. Furthermore, the tools created in Aim 2 in partnership with GravityTank will also be made publically available, free-of-charge to clinics around the country. If the ITS trial is successful, we will seek additional opportunities for broad national dissemination, including using our results to inform the design of the ACR's RISE national registry performance dashboards.

Aim Independence and Inter-dependence. We stress that our three aims are complementary but not dependent. Developing and testing SmartForms and Templates to more efficiently collect RA outcomes in routine clinical practice would itself be highly informative. This is particularly true because our UCSF practices use the two most popular EHR systems in the United States and *because we plan to make the forms generated in this proposal available in the public domain*; therefore our methods can immediately be replicated or customized in other practices using these EHR systems. Although we plan to use the more efficiently collected workflow in Aim 1 to generate data to inform Aim 2, even without this new workflow, we can prototype RA quality measure performance dashboards *because providers in our practices are already collecting these measures in practice*. Finally, Aim 3, an interrupted time series analysis, can be used to evaluate *any* system redesign we are able to implement within the timeframe of this project, even if revisions to Aims 1 or 2 are required.

Potential problems and alternative strategies. We do not anticipate problems with designing or implementing either SmartForms or Templates within our EHR systems, since the investigators have experience creating these tools for other conditions. However, providers may not consistently implement these new tools even if we engage them in the development, implementation, and educational process (Aim 1). To address this problem, we will try to iterate these new tools to customize them to clinician needs and formally study barriers to implementation, something that is rarely reported in the medical literature but critically important to inform future efforts. For Aim 2, we have successfully worked with GravityTank in the past to redesign systems to address patient safety through the AHRQ-funded San Francisco Ambulatory Safety Center for iNnovation (ASCENT), so we are confident in their ability to execute the proposed work. However, there may be barriers to implementing their performance reporting solution related to institutional HIT support and capacity to incorporate this information within our current EHR systems' capacities. If we encounter such barriers, we will implement our dashboard outside of the EHR, using data pulled on the backend from our electronic data warehouses. This information can then be visually depicted on paper and prepared for patients and providers during each RA clinic. This back-up plan is highly feasible since our team already has full access to the data warehouses for both the UCSF and SFGH EHRs.

Finally, our interrupted time series analyses will not allow us to separate the effects of the individual components of the intervention. While we will not be able to assess the independent impact of these components, we believe our approach reflects the complexity of real-world RA clinical care, in which achieving T2T requires not only more efficient means for collecting RA outcomes, but also bringing design thinking to feeding this information back to clinicians and patients.

Innovation. This proposal brings new approaches to solving the documented gaps in implementing T2T in RA, including, for the first time, partnering with experts in innovation and design thinking to create a human-centered approach to RA quality measurement and improvement.

3. Detailed Work Plan and Deliverables Schedule

The proposed studies are feasible within the 3-year timeframe allotted for this award given the infrastructure we have already created to access clinical data at UCSF and SFGH, and our highly experienced investigative team of clinicians, researchers and designers that have a successful track record of collaboration. Our specific work plan is outlined in Table 1 below. We plan to perform work to develop HIT tools for more efficient collection of RA outcomes during routine clinical care (Aim 1) in Year 1. Design work and prototype iterations with patients and providers will occur in Years 1 and 2 (Aim 2), and the ITS trial will occur in the final year of the award.

Specific deliverables include:

- Aim 1: HIT-enabled tools to increase the efficiency of collecting RA outcomes in routine clinical practice, including Epic SmartForms and eClinicalWorks templates.
- Aim 2: Prototype dashboards to facilitate T2T that derive from qualitative studies with patients and clinicians and our collaboration with GravityTank, a leading firm in human-centered design thinking.
- Aim 3: Results of the ITS trial to examine the impact of a redesigned system of care for RA on performance on nationally endorsed quality measures and achievement of T2T.

Our group has been successful disseminating quality improvement projects on a national scale, particularly in our work with the National Quality Forum and American College of Rheumatology. We will leverage these existing collaborations and networks to ensure the project has the broadest possible impact.

Table 1. Timeline for completing ADAPT study activities.

	Year 1		Year 2		Year 3	
Aim 1: Prototype SmartForm for Epic, Template for EPIC and eClinicalWorks	√	√				
Aim 1: Clinician education sessions at 2 clinics			√			
Aim 2: Design innovation meetings with GravityTank consultants		√	√			
Aim 2: Focus groups to iterate prototype performance dashboards (patient and provider)			√	√		
Aim 3: Implementation of HIT and Performance Tool into clinics				√		
Aim 3: Interrupted Time Series Trial					√	√
Publications and presentations				√	√	√