Coupled Effect of Electronic Medical Record Modifications and Lean Six Sigma Methodology on Rheumatoid Arthritis Disease Activity Measurement and Treat-to-Target Outcomes

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Objective. Rheumatoid arthritis (RA) disease activity assessment is critical for treatment decisions and treat to target (T2T) outcomes. Utilization of the electronic medical record (EMR) and techniques to improve the routine capture of disease activity measures in clinical practice are not well described. We leveraged a Lean Six Sigma (LSS) approach, a data-driven five-step process improvement and problem-solving methodology, coupled with EMR modifications to evaluate improvement in disease activity documentation and patient outcomes.

Methods. A RA registry was established, and structured fields for Routine Assessment of Patient Index Data (RAPID3) and Clinical Disease Activity Index (CDAI) were built in the EMR, along with a dashboard to display provider performance rates. An initial rapid-cycle improvement intervention was launched, and subsequent LSS improvement cycles helped in standardization of clinic workflow, modifying provider behaviors, and motivating better documentation practices. Trends related to CDAI score categories were compared over time using run charts.

Results. Our project included 1322 patients with RA and 10 241 encounters between April 2016 and December 2019. Initially, RAPID3 completion rates increased from 16% to 50%, and CDAI from 15% to 44% from the RCI intervention. Post LSS intervention, the RAPID3 rate increased to more than 90% (sustained at 85%), and CDAI rate increased to more than 80% (sustained at 72%). The patients in the low disease/remission category increased from 54% to 66% (p < 0.001), and those in the high disease category decreased from 15% to 7% (p < 0.001), demonstrating improved T2T outcomes.

Conclusion. Combining EMR modifications with systems redesign utilizing LSS approach led to impressive and sustained improvement in disease activity documentation and T2T outcomes.

INTRODUCTION

In the past 30 years, health care quality measurement has expanded rapidly in the United States. The Medicare Access and CHIP Reauthorization Act (MACRA), signed in April 2015, required the Center for Medicare/Medicaid Services (CMS) to enact comprehensive changes significantly affecting the medical providers and their practices (1). To meet the CMS requirements, the American College of Rheumatology (ACR) developed a variety of quality measures specifically for rheumatology professionals. Building quality measures for rheumatoid arthritis (RA) was a priority for the ACR because of the high prevalence of RA, which affects 1.3 million Americans, and its associated morbidity and cost implications (2). The RA-related measures developed by the ACR are included in the Rheumatology Informatics System for Effectiveness (RISE) registry (3). An important metric among the set of RA measures involves periodic assessment of disease activity. This is defined as the percentage of patients aged 18 years and older with a diagnosis of RA who had an assessment and classification of disease activity within 12 months (4). Evaluating disease activity in patients with RA is helpful to clinicians in assessment of the effectiveness of treatment and to facilitate clinical decision making. There is evidence that treating to achieve the target of reducing disease activity to very low levels reduces structural joint damage and enhances

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Submitted for publication August 9, 2020; accepted in revised form January 12, 2021.
quality of life outcomes over the course of the disease. There has been a push for achieving the target of low disease activity, which has led to the development of the concept of “treat to target” (T2T) in the practice of treating RA (5). T2T strategies and outcome measures based on tight control of RA utilizing disease activity assessment have resulted in improved outcomes in these patients (6).

Continuous assessment of RA disease activity and functional status is critical for clinical cognizance, treatment selection, and improved communication with patients. There is a scarcity of available literature on how to best capture disease activity measures in the electronic medical record (EMR) and implement it in the routine clinical practice for consistent documentation. Improvement in data capture and documentation may require the development or adoption of specific software that gathers data from various locations with the EMR and appears as a separate “pop-up” window (7). Workflow standardization using paper forms has been used to achieve better documentation of disease activity (8). Modifications to the EMR, clinical workflows, and clinic culture have improved the capture rate of RA disease activity measures; however, they did not result in improvement in the T2T outcomes (9).

In this study, we utilized Lean Six Sigma (LSS) methodology, which originated from the manufacturing industry. It uses a data-driven approach for process improvement and problem-solving with the intent of reducing the variation in a process. This is accomplished using a five-step quality improvement cycle known as DMAIC: define, measure, analyze, improve, and control (10,11). Utilizing LSS methodology helped maximize the performance in reliable documentation of disease activity measures in our large academic medical practice. We evaluated the effect of LSS tools and techniques, such as fishbone diagram, Pareto chart, and process map, on improving the documentation of the disease activity measures and its effectiveness in sustaining that improvement. We built and leveraged EMR tools such as flowsheets and performance dashboard to capture RA disease activity measures. We further studied whether these changes affected the clinical outcomes of patients over time.

**SIGNIFICANCE & INNOVATIONS**
- We utilized a Lean Six Sigma data-driven approach for process improvement methodology, coupled with electronic medical record modifications to improve disease activity documentation.
- There were significant improvements from baseline in the Routine Assessment of Patient Index Data and Clinical Disease Activity Index completion rates, which sustained over time.
- We observed an improvement in the treat to target clinical outcomes in our population.

**METHODS**

**Study settings.** This project was executed in a large multisite rheumatology clinic that is part of an academic medical center. The rheumatology clinic consists of a larger clinic in the main campus of the medical center and two satellite clinics in the community. Patients with RA were seen by 14 faculty physicians, 2 nurse practitioners, and 10 rotating rheumatology fellows during the study period. The academic center employs a single EMR (Epic) across all inpatient and ambulatory settings, including the rheumatology clinics. The University of Texas Southwestern Medical Center (UTSW) Human Research Protection Program determined that this is a quality improvement project, thus was exempt and did not require internal review board approval.

**Disease activity measures.** The Routine Assessment of Patient Index Data (RAPID3) tool for RA disease activity is based on a set of three patient-reported measures: physical function, pain, and the patient global estimate of health status. The questionnaire can be completed in 5 to 10 minutes and is easy to score. The total score provides a measure of disease activity. A total score greater than 12 indicates high activity, 6.1 to 12 indicates moderate activity, 3.1 to 6 indicates low activity, and 3 or less indicates remission. Improvements in the patient’s condition will lead to lower scores after each successive examination until the patient reaches a low level of RA activity or remission (12,13).

The Clinical Disease Activity Index (CDAI) tool is based on four measures: a provider’s count of tender joints and swollen joints, the patient and provider global assessments of RA activity. The CDAI tool is scored out of a total of 76 points. A score from 22.1 to 76.0 indicates high activity, 10.1 to 22.0 indicates moderate activity, 2.9 to 10.0 indicates low activity, and 0 to 2.8 indicates remission. The difference between the CDAI and RAPID3 tools is that the CDAI questionnaire requires input from both the physician and the patient, whereas the RAPID3 requires only the patient’s input (14).

**Data sources and rheumatoid arthritis registry.** Beginning in 2015, UTSW expanded its focus on population health management to specialty care. Disease-specific registries were developed using high-fidelity data from the EMR and enterprise data warehouse (15,16). Actionable patient lists and relevant data were generated from the registries that amplified transparency of the care delivered to the patients at the provider and clinic levels. A single institution rheumatoid arthritis registry was created in early 2015 that included patients 18 years of age or older, with a diagnosis of RA in the problem list, who were seen at least twice in the last 24 months by a rheumatologist, and one of those visits had to be in the last 12 months.

**Outcomes.** Numerator and denominator criteria for the CDAI scores were similar to those developed and endorsed by the ACR in 2008, and they were included in the CMS Physician
Quality Reporting System (PQRS) RA measure group #177, which was also collected by the ACR’s RISE registry (4). The denominator for our CDAI measure included patients with established RA who were 18 years of age or older, who had been seen at least twice in the past 24 months, and once within the past 12 months by a rheumatology provider. The numerator was assessment of disease activity using CDAI score in this RA population, at least once in the last 12 months.

The RAPID3 completion rate measure was evaluated for each individual month and was based on visit-level completion of the questionnaire. The denominator included all patients seen by any provider in the rheumatology clinic within the specific month. The numerator was comprised of patients that had RAPID3 completed by the patient or by the clinic’s medical assistant (MA)/registered nurse and were documented in the EMR during that visit encounter.

The aim of the project was to improve the completion of RAPID3 and CDAI tools at each patient visit so that disease activity scores can be used throughout the patient treatment course. The baseline data at the UTSW rheumatology clinics from April 2015 to March 2016 indicated a low performance, with the average completion rate for RAPID3 at 16% and CDAI at 17%. The goal of the quality improvement project was to improve completion of both tools to 75% or more over the next 9 months, ending in December 2016, and sustain the results thereafter.

In addition, we assessed clinical outcomes by evaluating the proportion of patients in the high disease, moderate disease, or low disease/remission categories based on their CDAI scores. We compared the number of patients in these categories from the baseline period in April 2017 to the end of the study in December 2019. We did not have information on these categories prior to April 2017, as they were not being defined or captured in discrete fields prior to that.

**Interventions.** The project started in April 2016 and completed in December 2019. The CDAI disease activity measurement started at the main campus rheumatology clinic in April 2015, and in the two satellite clinics in March 2018. The RAPID3 disease activity completion rate measurement started at the main campus and one of the satellite rheumatology clinics in April 2015 and in the second satellite clinic in January 2017.

**CDAI/RAPID3 flowsheet and dashboard.** The RAPID3 and CDAI flowsheets were built in the EMR along with the RA registry, which allowed the clinic staff and providers to input disease activity data. RAPID3 questionnaire was made available in the patient portal (MyChart), to be sent to all rheumatology patients for completion 7 days prior to clinic appointment date. Once completed, patient responses could be pulled into the EMR encounter at the time of clinic visit. Patients who did not have patient portal access or who had not provided responses, were given the RAPID3 questionnaire in paper form on their arrival to the clinic. They completed the questionnaire in the waiting room before their scheduled appointment time. Completion of the questionnaire was not mandatory but was highly encouraged. These responses on the paper forms were manually entered by the MA in the RAPID3 flowsheet while rooming the patient. In our observations, this did not significantly delay the rooming-in process or the provider schedule. Beginning June 2018, the clinic made tablets available for patients to complete the questionnaire upon arrival to the clinic, if needed. Once the RAPID3 responses were filled in the structured fields, the flowsheet generated a cumulative RAPID3 score.

The response on the patient global estimate of health status in the RAPID3 form, once populated, was set up to serve as the response for the CDAI flowsheet. The provider then had the opportunity to enter the count of tender and swollen joints, and the provider’s assessments of RA activity in the CDAI flowsheet. Once all the CDAI responses were available in the structured fields, the flowsheet could provide the cumulative CDAI score. Based on the CDAI score, the flowsheet was set up to classify the patient into high disease activity, moderate disease activity, or low disease activity/remission categories for that clinic visit. This provided RAPID3 and CDAI scores in real time in the EMR.

A dashboard displaying the performance rate of individual provider and the clinic (combined performance of the providers) was created in the EMR and updated monthly. The performance rate included CDAI documentation rate for each month and the number of patients each month who were in high/moderate/low disease activity or remission. Each provider was able to view and compare their own performance against that of the clinic, but they did not have access on the dashboard to the performance of other individual providers.

**Preliminary efforts.** Baseline completion of CDAI and RAPID3 tools in the rheumatology clinic in the months prior to March 2016 was consistently low. Because one of the RAPID3 questions was part of the CDAI tool, poor completion of RAPID3 resulted in poor completion of CDAI. Obtaining consistent and timely CDAI and RAPID3 scores were determined to be critical to quality. A rapid-cycle improvement intervention (RCI) was launched with a change in MA workflow to complete the RAPID3 documentation in the EMR at every clinic visit. We continued to observe discrepancies in the workflow, including RAPID3 not always being completed by the patient prior to the appointment, MAs not consistently entering the completed questionnaires into the EMR, and paper copies of questionnaires sometimes inadvertently shredded or left in the room. This impeded the process, resulting in low completion rates.

**LSS methodology.** An LSS DMAIC (define, measure, analyze, improve, and control) project was launched in August 2016 to create a well-defined workflow to streamline the process of obtaining the questionnaire data.

The process improvement team was comprised of several members of the clinic, including a physician champion; clinic management; nursing and MA staff; and consultants from...
data analytics, information resources, and clinical operations. Process improvement experts trained in LSS methodology provided the necessary expertise needed through the different cycles of the project.

Using the DMAIC methodology, the project team used a variety of tools and techniques, such as fishbone diagram, Pareto chart, and process map, as a roadmap for problem-solving and process improvement (17). Mapping the current-state process flow aided the team in brainstorming ideas for improving the process and creating the future-state process flow map. The process maps were created based on input from the key representatives of all members of the clinic. Progress at each phase, proposed interventions, and supportive data analysis were communicated to the key stakeholders regularly. Feedback and exchange of ideas were encouraged to engage the clinic and refine the plan of action.

Root cause analysis. To understand the barriers in the clinic workflow for documenting the disease activity scores, a brainstorming exercise was completed with the clinic staff and providers (Figure 1). Input was gathered around the RAPID3 and CDAI scores (measurement), clinic environment, staff involved in the workflow (people), paper and online questionnaires (materials), workflow (methods), and EMR and other computer issues (machine). A Pareto analysis of the barriers helped identify the significant barriers toward completion rates (18):

- Providers were unable to recall tender/swollen joint count at the time of documentation, which was typically toward the end of the clinic.
- Providers forgot to document score.
- Providers felt that the score may be misleading for some patients, and those patients might have difficulty interpreting it clinically.
- Gaps in availability of RAPID3 and CDAI scores from previous visits that would have otherwise guided the therapy caused the providers to be disengaged.
- Low performance with RAPID3 documentation in the EMR by the MAs discouraged providers from completing the CDAI score.

In order to mitigate these barriers, visual cues were developed, such as reminder “CDAI” stickers, which were placed at the bottom of each computer screen in patient rooms and workstations.

Table 1. Characteristics of the population of patients with rheumatoid arthritis in the study

| Characteristics                  | Number |
|----------------------------------|--------|
| Total encounters during study period | 10,241 |
| New patient encounters            | 748    |
| Established patient encounters    | 9,493  |
| Average RA encounters per month during study period | 173    |
| Average number of visits per patient during study period | 7.78   |
| Female                            | 1,083  |
| Male                              | 239    |
| Mean age (y)                      | 61     |
| Race                              |        |
| White                             | 58%    |
| African American                  | 19%    |
| Asian                             | 3%     |
| Other                             | 5%     |
| Unavailable                       | 15%    |
| Total number of RA patients       | 1,322  |
| Rheumatoid factor–positive        | 71%    |
| Cyclic citrullinated peptide–positive | 69%    |

RA, rheumatoid arthritis.
Printed copies of a homunculus (schematic skeleton to record the joint examination) were placed in all the patient rooms to quickly document the tender and swollen joint count. A CDAI trend chart that included the last three CDAI scores was made available within provider’s progress note in the EMR. A standardized future-state workflow was developed in which MAs were designated to enter the RAPID3 responses in the EMR for every patient seen in the clinic during the rooming process.

The impact of the interventions was assessed throughout the course of the project. Data on the CDAI and RAPID3 documentation rate were collected via ad hoc reports and displayed monthly on the EMR dashboard. The CDAI score dashboard was added to the provider’s screen in the EMR as a visual cue. Individual- and clinic-level CDAI completion rates were communicated regularly via email to the providers to maintain transparency and so that providers could evaluate how they were performing in comparison with their peers. Feedback was collected from the MAs, nurses, and providers regularly. RAPID3 completion rates were made available to the clinic staff and leadership and posted in the clinic for visibility. The clinic workflow changes were discussed at regular intervals at faculty and clinic staff meetings.

**Statistical analysis.** We used descriptive statistics to summarize patient age and gender. Modified control charts (P charts) were used to trend improvement from baseline to the end of the project using Excel (Microsoft) and Minitab. Statistical significance of improvement in disease activity was determined by two sample t tests using Minitab (version 19.2020.1).

**RESULTS**

Our project included 1322 patients with rheumatoid arthritis, with a total of 10241 encounters during the study period (April 2016 to December 2019), which included 748 new patient and 9493 established patient encounters. We averaged 173 RA encounters per month. Each patient had 7.78 clinic encounters during the study period. The average age of the population was 61 years, and 80% were females. The majority of patients were

![Figure 2](https://example.com/figure2.png)  
**Figure 2.** Modified control chart: X bar and moving range chart for RAPID3 completion from April 2015 through December 2019. DMAIC, define, measure, analyze, improve, and control; RA, rheumatoid arthritis; RAPID3, Routine Assessment of Patient Index Data; RCI, rapid-cycle intervention.
White (58%). Eighty percent of our population had rheumatoid factor (RF) or cyclic citrullinated peptide (CCP) values available in the EMR. Among those, 71% were RF positive, 69% were CCP positive, and 4% were RF and CCP negative (Table 1).

Modified control charts (for baseline, intervention 1 was RCI and intervention 2 was DMAIC) were developed (Figures 2 and 3). The average RAPID3 and CDAI completion rates at the beginning of the project were 16% and 17%, respectively. The initial RCI improved RAPID3 completion to 50% and CDAI to 44% by the end of July 2016. The new DMAIC processes were implemented in August 2016 and tracked until December 2019. RAPID3 completion improved to more than 90% and continued to sustain at an average of 85% completion rate until December 2019. CDAI completion improved to 70% and continued to sustain at an average of 72% completion rate.

To highlight the T2T strategy, the RA disease activity outcomes were tracked in the rheumatology dashboard in the form of high/moderate/low disease activity and remission (Figure 4). We noticed a gradual increase in low disease/remission activity from 54% to 66% ($p < 0.001$) and a decrease in high disease activity from 15% to 7% ($p < 0.001$) as of December 2019. Moderate disease activity decreased from 31% initially to 27%, which was not statistically significant ($p = 0.14$).

**DISCUSSION**

Routine documentation of disease activity scores at clinic visits for patients with RA is vital for improving shared decision making and tailoring treatment to improve patient outcomes, but there is insufficient data available on how to best achieve and sustain that. An LSS approach was used in this study to assess its impact on accomplishing a higher documentation rate and to evaluate whether it had an effect on the T2T outcomes for this population of patients with RA.

Our initial RCI resulted in significant improvement for both scores, but the rates seem to plateau or decrease over time. Because the clinic workflow was not well defined and the process was not hardwired, the LSS process improvement led to the further advancement in the RAPID3 and CDAI score completion rates to reach their respective goals. The clinic achieved the goal...
for RAPID3 completion rate by the end of the project in December 2016, but the goal for CDAI was not achieved until a month later in January 2017. The process remained stable for 3 years throughout the project, and we continue to monitor the measures to ensure sustainability. The RAPID3 rate continued to sustain above the goal of 75% or greater. The brief decline in the RAPID3 completion rate between June and October 2018 was related to the change in clinic location on the campus and introduction of tablets for patients to complete the RAPID3 questionnaire upon arrival for their appointments. The workflow was quickly redefined and re-established to reach the desired completion rates. The CDAI completion rate increased to greater than 80% and maintained above the goal of greater than 75% until February 2018. The CDAI data from two satellite clinics were added in March 2018, which led to some decline in the CDAI rates, but it later stabilized at an average of 72%.

We believe that our approach was novel because we coupled data-driven LSS methodology with EMR modifications for process improvement. The tools and techniques included in the DMAIC process helped identify opportunities to overcome barriers and aided in motivating providers throughout the study period, enabling us to sustain the gains achieved in the initial 9 months. The project demonstrates that streamlining work processes to create a continuous flow of activities may lead to consistent results (completion rates) during the majority of the patient visits. A streamlined process also helped to eliminate rework and improve efficiency. In the absence of this rigorous data-driven methodology, we believe the rates likely would have dropped back down to lower levels.

Not all interventions that we developed based on the fishbone and Pareto activities made a significant impact. The interventions that were found to have the most effect or to have received the most engagement from the clinic staff and providers were as follows: involving all the stakeholders in the standardization of the workflow, emailing/publishing the RAPID3/CDAI completion rates, and regularly discussing the workflow and RAPID3/CDAI performance rate at the faculty and clinic staff meetings. Placing the CDAI stickers and sheets with homunculus in all patient rooms to help providers quickly document the tender and swollen joint count did not prove as effective. Only a small percentage of providers documented on paper during the clinic visit.

The ACR and the European League Against Rheumatism recommend a T2T approach utilizing one of the several RA disease activity measures, including RAPID3 and CDAI, to achieve lower disease activity (19). We had a gradual increase in low disease/remission activity from 54% to 66%, a decrease in high disease activity from 15% to 7%, and moderate disease activity decreased from 31% to 27%. Although it is difficult to identify the exact underlying reasons behind these changes, we believe that an increase in documentation and tracking of the disease activity scores provided immediate feedback to the providers, which might have contributed toward the modification of therapy to achieve better disease control in this patient population.

Utilization of EMR enhancements to improve disease activity documentation has been demonstrated in other studies in the past. Newman et al (7) were able to develop, integrate, and adopt
an innovative software tool (Rheum-PACER) in their EMR to show improvement in data capture and documentation of disease activity (61% of patients with RA with completed CDAI over 2 years), function, and patient-reported outcomes, and they also demonstrated improvements in quality, efficiency of care, and productivity in their rheumatology clinics. The study showed a strong positive correlation between the physician use of the software tool and improvement in the percentage of patients who achieved low disease activity over time (7). Gandrup et al (9) demonstrated improvement in the capture rate of RA disease activity scores (CDAI completion in 64% of eligible clinic visits) and physician satisfaction through modifications to EMR, clinical workflows, and provider culture. However, it did not result in parallel improvements in RA clinical outcomes. Our study had a higher CDAI completion rate at an average of 72% and used not only EMR modifications but also systems redesign utilizing LSS methodology. In addition, we observed an improvement in the T2T clinical outcomes in our population.

We had several challenges during the course of the project, which included obtaining the initial baseline data to assess current level of performance, integrating the use of disease activity instruments into the care of patients, and changing provider behavior and documentation practices to increase entry of important clinical information into the correct locations within the patient’s medical record. Key lessons learned that led to the success of the project were to obtain buy-in and early engagement from the clinic leadership and stakeholders and to effectively engage the clinic faculty and staff in developing processes that impact them and patient care.

We acknowledge the limitations of our study. Our study was conducted at an academic institution with good EMR support, and we were able to replicate in two other satellite clinics in our system, but also realize that this may or may not be reproducible in every clinical setting. We did not explore which specific interventions had the maximum impact on the improvement in documentation or change in provider behavior. We did not have a control group of providers to compare the effectiveness of our interventions against this group. For 20% of patients, we did not have RF or CCP values in our EMR.

In summary, systems engineering utilizing the LSS approach coupled with EMR modifications led to impressive improvements in performance of disease activity documentation and in modifying provider behaviors. High-quality data facilitated high-quality processes, and vice versa. Performance expectations were clearly communicated, improvements were sustained, and long-term data showed improved T2T outcomes at the practice level. Further studies are needed to establish whether improvement in documentation of disease activity leads to better outcomes.

ACKNOWLEDGMENTS

The authors thank Karla Strange for critically reviewing the manuscript, Vaishnavi Kannan for developing the EMR dashboards, and Shilu Varghese and Paul Padilla for helping with the implementation of the clinic workflow.

AUTHOR CONTRIBUTIONS

Dr. Bajaj, Ms. Kollipara, and Drs. Fish, and Karp implemented the project and wrote the manuscript. Mr. Koganti and Cheenu helped with data analysis and contributed to the manuscript. Ms. Mutz helped supervise the implementation of the project and contributed to the manuscript. Ms. Wang, Dr. Willett, and Ms. Bhat provided support with information resources tools, data abstraction, and contributed to the manuscript. Drs. Fish and Willett provided guidance as quality and informatics experts and contributed to the manuscript.

Study conception and design. Bajaj, Fish, Karp.

Acquisition of data. Kollipara, Wang, Bhat.

Analysis and interpretation of data. Koganti, Chennu.

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