Patient Reported Outcomes - The Patient's Perspective

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Puneet Bajaj MD, MPH

Assistant Professor

Division of Rheumatic Diseases

University of Texas Southwestern Medical Center

Disclosures: This is to acknowledge that Puneet Bajaj, MD, MPH has disclosed that he does not have any financial interests or other relationships with commercial concerns related directly or indirectly to this program. Dr. Bajaj will not be discussing off-label uses in his presentation.

Biographical Information

Puneet Bajaj MD, MPH is an assistant professor in the Division of Rheumatic Diseases. He is also the Associate Chief Quality Officer in the Southwestern Health Resources.

Purpose & Overview

The purpose of this presentation is to help understand the concept of patient reported outcomes, and the critical role they play in enhancing patient care and capturing whether the care delivered is actually improving patients' health and sense of well-being.

Educational Objectives

At the conclusion of this lecture, the listener should be able to understand:

- 1. What is a Patient Reported Outcome (PRO)?
- 2. What is a patient reported outcome tool?
- 3. How patient reported outcomes improve patient care?
- 4. How patient reported outcomes enhance shared decision making?

Do patients who come to us for care get better? Understanding what patients value using Patient Reported Outcome surveys.

As a healthcare institution we are always trying to answer the question: "Do the patients who come to us for care get better?" From a clinical perspective we can answer this question through the provider's educated interpretation of lab results, x-rays, and a wide variety of other validated clinical tests pre- and post-intervention. But what about the patient's perspective? Do they believe that the intervention helped them get better?

Porter defines health care value as the "health outcomes achieved which matter to patients relative to the cost of achieving those outcomes [For example,] Patients care about mortality rates, of course, but they're also concerned about their functional status. In the case of prostate cancer treatment, for example, fiver-year survival rates are typically 90% or higher, so patients are more interested in their providers performance on crucial functional outcomes, such as incontinence and sexual function where variability among providers is much greater".(1)

True success of any intervention must be measured by the combined perspectives of patients who seek value for payment, and providers who are challenged to personalize care for the patient right in front of them, given their current knowledge and experience, while working to keep up with the latest medical advances.

What matters to patients?

To understand a little more about the patient's perspective regarding value, let's use an example of a patient who comes to an orthopedic surgeon with knee pain. They've tried over the counter medications, exercise and everything they could think of to help alleviate the pain on their own with little to no success. They wake up every few hours in pain and can no longer participate in the social activities they prefer. Even activities of daily living have become a challenge. They've decided to seek expert advice. After a clinical evaluation the surgeon recommends a total knee replacement. The patient agrees and undergoes the surgery. From a clinical perspective the definition of success may be measured as: no infection post-surgery, able to ambulate 40 feet prior to discharge, and a return to a full range of motion within a specified time frame. But what about the patient's perspective? Perhaps, the patient would agree that their range of motion has improved, but has their pain been well managed? Are they now able to participate in their social activities of choice? Did they feel cared about as an individual? Did they feel like a true partner and equally shared in the decision making process? Was the clinical intervention worth the cost and benefit received? Given the choice again, would the patient choose that intervention or would they choose something else?



Pain Management
Functional Status
Quality of Life
Patient Experience of Care
Patient Satisfaction with Care

Lab Results X-ray Results Range of Motion 6 minute walking test Stress test ...

Why do we care about the patient's perspective?

From a clinical perspective, we value the patient's point of view because they are the ones we seek to serve, but in addition, clinicians value the validated and researched clinical outcomes data that allow them to objectively compare their results to their peers. Clinical outcomes do not always satisfy the hopes and desires of the patient.

While healthcare providers are inarguably the authoritative source for the interpretation of clinical data as it relates to clinical outcomes, the patient is the authoritative source for information related to pain, functional status, quality of life, their experience of care and their satisfaction with that care. Only patient can decide whether they received the value they believe they paid for. There is no subjective test to validate the patient's perspective, nonetheless it may be the most important perspective in healthcare.

From a purely business standpoint, we must understand that it is the patient's perspective that will be shared with others. In today's virtual society, the number of places to hear these stories has exploded exponentially. The patient's perspective is no longer just shared verbally with family and friends. It is shared with virtual "friends", extensive connections, rating sites, and anyone else who stumbles on that perspective posted on the internet. Our current and future customers will be influenced by what they read and hear.

How can we reliably collect and interpret the patient's perspective?

On the clinical side, the provider uses scientifically proven diagnostic tests to determine the root cause of the patient's complaint. Then using their clinical expertise recommends an intervention that has been scientifically proven to be effective for the root cause. In addition, they use their clinical experience in treating patients with similar symptoms, test results, and co-morbid conditions to help set the expectation of the patient for how well the intervention may work, how long it might take for the intervention to take full effect and an estimate on how long the intervention will last based on studies of similar patients. Can we bring this same rigor to collecting and interpreting the patient's perspective?

Given the importance of the patient's perspective, is there a way to bring a more scientific methodology to the collection and interpretation of the patient's perspective? This is not a new question. Researchers have been developing and testing methodologies to do this for many years. Hundreds of patient reported outcome tools have been developed, tested and validated.

What is a Patient Reported Outcome (PRO) tool?

The National Quality Forum states, "PRO tools measure what patients are able to do and how they feel by asking questions. These tools enable assessment of patient—reported health status for physical, mental, and social well—being."



Using a validated, standardized tool, consistently over time, and consistently across providers gives us the ability to compare results and begin to understand, from the patient's perspective, what works and what doesn't. To reliably collect and use the patient's perspective, we must first become grounded in a few fundamental concepts.

Patient Reported: What does it mean to be "patient reported"? The National Quality Forum, defines patient reported data as: "Any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else."

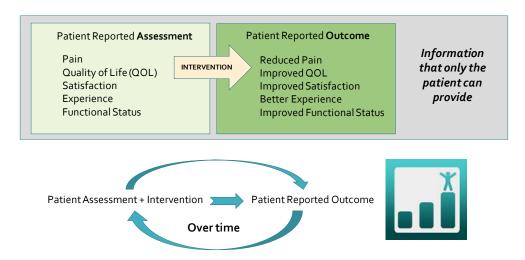
There are five major categories of patient reported information:

- 1. Pain
- 2. Quality of Life
- 3. Patient Satisfaction
- 4. Experience of Care
- 5. Functional Status

Data only the patient can provide.

No objective test is available to measure or validate this type of information. This is data that only the patient can provide.

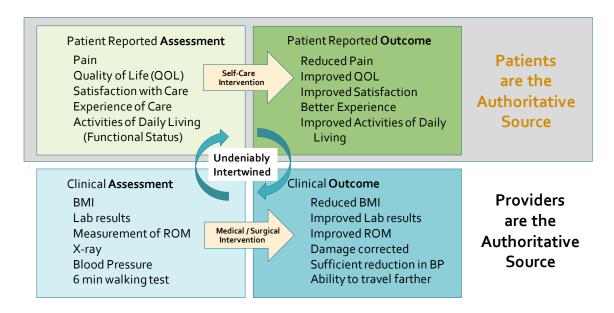
Patient Reported Outcome: What turns patient reported data into a patient reported outcome? An outcome requires an **intervention.** For example, a patient reports their pain level every day on a scale of 0 to 10 for a period of three weeks. The collection of this data, in and of itself, has no effect on whether or not the patient's pain improves. Some intervention must be introduced such as exercise, oral medication, a targeted injection or in severe cases a surgical intervention. One or more of these interventions are used to help the patient achieve their goal of pain elimination or reduction.



Goal-setting and a mutually agreed upon Plan of Care: Prior to any intervention, it is important for the provider and patient to understand what each hopes to achieve with that intervention. Providers speak to the risks and benefits which are known but not always documented as specific goals. Patients may articulate their hopes but these are rarely quantified and documented for future reference. Mutual goal-setting is the first step to ensuring patient centered care and helps to manage patient's expectations.

Before and after: The patient reported data collected prior to the intervention is characterized as **baseline data**. The **date and type of intervention** is documented, and the patient reported data **post-intervention** is collected for a specified period of time. Comparing the post-intervention patient reported data to the baseline data can be used to determine if the intervention was a success from the patient's perspective.

Medical care meets self-care: We must acknowledge that the final outcome for the patient is a combination of self-care interventions and medical/surgical interventions. Both the patient and provider play an equal role in the success or failure of an intervention. A patient may have tried multiple self-care interventions before they seek professional help and may continue applying those self-care interventions in addition to the medical or surgical intervention prescribed by the provider. In addition, a physician may prescribe a medication, but the patient must take that medication as prescribed to gain the expected benefit. Medical professionals do not pretend to control all the factors that lead to the success or failure of an intervention. We must partner with our patients, with full disclosure, to maximize outcomes.



From a clinical perspective, we recognize that our interventions are targeted at improving patient's lives. The science of healthcare helps us objectively measure a small subset of very important variables which begins to make it possible to objectively compare one treatment pathway against another or one provider's success with another. This objective measurement is vital but it is not the complete story.

PROs at UT Southwestern

UT Southwestern (UTSW) in 2014 started focusing on developing and implementing quality improvement initiatives within ambulatory specialty care clinics. A 'Quadrad' approach was taken to achieve this and it included collaboration between four different departments: Quality Office, Data Analytics, Information Resources, and Clinical Operations. The teams worked with each specialty to implement one quality improvement initiative to be phased in over two years. Each specialty was encouraged to adopt at least one clinical outcomes measure if possible. There were several clinics within UTSW who were interested in patient reported outcomes as their quality initiatives. As a result of this Quadrad approach, over the next three years, 88+chronic disease population registries were defined and deployed. 200+ assessments/surveys were selected, built in EPIC, and deployed in different clinics. MyChart, tablets and in-clinic infrastructure and workflows were made operational. In addition, thousands of PRO-survey responses were collected.

Psychiatry and Spine Center were part of those several clinics that led the development and deployment of PROs in their clinics. The **Psychiatry department** deployed a core set of 6 PRO surveys to be completed by every patient at every clinic visit. Additional condition-specific surveys were triggered based on the diagnosis in the patient's problem list. In order to allow for survey completion and nurse assessment, they introduced a 30- minute pre-visit time in the clinic, which was just before their actual clinic visit with the provider. Within 18 months, they were able to capture PROs on approximately 4,900 patients through 13,000 encounters, with around 93,450 questionnaires answered, and had an impressive return rate of 78%. In addition,

they were able to build an Epic report that gave provider a trend of the completed surveys by each patient, and flagged any scores that were above a certain threshold.

The **Spine Center** was able to look at patient reported pain scores for patients receiving surgical or non-surgical interventions for the treatment of lumbar radiculopathy. They compared the mean Visual Analog Scale (VAS) for leg pain at the baseline visit to the mean VAS for leg pain at the last follow up visit after a surgical or non-surgical intervention. The data showed that the mean change in VAS for leg pain for both surgical and non-surgical intervention patients was above the minimal clinically important difference (MCID), demonstrating improved perceived outcomes in those patients, no matter what intervention they chose.

PROs in Rheumatology

Development of quality measures and patient reported outcomes for rheumatoid arthritis (RA) has been a priority for the American College of Rheumatology (ACR) due to the high prevalence of RA, affecting 1.3 million Americans, its associated morbidity and cost implications, and the paucity of PROs for assessing rheumatologic care.(2) The ACR maintains the Rheumatology Informatics System for Effectiveness (RISE) registry, which allows participating providers to report on a variety of quality measures that were developed specifically for rheumatology professionals. Quality measures related to RA were initially developed and endorsed by the ACR in 2008, later revised and tested in 2014, and are now included in the 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 RA patients 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 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. Designing quality measures that assess patient outcomes has definite benefits, but comes with several challenges including the need for close collaboration among patients, providers, measure developers and policymakers.(6)

RA is a chronic, progressive disease that causes inflammation in the joints and results in painful deformity and immobility for which there is no cure. With appropriate immunosuppressive treatment and routine monitoring, the disease burden can be mitigated. Specifically, the continuous assessment of RA disease activity and functional status is critical for clinical cognizance, treatment selection, and improved communication with patients. Being able to recognize the disease activity and functional status of these patients with a validated clinical decision support or a PRO tool at every clinic visit helps providers tailor the medications to treat to a target of little or no disease activity and reach optimal clinical outcomes for this patient population. The ACR endorses six validated RA disease activity tools. We focused on two of those in the rheumatology clinic: the Routine Assessment of Patient Index Data (RAPID) 3 and the Clinical Disease Activity Index (CDAI).

Clinical Decision Support & PRO Tools: The 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 functional status. The questionnaire takes patients approximately five to ten minutes to complete and is scored in five to ten seconds. The total score provides a value to measure disease activity. A total score >12 indicates high activity of RA, 6.1-12 indicates moderate activity of RA, 3.1-6 indicates low activity of RA, and \leq 3 indicates remission. The RAPID3 tool is used throughout the patient treatment to generate a timeline of the disease progression starting from a baseline score. Improvements in the patient's condition will lead to lower scores after each successive exam until the patient reaches a low level of RA activity or remission. (7, 8)

The CDAI tool is based on four measures: a provider's count of tender and swollen joints, provider's assessment of RA activity, and one patient-reported measure on the patient's assessments of RA activity. The CDAI tool is scored out of a maximum total of 76 points. A score from 22.1 to 76.0 indicates high activity of RA, 10.1-22.0 indicates moderate activity of RA, 2.9 to 10.0 indicates low activity of RA, and 0 to 2.8 indicates remission. The difference between CDAI and RAPID3 tools is that the CDAI questionnaire requires input from both the physician and the patient, while the RAPID3 requires just the patient's input. The combination of RAPID3 and clinical assessment generate the unique CDAI score, which helps the provider to strategize the treatment based on the disease activity.(9)

RA Registry and Measure Criteria

As a result of the focus on population health management in specialty care clinics at UTSW, disease-specific registries were developed using high fidelity data from the enterprise data warehouse.(10, 11) 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. The Rheumatoid Arthritis registry was created in early 2015, which included patients 18 years of age or older, with a diagnosis of RA. The ACR RA quality measure data variables such as, appropriate use of Disease-Modifying Antirheumatic Drugs (DMARDs), and CDAI and RAPID3 scores were abstracted in real time as a clinic level report. An EMR dashboard on the CDAI documentation rate was developed and updated on a monthly basis.

Numerator and denominator criteria for the DMARDs, CDAI and RAPID3 scores were similar to those endorsed by the ACR and included in the CMS Physician Quality Reporting System (PQRS) RA measures group #108, #177 and #178, which are also collected by the ACR RISE registry.(4) The denominator for our measures included established RA patients 18 years of age or older, who had been seen at least twice in the past twenty-four months, and once within the past twelve months by a rheumatology provider. The numerator for DMARDs was the prescription or administration of at least one ambulatory prescription for a DMARD. The numerator for CDAI 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 updated on a monthly basis. The denominator included all patients seen by any provider in the rheumatology clinic within the specific month. The numerator comprised of patients that had RAPID3 completed by the patient or the clinic's Medical Assistant (MA)/Registered Nurse (RN) and documented in the EMR during that visit encounter.

Baseline and Goal: Our baseline scores for the DMARD measure in March of 2016 were at 96%, which improved to 99% within the next 5-6 months. The baseline data for CDAI and RAPID3 measures at the rheumatology clinic from April 2015 to March 2016 indicated a low compliance, with the average completion rate for RAPID3 at 16 % and CDAI at 17%. 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 to improve the completion rates of RAPID3 by the MAs at every visit. Several discrepancies in the workflow continued to impede the process, resulting in moderate improvements in completion rates. RAPID3 was not always completed by the patient prior to the appointment, and there was no consistent process on who was responsible for the entry of the completed results into the EMR. Paper copies of the questionnaires were shredded or left in the room.

It was determined that a well-defined workflow was needed to streamline the process of obtaining the RAPID3 and CDAI questionnaire data. Thus, a Six Sigma DMAIC (Define, Measure, Analyze, Improve, and Control) project was launched in August 2016. The aim of the project was to improve the completion of RAPID3 and CDAI tools at each patient visit, so that the severity scores can be used throughout the patient treatment course to generate a timeline of the disease progression starting from initial assessment. The goal of the quality improvement project was to improve completion of both tools to 75% or more over the next nine months ending in December 2016.

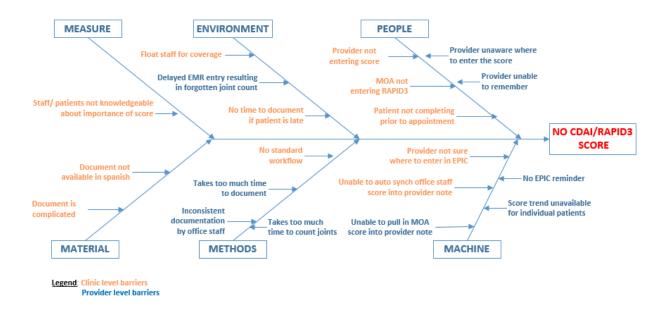
Six Sigma Methodology

Six Sigma methodology 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.(12, 13)

The Six Sigma process improvement team included 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 Six Sigma methodology led the team at each phase until completion of the project.

Using the DMAIC methodology, the project team used a variety of tools and techniques as a roadmap for problem-solving and process improvement.(14) Mapping the current state process flow aided the team in brainstorming ideas for improving the process and creating the future state process flow map. Progress at each phase, including dissemination of the problem, proposed interventions and supportive data analysis, was communicated to the key stakeholders via scheduled meetings and email communications. Feedback and exchange of ideas was encouraged to engage the clinic and refine the plan of action. We obtained 'Voice of the Customer' input from RA patients through a short questionnaire that captured the level of difficulty with answering the RAPID3 questions online or on paper. Majority of patients surveyed felt the questionnaire was easy to complete.

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 to create a fishbone diagram.



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 was then completed, where the barriers identified in the brainstorming session and some others were rated by providers to determine the ones with the most significant impact on documentation of the CDAI score.(15)

The following barriers were determined to be the significant contributors towards low completion rates:

- Providers were unable to remember tender/swollen joint count by the end of the clinic, which is when they usually completed their documentation in the EMR.
- Providers were not able to remember to complete the score at the end of the clinic.
- Providers felt that the score may be misleading for some patients, and those patients might have difficulty interpreting it clinically.
- Unavailability of a CDAI score trend based on the last few scores to guide therapy discouraged providers from completing the score.
- Low compliance with RAPID3 documentation in the EMR by the MAs discouraged providers from completing the CDAI score.

In order to mitigate these barriers, several visual cues were developed, such as reminder "CDAI" stickers placed at the bottom of each computer screen in patient rooms and workstation. Printed copies of a homunculus (schematic skeleton to record the joint examination) placed in all the patient rooms to quickly document the tender and swollen joint count for completion of the

CDAI score. A CDAI trend chart including the last three CDAI scores was displayed within provider's progress note in EPIC to provide meaningful feedback on patient's progress. A standardized future state workflow was developed where MAs were designated to enter the RAPID3 responses in the EMR for every patient seen in the clinic during the rooming process.

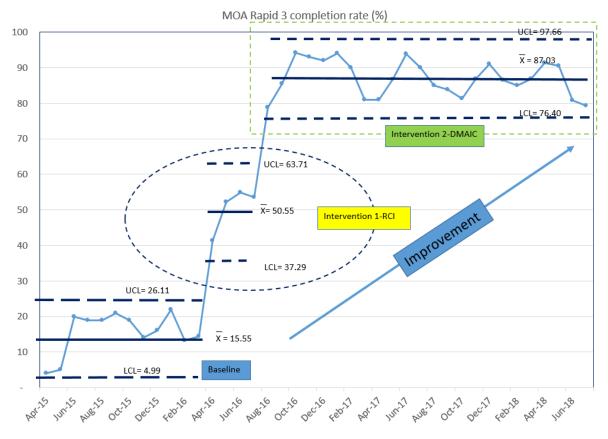
The impact of the interventions was assessed throughout the course of the project. Data on the CDAI and RAPID3 documentation rate was collected via ad-hoc reports and monthly on the EMR dashboard. The CDAI score dashboard was added to the provider's screen in the EMR as a visual cue, thus encouraging the providers to review their own completion rate against the overall clinic rates. Individual and clinic level CDAI completion rates were communicated regularly to the physician team to provide transparency. Feedback was collected from the MAs, nurses and providers at the regularly scheduled clinic staff and provider meetings, and through email communications. RAPID3 completion rates were emailed to the clinic manager, nurse supervisor, MA supervisor, and MAs; and improvement rates were posted in the clinic for visibility. The clinic CDAI rates and workflow were discussed at regular intervals at the faculty and clinic staff meetings.

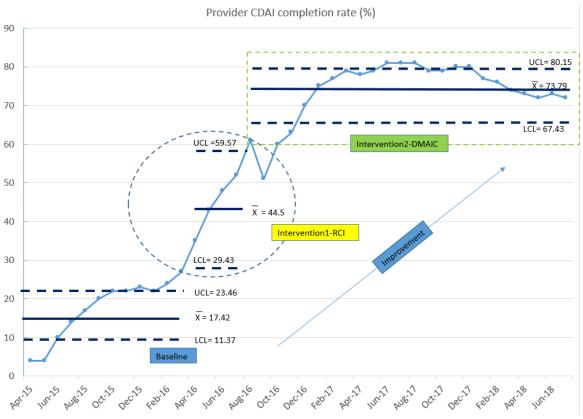
Results

The RA registry had approximately 500 patients during the 9 months of the project between March 2016 and December 2019. The RA population increased to approximately 800 patients by July 2018 as RA patients from the two satellite clinics were added to the registry in March 2018. The average age of the population was 61 years, and 80% were females.

The average RAPID3 and CDAI completion rates from April 2015 thru March 2016 were at 16% and 17% respectively. The initial rapid cycle intervention improved RAPID3 to 51% and CDAI to 44.5% by end of July 2016.

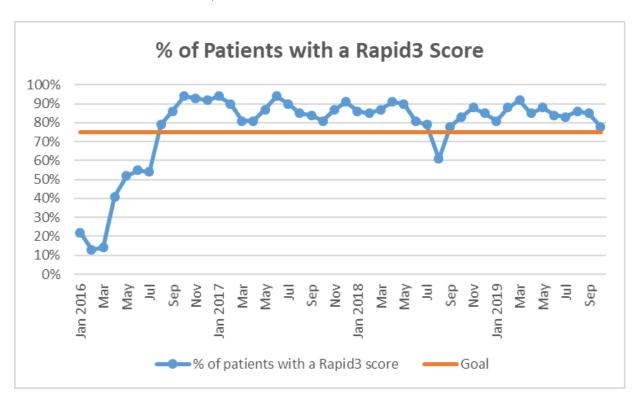
The new processes were implemented in August 2016. RAPID3 completion improved to >90% by the end of 9 months in December 2016 and continued to sustain at an average of 87% completion rate up to 18 months (June 2018) after completing the quality improvement project. CDAI completion improved to 70% by the end of December 2016 and continued to sustain at an average of 74% completion rate up to 18 months (June 2018) after completing the project. Modified control charts (for baseline, Intervention 1-RCI and Intervention 2- DMAIC) are shown below. A control chart is a graph used to study how a process changes over time.

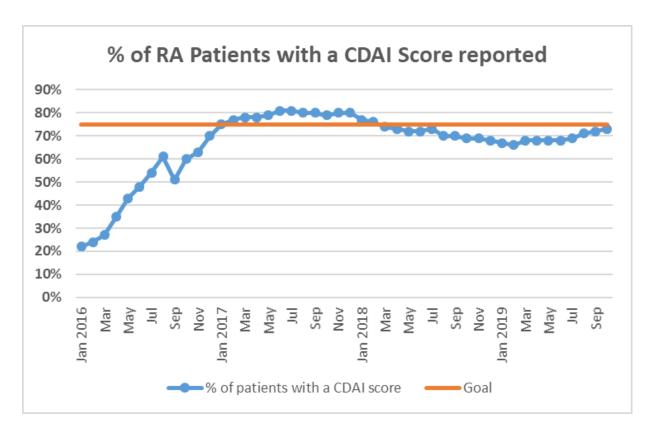




Current State

We expanded the project from the main campus to the two other rheumatology satellite clinics in March of 2018, and continued to follow our completion rates. As of October 2019, The RAPID3 rate have sustained above 75%, and the CDAI rate is at 73%.





<u>Collaborations</u>: The clinic is now collaborating with the RISE Learning Collaborative, which is a learning network across public hospitals with focus on improving quality and outcomes. The institutions within this network share data and experiences, disseminate best practices, and plan to apply innovative methods to track these outcomes using ACR's RISE registry. This collaborative has created a worksheet for improving shared decision making among RA patients. The worksheet takes input from the patients by asking them what is on their mind for today's visit and their goals. It also allows the provider to share information on disease activity with the patient, thus involving them in the decision making process about the next treatment options. This worksheet is being piloted at the UTSW rheumatology clinic.

The clinic is involved in another collaboration with the **Rheumatology Learning Health System** (RLHS), which is composed of the Dartmouth Institute, the Arthritis Foundation and several established rheumatology registry organizations in the U.S. They are working on a Coproduction model, which is based on the concept that consumers should be engaged in the development of a service or product. At the clinic level, this requires active collaboration between the patients and the providers to create value. With the patient being in the center, RLHS collaborators are trying to feed forward PRO and clinical data to enhance the interaction at the point of care, and using that information to enrich the data in existing registries to improve deliver of care. As part of this collaboration with RLHS, we plan to use the rheumatology joint exam module within the new 2019 Epic upgrade to improve shared decision making. The rheumatology module allows the provider to enter information about patients' disease activity scores, and provides a trend of the CDAI and RAPID3 scores over time. This module may be used by the providers to share information with their patients to made decisions on future treatment options.

Conclusion

Patient reported outcome is the status of a patient's health condition that comes directly from the patient without interpretation from anyone else. Sometimes the patient's perspective is taken less seriously than the clinical perspective because the clinical perspective is considered more objective. The clinical perspective has its roots in validated research. Add to that the provider's clinical expertise and experience, it is easy to see why the provider's perspective is valued. In contrast, the patient's perspective is often characterized as subjective and considered highly influenced by the patient's unique situation such as their level of health literacy, their ability to pay for treatments, co-morbid conditions, level of education, self-motivation, and the level of patient expectations to name just a few. Applying scientific rigor and standardizing the collection of PRO data can help us to reliably convert this subjective information into data that can be used to compare outcomes related to individual patients, populations, providers, and treatment pathways.

PROs data is not only useful at the individual patient level, but can be very helpful at the population level too. Websites like 'People like me' allows patients to share real world experiences and outcomes. PROs are also being used for reporting performance data through value based models like Merit-based Incentive Payment System (MIPS) and Oncology Care Model (OCM).

PROs can enhance patient care by improving mutual understanding, goal alignment and shared decision making between the patient and provider. PROs in combination with clinical assessment can provide a comprehensive report of how patients function or feel with respect to their physical, mental, and social well–being.(16) The ultimate goal is to be able to reliably collect, interpret and combine the clinical perspective with the patient's perspective to make better treatment decisions and achieve better outcomes.

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