Pragmatic Trial of an EHR Application to Display Real-time PRO Data: Successes and Challenges

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August 2023

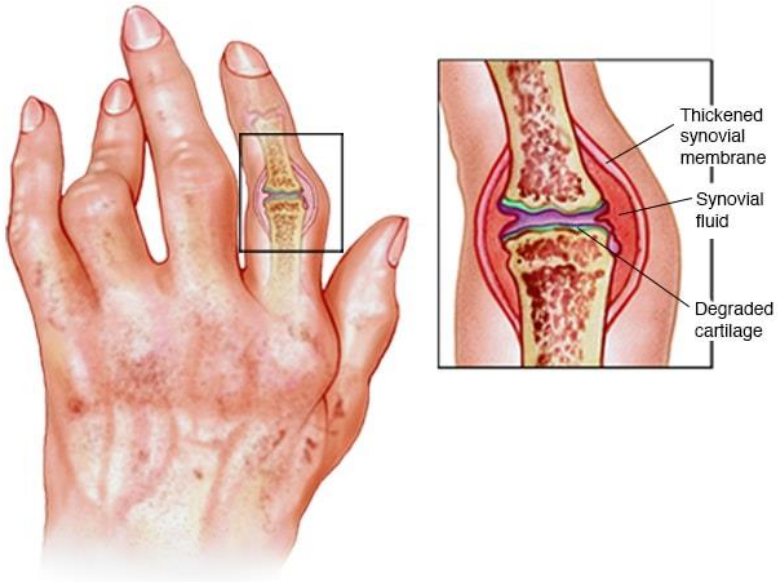
Outline

- Background
  - RA and patient reported outcomes
  - Bridging the gap for PROs
- Methods
  - Dashboard design and implementation
  - Planned integration into clinical workflows
  - Clinic deployment – strategies to promote adoption
  - Stepped wedge design and planned outcomes
- Results: Quantitative, qualitative
- Discussion of successes and challenges

Background

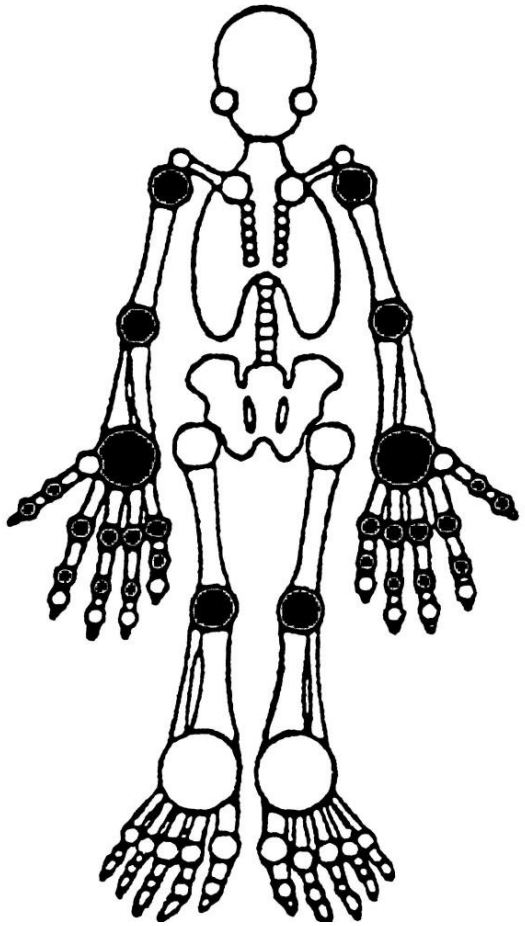
What is Rheumatoid Arthritis (RA)?

- Chronic inflammatory disease
- Females > males
- Symptoms: Join pain, stiffness, and swelling especially in hands and wrists
- Longstanding active disease results in deformity and loss of function
- Treatment: Immunosuppressants such as methotrexate or biologics (e.g., TNF inhibitors)



https://www.mayoclinic.org/diseases-conditions/rheumatoid-arthritis/symptoms-causes/syc-20353648

Patient-Reported Outcomes (PROs) in RA



Lack of "objective" outcome measures

We rely on patient-reported outcomes (PROs)

1. **Disease activity** – Clinical Disease Activity Index (CDAI): Tender joint count + swollen joint count + patient global + physician global
2. **Functional status** – Patient-Reported Outcomes Measurement Information System (PROMIS) physical function: 10 questions about activities of daily living (ADLs) and other daily activities
3. **Pain Score**

Treat-to-Target Approach

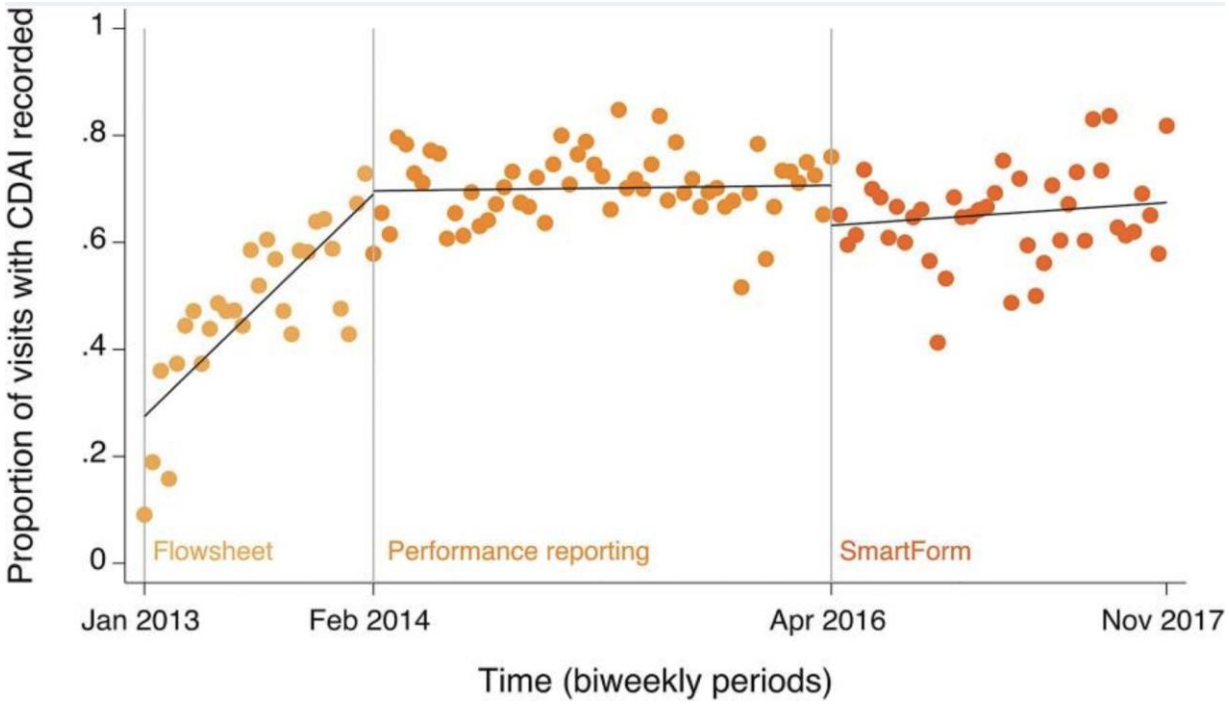
- Persistent, high disease activity is associated with physical damage
- **Treatment philosophy**: “Treat-to-target” based on patient-reported outcomes (disease activity scores)
  1. Record disease activity using a composite measure, every 3 months
  2. Specify disease activity target (LOW disease activity or REMISSION)
  3. Adjust medications to target
  4. Document shared decision making

https://www.newyorker.com/cartoon/a27820

"Please fill out these medical forms, which are identical to the ones you filled out earlier online, and have the exact same questions your doctor will ask you later in the exam room."

Bridging the gap between PRO collection and “meaningful” use during clinical encounters

PROs are being collected…



doi: 10.1002/acr.23848

…but few clinicians are discussing them

Patient survey question, 2018	**N=50**
Has your doctor ever told you about a score that is used to describe how healthy your joints are?	
Yes	5
No	45

Methods

RA Dashboard Development Roadmap

DEVELOP

- Using principles of human-centered design, patient and clinician stakeholders helped design an EHR-based tool to support shared decision making for RA patients.
- **Key features requested**: trajectories of disease activity, functional status, medications, and labs; ability to print and share with family and other doctors

BUILD

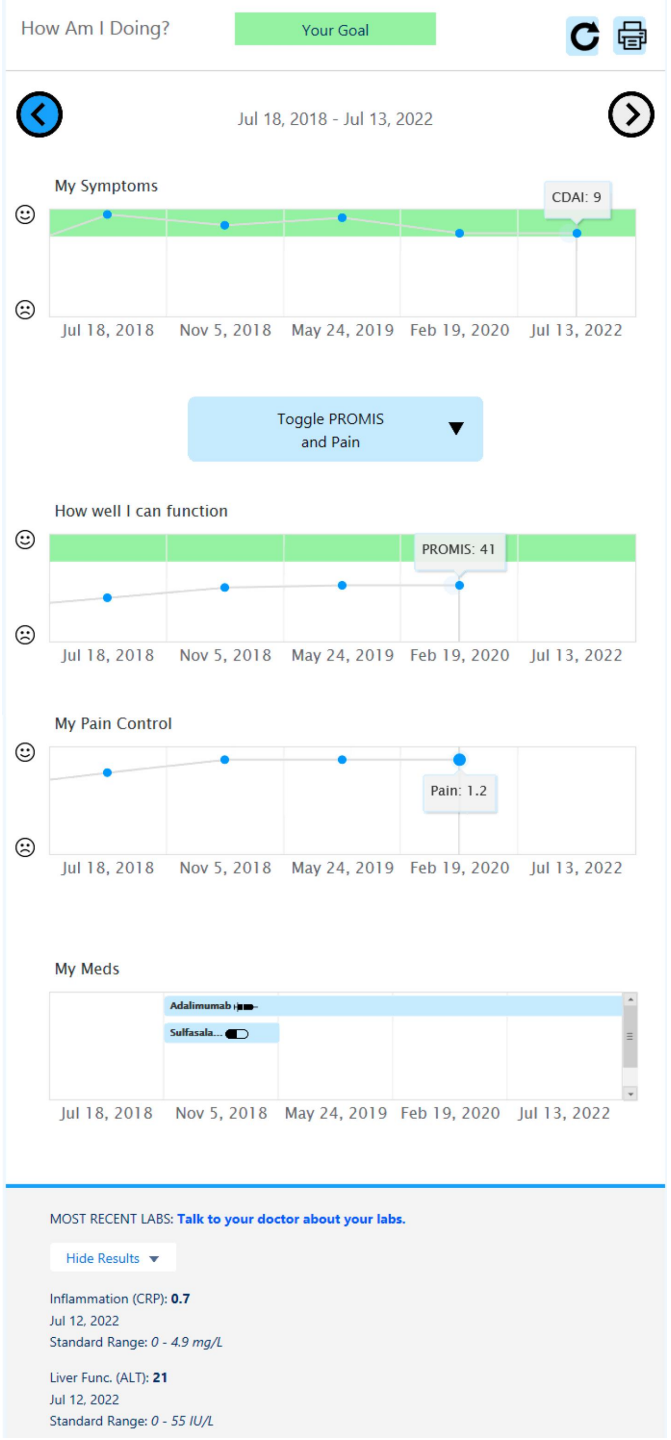
- Technical team embedded in our health system built an application that would pull information directly from the EHR.
- **Key features built**: pulls historical and real-time data from EHR for PROs, medications, and labs; user-friendly interface designed for low-literacy patients.

IMPLEMENT

- Risk assessments and regulatory approvals completed.
- Pilot testing by users (clinicians and patients) in both sandbox and production environments.

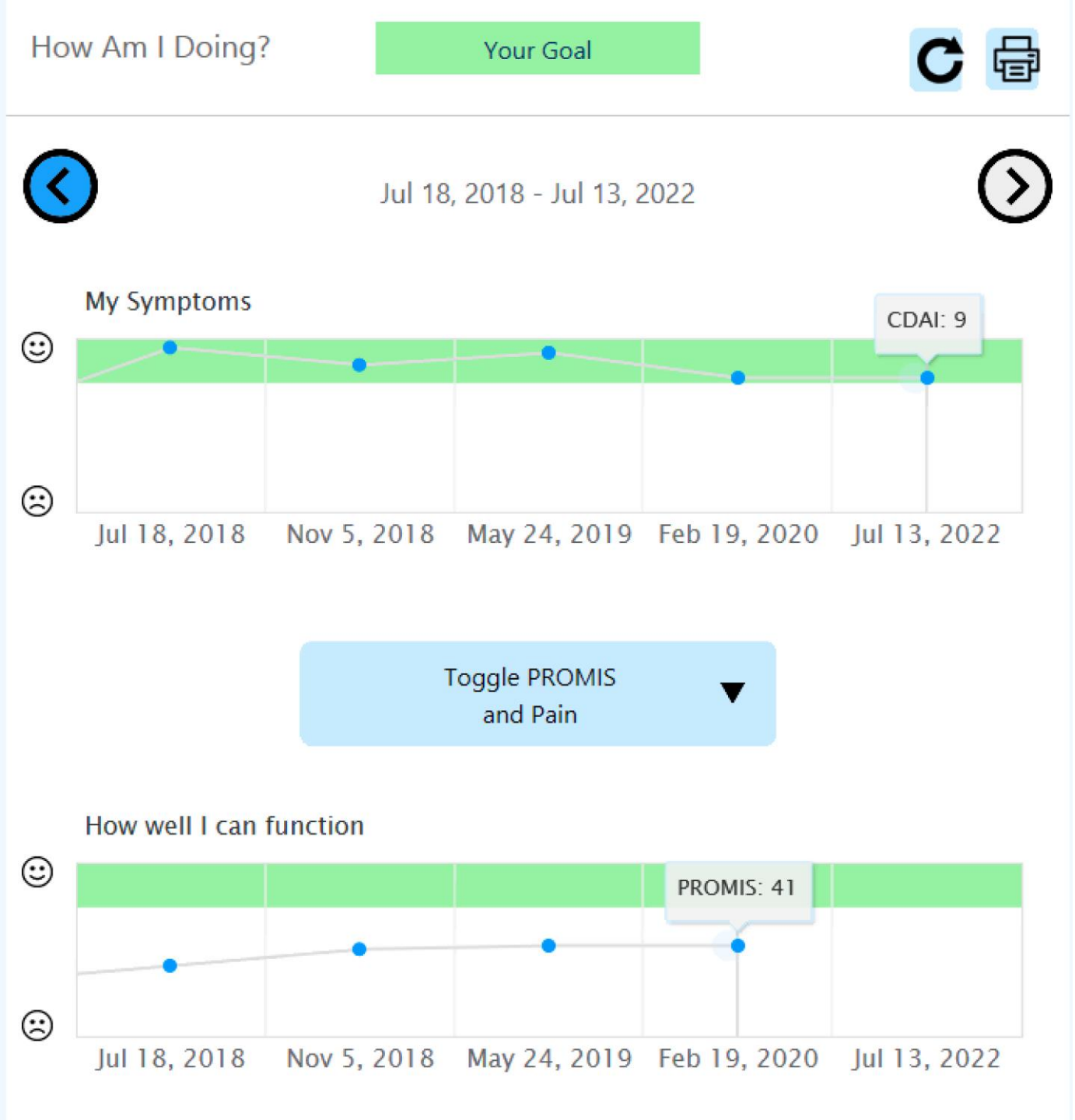
TEST

- Pragmatic cluster-randomized trial of the dashboard is underway to assess how its use may affect shared decision making, patient satisfaction, self-efficacy, medication adherence, and PROs.
- Continued feedback from patients and clinicians through surveys, interviews, and focus groups.



Features

- Historical and real-time data from the EHR including:
  - PROs: CDAI, PROMIS, pain from same day's visit
- Tracking scores over time
- Customizable (toggles and “view” buttons)
- Printable for after-visit review
- Automatic launch within Epic (no separate login process)
- User logs / analytics



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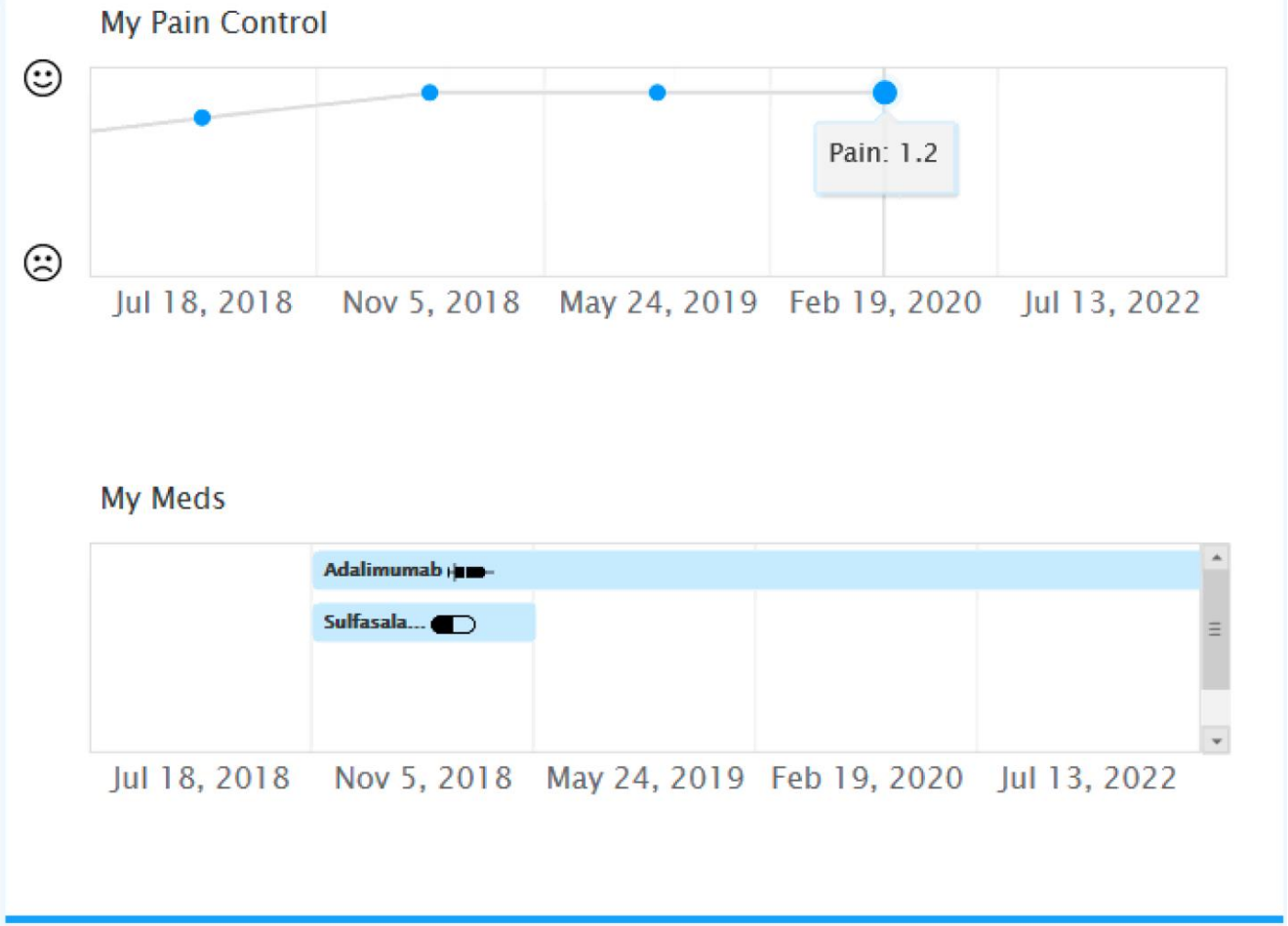

MOST RECENT LABS: **Talk to your doctor about your labs.**

Hide Results

Inflammation (CRP): **0.7**
Jul 12, 2022
Standard Range: *0 - 4.9 mg/L*

Liver Func. (ALT): **21**
Jul 12, 2022
Standard Range: *0 - 55 IU/L*

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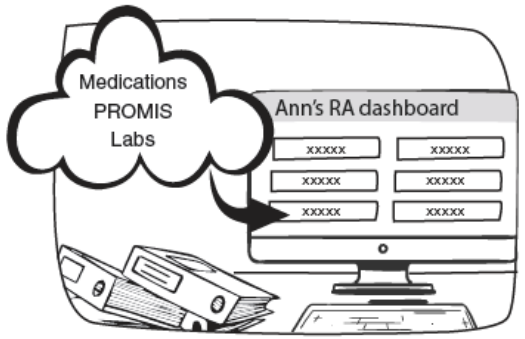
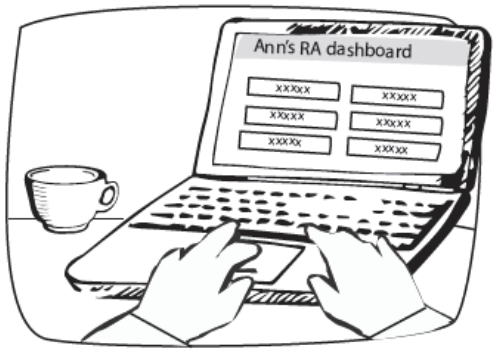
Clinical Workflow with the Dashboard

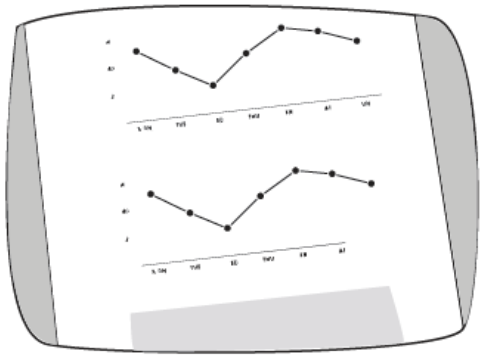


Pre-visit data is auto-loaded from EHR into Ann's RA dashboard.

During Ann's visit, Dr. Gomez updates EHR with data from her exam, such as swollen and tender joints. This data updates her dashborad.



Dr. Gomez launches Ann's dashboard from the RA Navigator in Epic.

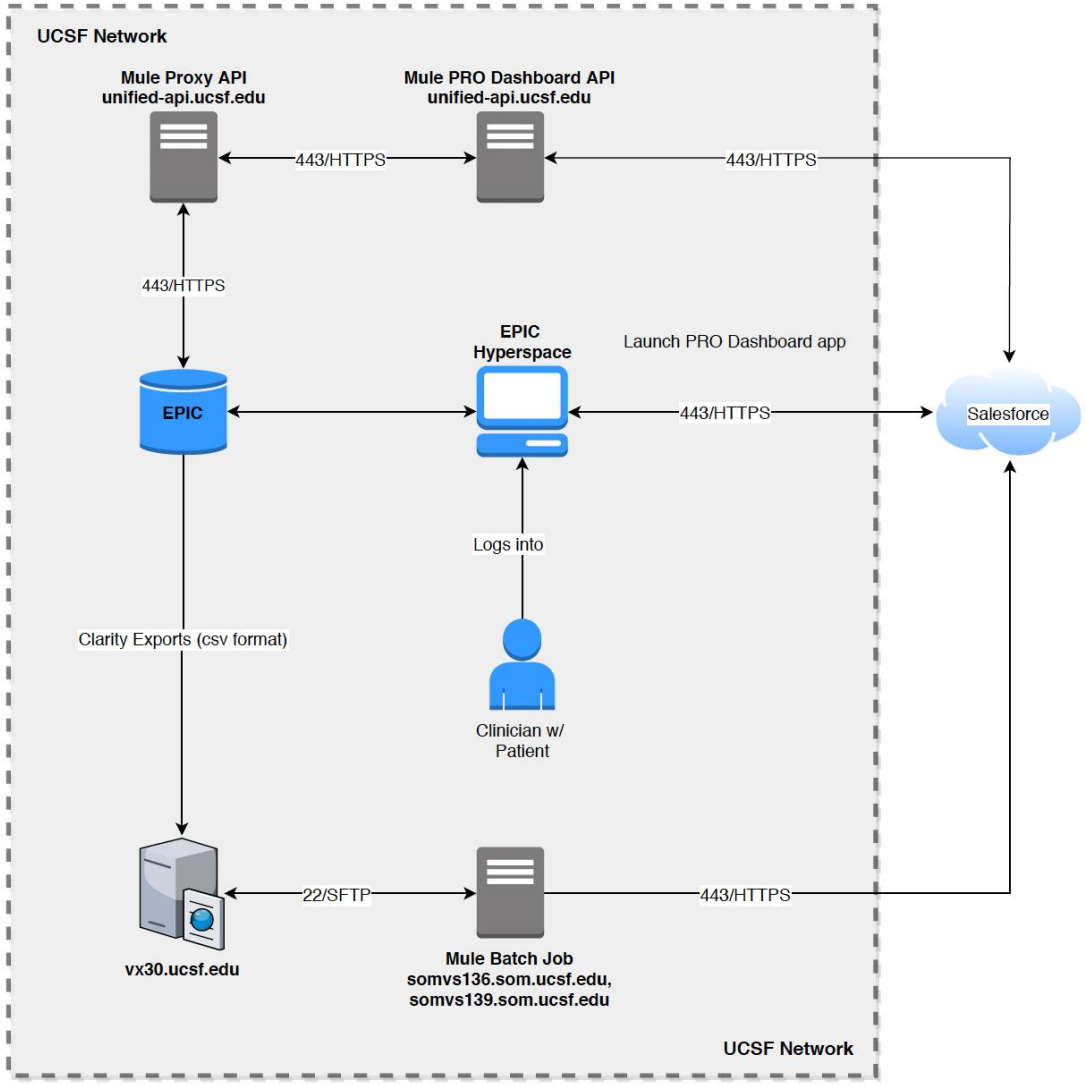


Dr. Gomez and Ann look at all of her data together and discuss progress, medications, treatment, lifestyle and goals.

Ann takes a printout of these options with her, which she can also access later through MyChart.

Later she references the printout when discussing her medication options with her sister.

Implementation of the RA PRO Dashboard



Dashboard built using Salesforce as a “side-car” application

👍 Development can focus on user interface

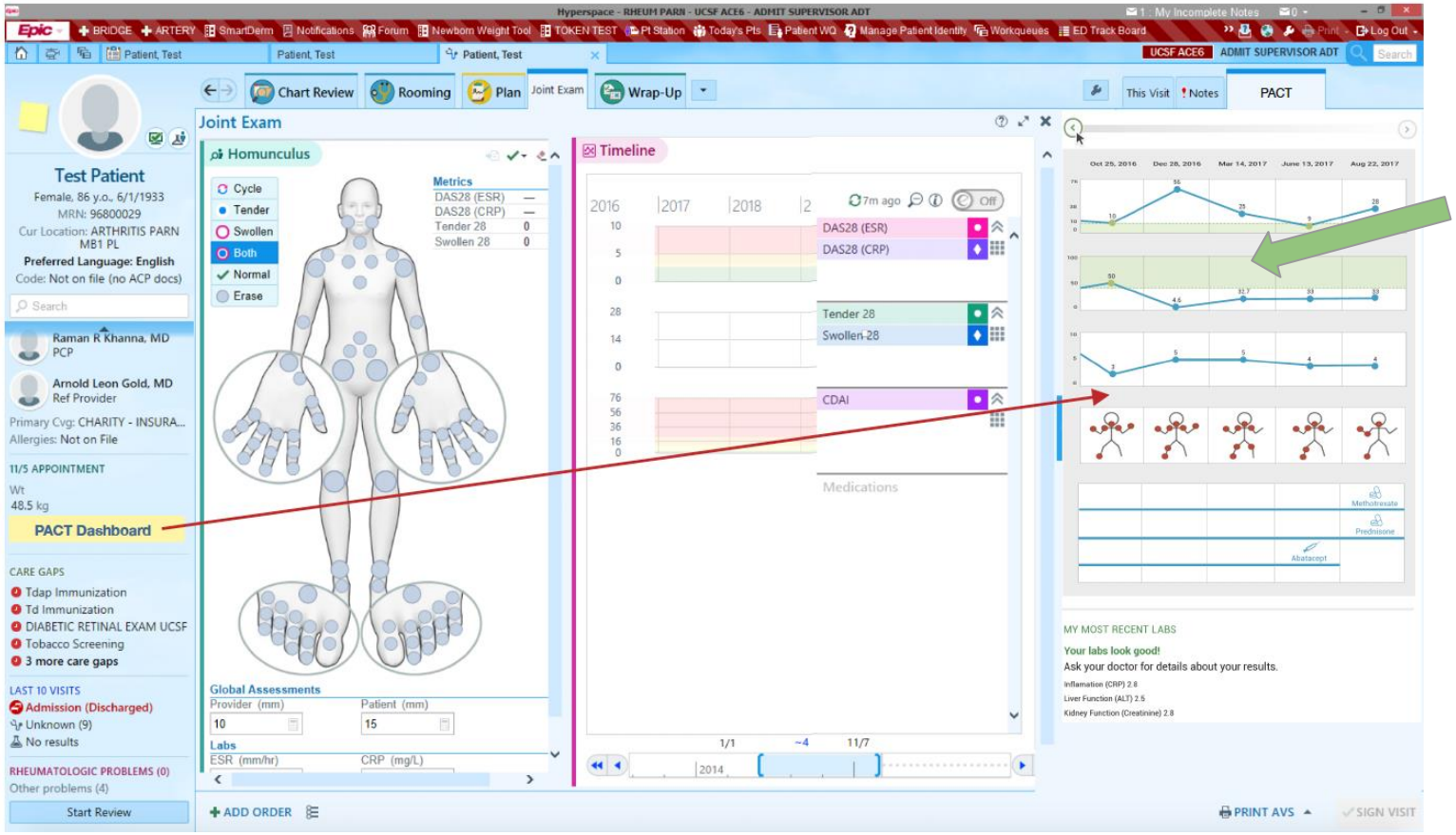
👍 Customization is possible

👍 Designed to pull historical and real-time data

👎 Design requires data flow from multiple sources

👎 Cost to license side-car app

Dashboard Auto-Launch



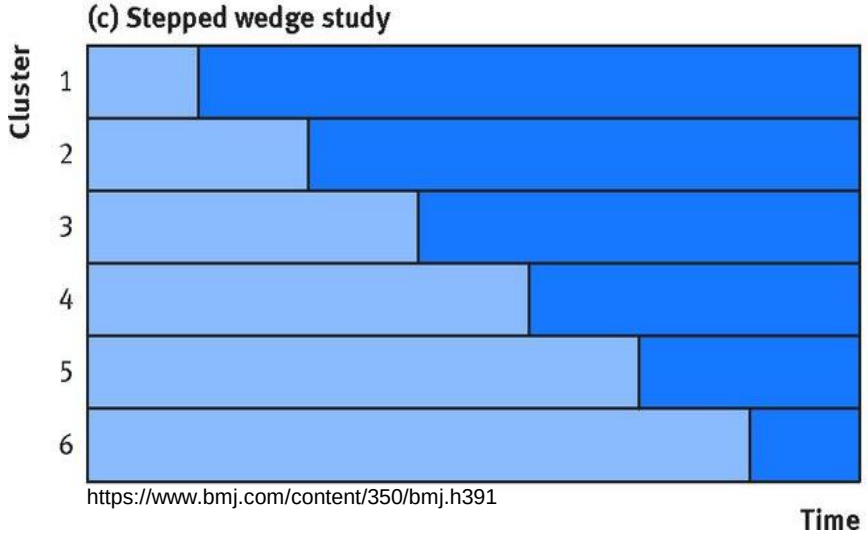
RA Dashboard will automatically:

1. Open up on Epic for patients with at least one CDAI or PROMIS score.

2. Display CDAI, PROMIS, and pain scores after input during today's visit.

Stepped Wedge Cluster Randomized Trial Design

- **Hypothesis**: The RA PRO dashboard used during clinical encounters will increase patient engagement, foster shared decision making, and improve health outcomes for patients with RA.
- **Design**: Stepped wedge, cluster randomized at clinician level.
  - Access is provisioned to clusters of 4-6 clinicians
- **Clinic deployment**
  - 1:1 training and regular reminders on how to use it during the visit
  - Q2month conferences for clinicians to share successes and challenges
  - Training for MA on PRO collection
  - Information sheet for patients on PRO collection



https://www.bmj.com/content/350/bmj.h391

Stepped Wedge Cluster Randomized Trial Outcomes

Outcome	Measure
Shared decision making	SURE Scale
Medication adherence	Missed medications in the past week (single question)
Attitudes toward RA medications	Beliefs About Medicines Questionnaire (necessity-concerns differential)
Self-efficacy	PROMIS- symptom management questionnaire
~~Patient satisfaction~~	~~1-question Likert scale~~
~~Personal interactions and shared decision making~~	~~Interpersoncal Processes of Care~~
~~Personal interactions and shared decision making~~	~~CARE measure~~
RA outcomes [collected during routine care]	Disease activity (CDAI) Physician function (PROMIS)
Perceptions of the dashboard	10-question survey

Stepped Wedge Cluster Randomized Trial Balancing measures

Outcome	Measure/source of data
Clinician satisfaction	1-question Likert scale
Time in appointment	EHR meta-data
Time using dashboard	User-log data
Qualitative study	Focus group analysis

Stepped Wedge Cluster Randomized Trial Analysis

- Enrollment information
- Clinician engagement: audit logs and surveys
- Quantitative analysis: stepped wedge analysis (intention to treat)
- Qualitative analysis:
  - Patient interviews
  - Clinician focus groups

Results

Study timeline

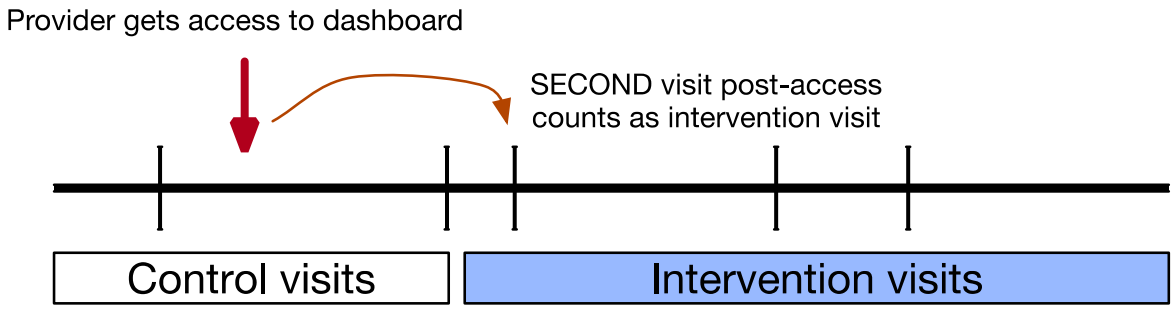
Dates	Activity
May - August 2018	Human-centered design process (focus groups, etc)
September 2019	Initial engagement with technical team
October 2019 – September 2021	Risk assessment and regulatory approvals
December 2019	Technical design and planning sessions
December 2019 – April 2020	Application build (sprints)
July 2021	User testing
August 2021	RA PRO Dashboard go-live
August 2021	Stepped-wedge pragmatic trial begins

Enrollment Table

Time	baseline	8/11/21	2/1/22	5/2/22	9/26/22	
Provider Cluster						**Total**
1	58	74	36	53	108	329
2	23	23	10	15	20	91
3	41	26	18	46	82	213
4	74	73	39	62	148	396
Total	196	196	103	176	358	1029

Intervention
Control

How to define “intervention visits?”

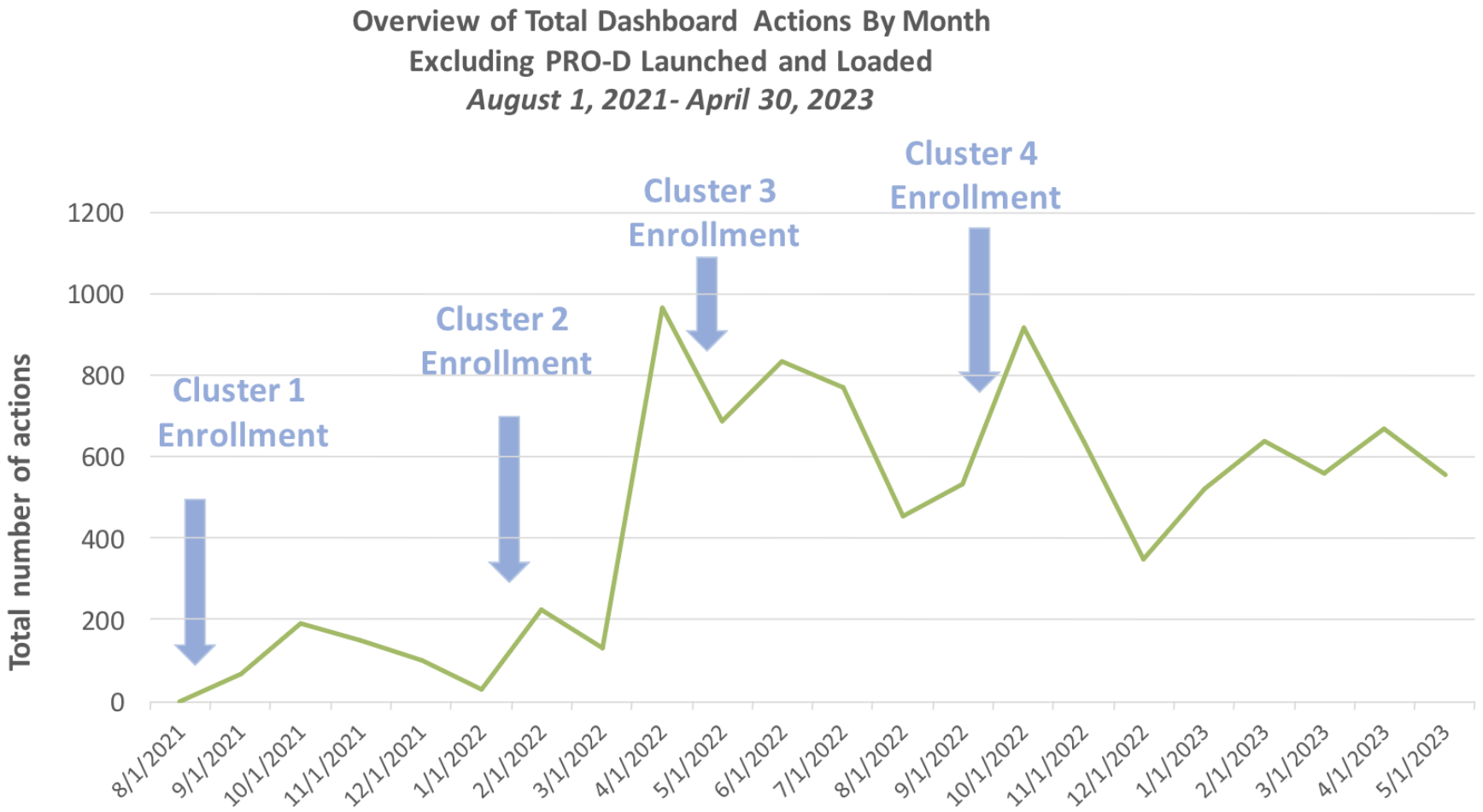


Patient characteristics

Table 1. Patient characteristics

	Total
N (%)	552
Age, mean (SD)	60.1 (15.3)
Female	451 (81.7)
Race/ethnicity	
White	311 (56.4)
Asian	81 (14.7)
Hispanic	73 (13.2)
African American	41 (7.4)
Other/unknown	46 (8.1)
Insurance	
Medicare	261 (47.3)
Private/Commercial	213 (38.6)
Medicaid	71 (12.9)
Other	7 (1.3)
Baseline info*	
Low or remission CDAI, n=296	131 (44.3)
PROMIS 10 PF (n=431), mean (SD)	42.0 (10.2)
Pain (n=407), mean (SD)	40.3 (28.9)
RA Medications	
tDMARDs	29 (5.3)
cDMARDs	425 (77)
bDMARDs	307 (55.6)
Glucocorticoids	302 (54.7)

Clinician Engagement



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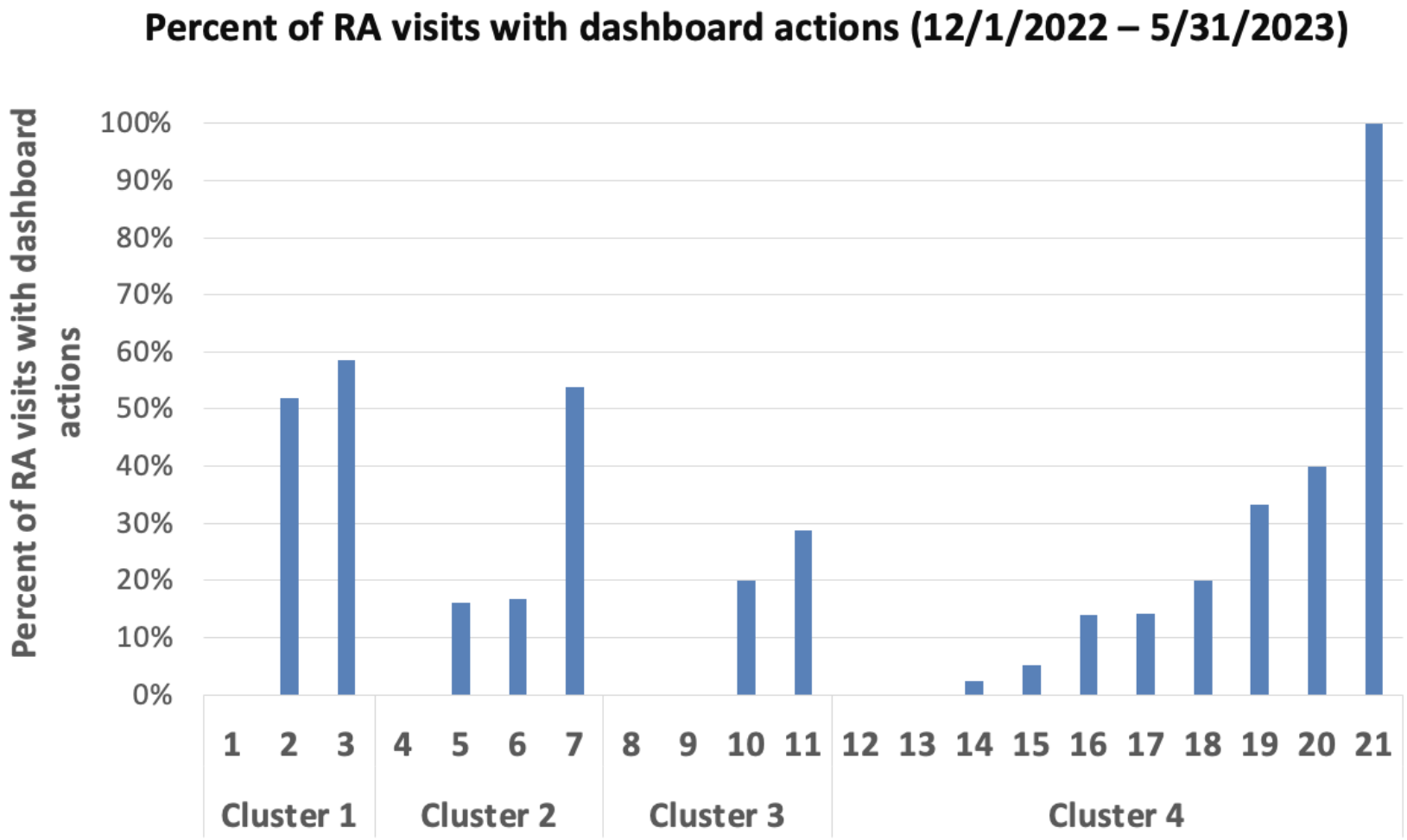


Clinician ”non-use” survey: Why did you not use the dashboard with your RA patient today?

Reason	N=144
Did not think it would be useful for this patient	27%
Ran out of time	19%
Forgot to use	16%
Lack of patient data in the dashboard	13%
Discussing other topics	8%
Dashboard did not launch	7%

Quantitative analysis

Balancing measure analyses pending.

Patient Dashboard Survey

Selected survey questions	N	Yes (%)	Somewhat (%)	No (%)	Unsure (%)
Overall					
Would you like to see the dashboard again at your next visit?	181	79%	NA	8%	13%
Patient-provider communication					
Did the dashboard help you talk to your doctor about your arthritis or your symptoms?	180	76%	15%	8%	2%
Did the dashboard help you talk to your doctor about your medicines?	181	71%	14%	10%	5%
Did the dashboard help you talk about things that are important to managing your disease, other than your medicines?	179	61%	17%	17%	4%
Patient knowledge					
Did the dashboard help you understand more about your arthritis?	178	71%	21%	5%	2%
Did the dashboard help you understand more about why you take certain medicines?	179	60%	16%	18%	6%
Shared decision making					
Did the dashboard help you make better decisions about your arthritis care?	176	67%	19%	10%	5%
Do you think using the dashboard helped your doctor to better understand what's most important to you?	175	46%	21%	22%	11%

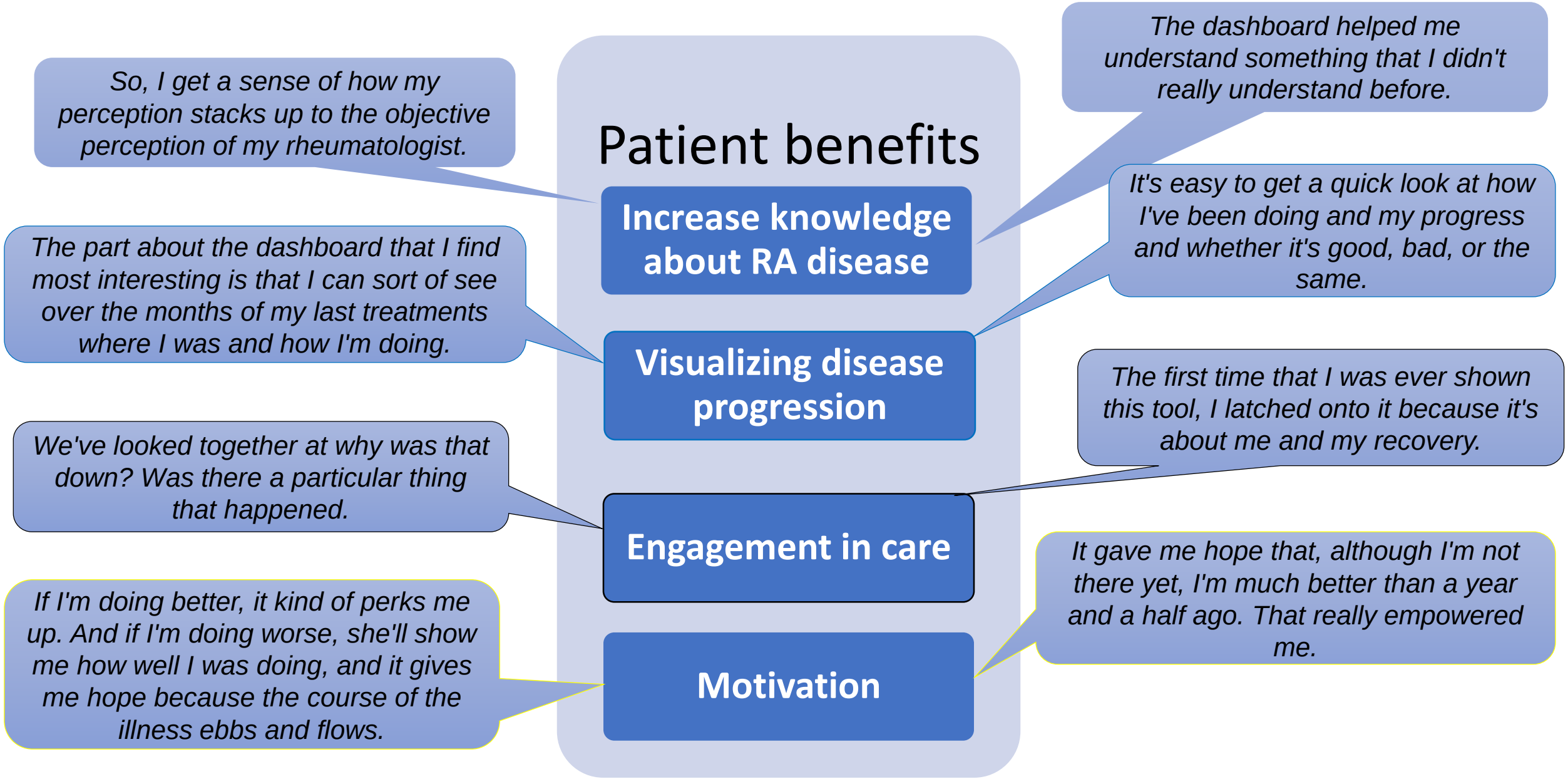
Qualitative analysis: Patients

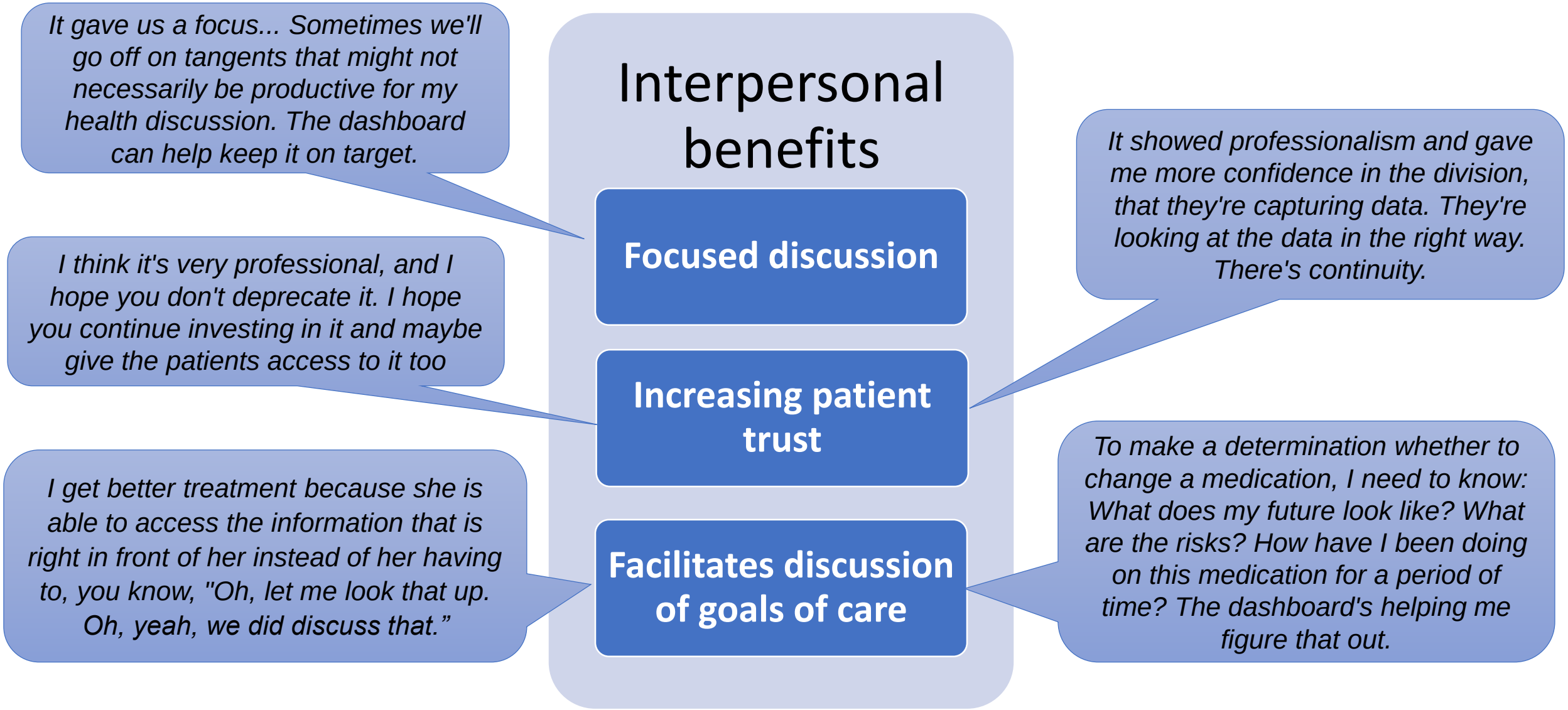
Aim: Assess patient's perceptions of the RA-PRO dashboard and recommendations for improvement.

Methods:

- Semi-structured interviews conducted with 29 patients whose clinicians used the dashboard during a visit
- Participants were recruited using purposive sampling to ensure that a range of usability perspectives were included
- Recorded interviews were transcribed verbatim and analyzed thematically using inductive and deductive techniques

Clinician ID	Number of patients
A	9
B	5
C	4
D	3
E	3
F	2
G	1
H	1
I	1


Patient benefits
Increase knowledge about RA disease
Visualizing disease progression
Engagement in care
Motivation
So, I get a sense of how my perception stacks up to the objective perception of my rheumatologist.
The part about the dashboard that I find most interesting is that I can sort of see over the months of my last treatments where I was and how I'm doing.
We've looked together at why was that down? Was there a particular thing that happened.
If I'm doing better, it kind of perks me up. And if I'm doing worse, she'll show me how well I was doing, and it gives me hope because the course of the illness ebbs and flows.
The dashboard helped me understand something that I didn't really understand before.
It's easy to get a quick look at how I've been doing and my progress and whether it's good, bad, or the same.
The first time that I was ever shown this tool, I latched onto it because it's about me and my recovery.
It gave me hope that, although I'm not there yet, I'm much better than a year and a half ago. That really empowered me.


Interpersonal benefits
Focused discussion
Increasing patient trust
Facilitates discussion of goals of care
It gave us a focus... Sometimes we'll go off on tangents that might not necessarily be productive for my health discussion. The dashboard can help keep it on target.
I think it's very professional, and I hope you don't deprecate it. I hope you continue investing in it and maybe give the patients access to it too
I get better treatment because she is able to access the information that is right in front of her instead of her having to, you know, "Oh, let me look that up. Oh, yeah, we did discuss that."
It showed professionalism and gave me more confidence in the division, that they're capturing data. They're looking at the data in the right way. There's continuity.
To make a determination whether to change a medication, I need to know: What does my future look like? What are the risks? How have I been doing on this medication for a period of time? The dashboard's helping me figure that out.

Patient Concerns

- **Design**
- **Content**
- **Explanation of measures**
- **Accessibility**
- **Technical difficulties**

The units seemed to be too complicated. I had to read about them on the facing page. Maybe you could put in parentheses "CDAI"

It's subjective in a way when you fill out the form about the pain level…I don't know how accurate these questionnaires are to the doctor.

[The doctor] did not [explain it]. That's why I said I didn't understand it.

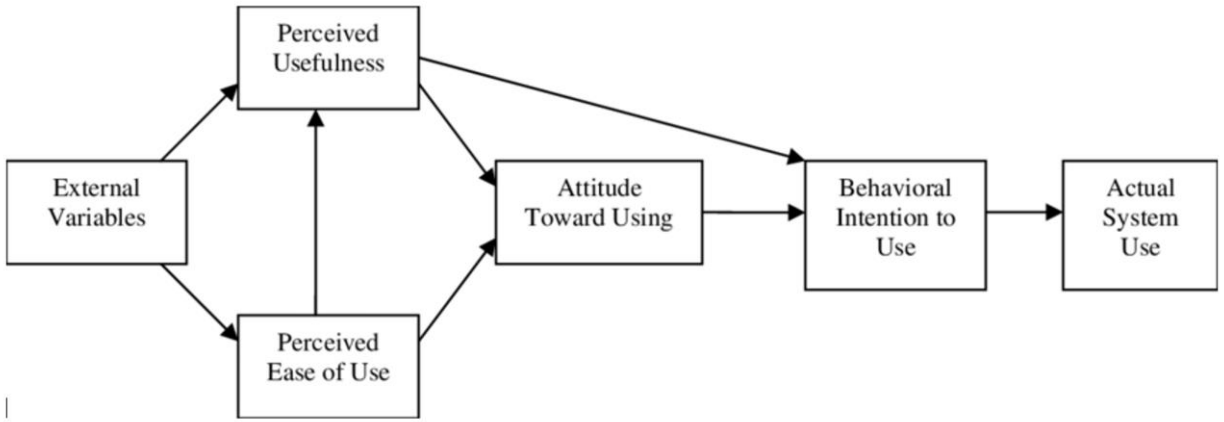
It would be beneficial for the patient to have access to it [at home], especially when you're asking questions about it, and I can't answer everything because I don't have access to the application

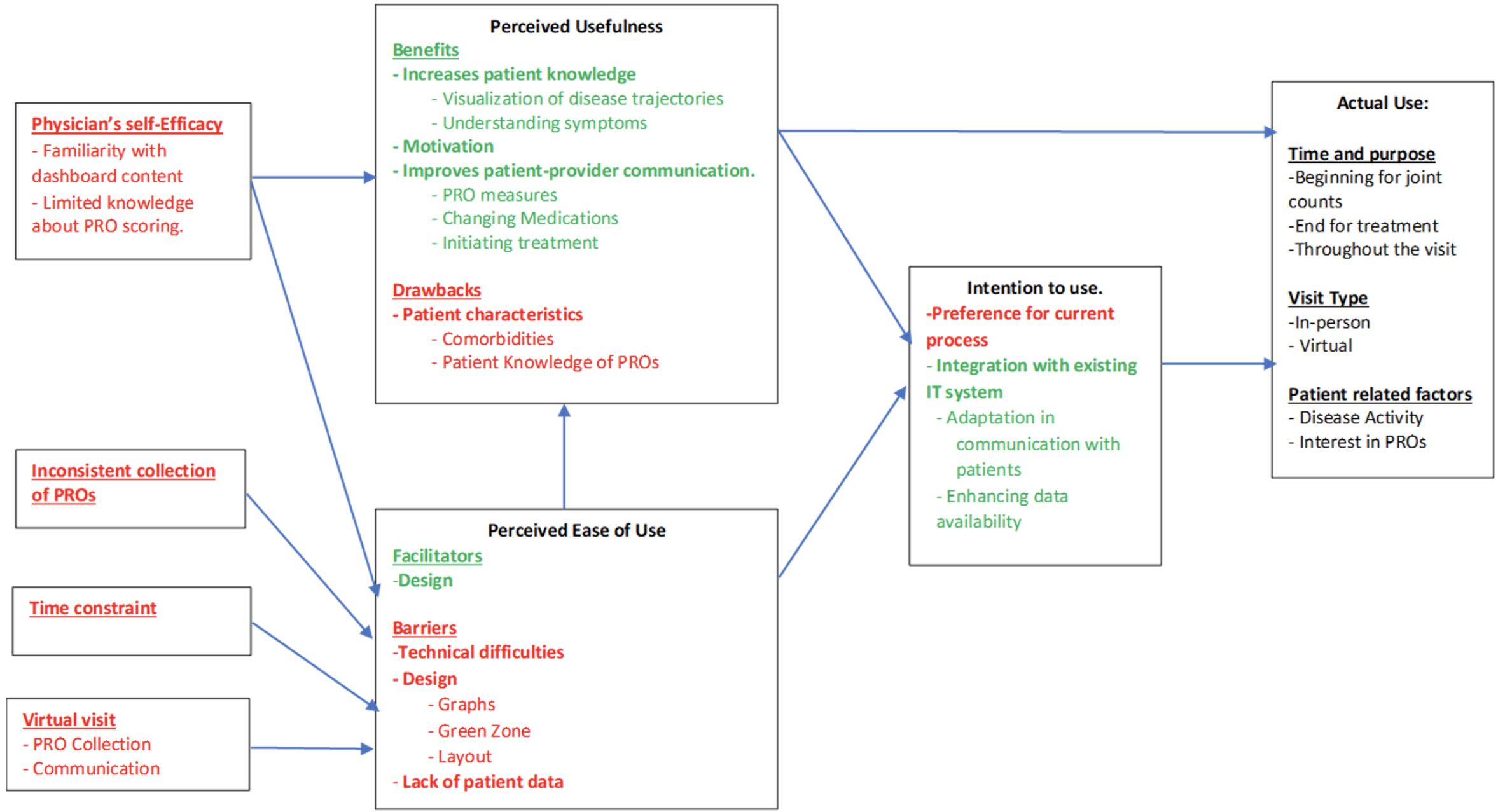
Last time the dashboard wasn't accessible. She was trying hard to get in there, and she couldn't open it.

Qualitative analysis: Clinicians

- 3 clinician discussions – 15 rheumatologists
- Highlighted a clinical champion at each session
- Analyzed as focus groups
- Recorded interviews were transcribed and analyzed thematically using inductive and deductive techniques
- Analysis based on the Technology Acceptance Model

Figure 1: Technology Acceptance Model




Physician's self-Efficacy
- Familiarity with dashboard content
- Limited knowledge about PRO scoring.
Inconsistent collection of PROs
Time constraint
Virtual visit
- PRO Collection
- Communication
Perceived Usefulness
Benefits
- Increases patient knowledge
- Visualization of disease trajectories
- Understanding symptoms
- Motivation
- Improves patient-provider communication.
- PRO measures
- Changing Medications
- Initiating treatment
Drawbacks
- Patient characteristics
- Comorbidities
- Patient Knowledge of PROs
Perceived Ease of Use
Facilitators
-Design
Barriers
-Technical difficulties
- Design
- Graphs
- Green Zone
- Layout
- Lack of patient data
Intention to use.
-Preference for current process
- Integration with existing IT system
- Adaptation in communication with patients
- Enhancing data availability
Actual Use:
Time and purpose
-Beginning for joint counts
-End for treatment
-Throughout the visit
Visit Type
-In-person
- Virtual
Patient related factors
- Disease Activity
- Interest in PROs

Discussion

Successes

- We built the dashboard, and it works!
- (Some) clinicians used it; some used it a lot
- (Many) patients loved it

Challenges

- Maintenance of intervention – technical and non-technical issues
- Clinician engagement
- Outcome selection

Technical challenges maintaining intervention

Maintenance challenge	**Example issue**	**Potential solutions**
Content updates	New medications (including new medications, or new versions of existing medications)	1. Set regular update timelines (monthly, quarterly) 2. Design application to be able to accommodate changes or additions to variable names
Software updates	Software or security updates to component systems were continual, (EHR, sandbox environments, Salesforce, and Google Analytics)	1. Plan for continual engagement with technology team to respond to software updates 2. Look ahead to know when software updates will occur to anticipate potential downstream consequences 3. Monitor data streams (e.g. user audit logs) and create alerts for reduced or missing data

Non-technical challenges maintaining intervention

Maintenance challenge	Example issue	Potential solutions
Major changes to clinical workflows	The explosion of telehealth visits during the COVID-19 pandemic resulted in a sharp decrease in the collection of RA outcomes, since assessment of disease activity (tender and swollen joints) requires a physician exam.	1. Routine data quality assessments 2. Stratification of quality assessments based on visit type
Data completeness	Turnover of MAs and clinicians (fellows) results in variable collection of PROs	1. Routine data quality assessments and feedback to all clinicians and staff 2. Frequent trainings and educational programs around PROs 3. Engagement with clinic leadership (MDs, RNs, MAs)

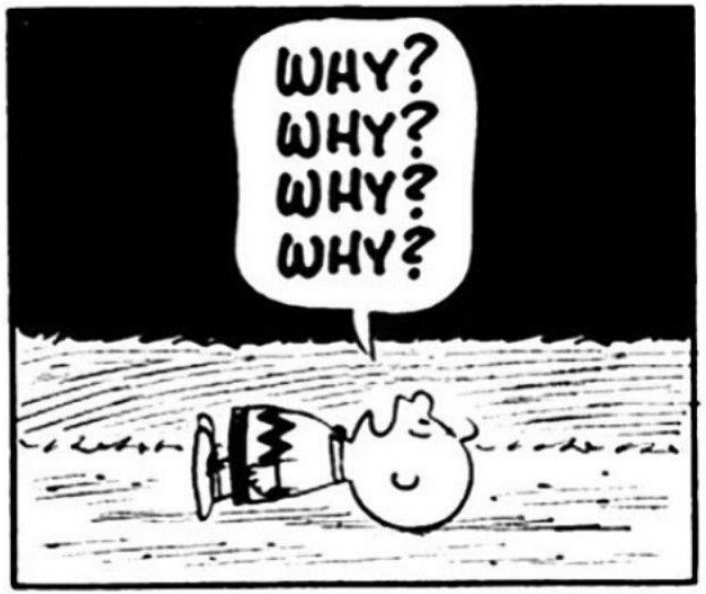
Challenges engaging clinicians

Challenge	Response
Perceived time constraints	Clinical champions shared successes during clinician discussion groups
Limited knowledge about PROs (surprising)	Clinician information sheets and scripts for how to discuss PROs
Patient selection: clinicians electing to use the dashboard only with patients who they think will appreciate it	Feed back qualitative data to clinicians, even from patients who stated they didn't like or didn't want to see the dashboard again
Technical challenges	Fewer hiccups than we expected, perhaps because of "at the elbow" support from CRCs embedded in the clinic

Challenges in detecting effects of intervention

- Quantitative analysis did not identify changes in patient outcomes – why?
  - Truly no effect
  - Sample size too small
  - Follow-up time too short
  - Ceiling effects of outcome measures
  - Wrong outcomes all together
- Next steps
  - “As-treated” and other subgroup analyses

-> Some discordance with qualitative data – highlights importance of collecting both



https://www.lovethispic.com/image/215871/why-why-why-why-why

Lessons Learned

Topic Area	Lessons
Design	Putting patients at the center of application development can yield a well-accepted, usable data visualization tool for PRO; Patient feature requests bring credibility to design choices
	Design process needs to address key features and clinical workflows
Clinic deployment	Multiple clinical champions are needed to encourage other clinicians to use and access the dashboard with patients
	Clinician participatory approach: Regular meetings and discussions with clinicians to address challenges faced when using the dashboard and share possible solutions
Outcomes	Ceiling effects; outcomes may change more slowly than desired
	Quantitative and qualitative data can be complementary
Maintenance of the intervention	Building an EHR-based application that works requires *infrastructure, time, funding, energy* to iterate and maintain: • Continuous, automated checks on data quality • Continuous checks on workflow hiccups • Continuous feedback from frequent users • Ongoing collaboration (daily/weekly) between technical and clinical teams

Thank You!

Quality and Informatics Lab (QUIL)

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