Data Extraction and Quality Challenges/ Lessons Learned

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NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Panelists

- Dana Dailey, PhD
  - Fibromyalgia TENS in Physical Therapy Study (FM-TIPS)
- Shruti Gohil, MD
  - INtelligent Stewardship Prompts to Improve Real-time Empiric Antibiotic Selection for Patients (INSPIRE)
- Corita Grudzen, MD
  - Primary Palliative Care for Emergency Medicine (PRIM-ER)

Session Goals

- Learn about issues encountered with EHR integration, data extraction, and data quality
- Share ways to mitigate data-related challenges, such as implementation monitoring and strong cross-collaborative team structures

FM-TIPS: Lessons Learned

Data Extraction and Quality

An Embedded Pragmatic Clinical Trial in Physical Therapy (PT) Clinics

Dana Dailey, PT, PhD

FM-TIPS
Fibromyalgia TENS In Physical Therapy Study

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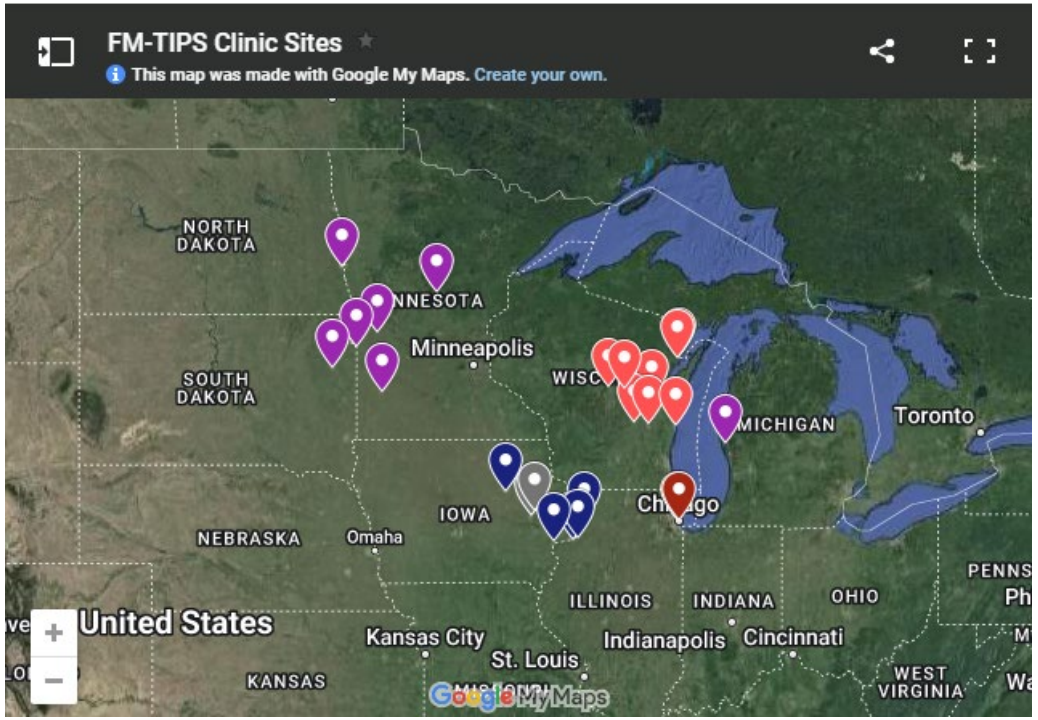
FM-TIPS
Fibromyalgia TENS In Physical Therapy Study

FM-TIPS Study Overview

The goal of FM-TIPS is to test the feasibility and effectiveness of adding transcutaneous electrical nerve stimulation (TENS) to standard physical therapy (PT) care in a real-world physical therapy setting



- 25 active physical therapy clinics
- 100+ physical therapists
- 5 active healthcare systems
- 11 EHRs

FM-TIPS Data Overview

FM-TIPS
Fibromyalgia TENS In Physical Therapy Study

REDCap: Participant Entered, Primary & Secondary Outcomes

EHR: Therapist Entered, Secondary Outcomes

TENS Usage Data

Episode of Care

Study Flag, Name, DOB, Site, Start/End Dates, ICD 10 codes, # visits attended, # visits scheduled

Visit Level

Study Flag, Name, DOB, Site, Visit Date, CPT Codes, *PSFS

*PSFS: Patient reported outcome measure initially done with therapist and moved to REDCap

1 Lesson 1: Initial planning – do your homework

FM-TIPS
Fibromyalgia TENS In Physical Therapy Study

At the grant writing stage

- Consult with data managers about your data and the process
- Consult with multiple clinics/providers about the EHR and data extraction process
- Include data extraction costs in your budget
  - Setting up the process on the clinic side cost
  - Periodic extraction cost
  - Cleaning, mapping, and reporting of data

2 Lesson 2: Clinicians need support

FM-TIPS
Fibromyalgia TENS In Physical Therapy Study

- Limited Time
  - PT's who manage data extraction are focused on patient care
  - Building relationships with clinicians can be challenging
    - Limited availability of the clinician
    - Multiple people involved in the process of data extraction (clinicians, coders, billers, etc.)
    - Starting a study during a pandemic is hard
- Limited Experience
  - The people who manage data extraction have limited experience in data extraction for research
  - Limited experience in data transfer
- Limited Funds
  - Each healthcare system has different costs associated with data extraction
  - The study may have limitations in funding
  - Implications for patient care

3 Lesson 3: Data managers are integral to the process

- Data collection
- Data extraction
  - Timeframes
  - Data
- Integration of extracted data
  - Matching data
  - Coding data
  - Interpreting data
  - Reporting of the data

4 Lesson 4: It always takes longer than you think

FM-TIPS
Fibromyalgia TENS In Physical Therapy Study

- Developing relationships
- Learning curve for the clinics and clinicians
- Transfer of information – method, process, firewalls, etc.
- Matching and coding of data
- Invoicing for data extraction

2021	• Healthcare System 1-5 Activated • First Participant February
2022	• Data transfers began • Healthcare System 6 Activated
2023	• Healthcare System 4 Deactivated • Regular data transfers
2024	• Regular data transfers
2025	• Last data transfer

FM-TIPS
Fibromyalgia TENS In Physical Therapy Study

Summary

- Data extraction is a challenging process
- No two EHR's are the same
- Clinicians who manage data extraction are busy
- Data managers and clinicians are crucial to the process of data extraction
- Develop relationships with the healthcare systems and clinicians
- Be patient and be persistent

FM-TIPS Team

INSPIRE Abdominal & Skin/Soft Tissue Infection Trials

INtelligent Stewardship Prompts to Improve Real-time Empiric Antibiotic Selection for Patients

NIH Collaboratory In-Person Steering Committee Meeting
Data Extraction and Quality Challenges Panel
May 10, 2024

Shruti K. Gohil, MD, MPH
Assistant Professor, Division of Infectious Diseases
Associate Medical Director, Epidemiology & Infection Prevention
University of California, Irvine School of Medicine

INSPIRE Trials: Purpose & Design

- **Purpose:** Reduce unnecessary empiric broad-spectrum antibiotic use
- **Design:** Cluster-randomized trials, 92 HCA Healthcare hospitals, non-ICU patients
- **Intervention:** CPOE prompts for abdominal or skin/soft tissue infections
- **Outcomes:**
  - **Effectiveness** – antibiotic use first 3 inpatient days
    - Primary – any broad-spectrum antibiotics
    - Secondary – antibiotic subsets
  - **Safety:** days to ICU transfer, hospital length of stay

Multidrug-Resistant Organism (MDRO) Models

Challenges in curating data during pre-trial modeling

- Extensive data streams and cleaning
- >60 variables from 140 hospitals > 500,000 patients across 3 years
- 10 separate models to predict MDRO infection risk

Lessons learned

- Pre-trial data helpful for revealing complexities
- Needs realistic budgeting of analytic time
- Pivoted to pull and clean data throughout trial

Speeding Up Data Cleaning

Challenges in data alignment - despite a central data repository

- Many to one matching for medication or lab data
- Data standards exist but user overrides occurs
- Variation in hospital or provider order sets

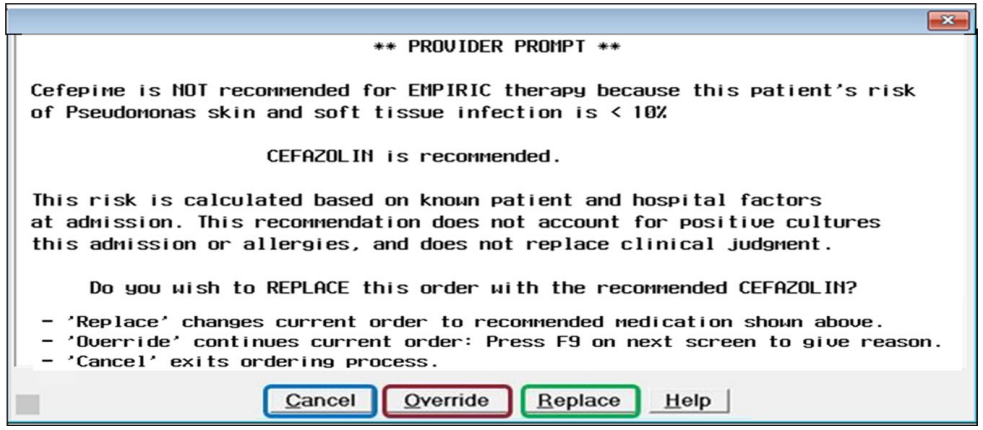
Lessons learned: proactive steps

- Smart sampling for layering data checks
- Monthly hospital data reports
- Monthly investigations and cleaning

Data From CPOE Prompts

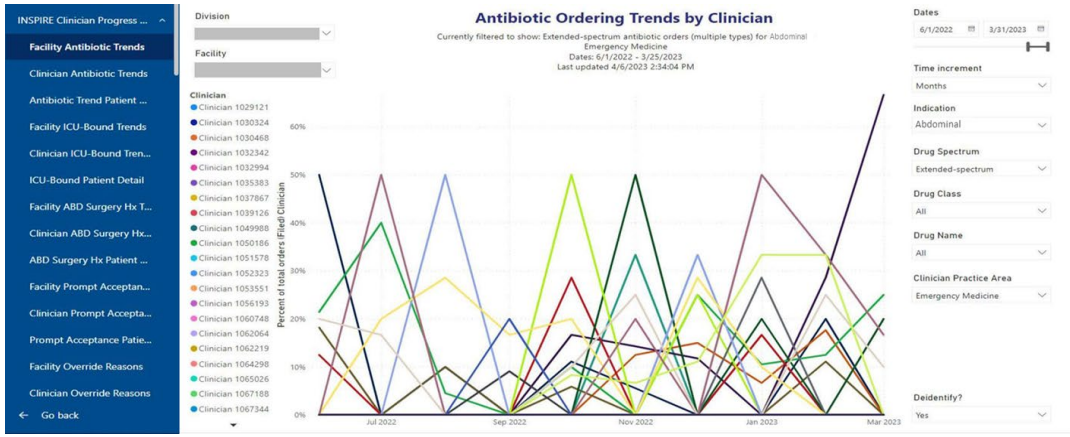
Build prompt *de novo*

- Specifications and queuing take time
- Capture prompt responses
- Feedback reports



Lessons learned

- Anticipate queuing time
- Leverage health system partners for support
- Allow health system solutions



Speeding Up Trial Analysis

Challenges in analysis

- Multiple models – effectiveness vs safety
- Hierarchical clustering – long run time, a few models failed to converge

Lessons learned: proactive steps

- More computing memory, server capacity
- Advanced coding for data cleaning, code review
- Test runs
  - Troubleshot issues with model convergence

Data Extraction and Quality:
what I know now that I wish I knew then

Corita R. Grudzen, MD, MSHS, FACEP
Division Head, Supportive and Acute Care Services
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Memorial Sloan Kettering Cancer Center
Professor of Emergency Medicine
Weill Cornell Medical College

Memorial Sloan Kettering
Cancer Center

Study Phase

- Planning
  - Pre-randomization must dos!
- Implementation
  - Monitoring of feasibility, acceptability, usability or fidelity
- Analysis
  - Advantages and disadvantages of push versus pull

Planning phase

Critical to examine BEFORE randomization:

- Assess infrastructure (*e.g.,* brick and mortar, staffing, software or IT resources)
- Check interoperability of data systems or electronic health record
- Evaluate data sharing capability and data use agreements
- Assess quality of outcome data
- “Willingness” or “get it done” attitude
- ….
- ….
- ….
- Adequate volume of eligible patients

Planning phase examples

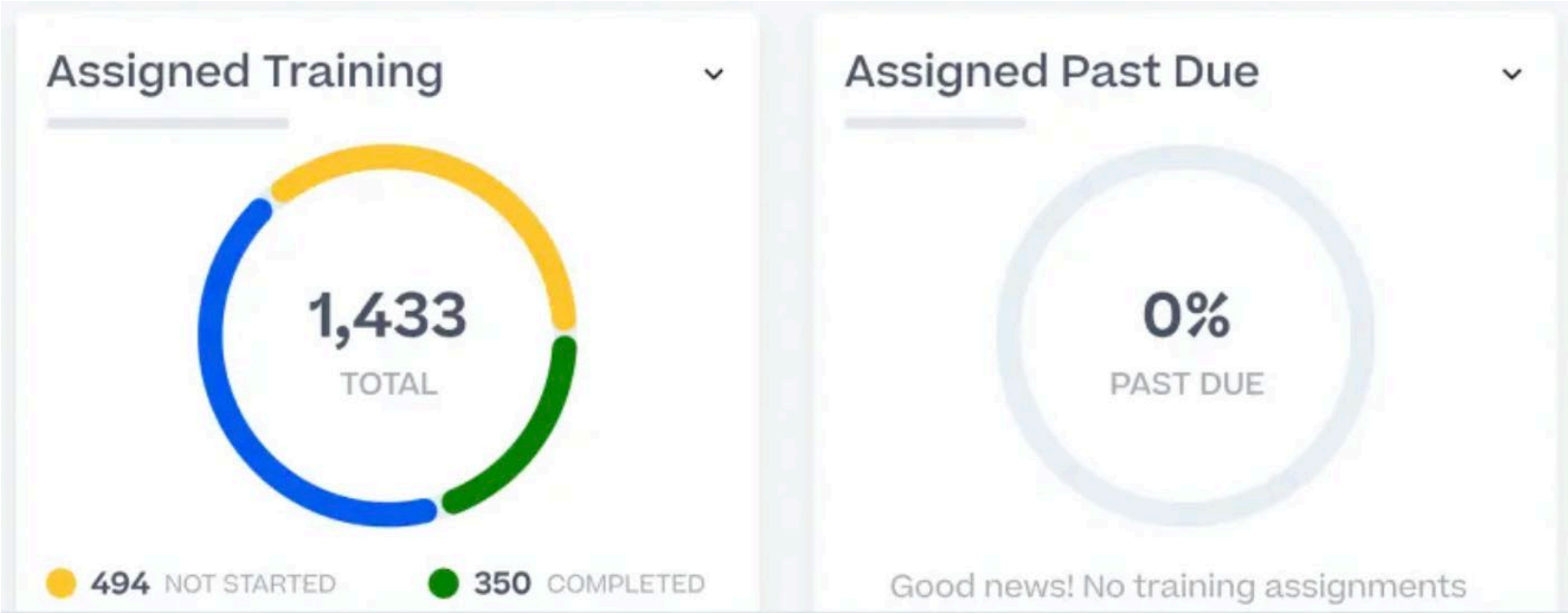
- Human resources
  - Outpatient specialty palliative care practice
  - ED social worker
- Electronic health record (*e.g.,* Epic)
  - Transition mid-project
- Data sharing
  - Test ability and willingness to obtain quality data, especially if PHI
- Inability to identify sites (free-standing EDs) in CMS data
- “Willingness” or “get it done” attitude can overcome almost anything!

Implementation

- Training data
- Feasibility (volume of patients, procedures, visits)
- Acceptability (survey completion)
- Fidelity to core function
- Usability of electronic tools

Implementation examples

- Learning Management System



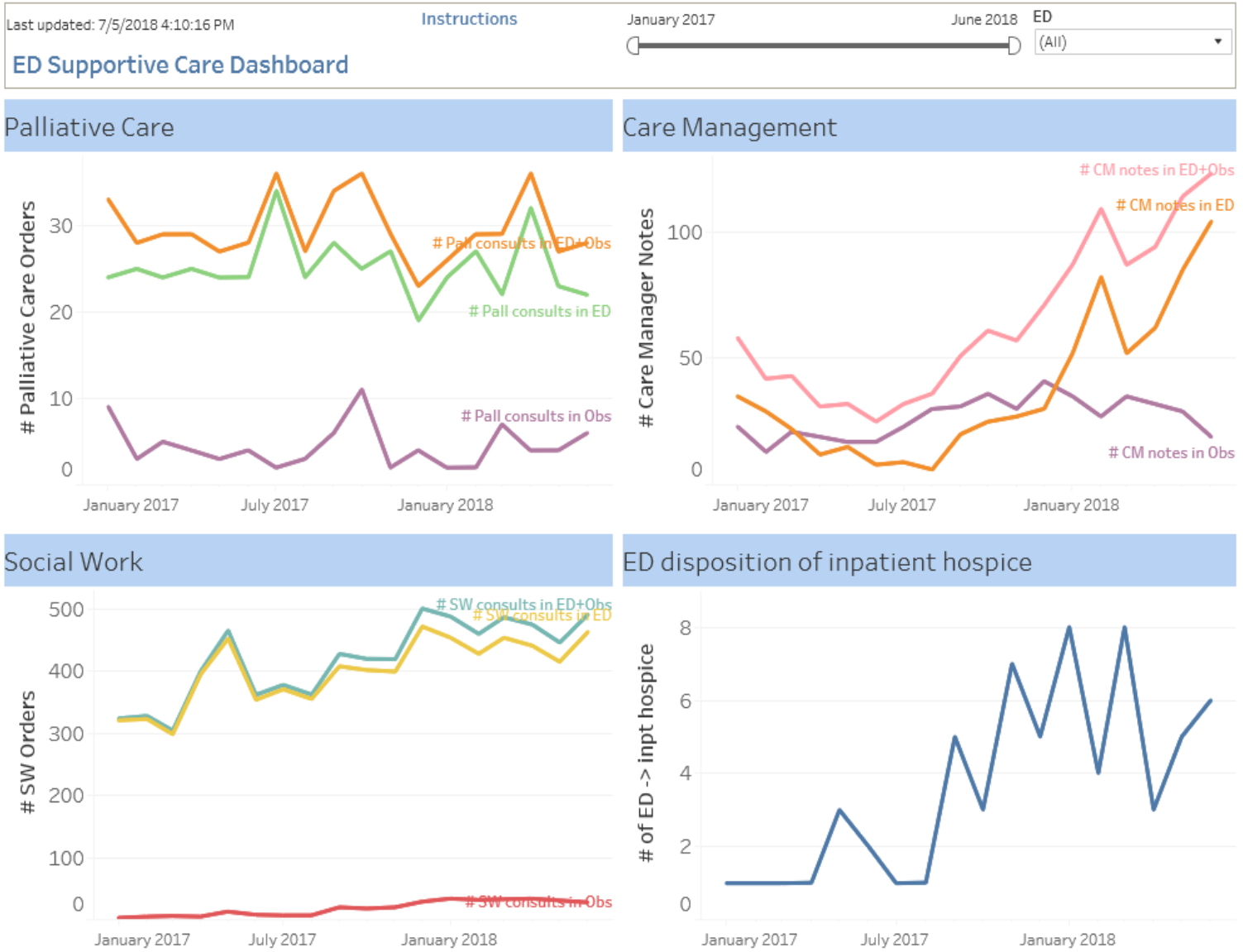
Implementation examples

- Survey completion rates
  - RECCap, Qualtrix

Record ID	Enrollment			Baseline data		Post data	
	Records	Sites	Student Survey	Test 1	Test 2	Test 1	Test 2
1001	●	●	●	●	●	●	○
1002	●	●	●	●	●	●	○
1004	●	●	●	●	●	●	○
1005	●	●	●	○	○	○	○
1009	●	●	●	○	●	●	○
1010	●	●	●	○	●	●	○
1011	●	●	●	●	○	●	○
1012	●	●	●	●	○	●	○
1013	●	●	●	●	●	●	○
1014	●	●	●	○	●	●	●
1015	●	●	●	●	●	●	●
1017	●	●	●	●	●	●	●
1020	●	●	●	●	●	●	●
1021	●	●	●	●	●	○	○
1022	●	●	●	●	●	○	○
1025	●	●	●	●	●	○	○

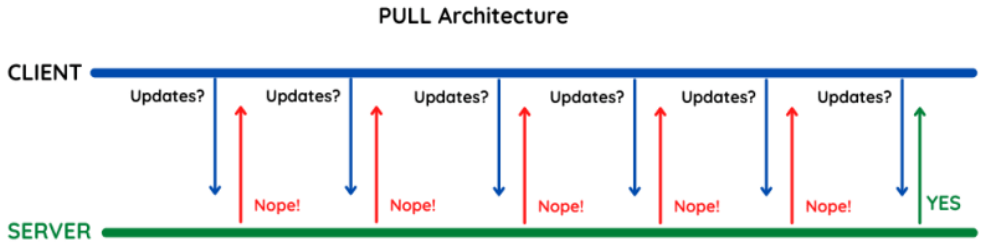
Implementation examples

- Clinical Decision Support
  - Process metrics

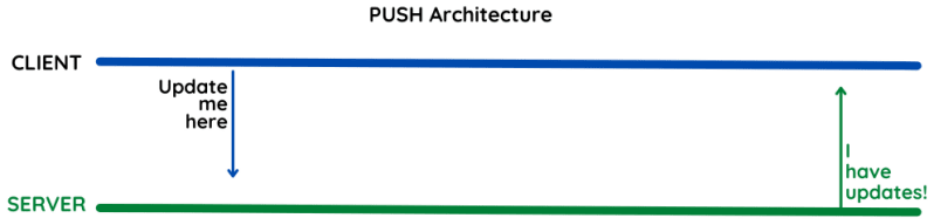


Analysis

- Pull architecture
  - Driven by a request
  - Requires more human resources
  - Pdf or excel spreadsheet



- Push architecture
  - Driven by an event and automatically pushed
  - Requires more technical expertise and lead time
  - Code provided to other sites



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Questions