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Data Acquisition, Data Management and Subject Tracking in an RCT: Promoting Breast Cancer Screening in Non-Adherent Women

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Disclosure of Conflict of Interest

I have no actual or potential conflict of interest in relation to this program/presentation

Study Overview

- 5- year study funded by National Cancer Institute
- Dynamic study population: Women age 51-84 (Later age 40-84)
  - Core eligibility: Fallon Community Health Plan (FCHP) member >=18 months with a Fallon (Reliant) Clinic PCP
    - Later added 3 other health plans and reduced time in plan to 13 months
  - Baseline n=23,000
  - New subjects added as they become eligible (Health plan membership >=18 months with Fallon/Reliant PCP)
  - Subjects excluded when no longer eligible, but may return if core eligibility regained

Study Overview

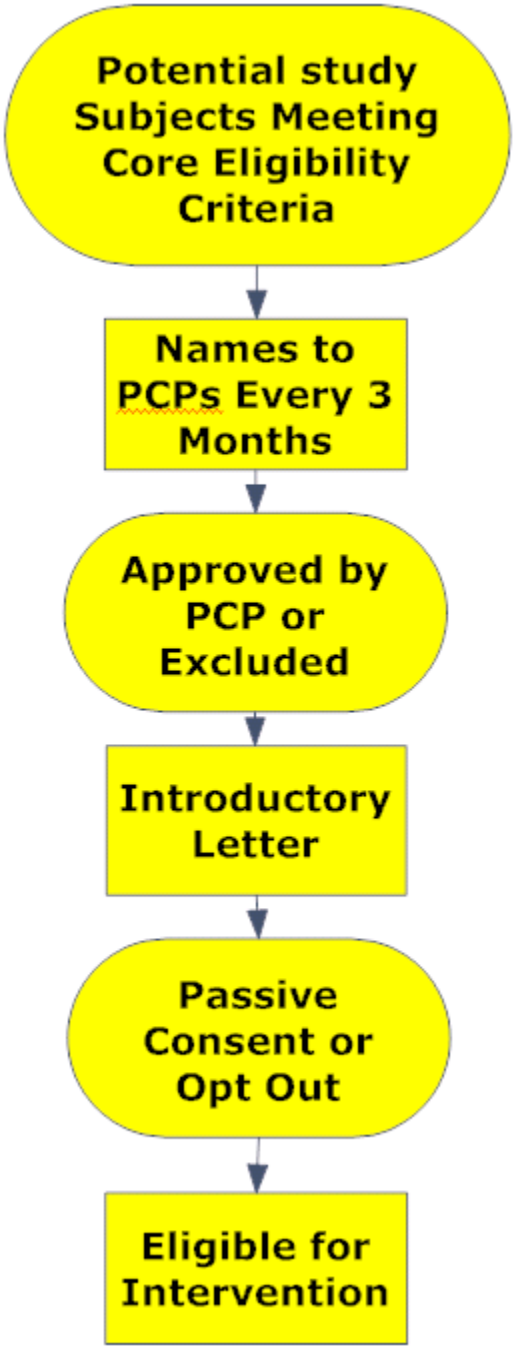
Main objective:

- Compare the effectiveness of 3 different interventions arms in promoting adherence to screening mammography over 4-years.
- When first meeting core eligibility requirements, women are randomized to three study arms:

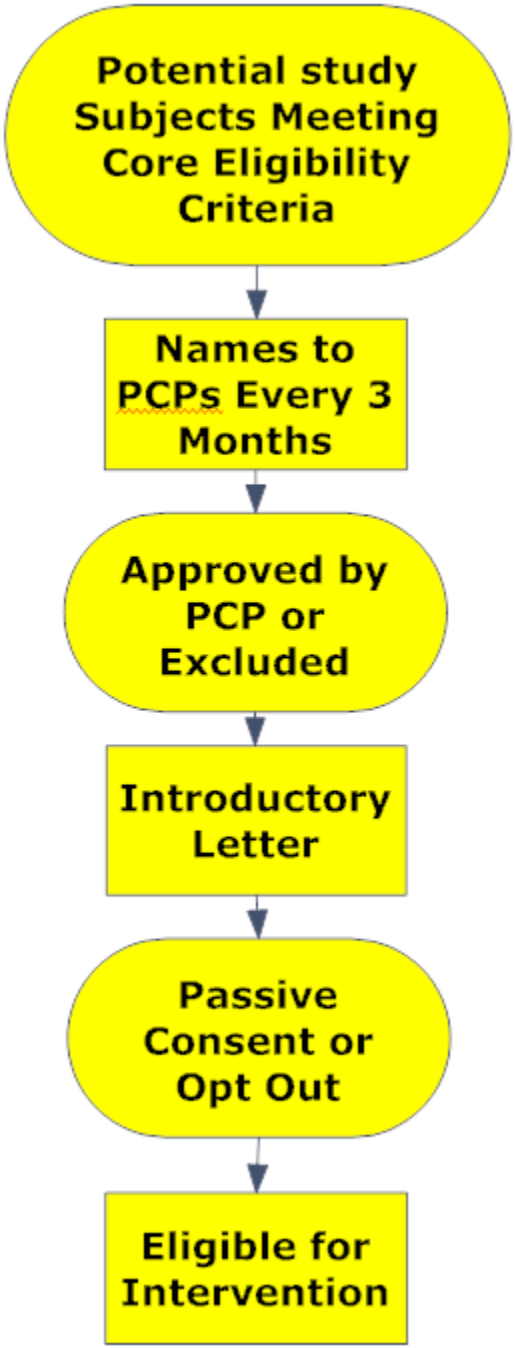
1. Reminder letter (control, usual care)
2. Reminder letter followed by reminder/scheduling call to nonresponders
3. Reminder letter and educational booklet followed by an enhanced tailored telephone counseling call to nonresponders.

   The call includes:
   - Reminding
   - Tailored review of information in educational booklet
   - Motivational interviewing as needed
   - Scheduling

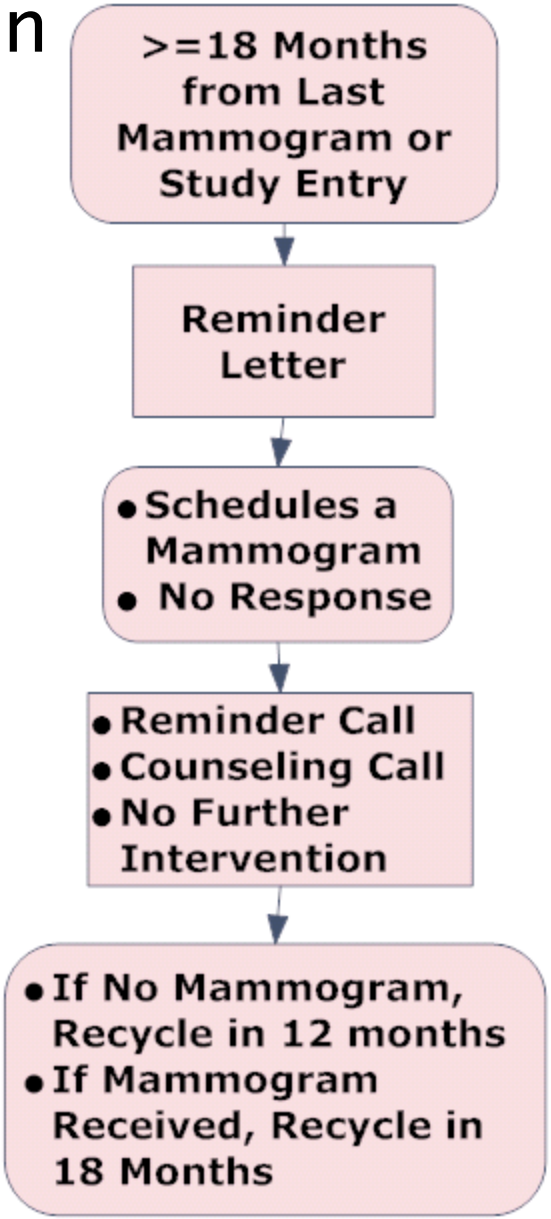
Establish Study Eligibility



Establish Study Eligibility

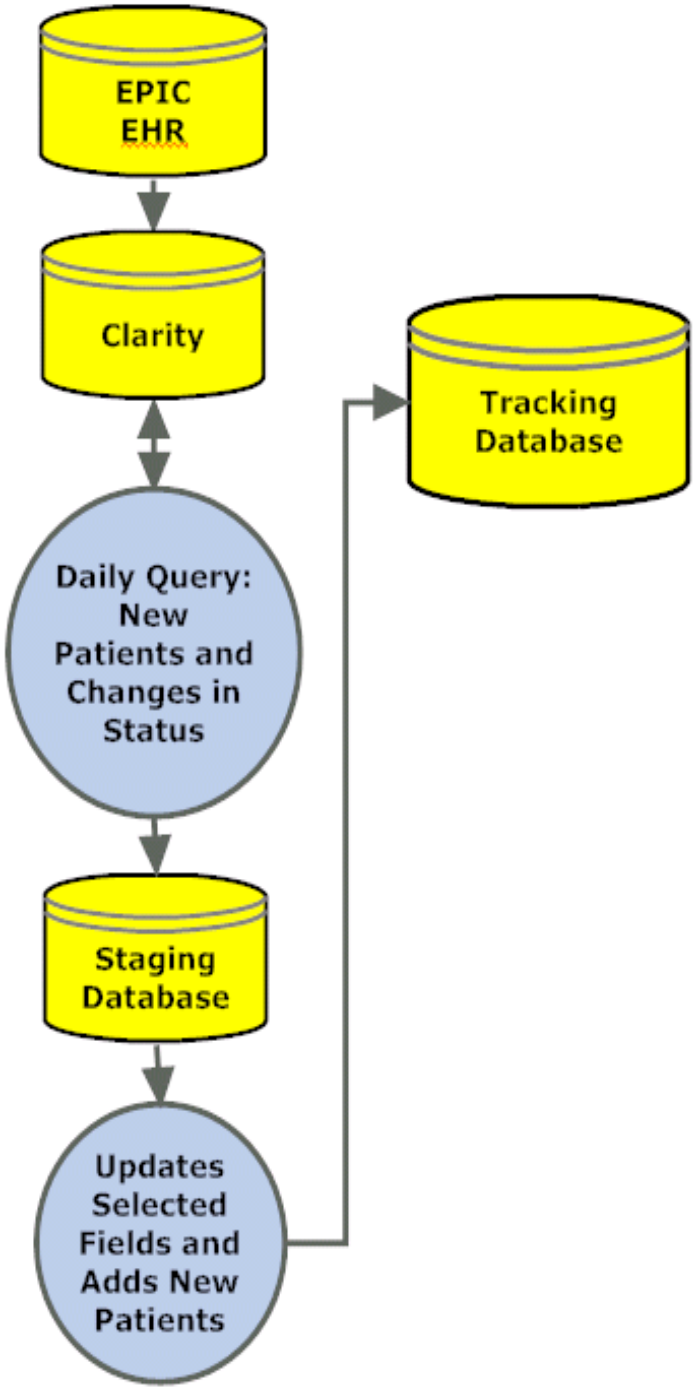


Intervention Delivery



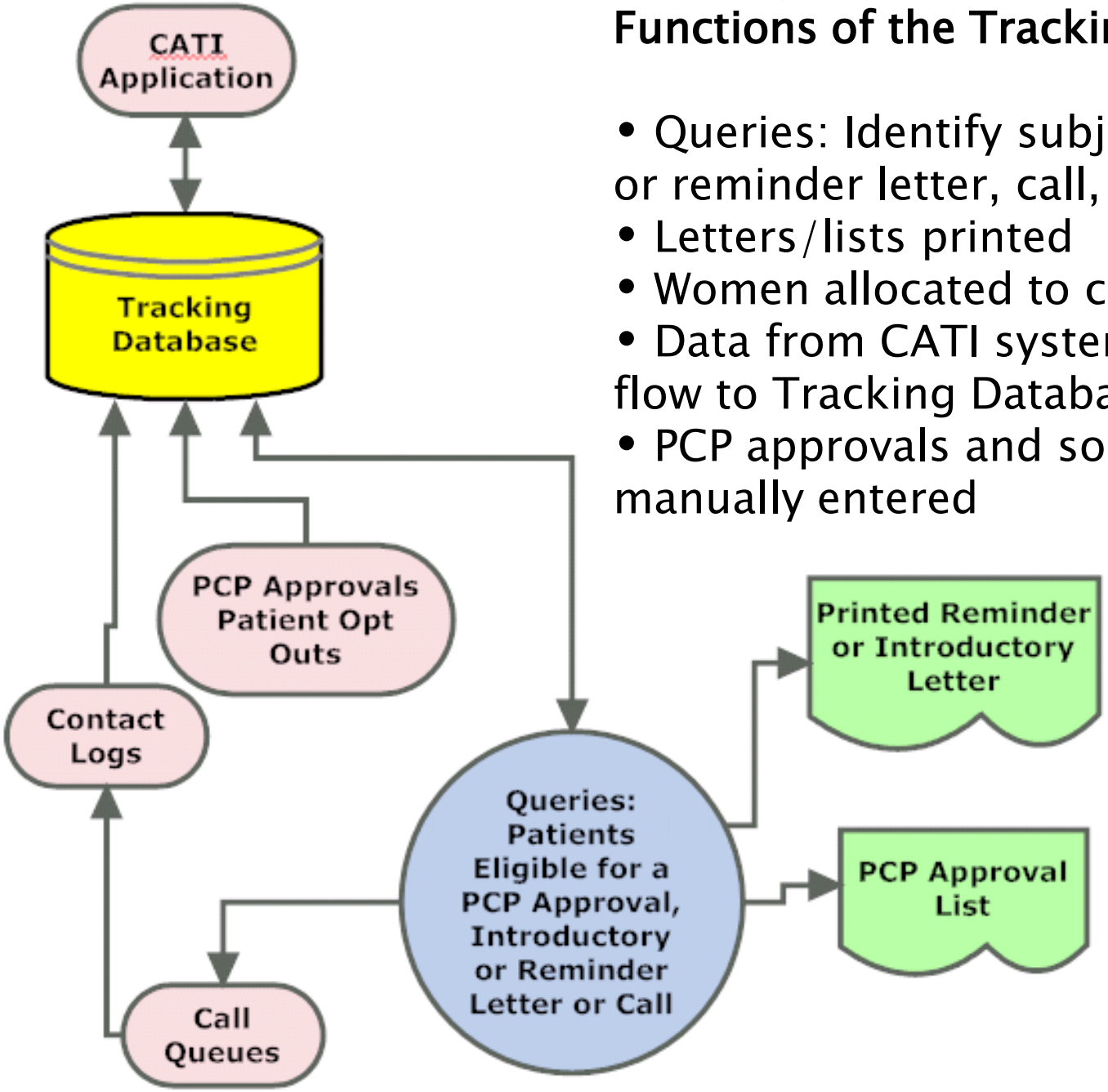
Data Flow: Core Eligibility and Mammogram Tracking

- EHR data flows into Clarity data repository
- Automated daily query of Clarity: Data on women >=40 loads into Staging Database
- Eligibility flag is set (Yes/no) based on core eligibility criteria
- Tracking Database updated:
  - Newly eligible subjects added
  - Eligibility flag, contact info, date of last and next scheduled mammogram updated



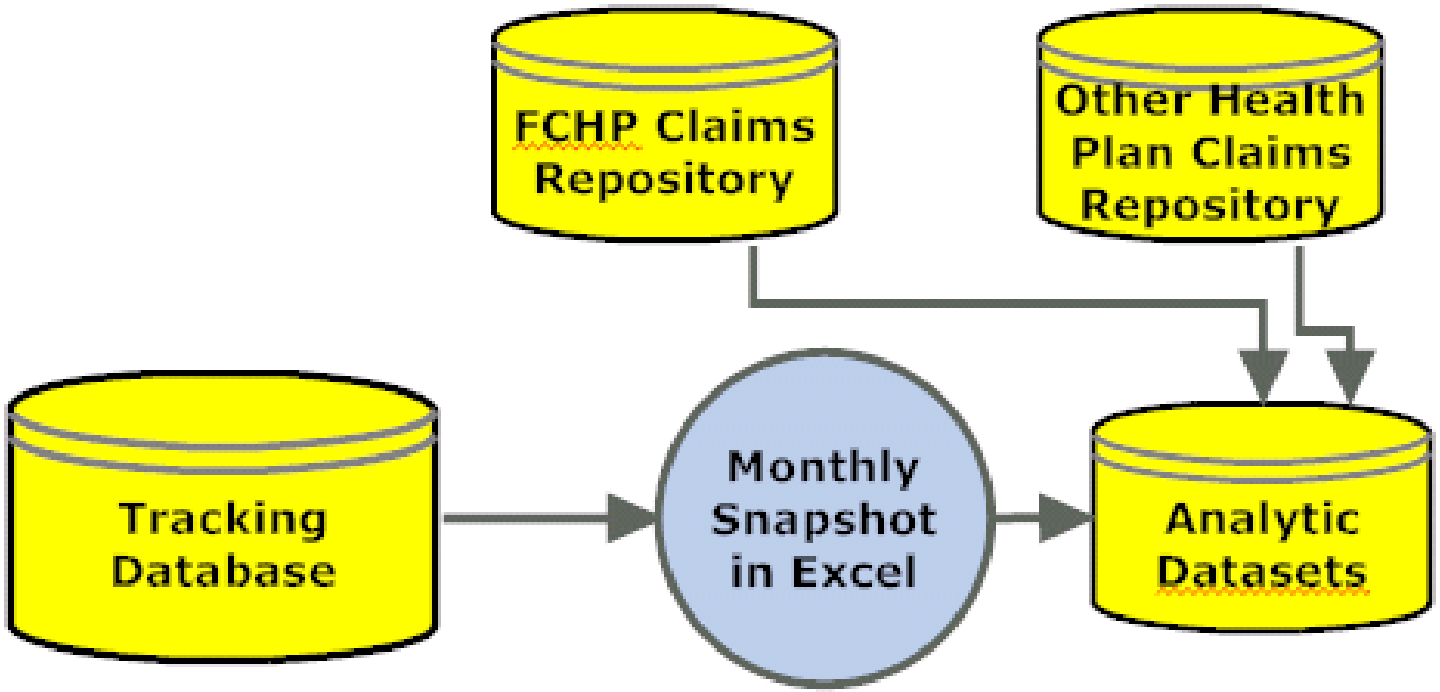
Tracking and Application Support Functions of the Tracking Database

- Queries: Identify subjects for introductory or reminder letter, call, or PCP approval
- Letters/lists printed
- Women allocated to call queues
- Data from CATI system and contact logs flow to Tracking Database
- PCP approvals and some “Opt Outs” manually entered

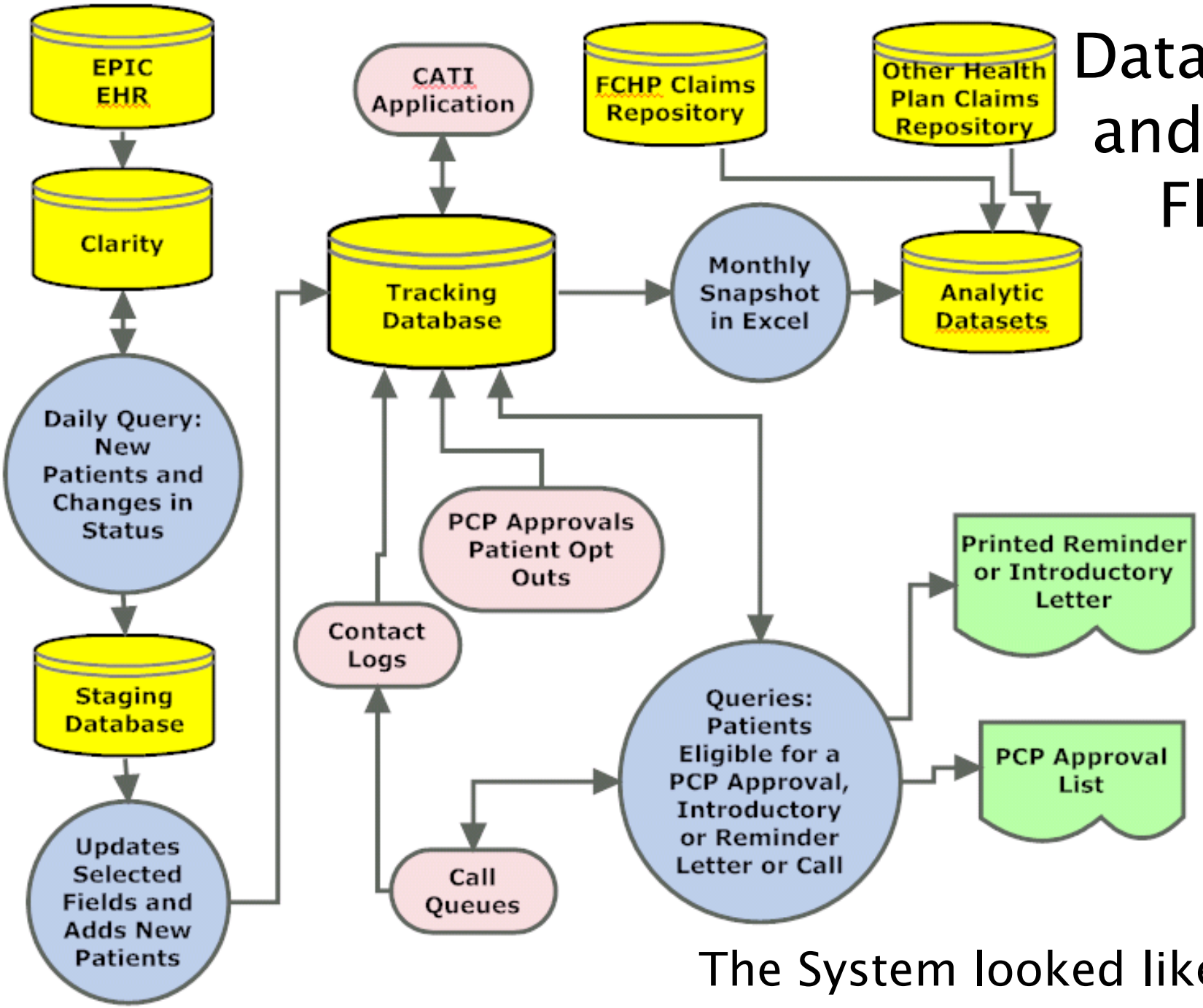


Data Flow to Analytic Datasets

- Monthly snapshots merged as needed for analysis
- Data from fields written to >1 time in a month are lost
- Claims from multiple years extracted and merged with data from Tracking Database

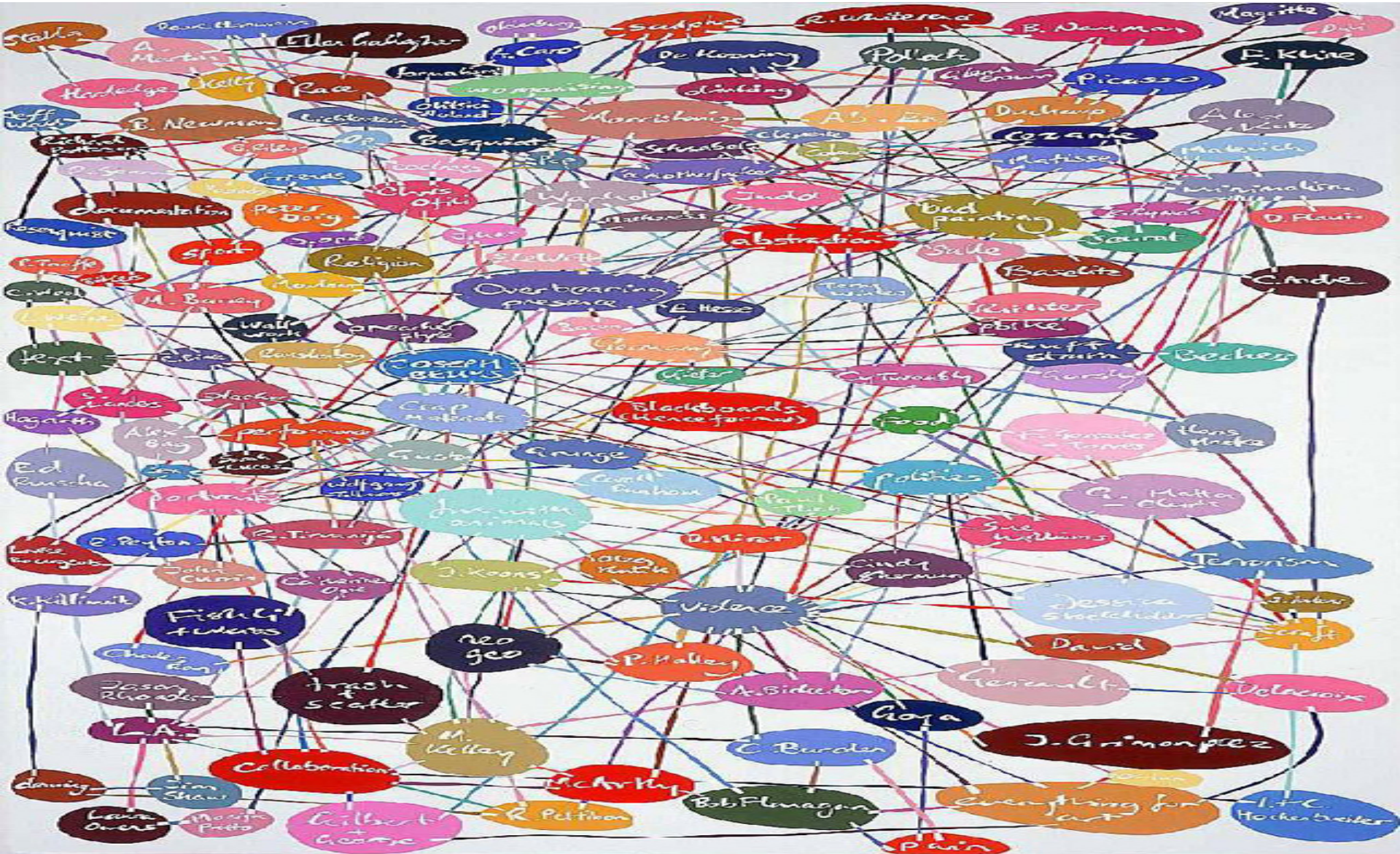


Databases and Data Flow



The System looked like this…

But it FELT like this…



Challenges and Issues

- Inconsistent field names and terminology (e.g. 4 types of “eligibility”)
- Losing/Regaining eligibility (Overwriting fields and loss of history) and specifying eligibility in staging dataset
- 3 data sources for core eligibility , sometimes in conflict (Clarity, FCHP claims, CATI)
- 1 – 4 repeats (waves) of interventions
- Repeated snapshots of tracking data is inefficient and ineffective way to create an analytic dataset

Lessons Learned

- Use consistent field names that indicate data source when possible
- Identify and resolve any potential conflicts in the design phase
- Develop a flow chart of all eligibility processes and waves of intervention when designing the system
- Maintain control of all eligibility rules and of updating of the tracking database
- Do not overwrite values in any variable
- Date and time stamp all entries
- Specify analytic dataset as subset of tracking database in the design phase

Expertise Needed for Building Effective Data Acquisition/Management and Tracking Systems

Expertise in:

- Source data content and organization
- Source data extraction, transfer, and loading (ETL)
- Database design
- System design (Data flow, automated queries, interfaces, hardware)
- Data management (Field names and formats, record structure, analytic dataset construction)
- Data analysis (Biostatistics)
- Software development for custom applications
- Facilitation of process of specifying all system requirements