Study Design

Digital Transformation of Healthcare

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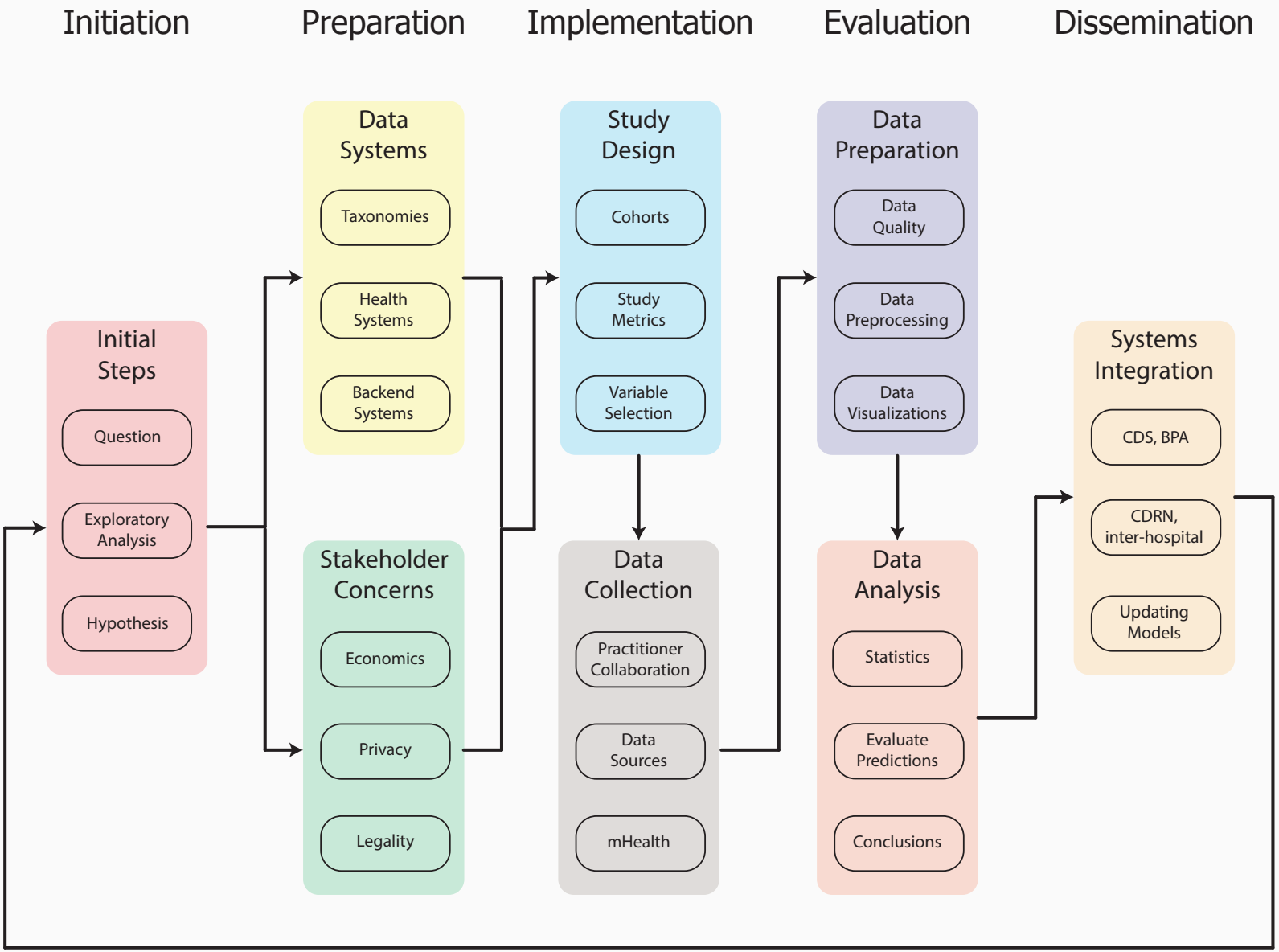
Digital Transformation of Healthcare

- How can I answer questions using automatically collected data?
- What do I need to consider when designing a study using patient data?

Bioinformatics Pipeline



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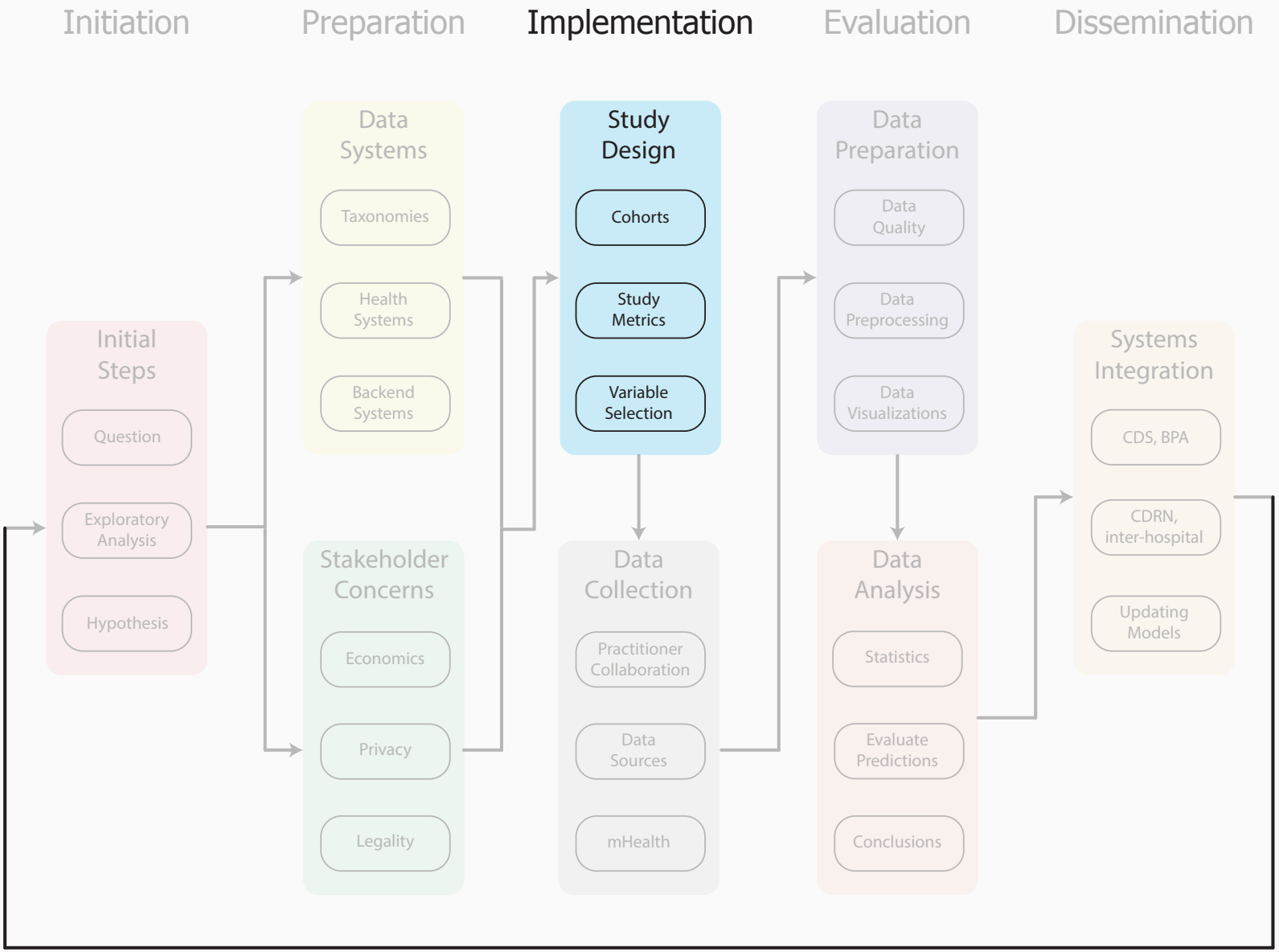

Medication Reconciliation

- Medication reconciliation (Med Rec) is the process of
  - comparing a patient's medication orders to all of the medications they have been taking
  - understanding why they're taking each medication
  - comparing that list against new orders
- The goal of Med Rec is to provide correct medications to the patient at all transition points within the hospital.

Medication Reconciliation

- According to The Institute of Safe Medication Practice, Med Rec has the potential to eliminate
  - 50% of medication errors
  - 20% of adverse medical events
- Care providers in Montefiore write
  - About 4 million prescriptions a year (averages out to more than 10,000 a day)
  - Prescriptions to over 400,000 different patients
  - Prescriptions for more than 11,000 different medications

Med Rec Case Study - Definitions

Roses hospital wants to develop a pilot Med Rec system in their Pediatrics department. You are working with a team of institutional stakeholders tasked with comparing the pre- and post-implementation effects of this system. You meet with the bioinformatics core to discuss the data collection for the study, as the domain knowledge expert, they ask you following questions

- What qualifies as an adverse drug event (ADE)?
- What qualifies as a medication error?
- How would you sub-classify each and where do they overlap?

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1. an ADE is an injury due to a medication, e.g., cough due to ACE-I in pt w/o hx of cough, nausea after tamiflu, anaphylaxis due to allergy
2. A medication error is any mistake along the path of ordering, transcribing, dispensing, administrating, and monitoring, e.g., docusate given 2 hours late (harmless), critical abx never given (harmful), wrong medication given(anywhere from harmless to fatal), ...
3. Medication errors range from minor, which have little or no harm potential (late docusate) and are not ADEs, to possible, which could have caused injury but did not, either because they were caught in time or the pt did not have a negative rxn (even if they should have) and these are termed potential ADEs, to fatal which are ADEs
4. ADEs are split into potential ADEs, which are always medication errors but were either intercepted or non-injurious, preventable ADEs which are the result of medication errors and non-preventable ADEs, which are not the result of medication errors, such as allergic rxn in a heretofore non-allergic pt

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- What qualifies as a medication error?
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- At what points along the pathway from prescription to ingestion can medication errors occur?
- How do you identify and retrace a medication error, an ADE?

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1. Prescription writing (autocomplete, autofill, patient charts, dosing, allergies), filling prescription (wrong medication, medication interactions, allergies), prescription handoff, administration (route, dosing, delay), patient ingestion (misinterpret instructions, ignore instructions)
2. self reported, pt surveys, cross-reference medication interactions, lab results, deviations in dosing, e.g., 5mg jumps to 5g, ICD codes, e.g., urticaria (ppv of only about 2%)
3. look for any irregularity in the patient's condition such as change in mental status, sudden drop in blood pressure, sudden drop in oxygen saturation, new rash, or new diarrhea, and then to consider whether it might be related to a medication

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- At what points along the pathway from prescription to ingestion can medication errors occur?
- How do you identify and retrace a medication error, an ADE?
- What is the goal of Med Rec with respect to medication errors and ADEs?

Med Rec Case Study - Error Metrics

Roses hospital wants to develop a pilot Med Rec system in their Pediatrics department. You are working with a team of institutional stakeholders tasked with comparing the pre- and post-implementation effects of this system. The bioinformatics core has assembled all the data as per your earlier discussions. Before the statisticians can analyze the results they would like you to help narrow down the scope of their analyses.

- Which type(s) of ADEs and/or medication errors do you want to report?
- How do you want to quantify the different aspects of incidents?
- How do you want to break down the errors, e.g., per hour, per provider, ...?

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1. severity, preventability, the level of disability, the stage in the medication use process at which the error occurred, and the category of healthcare personnel responsible for the error can be classified
2. medication class, hour of day, per day of week, age of patient, number of concurrent medications, inpatient vs outpatient

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- Which type(s) of ADEs and/or medication errors do you want to report?
- How do you want to quantify the different aspects of incidents?
- How do you want to break down the errors, e.g., per hour, per provider, ...?
- How do you want to quantify the cost/benefit of implementing a Med Rec system?

Study Parameters

- Objective
- Setting
- Phases and Participants
- Outcome Measures

Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors

Bates, D. W., Leape, L. L., Cullen, D. J., Laird, N., Petersen, L. A., Teich, J. M., ... & Vander Vliet, M. (1998). Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. Jama, 280(15), 1311-1316.

Study Parameters

- Objective
  - To evaluate the efficacy of 2 interventions for preventing nonintercepted serious medication errors
- Setting
  - Large tertiary care hospital
- Phases and Participants
  - Phase 1 - conducted prior to the implementation of POE
    - All patients admitted to a stratified random sample of 6 medical and surgical units over a 6-month period
  - Phase 2 - conducted after the implementation of POE
    - All patients admitted to the same units and 2 randomly selected additional units over a subsequent 9-month period
- Outcome Measures
  - Nonintercepted serious medication errors.

Overall Reductions

	Phase 1	Phase 2	% Difference	*P*
Nonintercepted serious medication errors	10.7	4.86	-55	0.01
Preventable ADEs	4.69	3.88	-17	0.37
Life Threatening	0.65	0.65		
Serious	0.98	1.96		
Significant	2.86	1.55		
Nonintercepted potential ADEs	5.99	0.98	-84	0.002
Life Threatening	0.82	0.04		
Serious	2.37	0.69		
Significant	2.70	0.6		
All ADEs	16.0	15.2	-5	0.77
Nonpreventable ADEs	11.3	11.3	0	0.99
Life Threatening	1.07	0.69		
Serious	2.37	2.89		
Significant	7.78	9.37		
All potential ADEs	11.7	3.38	-71	0.02
Intercepted potential ADEs	5.67	2.40	-58	0.15

Mean rates (events per 1000 patient days) of incidents in Phase 1 and Phase 2. Paired comparisons were made using *t*-tests

Reductions by Error Type

	Phase 1	Phase 2	% Difference	*P*
Mistake in Ordering	4.1	3.3	-19	0.03
Mistake in Transcription	1.3	0.20	-84	< 0.001
Mistake in Dispensing	0.90	0.29	-66	0.001
Mistake in Administration	4.1	1.7	-59	< 0.001
Wrong Doses	0.96	1.51	-23	0.02
Wrong Choices	1.39	0.77	-44	0.07
Wrong Techniques	0.98	0.24	-75	< 0.001
Delays	0.90	0.20	-77	0.01
Known Allergies	0.65	0.29	-56	0.009
Missed Doses	0.57	0.12	-79	0.07
Wrong Drugs	0.49	0.04	-92	0.05
Drug-Drug Interactions	0.41	0.24	-40	0.89
Wrong Frequencies	0.33	0.33	0	0.93
Wrong Routes	0.16	0.04	-75	0.21
Failures to Act on Monitoring	0.16	0.29	74	0.21
Others	2.37	1.38	-43	0.05

Unpaired comparison of mean rates (events per 1000 patient days), controlling for level of care and service, using generalized estimating approaches to control for correlation between phases

Reductions by Drug Type

	Phase 1	Phase 2	% Difference	*P*
Analgesics	2.05	1.14	-44	0.01
Antibiotics	1.72	0.86	-50	0.04
Sedatives	0.49	0.98	+99	0.38
Antineoplastics	0.49	0.24	-50	0.34
Cardiovascular Drugs	0.25	0.08	-67	0.08
Anticoagulants	0.98	0.24	-75	0.01
Antipsychotics	0.41	0.16	-60	0.15
Diabetic Drugs	0.49	0.24	-50	0.49
Electrolytes	0.90	0.20	-77	< 0.001
Others	2.62	1.59	-39	0.007

Unpaired comparison of mean rates (events per 1000 patient days), controlling for level of care and service, using generalized estimating approaches to control for correlation between phases

Economic Savings

- Estimated annual costs of preventable ADEs of $2.8 million.
- If the observed 17% decrease in the preventable ADE were the hospital-wide decrease, the annual savings would be $0.48 million.
  - This does not include the costs of injuries borne by patients, of admissions due to drug errors, of malpractice suits, or of the extra work generated by the nonserious medication errors.
- The costs of developing and implementing POE have been estimated to be $1.9 million, with maintenance costs of $0.5 million per year
- The net savings have been estimated to be between $5 to $10 million per year.