Study Design

Digital Transformation of Healthcare

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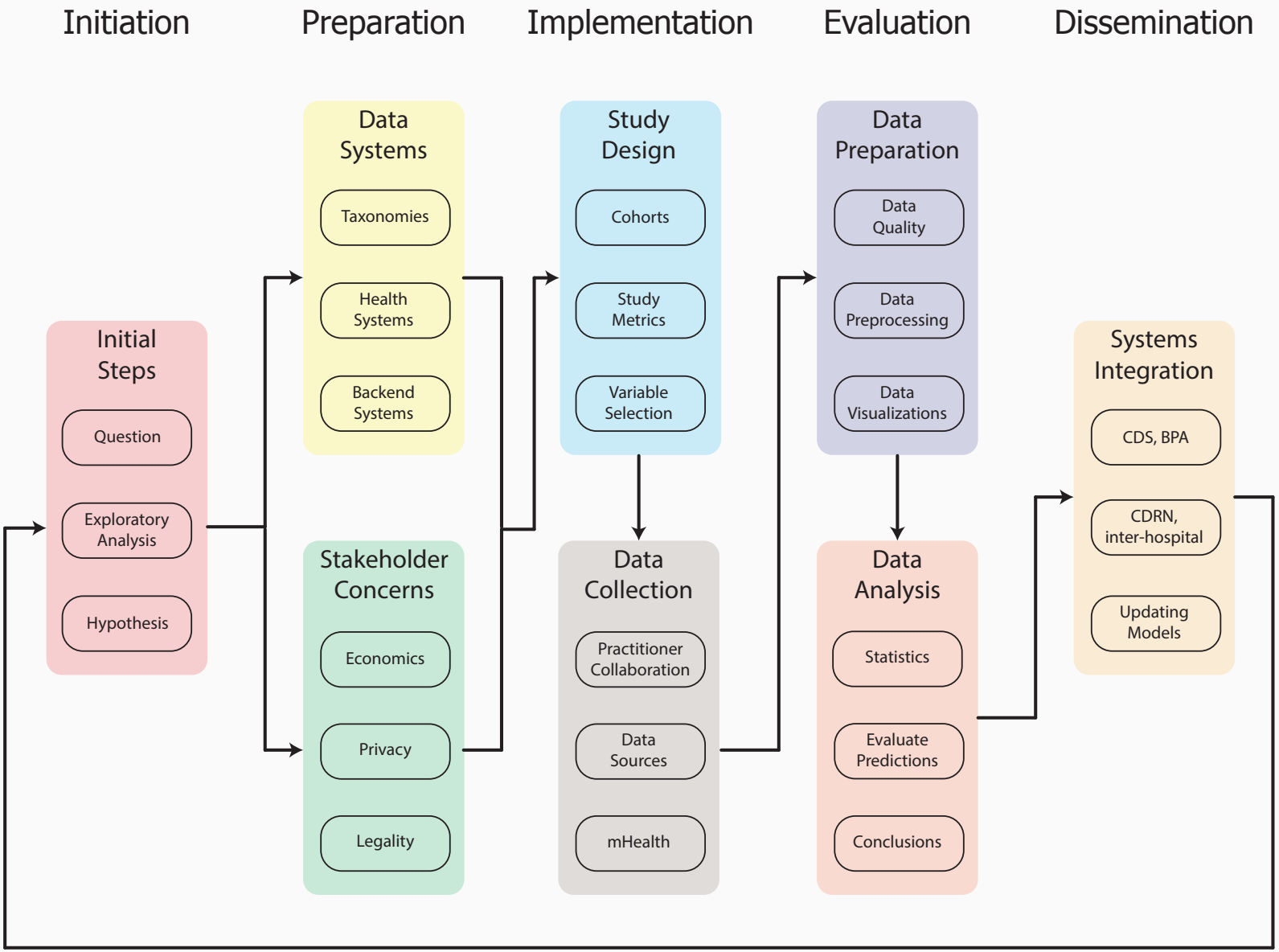
Digital Transformation of Healthcare

- 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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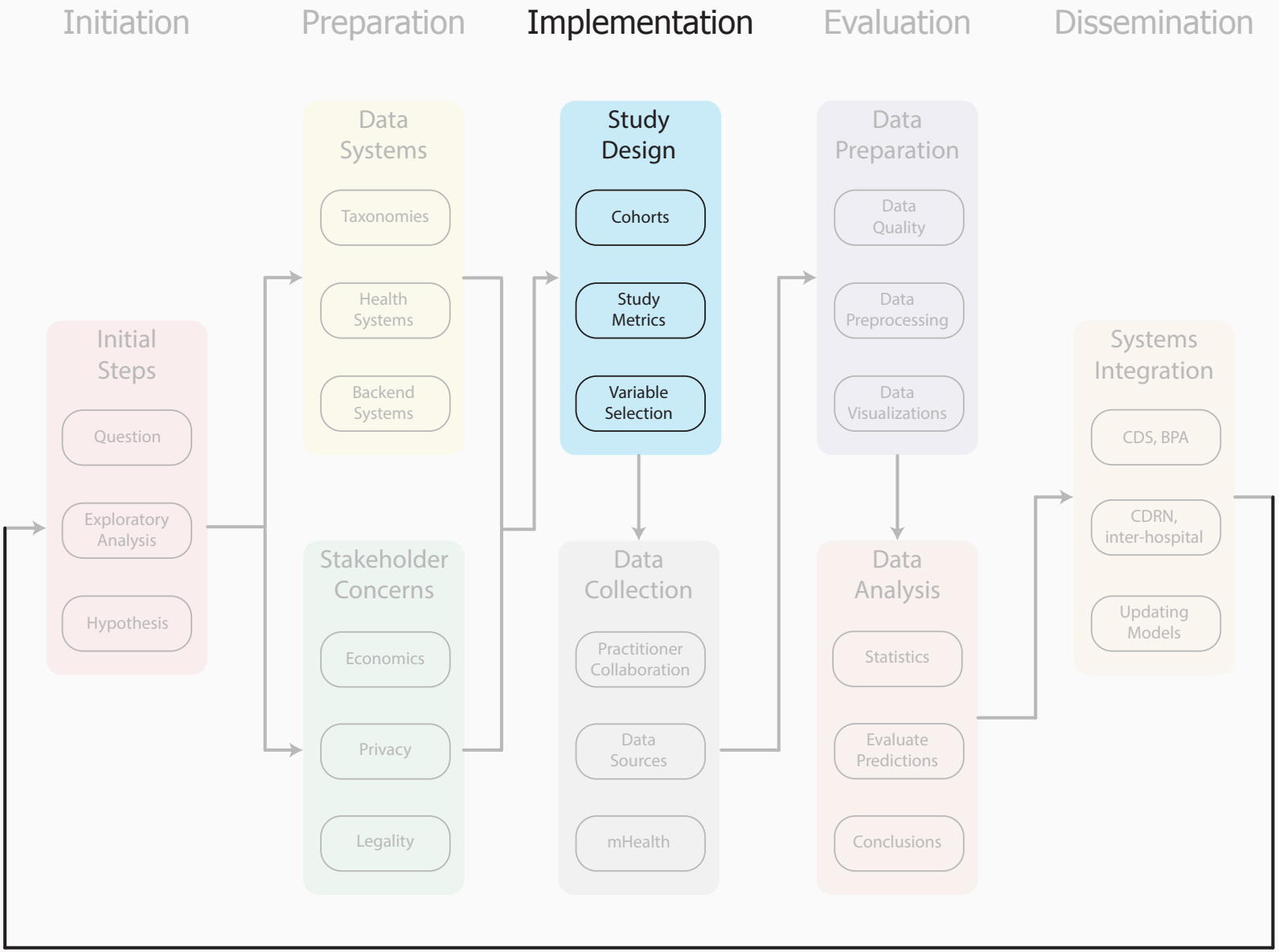

Medication Reconciliation

- 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 studying the effects of this soon to be implemented 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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- 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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- 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 studying the effects of this soon to be implemented 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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- 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?

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 Paraneters

- Objective
  - To evaluate the efficacy of 2 interventions for preventing nonintercepted serious medication errors
- Setting
  - Large tertiary care hospital
- Participants
  - Phase 1
    - All patients admitted to a stratified random sample of 6 medical and surgical units over a 6-month period
  - Phase 2
    - 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

Table 2.—Paired Comparison of Rates of Nonintercepted Serious Medication Errors, Adverse Drug Events (ADEs), and Potential ADEs Before (Phase 1) and After (Phase 2) Interventions Were Implemented*

	Phase 1 Rate (Events/1000 Patient-Days, Mean)	Phase 2 Rate (Events/1000 Patient-Days, Mean)	% Difference	*P*
Nonintercepted serious medication errors†	10.7	4.86	−55	.01
Preventable ADEs	4.69	3.88	−17	.37
Nonintercepted potential ADEs	5.99	0.98	−84	.002
All ADEs	16.0	15.2	−5	.77
Nonpreventable ADEs	11.3	11.3	0	.99
All potential ADEs	11.7	3.38	−71	.02
Intercepted potential ADEs	5.67	2.40	−58	.15

*Paired comparison between phase 1 and 2 made using *t* test, including only the 6 units in both phases.

†Sum of nonintercepted potential ADEs and preventable ADEs.

- Does these differences seem reasonable?
- Are there any other broad categories which you feel we should include?

Reductions by Severity

Table 4.—Severity of Nonintercepted Serious Medication Errors and Adverse Drug Events (ADEs) Before (Phase 1) and After (Phase 2) Interventions Were Implemented*

	Phase 1		Phase 2	
	No. (%)	Rate/1000 Patient-Days	No. (%)	Rate/1000 Patient-Days
Nonintercepted serious medication errors	**127**	10.4	**134**	5.46
Life threatening	18 (14)	1.47	17 (13)	0.69
Serious	41 (32)	3.36	65 (49)	2.65
Significant	68 (54)	5.57	52 (39)	2.12
Nonintercepted potential ADEs	**72**	5.89	**32**	1.30
Life threatening	10 (14)	0.82	1 (3)	0.04
Serious	29 (40)	2.37	17 (53)	0.69
Significant	33 (46)	2.70	14 (44)	0.6
Preventable ADEs	**55**	4.50	**102**	4.16
Life threatening	8 (15)	0.65	16 (16)	0.65
Serious	12 (22)	0.98	48 (47)	1.96
Significant	35 (64)	2.86	38 (37)	1.55
Nonpreventable ADEs	**137**	11.2	**318**	13.0
Life threatening	13 (9)†	1.07	17 (5)	0.69
Serious	29 (21)	2.37	71 (22)	2.89
Significant	95 (69)	7.78	230 (72)	9.37

*Unpaired comparison controlling for level of care and service, using a generalized estimating approach to control for correlation between phase 1 and 2 rates. Percentages may not add to 100 because of rounding. Phase 2 data include both POE and POE plus team.

†Three of these events were fatal. There were no fatal ADEs in phase 2, and none of the preventable ADEs were fatal in either phase.

Reductions by Error Type

Table 5.—Frequency of Nonintercepted Serious Medication Errors, by Stage of Ordering, Before (Phase 1) and After (Phase 2) Interventions Were Implemented

Stages of Ordering (Rate/1000 Patient-Days)	Phase 1	Phase 2						
		Overall	% Difference*	P*	POE Only†	POE + Team	% Difference†	P†
No. ordered	50 (4.1)	81 (3.3)	−19	.03	29 (2.6)	52 (3.9)	51	.17
No. of transcriptions	16 (1.3)	5 (0.20)	−84	<.001	3 (0.27)	2 (0.15)	−44	.40
No. dispensed	11 (0.90)	7 (0.29)	−68	.001	2 (0.18)	5 (0.38)	111	.75
No. administered	50 (4.1)	41 (1.7)	−59	<.001	20 (1.8)	21 (1.6)	−11	.59

*Unpaired comparison between phase 1 and 2, controlling for level of care and service, using generalized estimating approach to control for correlation between the 2 phases. POE indicates physician computer order entry.
†Unpaired comparison between POE + team and POE-only units in phase 2, controlling for level of care and service.

Table 6.—Specific Types of Nonintercepted Serious Medication Errors and Frequencies, by Error Type

Medication Error (Rate/1000 Patient-Days)	Phase 1	Phase 2	% Difference*	P*
No. of wrong doses	24 (1.96)	37 (1.51)	−23	.02
No. of wrong choices	17 (1.39)	19 (0.77)	−44	.07
No. of wrong techniques	12 (0.98)	6 (0.24)	−75	<.001
No. of delays	11 (0.90)	5 (0.20)	−77	.01
No. of known allergies	8 (0.65)	7 (0.29)	−56	.009
No. of missed doses	7 (0.57)	3 (0.12)	−79	.07
No. of wrong drugs	6 (0.49)	1 (0.04)	−92	.05
No. of drug-drug interactions	5 (0.41)	6 (0.24)	−40	.89
No. of wrong frequencies	4 (0.33)	8 (0.33)	0	.93
No. of wrong routes	2 (0.16)	1 (0.04)	−75	.21
No. of failures to act on monitoring	2 (0.16)	7 (0.29)	74	.21
No. of others	29 (2.37)	34 (1.38)	−43	.05

*Unpaired comparison between phase 1 and 2 (before and after intervention was implemented, respectively), controlling for level of care and service, using generalized estimating approaches to control for correlation between the 2 phases.

Reductions by Drug Type

Table 7.—Nonintercepted Serious Medication Error Rates, by Drug Class

Drug Class (Rate/1000 Patient-Days)	Phase 1	Phase 2	% Difference	*P**
No. with analgesics	25 (2.05)	28 (1.14)	–44	.01
No. with antibiotics	21 (1.72)	21 (0.86)	–50	.04
No. with sedatives	6 (0.49)	23 (0.98)	+99	.38
No. with antineoplastics	6 (0.49)	6 (0.24)	–50	.34
No. with cardiovascular drugs	3 (0.25)	2 (0.08)	–67	.08
No. with anticoagulants	12 (0.98)	6 (0.24)	–75	.01
No. with antipsychotics	5 (0.41)	4 (0.16)	–60	.15
No. with diabetic drugs	6 (0.49)	6 (0.24)	–50	.49
No. with electrolytes	11 (0.90)	5 (0.20)	–77	<.001
No. with others	32 (2.62)	33 (1.59)	–39	.007

*Unpaired comparison between phase 1 and 2 (before and after intervention was implemented, respectively), controlling for level of care and service, using generalized estimating approaches to control for correlation between the 2 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.