

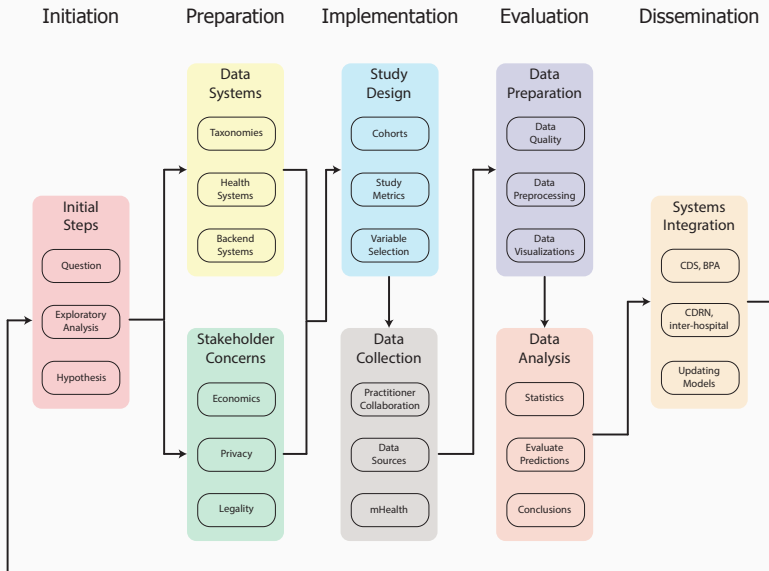
Study Design

Digital Transformation of Healthcare

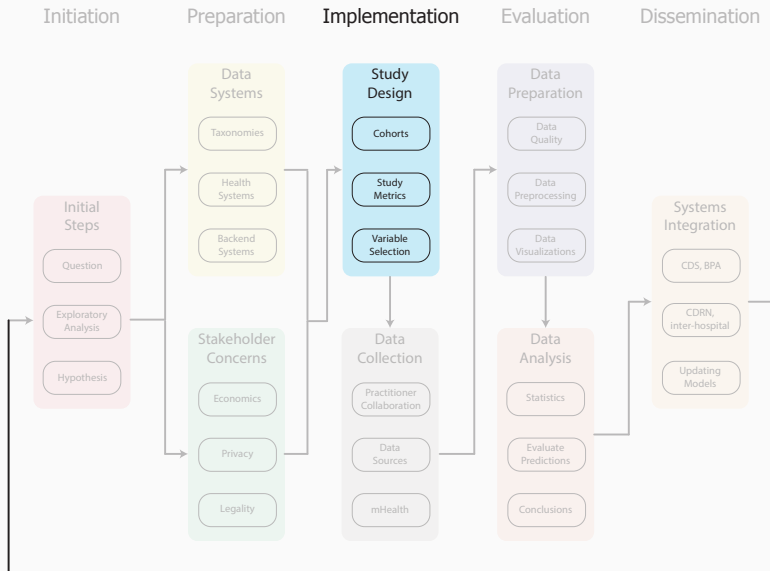
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Bioinformatics Pipeline



Study Design



Medication Reconciliation

- Medication reconciliation (Med Rec) is the process of comparing a patient's medication orders to all of the medications he/she has been taking
- 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

Case Study 1 - Data Collection

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 is the difference between a medication error and an adverse drug event (ADE)?
- What qualifies as a medication error?
- Are all medication errors equal?

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1. ADE \rightarrow intercepted, preventable, non-preventable
2. preventable ADE \rightarrow non-injurious, injurious
3. potential ADE = intercepted or non-injurious

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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?

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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, cross-reference medication interactions, deviations in dosing, e.g., 5mg jumps to 5g

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 do you want to report?
- How do you want to break down the errors, e.g., per hour, per provider, ...?

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1. 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 do you want to report?
- 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 Parameters

- 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.

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†
No. ordered	50 (4.1)	81 (3.3)	-19	.03	29 (2.6)	52 (3.9)	51
No. of transcriptions	16 (1.3)	5 (0.20)	-84	<.001	3 (0.27)	2 (0.15)	-44
No. dispensed	11 (0.90)	7 (0.29)	-68	.001	2 (0.18)	5 (0.38)	111
No. administered	50 (4.1)	41 (1.7)	-59	<.001	20 (1.8)	21 (1.6)	-11

*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.