Challenges of Integrating Data (like heart sounds) into Clinical Care

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Disclosure of Conflicts of Interest

I have no relevant conflicts of interest to disclose.

Learning objectives

1. Describe the current challenges of recording data as data, not documents
2. Understand the need for data cleaning before developing AI algorithms

The Cardiac Implantable Electronic Device (CIED) Use Case

Cardiac Implantable Electronic Devices

- World-wide over 1 Million pacemakers and 325,000 implantable defibrillators are implanted each year.

Life-sustaining devices-Remote Monitoring:

- Early detection of device malfunction
- Early detection of actionable arrhythmias
- Reduction in ED & office visits
- Reduced healthcare costs
- Associated with improved survival (ICDs)

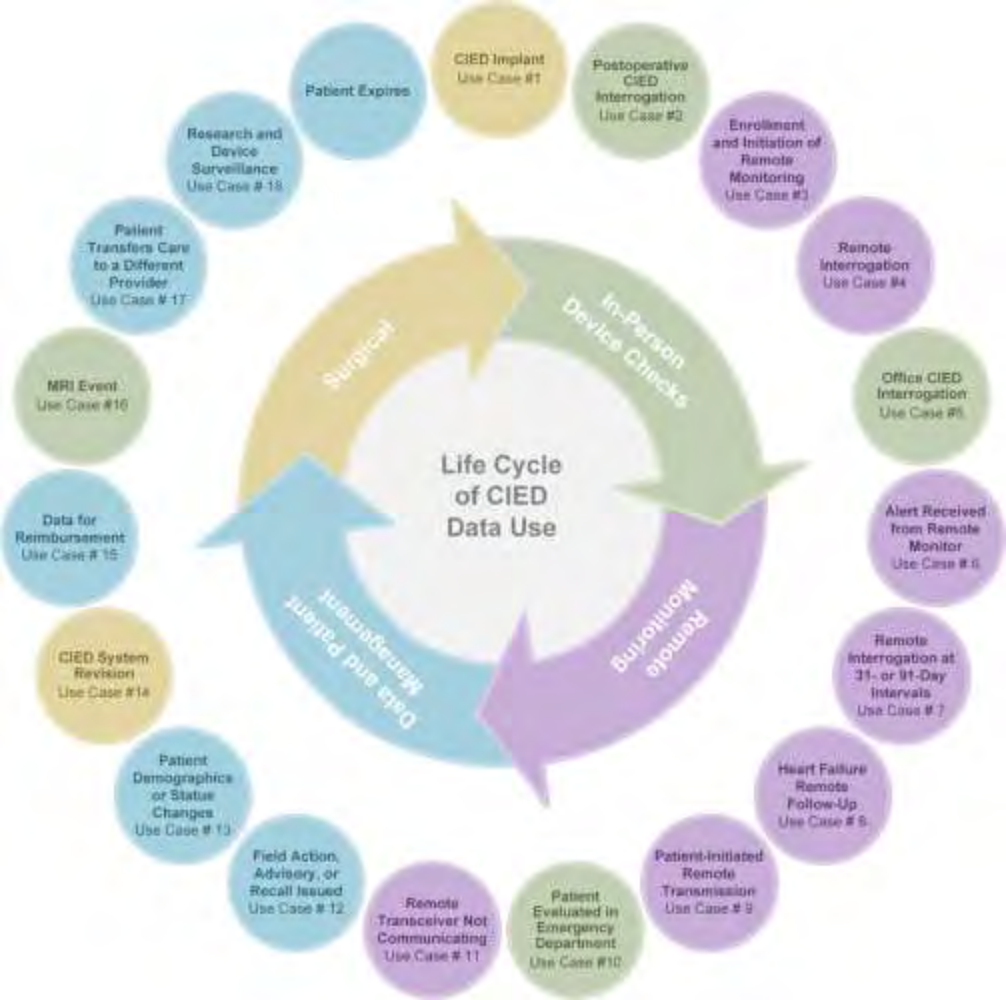
The CIED Use-Case

Card Electrophysiol Clin 7 (2015) 797–807 – modified for this presentation

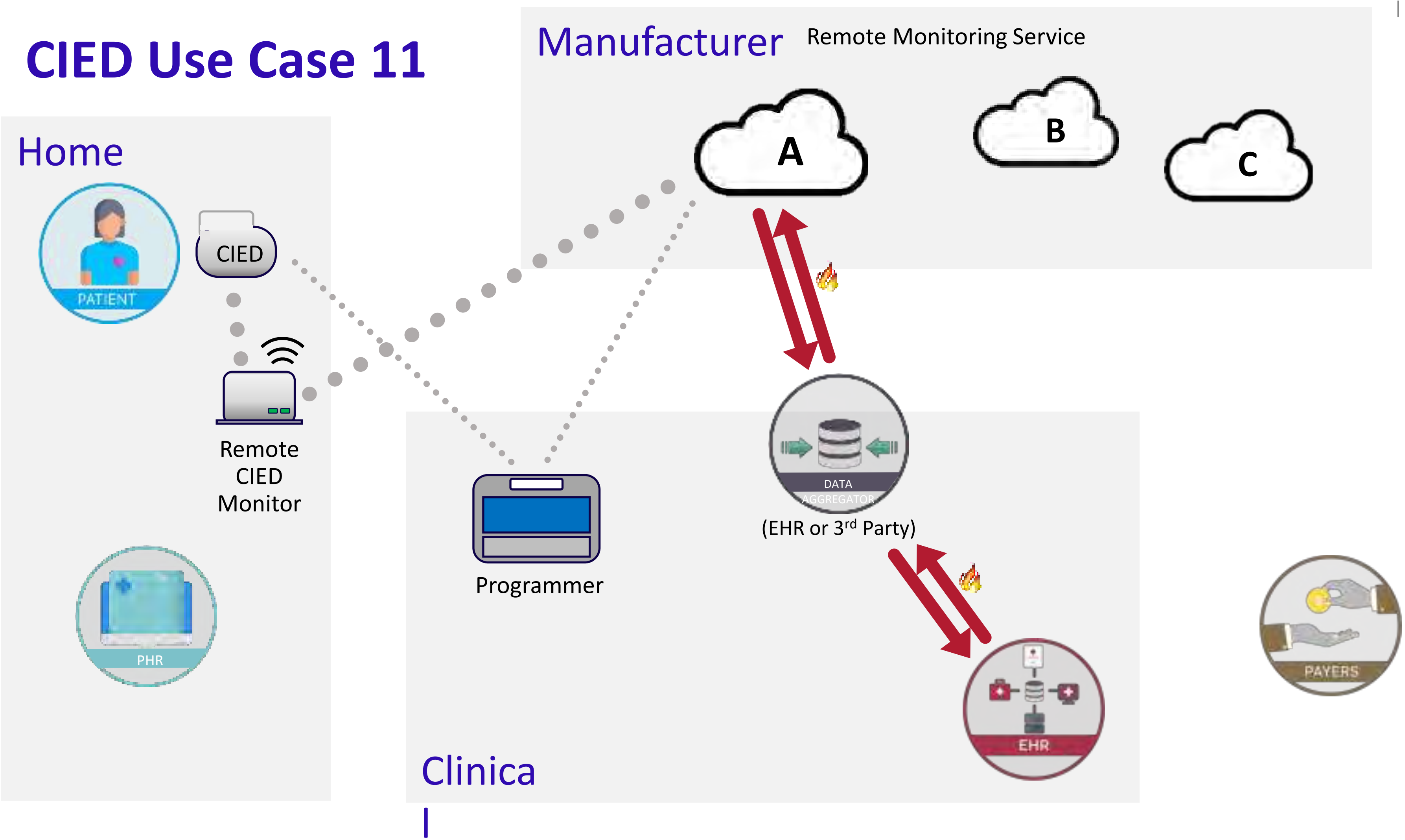
The CIED Use Case

- Need to understand data flow and workflow (business process mapping)
- Over 1100 clinical concepts/individual data elements across the CIED life cycle

CIED Use Case: The CIED Life Cycle



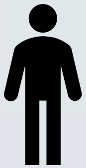
CIED Use Case 11



CardX

Use Case Proposal: Disconnected CIED

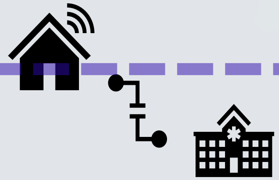
Summary of the Use Case from the patient perspective



- John Doe, a 67-year-old farmer living a relatively healthy life.
- Started experiencing episodes of shortness of breath, lightheadedness, and palpitations.

- John visits his family doctor.
- The doctor conducted a physical examination and ordered several tests.

- Test results showed John had a second-degree atrioventricular block.
- Doctor recommended placement of a cardiovascular implantable electronic device (CIED) to regulate John's heartbeat.



- Following hospital discharge, John was unable to install the home transceiver for remote monitoring.
- Cardiology office was unaware that the remote monitoring was not established.

John had near syncopal event without his cardiology office being notified.

Monitoring Not Communicating Step 11 in CIED Use Case

- Issues:
  - Lack of notification of the absence of periodic CIED reporting
  - Lack of standardized approach across CIED manufacturers
  - Patients cannot determine whether CIED is communicating successfully
- Potential points of failure:
  - Home transceiver not installed / configured properly
  - CIED not communicating with transceiver (rare)
  - Transceiver not communicating with server (rare)
  - Notification not sent from server, not retrieved/received by clinic
- Implications:
  - Challenging, time-consuming process to identify disconnected (non-reporting) CIEDs
  - Potential for adverse patient complications
- Proposal
  - Proactive notification of clinicians and data aggregators (CVIS or EHR) whenever CIED disconnected via a universal, FHIR-enabled interface.

The Hypertension Use-Case

- 120,000,000 Americans have hypertension
- Hypertension contributes to the death of over 500,000 Americans annually through its effects on the kidney, heart and vascular system.
- Hypertension is particularly devastating to the African-American Population

Hypertension Clinical Practice Guidelines

Hypertension
Volume 71, Issue 6, June 2018; Pages e13-e115
https://doi.org/10.1161/HYP.0000000000000065

American Heart Association.

CLINICAL PRACTICE GUIDELINE

2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

Paul K. Whelton, MB, MD, MSc, FAHA, Robert M. Carey, MD, FAHA, Wilbert S. Aronow, MD,

Two readings of ≥130/≥80, on two separate occasions

Hypertension Clinical Performance and Quality Measures

Circulation: Cardiovascular Quality and Outcomes
Volume 12, Issue 11, November 2019
https://doi.org/10.1161/HCQ.0000000000000057

American Heart Association.

AHA/ACC PERFORMANCE MEASURES

2019 AHA/ACC Clinical Performance and Quality Measures for Adults With High Blood Pressure: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures

Donald E. Casey Jr, MD, MPH, MBA, FAHA, Chair, Randal J. Thomas, MD, MS, FACC, FAHA, Vice Chair[*], Vivek Bhalla, MD, FAHA, Yvonne Commodore-Mensah, PhD, RN, FAHA, FPCNA[†], Paul A. Heidenreich, MD, MS, FACC, FAHA, Dhaval Kolte, MD, PhD, Paul Muntner, PhD, FAHA, Sidney C. Smith Jr, MD, MACC, FAHA, John A. Spertus, MD, MPH, FACC, FAHA, John R. Windle, MD, FACC, Gregory D. Wozniak, PhD[‡], and Boback Ziaeian, MD, PhD, FACC

Two readings of ≥130/≥80, on two separate occasions

Hypertension Clinical Performance and Quality Measures

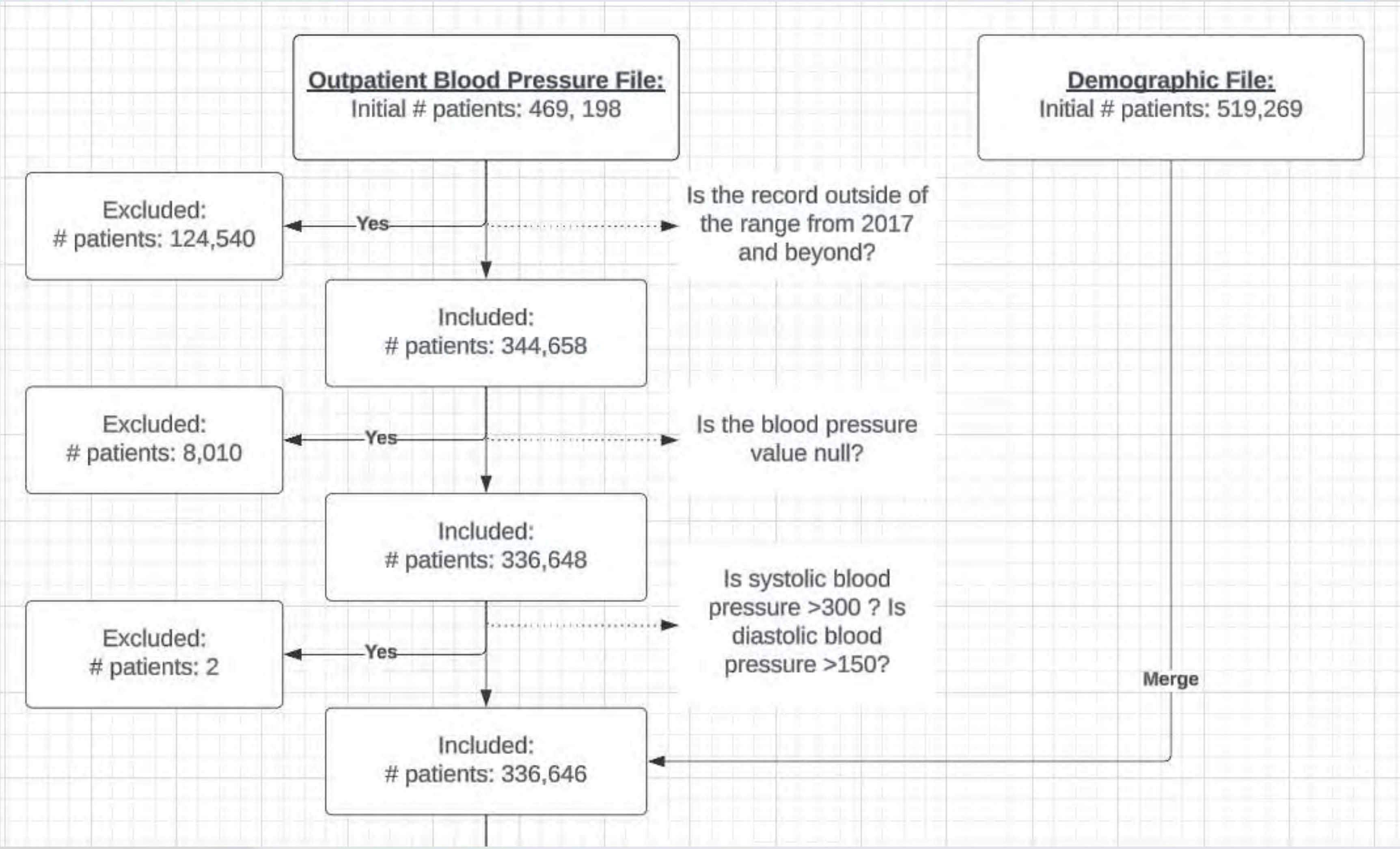
- We have proven pharmacologic and non-pharmacologic therapies to treating hypertension.
- Despite robust guidelines, hypertension is both underdiagnosed and misdiagnosed with only 27% of patients treated to target.

The Goal: Can we map the guidelines and performance measures and use machine learning to create an automated computable phenotype?

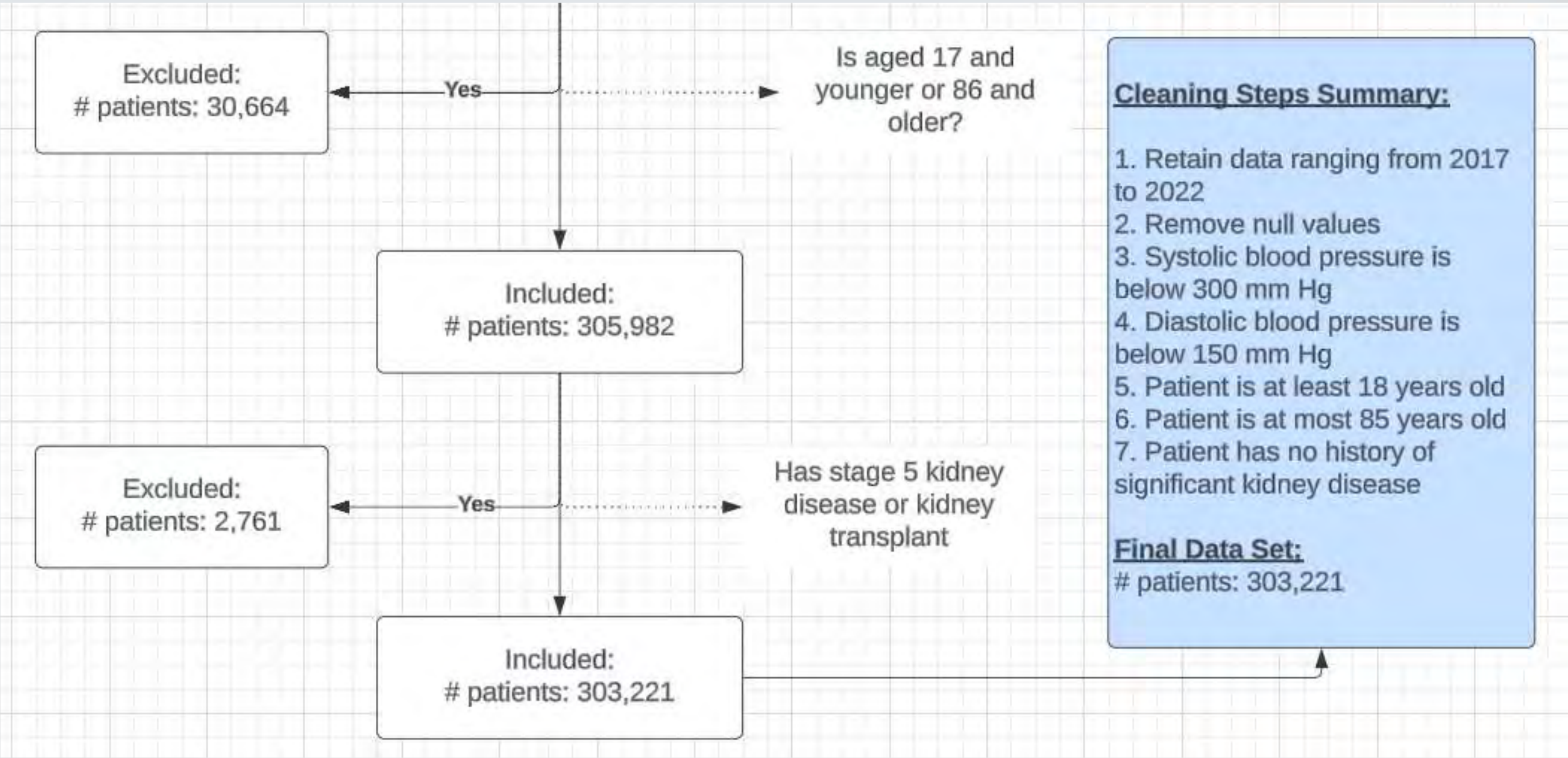
Data preparation and analytics

- We utilized the 2017 and 2019 AHA/ACC Clinical Practice Guidelines for the definition of hypertension: ≥130/≥80, 2 readings, 2 separate occasions.
- Mapped the guidelines into data elements for analysis:
  - Basic Demographics, SBP, DBP
  - ICD-10/SNOMED-CT diagnoses
  - Anti-hypertensive medications using RxNorm

Data Preparation



Data Preparation



Excluded causes of Secondary Hypertension.

Preliminary Analysis

Our ML Algorithm was over 99.8% accurate in mapping recorded blood pressures to AHA/ACC classifications. Our analysis of ~305,000 patients:

- **46%** of patients were classified as hypertensive based on the ACC/AHA guideline definition of hypertension
- However, only **20%** were diagnosed as hypertensive
- **Why is there a gap?**

Why is there a gap?

- We convened clinical experts (qualitative analysis and Delphi modeling).
- Qualitative analysis established several potential sources of the gap:
  - The day-to-day and hour-to-hour variability of blood pressures
  - Differences in technique, especially the application of poor techniques
  - Situational variability in blood pressure
- Experts posited that besides measured blood pressure, a more accurate phenotype could be developed by including both ICD-10/SNOMED-CT diagnosis of hypertension and the prescription of antihypertensive medications.

Delphi modeling with 5 clinicians

- Using the clinical concepts, we created 8 different patient vignettes
  - Ex: 65yoM presents to clinic with blood pressure of 144/92 on two different occasions. They have no prior diagnosis of hypertension and not taking any medications.
  - Presented each vignette to experts
  - What is the likelihood that this patient is hypertensive? (0-100%)

8 Chamber Framework – Expert Analysis

Chamber	High Blood Pressure	ICD-10 I10 Code	Hypertension Medication	Clinical Experts Hypertension Likelihood (%)	Ideal	Modifiers	# of Patients Classified	% of Patients Classified
1	0	0	0	12.2 +/- 7.2	Normotensive	Up to 10% Masked Hypertension	107,616	35.49%
2	1	0	0	70 +/- 12.2	Undiagnosed/Untreated hypertension	Up to 30% white coat hypertension or inappropriate technique	69,441	22.90%
3	0	1	0	55 +/- 25.7	Controlled hypertension with non-pharmacologic	False positive diagnosis	2,708	0.89%
4	0	0	1	63 +/- 17.8	Medications prescribed for non-hypertensive diagnosis	Failure to document hypertension as a problem	30,265	9.98%
5	1	1	0	86 +/- 13.2	Untreated hypertension	Up to 30% white coat hypertension or inappropriate technique/misdiagnosis	4,111	1.36%
6	1	0	1	91.8 +/- 6.6	Hypertensive but undocumented hypertension		35,186	11.60%
7	0	1	1	93.4 +/- 5.3	Controlled Hypertension		23,939	7.89%
8	1	1	1	95.6 +/- 2.0	Uncontrolled hypertension		29,955	9.88%
						Total # of Patients in Dataset:	303,221	

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Takeaways from the 8 Chamber

- Experts had **low confidence** that **any single value** accurately classified the patient as hypertensive
- The presence of two or more elements achieved high trust and concordance among experts (chambers 5-8)
- Using our framework, **~31%** of patients would be classified as **hypertensive** (chambers 5-8)

Independent Validation

- Assembled 10 clinical experts not exposed to the 8 Chamber Framework.
- IRB-approved chart review of 20 randomly chosen patients.
  - The patients must have had at least 3 clinic visits between 2017-2022
- Quantitative and Qualitative Analysis by the Experts: Was the patient hypertensive?
- Experts performed open chart reviews to discern hypertension diagnosis

Expert Validation Analysis

- Mixed-effects model to assess impact of each doctor on patient ratings

Tukey-Kramer Grouping for Doctor Least Squares Means (Alpha=0.05) LS-means with the same letter are not significantly different.		
Doctor		
10		A
		A
2		A
		A
1		A
		A
7		A
		A
3		A
		A
8	B	A
	B	A
6	B	A
	B	A
5	B	A
	B	A
4	B	A
	B	
9	B	

Expert Validation Analysis

Clinical Concept	Sub-category	# of Providers	# of References
Medication		10	135
	Medication Use	10	117
	Medication Ambiguity	6	13
	Absence of Medication	7	9
BP Readings		10	132
History		6	60
	Diagnosis of Hypertension	3	27
	Clinic Notes	2	23
	History of Hypertension	2	6
	Risk Factors	1	2
	Situational Blood Pressure	2	2
LVH on Echo		2	3

Summary

- Our study demonstrates a significant benefit of human-in-the-loop relative to ML learning based on published clinical guidelines.
- The 8-chamber framework for an improved hypertension phenotype is readily interpretable and computable, and mirrors clinical experts' decision-making, forming ground truth.
- The next step is to validate this work with real-world implementation.

Conclusions

- Clinical Guidelines can be accurately mapped into a knowledge base and prepped for AI/ML.
- We must replace documents with data (moving from file cabinets to dashboards).
- Good data is essential to promote good AI.

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