UCSD Applied Pharmacoeconomics and Outcomes Research Forum

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Disclosure

- The project described during today's presentation is a quality improvement project performed to improve patient care within the VA.
- The results of this quality improvement project may not be generalizable outside of VA.
- The contents of this presentation represent the views of the myself as project manager and do not represent the views of the Department of Veterans Affairs or the United States Government.

Introduction

- VA Clinical Pharmacists play an important role in assuring medication safety, providing medication management services, and improving clinical outcomes.
- The *Pharmacists Achieve Results with Medication Documentation (PhARMD)* Project
  - operational project which deployed a national data collection tool to document specific interventions and patient outcomes made by VA Clinical Pharmacists in their direct patient care role as non-physician providers.
  - data provides a means to identify patients receiving care from a Clinical Pharmacist and the disease state being treated.
  - patient demographics and biomarkers may be pulled from the electronic health record allowing for analysis of the outcomes achieved in that particular patient population.

Introduction

The Archimedes Model is a validated pharmacoeconomic tool which can accurately project long term clinical and economic consequences of changes in patient biomarkers over time adjusted for specific patient population demographics.

Validated tools, such as *The Archimedes Model,* allow for rapid and accurate estimation of the clinical outcomes one would expect to see based on the population biomarkers and those outcomes seen in large, randomized clinical trials.

This provides clinical outcomes data while eliminating the need to wait years to measure the incidence of hard outcomes.

In many disease states there is strong correlation between these biomarkers and clinical outcomes; including those covered by *The Archimedes Model* (Diabetes, Hypertension and Hyperlipidemia).

Infrastructure

Clinical Pharmacy Health Services Research Team

- Chartered in 2012
- Physician, Pharmacist and Health Services Researcher representation
- Pharmacoeconomic Modeling Workgroup

Collaboration on design, methods, implications, and conclusions of various projects

- Research
- Quality Improvement

Challenges

Resources

- Development of a Novel Model for VA Health System Use
  - Combining *PhARMD Project* data with *The Archimedes Model* simulation results can provide healthcare managers with important information on the cost benefits of various clinical pharmacy interventions and outcomes.
  - It is not feasible for every VA pharmacy department to obtain access to *The Archimedes Model*; PBM CPPO has performed multiple simulations and analyses utilizing national data that allow for local calculation of benefit-cost ratios for outcomes achieved by Clinical Pharmacists treating diabetes.

Changes in practice over time

- Lack of pharmacoeconomic models reflecting current clinical pharmacy practice patterns in the literature

The Archimedes Model

- Clinical trial-validated, individual-level simulation model of human physiology, disease progression and healthcare utilization.
- Represents the average level of U.S. healthcare delivery and includes care processes representative of current national treatment guidelines.
- Model has been used extensively for diabetes and the diabetes portion of the model has been validated by simulating 18 different clinical trials.
- Simulated individuals have a unique physiology that is evolutionary over time and causes them to acquire diseases, have symptoms and seek medical care.
- In diabetes, this evolution may result in health-related outcomes, such as a myocardial infarction or foot amputation.
- The model tracks events that could affect utilization, costs, health outcomes and quality of life.
- Visits, admissions, tests and procedures are included in utilization events.

Simulated Outcomes

Death	Major Adverse Cardiac Events (MACE)	Myocardial Infarction	Acute Heart Failure
Congestive Heart Failure	Coronary Artery Disease	Foot Ulcer	Foot Amputation
	Proliferative Diabetic Retinopathy	Stage III and Above Chronic Kidney Disease	

The absolute risk reduction (ARR) was reported for 2, 3, 5, and 10 year time horizons along with the corresponding number needed to treat (NNT)

Archimedes Outcomes

- Results were stratified by baseline HbA1c and achieved absolute reduction in HbA1c

	Baseline A1c 9-10%	Baseline A1c >10%
Sample Size	2,000	2,460
Achieved A1c Reduction	-0.8%	-2.1%

- Outcomes were evaluated at years 2, 3, 5, and 10
- Eight simulations were conducted based on the characteristics of the patients as determined by analysis of PhARMD Tool data
- Results reaching statistical significance ($p < 0.05$) are highlighted green
- ARR and NNT are included for all results to allow for contextual reference

HbA1c >10% with 3% HbA1c Reduction

Outcome	ARR (%) 2yr	2yr NNT	ARR (%) 3yr	3yr NNT	ARR (%) 5yr	5yr NNT	ARR (%) 10yr	10yr NNT
Death	0.20	500	0.35	289	0.70	143	1.45	69
MACE	0.65	154	0.80	125	1.32	76	2.55	39
MI	0.56	179	0.69	145	1.16	86	2.52	40
Acute HF	1.03	97	1.50	67	2.18	46	3.91	26
CHF	0.73	137	1.15	87	1.81	55	3.66	27
CAD	0.81	123	0.98	102	1.60	63	3.28	31
Foot Ulcer	2.12	47	2.99	33	4.52	22	7.73	13
Foot Amputation	0.71	141	1.05	95	1.34	75	3.02	33
PDR	0.07	1,388	0.14	732	0.44	228	1.40	71
Stage3 CKD and Above	0.32	307	0.64	156	0.97	103	1.43	70

Simulation Results

- Increasing HbA1c reductions from baseline decreases the likelihood of adverse events largely in the context of cardiovascular disease and foot-related outcomes
- Patients with a baseline HbA1c of >10% tended to separate from the control group over a shorter period of time than patients with baseline HbA1c 9-10%, particularly related to cardiovascular outcomes
- The largest evaluated cohort of PhARMD Reminder patients were those with a baseline HbA1c of >10%. These patients achieved a 2.1% decrease in HbA1c from baseline.
  - 2 years: decreased incidence of MI, CHF, foot ulcer, and foot amputation
  - 3 years: decreased Acute HF and CAD
  - 5 years: decreased MACE
  - 10 years: decreased PDR

Application: Cost-Benefit Analysis

Cost-Benefit Ratio: Determining Cost of Care

- **Local salary costs, baseline HbA1c, and achieved outcomes should be substituted for the data represented below**
- **Cost of CPS time:**
  - Annual Cost: $168,463 ($1.35/minute)
    - 1 CPS FTEE (GS-13, Step 5): $129,587
    - 30% fringe benefits: $38,876
- **Cost of CPS Care:**
  - (# of Visits) x (Avg Minutes/Visit) x $1.35/minute

Baseline HbA1c >10% with 3% HbA1c reduction at 5 years

Disease Cohort	Clinical Outcome	NNT	# Visits (Avg.)	$ Cost/Visit (Avg.)	Estimated Event Cost[a]	Benefit: Cost Ratio
Diabetes	Death					
	MACE					
	MI	86	6	$37.67	$26,562[b]	1.4:1
	Acute HF	46	6	$37.67	$2,552	0.2:1
	CHF	55	6	$37.67	$11,331	0.9:1
	CAD					
	Foot Ulcer	22	6	$37.67	$13,179	2.7:1
	Foot Amputation	75	6	$37.67	$60,647	3.6:1
	PDR					
	Stage3 CKD and Above	103	6	$37.67	$11,437	0.5:1

[a]Cost represents average value when more than one source is reported in Appendix A
[b]Cost represents acute event and subsequent annual cost for the following 4 years

Event costs derived from published literature sources.

MI: Baseline HbA1c >10% with 3% HbA1c reduction at 5 years

Clinical Outcome	NNT	# Visits (Avg.)	$ Cost/Visit (Avg.)	Estimated Event Cost[a]	Benefit: Cost Ratio
MI	86	6	$37.67	$26,562[b]	1.4:1

a) 86 NNT x 6 visits = 516 visits to prevent one MI at 5 years
b) 516 visits = 27.9 min/visit = 14,396 encounter minutes to prevent one MI
c) 14,396 min x $1.35/min = $19,436 employee cost to prevent one MI
d) Estimated Event Cost (MI): $26,562
e) $26,562 / $19,436 = 1.4:1

Cumulative Benefit

- All differences in event rates were achieved during the same set of visits
- There is overlap between the measured outcomes
  - A foot ulcer would precede a foot amputation. It is not correct to say that the event cost of a foot amputation is foot amputation plus foot ulcer.
- Having a composite outcome and associating a cost of that, would be necessary to determine a true return on investment
- Archimedes outputs didn't allow for the calculation of composite outcomes
- Not able to add the individual costs and benefits together

Lessons Learned

- Even with resources and infrastructure in place, difficulties remain
- Modeling needs exist in clinical areas not covered by a validated model such as Archimedes
- Lack of available literature requires building models from scratch
- Leverage expertise throughout the organization