Testing for equivalence: Establishing benchmarks to validate the use of primary care electronic health records as a chronic disease surveillance tool

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Testing for Equivalence:

Establishing benchmarks to validate Primary Care Electronic Health Records as a chronic disease surveillance tool

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Presenter Disclosures

Kathleen Tatem

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No relationships to disclose



Overview

- Background
- Equivalence Testing Methodology
- Benchmarking Study
 - Goals
 - Methods
 - Results
 - Conclusions



Electronic Health Record (EHR) Use





NYC Macroscope



Chronic Disease Surveillance

Diabetes	Х	%
Hypertension	Х	%
High Cholesterol	.X	%
Smoking	Х	%
Depression	Х	%
Obesity	Х	%
Influenza vaccination	.Х	%







Equivalence testing (TOST)

- Schuirman's (1987) TOST method:
 - Conduct two one-sided t-test for mean or mean difference
 - Question: "Are these two measures significantly the same?"
 - Commonly used in non-inferiority/equivalence randomized controlled trials
- **KEY:** Establish an *"equivalence margin"* that can be justified



Hypothesis Testing



Health

8

Hypothesis Testing Cont...

Difference (Two-sided t-test)

95% CI= (1- α)*100 •



Equivalence (TOST)

90% CI = $(1-2\alpha)$ *100





Images adapted from: Walker, E., & Nowacki, A. S. (2010). Understanding equivalence and noninferiority testing. Journal of General Internal Medicine, 26, 192–196. 9

Hypothesis Testing Cont...

Equivalence (TOST)

Survey	Mea	an	Lower Bound	90% CL	. Mean*	Upper Bound	Assessment
				> -	-0.1905		
Diff (1-2)	-2.8	265	-5	5.4618	<	5	Not equivalent
		Test*	Null	DF	t Value	P-Valu	e
		Lower	-5	1714.3	3 1.36	0.0874	
		Upper	5	1714.3	3 -4.89	<.0001	L
		Overal				0.0874	1

*Satterthwaite method for unequal variances



Benchmarking Study Goal

- Aim 1: Determine the most appropriate equivalence margins to compare NYC Macroscope prevalence estimates to current gold-standard survey estimates
- Aim2: Quantify the maximum difference between NYC HANES and CHS point estimates for health indicators of interest to set empirical benchmark values to provide greater context for interpretation of the NYC Macroscope validation studies.



BENCHMARK STUDY: NYC HANES AND CHS



Methods: Study Populations

- Restricted to "in-care" population ages 20 and older
- Weighted to NYC population based on 2012 and 2013 ACS and ageadjusted to US 2000 Standard Population

- NYC HANES (HANES), 2013-2014

- Gold-standard survey
- Household –based sampling with in person interviews, physical examination, collection of biological specimens/labs
- Estimated N=1135

- Community Health Survey (CHS), 2013

- Annual, representative, population-based, random-digit dialed telephone survey of adults in NYC modeled—self report
- Estimated N=6166

*In-care= reported seeing a doctor or health-care professional within the last 12 months



Health Indicators

Diabetes

Ever told
*A1C >=6.5 or told + prescribed med (H) vs. Ever told (C)

Hypertension

• Ever told

• *HTN I/II or ever told + prescribed med (H) vs. Ever told (C)

High Cholesterol

• Ever told

 *Chol. >=240 or ever told + prescribed med (H) vs.
 Ever told (C)

Smoking

• Current Smoker

Depression

• Ever told

Obesity

• Obese/overweight (BMI > 25)

- Obese (BMI<u>></u>30)
- Extreme obesity (BMI >40)

Influenza vaccination (within last 12 months)

*Gold standard measure



Methods: Statistical Analysis

- Prevalence estimates and 95% CI
- Metrics of goodness-of-fit (a priori criteria):
 - Equivalence test— TOST
 - (-/+δ= 5; p<0.05)
 - Mean difference—two sample t-test (p<0.05)
 - Prevalence difference (5 points)
 - Prevalence ratio (0.85-1.15)



NYC HANES AND CHS RESULTS







CHS vs. NYC HANES (+/-5)

Equivalent and		EQUIVALENCE TEST			
(EOUAL)			Significant	Not Significant	
((equal)	(not equal)	
			- Depression (Ever told)		
Not equivalent	⊢⊢		- Serious Psychological	- Current Smoker	
and not different	ES	Not	Distress (PSD)		
(Undetermined)	H	는 Significant 巴 (not	- Diabetes (Ever Told)		
	<u> </u>		- Flu Vaccine		
Equivalent and		aifferent)	- Hypertension (Ever Told)		
different	ER		- High Cholesterol (Ever Told)		
(Equivalent difference is negligible)	DIFF	Significant	- Extreme Obesity	 Diabetes (Gold standard) Hypertension (Gold standard) Obese 	
		(different)		- High Cholesterol—	
Not equivalent				(Gold standard)	
but different					



(DIFFERENT)





CHS vs. NYC HANES (+/-2.5)

Equivalent and			EQUIVALE	NCE TEST		
(FOUAL)			Significant	Not Significant		
			(equal)	(not equal)		
Net envirelant				- Depression (Ever told)		
Not equivalent	μ.	N I - 1	- Serious Psychological	- Current Smoker		
and not different	ES	NOT	Distress (PSD)			
(Undetermined)		Significant		- Diabetes (Ever Told)		
		(not different)		- Flu Vaccine		
Equivalent and		amerentj		- Hypertension (Ever Told)		
different	ER			- High Cholesterol (Ever Told)		
(Equivalent				- Diabetes (Gold standard)		
difference is				- Hypertension (Gold standard)		
negligible)		Significant		- Obese		
		(different)		- Extreme Obesity		
Not equivalent but different				- High Cholesterol— (Gold standard)		
Sacamerent						



(DIFFERENT)





CHS vs. NYC HANES (+/-7.5)

Equivalent and			EQUIVALENCE T	EST
(EQUAL)			Significant	Not Significant
			(equal)	(not equal)
Not equivalent			- Current Smoker	
and not different			- Depression (Ever told)	
(Undetermined)	ST	Not	- Serious Psychological	
(Ondetermined)	Ē	Significant	Distress (PSD)	
	Щ	(not	- Diabetes (Ever Told)	
Equivalent and	Ž	different)	- Flu Vaccine	
different	RE		- Hypertension (Ever Told)	
(Equivalent			- High Cholesterol (Ever Told)	
difference is negligible)	ΗC		- Diabetes (Gold standard)	
		<u>.</u>	- Hypertension (Gold standard)	
		Significant	- Extreme Obesity	- Obese
Not equivalent		(different)		- High Cholesterol—
but different				(Gold standard)
(DIFFERENT)				



Which margin is best?

Margin	Equivalent/ No diff	Not equal/No Diff (Discordant)	Equal/ Diff (Discordant)	Not equal/Different
+/- 2.5	1	5	0	6
+/- 5	6	1	1	4
+/- 7.5	6	0	4	2



Consistently Equivalent: Hypertension(ever told)

CHS % (95% CI)	HANES % (95% CI)	Difference	90% CI (TOST)	95% Cl (T-test)
31.6 (30.2-33.0)	32.4 (29.3-35.6)	-0.81	(-3.7,2.1)	(-4.3 <i>,</i> 2.6)

	TOST (+/-δ=5)	Student's T-Test
A Priori Criteria	P< .05	P< .05
Benchmark CHS vs. HANES	0.0085	0.6453



Consistently Different: Obesity

CHS % (95% CI)	HANES % (95% CI)	Difference	90% CI (TOST)	95% Cl (T-test)
24.7 (23.2-26.3)	31.3 (28.5-34.2)	-6.56	(-9.3,-3.8)	(-9.8,-3.3)

	TOST (+/-δ=5)	Student's T-Test
A Priori Criteria	P< .05	P< .05
Benchmark CHS vs. HANES	0.8256	<.001



Inconclusive: Smoking

CHS % (95% CI)	HANES % (95% CI)	Difference	90% CI (TOST)	95% Cl (T-test)
14.9 (13.6-16.3)	17.7 (15.1-20.8)	-2.8	(-5.5,-0.2)	(-6.0, 0.3)

	TOST (+/-δ=5)	Student's T-Test
A Priori Criteria	P< .05	P< .05
Benchmark CHS vs. HANES	0.09	0.08



Exception: Small prevalence, smaller margin? Extreme Obesity & SPD

Indicator	CHS % (95% CI)	HANES % (95% CI)	Difference	90% CI (TOST)	95% Cl (T-test)
Extreme Obesity	3.50 (2.90, 4.21)	5.14 (3.85, 6.83)	-1.7	(-9.3,-3.8)	(-3.3 <i>,</i> - 0.05)
SPD	5.38 (4.74, 6.09)	4.77 (3.49 <i>,</i> 6.47)	0.6	(-0.7, 2.0)	(-1.0, 2.2)

	Indicator	TOST (+/-=5)	TOST (+/-=2.5)	Student's T- Test
A Priori Criteria	—	P< .05	P<.05	P< .05
Benchmark	Extreme Obesity	<.0001	0.1475	0.0438
CHS vs. HANES	SPD	<.0001	0.0107	0.4533



Validation methods

- <u>Metrics of goodness-of-fit (*a priori* criteria):</u>
 - Equivalence test— TOST
 - (-/+= 5; p<0.05)
 - Mean difference—two sample t-test (p<0.05)

Conclusions

- Aim1: An equivalence margin of +/- 5 appeared to be the most appropriate margin for estimates with a prevalence estimate larger than 10
 - A margin of +/-2.5 may be a more appropriate margin for indicators with a prevalence estimate less than 10
- Aim 2: Global comparisons of NYC HANES and CHS produced established benchmarks to offer guidance/context to interpret NYC Macroscope v NYC HANES results



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Questions?

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