Are Misinterpreted, Hospital-level Relationships Between Process Performance Measures and Outcomes Undermining Evidence-based Patient Care?

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Outline of Presentation

- Introduction
- Background: The “Ecological Fallacy”
- Continuing Care PM for Patients with Substance Use Disorders – Illustrative Data
- How Differences Occur Between Facility- and Patient-Level PPM-Outcome Relationships
- Why Differences Occur Between Facility- and Patient-Level PPM-Outcome Relationships
- Implications for Health Care Quality Management and Research

Introduction

- Performance measurement – one factor pointed to as driving substantial improvement in health care
- Many performance measures (PMs) assess the extent to which processes of care, that have been shown to "cause" or at least to relate to positive outcomes among research participants, are applied in a health care facility (process performance measures - PPMs)
- Used to rate health care providers, facilities (e.g., hospitals), health care systems, states, and countries on quality of care

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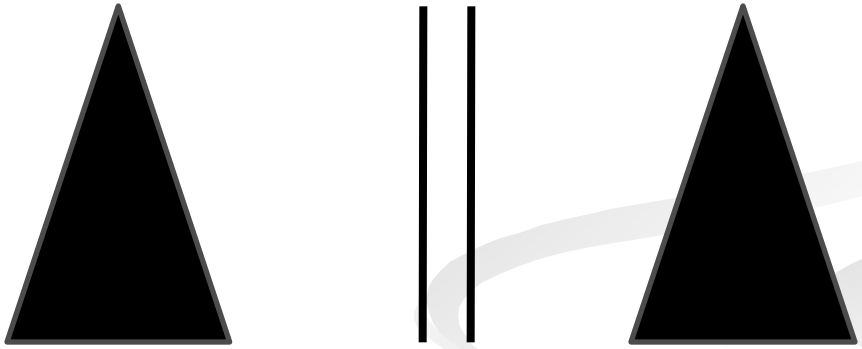
Introduction

Process measures of health care quality typically are implemented on the assumption that:

- Patient-level care processes aggregated to the facility level are associated with positive facility-level (aggregated) outcomes in the same way as was found at the patient-level in supporting research.

Introduction

Facilities: PM Care Rate → Outcome Rate



Patients: PM Care Y/N → Outcome

Introduction

An example of the “homology” assumption – the assumption that things work the same at different levels of organization or analysis (Hannon, 1970)

Introduction

Linking facility performance rates to facility outcomes is thought of as one way to validate process of care performance measures or as a form of “post-implementation surveillance”:

But, investigators examining facility-level PPM-outcome linkages sometimes have found weak or non-existent relationships.

Hospital Quality for Acute Myocardial Infarction

Correlation Among Process Measures and Relationship With Short-term Mortality

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Context The Centers for Medicare & Medicaid Services (CMS) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) measure and report quality process measures for acute myocardial infarction (AMI), but little is known about how these measures are correlated with each other and the degree to which inferences about a hospital's outcomes can be made from its performance on publicly reported processes.

Objective To determine correlations among AMI core process measures and the degree to which they explain the variation in hospital-specific, risk-standardized, 30-day mortality rates.

Design, Setting, and Participants We assessed hospital performance in the CMS/JCAHO AMI core process measures using 2002-2003 data from 962 hospitals participating in the National Registry of Myocardial Infarction (NRMI) and correlated these measures with each other and with hospital-level, risk-standardized, 30-day mortality rates derived from Medicare claims data.

Main Outcome Measures Hospital performance on AMI core measures; hospital-specific, risk-standardized, 30-day mortality rates for AMI patients aged 66 years or older.

Results We found moderately strong correlations (correlation coefficients ≥0.40; *P* values <.001) for all pairwise comparisons between β-blocker use at admission and discharge, aspirin use at admission and discharge, and angiotensin-converting enzyme inhibitor use, and weaker, but statistically significant, correlations between these medication measures and smoking cessation counseling and time to reperfusion therapy measures (correlation coefficients <0.40; *P* values <.001). Some process measures were significantly correlated with risk-standardized, 30-day mortality rates (*P* values <.001) but together explained only 6.0% of hospital-level variation in risk-standardized, 30-day mortality rates for patients with AMI.

Conclusions The publicly reported AMI process measures capture a small proportion of the variation in hospitals' risk-standardized short-term mortality rates. Multiple measures that reflect a variety of processes and also outcomes, such as risk-standardized mortality rates, are needed to more fully characterize hospital performance.

JAMA. 2006;296:72-78 www.jama.com

As part of the national effort to improve hospital quality, the Centers for Medicare & Medicaid Services (CMS) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) monitor and publicly report hospital performance on acute myocardial infarction (AMI) "core" process measures approved by the Hospital Quality Alliance.[1] Although the CMS/JCAHO process measures are considered indicators of quality of AMI care,[2] little is known about how these measures track with each other. Five of the 7 CMS/JCAHO process measures assess medication prescription practices. Because these processes are likely to be amenable to similar quality improvement interventions, one might expect them to be strongly correlated at the hospital level. In contrast, timely reperfusion therapy, which involves coordination

For editorial comment see p 95.

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Bradley et al. (2006)

Centers for Medicare & Medicaid Services (CMS) and Joint Commission on Accreditation of Healthcare Organizations "Core" Processes for AMI

	Beta Blocker Admit	Beta Blocker Dischg.	Aspirin Admit	Aspirin Dischg.	ACE Inhib Admit	Smoking Cessation	Timely Reper-fusion Therapy	Composite
30-day, all-cause risk-adj. mortality rate	**−0.03**	**−0.16†**	**−0.06**	**−0.18†**	**−0.10**	**−0.03**	**−0.18†**	**−0.25†**
In-hospital, all-cause risk-adj. mortality rate	**−0.04**	**0.07**	**−0.12**	**0.10**	**0.06**	**−0.01**	**−0.04**	**0.02**

†p<.001
N=962 hospitals

Relationship Between Medicare's Hospital Compare Performance Measures and Mortality Rates

Rachel M. Werner, MD, PhD
Eric T. Bradlow, PhD

Context In response to concerns about the quality of care in US hospitals, the Centers for Medicare & Medicaid Services began measuring hospital performance and reporting this performance on their Web site, Hospital Compare. It is unknown whether these process performance measures are related to hospital-level outcomes.

Objective To determine whether quality measured with the process measures used in Hospital Compare are correlated with and predictive of hospitals' risk-adjusted mortality rates.

Design, Setting, and Participants Cross-sectional study of hospital care between January 1 and December 31, 2004, for acute myocardial infarction, heart failure, and pneumonia at acute care hospitals in the United States included on the Hospital Compare Web site. Ten process performance measures included in Hospital Compare were compared with hospital risk-adjusted mortality rates, which were measured using Medicare Part A claims data.

Main Outcome Measures Condition-specific inpatient, 30-day, and 1-year risk-adjusted mortality rates.

Results A total of 3657 acute care hospitals were included in the study based on their performance as reported in Hospital Compare. Across all acute myocardial infarction performance measures, the absolute reduction in risk-adjusted mortality rates between hospitals performing in the 25th percentile vs those performing in the 75th percentile was 0.005 for inpatient mortality, 0.006 for 30-day mortality, and 0.012 for 1-year mortality ($P<.001$ for each comparison). For the heart failure performance measures, the absolute mortality reduction was smaller, ranging from 0.001 for inpatient mortality ($P=.03$) to 0.002 for 1-year mortality ($P=.08$). For the pneumonia performance measures, the absolute reduction in mortality ranged from 0.001 for 30-day mortality ($P=.05$) to 0.005 for inpatient mortality ($P<.001$). Differences in mortality rates for hospitals performing in the 75th percentile on all measures within a condition vs those performing lower than the 25th percentile on all reported measures for acute myocardial infarction ranged between 0.008 ($P=.06$) and 0.018 ($P=.008$). For pneumonia, the effects ranged between 0.003 ($P=.09$) and 0.014 ($P<.001$); for heart failure, the effects ranged between −0.013 ($P=.06$) and −0.038 ($P=.45$).

Conclusions Hospital performance measures predict small differences in hospital risk-adjusted mortality rates. Efforts should be made to develop performance measures that are tightly linked to patient outcomes.

JAMA. 2006;296:2694-2702 www.jama.com

IT IS WIDELY RECOGNIZED THAT THE quality of health care in the United States is uneven and often inadequate.[1,2] In the outpatient setting, quality of care varies across individuals depending on age, sex, race, and socioeconomic status.[3] Overall, only half of US individuals receive recommended care.[1] In hospitals, quality of care is also variable. Compliance with hospital performance measures varies not only across US hospitals but also across regions, conditions, and performance measures.[4]

Because it is assumed that measuring quality of care is a key component in improving care, quality measurement is playing an increasingly prominent role in quality improvement. For example, quality is measured and in many cases reported for hospitals,[5-10] health plans,[11] nursing homes,[12] home health agencies,[13] and physicians.[14-16] These efforts are designed to provide an incentive to improve the quality of the care delivered and to influence consumer choice of providers.[17,18] These measures also are increasingly being used to determine clinicians' reimbursement.[19-21]

Recently, the US Centers for Medicare & Medicaid Services (CMS), along with other health care organiza-

See also p 2731.

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Werner and Bradlow (2006)

Absolute Reduction in Risk-adjusted Mortality Between Hospitals Performing in the 75th versus 25th Percentiles (N=3,657 Acute Care Hospitals)

CMS Composite Performance Measure for:	Inpatient Mortality	30-day Mortality	1-year Mortality
Myocardial Infarction	0.005 *(p=.003)*	*0.007 (p=.002)*	0.012 (p<.001)
Heart Failure	0.001 *(p=.08)*	0.001 *(p=.14)*	0.002 *(p=.23)*
Pneumonia	*0.005 (p=.01)*	*0.003 (p=.15)*	*0.007 (p=.02)*

(Italicized from a correction in JAMA, 2007, 297(7), p. 700.)

ORIGINAL ARTICLE

Hospital Process Compliance and Surgical Outcomes in Medicare Beneficiaries

Lauren H. Nicholas, PhD; Nicholas H. Osborne, MD; John D. Birkmeyer, MD; Justin B. Dimick, MD, MPH

Objectives: To determine whether high rates of compliance with perioperative processes of care used for public reporting and pay-for-performance are associated with lower rates of risk-adjusted mortality and high-risk surgical complications.

Design: Retrospective analysis of Medicare inpatient claims data (from January 1, 2005, through December 31, 2006). Hierarchical logistic regression models assessed the relationship between adverse outcomes and hospital compliance with the surgical processes of care reported on the Hospital Compare Web site.

Setting: Two thousand US hospitals.

Participants: Beneficiaries who underwent 1 of 6 high-risk operations in 2005 and 2006.

Main Outcome Measures: Thirty-day postoperative mortality rate, venous thromboembolism, and surgical site infection.

Results: Process compliance ranged from 53.7% in low compliance hospitals to 91.4% in high compliance hospitals. Risk-adjusted outcomes did not vary at high compliance hospitals relative to medium compliance hospitals for mortality rate (odds ratio, 0.98; 95% confidence interval, 0.92-1.05), surgical site infection (1.01; 0.90-1.13), or venous thromboembolism (1.04; 0.89-1.20). Outcomes also did not vary at low compliance hospitals. Stratified analyses by operation type confirm these trends for the 6 procedures individually.

Conclusions: Currently available information on the Hospital Compare Web site will not help patients identify hospitals with better outcomes for high-risk surgery. The Centers for Medicare and Medicaid Services needs to identify higher leverage process measures and devote greater attention to profiling hospitals based on outcomes to improve public reporting and pay-for-performance efforts.

Arch Surg. 2010;145(10):999-1004

As variations in surgical quality are increasingly observed, payers are escalating efforts to reduce them.[1-3] The Centers for Medicare and Medicaid Services (CMS), the largest public payer, now mandates public reporting of 2 sets of the Surgical Care Improvement Project (SCIP) measures covering infection and venous thromboembolism. Hospitals are required to submit data quarterly, which are posted on the Hospital Compare Web site (http://www.hospitalcompare.hhs.gov/), to receive annual Medicare payment updates.[4] This reporting is believed to aid patients and payers in choosing high-quality hospitals and to stimulate quality improvement among reporting hospitals.[5-7]

See Invited Critique at end of article

It is unclear whether these efforts will translate into better outcomes for surgical patients. Although the SCIP measures were selected because of strong evidence linking them to certain outcomes, there is reason to be skeptical that improved compliance will result in significant improvements in the most important outcome, risk-adjusted mortality rate. Namely, SCIP processes are associated with outcomes that are rare (eg, deep venous thrombosis and pulmonary embolism) or considered secondary (eg, superficial surgical site infections).[8,9] It is unknown whether measured processes of care are important determinants of surgical outcomes. If there is a weak link between process compliance and surgical outcomes, CMS public reporting and pay-for-performance efforts will be unlikely to stimulate important improvements or to help patients find the safest hospitals.[10,11]

In this context, we sought to determine whether hospital compliance rates for targeted surgical processes of care reported on the Hospital Compare Web site are related to risk-adjusted mortality rate, venous thromboembolism, and surgical site infection. We used national Medicare

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Nicholas et al. (2010)

CMS Surgical Care Improvement Project (SCIP) data for 2,000 U.S. hospitals:

Odds of Risk-Adjusted Surgical Mortality Rate in High and Low SCIP Compliant Hospitals, 2005-2006

Overall	Contemporaneous	Lagged
Highest quintile quality	0.98 (0.92-1.05)	0.96 (0.86-1.06)
Lowest quintile quality	1.06 (0.97-1.16)	1.09 (0.97-1.22)

Nicholas, LH, Osborne NH, Birkmeyer JD, and Dimick JB. 2010. Hospital process compliance and surgical outcomes in Medicare beneficiaries. *Archives of Surgery* 145: 999-1004.

Reactions to Findings

Bradley et al. (2006) and Werner and Bradlow (2006) noted a variety of factors that might have reduced relationships between facility-level PPM rates and facility-level mortality rates:

E.g., high level of compliance (restricted range) for some practices (e.g., aspirin at admission for AMI).

Insensitivity of in-hospital and 30-day mortality as outcomes.

Reactions to Findings

Mabry (2010), commenting on Nicholas et al. (2010):

"These findings, if true, call into serious question the increased time, labor, and effort currently expended by hospitals and surgeons across the United States to comply with the SCIP program process measures. . . . How can it be that the National Quality Forum, CMS, and others got it wrong?'" (p. 1104).

Mabry CD. 2010. "Say it ain't so, Joe." Archives of Surgery, 145(10), 1004-1005.

Reactions to Findings

Surgeons in the VA and at Stanford University have questioned why they should be held accountable to surgical practice performance measures that are not related to patient outcomes.

Reactions to Findings

"Efforts should be made to develop performance measures that are tightly linked to patient outcomes" (Werner & Bradlow, 2006, p. 2,694).

But neither they, nor any of the authors cited earlier, raised the possibility that PM-specified practices might relate differently to outcomes at the patient level than at the hospital level.

Werner RM, and Bradlow ET. 2006. Relationship between Medicare's Hospital Compare performance measures and mortality rates. *JAMA 296*(22): 2694-2702.

Aim of AJPH Article

Provide a non-technical overview of relevant multilevel issues that would be accessible to a wide range of stakeholders:

- Clinicians
- Researchers
- Quality managers
- Health care leaders
- Members of performance measure bodies

Drew on Alex's statistical expertise and on the relevant epidemiological, sociological and statistical literature.

Background: The “Ecological Fallacy”

1930 Census Data

State level: Proportion foreign-born state residents correlated -.53 with state English illiteracy rate

Individual level: Correlation +.12

Conclusion: Cannot infer relationships for individuals from relationships for higher-level units.

Robinson WS. 1950. Ecological correlations and the behavior of individuals. *American Sociological Review 15:*351-357.

Later Methodological Literature

More recent considerations of this issue (e.g., Firebaugh 1978; Greenland 2001; 2002; Greenland and Morgenstern 1982; Morgenstern 1982; Schwartz 1994; Subramanian et al. 2009; Susser 1994):

- Have been more even-handed: addressing problems of inference in moving from lower- to higher-level units, as well as from higher- to lower-level units
- Addressed the incompleteness of many single-level analyses
- Stressed the need for multilevel analyses (e.g., Duncan et al., 1998; Greenland 2002; Localio et al., 2001)

Continuing Care PM for Patients with Substance Use Disorders: Illustrative Data

To meet the PPM, a patient must have had at least 2 SUD clinic visits in each of three consecutive 30-day periods following a “qualifying” discharge or visit.

Harris, AHS, Humphreys K, Bowe T, Kivlahan D, and Finney JW. 2009. Measuring the quality of substance use disorder treatment: Evaluating the validity of the VHA continuity of care performance measure. *Journal of Substance Abuse Treatment 36*: 294-305.

Continuing Care PM for Patients with Substance Use Disorders: Illustrative Data

For simplicity, we:

- Randomly selected one of five datasets with imputed missing data that were averaged in Harris et al. (2009)
- Ignored the fact that at some facilities' patients were drawn from more than one SUD program, and at other facilities patients were not sampled from all the SUD programs
- Ignored providers and programs/clinics as intervening levels
- Did not control for covariates (will discuss confounding later)

Continuing Care PM for Patients with Substance Use Disorders: Illustrative Data

- Subgroup of 1,485 patients in VHA SUD treatment identified by Harris et al. (2009) as non-abstinent (alcohol or drugs) in the 30 days prior to a baseline assessment – selected for a reason.
- Subgroup from non-methadone SUD programs at 72 facilities.
- Followed-up an average of 7.3 months later, at which point abstinence for the past 30 days was assessed.
- Follow-up rate was a little over 65%.
- Outcome data imputed for those individuals not followed (see Harris et al., 2009, for more details on the sample and data collection and imputation methods).

Continuing Care PM for Patients with Substance Use Disorders: Illustrative Data

Ran three analyses to examine CC PM-abstinence relationships:

1. Facility-level analysis

2. Mixed-effects analysis with facility as random factor

3. Multilevel analysis

Analysis 1: Regression Analysis Linking Facility CC Performance Rate to Facility Abstinence Rate

(N=72 Facilities)

Variable	Regression Coefficient	Standard Error	Significance Level
Intercept	.447	.023	<.001
Rate of CC	.045	.065	.489 (ns)

Analysis 2: Mixed-effects Patient-level Analysis with Facility as a Random Factor (N=1,485 Patients)

Variable	Regression Coefficient	Standard Error	Significance Level	OR	CI
Intercept	-.323	.063	<.001		
CC (Y/N)	.558	.115	<.001	1.75	1.40-2.19

Analysis 3: Multilevel Analysis of Between- and Within-facility (Patient-level) Relationships

Variable	Regression Coefficient	Standard Error	Significance Level	OR	CI
Intercept	-.193	.100	.055		
CC (Y/N)					
Rate of CC	-.509	.305	<.100	.60	.33-1.09

Analysis 3: Multilevel Analysis of Between- and Within-facility (Patient-level) Relationships

Variable	Regression Coefficient	Standard Error	Significance Level	OR	CI
Intercept	-.193	.100	.055		
CC (Y/N)	.647	.127	<.001	1.91	1.49-2.45
Rate of CC	-.509	.305	<.100	.60	.33-1.09

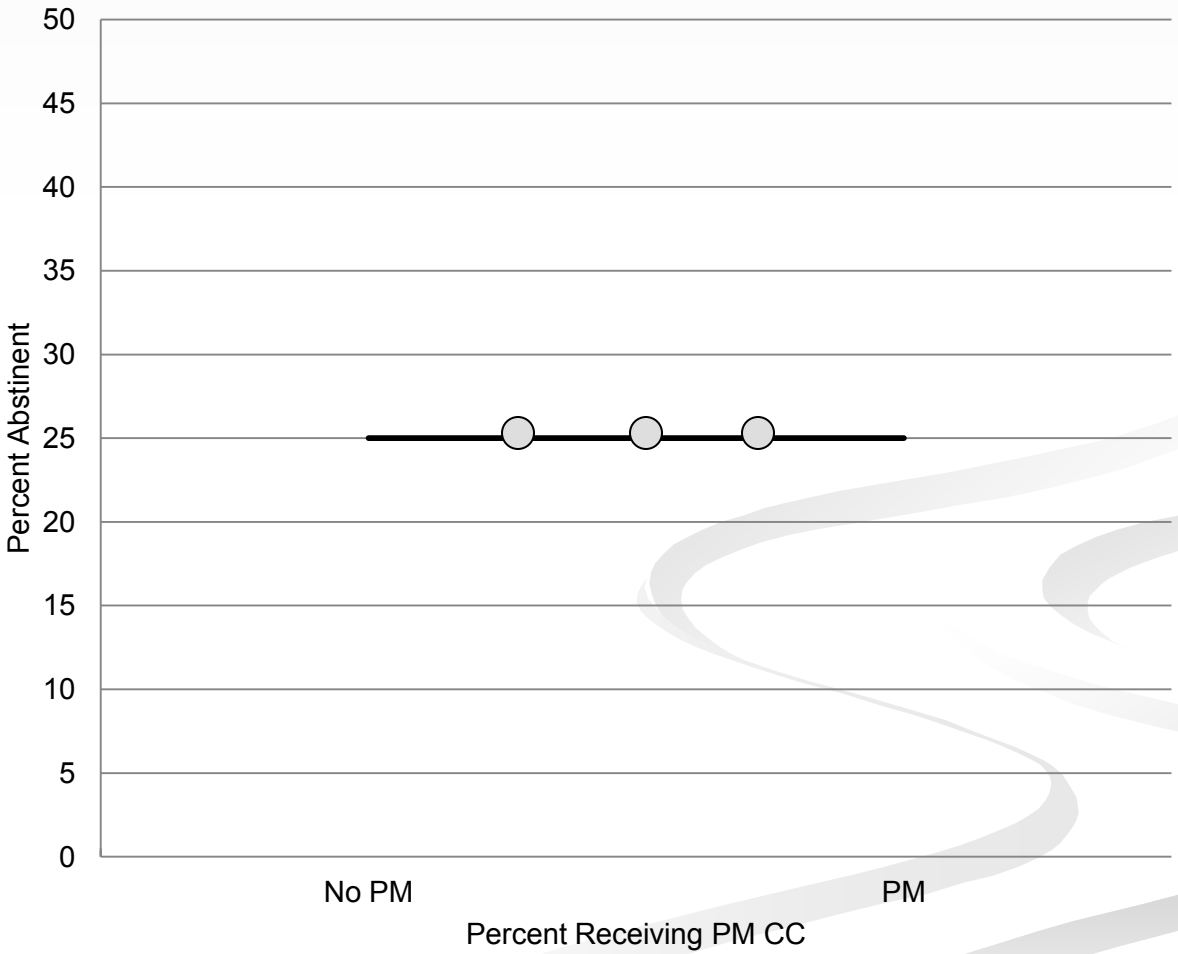
How Do Differences Occur Between Facility- and Patient-Level PPM-Outcome Relationships?

(Greenland & Morgenstern, 1989; Greenland, 2001)

Three Hypothetical Facilities with the Different CC PM Rates and the Same Abstinence Rate

	Facility A	Facility B	Facility C
CC PM Rate	**33%**	**52%**	**72%**
Abstinence Rate	**25%**	**25%**	**25%**

Zero Facility-level Relationship of CC PM to Abstinence for Three Hypothetical Facilities



Three Hypothetical Facilities with the Different CC PM Rates and the Same Abstinence Rate - Marginal Distributions

		Facility A			Facility B			Facility C		
		Abstinence			Abstinence			Abstinence		
		Y	N		Y	N		Y	N	
PM	Y			33%			52%			72%
	N			67%			48%			28%
		25%	75%	100%	25%	75%	100%	25%	75%	100%

Three Hypothetical Facilities with the Different CC PM Rates and the Same Abstinence Rate - Marginal and Joint Distributions

		Facility A			Facility B			Facility C		
		Abstinence			Abstinence			Abstinence		
		Y	N		Y	N		Y	N	
PM	Y	---	---	33%	---	---	52%	---	---	72%
	N	---	---	67%	---	---	48%	---	---	28%
		25%	75%	100%	25%	75%	100%	25%	75%	100%

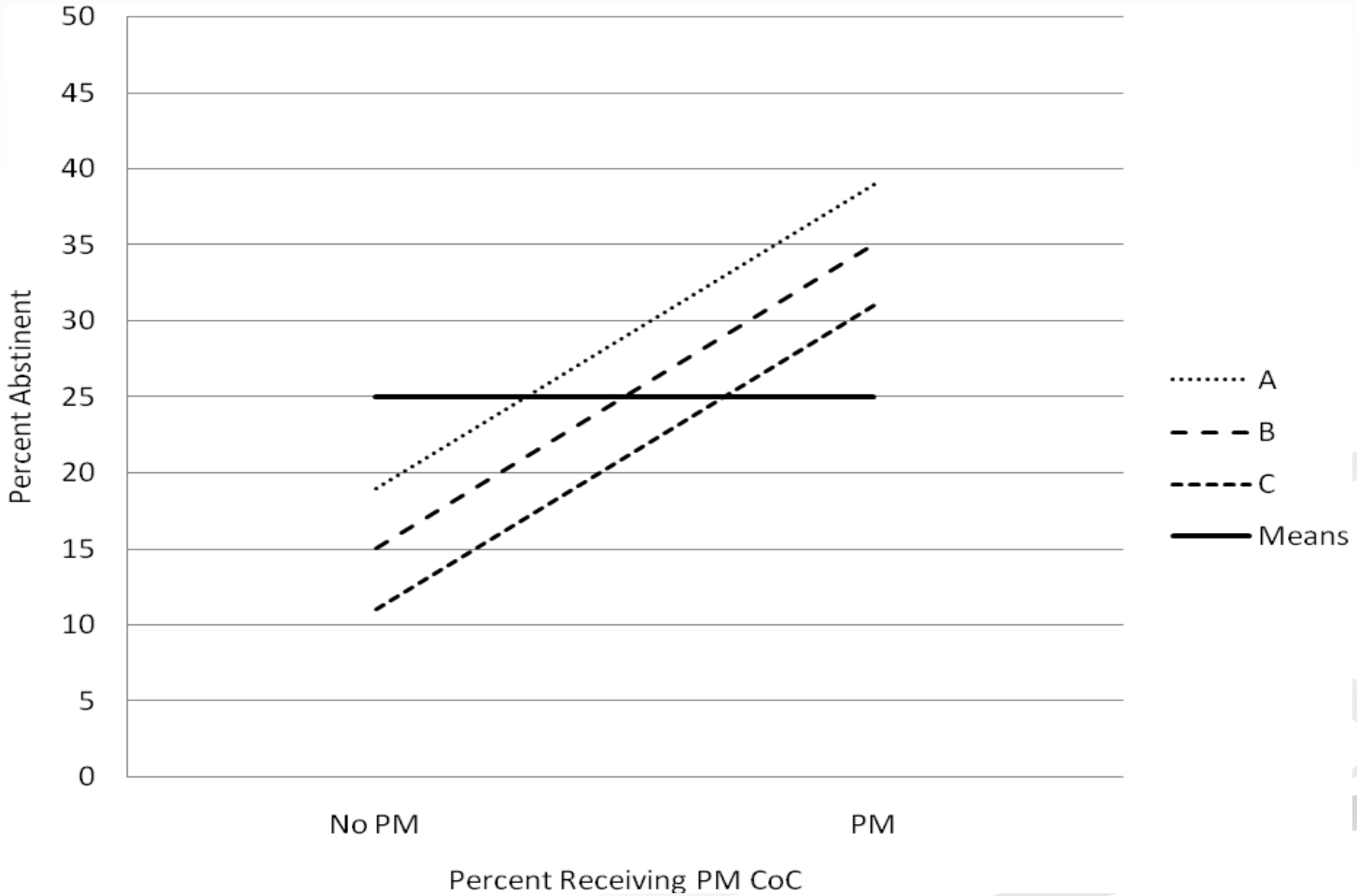
Three Hypothetical Facilities with the Different CC PM Rates and the Same Abstinence Rate - Marginal and Joint Distributions

		Facility A			Facility B			Facility C		
		Abstinence			Abstinence			Abstinence		
		Y	N		Y	N		Y	N	
PM	Y	---	---	66	---	---	104	---	---	144
	N	---	---	134	---	---	96	---	---	56
		50	150	200	50	150	200	50	150	200

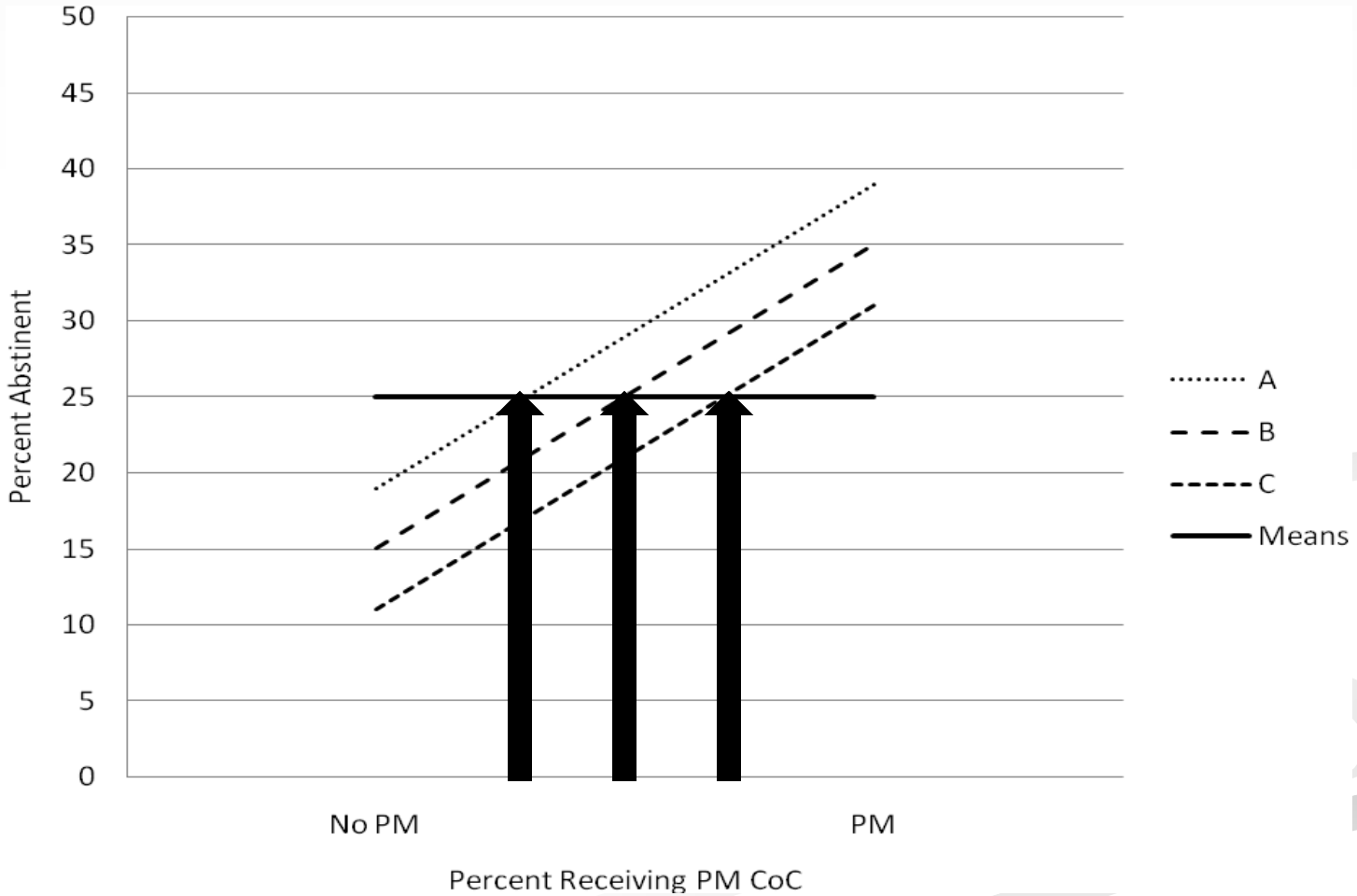
Three Hypothetical Facilities with the Different CC PM Rates and the Same Abstinence Rate - Marginal and Joint Distributions

		Facility A			Facility B			Facility C		
		Abstinence			Abstinence			Abstinence		
		Y	N		Y	N		Y	N	
PM	Y	*26*	*40*	66	*36*	*68*	104	*44*	*100*	144
	N	*24*	*110*	134	*14*	*82*	96	*6*	*50*	56
		50	150	200	50	150	200	50	150	200

Zero Facility-level Relationship of CC PM to Abstinence with Similar Positive PPM-Abstinence Relationships for Patients Within Three Hypothetical Facilities



Zero Facility-level Relationship of CoC PM to Abstinence with Similar Positive PPM-Abstinence Relationships for Patients Within Three Hypothetical Facilities



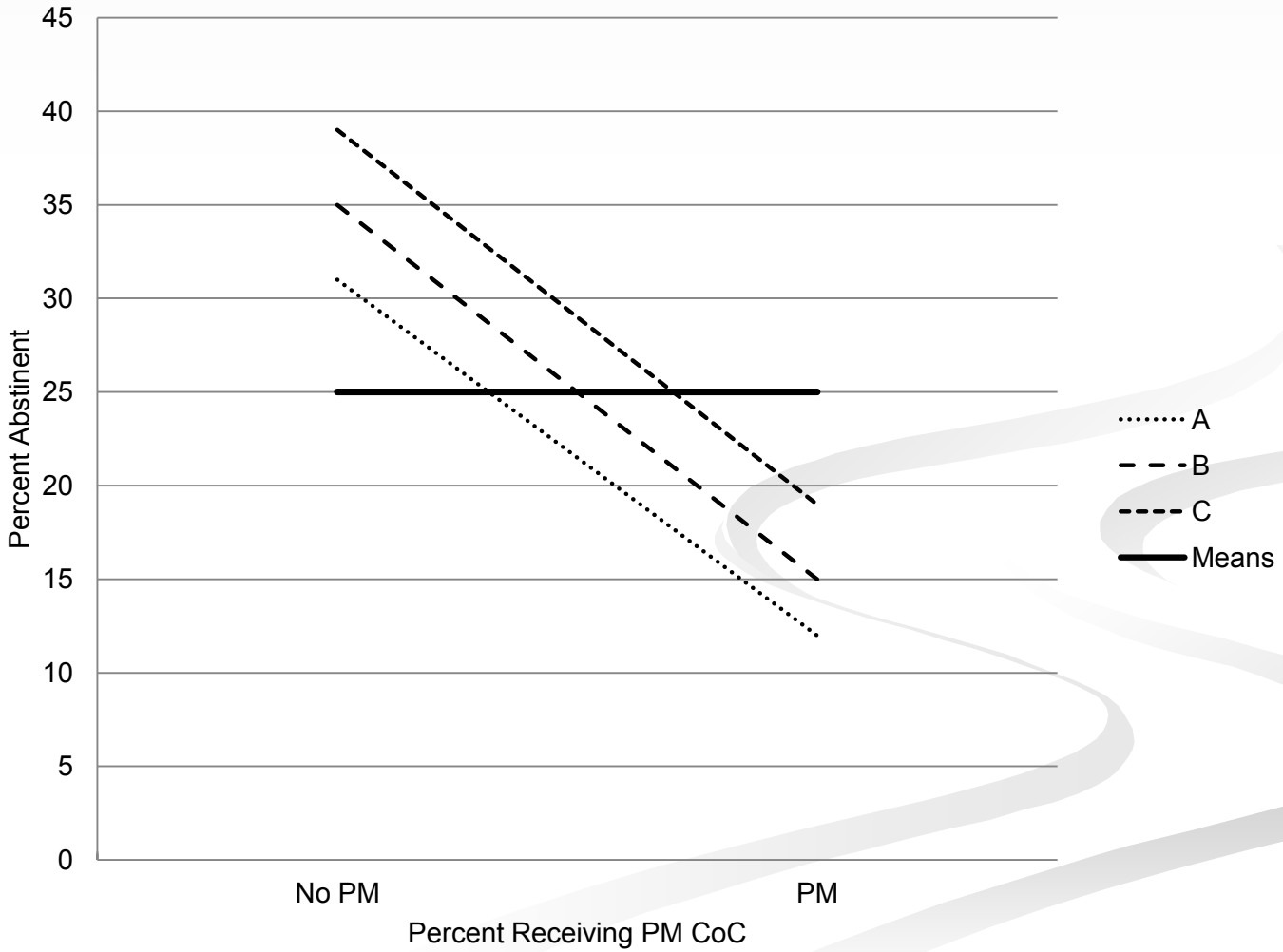
Three Hypothetical Facilities with the Different CC PM Rates and the Same Abstinence Rate - Marginal and Joint Distributions

		Facility A			Facility B			Facility C		
		Abstinence			Abstinence			Abstinence		
		Y	N		Y	N		Y	N	
PM	Y	---	---	66	---	---	104	---	---	144
	N	---	---	134	---	---	96	---	---	56
		50	150	200	50	150	200	50	150	200

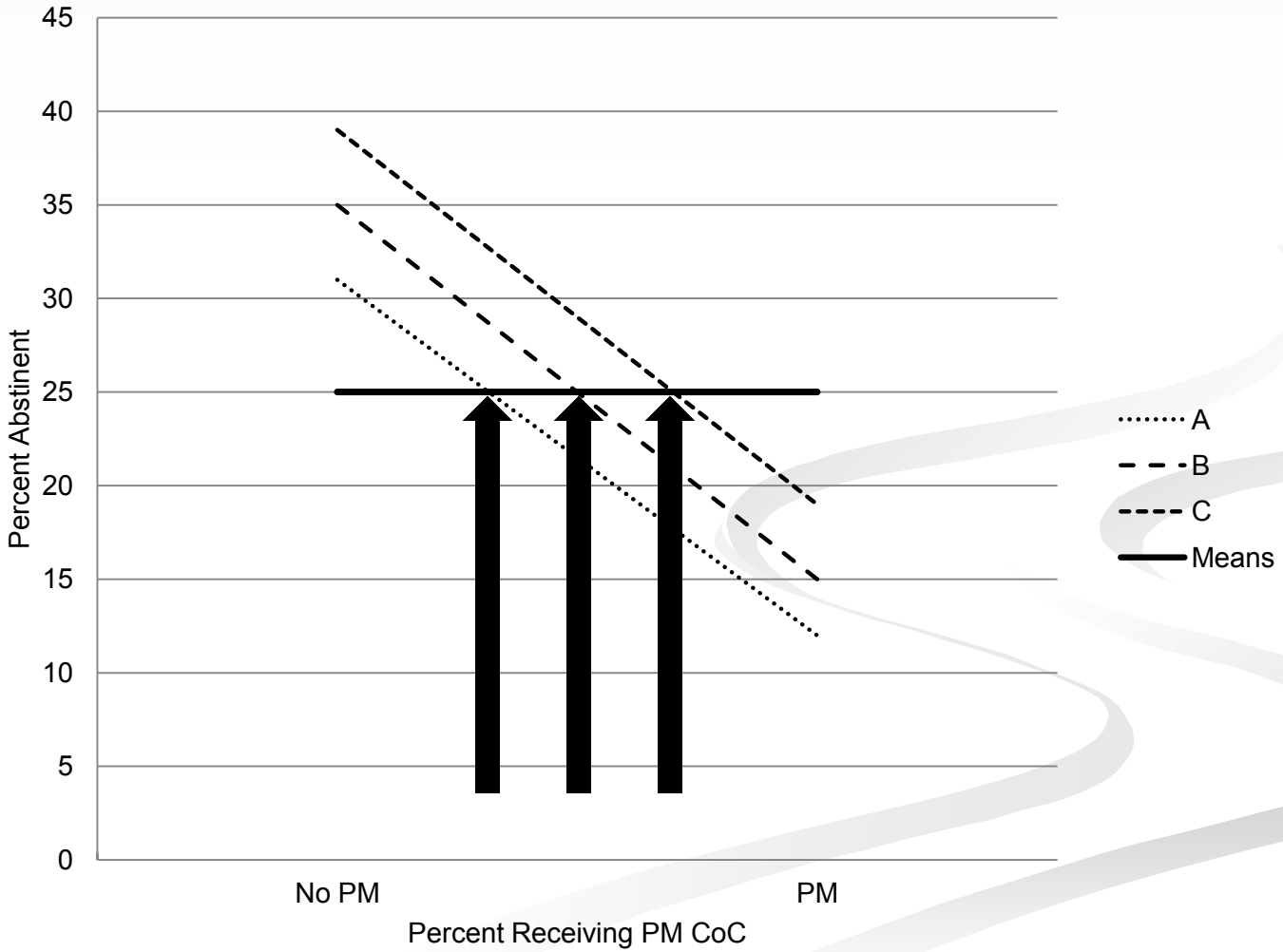
Three Hypothetical Facilities with the Different CC PM Rates and the Same Abstinence Rate - Marginal and Joint Distributions

		Facility A			Facility B			Facility C		
		Abstinence			Abstinence			Abstinence		
		Y	N		Y	N		Y	N	
PM	Y	*8*	*58*	66	*16*	*88*	104	*28*	*116*	144
	N	*42*	*92*	134	*34*	*62*	96	22	*34*	56
		50	150	200	50	150	200	50	150	200

Zero Facility-level Relationship of CC PM to Abstinence with Similar Positive PPM-Abstinence Relationships for Patients Within Three Hypothetical Facilities



Zero Facility-level Relationship of CC PM to Abstinence with Similar Positive PPM-Abstinence Relationships for Patients Within Three Hypothetical Facilities



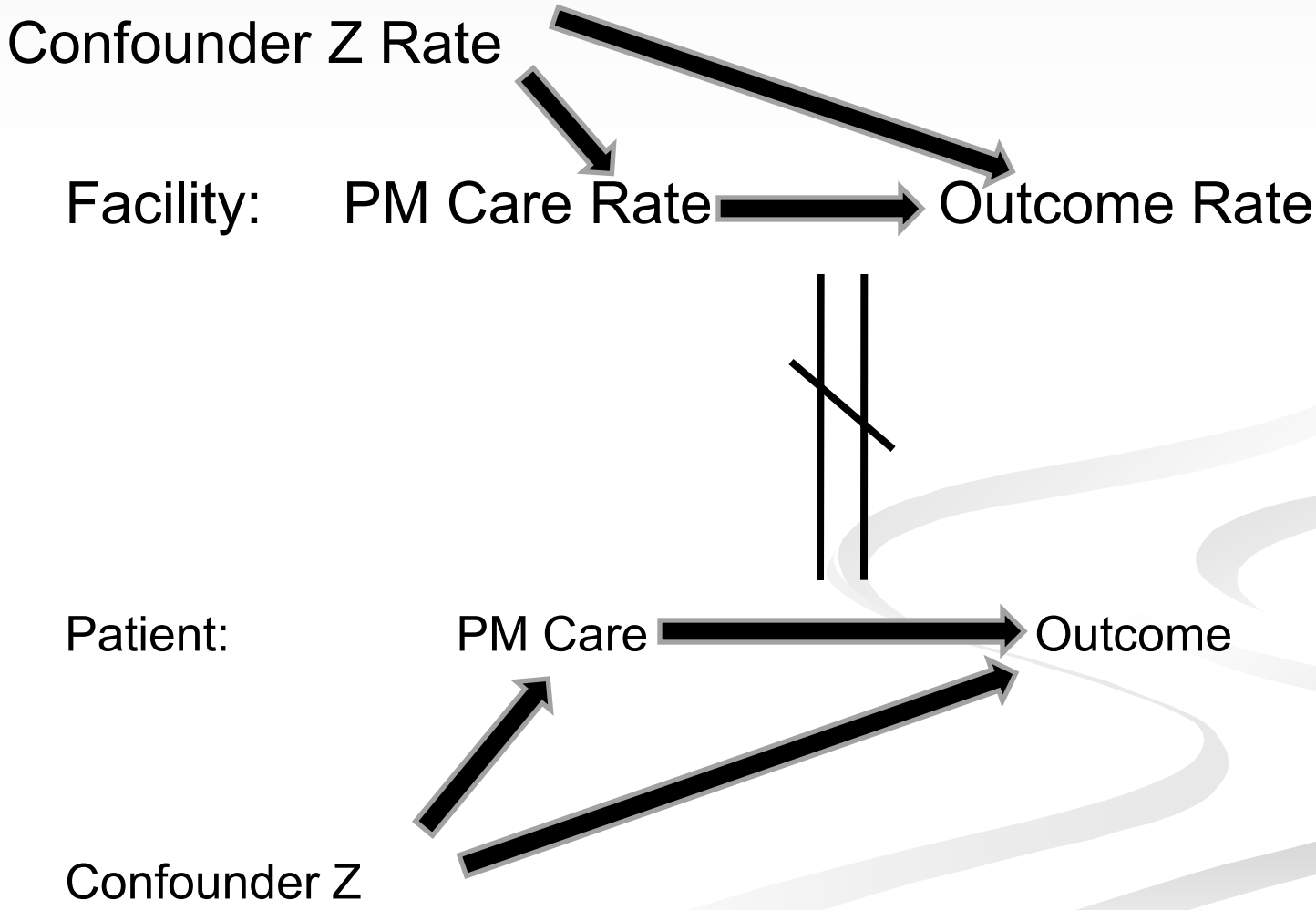
Why Do Differences Occur Between Facility- and Patient-Level PPM-Outcome Relationships?

- Effect modification
- Differential effects of measurement error, especially in the “exposure” variable

Why Do Differences Occur Between Facility- and Patient-Level PPM-Outcome Relationships?

Different confounding variables at patient and facility levels (Morgenstern, 1982; Greenland and Morgenstern, 1989)

Different Confounding Variables



Different Confounding Variables

Effects of aggregated confounders can be disaggregated into their between- and within-facility (patient-level) effects (Neuhaus & Kalbfleisch 1998).

Neuhaus JM, and Kalbfleisch JD. 1998. Between- and within-cluster covariate effects in the analysis of clustered data. *Biometrics* 54: 638-645.

“Integral” or “Structural” Properties of Higher-level Units

Grouping data or only collecting data at the health care facility level may allow new variables to affect the relationship between a PPM and outcomes - i.e., variables that may not come into play or have different “effects” on the PPM-outcome relationship at the patient level.

Blalock (1964): “The key to the problem may come with the realization that in shifting units we may be affecting the degree to which *other* unknown or unmeasured variables are influencing the picture” (p. 99).

“Integral” or “Structural” Properties of Higher-level Units

Higher level units, such as health care facilities, have “integral” properties (Susser, 1994) – not aggregated characteristics of the individuals comprising them.

E.g., different health care facilities have different leaders, local policies, and structural properties, such as staff-patient ratios, and may operate in different environmental contexts.

These factors may confound facility-level relationships between PM performance and outcomes, but could have quite different impacts or no impact on patient-level PM-outcome relationships.

Implications of Different Confounders at Different Levels

The fact that different variables may or may not relate to “PPMs” at the patient versus the hospital level implies that:

A performance measure at the hospital level may be assessing <u>something quite different</u> than the performance measure at the patient level.

Implications of Different Confounders at Different Levels

This “different constructs at different levels of aggregation/analysis” argument has been made by many observers (e.g., Firebaugh, 1978; Glick, 1980).

E.g., state rate of English illiteracy among foreign-born residents turned out to be a proxy for, or confounded with, the literacy rate among native-born state residents (Robinson, 1950).

Lack of Confounding

What PPMs are not confounded with may be as important or more important as the factors with which they are confounded.

Part of the confidence in hospital-level PPM-outcome analyses stems from a belief that various indicators of quality are positively correlated.

Lack of Confounding

"[H]ospital mortality rates, even risk-standardized, are likely influenced by many factors that are independent of the core measures, including processes that involve patient safety, staffing, response to emergencies, and clinical strategies that may contribute to a hospital's outcome performance" (Bradley et al., 2006, p. 77).

Lack of Confounding

Isaac and Jha (2008) found "inconsistent and usually poor associations among the PSIs [Patient Safety Indicators] and other hospital quality measures . . . ."

Isaac T, and AK Jha. 2008. Are patient safety indicators related to widely used measures of hospital quality? *Journal of General Internal Medicine* 23(9): 1373-1378.

Implications for Quality Management

1. Quality managers who only have findings on facility-level PPM-outcome relationships should view those relationships with caution.

   Possible that they reflect the PPM-outcome relationships at the patient level within facilities, but likely that they do not.

   Facility-level PPM-outcome relationship may even be in the opposite direction of the relationship at the (within-facility) patient level.

Implications for Quality Management

Piantadosi (1994) concluded that with aggregated data:

"[W]e not only lose all ability to extend inferences reliably to less aggregated data but we even lose the ability to estimate the direction and magnitude of bias. We cannot rely on the addition of more grouped data to eliminate the bias" (p. 763).

Implications for Quality Management

In addition to Robinson's (1950) findings, Greenland and Robins (1991) note that ecologic analyses have been conducted that, if taken at face value, would support the conclusions that:

- Radon exposure has a *protective effect* for lung cancer (Cohen, 1990; 1,729 counties in the U.S).
- Cigarette smoking has a *protective effect* for oesophageal cancer (Richardson et al. 1987; 22 administrative regions [départements] in France).

Implications for Quality Management

Quality managers should keep in mind Naylor's (1999) recommendation concerning ecologic analyses of treatment effects:

Implications for Quality Management

Quality managers should keep in mind Naylor's (1999) recommendation concerning ecologic analyses of treatment effects: "*caveat emptor*."

Implications for Quality Management

2. If a PPM is associated with positive outcomes at the patient level, but not the facility level, health care system leaders should encourage the use of that practice through facility-level performance measures.

Implications for Quality Management

3. If a PPM is associated with positive outcomes at the patient level, but not the facility level, health care system leaders should try to determine what, at the facility level, is “canceling out” the patient-level “effect” of the PM-specified care.

Implications for Quality Management

On the other hand:

The proportion of facility patients meeting the PPM may be positively related to desired outcomes, with a negative or no relationship between patient receipt of the PM-specified care and outcome (e.g., Berlin et al., 1999).

Implications for Quality Management

E.g., within hospitals, patients who receive a particular surgical procedure might be more likely to die.

However, facilities at which that surgical procedure is performed for higher percentages of patients might also tend to provide better infection control or send patients to safer extended care facilities.

If so, the challenge would be to ensure a safer surgical procedure at all facilities, while preserving or enhancing infection control and patient safety measures.

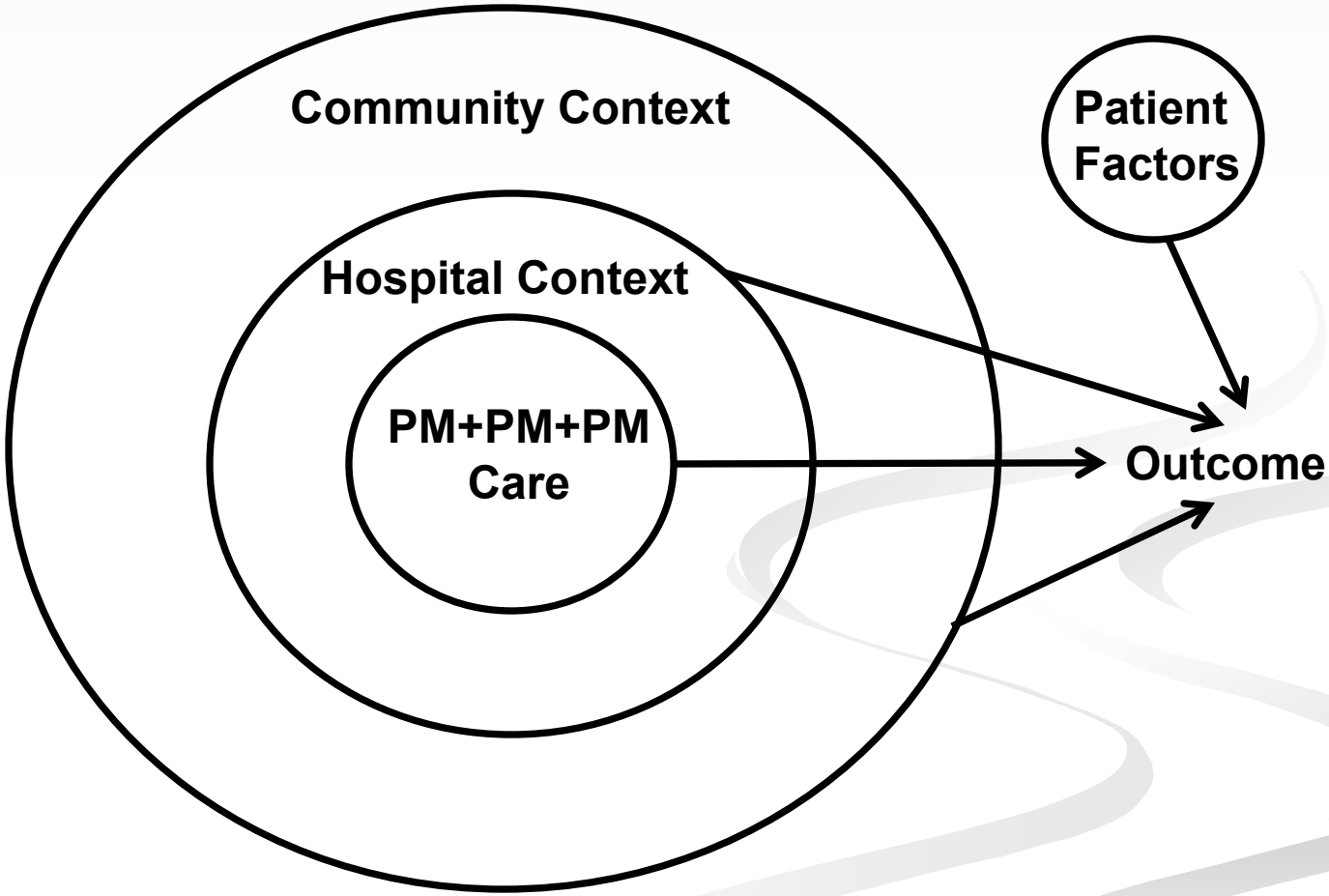
Implications for Quality Management

Overall, “false negative” hospital-level PPM-outcome findings are of more concern than “false positive” results, if patient-level evidence from RCTs and other sources supports the PPM.

Implications for Quality Management

Multilevel findings provide more useful, but also more nuanced, information to quality managers on how outcomes might be improved with interventions targeting patients and their care, as well as the health care facility and, perhaps, the broader community context.

Broader Conceptual Model



Implications for Research on Performance Measures

Two questions capture the inherently multilevel nature of PPMs and their relationships to clinical outcomes:

1. Independent of the proportion of patients for whom PM-specified care is provided at their hospitals, is the PM-specified care linked to better patient outcomes within hospitals?

2. Independent of the relationship of PM-specified care to outcome for patients within hospitals, is the proportion of patients receiving the PM-specified care across facilities linked to better outcomes?

Implications for Research on Performance Measures

The following types of analyses do not address those questions: Analyses of:

- The facility-level relationship between a PPM and outcome.
- The relationship between a PPM and outcome across all patients in the system ignoring the facility in which they received care.
- The patient-level relationship between a PPM and outcome controlling for clustering of patients (on outcomes) within facilities.

Why not? Because findings reflect a mixture of between- and within-facility relationships.

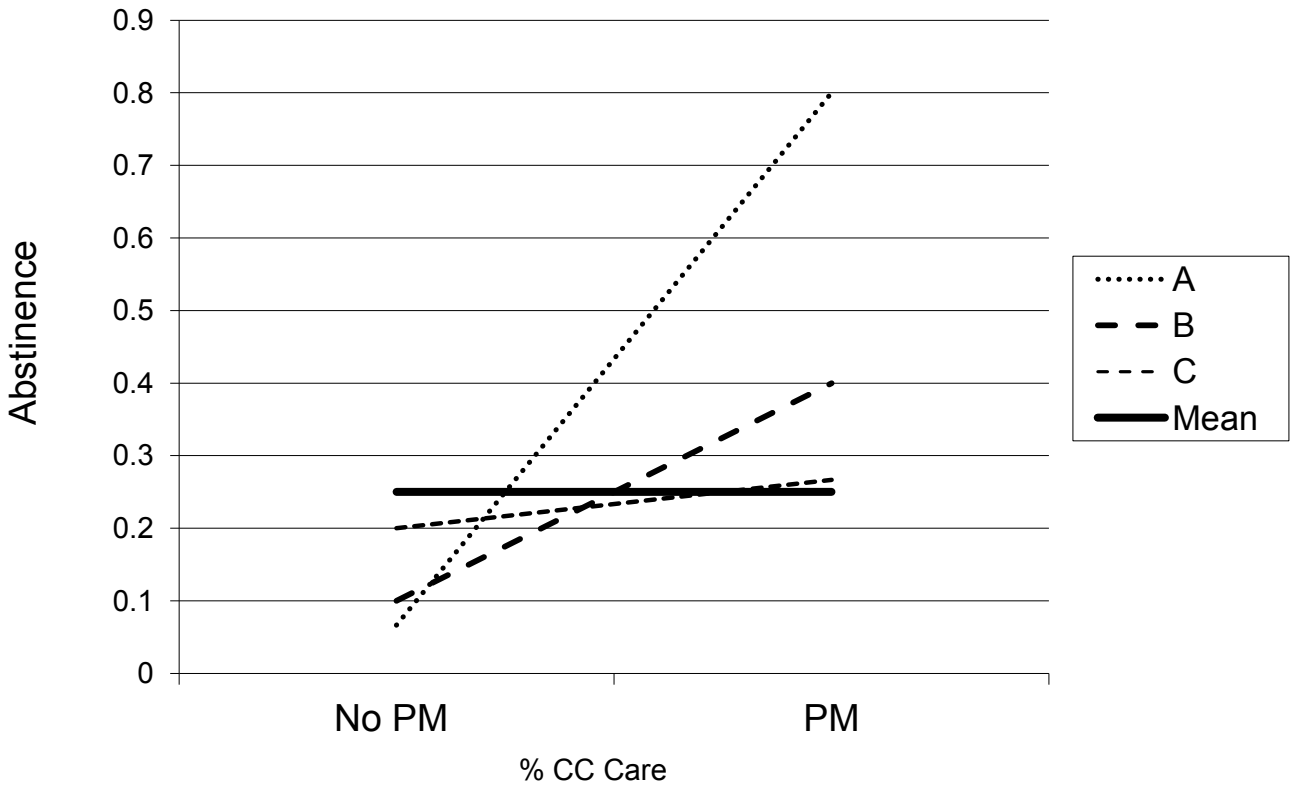
Implications for Research on Performance Measures

Firebaugh (2009) notes: "[S]ingle-level analyses are subject to severe omitted-variable bias in the presence of multilevel effects" (p. 369).

Strong implication for researchers:

- Studies of performance measures or quality indicators should be guided by multilevel conceptual models and use multilevel analyses to examine them whenever possible (Duncan et al., 1998; Localio et al., 2001).

Varied Within-facility Relationships of PPM to Abstinence with Flat Facility-level PM-Abstinence Relationship for Patients Within Three Hypothetical Facilities



But . . . .

Why not use facility-level performance as a “pseudo-instrumental variable” in examining relationships between PM-specified practices and patient outcomes to counteract the confounding by indication that can occur at the patient level?

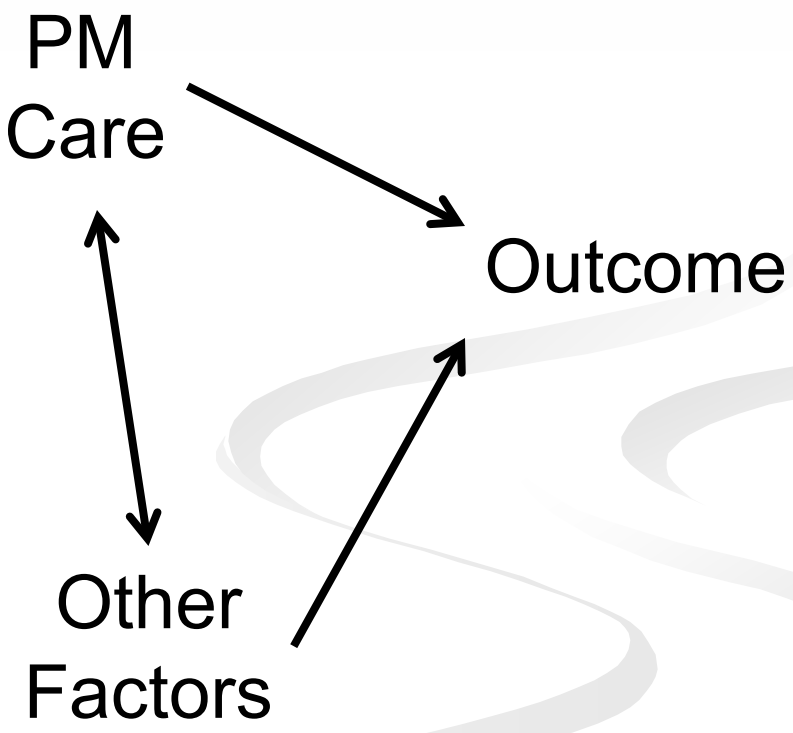
Performance Rate as an Instrumental Variable

Johnston SC. 2000. Combining ecological and individual variables to reduce confounding by indication: Case study – subarachnoid hemorrhage treatment. *Journal of Clinical Epidemiology* 53: 1236-1241.

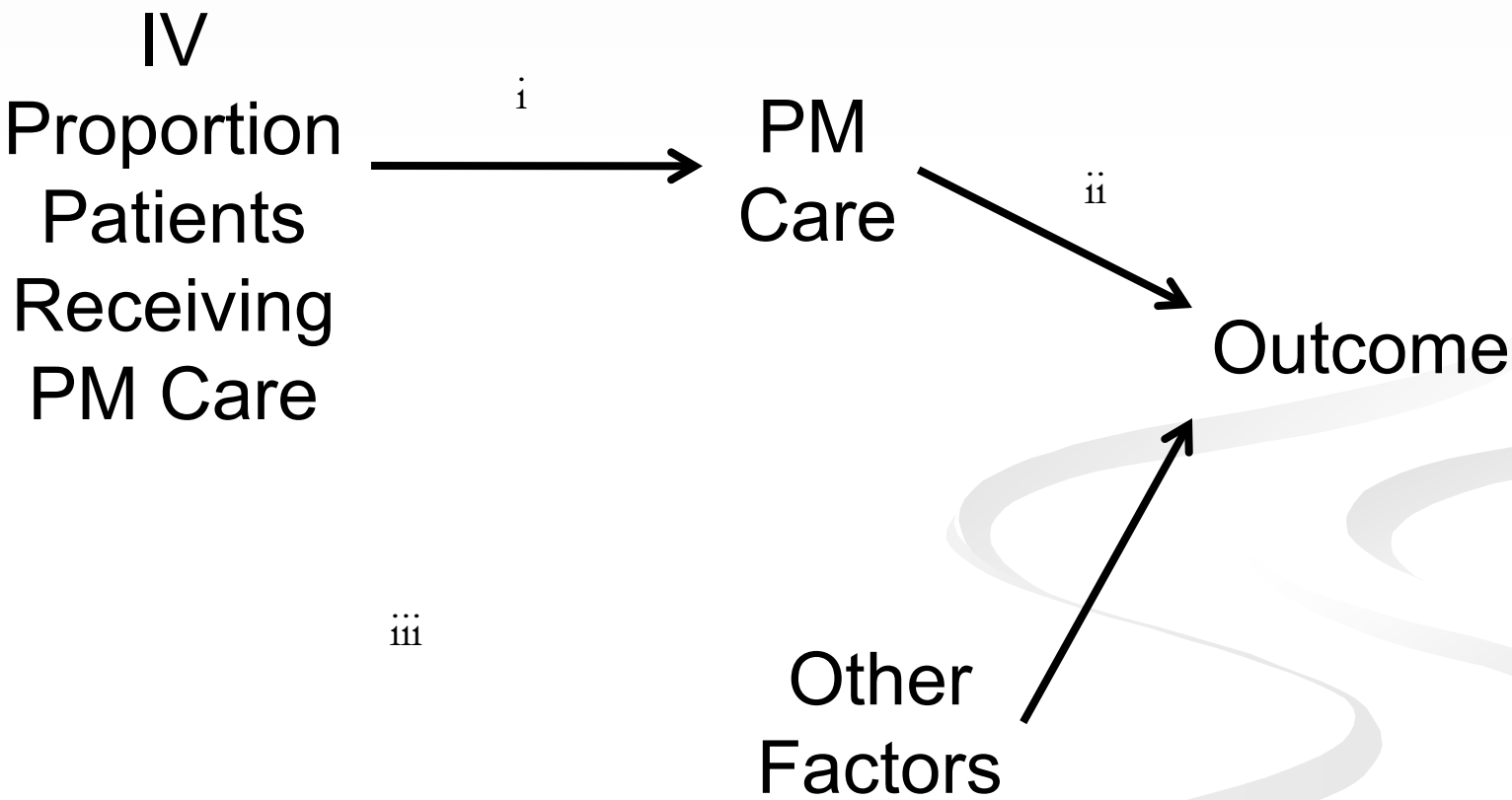
Johnston SC, Henneman T, McCulloch CE, and van der Laan M. 2002. Modeling treatment effects on binary outcomes with grouped-treatment variables and individual covariates. *American Journal of Epidemiology* 156 (8): 753-60.

Selby JV., Uratsu CS, Fireman B, Schmittdiel JA, Peng T, Rodondi N, Karter AJ, and Kerr EA. 2009. Treatment intensification and risk factor control: Toward more clinically relevant quality measures. *Medical Care* 47(40): 395-402.

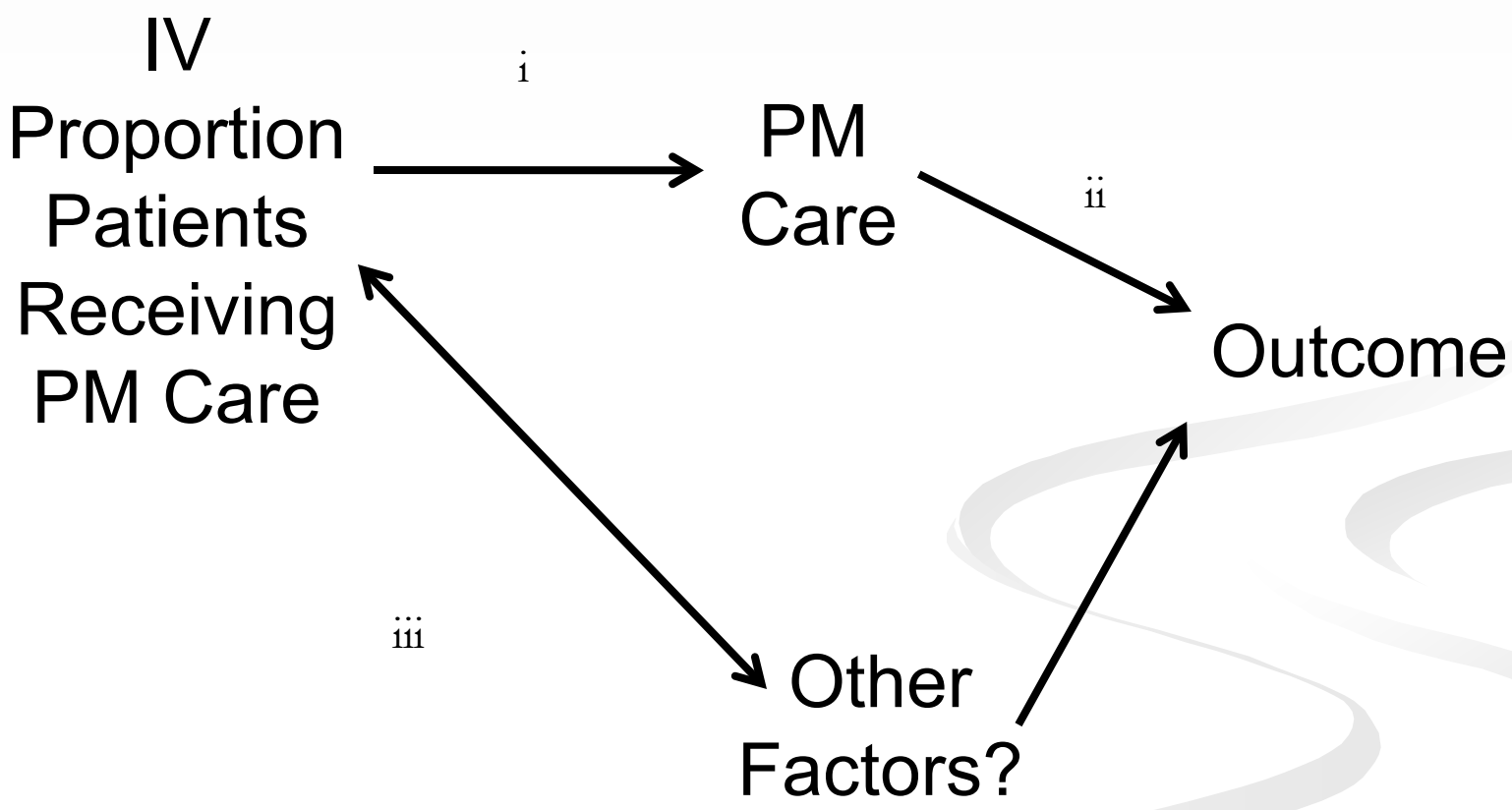
Performance Rate as an Instrumental Variable



Performance Rate as an Instrumental Variable



Performance Rate as an Instrumental Variable

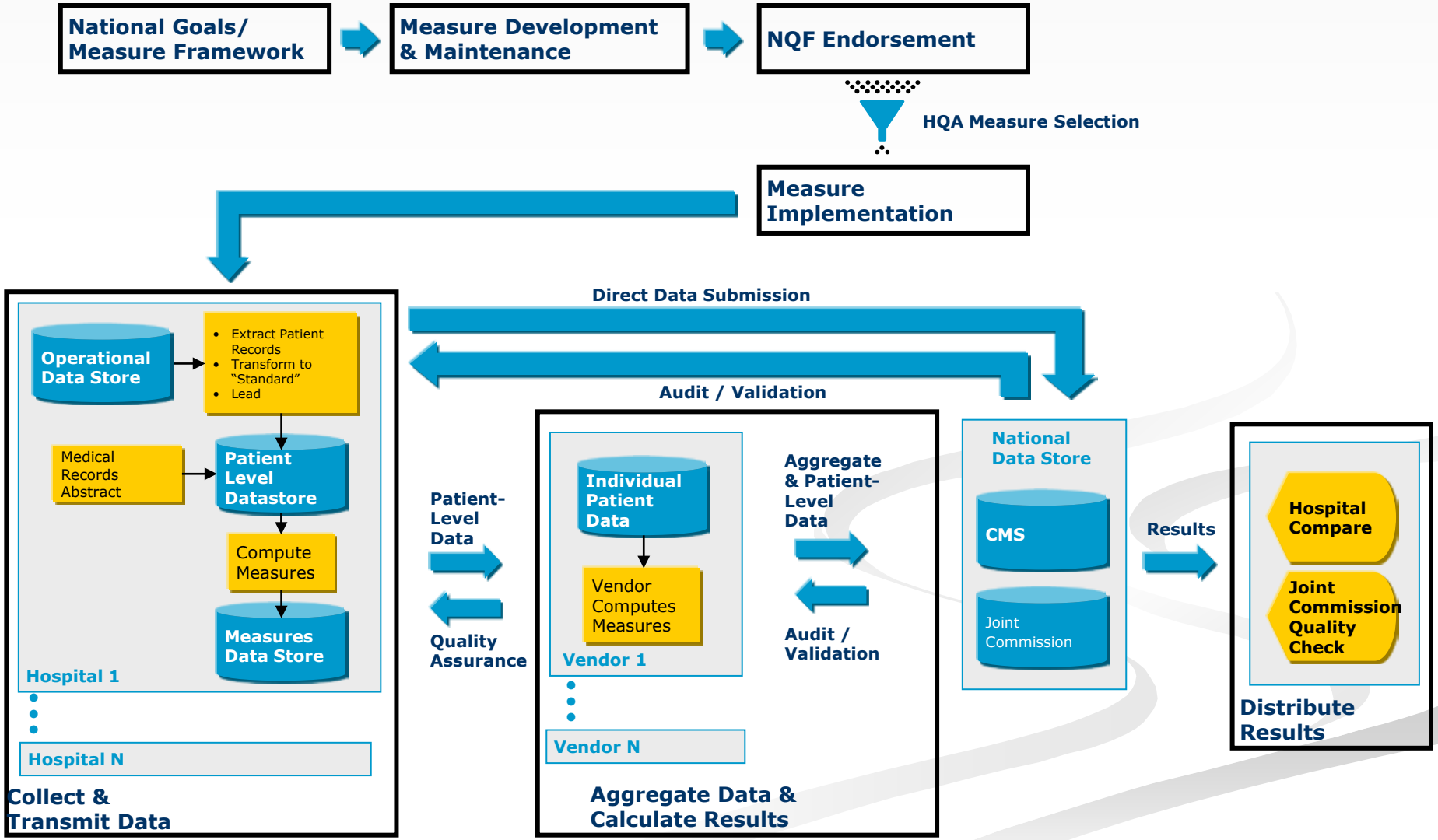


Implications for Quality Management Organizations

Health care quality organizations (e.g., CMS, Hospital Quality Alliance) should consider:

- Making de-identified patient data on both processes of care and outcomes (assuming a sufficiently large N within hospitals) available to researchers so that multilevel relationships could be examined and reported;
- Or conducting and reporting multilevel analyses of process performance measure-outcome relationships themselves.

Quality Measurement Enterprise



http://www.hospitalqualityalliance.org/hospitalqualityalliance/resources/resources_page.html

Conclusion

Misinterpreted hospital-level analyses of relationships between process performance measures and clinical outcomes can undermine evidence-based patient care.

Conclusion

Consideration of multilevel conceptual and methodological issues reinforces the wisdom of Donabedian's (1980) early call to focus on a [multilevel] *system* of structure, process, and outcome performance indicators.

Questions?

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