

Clinical Practice Improvement

A Scientific Methodology to Discover
Best Medical Practices

by
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Outline of Presentation

- *Brief description of CPI* and how it differs from other methodologies
- *CPI examples* showing breadth of findings from comprehensive data sets
- *Informatics infrastructure* to support CPI studies

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Clinical Practice Improvement

Analyzes the *content and timing* of individual steps of a health care process, in order to determine how to achieve:

- *superior medical outcomes* for the
- *least necessary cost* over the
- *continuum* of a patient's care

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CPI Study Design

Process to Develop Decidable and Executable Dynamic Protocols

Improve/Standardize:

Process Factors

- Management Strategies
- Interventions
- Medications

Control for:

Patient Factors

- Disease
 - > physiologic signs and symptoms
 - > complexity/psychosocial factors
- Multiple Points in Time

Measure:

Outcomes

- Clinical
- Health Status
- Cost/LOS/Encounters

Clinical Practice Improvement Study

- CPI goes beyond outcomes research, which
 - identifies only outcomes
 - is not connected to detailed process steps
 - does not adjust for severity of illness

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Clinical Practice Improvement Study

- CPI goes beyond guidelines, which are
 - *not decidable:*
give a vague description of patients
 - *not executable:*
give a menu of process steps to follow
 - *not connected to outcomes*

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RCT	CPI
<ul style="list-style-type: none"> • Rigorous exclusion; 15% of patients qualify • One variable at a time • Costs in millions • Based on controlled circumstances 	<ul style="list-style-type: none"> • Adjusts for severity All patients qualify • Examines all variables • Costs in thousands • Based on everyday clinical practice

Clinical Practice Improvement vs. Randomized Controlled Trials

How do results from CPI and RCT differ?

- CPI is a comprehensive analysis of patient, process, and outcome variables
- CPI studies are based on everyday clinical practice, not controlled circumstances.

RCT vs. CPI

- RCTs are considered to be evidence of the highest grade.
- Observational (CPI) studies are viewed as having less validity because they reportedly over-estimate treatment effects.*

* New England Journal of Medicine 2000; (June 22, 2000) 342:1887-92.

RCT vs. CPI

Results from 2 new studies

“Average results of the observational studies were remarkably similar to those of the randomized, controlled trials.”

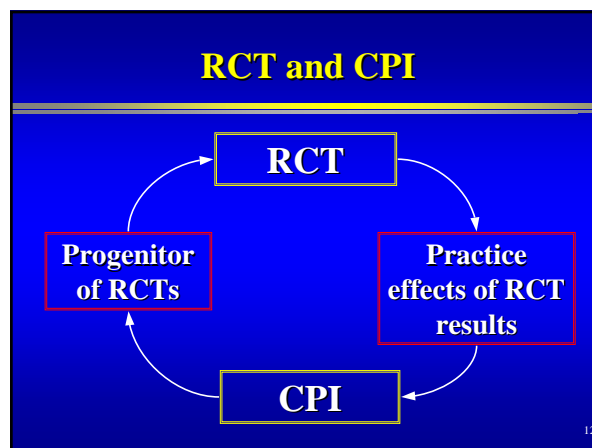
* New England Journal of Medicine 2000; (June 22, 2000) 342:1878-92.

RCT vs. CPI

Conclusions

Well-designed observational studies do not systematically over-estimate the magnitude of the effects of treatment as compared with those in randomized, controlled trials on the same topic.*

* New England Journal of Medicine 2000; (June 22, 2000) 342:1887-92.



Clinical Practice Improvement Study

- Connects outcomes with detailed process steps
- Adjusts for severity of illness

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Pneumonia Criteria Set

480.0-486; 506.3; 507.0-507.1; 516.8; 517.1; 518.3; 518.5; 668.00-668.04; 997.3; 112.4; 136.3; 055.1

CATEGORY	1	2	3	4
Cardiovascular	*pulse rate 51-100; ST segment changes-EKG; systolic BP \geq 90mmHg	*pulse rate 100-129; 41-50; PACs, PAT, PVCs-EKG; systolic BP 10-89mmHg	*pulse rate \geq 130; 31-40; systolic BP 61-79mmHg	*pulse rate \geq 50; asystole; VT, VF, V flutter; systolic BP \leq 60 mmHg
Fever	* \geq 96.8-100.4 and/or chills	*100.5-102.0 oral; \geq 98.0-98.7	*102.1-103.9; 90.1-93.9 and/or rigors	* \geq 104.0 \leq 90.0
Labs ABGs	*pH 7.35-7.45 *pO ₂ \geq 61mmHg	*pH \geq 7.46 7.25-7.34	*pH 7.10-7.24 *pO ₂ 51-60mmHg	*pH \leq 7.09; *pO ₂ \leq 50mmHg
Hematology	*WBC 4.5-11.0K/cu mm; bands <10%;	*WBC 11.1-20.0K/cu mm; 2-4-4K/cu mm; bands 10-20%	*WBC 20.1-30.0K/cu mm; 1.0-2.0K/cu mm; bands 21-40%	*WBC \geq 30.1K/cu mm; \leq 1.0K/cu mm; bands \geq 40%
Neuro Status Lowest Glasgow coma score	* \geq 12	*chronic confusion *9-11	*acute confusion *6-8	*unresponsive *5
Radiology Chest X-Ray or CT Scan		*infiltrate and/or consolidation in \leq 1 lobe; pleural effusion	*infiltrate and/or consolidation in \geq 1 but \leq 3 lobes;	*infiltrate and/or consolidation in \geq 3 lobes cavitation or lung necrosis
Respiratory		*dyspnea on exertion; stridor; rales \leq 50%/ \leq 3 lobes; decreased breath sounds \leq 50%/ \leq 3 lobes; positive for fremitus; stridor *hemoptysis NOS; blood tinged or purulent or frothy sputum	*cyanosis present *dyspnea at rest; rales \geq 50%/ \geq 3 lobes; decreased breath sounds \geq 50%/ \geq 3 lobes * frank hemoptysis	*apnea absent breath sounds \geq 50%/ \geq 3 lobes

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Summary of Findings

Curtailling access to medications via cost-control mechanisms can adversely affect other healthcare utilization:

- Additional office visits for dose titration/monitoring
- ER/hospital visits
- Concomitant medications

and increase total healthcare costs.

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Intended and Unintended Consequences of HMO Cost-Containment Strategies

Results from the Managed Care Outcomes Project

American Journal of Managed Care
March 1996

Main Study Question

“When one looks across multiple managed care organizations at a year’s worth of actual data on the care of thousands of typical patients treated by their regular doctors, how is the amount of health care services used associated with cost-containment efforts by the HMO?”

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Managed Care Outcomes Project

HMO Sites

- One each in the Northeast, central East, Southeast, central West;
- Two in the Southwest

- Each site had various levels of limitations on reimbursable prescription drugs and other cost-containment practices

- Half were not-for-profit
- Half were for-profit

- All were either group- or staff-model plans

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Managed Care Outcomes Project

Disease groups studied:

Ear Infection

Arthritis

Hypertension

Asthma

Ulcers

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Managed Care Outcomes Project

Patient Population:

Nearly 13,000 patients were included in the study:

- 1,309 - 3,938 patients for each disease group

➔

This represented more than:

- 99,000 office visits
- 480 emergency room visits
- 1,000 hospitalizations
- 240,000 prescriptions

Length of study period:

- One year

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Managed Care Outcomes Project

Study controlled for patient, cost-containment practice, and HMO site variables

<u>Patient variables</u>	<u>Cost-Containment Practice Variables</u>	<u>HMO Site Variables</u>
<ul style="list-style-type: none"> •Severity of patient illness •Age and gender •Time in study •Number of physicians seen by patient 	<ul style="list-style-type: none"> •Second-opinion requirements •Strictness of site's gatekeeper •Strictness of case mgt. •Drug and visit co-pays •Restrictions of formulary •Extent of generic drug use 	<ul style="list-style-type: none"> •Physician payment method •HMO profit status •Geographical location

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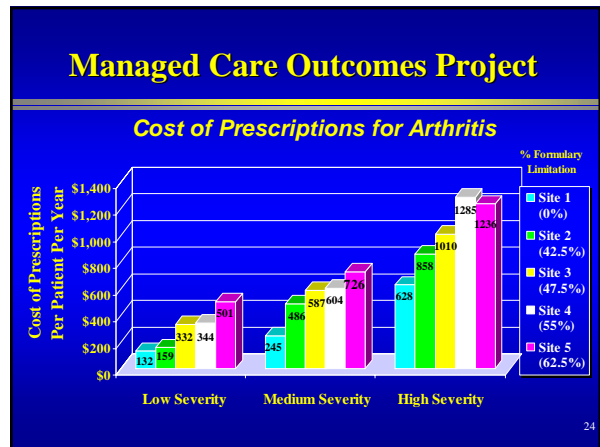
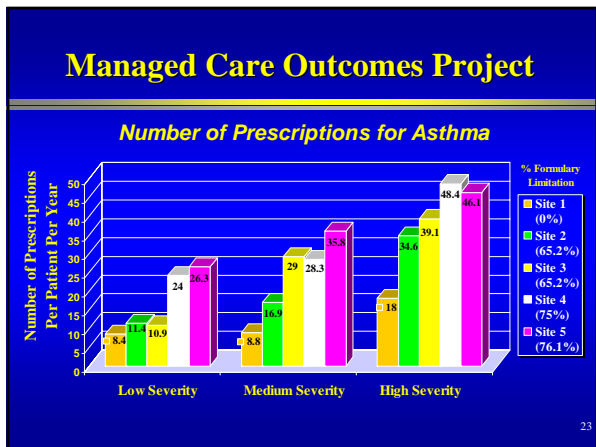
Managed Care Outcomes Project

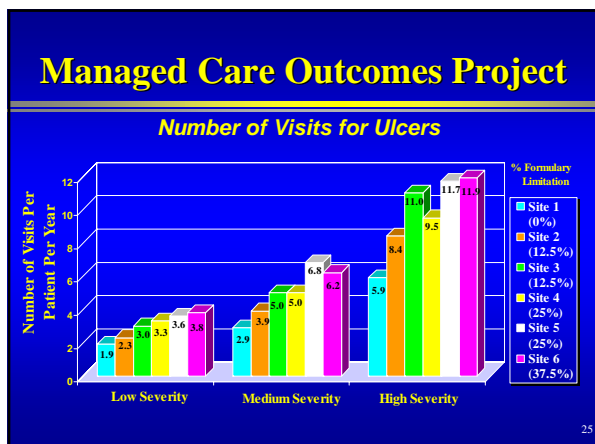
Findings

With increased formulary restrictiveness, the study found:

- More patient visits to physicians
- More emergency room visits
- More hospitalizations
- Greater estimated cost of prescriptions per year
- Greater number of prescriptions per year

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Why Might Elderly Be At Greater Risk with Formulary Limitations?

- Physiologic differences in elderly may affect -absorption -distribution -metabolism -elimination
- Elderly often take multiple medications and are at greater risk for adverse drug reactions and significant drug-drug interactions.

Regression Coefficients for Specific Drug Class Limitations By Age Category

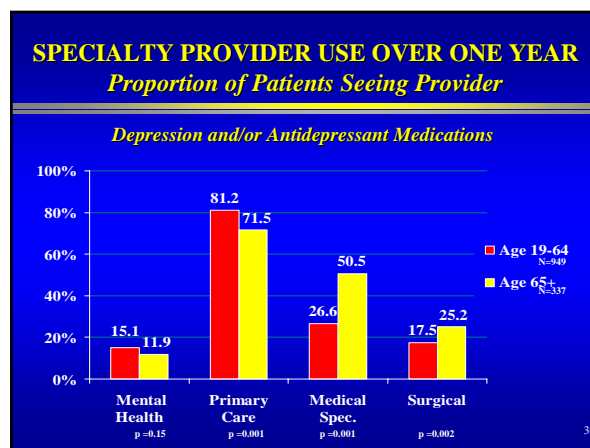
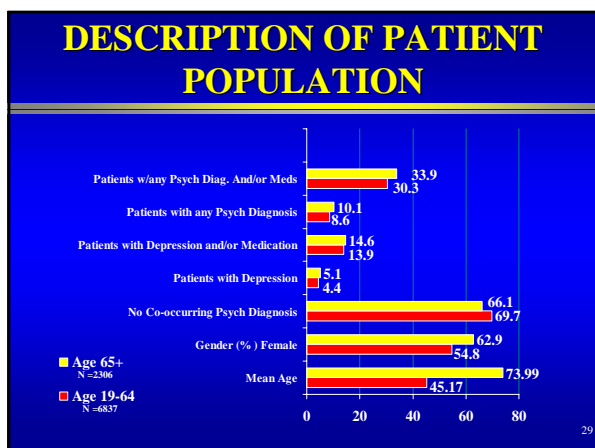
Hypertension

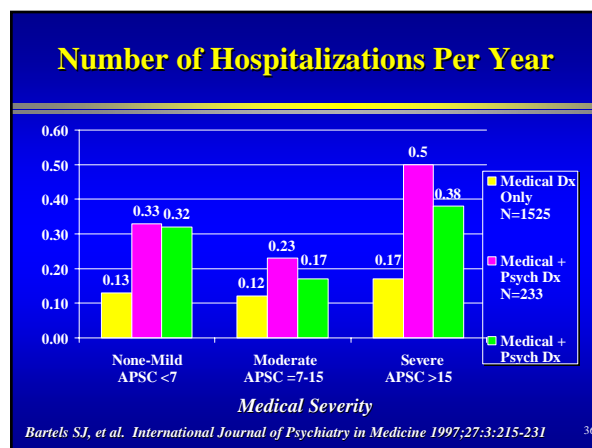
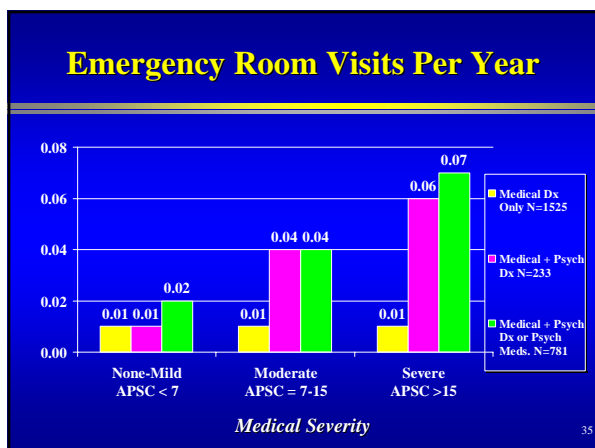
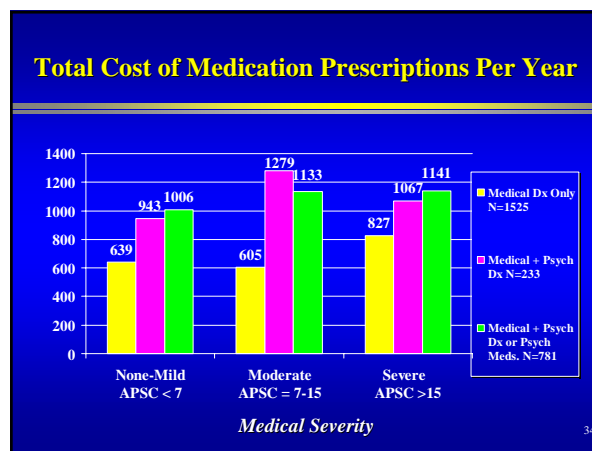
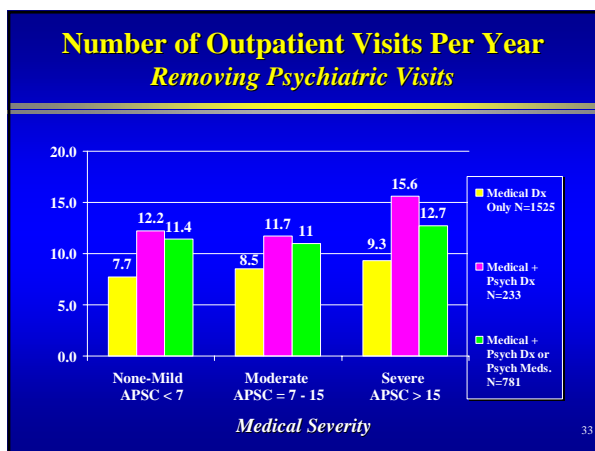
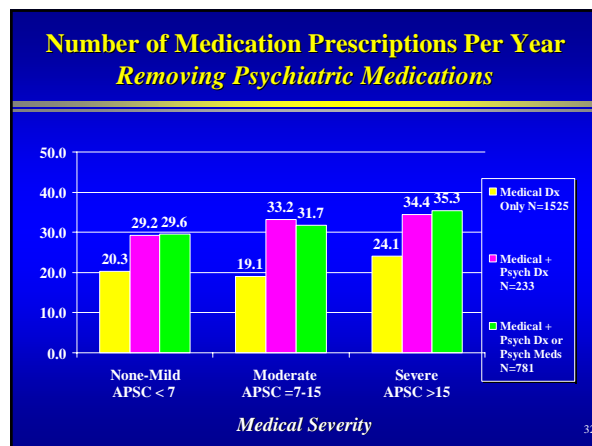
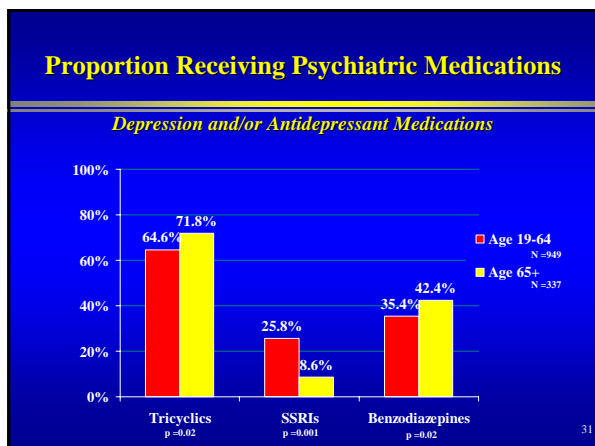
Description	0-64 Years		65+ Years	
	Drug Cost (Total)	Drug Cost (Study Disease)	Drug Cost (Total)	Drug Cost (Study Disease)
Loop Diuretics	.002 (.69)	.0001 (.98)	.023 (.0001)	.0186 (.0001)
Severity Sum	.003 (.009)	.007 (.0001)	.005 (.0007)	.0010 (.0001)
Sample Size	2,187		969	

Limiting Mental Health Services Increases Total Health Care Costs

Conclusions

“...limiting mental health services [visits to mental health providers and psychiatric drugs] was associated with higher total health care costs.”





Managed Care Outcomes Project

Findings

- Strong relationship between formulary restrictiveness and increased resource use for all five study diseases and for all levels of illness severity.
- Sites most severely restricting formularies often had double the use of healthcare services vs. sites with no formulary restrictions.
- Site with no formulary almost always had lowest use of healthcare.

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Managed Care Outcomes Project

Findings suggest the need for a systems or disease/case management approach to the use of cost-containment tools

- Should be viewed as an interrelated system.
- Should comprehensively evaluate the impact of cost-containment practices on all components of care and overall quality of care.

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Enhanced Productivity and Pharmaceutical Innovation

Enhancing Productivity

Pharmaceutical innovation also may have a direct impact on the economy through reduced absenteeism and enhanced productivity.

Meyer JA. Assessing Impact of Pharmaceutical Innovation: A Comprehensive Framework. February 2002. New Directions for Policy, Washington D.C. 39

Enhanced Productivity and Pharmaceutical Innovation

Newer drugs are associated with:

- More active and productive employees.
- Reduced absenteeism from work.
- Greater labor productivity.
- Lower employee turnover.

Lichtenberg P. Are the Benefits of Newer Drugs Worth Their Cost? Evidence From the 1996 MEPS. Health Affairs, 2001; 20(5):241-251. 40

Antibiotic Guideline Study

	1988	1994
Percentage of patients receiving antibiotics	31.8%	53.1%
Percentage receiving broad spectrum antibiotics	24%	47%
Medicare case mix index	1.75	2.05
Total antibiotic acquisition costs (adjusted for inflation)	\$987,547	\$612,500
Percentage of pharmacy budget	24.8%	12.9%

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Antibiotic Guideline Study

	1988	1994
Antibiotic cost per treated patient (adjusted for inflation)	\$122.66	\$51.90
Appropriate pre-op antibiotic use	40%	99.1%
Average number of doses of prophylactic antibiotic	19	5.3
Antibiotic associated ADE (adverse drug events)		↓30%
Mortality	3.65%	2.65%

Pestotnik SL, et al. Annals of Internal Medicine 1996;124:884-890 42

Nursing Home Study (NPULS) 1996-1997

- 6 long-term care provider organizations
- 109 facilities
- 2,490 residents studied
- 1,343 residents with pressure ulcer; 1,147 at risk
- 70% female, 30% male
- Average age = 79.8 years

Funded by Ross Products Division, Abbott Laboratories

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RESULTS Outcome: Develop Pressure Ulcer

General Care

General Assessment	Incontinence Interventions	Pressure Relief Interventions	Staffing Interventions
+ Age ≥ 85 + Male + Severity of Illness + History of PU + Dependency in >= 7 ADLs + Diabetes + History of tobacco use	+ Mechanical devices for the containment of urine (catheters) (treatment time >= 14 days) - Disposable briefs (treatment time >= 14 days) - Toileting Program (treatment time >= 21days)	+Static pressure reduction; protective device (treatment time >= 14 days) +Positioning; protective device (treatment time >= 14 days) (p=.07)	- RN hours per resident day >=0.25 - CNA hours per resident day >= 2 -LPN hours per resident day >=0.75 - Antidepressant

Medications

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RESULTS Outcome: Develop Pressure Ulcer

Nutritional Care

Nutritional Assessment	Nutritional Interventions
+ Dehydration signs and symptoms: low systolic blood pressure, high temperature, dysphagia, high BUN, diarrhea, dehydration + Weight Loss: >=5% in last 30 days or >=10% in last 180 days	- Fluid Order - Nutritional Supplements • standard medical - Enteral Supplements • disease-specific • high calorie/high protein

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Effects of Nutritional Support in Long Term Care

Nutritional Treatment Strategies	N	Pressure Ulcer Develop Rate
Enteral Formula Only	189	26.0%
Oral Supplement / Standard Medical Only	91	28.6%
Combinations	796	31.4%
No Nutritional Risk -- No Nutritional Treatment	183	31.7%
At Nutritional Risk -- No Nutritional Support	460	41.5%

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Bladder Incontinence Management in LTC

Treatments	N	PU Develop Rate
Incontinent -- Use of one or more of the following treatments:	1,441	34.2%
- Toileting Program	519	27.4%
- Briefs, disposable	527	26.9%
- Bed pads, disposable	212	30.7%
- Topical Treatment	1,148	34%
- Briefs, reusable	115	34.8%
- Bed pads, reusable	223	38.1%
- Use of mechanical device (catheter)	230	53.5%
Continent -- No incontinence treatment	93	20.4%

Long-Term Care Residents with Agitation in Dementia *Recommended Practice Guidelines*

- Use fewest number of medications possible (OBRA 1988)
- Minimize use of benzodiazepines
- Use atypical over typical antipsychotics
- Use SSRIs over tertiary amine antidepressants
- Avoid combination therapy

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Medications from NPULS Study

Optimal Medications Dementia & Agitation n = 803

No Psych Meds	32.5%
Antipsychotics	31.5%
Antidepressants	34.6%
Anti-anxiety	34.9%

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Medication Use and Outcomes for Elderly with Dementia with Agitation

Medication	% Hospital + ER	% Urinary Incontinence	% Pressure Ulcers
Monotherapy ^b	20.8	66.1	37.2
Combination Therapy ^c	14.3*	52.9**	23.5**
SSRI +	11.6**	47.4**	16.8**

^b=Monotherapy includes Antipsychotic only or antidepressant only

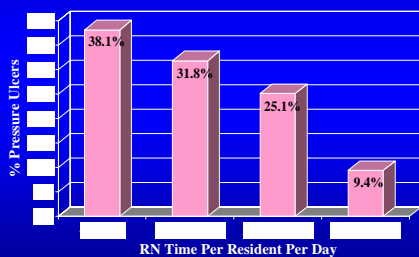
^c=Combination Therapy includes Antipsychotic plus or Antidepressant plus, with crossover individuals being removed.

*p≤.05 **p≤.01

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Economic Value of Nurses

DEVELOP PRESSURE ULCER by RN Time

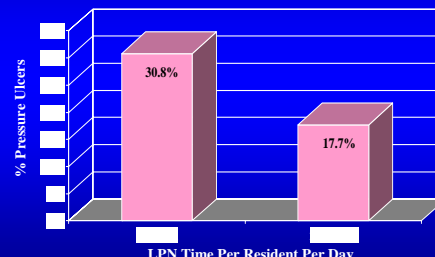


Chi-Square (6 df) = 50.86, p<.0001, n=1,376

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Economic Value of Nurses

DEVELOP PRESSURE ULCER by LPN Time

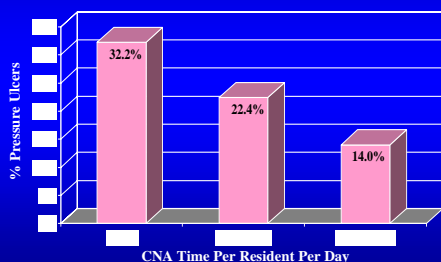


Chi-Square (1 df) = 17.77, p<.0001, n=1,543

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Economic Value of Nurses

DEVELOP PRESSURE ULCER by CNA Time



Chi-Square (2 df) = 27.74, p<.0001, n=1,542

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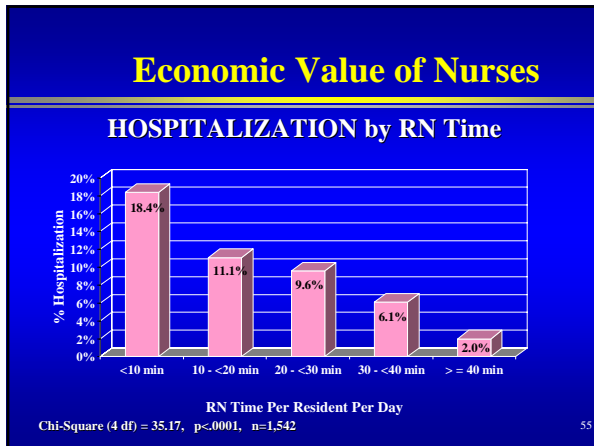
Economic Value of Nurses

Logistic Regression: DEVELOP PU -- RN/LPN/CNA Time and Other

Parameter	Effects		
	Estimate	Chi-Square	Pr > ChiSq
ADLs_78	0.28	4.68	0.0305
CSI Severity	0.01	18.19	<.0001
MDS_PU_hx	0.75	15.00	0.0001
Wt_loss	0.34	6.04	0.0246
Oral_eat_prob	0.39	9.33	0.0023
Catheter	0.78	16.98	<.0001
Entcalpr	-0.55	6.77	0.0093
Ent_dis	-0.98	6.00	0.0143
Fluid_order	-0.43	8.43	0.0037
RN_10-20m	-0.41	7.84	0.0051
RN_20-30m	-0.62	13.12	0.0003
RN_30-40m	-1.86	42.82	<.0001
CNA >2.25h	-0.64	5.76	0.0164
LPN >=45m	-0.64	8.74	0.0031

c = 0.727

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Economic Value of Nurses

Logistic Regression: HOSPITALIZATION

RN Time and Other Effects

Parameter	Estimate	Chi-Square	Pr>ChiSq
ADL chg	0.94	25.06	<.0001
Diet missing	2.04	8.70	.0032
CSI Severity	0.02	44.17	<.0001
Catheter	0.65	8.40	.0038
RN 10-20m	-0.72	10.85	.0010
RN 20-30m	-1.17	20.57	<.0001
RN 30-40m	-1.11	8.59	.0034
RN ≥40m	-2.94	22.19	<.0001

c = 0.762

Economic Value of Nurses

Cost/Benefit Analysis of More RN Time

\$ Per 100 at-risk residents per year (Y2000 dollars)

Cost of additional 30 min RN care per resident day \$415,000 to \$526,500	Savings in avoided PU treatment cost \$823,400 Savings in avoided hospitalizations \$546,400
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Net Savings \$843,300 to \$954,800

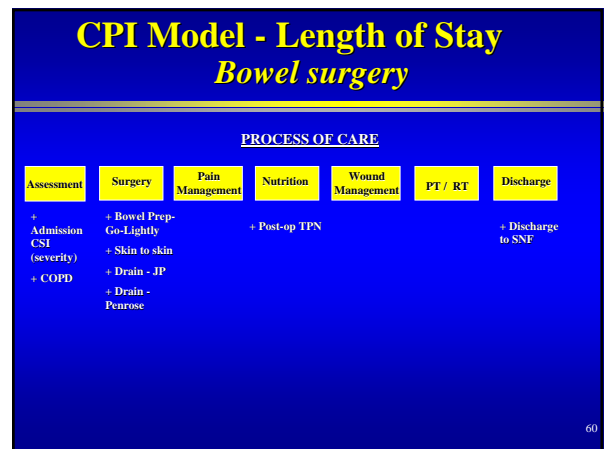
Assumptions: \$7,170 wtd avg to treat PU across stages, \$11,143 avg for Medicare hospitalization, \$48K to 60K RN salary & FB/yr

Economic Value of Nurses

Conclusions

Increasing RN time to 30-40 minutes per at-risk LTC resident per day gives net expected annual savings of \$843,300 to \$954,800 per 100 residents.

- ### ABDOMINAL SURGERIES
- Rectal Resection
 - Major Small and Large Bowel Procedures
 - Minor Small and Large Bowel Procedures
 - Peritoneal Adhesiolysis
 - Stomach, Esophageal, and Duodenal Procedures
 - Anal and Stomal Procedures
 - Appendectomy



CPI Model - Infection

PROCESS OF CARE

Assessment	Surgery	Pain Management	Nutrition	Wound Management	PT / RT	Pharmacy
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- + Mal-nutrition
- + Cortico-steroids
- + BMI
- + Mobility: assistance
- + Pre-admission vomiting
- + Lung Complications

- + Skin to Skin time
- + PCA

OUTCOME

Surgical Infection:

- SWI
- DWI
- Sepsis
- Abscess

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All Bowel Surgery Patients Effects of PCA Pump Use

		<u>PCA Use</u>		
Superficial or Deep Infection After PCA (Col. %)		No	Yes	
	No	289 (96)	189 (88)	478
Yes	12 (4)	25 (12)	37	
		301	214	515

Patients with PCA pump have higher infection rate (12% vs. 4%); $p < .0001$.

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All Bowel Surgery Patients Effects of PCA Pump Use

		<u>PCA Use</u>		
Deep Infection (Col. %)		No	Yes	
	No	298 (99)	205 (95.8)	503
Yes	3 (1)	9 (4.2)	12	
Totals		301	214	515

PCA pump associated with more infections; $p = .033$.

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All Bowel Surgery Patients Effects of PCA Pump Use

Clean-Contaminated Wound

		<u>PCA Use</u>		
Superficial or Deep Infection After PCA (Col. %)		No	Yes	
	No	201 (96.2)	159 (91.4)	360 (94.0)
Yes	8 (3.8)	15 (8.6)	23 (6.0)	
		209	174	383

Fisher Exact $p = .054$

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All Bowel Surgery Patients Effects of PCA Pump Use

Contaminated Wound

		<u>PCA Use</u>		
Superficial or Deep Infection After PCA (Col. %)		No	Yes	
	No	55 (96.5)	19 (76)	74 (90.2)
Yes	2 (3.5)	6 (24)	8 (9.8)	
		57	25	82

Fisher Exact $p = .009$

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Abdominal Surgery Nutrition Study Disease CSI Score

<u>Intervention Subgroup</u>	<u>N</u>	<u>Mean</u>
Early & Sufficient	42	50.7
Not Early & Not Sufficient	61	49.3
Not Early & Sufficient	25	48.8
Early & Not Sufficient	55	41.8

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Abdominal Surgery Nutrition Study

Nutrition CSI Score (Deaths and Transfers Removed)

Intervention Subgroup	N	Mean
Early & Sufficient	29	9.8
Not Early & Not Sufficient	47	7.7
Not Early & Sufficient	21	8.0
Early & Not Sufficient	43	7.7

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Abdominal Surgery Nutrition Study

Length of Stay (Deaths and Transfers Removed)

Intervention Subgroup	N	Mean
Not Early & Not Sufficient	47	14.8
Not Early & Sufficient	21	14.6
Early & Not Sufficient	43	13.3
Early & Sufficient	29	11.9

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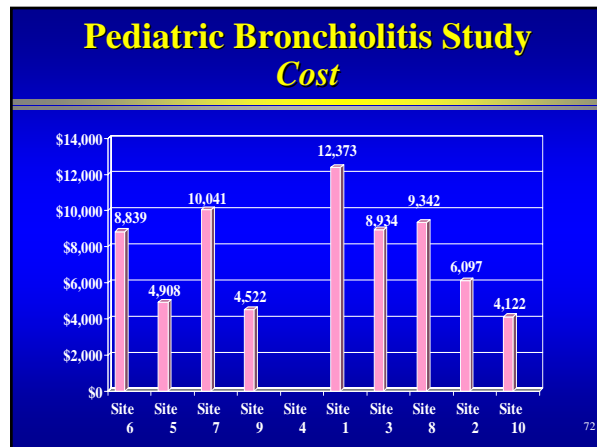
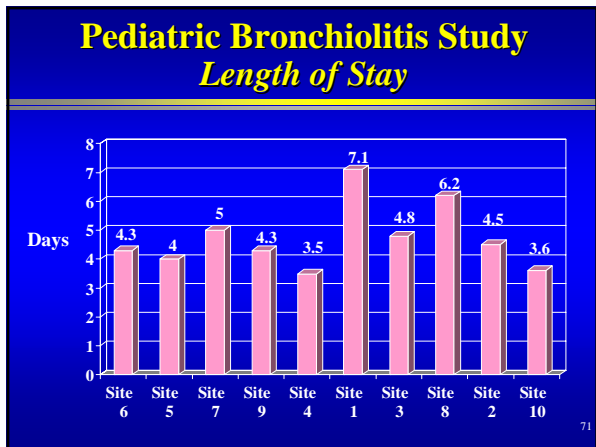
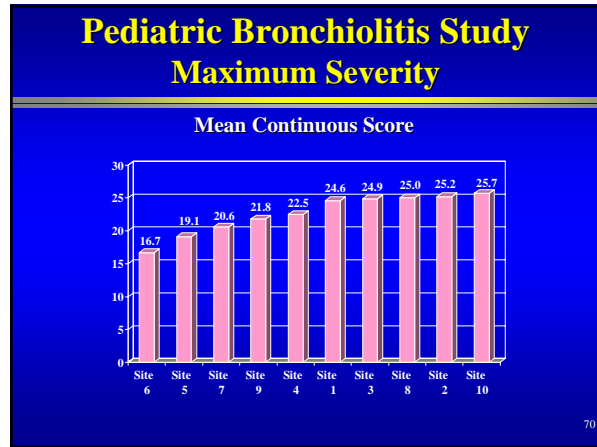
Abdominal Surgery Nutrition Study

Total Charges (Deaths & Transfers Removed)

Intervention Subgroup	N	Mean
Not Early & Sufficient	13	39,883
Not Early & Not Sufficient	35	38,578
Early & Not Sufficient	35	36,542
Early & Sufficient	20	34,602

Neumayer LA, et al. Journal of Surgical Research 95:1 (Jan 2001) 73-77.

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Pediatric Bronchiolitis Study

Outcome = Cost n=722 R²= .73

Assessment	Procedures
<ul style="list-style-type: none"> - Age in months (.0001) + MCSIC (.0001) 	<ul style="list-style-type: none"> + Admitted to PICU (.0001) + Arterial line (.04) + Central line (.003) + Continuous nebulization (.0002) + Interaction of chest pt & atelectasis (.005) + Intubation (.0001) + Ipratropium bromide (.005) + Lasix (.0001) + Ribavirin (.0001) + Steroids (.0003)

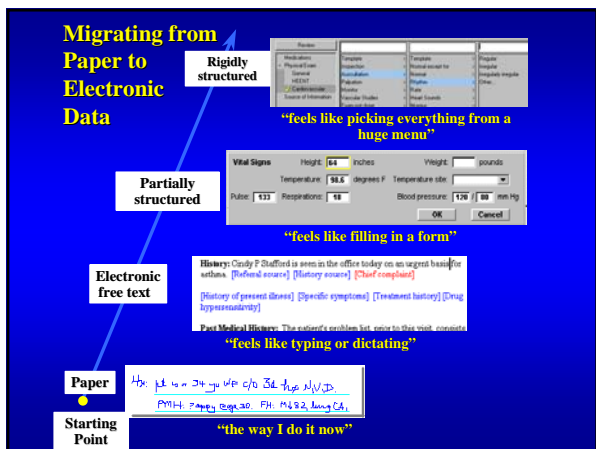
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Health Information Systems to Support CPI

To support CPI, effective health information management systems should:

- provide relevant clinical, financial, and outcomes data
- facilitate access to information to improve the clinical decision-making process
- be a by-product of routine care (should not impose additional work)

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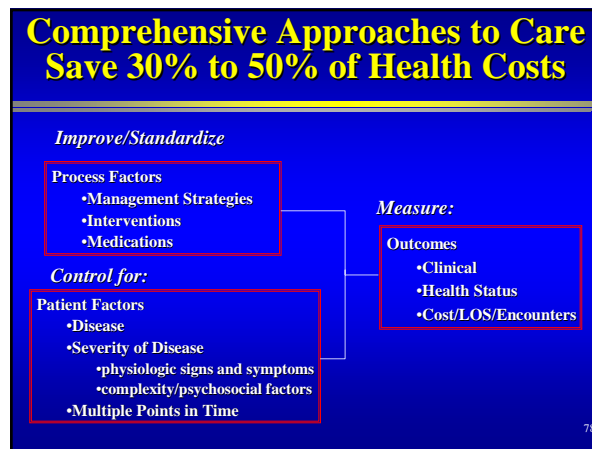


CPI provides a mechanism to create rigidly structured data

Health Information Systems to Support CPI

CPI can recoup the investment in health information management systems by improving patient outcomes, with the least necessary use of resources.

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Conclusions/Recommendations

- **To reduce costs and improve outcomes**, need comprehensive patient, treatment, and outcomes data.
- If these data are in rigidly-structured computerized information systems, **CPI studies and implementation of best practice** are facilitated.
- **Clinical information systems ultimately pay for themselves**. Because of high initial outlay, need external support to enable IT potential.

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Clinical Practice Improvement

For more information about
Clinical Practice Improvement concepts,
see the book:

*Clinical Practice Improvement Methodology:
Implementation and Evaluation*,
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