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Leonard D. Schaeffer Center for Health Policy & Economics

Using Artificial Technology and Big Data to Personalize Efficient and Effective Wound Care

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President, National Pressure Injury Advisory Panel (NPIAP)

AAWC 2022 Annual Conference

Salt Lake City, UT

November 12, 2022

Disclosures

- **Grants**
  - **NIH OER KL2**
  - **PhRMA Foundation Value Assessment Initiative**
  - **Bill & Melinda Gates Foundation**
  - **BMS**
  - **Abbvie**
- **Personal Fees**
  - **Monument Analytics, including equity**
  - **Molnlycke, Smith & Nephew, Pfizer, Abbott, MiMedx, Urgo, Takeda, BMS, Masimo, Dabir, Arjo, BBI, Rehabtronics, Phoenix Tissue Repair, George Mason University, 3M, Avana Health, IR-Med, AMBU, Atlas Lift, Bausch Health, Amgen, Cosm, Essity, Immunochem, Iterative Scopes, Lilly, Medline, PhRMA, Regenesis, Value Health, AirMid**

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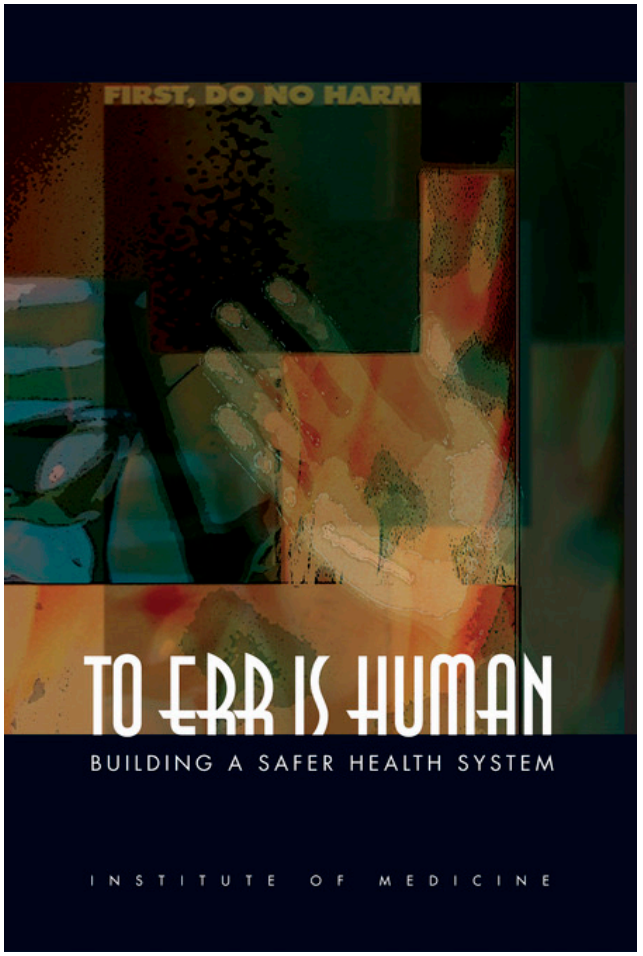
Chapter 1

The spark that lit 100,000 fires



The Josie King Story

- Josie King, 18 months old
- 1st and 2nd degree burns from falling into hot bathtub
- Admitted to Johns Hopkins Hospital, winter 2001
- Recovered well in under 2 weeks
- Expected to go home the next day
- Taken off central line, discharged from PICU

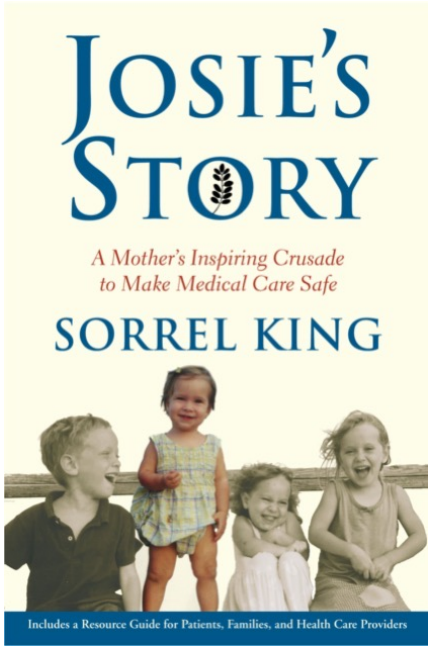
A Story Steeped in Tragedy

- The day before expected discharge, Sorrell King notices her daughter thirsty, disoriented
- Clinicians worried about negative reaction to narcotics
- Issued Narcan to Josie
- Josie decompensated quickly
- The next day, issued Methodone
- Failure to realize Josie had a central line infection and was severely dehydrated

Learning from the Gravest of Mistakes

Could you tell me that this won't happen to my other 3 daughters?

-Sorrel King to Johns Hopkins Leadership



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Chapter 1

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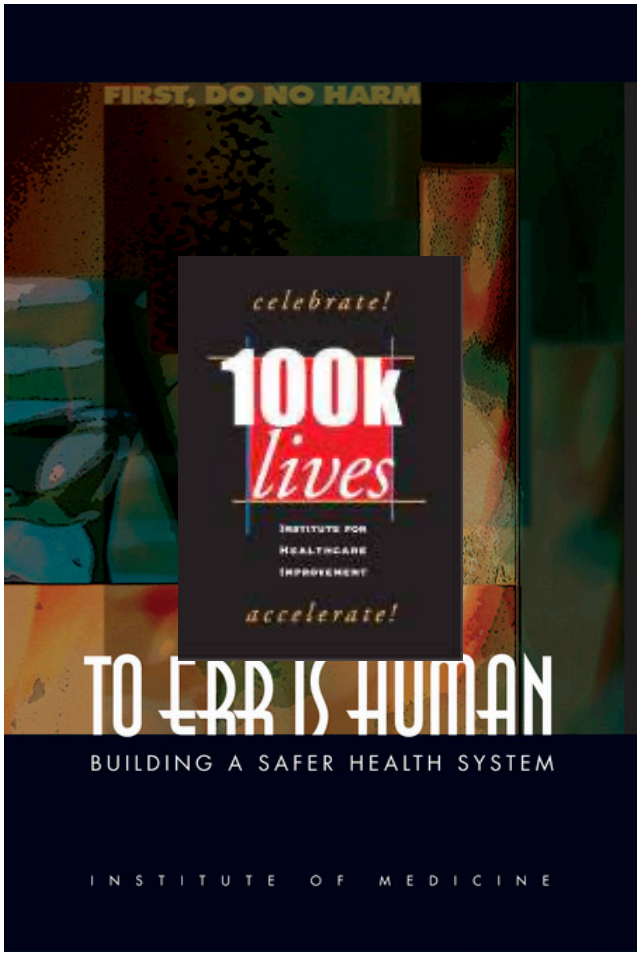

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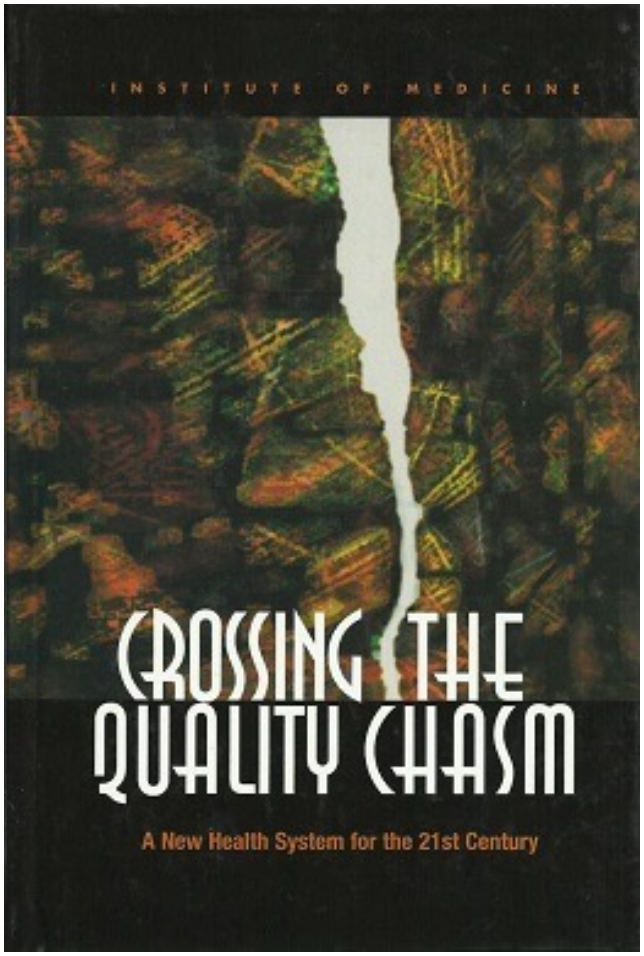
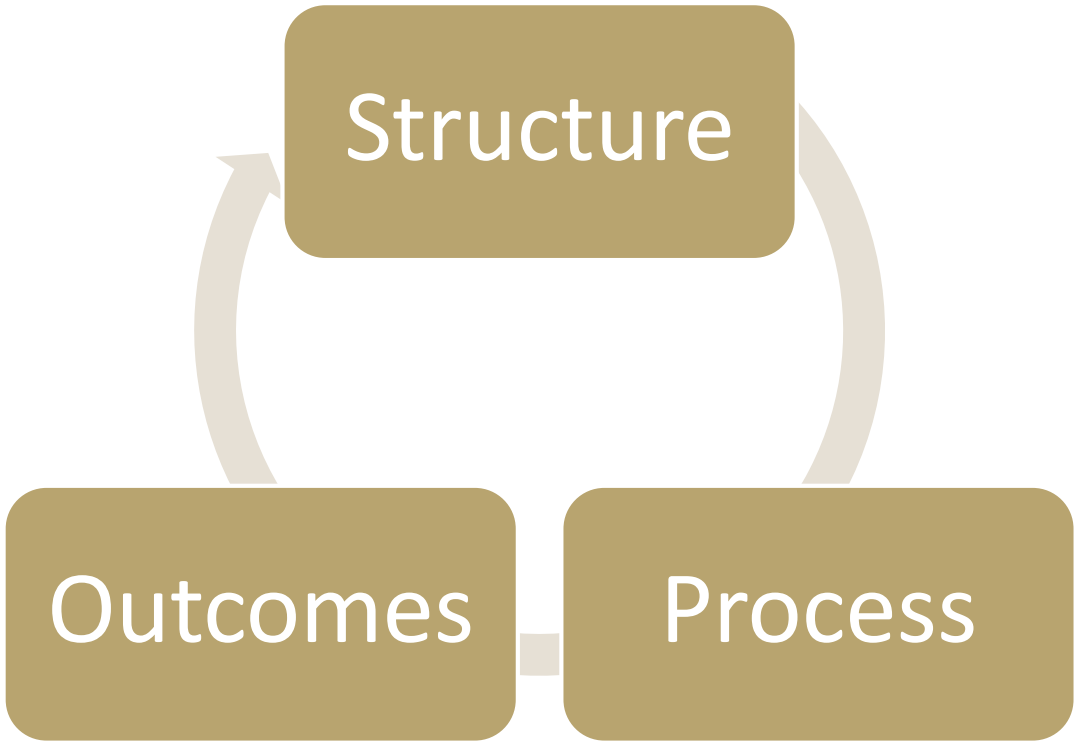
Chapter 2

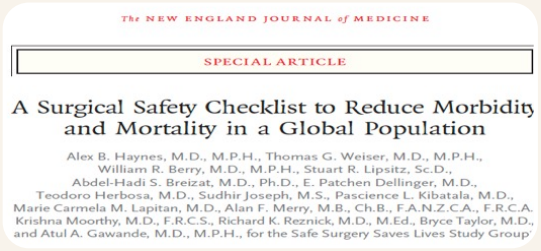
A new beginning…



The Donabedian Model



US Healthcare is Efficient when it comes to Innovating Structure


The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population

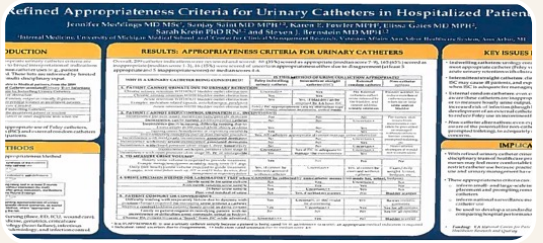
Alex B. Haynes, M.D., M.P.H., Thomas G. Weiser, M.D., M.P.H., William R. Berry, M.D., M.P.H., Stuart R. Lipsitz, Sc.D., Abdel-Hadi S. Breizat, M.D., Ph.D., E. Patchen Dellinger, M.D., Teodoro Herbosa, M.D., Sudhir Joseph, M.S., Pascience L. Kibatala, M.D., Marie Carmela M. Lapitan, M.D., Alan F. Merry, M.B., Ch.B., F.A.N.Z.C.A., F.R.C.A., Krishna Moorthy, M.D., F.R.C.S., Richard K. Reznick, M.D., M.Ed., Bryce Taylor, M.D., and Atul A. Gawande, M.D., M.P.H., for the Safe Surgery Saves Lives Study Group


BMJ

RESEARCH

Sustaining reductions in catheter related bloodstream infections in Michigan intensive care units: observational study

Peter J Pronovost, professor,[1] Christine A Goeschel, director, patient safety and quality initiatives,[1] Elizabeth Colantuoni, assistant professor,[1] Sam Watson, senior vice president, patient safety and quality,[2] Lisa H Lubomski, assistant professor,[1] Sean M Berenholtz, associate professor,[1] David A Thompson, assistant professor,[1] David J Sinopoli, instructor,[3] Sara Cosgrove, assistant professor,[3] J Bryan Sexton, associate professor,[1] Jill A Marsteller, assistant professor,[3] Robert C Hyzy, associate professor,[4] Robert Welsh, chief,[5] Patricia Posa, special project coordinator,[6] Kathy Schumacher, director, quality, safety, standards and outcomes,[6] Dale Needham, assistant professor[1][7]


efined Appropriateness Criteria for Urinary Catheters in Hospitalized Patien

RESULTS: APPROPRIATENESS CRITERIA FOR URINARY CATHETERS

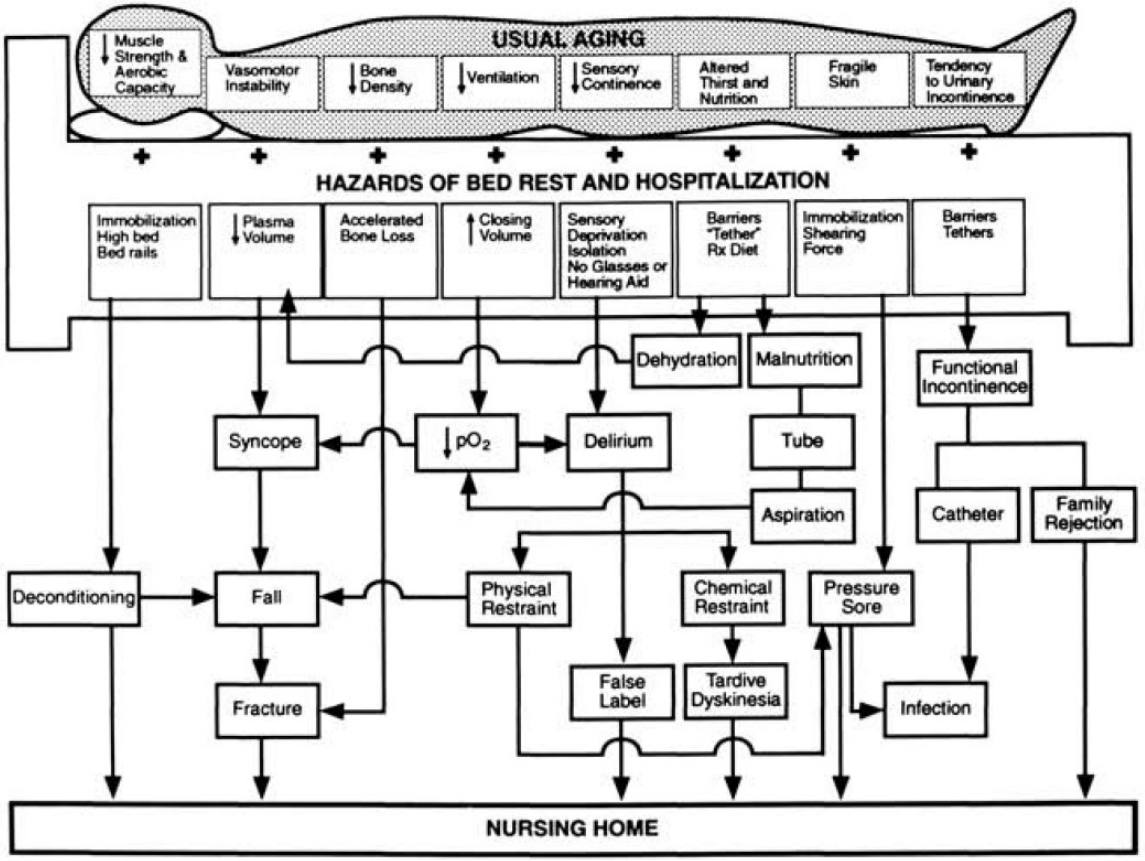
Surgical Safety (SSI)

Central Line Insertion (CLABSI)

Catheter Removal (CAUTI)

Developing a Process to Implementing Structure is Complicated

Hazards of Hospitalization of the Elderly
Morton C. Creditor, MD
Annals of Internal Medicine. 1993;**118**:219-223.



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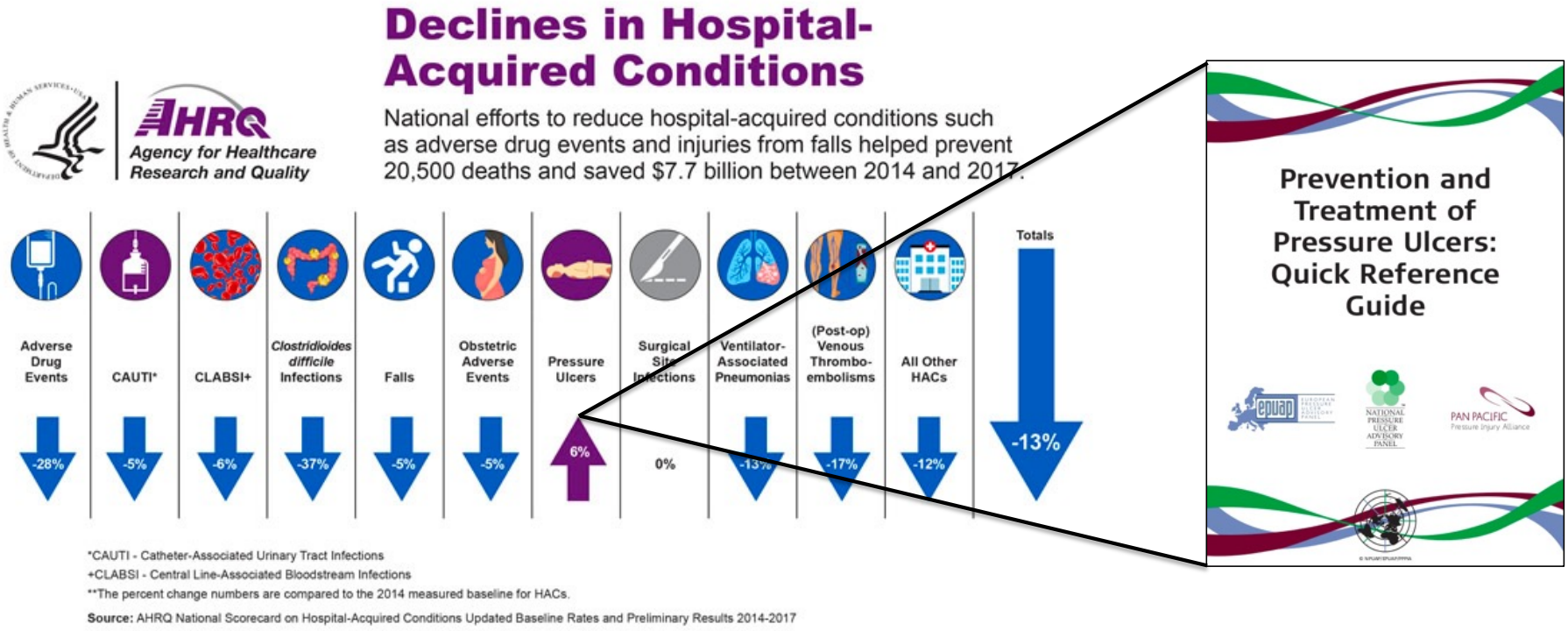
Naturally, some Priorities with Structure will fall behind



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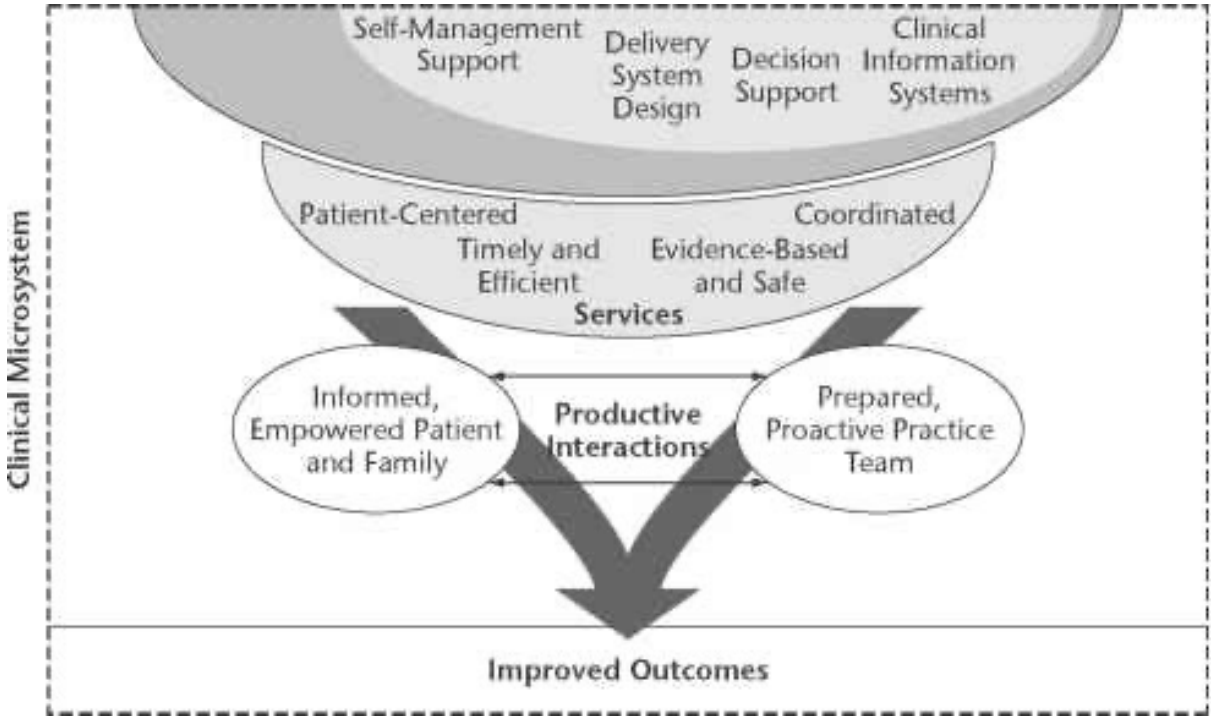
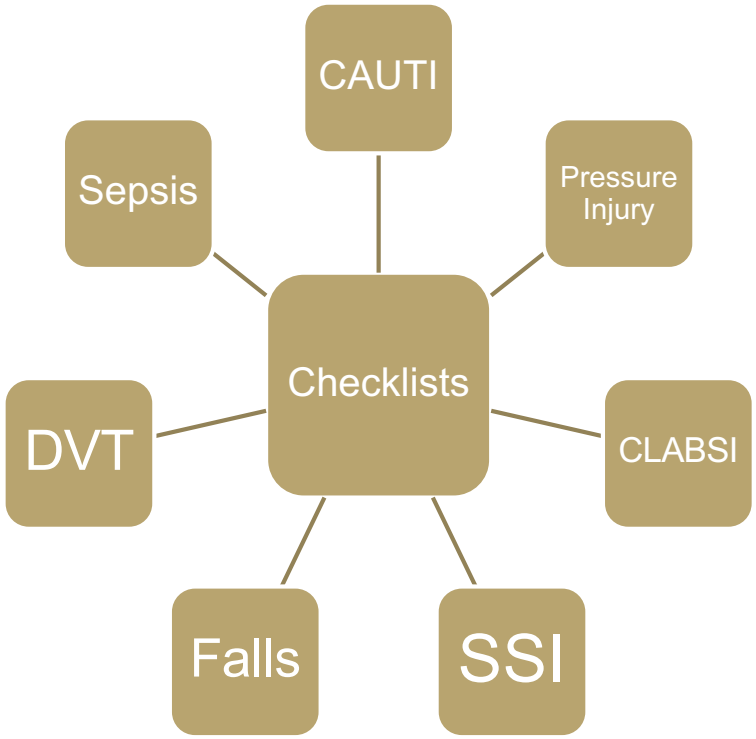
Chapter 3

Repairing the Clinical Microsystem



Complexity Bias

Systems have a tendency to over-complicate the reduction of patient harm, and in a state of confusion, break it down into many parts that address limited components of the greater problem.



Gestalt Principle: The Whole is Greater than the Sum of its Parts

MAYO CLINIC

PERSPECTIVE AND CONTROVERSY

Complexity Bias in the Prevention of Iatrogenic Injury: Why Specific Harms May Inhibit Performance

William V. Padula, PhD; David G. Armstrong, DPM, MD, PhD; and Dana P. Goldman, PhD

Iatrogenic injury is a subject of great concern, fueled, in part, by research finding that medical error as the third leading cause of death worldwide.[1,2] The US Agency for Healthcare Research and Quality (AHRQ) reported a 13% decrease between 2014 and 2017 across major patient safety events, most of which are related to iatrogenic injury in patients with complex conditions. These reductions in infections and injuries have saved $7.7 billion and averted 20,500 deaths.[3]

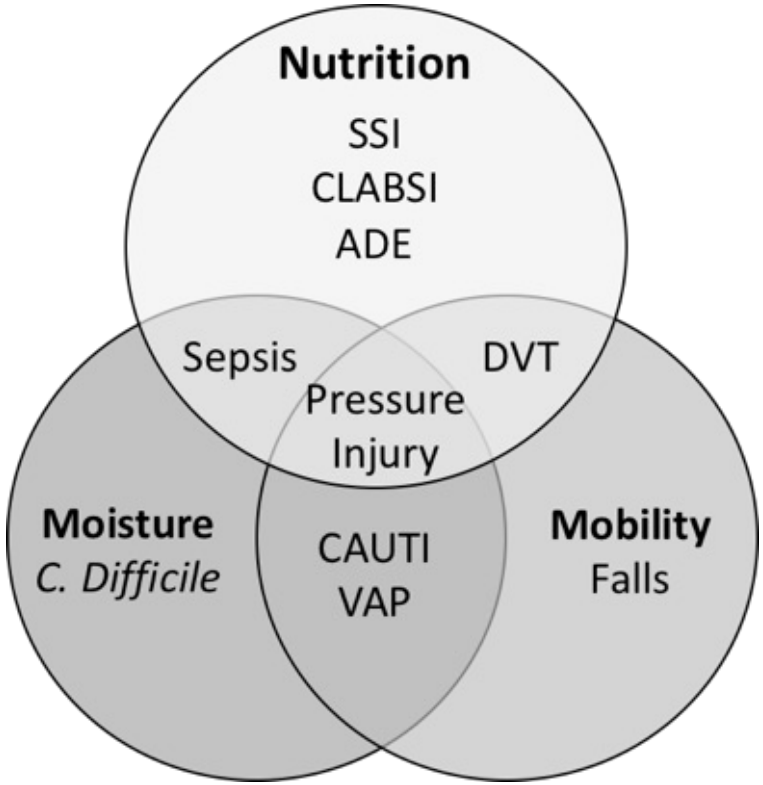
But hospitals and the US Centers for Medicare and Medicaid Services (CMS) are missing a chance for even greater impact, particularly among patients who remain bedridden after complicated procedures. Hospitals need to reduce the complexity that builds from trying to reduce harms individually, rather than systematically, and CMS needs to recognize that its incentives for reduction of harm are not functioning properly to address the safety needs of factors that could be addressed in a more efficient, unified, and replicable manner.

There is little doubt that CMS penalties have spurred some reductions in iatrogenic injuries overall, with the intent of addressing this complexity bias. In 2014, CMS installed a 1% reimbursement penalty on lowest-performing health care systems in addition to withholding payment on composite rates of 11 outcomes, termed *Patient Safety Indicator 90 (PSI90)*.[5] AHRQ attributed much of the observed reduction across these iatrogenic injuries to CMS payment changes, as do independent analyses exploring these associations over time.[6] However, the rate reductions have not been equal across all iatrogenic injuries. In fact, some hospitalized patients may be less safe as a result of these reimbursement policies.[7,8]

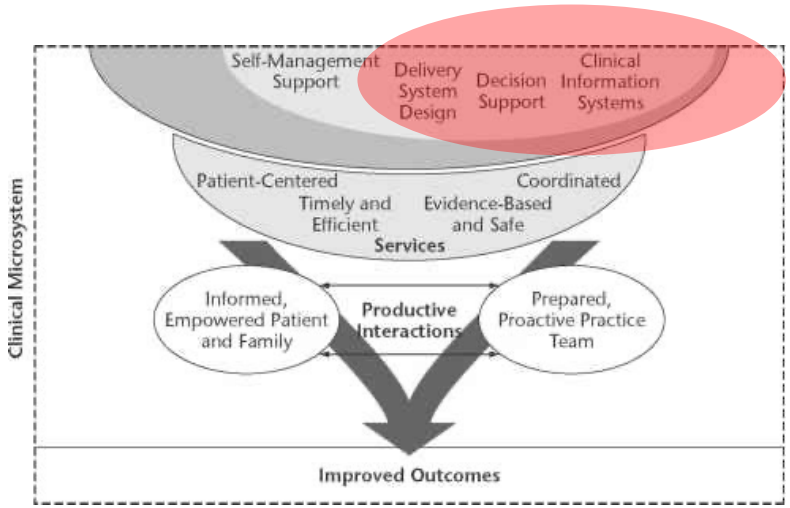
Pressure injuries increased 6% between 2014 and 2017, representing more than $25 billion in waste and potentially causing nearly 60,000 deaths each year.[3,9] Likewise, catheter-

For editorial comment, see page 205

From the Department of Pharmaceutical and Health Economics, School of Pharmacy, University of Southern California, Los Angeles, CA (W.V.P., D.P.G.); Leonard D. Schaeffer Center for Health Policy and Economics, University of Southern California, Los Angeles, CA (W.V.P., D.G.A., D.P.G.); Department of Acute & Chronic Care, Johns Hopkins School of Nursing, Baltimore, MD (W.V.P.); Department of Surgery, Keck School of Medicine of University of Southern California, Los Angeles, CA (D.G.A.); and Price School of Public Policy, University of Southern California, Los Angeles, CA (D.P.G.).



The Potential of Information Systems



- **The Information System – and its complementary components – can reduce the complexity of healthcare delivery**
- **Streamline implementation of competing clinical processes**
- **Navigate clinician workflow**

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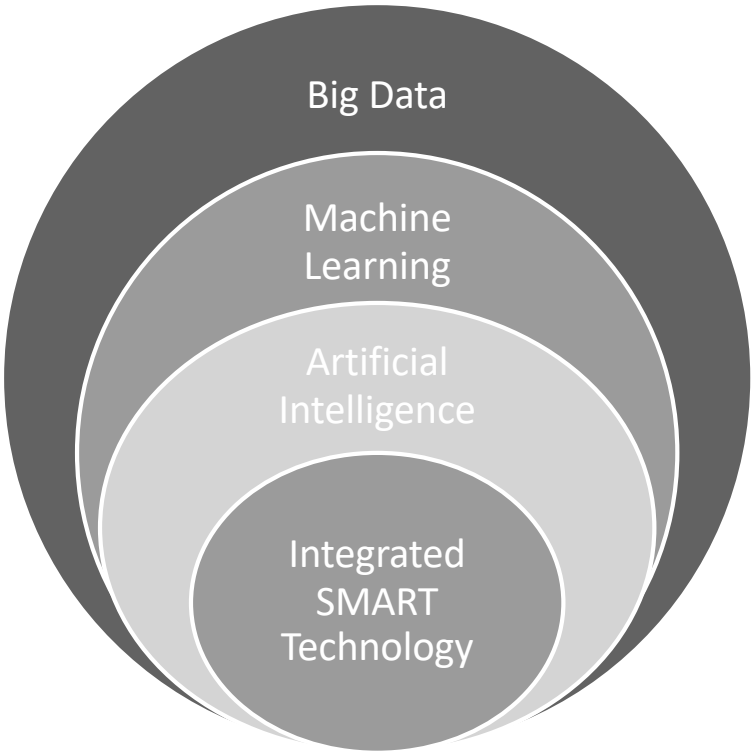
Chapter 3

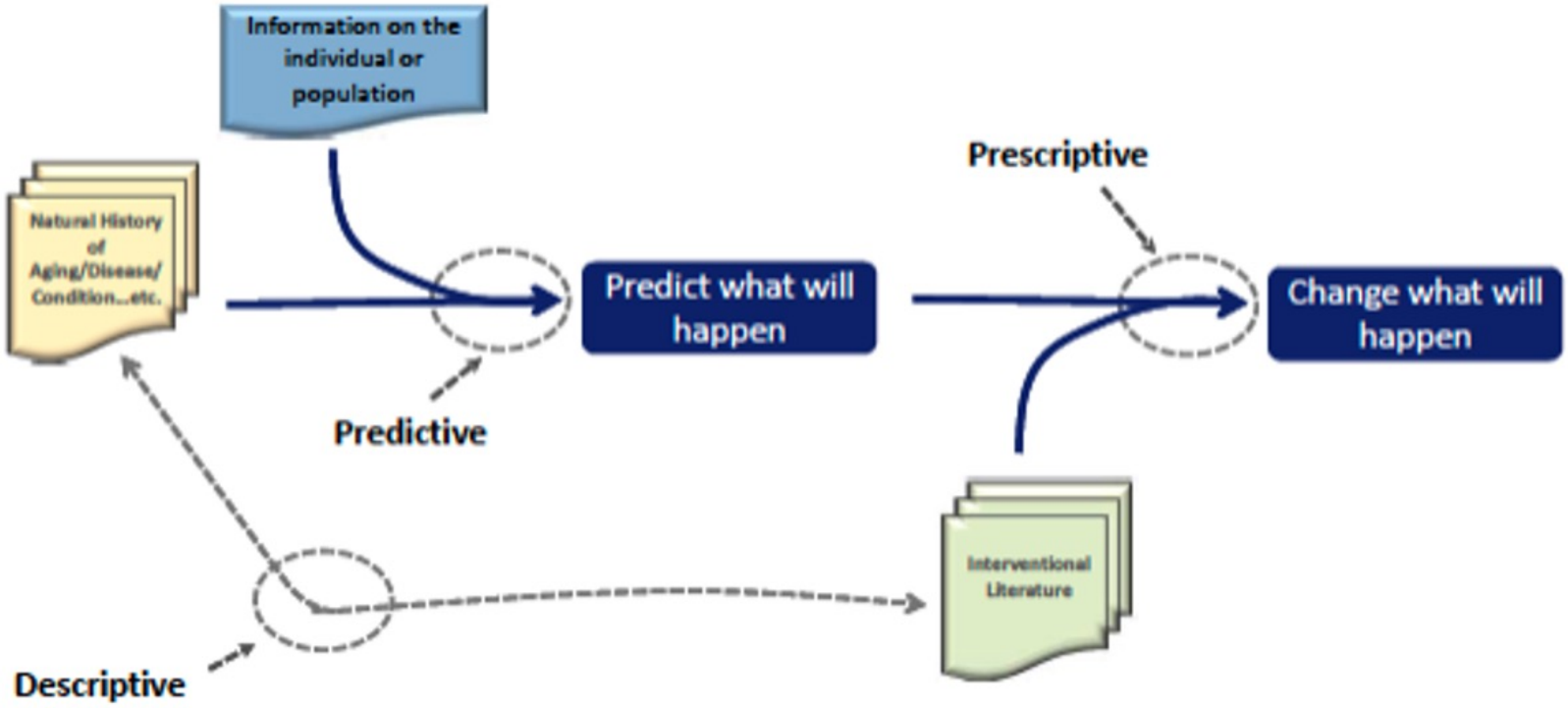
Introducing Topics in Big Data

Stepwise Components of Data Science



- **Big Data:** Sets of data too large or complex to be dealt with using traditional data processing techniques
- **Machine Learning (ML):** A family of mathematical and statistical methods for classification and prediction
- **Artificial Intelligence (AI):** Automation of analytical process with high volumes of information
- **Smart Technology**: Technology integrated with AI features and continuous flow of big data

The Potential for Big Data in Healthcare



How Big Data Applies to Wound Care: Pressure Injury Risk Assessment

- **Descriptive Information: Braden Scale for Risk Assessment**

BRADEN SCALE FOR PREDICTING PRESSURE SORE RISK

Patient's Name _____ Evaluator's Name_____ Date of Assessment

SENSORY PERCEPTION ability to respond meaningfully to pressure-related discomfort	**1. Completely Limited** Unresponsive (does not moan, flinch, or grasp) to painful stimuli, due to diminished level of consciousness or sedation. OR limited ability to feel pain over most of body	**2. Very Limited** Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness OR has a sensory impairment which limits the ability to feel pain or discomfort over ½ of body.	**3. Slightly Limited** Responds to verbal commands, but cannot always communicate discomfort or the need to be turned. OR has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities.	**4. No Impairment** Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort.				
MOISTURE degree to which skin is exposed to moisture	**1. Constantly Moist** Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned.	**2. Very Moist** Skin is often, but not always moist. Linen must be changed at least once a shift.	**3. Occasionally Moist:** Skin is occasionally moist, requiring an extra linen change approximately once a day.	**4. Rarely Moist** Skin is usually dry, linen only requires changing at routine intervals.				
ACTIVITY degree of physical activity	**1. Bedfast** Confined to bed.	**2. Chairfast** Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair.	**3. Walks Occasionally** Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair	**4. Walks Frequently** Walks outside room at least twice a day and inside room at least once every two hours during waking hours				
MOBILITY ability to change and control body position	**1. Completely Immobile** Does not make even slight changes in body or extremity position without assistance	**2. Very Limited** Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently.	**3. Slightly Limited** Makes frequent though slight changes in body or extremity position independently.	**4. No Limitation** Makes major and frequent changes in position without assistance				
NUTRITION usual food intake pattern	**1. Very Poor** Never eats a complete meal. Rarely eats more than ½ of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take a liquid dietary supplement OR is NPO and/or maintained on clear liquids or IV's for more than 5 days.	**2. Probably Inadequate** Rarely eats a complete meal and generally eats only about ½ of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement OR receives less than optimum amount of liquid diet or tube feeding	**3. Adequate** Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products per day. Occasionally will refuse a meal, but will usually take a supplement when offered OR is on a tube feeding or TPN regimen which probably meets most of nutritional needs	**4. Excellent** Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation.				
FRICTION & SHEAR	**1. Problem** Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance. Spasticity, contractures or agitation leads to almost constant friction	**2. Potential Problem** Moves feebly or requires minimum assistance. During a move skin probably slides to some extent against sheets, chair, restraints or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down.	**3. No Apparent Problem** Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair.					
				Total Score				

- **Predictive Information**
  - Patient Age?
  - Patient Skin Color?
  - Prescription Drugs?
  - History of Skin Disorders?
  - Proxy Measures of Braden Subscores?

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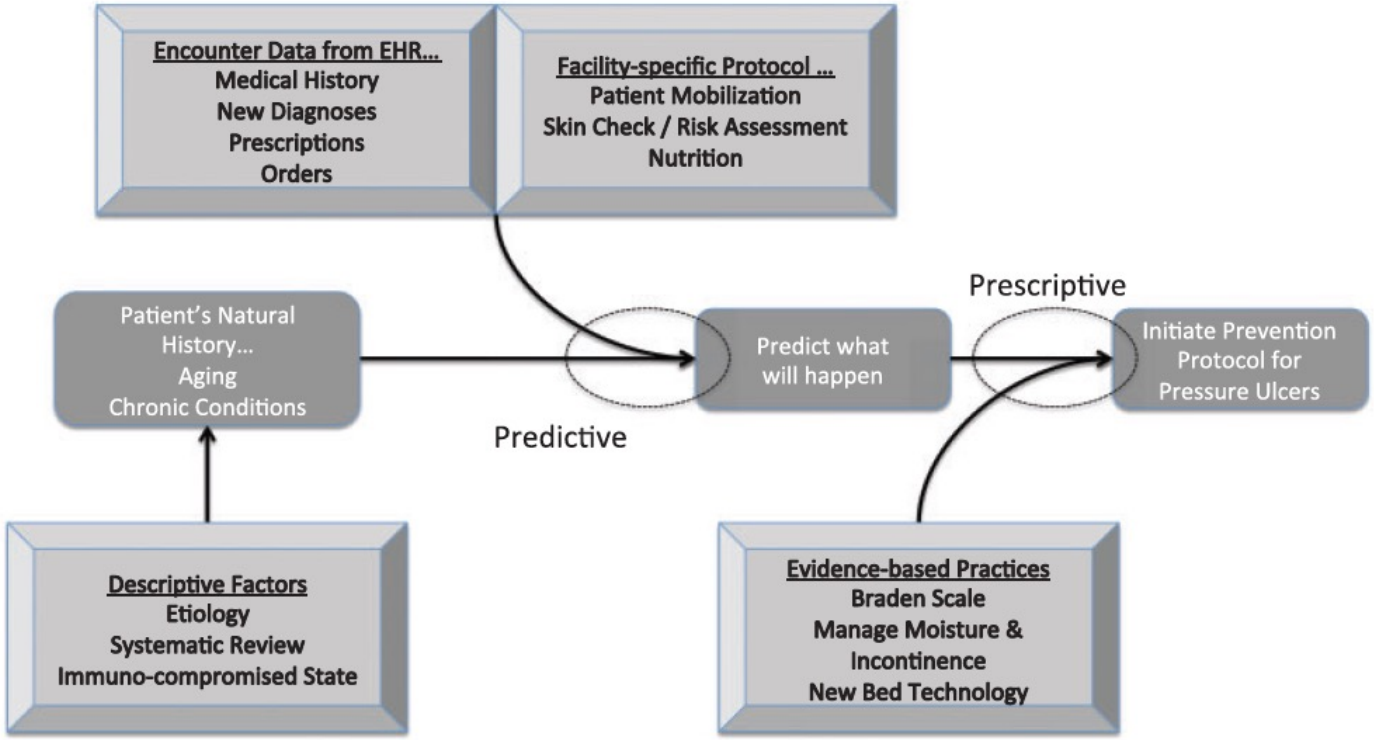
Chapter 4

Translation of Big Data with Machine Learning Directly to Improve Patient Care

Using EHR data to predict outcomes, combined with existing interventional literature, creates a smarter, more efficient health



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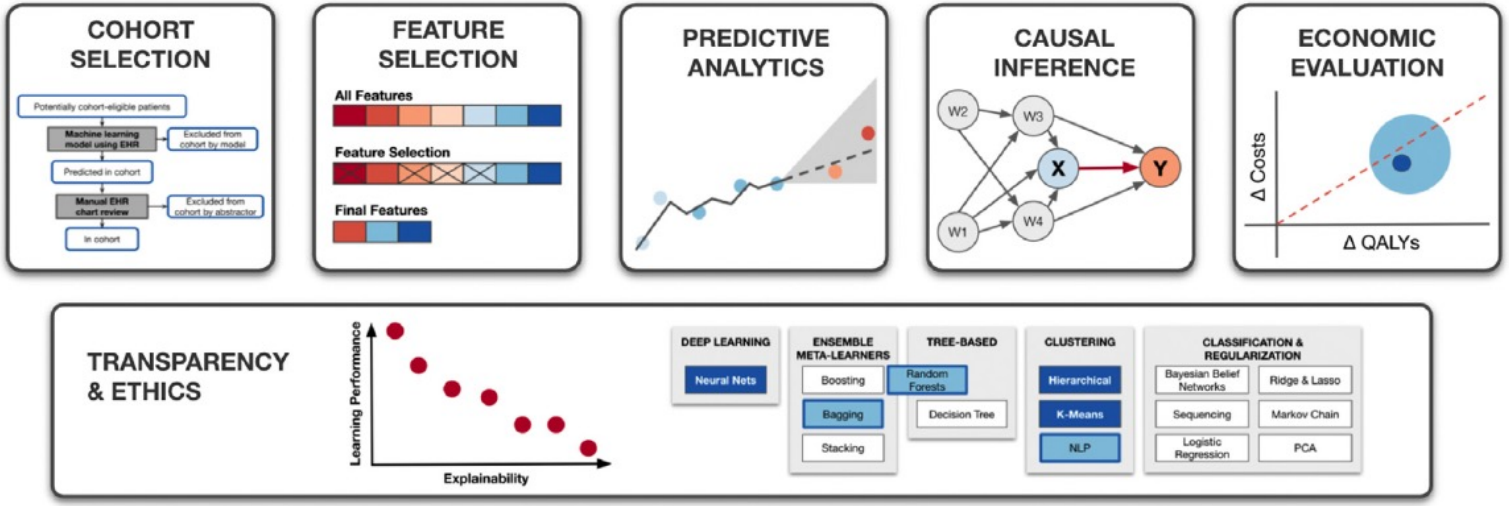
Machine Learning can be used to predict patient outcomes

ISPOR Report

Machine Learning Methods in Health Economics and Outcomes Research—The PALISADE Checklist: A Good Practices Report of an ISPOR Task Force

William V. Padula, PhD, Noemi Kreif, PhD, David J. Vanness, PhD, Blythe Adamson, PhD, Juan-David Rueda, MD, PhD, Federico Felizzi, PhD, MBA, Pall Jonsson, PhD, Maarten J. IJzerman, PhD, Atul Butte, MD, PhD, William Crown, PhD



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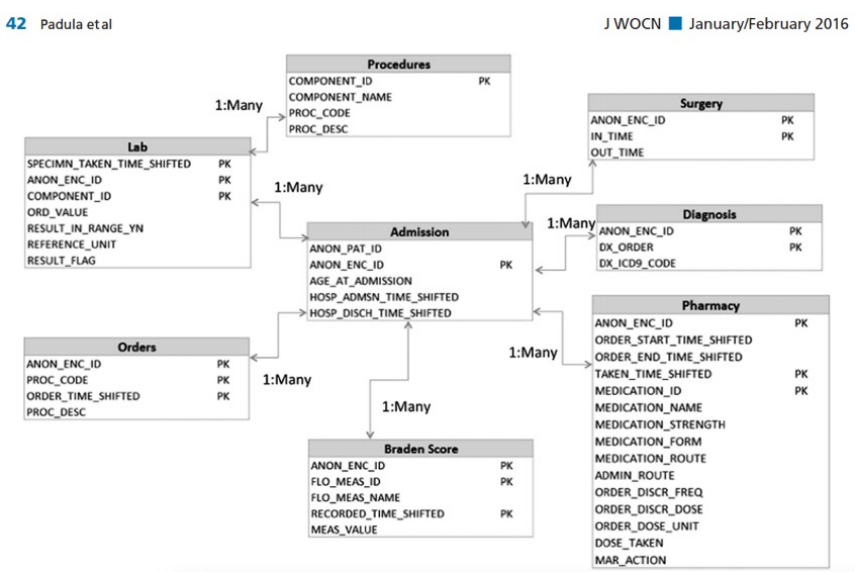
Leveraging EHR Data for Predicting Pressure Injury Risk

Machine Learning can be used to mine EHR Data



Pressure Injury Risk is Predictable, not with explicit sensory data, but using Big Data that is captured in the EHR

Journal of the American Medical Informatics Association, 24(e1), 2017, e95–e102
doi: 10.1093/jamia/ocw118
Advance Access Publication Date: 18 August 2016
Research and Applications

Research and Applications

Using clinical data to predict high-cost performance coding issues associated with pressure ulcers: a multilevel cohort model

William V Padula,[1] Robert D Gibbons,[2,3] Peter J Pronovost,[4,5] Donald Hedeker,[3] Manish K Mishra,[6] Mary Beth F Makic,[7] John FP Bridges,[1] Heidi L Wald,[8] Robert J Valuck,[9] Adam J Ginensky,[10] Anthony Ursitti,[10] Laura Ruth Venable,[10] Ziv Epstein,[11] and David O Meltzer[12]

Equation 1: Predictive model of pressure ulcer incidence using multilevel logistic regression.

$$\text{Logistic}\left[E\left(\text{HAPU}_{ij}\right)\right] = (\beta_0 + u_{0i}) + \beta_1 * \text{BradenScore}_{ij} + \beta_2 * Rx_{ij} + \beta_3 * Dx_{ij} + \beta_4 * \text{Lab}_{ij} + \beta_5 * \text{Age}_{ij}$$

NONE OF THIS IS IN THE ORIGINAL BRADEN SCALE

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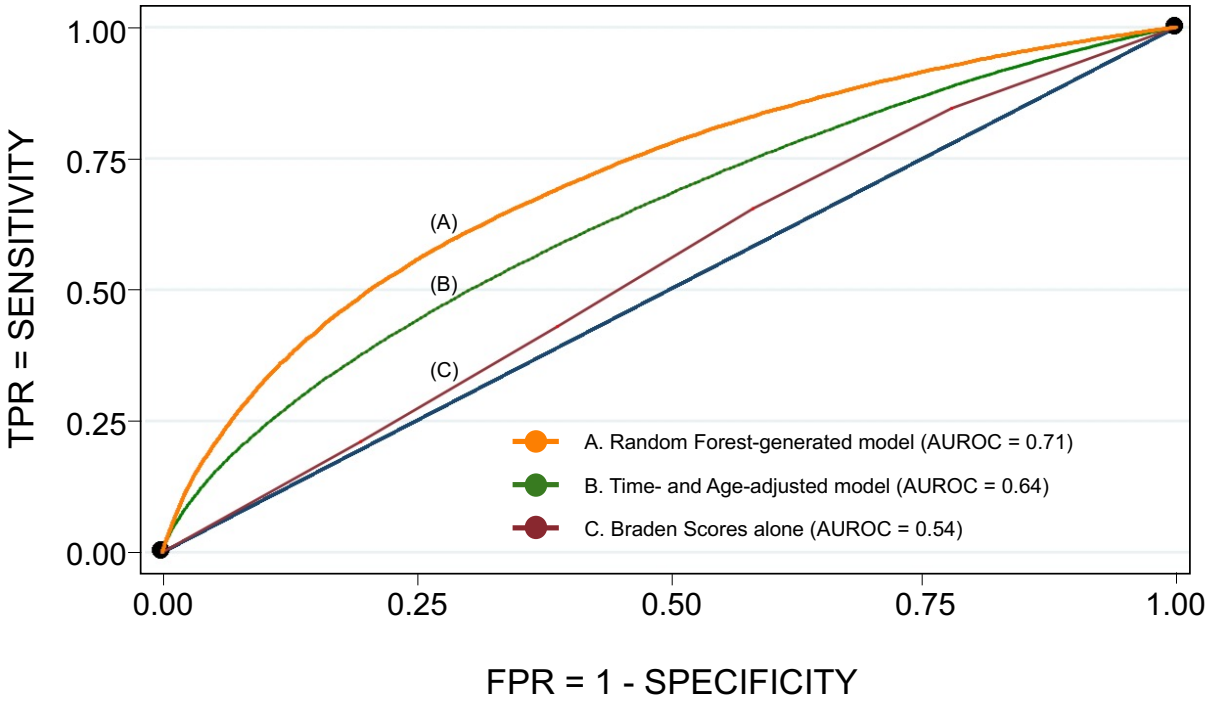
				Total Score				

- **Standout Odds Ratios on Pressure Injury Risk:**
  - Vassopressin Rx = 16.4 OR
  - Beta Blocker Rx = 4.8 OR
  - Urinalysis Order = 9.1 OR
  - Lipid Panel Order = 5.6 OR
  - Age *matters*
  - Time in the hospital *matters*

ROC Curve of Prediction Model Using EHR Data



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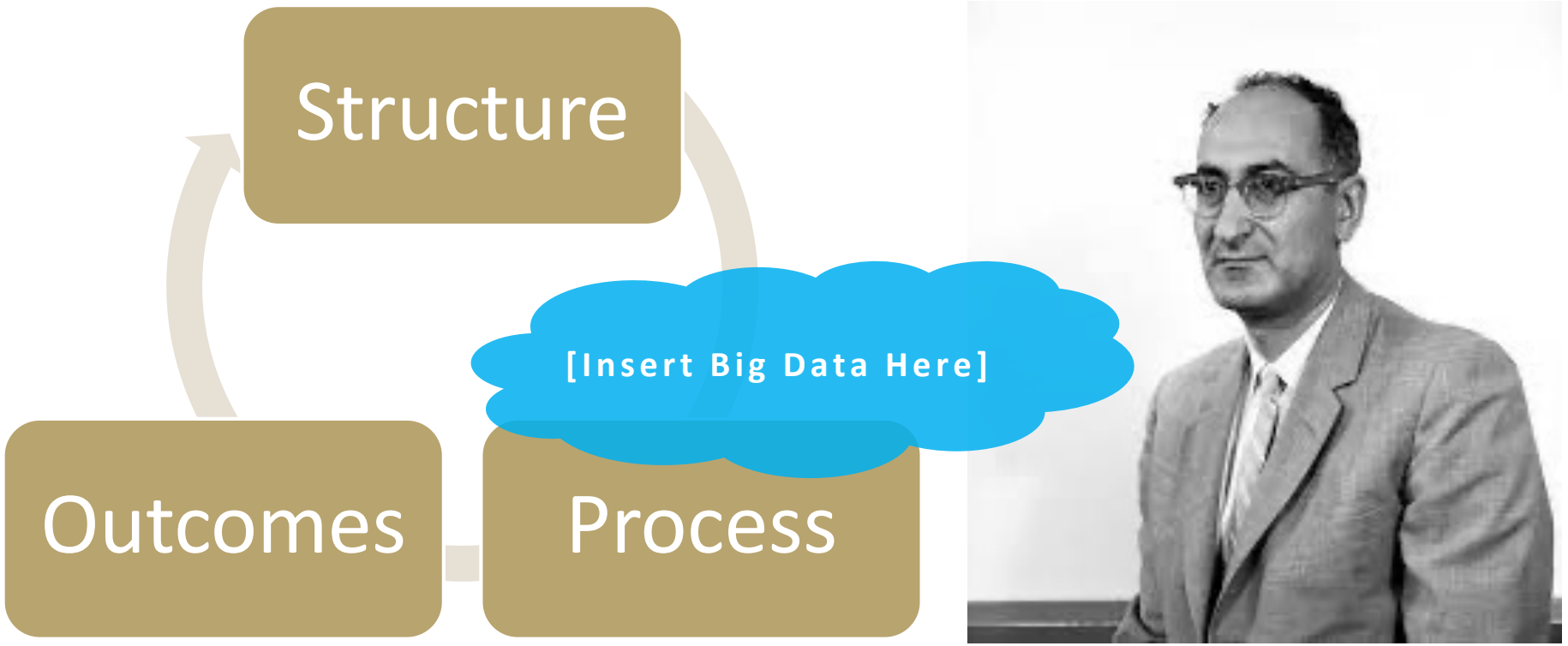
The Donabedian Model



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Chapter 5

Integrating Big Data into Smart Technology

Wound Care: Medicine's Favorite Topic to Poke at

ACP American College of Physicians℠ Leading Internal Medicine, Improving Lives

CLINICAL GUIDELINE

Risk Assessment and Prevention of Pressure Ulcers: A Clinical Practice Guideline From the American College of Physicians

Amir Qaseem, MD, PhD, MHA; Tanveer P. Mir, MD; Melissa Starkey, PhD; and Thomas D. Denberg, MD, PhD, for the Clinical Guidelines Committee of the American College of Physicians*

Recommendation 1: ACP recommends that clinicians should perform a risk assessment to identify patients who are at risk of developing pressure ulcers. (Grade: weak recommendation, low-quality evidence)

COMPARATIVE DIAGNOSTIC ACCURACY OF RISK ASSESSMENT TOOLS FOR PREDICTING THE INCIDENCE OF PRESSURE ULCERS

Moderate-quality evidence showed that the Braden, Cubbin and Jackson, Norton, and Waterlow scales had low sensitivity and specificity to identify patients at risk for pressure ulcers. In addition, moderate-quality evidence showed that diagnostic accuracy did not differ substantially among the scales (15). Low-quality evidence showed no clear differences in diagnostic accuracy of the Braden scale according to patient characteristics or settings, with lower optimal cutoffs for surgical or acute care patients. Moderate-quality evidence showed no clear differences in diagnostic accuracy of the Braden scale according to baseline pressure ulcer risk. Although the Cubbin and

The Field of Wound Care Needs to Respond by Doing More, and Sensor Technology Can Help

Annals of Internal Medicine

EDITORIAL

Pressure Ulcer Prevention and Management: A Dire Need for Good Science

Joyce Black, PhD, RN, CWCN

The ACP guidance reflects that risk assessment tools for pressure ulcers are imperfect predictors of risk. Pressure ulcers typically develop in patients with limited ability to participate in their own care. Therefore, application of the principles that are used to predict risk for other conditions, such as cancer, is problematic. First, patients with pressure ulcers often cannot participate in decisions about whether to have risk assessment. Second, the low sensitivity and specificity of pressure ulcer risk assessment are expected because risk can change within minutes (for example, from anesthesia or sedation). These varying risks are not captured unless the risk assessment tool is completed contemporaneously with changes in patient condition. Further, tools to assess pressure ulcer risk are often used in populations that differ from those in which they were developed. The Braden Scale, the most commonly used tool in the United States, was initially developed for long-term care residents. When applied in

Objective Measurement: Sensor Technology

Efficacy of Monitoring Devices in Support of Prevention of Pressure Injuries: Systematic Review and Meta-analysis

ADVANCES IN SKIN & WOUND CARE • DECEMBER 2016

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- **Pressure Sensing**
- **Temperature Sensing**
- **Moisture Sensing**
- **Mobility/Positional Sensing**
- **Activity Sensing**
- **Oxygen Sensing**
- **Nutrient Sensing**
- **Photography**

These are effectively the Braden Subscales measured by sensors

Sensors that objectify Braden subscales overcome clinical judgement, validate risk and increase the economics of pressure injury prevention

Original Research

The cost-effectiveness c
moisture scanning to as
injury risk in U.S. healtl

William V Padula[1,2], Shreena Ma
Sue Creehan[3], Barbara Delmore[4]

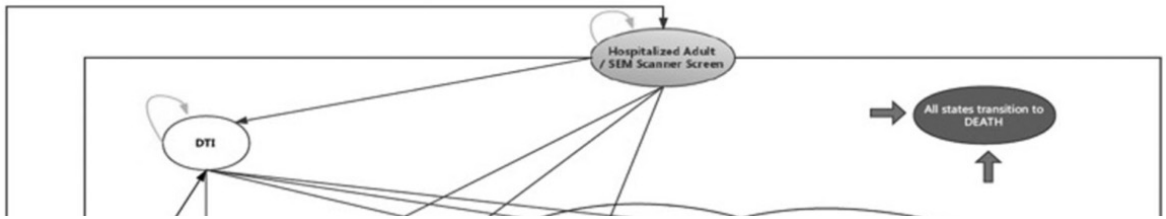

Table 3. Expected results of the cost-effectiveness analysis comparing SEM scanning to standard care for pressure injury prevention in hospitals.

Intervention	Cost (2018 USD)	Incremental cost	Effectiveness (QALYs)	Incremental effectiveness	ICER ($/QALY)
Standard care	4966	4054	12.19	−0.35	Dominated
SEM scanner	912		12.55		

SEM: sub-epidermal moisture; QALY: quality-adjusted life year.

Pros and Cons of Data-based Sensor Technology

- **Pros**
  - **High Sensitivity and Specificity**
  - **Functions wrt. Subscales are clear**
  - **Handheld**
  - **Affordable**
  - **Multiple purchase/lease options may exist**
- **Cons**
  - **Variable shelf life**
  - **Capital equipment (depreciates)**
  - **Requires tuneups to remain valid**
  - **User Error**
  - **Lack of integratability for some information systems**

Big Win: Health Equity

There is a greater amount of difficulty associated with [Visual Skin and Tissue Assessment]…due to the complexity of not recognizing the redness in darker skin tones.

-Prof Barbara Bates-Jensen, 2021

- **Big Data does not discriminate**
- **Darker Skin Tones do not deter the accuracy of Big Data**
- **Moving from a field of clinical judgement, whether structured or not, into codependence on technology for risk subscales ensure that all patient risk is measured equitably**

Conclusion: Putting Sacred Cows out to Pasture

- Methods for ML/AI are Advancing Quickly
- Laborious Nurse-Driven Protocols Can be supplemented with Big Data and Machine Learning Algorithms
- Artificial Technology Can Reduce Bias in the Analysis of Patient Risk Factors
- Consult your local Data Scientist for more information

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Thank you!

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