Navigating Through Turbulence

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Conflict of Interest Disclosure
Paul Arnstein 2012 - 2014

- Sterling Labs: Scientific Advisory Panel
- Zogenix: Scientific Advisory Panel
- Janssen: Scientific Advisory Panel
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- Gannet publications: Author & editor
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- American Pain Society: Speaker (FDA-REMS content)

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Pain & its Treatments in Context

- Pain as Punishment
- Pain as an Emotion
- Pain as Physical Sensation
- Sociocultural Learned Responses
- Pain in a Post-modern Era of Medical Science
- Impact of Healthcare Trends on Pain Treatments
Pain affects the whole person
• Severe or persistent pain sends ripples through the nervous system, invading the person's whole life... personality... and relationship with the world... and the lives of others...

Duty to relieve pain & suffering
• Health professionals have an ethical duty
  – To alleviate suffering
  – To provide services in a competent & humane way
• Suffering occurs when....
  – Pain is overwhelming
  – Person feels out of control
  – Source of pain is unknown
  – Meaning of pain is dire
• Withholding pain treatment is profoundly wrong, leading to unnecessary, harmful suffering*...

[Declaration of Montreal, 2010 – signed by U.S. over 40 countries]

Resolving Ethical Dilemmas
• Beneficence vs. Nonmaleficence
  – Balancing concerns
    • Maximizing benefit, minimizing harm
• Paternalism vs. Autonomy
  – Power struggles, professionals vs. patients
• Justice
  – Fair allocation
• Umbrella Principles
  – Medicine vs. Nursing
Pathological Effects of Severe Acute Pain
(IN VULNERABLE PATIENTS)

• Cardiovascular Morbidity / Mortality
  – Hypertension, MI, Stroke, CHF
  – Hypercoagulable state (Thromboembolism)
• Endocrine / Immune compromise
  – Hyperglycemia, negative nitrogen balance
    • Immune compromise
• Renal retention of sodium and water
• Decreased GI Motility
• Poor healing, tissue wasting if prolonged
• Immune compromise
• Psychosocial impact
  – Anxiety, PTSD, depression
    – Impaired sleep

Poorly Controlled Pain: a Prevalent and Costly Public Health Problem

<table>
<thead>
<tr>
<th>Impaired Sleep</th>
<th>Emotional Distress</th>
<th>CV stress, DVT / PE</th>
<th>Atelectasis, PNA</th>
<th>Catabolism, Immunologic suppression</th>
<th>Longer LOS ICU/Hospital</th>
<th>Opioid-related ADEs</th>
<th>Impaired or Delayed Rehabilitation</th>
<th>Higher Costs</th>
<th>Chronic Pain</th>
<th>Dissatisfaction</th>
<th>Lower payment rate</th>
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<td>Pain</td>
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Undesirable Effects of Chronic Pain

• Long-term exposure to potential dangerous drugs
• Expenditures on health care average $10,000/pt. year
• Increase in all-cause mortality in 10 years
• Leading burden of illness & disability worldwide
• Chronic pain is a common reason for:
  – Seeking health care,
  – Specialist consultation
  – Prolonged hospitalization
  – Unplanned readmissions
  – Low HCAHPS Scores

NATIONAL CENTER FOR HEALTH STATISTICS (2006). Special Feature on Pain
Potential Harm from Pain Medications

- Leading cause of drug-related hospitalization
  - 25% involving older adults related NSAID toxicity
  - >1 million opioid (70% Medicare, 30% Medicaid) hospitalizations
- 1 million older adults/y go to ED for ADEs
  - 9% involve opioids & 8% nonopioid analgesics
- Opioids leading cause of overdose deaths
  - 77% Benzodiazepine deaths – also had opioids
  - 65% antiepileptic/anti-parkinson deaths w/ opioid

WHO* 3-Step Approach to Relief

1. Non-opioids for mild to moderate pain ± Adjunct
2. Opioids for mild to moderate pain ± Adjunct
3. Opioids for moderate to severe pain ± Adjunct

- Adjunct examples
- Drugs: Non-drugs: Interventions
  - Nerve blocks
  - Non-drugs: Invasive
  - Distraction
  - Non-drug
  - Acupuncture
  - Exercise

1994 - 2004

Driving Forces
Confidence in new & existing therapy
Public outcry: use all weapons to treat pain
Focus on Practice-Based Evidence
Regulator focus on the need to better assess, plan & manage pain

2004 - 2014

Restraining Forces
Immobilizing fear of new & existing therapy
Public outcry: limit access to pain-killers*
Focus on Evidence-Based Medicine (RCT-based)
Regulator focus on defining appropriate quotas when prescribing, dispensing & using opioids to manage pain

*Except dying cancer patients
ASPMN New Name & Logo
Re-affirmed our core

- **PURPOSE:**
  To promote optimal pain management

- **MISSION:**
  To advance & promote optimal nursing care for people affected by pain

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**Big Audacious Goal**
(10-30 year envisioned future of ASPMN in 2004-2005)

Be the leader whose pre-eminent voice & unparalleled resources catalyzed the integration of pain management nursing into all aspects of healthcare.

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**Promote Access to Quality Care**
(5-year goal established in 2004-2005)

All people will have access to healthcare services that provide quality pain management care.

- Do They?
  - Disparities in access to Pain Specialists
  - “Real time” pain info for generalists
  - Advocate for payer policy changes
**Promote Access to Professional Resources**
(5-year goal established in 2004-2005)

Members have instant, easy & affordable access to current, clinically relevant, evidence-based resources.

**Do We?**
- High quality of easy to use products
- Technologies to facilitate access
- Update products regularly

**Promote Public Awareness**
(5-year goal established in 2004-2005)

The public will demonstrate self-advocacy skills essential to their pain care needs.

**Can They?**
- Community standards raised re: what constitutes acceptable, and expected pain management
- Increase the public outrage against inadequate pain control

**Promote Professional Recognition**
(5-year goal established in 2004-2005)

Certified Pain Management Nurses will be respected, valued and compensated for their expertise as an integrated and indispensable member of the healthcare team.

- Promote and market Certification (professional & APN level) in Pain Management Nurses
- Advocate for better pay, benefits & work conditions

**Are We?**
Others must learn what we know

- Unrelieved pain is unacceptable
  - But more common than pain relief
  - and it’s tolerated... why?
- Strong medicines are not pain KILLERS,
  - Strong pain is a killer of people’s quality of life
- People don’t want pain relief for 2ndary gain
  - They just want to avoid 2ndary losses

Do Others Know/Believe This?

Remarkable Gains Past 10 years

- # Certified Pain Management Nurses
- Development of an APRN Certification
- Enormous # of Research Studies
  - Multitude of systematic reviews, guidelines, etc.
- Improved Pain Education Materials
- Multitude of Professional Resources
- Raised public awareness
- Improved Public Policy (report cards)

Pain: A Public Health Problem

- Pain is a top reason people seek healthcare
- 15% Americans major trauma/surgery pain
- >100 million Americans have chronic pain
  - Costs $600Bil/year, > heart disease & CA
- Poor acute pain control can cause chronic pain
  - cancer, back pain, diabetes, arthritis
- 30% give low marks for pain control

CDC (2007) Fast Facts A-Z @ CDC.gov
Ries et al. (2008). SEER Cancer Statistics Review
CDC (2008). Targeting Arthritis: @cdc.gov
National Center for Health Statistics (2006), Special Feature on Pain
Jha et al. (2008) [HCAHPS] NEJM, 359 (18):1921-31
1.1. To achieve vital improvements in the assessment and treatment of pain will require a cultural transformation.

“...the unreasonable failure to treat pain is viewed worldwide as poor medicine, unethical practice, and an abrogation of a fundamental human right.”

Current State of Pain

- Costly, prevalent public health crisis
- Plethora of guidelines & position papers
  - No standard entry-level competencies
- Health professionals unprepared to treat pain
  - <4% Medical schools have course on pain

Research, Education & Practice Gaps

- Research suggests 70-90% of patients with acute or cancer pain could have it prevented or relieved
- Adequate treatment received by
  - ~25% acute pain patients
  - < 50% cancer pain patients
  - 25-60% chronic pain patients
  - < 50% nursing home residents
- Disparities / age, gender, race, disorder
- When guidelines are followed outcomes are improved

Education on Pain in Medical Schools

- 25% ≤ 5hrs
  - USA (median: 7)
  - Canada (median: 14)
  - Veterinarian schools: 87 hours on pain*
**IOM (2011) Report on Pain**

- Pain’s intricacy demands expertise of >1 discipline
- All disciplines need to improve education
  - Demands valuing & respecting others’ insights
  - Need interprofessional teams to coordinate/implement multi-professional treatment plans
- Innovative pain education greatly needed
- Develop shared & role-specific competency
- Collaborate between institutions to disseminate refined content with diverse teaching strategies
- Incorporate novel teaching into existing curricula
  - (e.g. CoEPE’s)

Pain Education Dissemination & Impact

- Inter-professional unity needed to:
  - Promote effective teamwork between health professionals
  - Disseminate evidence-based pain curriculum:
    - To establish universal pain standards for all disciplines
  - Develop liaisons with administration and curriculum committees to ensure implementation:
    - National initiative needed to directly influence education locally
  - Collaborate with Pain Champions at other institutions:
    - Unified approach increases patient comfort & safety
    - Remove “silo-ism” between professionals & institutions

Interprofessional Pain Competency ...

A win-win

- Consensus-derived domains are established
- All professionals must be able to:
  - Articulate the multidimensional nature of pain
  - Assess pain in a consistent measurable way
  - Approach pain Rx in a collaborative way
  - Apply competencies across lifespan ...
    - in different settings
    - with different resources (care teams) available
    - aligned with the needs of the population served


*Recommended by International Association for the Study of Pain

The Perfect Storm of Controversy

Opioids Help

- Opioids work if doses personalized
- Tolerance is relatively rare once stable
- ER/LA opioids have many physical and psychological health benefits
- Opioids facilitate rehabilitation & improve function
- CNCP is a bigger public health problem than addiction & deserves treatment as a disease

Opioids Hurt

- Don’t work for chronic pain
- Make pain worse (OIH)
- Tolerance inevitably cuts efficacy
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- Tolerance inevitably cuts efficacy
- Iatrogenic addiction is common
- Opioids impede rehabilitation, by diminishing cognition, alertness, & motor function
- Long-term harm is unknown

An ethical obligation to use effective method to alleviate suffering & negative impact of CNCP
Opioid Deaths Are the “Tip of the Iceberg”

People living with Pain
Chronic: >110,000,000
Acute: >50,000,000

11/2011, there were 10,800 (prescription opioid-related) deaths.*

For every 1 death there are... 15 treatment admissions for opioids 38 emergency department visits for release or detox 20 people who overdose or die dependent

Plus 608 people prescribed chronic opioid therapy

People living with Chronic Pain, 6,757

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ConsumerReports.org

Special report: The dangers of painkillers
Every year, Percocet, Vicodin, and other opioids kill 17,000 Americans and acetaminophen sends 80,000 people to the ER
Published July 2014

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AHRQ Report this month on chronic opioid therapy effectiveness & risks

- 38 of 3,793 studies met quality standards
  - Differences in definitions & measures preclude the ability to deduce comparative effectiveness & risks
  - Strength of evidence was rated no higher than low
- Lack evidence to know benefits & harms
- Most patients do not develop drug problems
  - Opioid abuse 0.6% to 8%
  - Rates of dependence were 3.1% to 26%
  - Aberrant drug-related behaviors 5.7% to 37.1%

AHRQ Report this month on chronic opioid therapy effectiveness & risks
Comparative Effectiveness Review: Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain
Navigating the Turbulence

- Rise above the opioid debate
- We need a clear vision & goals
- Link to our duty, mission, and patient needs
  -- Patient focused teams that understand & treat “Total Pain”

Changing Own Practice: Fairly Easy

- Insight regarding moral/clinical need
- Expand knowledge
  -- Current clinical guidelines
  -- Professional standards,
  -- Codes of conduct & accreditation
- Identify biases, attitudes and values
- Patient advocacy for effective pain control
- Develop skills & a professional network

Changing Organizations: Difficult

- Gather information about problem
  -- Link to facts, standards & codes of conduct
- Garner input & administrative support
  -- Individuals, committee & community resources
  -- May need material resources & data management
- Align with key stakeholders
  -- Policy Makers
  -- Those who will do work or be affected
- Change Practice and Culture of Care Delivery
Identify a focused improvement opportunity

- Analyze safety report trends
- Use Magnet format for improvement if applicable
- Patient satisfaction (e.g. HCAHPS, Press Ganey)
- Medical record review/audit
- Interviews with staff and/or patients
- Electronic data (e.g. Medication administration, Readmissions)
- Clinical observations
- Patient complaints/comments

Outcome Elements examples

- Prevalence of pain > midpoint of pain scale for >1 day
- Delayed or cancelled treatments/therapy due to pain
- Patient dissatisfaction / complaints
- Prolonged length of stay due to pain
- Develops complications due to pain or its treatments
- Unplanned readmissions due to pain or its treatment

Accessing the Severe Pain Report

Go into eMAR (any patient), hover over reports, drop cursor down to select other reports, then draw cursor down to select Severe Pain Report
Select Unit Date, and how you want the data organized. The report is difficult to navigate now. Send me any suggestions to make it more user friendly.

Leadership Support When Dollars at Risk*

Value-based Purchasing
Process of care & patient experience (HCAHPS) begins FY2013, full 2% annual payment update at risk by FY2017

30-Day Readmissions
Up to 8 conditions targeted including AMI, HF, PNA
10% DRG payment penalty beginning FY2013, rising to 15% by FY2017

Hospital-Acquired Conditions
Up to 8 conditions targeted
1% DRG payment penalty for hospitals in worst quartile beginning FY2015

By FY2017, 66 out of every $100 Medicare DRG reimbursement potentially is at risk

*Initiated by CMS, adopted by other payors

“Patient Experience” measured by The HCAHPS Survey*

The HCAHPS survey measures patients perception of how often they received high quality care and service.

Questions on the survey about Pain Management:
• How often was your pain well controlled?
• How often did the staff do everything they could to help with your pain?

Rating Scale
Never Sometimes Usually Always

HCAHPS ONLY publicly reports the percentage of patients who rate us “ALWAYS”

*Hospital Consumer Assessment of Healthcare Providers & Systems is one part of the quality of care formula used to calculate reimbursement rate
HCAHPS Drill-Down to target change

Example #1

Example #2

Articulate a Problem Statement
(Why do we need to set sail – get moving?)

Purpose: Describe what’s not meeting the shared goal.
A good one...
- Describes the concern or opportunity objectively
- Describes the extent of the problem
- Describes the impact of the problem

Example*: On publically-available report cards, 30% of our patients are not always satisfied with the way their pain is treated, and dozens of complaints monthly are received about inadequacies in this area of practice. Patients with sustained severe pain have 20% longer stays than patients with the same diagnosis whose pain is controlled; and report lower satisfaction.

*Individualize the percentages based on actual data obtained (e.g. HCAHPS, audits)

Envision the Desired State*:
(Where do we want to be?)

- Pain will be consistently addressed & not allowed to become severe or intolerable
- Conventional & integrative treatments will be used when first-line treatment fails
- Patients will be safer & more satisfied
- Pain will not impede recovery, prolong stay or require readmission for unresolved severe pain
- Interprofessional teams will establish a treatment plan aligned with best practices & patient values

*Provided is an example of potentially measurable desired states
Develop a Process Map?
(Chart a course & adjust to stay on course)

- Understand the process to be improved
- Agree on the scope of project
- Compare actual with expected processes
- Find unnecessary, complex & redundant steps
- Reveal variation in the process
- Identify steps where additional data is needed
  - Data-based baseline, goals and monitoring plan

Use Quality Improvement Tools
(Navigate along the way)

- Understanding the process and needs
  - Process flow diagrams
  - Brainstorming
  - Cause-effect diagrams (Fishbone)
  - Prioritized List of Changes (Priority/Pay-Off Matrix)
- Feasible data collection/measurement tools
- Data analysis tools
  - Pareto charts: Highlighting the most common causes
  - Histograms: Visualizing Process Variation
  - Statistical Process Control Charts:
    - Understanding signal vs. noise

Prioritize List of Change: Priority/Pay-Off Matrix
(Build momentum)

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<thead>
<tr>
<th>Impact</th>
<th>Ease of Implementation</th>
<th>Difficulty</th>
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<tr>
<td>High</td>
<td>High impact / Easy Solutions</td>
<td>High impact / Difficult Solutions</td>
</tr>
<tr>
<td>Low</td>
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<td></td>
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<td>Difficult</td>
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</table>
Implementing a National Pain Strategy
Extremely Difficult & Political

- Cultural transformation to change the way pain is perceived, judged and treated (need to go)
- Need a National Pain Strategy (need a map)
  - Population-based, disease management approach to pain care
  - Support PCPs, facilitate access to pain specialists
  - Care delivery by integrated, interprofessional, patient-centered teams

Fulfill IOM (2011) recommendation 2.2

- Develop a comprehensive, population health-level strategy to
  - Establish public/private partnerships
  - Coordinate research, education, communication & care
  - Reduce pain and its consequences
  - Prevent development/worsening of chronic pain
  - Eliminate disparities in the experience of pain
  - Use standard (physical, psychological, therapeutic) outcome measures
  - Improve reimbursement for pain assessment & management
- Enhance public awareness about the nature of chronic pain
  - Including the role of self-care in its management.

Service Delivery & Reimbursement
Problem Statement

- Wide variation in practice & patients’ responses
- Repeated use of ineffective, risky treatments
  - Result in poor outcomes & the high costs of chronic pain care.
  - Fee-for-service approach perpetuates this pattern.
- When treatment fails, patients need
  - Consistent and complete pain assessments,
  - Coordinated and evidence-based pain care plan
  - An integrated, multimodal, interdisciplinary approach
  - Access to care through reimbursement reform
Primary care with or without specialist support

Expanded treatment teams that include professionals with expertise in Pain; Rehabilitation; Psych / Mental Health; &/or Substance Use Programs

Advanced pain management at an accredited program proving integrated care that addresses biopsychosocial & functional aspects of pain control

STEP 1
Guided Self-Management
Simple self-initiated non-drug methods with access to therapy using the appropriate strength / duration of analgesia therapy

STEP 2
Patient Centered Medical Home (PCMH) in Primary Care
Primary care with or without specialist support

STEP 3
Secondary Consultation
Expanded treatment teams that include professionals with expertise in Pain; Rehabilitation; Psych / Mental Health; &/or Substance Use Programs

STEP 4
Tertiary Pain Treatment
Advanced pain management at an accredited program proving integrated care that addresses biopsychosocial & functional aspects of pain control

THE NEW ENVISIONED FUTURE: SEEING 2020

Global Action Plan to be submitted Fall 2014 to Congress for appropriations, dissemination and delegation to multiple Agencies

Adapted from the VA Stepped Model

RISK

Comorbidities

Treatment Refractory

Complexity

National Pain Strategy Task Force
Have a good map and realistic plan
Prepare for storms and other obstacles
Assemble a knowledgeable crew with
  - Required skills
  - Shared values and vision
  - Teamwork
Execute the plan
Frequent monitoring & adjustments
  - Automate monitoring
  - Accountability for adjustments
Succession planning for sustainability