Using Audits and EBM to Implement Change in PIV Products, Practice, Policy and People

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Disclosures

• Russ Nassof is a paid consultant/speaker for Becton Dickinson (BD)
• Russ Nassof is the owner of RiskNomics, a consulting company.
Objectives

• Understand the difference between clinical practice guidelines (CPGs) and evidence based medicine (EBM) and their effect on current practice and policies.

• Identify the elements of a healthcare audit as well as the need for regular and systematic vascular access audits of products, practice, people, and policy.

• Discuss how the pre and post audit process can effectuate change and result in positive improvements in vascular access.
The Problem with Products

One of these things is not like the other....
But Products Can Be The Answer…

HEALTHCARE WHEEL OF FORTUNE

- Evidence based products, practice, medicine
- Meeting the SOC
- Data Driven

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- Profit
- Salary
- Bonus
- Happy C Suite

↑ Quality of Care
↑ Safety/efficiency
↑ Patient Satisfaction
↓ Risk
↓ Liability
↓ Costs

↑ Status
↑ Reporting Quality
↑ Morale

ACA
← Readmissions
← HACs
← VBP (Improvement, achievement)

Improving Outcomes

Investment

$\$\$

ACA

↑ Profit
↑ Salary
↑ Bonus
Happy C Suite
The Problem with Practice

- This is how we have always done it - WIIFM
- Do what any prudent nurse would do in the same situation
- Variation across the continuum of care - lack of uniformity and consistency
But Practice Can Be The Answer...

What happened to Critical Thinking AND the Power of Nursing?
The Problem With Policy

- Policy can inhibit change
- People can hide behind policy
- Policy must be continuously updated and validated
- Policy can conflict with standards and practice
- Policy must be uniform and consistent
- Policies that are not evidence based may not meet the SOC

Once policies are implemented... compliance is mandatory and the failure to comply is worse than having no policy at all.
But Policy Can Be The Answer

- Policies must be evidence based and must meet the standard of care
- Practice should align with policy
- Evidence based policies which do not align with standards may still be defensible
- Policies which are evidence based can help inaugurate valuable improvements
- Policies can provide valuable direction to clinicians
- Evidence based policies which align with the standard of care can improve clinician satisfaction, training, education, and competency
- Evidence based policies can improve the bottom line
The Problem with People

• People may be trained and educated but not competent
• People will take short cuts and work arounds in healthcare which do not meet the SOC
• Changes in staff and “floating” are common in healthcare and leads to variation
• Politics often plays a role in healthcare performance (hierarchies rule)
• Difficult to find supportive cultures many times to implement change
• People are afraid to face criticism for new ideas
• People are afraid to take responsibility
• People want to fit in regardless of what’s right (part of the team)
• People work in silos in healthcare and don’t reach out
• We usually don’t have enough people and everyone is too busy !!!
But People Can Be The Answer

- Competent clinicians can improve healthcare
- Competent clinicians can improve patient satisfaction
- Competent clinicians can recognize the need for improvement and implement change
- Competent clinicians can break down silos and create a culture conducive to change
- Competent clinicians can break down hierarchies and earn respect to influence decisions
- Competent clinicians can lead others to improve
- Competent clinicians can educate others
- Competent clinicians can improve the bottom line for all
Product/Practice/Policy/People Innovation - What’s Stopping Us?
Improvements/Innovation - What’s Stopping Us?

• Fear of the Unknown
• Quality of Care
• Cost
• Liability
• Lack of Resources
• Fear of being the Canary—that’s not what everyone else is doing
• If it’s not in the guidelines... it shouldn’t be done
Clinical Practice Guidelines (CPGs)

Professional Consensus

- Combination of contemporary professional belief and customary practice
- Failure to perform in accordance with “customary practice” or a recognized guideline could raise an inference of failure to meet the SOC
- Clinician would have to at least explain WHY
- May limit innovation at least until new CPGs gain more adherents and become the SOC or “customary practice”
- Can be used by both plaintiffs/defendants
Clinical Practice Guidelines (CPGs)

Because every patient is like a Snowflake...

Customary based practice does NOT always equate to good patient care !!!
Clinical Practice Guidelines (CPGs)

“Clinical Practice Guidelines (CPGs) can be used to develop audit criteria”

- (Dixon et al, 2010)

Clinical Practice Guidelines can be developed from

• Professional Consensus AND/OR
• EVIDENCE BASED MEDICINE*

Evidence Based Medicine (EBM)

EBM

• EBM emphasizes current best practice **BUT also urges clinicians to keep informed of current best EVIDENCE and practice accordingly**

• CPGs may not necessarily be current and may be influenced by the organization involved drafting the CPG***

• EBM instructs clinicians to rely on current scientific evidence even before that evidence is regarded as the prevailing custom.*

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***Lars Noah, Medicine’s Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community, 44 Ariz. L. Rev. 373, 382 (2002).

***Mackey T, Liang B, The Role of Practice Guidelines in Medical Malpractice Litigation, Virtual Mentor, 2011;vol 13, Number 1:36-41.
• Early Adoption of any new medical device, product, practice, technology, etc. carries with it some form of liability (malpractice/negligence) risk.

• BUT Standards of care are evolutionary and not static and providers have an obligation to stay abreast of new techniques and developments*

• CPGs developed from EBM can be used to effectuate change BUT...CPGs do not always reflect CURRENT best evidence!

Effectuating Change – What Do The Courts Say?

• Customary Practice- maintains status quo and clinicians feel immunized from liability
• Courts moving to Reasonable Prudence/ Best Judgment*
• What is reasonable may NOT be customary

*Helling v. Carey (519 P.2d981 [Wash. 1974]
Effectuating Change – What Do The Courts Say???

- Evidence of Acceptable Practice- if the relevant practice or product was found acceptable by a reputable subset of the profession it would NOT be regarded as improper even if few clinicians had adopted it at that time.*
  - May be used AFFIRMATIVELY OR DEFENSIVELY
  - VALIDATES IMPORTANCE OF SMALL EVIDENCE BASED STUDIES

Liability

The Standard of Care: The caution that a Reasonable Person in SIMILAR CIRCUMSTANCES would exercise in providing care*.

You are allowed to be Wrong...

You are allowed to make Mistakes...

You are NOT allowed to be negligent as an EARLY ADOPTER or ANYTIME.

*http://www.west.net/~smith/negligence/html
Liability

Compliance with CPGs and Negligence

• Defendants have been held liable for medical malpractice for FAILURE to adopt new technologies or procedures even when near universal custom did not involve using them*

• Legal standards of care do change over time in response to new products/technology

• Legal doctrines governing malpractice standards of care also include a duty to stay abreast... and have an obligation to be aware of evolving practices of medical care and make appropriate use of new scientific knowledge as it emerges**

• If outdated, compliance will NOT excuse poor practice.


Effectuating Change

- **Standards**
  - EBM/EBP- Level I, II, III?
  - CPGs- Evidence Based and/or Professional Consensus- INS/ONS/AVA/CDC, etc.
- **Hospital Policies/Products/Processes**
  - Compliance with Standards?
- **Practice**
  - Alignment with standards/policies?
Effectuating Change

How Do You Effectuate Change?

Audit: Quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of Change*.

Effectuating Change

How Can You Effectuate Change???

“A Cochrane systematic review confirmed that clinical audits when done properly, can lead to small but important improvements” (Ivers et al, 2012)

Audits can provide the justification to make changes which result in improvements

“Less than ideal audit results can provide direction where you need to refocus your efforts”*

Effectuating Change

Performing audits based upon evidence based medicine will identify gaps in practice, process (i.e. failure to meet the standard of care), variability and should result in making improvements that may change policy even if in conflict with CPGs.
Effectuating Change

Audit Goals

- Facilitate vascular access and improve care/maintenance
- Enhance compliance with the SOC
- Improve patient/clinician satisfaction
- Reduce risk/liability
- Facilitate compliance with guidelines/regulations
- Improve the bottom line - hard/soft costs
- Identify issues with products, practice, policy, and people so that improvements can be made
PIV Audit Plan

PIV Audits: A Desperate Underappreciated Need
Background

- 300 million PIVs sold/year USA/over a billion worldwide*
- Up to 90% of patients receive a PIV during hospital stays*
- Up to 50% fail before therapy is complete*
- PIV infection rate is .2%* but this may amount to >500,000 infections based upon device sales
- Everyone gets one so how important can they be?
- Inconsistency of standards/consensus so importance is minimized
- Minimal training/education on insertion/maintenance
- Competency validation lacking
- Not officially tied to reimbursements like CVADs

It’s only a peripheral...

Product description implies lack of importance

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PIV Audits-A Desperate Need !!!

Central Line

PICC

Midline

PIV
Audit Process

Audit Components

- Plan
- Do
- Study
- Act
- Implement
Audit Process

PIV Audits- A Desperate Need

Plan

• Set A Goal-Purpose of Audit
• Identification of Problem/Issue
  - INS/CDC revise standards to increase dwell times
    BUT give NO guidance as to how to make this happen
  - “Asking the Good Question”
  - Conduct surveillance to obtain baseline data
    and identify gaps in products, practice, policy, people
  - Identify shortcomings, prioritize, and improve
  - Listen to Staff/Patients
Audit Process

PIV Audits-A Desperate Need

Do

• Surveillance is key- look before you leap or you may misidentify issues
• Criteria to be measured
• Process takes time/don’t rush it !!!
• Identify Issues/Make Improvements
• Collaboration needed between all involved parties
  - Products
    • Redundant devices
    • Substandard dressings
    • Stability/securement
    • Design/performance_interaction
  - Practice
    • Product duration
    • Insertion complications
    • Care/Maintenance
    • Infection risk/Complications
  - People
    • Competency
    • Satisfaction/Safety
    • User groups/staff to be involved
  - Policy
    • Review and make changes if necessary
    • Alignment with standards/practice
Audit Process

PIV Audits- A Desperate Need

- **Study**: Analysis Stage
  - Comparison of data collected with criteria/standards
  - Benchmark- internal/external

- **Act**: Recommendations for change/improvement
  - Who, What, Where, When

- **Implement and Sustain Change**
Audit Process

Plan: Asking the Good Question

- Moving to Clinically Indicated PIV Removal
  - INS (clinically indicated) vs.
  - CDC (“no more frequently than 72-96 hours”)
- Complex device with many parts/pieces facilitating opportunities for misuse
- No agreement on intervention bundle components
- Insertion, care and maintenance are critical risk exposure points
- Problems with CPGs and PIV potential adverse events
- What do you do when guidelines/standards collide?
Audit Process

Remember- You Can Use Small Evidence Based Studies to Make Your Case even if they are in conflict with CPGs

What Do the Small Evidence Based Studies Say???

• “Why are we putting our patients through this every 3-4 days?”
  – Webster, Osborne, Rickard & Hall/Cochrane

• “PIVs can remain in till no longer clinically indicated”
  – INS-2011/Lancet 2012 Rickard et al

• “PIVs should be changed no more frequently than every 72-96 hours”
  – CDC 2011- O’Grady et al.
Audit Process – Case Studies

Plan- Small Evidence Based Studies

Methodist Hospital, Gary Indiana

• Surveillance (internal infection control data baseline) identified gaps in PIV products, practice, people, and policy. A bacteremia cluster also helped drive development of the need for prevention around PIV risk and the need for a policy, practice and people bundle along with the introduction of new products.

• Goal of moving to clinically indicated PIV removal.

UF Health, Jacksonville, Florida

• Surveillance by nurses identified PIV process and performance varied among units, frequent missed starts on first insertion attempts resulting in patient discomfort and additional cost, delays in treatment, PIV complications, reduced patient throughput, overuse of products, time and monetary costs.

• Risk to HCWs for blood exposure/needlesticks in a high risk environment.

• “Nurses Voices Were Heard Loud and Clear”

• Goal of moving to clinically indicated PIV removal and reducing complications

• Goal of reducing risk to HCWs from blood exposure

• Improve standardization and clinician competency on first attempts
Audit Process – Case Studies

Do - Methodist Hospital, Gary, Indiana

Surveillance identified care and maintenance issues along with product (dressing, catheter hub) issues and clinician dissatisfaction.

- **Products: Engineer the Opportunity for Misuse Out of the Healthcare**
  - Intravenous catheter with integrated extension set
  - CHG impregnated sponge dressing
  - Securement dressing
  - Alcohol disinfection caps
  - Education bundle developed in conjunction with vendors to encourage confidence and competence in new product use

- **Practice/Policy**
  - GAP Analysis - practice/policy vs. evidence
  - Standardization from unit to unit
  - Bundle intervention compliance
  - Chlorhexidine skin prep
  - Sterile gloves
  - Ensure consistency/uniformity across continuum of care

- **People**
  - Training/education by staff and vendors
  - Competency validation
  - Education bundles
## Audit Process – Case Studies

### Do - UF Health, Jacksonville, Florida

Surveillance identified blood exposures, PIV catheter dwell times, insertion, and complications could be improved

<table>
<thead>
<tr>
<th>• Products</th>
<th>• Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluated 5 different catheters and let nurses select best product</td>
<td>GAP analysis-baseline product/practice assessment to identify areas of risk for blood exposure, needlesticks, BSIs, other complications</td>
</tr>
<tr>
<td>Product Standardization across the continuum of care</td>
<td>Standardized practice for use of extension sets/hypodermic needles</td>
</tr>
<tr>
<td>Selected IVs in Radiology which allowed for higher flow rates for CT Scans</td>
<td>Ensure that all clinicians adhere to PIV best practices/INS Standards</td>
</tr>
<tr>
<td>Catheters with blood control technology and integrated extension sets</td>
<td>Assessed pre-filled saline flush protocols to ensure sizes aligned with need</td>
</tr>
<tr>
<td>Catheters with integrated securement</td>
<td></td>
</tr>
<tr>
<td>Standardized skin prep to align with INS Standards – CHG/alcohol</td>
<td></td>
</tr>
<tr>
<td>Vendor supported clinician education/competency for new product use</td>
<td></td>
</tr>
</tbody>
</table>

- Vendor education/competency training with CE credit to develop skills and first stick PIV success
- Nurses had to develop new skills to use the new catheters and improve insertion
Audit Process – Case Studies

Study-Monitoring/Documentation/Criteria for PIV BSI Occurrence are critical

<table>
<thead>
<tr>
<th>Methodist</th>
<th>UF-Jacksonville</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 19% reduction in PIV BSIs</td>
<td>• Catheter dwell time increase from 2.4 to 4.3 days</td>
</tr>
<tr>
<td>• 48% reduction in PIV start kits</td>
<td>• 48% decrease in catheters requiring replacement in 48 hours</td>
</tr>
<tr>
<td>• Avg. dwell time increased to 4.2 days</td>
<td>• Avg. no. of catheters/patient decreased from 2.7 to 1.6</td>
</tr>
<tr>
<td>• 35% PIVs remain in place 5 days or longer</td>
<td>• Blood spillage/contamination reduced to zero</td>
</tr>
</tbody>
</table>
Audit Process – Case Studies

**Act**

**Methodist**
- Reduced BSIs
- Reduced Insertion Attempts
- Extended Dwell Times
- Improved patient satisfaction
- Facilitated Change to “clinically indicated”
- Continue to review and make improvements

**UF-Jacksonville**
- Improved dwell times
- Reduction in catheters/patient
- Decreased insertion attempts
- Improved patient satisfaction
- Reduced risk of blood spillage/needlesticks to HCWs
- Facilitated change to “clinically indicated”
- Continue to review and make improvements
Audit Process – Case Studies

Act

- What do your Hospital Policies Say?
- “Dare to Share”*
- Set Priorities
  - Feedback should lead to improvement- new product/practice introduction – not punishment
- Publish data so that new products/practice can be based upon Current best evidence
- Work with manufacturers- they can help and are NOT the enemy. Assessments, studies, education, share research, labeling instructions, speaker’s bureaus, CE, training, consult with professional medical societies to integrate technology into CPGs

Implementation Process

Implementation

Post Audit

• Improvements/Interventions/Limitations
• Sustainability
• Impediments to making change
  – Products
  – Practice
  – People
  – Policy
• Post Implementation Assessments
Implementation Process

Improvements/Interventions

- Must Consider Resource Availability/Needs
- Implement Change Gradually
- Must be Affordable/Attainable
- Consistent and Uniform
  - Consistency vs. Uniformity
  - Alternate Site Issues/Liability
  - Standardization/The Floating Nurse
Implementation Process

**Sustainability**

- Message Must Resonate
- Message Must be Memorable
- Message Must be Conveyed by Leaders
- Culture Must Support the Message
- Perception of Risk/Self Protection Encourage Compliance
- Incentives
- Sanctions
- Visible/Visual Reminders Encourage Compliance
Implementation Process

Implementation Impediments

• **Products**
  - Resources unavailable to facilitate compliance
  - Cost
  - Conflicts with hospital policies

• **People**
  - Lack of competency/education/training
  - Cultural barriers
  - Cost
  - Lack of administration support

• **Practice/Policy**
  - Conflicts with hospital policies
  - Not supported by CPGs/EBM
  - Competency
  - Cost
  - Time
  - Lack of administration support
Summary

• Conducting clinical audits using an integrated approach of comparing current policies, practices, and products to current evidence based and clinical practice guidelines (CPGs) have been shown to result in improved patient care and outcomes.

• Be aware that CPGs may or may not coincide with current evidence based vascular practice.

• Through the use of PIV audits (plan, do, study, act) clinicians can evaluate where product/practice/policy/people improvements are needed, if those improvements can be made, and whether change (such as a move to clinically indicated can be successfully effectuated.