

Case Study in Managing Vendor Representative Access to Perioperative Area and Throughout the Hospital

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UI Hospitals and Clinics Overview

- Over 41,000 Patient Admissions/Year
- Over 800,000 Clinic Visits/Year
- 769 Inpatient Beds
- 7,200 Staff
- 1,400 Staff Physicians and Dentists
- 2,100 Health Professional Students in Training

Perioperative Area Overview

- 20,000 cases annually
- Level 1 trauma center
- 22 main suites with 6 ASC suites
- Rooms run from 07:00 – 16:00 with some designated trauma or extended
- Main OR and ASC each have separate charge nurse

Overview

- The HIPAA Issue
- Our Solution
 - Policy and procedure development and implementation
- The Outcome

The HIPAA Issue

- Need to control access to PHI throughout hospital
 - Pharmaceutical Reps
 - Medical Device Reps
 - Other business vendors
- Do they *need* access to PHI?
 - For some - No
 - For others – Yes

The HIPAA Issue

- Vendors who do ***not*** need access to PHI:
 - Limit their access to hospital
- Vendors who ***do*** need access to PHI:
 - How do you categorize them?
 - Member of workforce – training, discipline
 - Visitor - Obtain patient authorization
 - Business associate

- Treating vendor representatives as Business Associates
 - Not BA if need PHI for public health
 - Not BA if they do not need PHI
 - BA if need access to PHI because physician (or nurse) asks for their presence for training purposes
- HHS FAQ re: medical device company

Principles of Policy Creation

- Meet HIPAA expectations:
 - Confidentiality, Access Control
- Surgeon must identify which cases need a vendor
- Reduce vendor access to Surgeons
- Identify vendor presence in OR areas
- Reduce # of vendors in OR
- Transition behavior of staff

Policy Creation

- Think outside the box
- Change is difficult
- Make it work for your system
- Be practical

Company Representatives in Perioperative Division

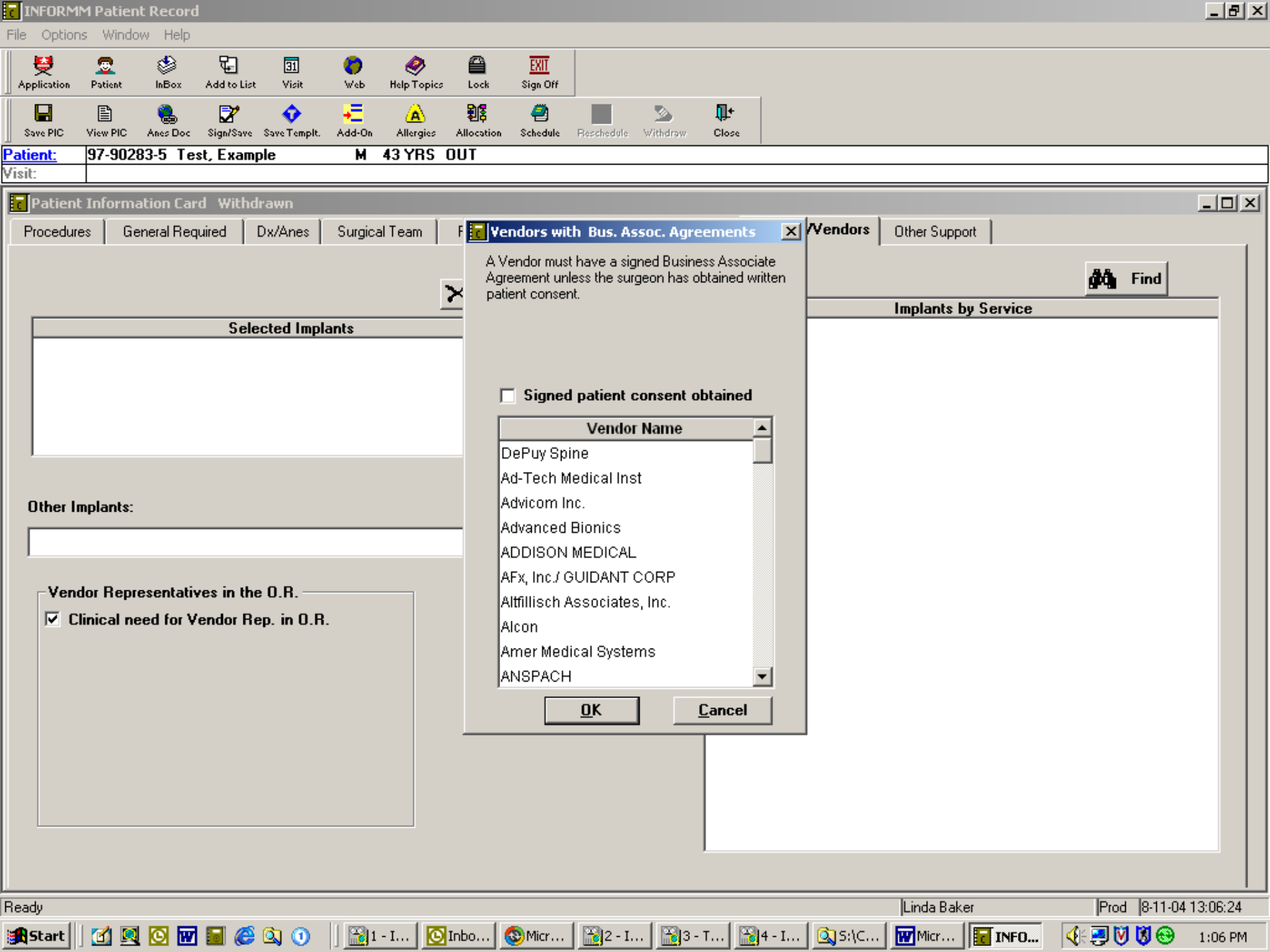
Approval for presence in perioperative care area may be granted **only if:**

a) Vendor company has a signed business associate agreement with UI Hospitals and Clinics

AND

b) The surgeon has documented that there is a clinical need for presence of representative on Patient Information Card (PIC)

- Representative will not be allowed in perioperative area if surgeon did not indicate a need for a representative



Application Patient InBox Add to List Visit Web Help Topics Lock Sign Off

Save PIC View PIC Anes Doc Sign/Save Save Templt. Add-On Allergies Allocation Schedule Reschedule Withdraw Close

Patient: 97-90283-5 Test, Example M 43 YRS OUT

Visit:

Patient Information Card Withdrawn

Procedures General Required Dx/Anes Surgical Team

Selected Implants

Other Implants:

Vendor Representatives in the O.R.

☒ Clinical need for Vendor Rep. in O.R.

Vendors with Bus. Assoc. Agreements

A Vendor must have a signed Business Associate Agreement unless the surgeon has obtained written patient consent.

☐ Signed patient consent obtained

- Vendor Name
- DePuy Spine
 - Ad-Tech Medical Inst
 - Advicom Inc.
 - Advanced Bionics
 - ADDISON MEDICAL
 - AFx, Inc./ GUIDANT CORP
 - Altifilisch Associates, Inc.
 - Alcon
 - Amer Medical Systems
 - ANSPACH

OK

Cancel

Vendors Other Support

Find

Implants by Service

Application Patient InBox Add to List Visit Web Help Topics Lock Sign Off

Save PIC View PIC Anes Doc Sign/Save Save Templt. Add-On Allergies Allocation Schedule Reschedule Withdraw Close

Patient: 97-90283-5 Test, Example M 43 YRS OUT
Visit:

Patient Information Card Withdrawn

Procedures General Required Dx/Anes Surgical Team Positioning Devices Special Equipment Implants/Vendors Other Support

Delete

Find

Selected Implants

< - Add

Implants by Service

Other Implants:

Vendor Representatives in the O.R.

☒ Clinical need for Vendor Rep. in O.R.

Vendor Name

Guidant Cardiac & Vascular

+ Add/Update

X Delete

Company Representatives in Perioperative Division

If there is documentation on the PIC but
no signed business associate agreement:

- c) The surgeon must obtain written
patient consent for the representative
to be present during the procedure

Check-In/Out Procedures

- Representative signs in with the **Procurement Services Department** office **prior** to coming to perioperative area
- Procurement Services will:
 - a) Assure that representative has undergone orientation
 - b) Check OR schedule
 - c) Verify that company has a signed business associate agreement or that patient consent is required
 - d) Provide a dated name badge to representative
 - e) Provide white scrubs to representative

Check-In/Out Procedures

After checking in with Procurement Services:

- Change into surgical attire, with badge visible
- Sign in with charge nurse and identify surgeon you will be working with
- Go to assigned operating room, reps only allowed in assigned operating room
- Identify yourself to circulating nurse

Upon completion of work:

- Sign out with charge nurse
- Change into street clothes
- Sign out and leave badge with Procurement Services

Discipline

Discipline for failure to follow policy:

- **First Offense:** Faculty physician paged and asked to verify clinical need. Representative reminded of policy and letter sent to District Manager.
- **Second Offense:** Faculty physician paged to verify clinical need. Letter sent to department head and chair. Access will not be granted to representative until vendor's district manager meets with named UIHC staff.
- **Third Offense:** All offending vendor company rep privileges suspended for 1 year.

Change Culture of Vendors and Staff

- Mandatory meeting with vendors
 - Discussed policy changes, answered questions
- In-service for OR nursing
- Charge Nurses
- Communication with surgeons, surgical services and others

Implementation

- Compliance staff assisted in monitoring this process
- Compliance was in procurement services
- Compliance was in the OR
- Issues were dealt with on the spot
 - Check-in/out
 - Scrubs
 - Surgeon compliance



Overall Benefits

- HIPAA Compliance:
 - Confidentiality
 - Security
- Easier identification of external people
- Staff empowerment

Benefits

- HIPAA Compliant
- Controlling access
- Have listing of who is in OR daily
- Up to date listing of vendors that have BAA
- Physicians no longer solicited in OR
- Long term- device control and supply chain optimization

Application Patient InBox Add to List Visit Web CME Help Topics Lock Sign Off

Prior Date Surgery Date Next Date Print Print Screen View PIC Op Record Allocation Anes Doc Help Close

Patient: 80-00306-7 Baker, A2 F 64 YRS 2RCE
Visit: 9 ORT - Children Scoliosis Complete OCLIN 06/06/03 IDX: 17701367

Schedule of Operations for Thursday, July 15, 2004

Anesthesia Staff Call #1 GERGIS,SAMIR D Triage Surgeon #1 SHIRAZI,SIROOS S Gen Surgeon Staff Call #1 SHIRAZI,SIROOS S
 Anesthesia Staff Call #2 OYOS,TANYA L Triage Surgeon #2 Gen Surgeon Staff Call #2

My Cases All Services Exclude Cancelled Exclude Completed

Main ASC Urology Satellite Entire Schedule

	Location	Time	Case	HCase	Call	In	Out	Patient Name	Age	Hosp #	Surgical Team	Vendor	Anesthesia Team
	MAIN	01	7:15	5'00		7:15		BAKER, TILLY HARDWARE REMOVAL HIP SPICA 1 1/2 OR 2 LEG PARTIAL RIB EXCISION	52	01-00078-0	WEINSTEIN,STUART L JOHNSTON,RICHARD C ALBRIGHT,JOHN P FALLON,BERNARD GANTZ,BRUCE J		OYOS,TANYA L
	MAIN	07	7:15	3'45				TEST, JULIE BIOPSY BONE TROCAR/NEEDLE DEEP	34	80-00033-9	BUCKWALTER,JOSEPH	V	FROM,ROBERT P
	MAIN	12	9:00	3'45	3'40	9:00		KOHLER, JUNE A POST SEG INSTRUM/7-12 VERT SEG	26	77-10011-8	WEINSTEIN,STUART L		(MAC)
	MAIN	14	11:30	3'00		11:30		HOYER, MARCUS RESECT VERTEBRAE, CERVICAL (EEG)	33	80-04815-4	WEINSTEIN,STUART L		GERGIS,SAMIR D
	MAIN	Addon	3'00	3'01				BAKER, A2 ANT CX DISCECTOMY W/DECOMPRESSION	64	80-00306-7	HITCHON,PATRICK	V	

Still to Come

- Implementing in other clinical areas performing procedures
- New security system