# National Healthcare Safety Network (NHSN)

## Overview and Potential for Surveillance of Transfusion-Related Adverse Events

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# Transfusion-Related Adverse Events
## Scope of the Problem

- 1 million per year[1]
  - Deaths or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood product[2]
- 5 million if near misses included

[1]Kohn LT et al, eds. To err is human: building a safer health system. 2000.

[2]National Quality Forum. Serious reportable events in patient safety: a National Quality Forum consensus report. 2002.

# Healthcare-Associated Infections
## Scope of the Problem

- 2 million hospital-associated infections
- 8 million hospital days
- 80,000 deaths
- > $ 4.5 billion

Source: MMWR, Oct 23, 1992, Vol 41, No 42; p783.

# DHQP Healthcare Surveillance

Designed to help infection control, dialysis, and occupational health programs promote patient and healthcare personnel safety by providing tools to:

- Identify problems that need to be addressed
- Monitor the success of interventions
- Trend data over time
- Determine which events to target for greatest efficiency and impact

# How?

- Provide standardized protocols and definitions
- Identify and monitor risk factors for adverse events/exposures
- Feedback risk-adjusted aggregated rates for comparison
- Provide access to prevention guidelines and other prevention tools

# DHQP Surveillance Systems

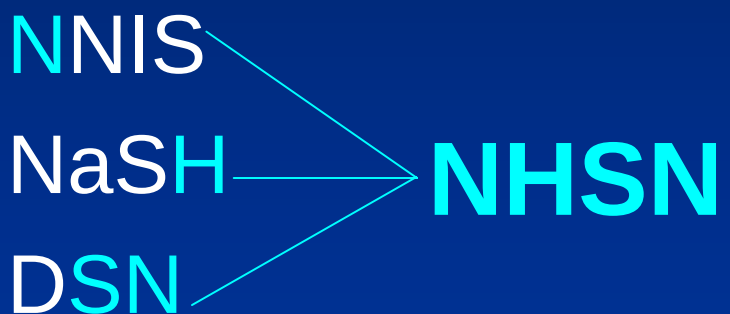
- NNIS: National Nosocomial Infections Surveillance System
- DSN: Dialysis Surveillance Network
- NaSH: National Surveillance System for Healthcare Workers

# Current Surveillance Systems

| NNIS | DSN | NaSH |
|---|---|---|
| Nosocomial (hospital-associated) infections in critical care and surgical patients | Bloodstream and vascular access infections in dialysis outpatients | Exposure to bloodborne pathogens; TB skin testing and exposure; Vaccine history and receipt and adverse events |
| 1970-2004 | 1999-2005 | 1996-present |

# What Is NHSN?

## Integration of 3 DHQP patient and healthcare personnel surveillance systems



# NHSN Components

- Patient Safety Component
  - Modules based on NNIS and DSN systems
  - Focused on events associated with the use of devices, procedures, and medications
- Healthcare Personnel Safety Component
  - Modules based on NaSH system
  - Focused on exposures, investigations, and interventions

## Patient Safety

- **Device-Associated**
  - Bloodstream infection
  - Urinary tract infection
  - Pneumonia
  - Dialysis incident
- **Procedure-Associated**
  - Surgical site infection
  - Post-procedure pneumonia
- **Medication-Associated**
  - Antimicrobial use and resistance

## Healthcare Personnel Safety

- **Exposures:**
  - Bloodborne pathogens
  - Vaccine-preventable diseases (VPD)
- **Investigations:**
  - Tuberculosis
  - VPD
- **Interventions:**
  - Lab testing
  - Post-exposure prophylaxis
  - Vaccinations

# NHSN Premises

- Share data in a timely manner while maintaining data security, integrity, and confidentiality
  - Between user and public health agencies
  - Between users (e.g., multi-hospital system)

# NHSN Premises

- Minimize user burden
  - Streamline data reporting protocols
  - Increase capacity for including data from existing electronic sources (e.g., Laboratory, pharmacy, clinical, administrative)
- Allow all healthcare delivery entities to participate

# Surveillance of Transfusion-Related Adverse Events

- Use/extend an existing system
  - AERS/MedWatch
  - BPD
  - Fatalities
  - MERS-TM
  - Add to NHSN under Procedure-associated Event Module

U.S. Department of Health and Human Services

# MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events and product problems

Page ____ of ____

Form Approved: OMB No. 0910-0291, Expires: 03/31/05
See OMB statement on reverse.

**FDA USE ONLY**

Triage unit sequence #

## A. PATIENT INFORMATION

1. Patient Identifier

In confidence

2. Age at Time of Event:

or

Date of Birth:

3. Sex

☐ Female
☐ Male

4. Weight

_____ lbs
or
_____ kgs

## B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: _____ *(mo/day/yr)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Disability
☐ Congenital Anomaly
☐ Required Intervention to Prevent Permanent Impairment/Damage
☐ Other: _____

3. Date of Event *(mo/day/year)*

4. Date of This Report *(mo/day/year)*

5. Describe Event or Problem

## C. SUSPECT MEDICATION(S)

1. Name *(Give labeled strength & mfr/labeler, if known)*

#1

#2

2. Dose, Frequency & Route Used

#1

#2

3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)

#1

#2

4. Diagnosis for Use *(Indication)*

#1

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot # *(if known)*

#1

#2

7. Exp. Date *(if known)*

#1

#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# *(For product problems only)*

– –

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

## D. SUSPECT MEDICAL DEVICE

1. Brand Name

ACK INK

Department of Health and Human Services

Food and Drug Administration

# Biological Product Deviation Report

| FDA Use Only |
|---|
| Date Received: |
| Date Reviewed: |
| BPD ID: |
| BPD No: |

*** Indicates Required Information**

## A. Facility Information

**1. Reporting Establishment Information:**

| | |
|---|---|
| * Reporting Establishment Name: | |
| * Street Address Line 1: | |
| Street Address Line 2: | |
| * City: | |
| * State: | * Zip Code: |
| Country: | |
| * Point of Contact: | |
| * Telephone #: | E-mail: |

**2. * Reporting Establishment Identification Number:**

FDA Registration #: CLIA #:

**3. If the BPD occurred somewhere other than the above facility, please complete this Section and Section A4, otherwise continue onto Section B1.**

| | |
|---|---|
| * Establishment Name: | |
| Street Address Line 1: | |
| Street Address Line 2: | |
| * City: | |
| * State: | Zip Code: |
| * Country: | |

**4. Establishment Identification Number:**

FDA Registration #: CLIA #:

## B. Biological Product Deviation (BPD) Information

**1. Establishment Tracking #:**

**2. Date BPD Occurred:**

**3. * Date BPD Discovered:**

**4. * Date BPD Reported:**

**5. * Description of BPD (use Page 2 for additional space):**

**6. * Description of Contributing Factors or Root Cause (use Page 3 for additional space):**

**7. * Follow-Up (use Page 4 for additional space):**

**8. * Please Enter the 6 character BPD Code:** ☐☐-☐☐-☐☐

## C. Unit/Product Information

Please check the type of product:

Blood ☐ (Continued on Page 5)

Non-Blood ☐ (Continued on Page 6)



**Form Approved:** OMB No: 0910-0458 Expires: 2/29/2004

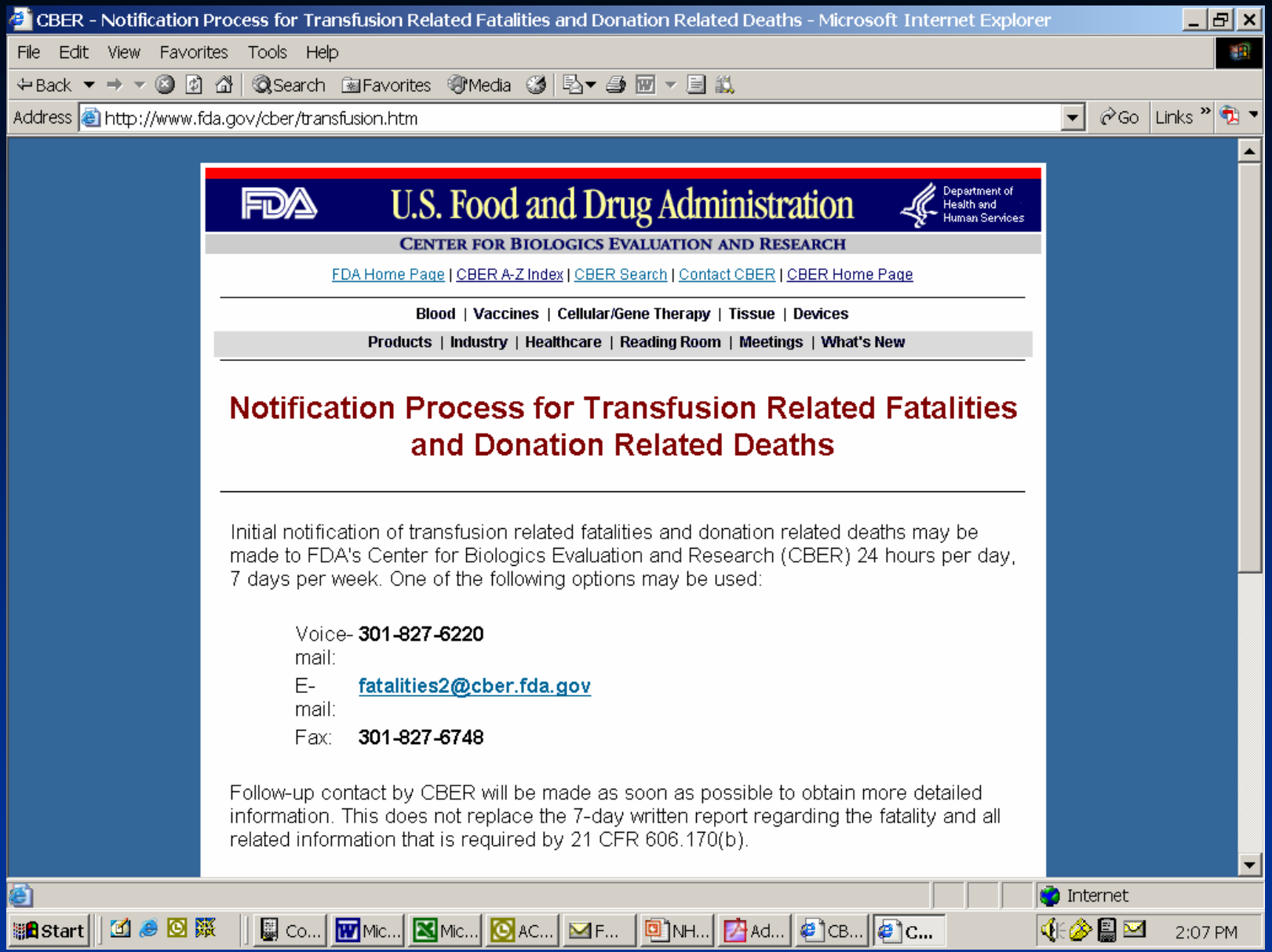
# Biological Product Deviation Report

## C1. Blood Products/Components

Total Number of Units: _____

** RN = Reverse Notification

| Unit # | Collection Date (MM/DD/YYYY) | Expiration Date (MM/DD/YYYY) | Product Code | Disposition | Notification (Y, N, RN**) |
|---|---|---|---|---|---|
| 1.) | | | | | |
| 2.) | | | | | |
| 3.) | | | | | |
| 4.) | | | | | |
| 5.) | | | | | |
| 6.) | | | | | |
| 7.) | | | | | |
| 8.) | | | | | |
| 9.) | | | | | |
| 10.) | | | | | |
| 11.) | | | | | |
| 12.) | | | | | |
| 13.) | | | | | |
| 14.) | | | | | |
| 15.) | | | | | |
| 16.) | | | | | |
| 17.) | | | | | |
| 18.) | | | | | |


CBER - Notification Process for Transfusion Related Fatalities and Donation Related Deaths - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites Media
Address http://www.fda.gov/cber/transfusion.htm
Go Links
FDA
U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
FDA Home Page | CBER A-Z Index | CBER Search | Contact CBER | CBER Home Page
Blood | Vaccines | Cellular/Gene Therapy | Tissue | Devices
Products | Industry | Healthcare | Reading Room | Meetings | What's New
Notification Process for Transfusion Related Fatalities and Donation Related Deaths
Initial notification of transfusion related fatalities and donation related deaths may be made to FDA's Center for Biologics Evaluation and Research (CBER) 24 hours per day, 7 days per week. One of the following options may be used:
Voice-mail: 301-827-6220
E-mail: fatalities2@cber.fda.gov
Fax: 301-827-6748
Follow-up contact by CBER will be made as soon as possible to obtain more detailed information. This does not replace the 7-day written report regarding the fatality and all related information that is required by 21 CFR 606.170(b).
Internet
Start
2:07 PM

## MERS-TM Event Discovery Report (worksheet)
## Transfusion Service

Instructions: Use this worksheet to collect event discovery/occurrence information, and then enter it into the online database.

**Section A – Discovery Information**

**1.** Report date: _____ mo./_____ day/_____year

**2.** Discovery date: _____ mo./_____ day/_____year

**3.** Day of discovery: ❒ Weekday ❒ Weekend/Holiday

**4.** Discovery time: ❒ 12-4 AM ❒ 4-8 AM ❒ 8-12 Noon ❒ 12-4 PM ❒ 4-8 PM ❒ 8-12 Mid.

**5.** Discoverer's job description: ❒ Clerk ❒ House staff ❒ MD/DO ❒ MLT ❒ MT ❒ RN ❒ LVN / LPN ❒ Other ❒ Supervisor ❒ QA/QC Discoverer's name: _____

**6.** Where in the institution was the event discovered?

❒ Trans. Serv. ❒ OR ❒ ER ❒ ICU ❒ L&D ❒ Clinic ❒ Hosp. Ward ❒ Other Location Code _____

**7.** Describe briefly the event you discovered.

_____

_____

_____

❒ Additional testing ❒ Pt. sample recollected ❒ Other

## Section B – Occurrence Information

**1.** Date the initial antecedent event occurred:

_____ mo./_____ day/_____year

**2.** Time initial antecedent occurred:

❒ 12-4 AM ❒ 4-8 AM ❒ 8-12 Noon
❒ 12-4 PM ❒ 4-8 PM ❒ 8-12 Mid.

**3.** Day initial antecedent occurred:

❒ Weekday ❒ Weekend/Holiday

**4.** Person involved: ❒ Clerk ❒ House staff ❒ MD/DO ❒ MLT ❒ MT ❒ RN ❒ LVN/LPN ❒ Other ❒ Supervisor ❒ QA/QC

Person involved: _____

**5.** Where in the process did the initial antecedent (occurrence) event first occur?

❒ Product Check-In ❒ Patient/Product Request ❒ Order Entry ❒ Sample Collection ❒ Sample Handling
❒ Sample Testing ❒ Product Storage ❒ Product Selection ❒ Product Manipulation ❒ Available for Issue
❒ Product Issue ❒ Product Administration ❒ Miscellaneous

**6.** Where in the institution did the initial antecedent (occurrence) event occur?

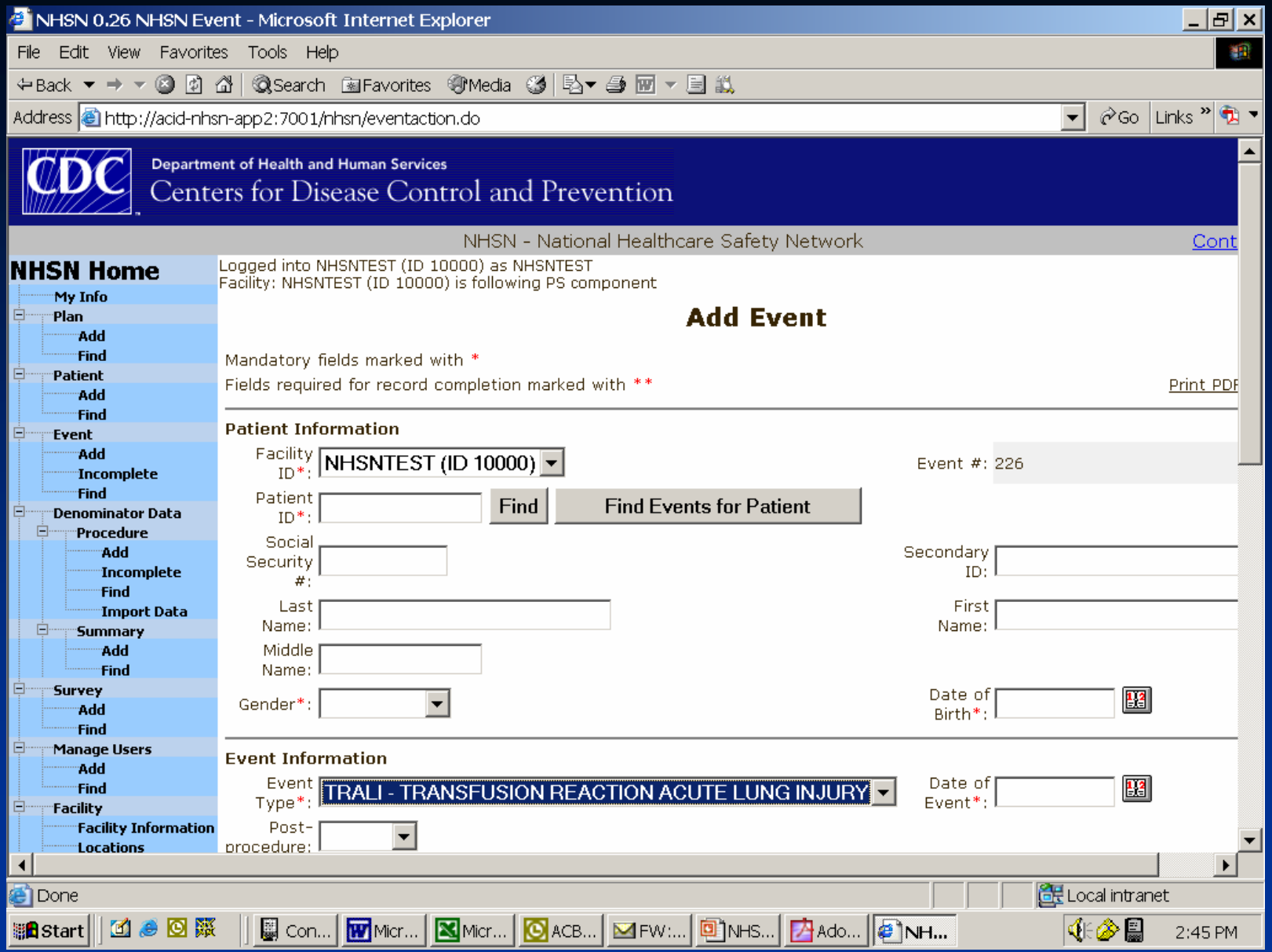
❒ Trans. Serv. ❒ OR ❒ ER ❒ ICU ❒ L&D ❒ Clinic ❒ Hosp. Ward ❒ Other Location Code _____

**7.** Product Issued? ❒ Yes ❒ No **8.** Product Administered? ❒ Yes ❒ No

Report Accession Number _____ Sub-site code (if applicable)_____

# NHSN Patient Safety Component

- Procedure-Associated Module
  - Transfusion-related adverse event
    - Numerator data = Patient data, transfusion reaction data (e.g., incompatibility; under transfusion; TRALI), risk factors
    - Denominator data = Relevant information on each blood product transfusion (type of product, origin, dates, etc.)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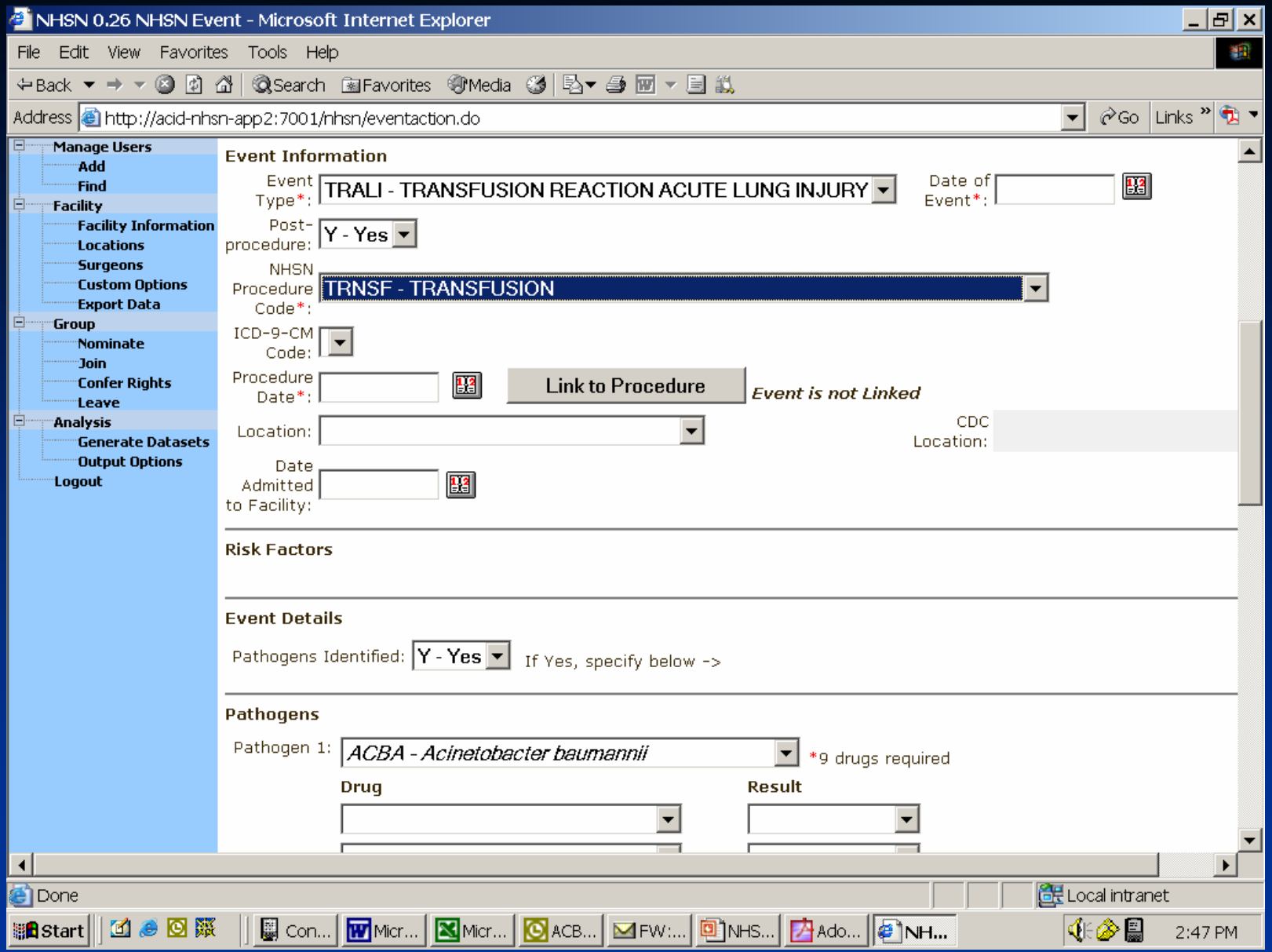
Go Links
CDC
Department of Health and Human Services
Centers for Disease Control and Prevention
NHSN - National Healthcare Safety Network
Cont
NHSN Home
My Info
Plan
Add
Find
Patient
Add
Find
Event
Add
Incomplete
Find
Denominator Data
Procedure
Add
Incomplete
Find
Import Data
Summary
Add
Find
Survey
Add
Find
Manage Users
Add
Find
Facility
Facility Information
Locations
Logged into NHSNTEST (ID 10000) as NHSNTEST
Facility: NHSNTEST (ID 10000) is following PS component
Add Event
Mandatory fields marked with *
Fields required for record completion marked with **
Print PDF
Patient Information
Facility ID*: NHSNTEST (ID 10000)
Event #: 226
Patient ID*:
Find
Find Events for Patient
Social Security #:
Secondary ID:
Last Name:
First Name:
Middle Name:
Gender*:
Date of Birth*:
Event Information
Event Type*: TRALI - TRANSFUSION REACTION ACUTE LUNG INJURY
Date of Event*:
Post-procedure:
Done
Local intranet
Start
Con...
Micr...
Micr...
ACB...
FW:...
NHS...
Ado...
NH...
2:45 PM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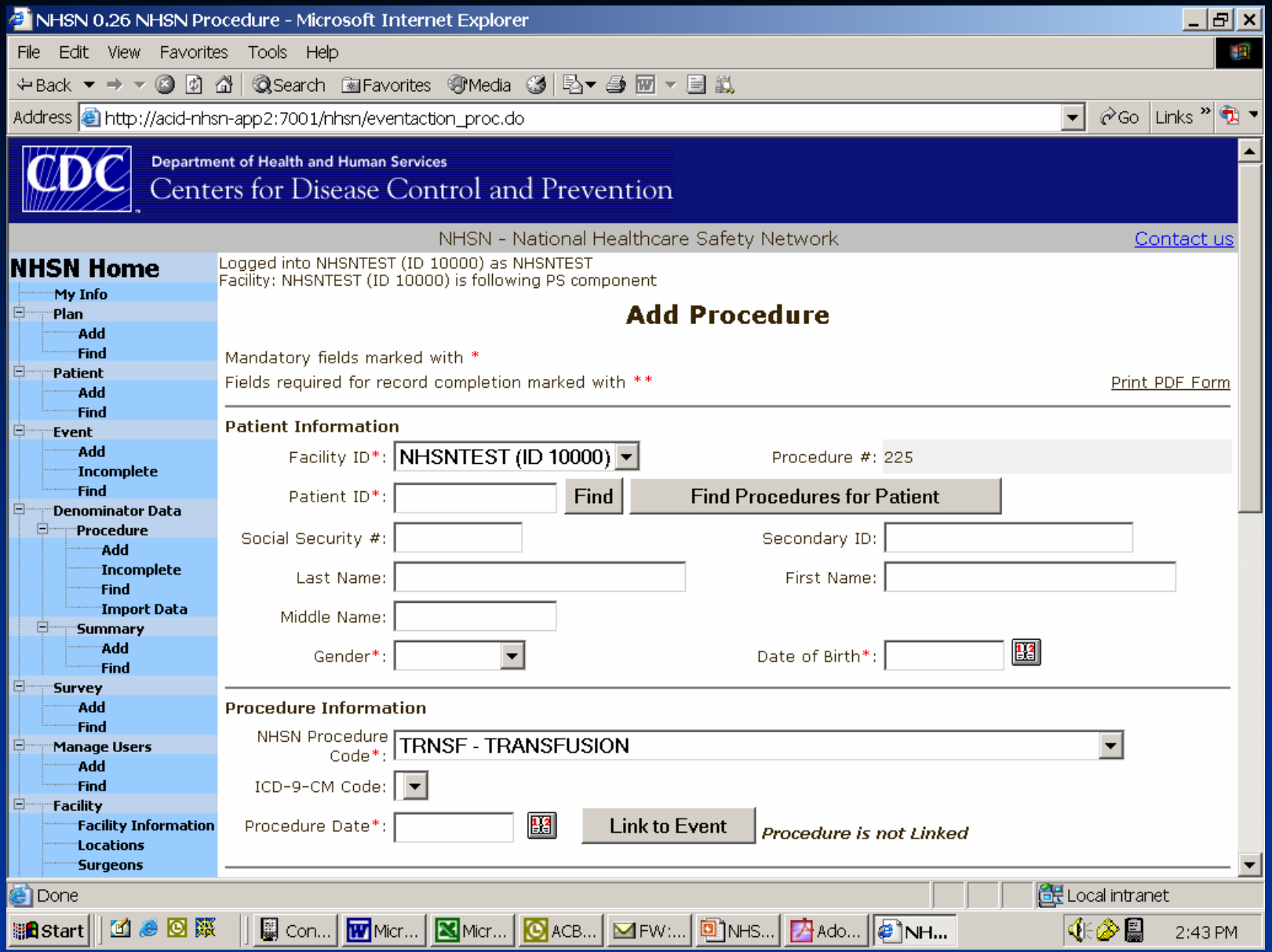
Address http://acid-nhsn-app2:7001/nhsn/eventaction.do
Go Links
Manage Users
Add
Find
Facility
Facility Information
Locations
Surgeons
Custom Options
Export Data
Group
Nominate
Join
Confer Rights
Leave
Analysis
Generate Datasets
Output Options
Logout
Event Information
Event Type*: TRALI - TRANSFUSION REACTION ACUTE LUNG INJURY
Date of Event*:
Post-procedure: Y - Yes
NHSN Procedure Code*: TRNSF - TRANSFUSION
ICD-9-CM Code:
Procedure Date*:
Link to Procedure
Event is not Linked
Location:
CDC Location:
Date Admitted to Facility:
Risk Factors
Event Details
Pathogens Identified: Y - Yes
If Yes, specify below ->
Pathogens
Pathogen 1: ACBA - Acinetobacter baumannii
*9 drugs required
Drug
Result
Done
Local intranet
Start
Con...
Micr...
Micr...
ACB...
FW:...
NHS...
Ado...
NH...
2:47 PM


NHSN 0.26 NHSN Procedure - Microsoft Internet Explorer
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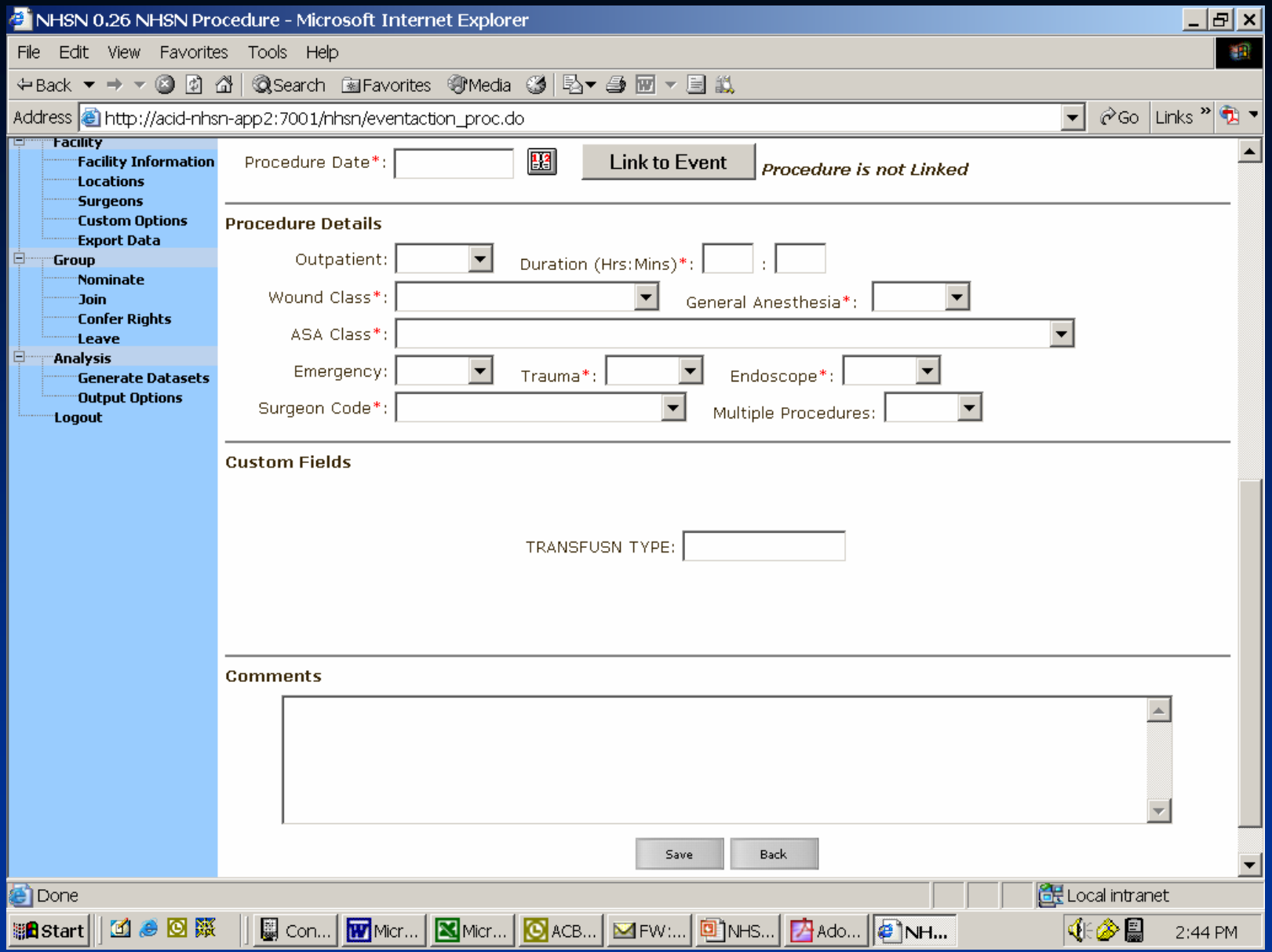
Go Links
Department of Health and Human Services
Centers for Disease Control and Prevention
NHSN - National Healthcare Safety Network
Contact us
NHSN Home
My Info
Plan
Add
Find
Patient
Add
Find
Event
Add
Incomplete
Find
Denominator Data
Procedure
Add
Incomplete
Find
Import Data
Summary
Add
Find
Survey
Add
Find
Manage Users
Add
Find
Facility
Facility Information
Locations
Surgeons
Logged into NHSNTEST (ID 10000) as NHSNTEST
Facility: NHSNTEST (ID 10000) is following PS component
Add Procedure
Mandatory fields marked with *
Fields required for record completion marked with **
Print PDF Form
Patient Information
Facility ID*: NHSNTEST (ID 10000)
Procedure #: 225
Patient ID*:
Find
Find Procedures for Patient
Social Security #:
Secondary ID:
Last Name:
First Name:
Middle Name:
Gender*:
Date of Birth*:
Procedure Information
NHSN Procedure Code*: TRNSF - TRANSFUSION
ICD-9-CM Code:
Procedure Date*:
Link to Event
Procedure is not Linked
Done
Local intranet
Start
Con...
Micr...
Micr...
ACB...
FW:...
NHS...
Ado...
NH...
2:43 PM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Go Links
Facility
Facility Information
Locations
Surgeons
Custom Options
Export Data
Group
Nominate
Join
Confer Rights
Leave
Analysis
Generate Datasets
Output Options
Logout
Procedure Date*:
Link to Event
Procedure is not Linked
Procedure Details
Outpatient:
Duration (Hrs:Mins)*:
Wound Class*:
General Anesthesia*:
ASA Class*:
Emergency:
Trauma*:
Endoscope*:
Surgeon Code*:
Multiple Procedures:
Custom Fields
TRANSFUSN TYPE:
Comments
Save
Back
Done
Local intranet
Start
Con...
Micr...
Micr...
ACB...
FW:...
NHS...
Ado...
NH...
2:44 PM

# Issues to Consider

- Are the data readily available?
  - Data sources (numerator/denominator)
  - Data collectors
- Which adverse events?
  - Sentinel or common
- What patient population(s)?
  - All or sample

# Issues to Consider

- Confidentiality needed?
- Voluntary or mandatory reporting?
- Link to other systems?
  - Data sharing agreements
  - Database management
  - Analysis
- Resources