HIV/STI Screening & Post Exposure Prophylaxis: Partnering to Improve Care

Presented by MATEC

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Disclosures

Malinda Boehler, MSW, LCSW, April Grudi, MPH, CHES and Pamela Terrill, MS, ARNP, SANE-A have no financial interest or relationships to disclose.

HRSA Education Committee Disclosures

HRSA Education Committee staff have no financial interest or relationships to disclose.

CME Staff Disclosures

Professional Education Services Group staff have no financial interest or relationships to disclose.

Learning Objectives:

By the end of this workshop, participants will be able to :

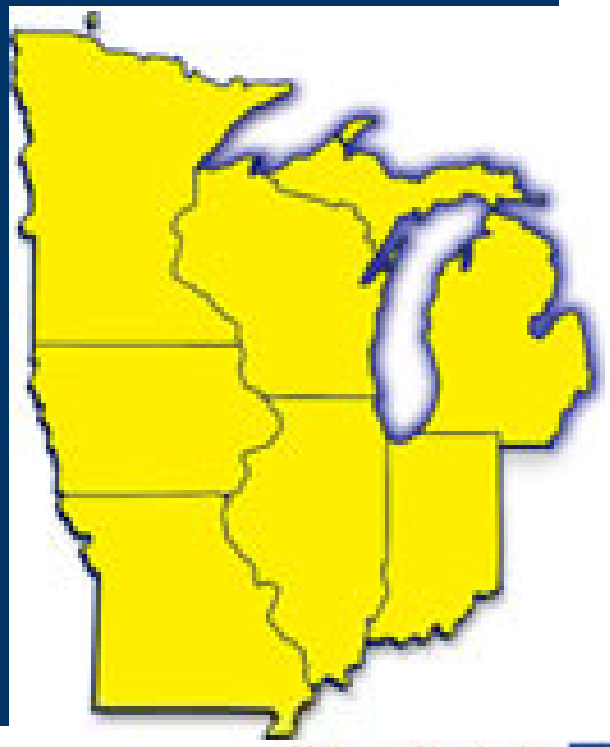
1. Describe the process of engaging and partnering with Sexual Assault Nurse Examiners.

2. Identify specific interventions aimed at improving STI (including HIV) screening, STI treatment and the appropriate prescribing of post exposure prophylaxis.

3. Explain the process and importance of patient focused outcome evaluation.

About the Midwest AIDS Training + Education Center (MATEC)

- Part F Funded
- Seven State Region
  - Illinois
  - Indiana
  - Iowa
  - Michigan
  - Minnesota
  - Missouri
  - Wisconsin



20 Years of Leadership
A LEGACY OF CARE

About the Presenters

- Malinda Boehler - Co-Director of MATEC Indiana
- April Grudi - HIV & MAI Training Coordinator at MATEC Indiana
- Pamela Terrill – Project Coordinator at MATEC Iowa

Using the Audience Response System

Equipment: A “clicker” and a Participant

System allows us to get audience input and allows the audience to see how everyone else answered a particular question.

What is your profession?

1. NP
2. Nurse
3. Physician
4. PA
5. Public Health
6. Other
7. Social Worker

Does your clinic/hospital/agency have a policy for offering HIV testing and/or post exposure prophylaxis to survivors of sexual assault?

1. Yes
2. No
3. Unsure?

Background

- MATEC-IN was attempting to implement routine HIV testing in Methodist ED
- SANE was a member of task force
- Resistance to full routine testing in ED
- Hospital suggested that we start with a sub-population
- Sexual assault was a natural choice because of existing relationship

Objectives

- Describe the process of engaging and partnering with sexual assault nurse examiners (SANE)
- Identify specific interventions aimed at improving STI (including HIV) screening, STI treatment and the appropriate prescribing of post exposure prophylaxis
- Explain the process and the importance of patient focused outcomes

Who are Sexual Assault Nurse Examiners?

- Registered Nurse (RN)
- SANE or SAFE
- SANE Training course + practicum
  - Adult/Adolescent and Pediatric
- International Association of Forensic Nurses (IAFN)

What do Sexual Assault Nurse Examiners do?

- Historical
- Provide care to survivors of sexual assault
  - Provide Forensic Medical Examinations
  - Provide Pharmacologic Treatment recommendations and medications
  - Refer survivors for follow up care
  - Testify in criminal proceedings as needed

Where do Sexual Assault Nurse Examiners practice?

- Hospitals; usually in ETC
- Women's Health Clinics
- Free standing Sexual Assault Centers
- Family Justice Centers
- Our project – SANE clinicians practice at Center of Hope, a program in the Methodist Hospital ED

Who Pays for Sexual Assault Treatment?

- Overview-State Specific
- In Iowa, Crime Victim Assistance Division (CVAD) Sexual Abuse Examination Program- set by legislature. Pays for examiner, institution and drugs.
- In Indiana, the Criminal Justice Institute (Victims of Violent Crimes fund) pays for the services provided at the Center of Hope– they do not include HIV or nPEP for HIV as part of sexual assault

Sexual Assault in the U.S.

Each year more than 33 incidents of sexual assault occur per 100,000 people, and the Centers for Disease Control and Prevention (CDC) estimates the risk of a sexually transmitted infection (STI) associated with a single assault to be 26.3%.*

*Straight JD, Heaton PC "Emergency department care for victims of sexual offense." *American Journal of Health-systems Pharmacists* 64(2007): 1845-1850.

National Protocol: STI Evaluation & Care Recommendations*

- Offer patients info: risks of STIs including HIV, symptoms, testing & txt options, follow-up, referrals
- Encourage patients to accept prophylaxis against STIs at time of initial exam
- Consider need for testing for STIs on case-by-case basis
- Encourage f/up STI exams/txt as needed
- Offer nPEP to patients at high risk for exposure

**National Protocol for Sexual Assault Medical Forensic Examinations . September 2004. US Department of Justice Office on Violence Against Women.*
http://www.ncjrs.gov/pdffiles1/ovw/206554.pdf

In Reality

- Less than 30% of all sexual assault survivors receive the appropriate prophylactic measures outlined by CDC*, which includes
  - Screening
  - Antibiotics
  - Emergency contraception
  - Non-occupational post exposure prophylaxis (n-PEP), when indicated.

*Straight JD, Heaton PC "Emergency department care for victims of sexual offense." *American Journal of Health-systems Pharmacists* 64(2007): 1845-1850.

A Natural Choice in Indiana

- Stationed in an Emergency Department
- Hundreds of patient visits each year
- Already screening and providing post exposure prophylaxis for STI/Pregnancy prevention
- MATEC-IN has an established relationship

Scope of Project

- Increase the number of sexual assault survivors who receive HIV screening
- Increase the number of sexual assault survivors who are prescribed post-exposure prophylaxis for:
  - HIV
  - Hepatitis B
  - Pregnancy
  - Chlamydia
  - Gonorrhea
  - Trichomonas
  - Bacterial Vaginosis (BV)

Engaging the SANE at Methodist

- MATEC-IN provides the HIV component of the SANE core training curriculum in Indianapolis area.
- In the Spring of 2007, MATEC-IN attempted to engage the Methodist ED in a discussion about offering Routine HIV Screening by sending them to a CDC training. The Director of the Center of Hope, a Sexual Assault Nurse Examiner, was in attendance.

Through these interactions the need for updated STI (including HIV) screening and post exposure prophylaxis order-sets for survivors of sexual assault were identified.

A Collaborative Effort

- Spearheaded by MATEC Indiana.
- Multidisciplinary Team included:
  - Clinical Pharmacists
  - ED Physician
  - Infectious Disease Physician
  - ED Nurses
  - Sexual Assault Nurse Examiners (SANE)
  - ED Social Workers

Importance of a Multidisciplinary Team

- Care Providers/Prescribers - Physicians, NPs and Nurses
- Pharmacists - Ensure proper storage, dosing, and dispensing. Develop order sets.
- Infectious Disease Specialists – HIV expertise, order set development , algorithm, and risk assessment.
- Social Workers – Provide psychosocial support and link to resources.
- MATEC – Link to resources, develop and execute training plan, and program evaluation.

Pre-Intervention Data

- 5 months of data was analyzed
  - 11.5% of patients had been screened for HIV
  - 7% of patients who met the CDC's guidelines for n-PEP were offered it
  - The following prophylaxis for commonly transmitted STI's during a sexual assault were offered:
    - Chlamydia (96%)
    - Emergency contraception (87%)
    - Gonorrhea (83%)
    - Trichomonas (61%)
    - Hepatitis B Vaccine (12%)

Based on the Data

- A comprehensive plan was designed to increase HIV screening and post exposure prophylaxis for STI's - including HIV, based on CDC guidelines
- The plan included the development of:
  - HIV risk assessment algorithm
  - Revised order-sets
  - Patient education materials
  - A training plan
  - Program evaluation

Why did we need a Risk Assessment Algorithm?

- HIV risk assessment is complicated
- Sexual assault further complicates the assessment

All types of sexual assault (exposures) provide the same risk of HIV infection to the patient

1. Yes
2. No

Realities of Risk Assessment

- Not uncommon for victim to say doesn't know who raped her or if she was raped.
- What happens if nPEP is not indicated, but the patient wants it?
- What happens if nPEP is indicated and the patient declines?

Determining Risk in Sexual Assault*

Risk Behavior:

- Did exposure to potentially HIV-infected blood or body fluid occur?
- Was the exposure an isolated or episodic event, or result of habitual behavior?

Degree of Transmission Risk Based on Type of Exposure:

- What was the route of exposure?
- Are factors present that are known to further increase transmission risk?

Exposure Source:

- Is the source known to be HIV infected?
- If HIV status of the source is unknown, what is the likelihood of the source being HIV infected ?

*New York State Department of Health. HIV prophylaxis following non-occupational exposure including sexual assault. New York (NY): New York State Department of Health; 2008 Jan. 35 p.

Source Known to be HIV Infected

Exposure Type	Risk of Transmission per 10,000 Exposure Events**	Exposure Risk Category
Cutaneous Exposures		
Fluid on intact skin Bite without break in skin	No risk	**No risk identified**
Skin with compromised integrity (eczema, chapped skin, dermatitis, abrasion, laceration, open wound)		**Low to intermediate**
Mucous Membranes Exposures		
Kissing	No risk	**No risk identified**
Oral sex Splash to eye or mouth	The per-act risk of HIV transmission from oral sex is not known, although HIV rarely has been transmitted this way.	**Low**
Vaginal sex without trauma	**Unprotected receptive vaginal intercourse**: 1 – 30 per 10,000 **Unprotected insertive vaginal intercourse**: 3-9 per 10,000	**Intermediate**
Receptive anal intercourse Traumatic sex with blood (sexual assault)	**Unprotected receptive anal intercourse**: 50-320 per 10,000	**High**
Percutaneous Exposure		
Bite with break in skin		**Low**

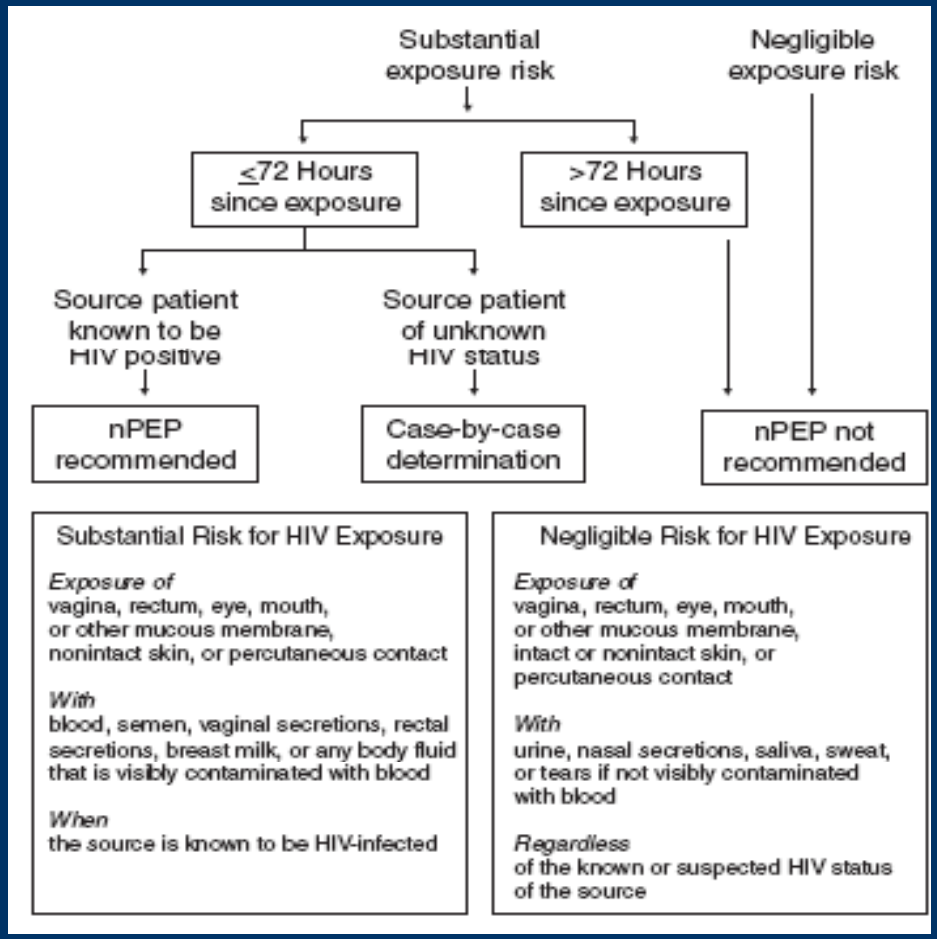
*New York State Department of Health. HIV prophylaxis following non-occupational exposure including sexual assault. New York (NY): New York State Department of Health; 2008 Jan.

Estimated Per Act Risk of HIV

Exposure Route	Risk per 10,000 exposures
Blood transfusion	9,000
Needle-sharing injection drug use	67
Receptive anal intercourse	50
Percutaneous needle stick	30
Receptive penile-vaginal intercourse	10
Insertive anal intercourse	6.5
Insertive penile-vaginal intercourse	10
Receptive oral intercourse	1
Insertive oral intercourse	0.5

Centers for Disease Control and Prevention. Antiretroviral post exposure prophylaxis after sexual, injection-drug use, or other non-occupational exposure to HIV in the United States: recommendations from the U.S. Department of Health and Human Services. MMWR 2005;54(No. RR-2)

Risk Assessment Algorithm



Centers for Disease Control and Prevention. Antiretroviral post exposure prophylaxis after sexual, injection-drug use, or other non-occupational exposure to HIV in the United States: recommendations from the U.S. Department of Health and Human Services. MMWR 2005;54(No. RR-2)

Real Life Scenarios

- 19 y/o female vaginally assaulted in her apartment by acquaintance; brother of her girl friend
- 26 y/o female “jumped” from behind in parking lot by 2 males. One held her down while the other raped her and then they switched. Her face was covered by her shirt.
- 24 y/o incarcerated male assaulted

Why did we need to revise order sets?

- They did not include HIV screening or HIV nPEP considerations
- They required updating to be consistent with latest CDC guidelines
- We have found that firm order-sets are the best way to implement a new/changed practice

Barriers to Revised Order Set

- Who would pay for HIV testing?
- Who would actually do the test?
- How would we provide starter packs?
- Who would manage the starter packs (safety)?
- How would un-insured patients get the remainder of the HIV nPEP regimen?
- How would un-insured patients get the required medical follow-up for HIV nPEP?

A Quick Review – Recommendations for HIV nPEP?

- Initiate nPEP within 72 hrs of exposure
- Patient should leave with nPEP starter pack
- Patients need written instructions & contact phone info
- Must plan to provide 4 weeks of medications
- Must plan to offer medical follow-up

Quick Review – nPEP Monitoring

TABLE 4. Recommended laboratory evaluation for nonoccupational postexposure prophylaxis (nPEP) of HIV infection

Test	Baseline	During nPEP*	4–6 Weeks after exposure	3 Months after exposure	6 Months after exposure
HIV antibody testing	E†, S§		E	E	E
Complete blood count with differential	E	E			
Serum liver enzymes	E	E			
Blood urea nitrogen/creatinine	E	E			
Sexually transmitted diseases screen (gonorrhea, chlamydia, syphilis)	E, S	E¶	E¶		
Hepatitis B serology	E, S		E¶	E¶	
Hepatitis C serology	E, S			E	E
Pregnancy test (for women of reproductive age)	E	E¶	E¶		
HIV viral load	S		E**	E**	E**
HIV resistance testing	S		E**	E**	E**
$CD4^+$T lymphocyte count	S		E**	E**	E**

* Other specific tests might be indicated dependent on the antiretrovirals prescribed. Literature pertaining to individual agents should be consulted.
† E = exposed patient, S = source.
§ HIV antibody testing of the source patient is indicated for sources of unknown serostatus.
¶ Additional testing for pregnancy, sexually transmitted diseases, and hepatitis B should be performed as clinically indicated.
** If determined to be HIV infected on follow-up testing; perform as clinically indicated once diagnosed.

Centers for Disease Control and Prevention. Antiretroviral post exposure prophylaxis after sexual, injection-drug use, or other non-occupational exposure to HIV in the United States: recommendations from the U.S. Department of Health and Human Services. MMWR 2005;54(No. RR-2)

Who would pay for HIV testing?

- State Specific-in Iowa it is a covered service
- Criminal Justice Institute not able to cover cost
- Indiana does not receive expanded testing dollars from CDC
- Current HIV testing dollars at the State Health Department had been allocated

In the end, Methodist ED willing to absorb cost as public service given size of sub-population

Who would actually perform the test?

- Point of Care Lab (POC) traditionally runs STAT labs, but they were concerned about increased demands of HIV rapid testing
- SANE nurses worried that they might not be able to read test in 20 minute window and test would have to be repeated

In the end, POC would take on responsibility for HIV screenings.

How would we provide starter packs?

- Guidelines suggest that all nPEP recipients be provided starter packs – in our case Truvada® or Truvada® + Kaletra®
- Abbott, maker of Kaletra®, offers a drug sampling program that ED was already using.
- Gilead, maker of Truvada®, does not….

Again, thanks to the size of sub-population, the Methodist Prescription Center provided Truvada® as community service and we obtained Kaletra® from sampling program.

Who would manage the starter packs (safety)?

- SANE did not have a process in place for storing or dispensing HIV nPEP
- Pharmacy is not open 24/7
- ED pharmacist had experience with managing such medications

In the end, we integrated the nPEP starter packs into the ED system for dispensing medications. Managed by ED pharmacist (records lot numbers, check expiration dates and maintain stock).

How would uninsured patients get the remainder of the HIV nPEP regimen?

- Prescription Center not able to provide 28 days of Truvada® as a community service
- Kaletra® sampling program would not support full 28 day supply to patient
- Researched patient assistance programs for non-HIV infected patients

In the end, the ED social workers and Prescription Center staff worked together to apply for patient assistance for those who were uninsured as part of nPEP follow-up procedures.

Reality: Many patients do not complete a 28 day regimen*

Vancouver 1996-1999

- 71 accepted nPEP and 8 completed 28 days
- 29 of 71 survivors on nPEP returned after 2-5 days

Boston 2001-2003

- 86 of 129 survivors referred to center for f/up
- 35 of 86 went for care and 13 of 35 completed 28 days

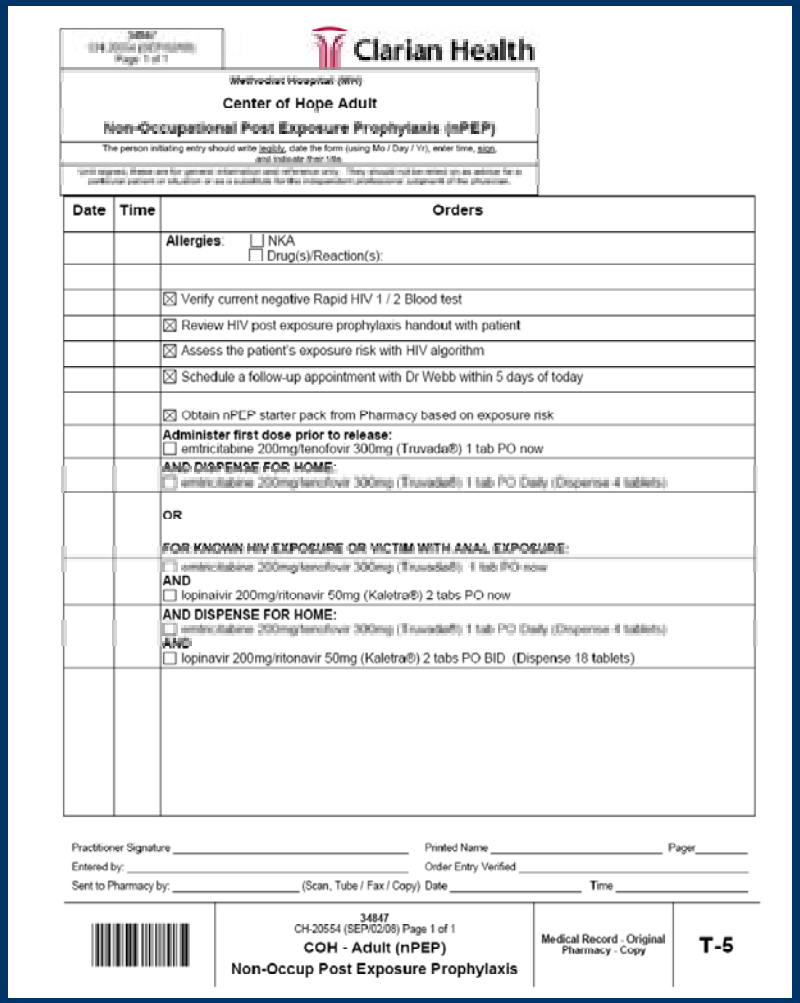
Human Immunodeficiency Virus Prophylaxis for Sexual Assault Survivors…. What we need to know. Editorial, Arch Pediatr Adoles Med/Vol 160, July 2006 754

How would uninsured patients get the required medical follow-up for HIV nPEP?

- nPEP requires substantial medical follow-up
- Methodist ED, Center of Hope program, did not have a physician on staff to manage nPEP follow-up

In the end, MATEC's Medical Director, agreed to provide follow-up at a Methodist Outpatient facility at no cost to patients. Methodist Hospital providing labs as community service.

Revised Order Set: Page 1



Clarian Health

Methodist Hospital (MH)

Center of Hope Adult

Non-Occupational Post Exposure Prophylaxis (nPEP)

The person initiating entry should write legibly, date the form (using Mo / Day / Yr), enter time, sign, and indicate their title.

Date	Time	Orders
		Allergies: ☐ NKA ☐ Drug(s)/Reaction(s):
		☒ Verify current negative Rapid HIV 1 / 2 Blood test
		☒ Review HIV post exposure prophylaxis handout with patient
		☒ Assess the patient's exposure risk with HIV algorithm
		☒ Schedule a follow-up appointment with Dr Webb within 5 days of today
		☒ Obtain nPEP starter pack from Pharmacy based on exposure risk
		Administer first dose prior to release: ☐ emtricitabine 200mg/tenofovir 300mg (Truvada®) 1 tab PO now
		AND DISPENSE FOR HOME: ☐ emtricitabine 200mg/tenofovir 300mg (Truvada®) 1 tab PO Daily (Dispense 4 tablets)
		OR **FOR KNOWN HIV EXPOSURE OR VICTIM WITH ANAL EXPOSURE:** ☐ emtricitabine 200mg/tenofovir 300mg (Truvada®) 1 tab PO now **AND** ☐ lopinavir 200mg/ritonavir 50mg (Kaletra®) 2 tabs PO now
		AND DISPENSE FOR HOME: ☐ emtricitabine 200mg/tenofovir 300mg (Truvada®) 1 tab PO Daily (Dispense 4 tablets) **AND** ☐ lopinavir 200mg/ritonavir 50mg (Kaletra®) 2 tabs PO BID (Dispense 18 tablets)

Practitioner Signature _____ Printed Name _____ Pager_____

Entered by: _____ Order Entry Verified _____

Sent to Pharmacy by: _____ (Scan, Tube / Fax / Copy) Date _____ Time _____

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CH-20554 (SEP/02/08) Page 1 of 1
COH - Adult (nPEP)
Non-Occup Post Exposure Prophylaxis

Medical Record - Original
Pharmacy - Copy

T-5

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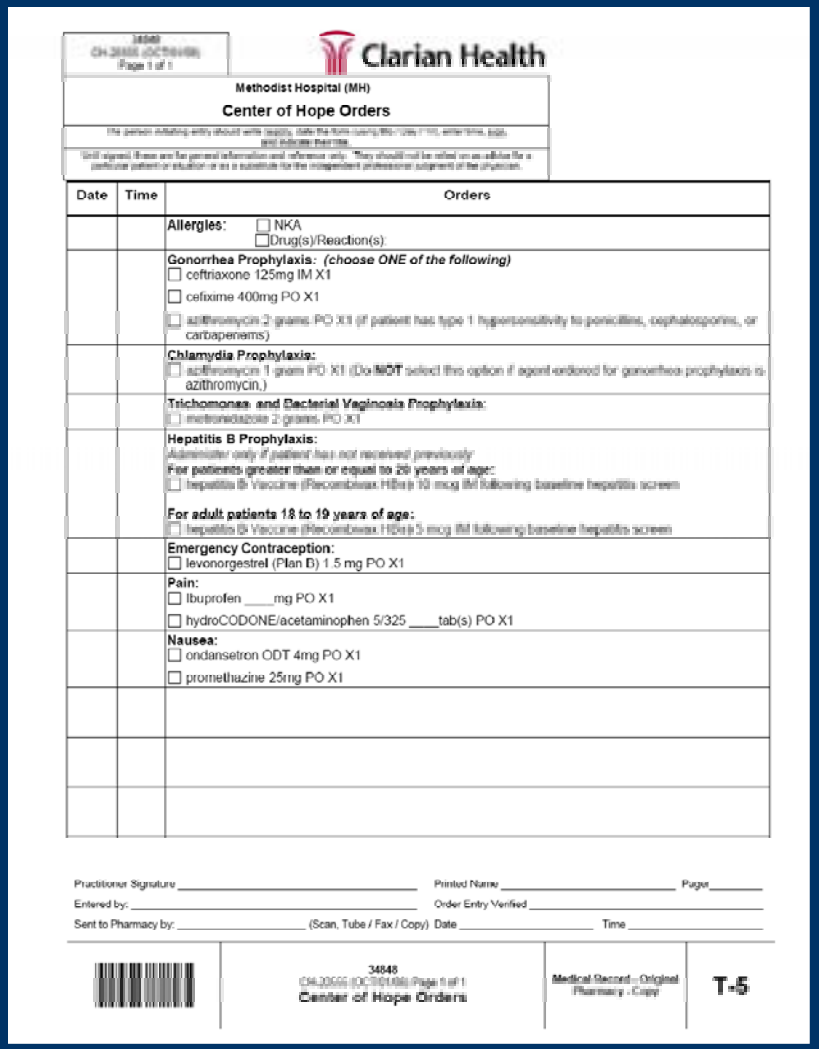
Revised Order Set: Page 2



Clarian Health

Methodist Hospital (MH)

Center of Hope Orders

Date	Time	Orders
		Allergies: ☐ NKA ☐ Drug(s)/Reaction(s):
		Gonorrhea Prophylaxis: ***(choose ONE of the following)*** ☐ ceftriaxone 125mg IM X1 ☐ cefixime 400mg PO X1 ☐ azithromycin 2 grams PO X1 (if patient has type 1 hypersensitivity to penicillins, cephalosporins, or carbapenems)
		Chlamydia Prophylaxis: ☐ azithromycin 1 gram PO X1 (Do **NOT** select this option if agent ordered for gonorrhea prophylaxis is azithromycin.)
		Trichomonas and Bacterial Vaginosis Prophylaxis: ☐ metronidazole 2 grams PO X1
		Hepatitis B Prophylaxis: *Administer only if patient has not received previously* **For patients greater than or equal to 20 years of age:** ☐ hepatitis B Vaccine (Recombivax HB) 10 mcg IM following baseline hepatitis screen **For adult patients 18 to 19 years of age:** ☐ hepatitis B Vaccine (Recombivax HB) 5 mcg IM following baseline hepatitis screen
		Emergency Contraception: ☐ levonorgestrel (Plan B) 1.5 mg PO X1
		Pain: ☐ Ibuprofen ____mg PO X1 ☐ hydroCODONE/acetaminophen 5/325 ____tab(s) PO X1
		Nausea: ☐ ondansetron ODT 4mg PO X1 ☐ promethazine 25mg PO X1

Practitioner Signature _____ Printed Name _____ Pager_____

Entered by: _____ Order Entry Verified _____

Sent to Pharmacy by: _____ (Scan, Tube / Fax / Copy) Date _____ Time _____

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Center of Hope Orders

Medical Record – Original
Pharmacy - Copy

T-5

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Patient Education Materials

- Created Patient Handout that included:
  - A description of HIV screening result
  - Information about Starter Pack
  - Potential side-effects
  - Detailed instructions for medical follow-up

Training Plan

- MATEC-IN developed a comprehensive training plan in collaboration with multidisciplinary team
- Didactic trainings included cases studies as skills building component
- Developed “scripts” for high-risk and low-risk exposures
- Offered at a variety of times, days and locations to meet the scheduling needs of the staff.
- Trainings were approved for nursing and social CE through Clarian Health
- nPEP is standard component of SANE training and continuing education

Training Evaluation

- Pre/Post Test developed for first training.
  - Results did not reveal a statistically significant change in knowledge and attitudes.
- Audience response system was incorporated into subsequent trainings.
  - Questions were designed to gauge audience comprehension.
  - Speaker able to immediately tailor presentation based on audience feedback.

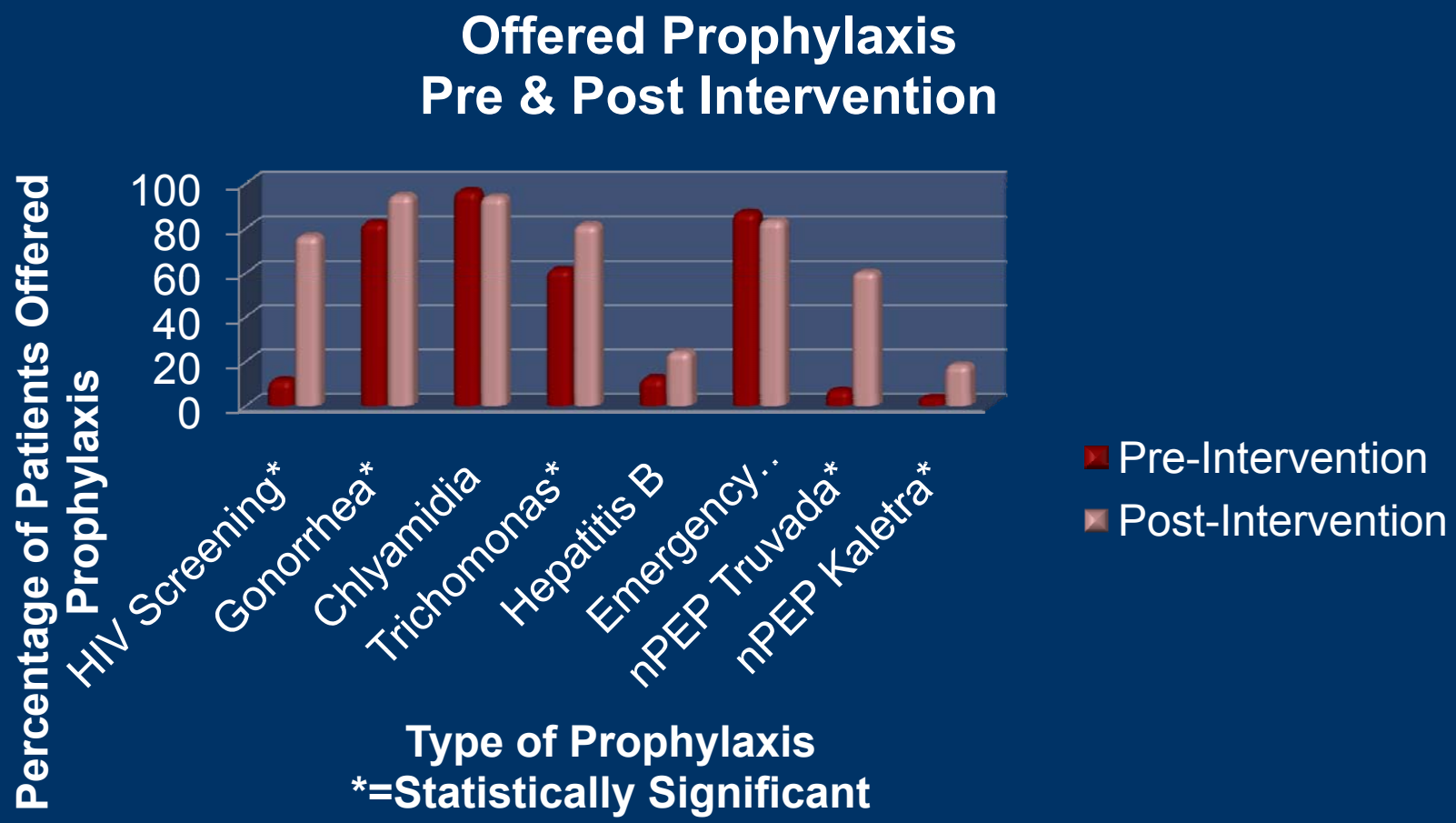
Patient Focused Outcomes – Data Collection

- *Data collection*: All patients, ≥18 years old, admitted to the Methodist Hospital ED and treated for sexual assault were included.
- *Unique Lessons Learned:* Pre-intervention data revealed a high acceptance rate for HIV screening/nPEP. The team credited this to the small number of patients offered the intervention and feared that it would not hold as the number of patients offered screening/nPEP increased. Surprisingly acceptance rates of HIV screenings and nPEP remained stable. This supports the belief that HIV screenings and nPEP are services wanted by patients.

Patient Focused Outcomes – Results

- Interventions were found to significantly improve:
  - HIV screenings (11% vs. 76%)
  - Gonorrhea (83% vs. 95%)
  - Trichomonas (61% vs. 81%)
  - Truvada® (7% vs. 60%)
  - Truvada® + Kaletra® (3% vs. 18%)
  - While not statistically significant, the order-set did trend toward improvement of the offering of a Hepatitis B vaccine (12% vs. 24%)
  - Prior to the intervention, Chlamydia prophylaxis and emergency contraception were appropriately offered to a high percentage of patients

Patient Focused Outcomes – Results



Innovation

- Cost-effective Model
  - Kaletra® was obtained through a sampling program at no cost to organization
  - Education and Training provided by local AETC at no cost to organization
  - Additional staff not needed

- Called on Organizational Resources
  - Truvada® provided at no charge by Methodist Prescription Center
  - Follow-up provided by MATEC Medical Director
  - Labs provided by Methodist

Lessons Learned

- Pre-Checked Boxes on Order Sets are not a good idea
- Need to add more detail to order sets regarding HIV and Hepatitis screening. Impossible to know if they were offered and refused – or simply not offered.
  - Options for offered, accepted, refused, not offered, test on file or open space for reason not offered should be added
  - In general better documentation is needed when services are not provided. Example – Metronidizole not given due to intoxication
- Standardized documentation in needed. Sometimes not enough information about assaults to determine appropriateness of nPEP or lack of nPEP
- Patient education materials need changes

Questions???