NFPRHA Winter Seasonal Meeting

Best Practices in Writing Policies, Procedures, and Protocols

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Today's Objectives

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

- Describe best practices for drafting, reviewing, and maintaining effective policies, procedures, and protocols (PPP)
- Identify possible improvements to organizational policies, procedures, and protocols
- Describe current PPP management cycle and identify possible improvements to the cycle

Importance of Policies, Procedures, and Protocols

Clarity of Purpose

Policy

- Definite course of action
- Select from available alternatives
- Guide decisions

Procedure

- Detailed steps
- Followed in a specific order
- Achieve desired result

Protocol

- System-specific clinical policies and procedures

Standard ● Guideline ● Protocol

Standard

- Minimum level of quality
- Established by experts
- "Musts"

Guideline

- Best practice for quality care
- "Shoulds"

Protocol

- System-specific clinical policies and procedures

Why These Documents Are Important

- Clarify roles and responsibilities
- Guide managers
- Protect patients, staff, volunteers, and agency
- Component of quality improvement and risk management programs

Employee Impact

- Improves confidence
- Improves consistency
- Improves accuracy
- Contributes to satisfaction

Manager Impact

- Provides guide for decision making
- Diminishes need for micro-managing
- Allows management by exception

Organizational Impact

- Improves overall effectiveness and efficiency
- Minimizes potential liability
- Protects reputation and brand
- Provides legal protection

INTERIM UPDATE

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

ACOG COMMITTEE OPINION

Number 792

(Replaces Committee Opinion Number 629, April 2015)

Committee on Patient Safety and Quality Improvement

INTERIM UPDATE: This Committee Opinion has been updated to reflect content oversight by the Committee on Patient Safety and Quality Improvement.

Clinical Guidelines and Standardization of Practice to Improve Outcomes

ABSTRACT: Protocols and checklists have been shown to reduce patient harm through improved standardization and communication. Implementation of protocols and guidelines often is delayed because of lack of health care provider awareness or difficult clinical algorithms in medical institutions. However, the use of checklists and protocols clearly has been demonstrated to improve outcomes and their use is strongly encouraged. Checklists and protocols should be incorporated into systems as a way to help practitioners provide the best evidence-based care to their patients.

ACOG, Obstetrics and Gynecology 10/2019; 134: e122-125

ACOG: Clinical Guidelines and Standardization of Practice to Improve Outcomes

- Standardization is an important goal because of the wide variation that exists in many areas of practice
- Two types of clinical variation
  1. Necessary variation dictated by differences such as a patient's age, ethnicity, weight, medical history, and desired outcomes
  2. Unexplained variation is that which is not accounted for by any of these things
- Variation in processes of care is problematic because it may lead to increased rates of error

ACOG: Clinical Guidelines and Standardization of Practice to Improve Outcomes

- Elimination of variation in processes has been a cornerstone of improved performance and reliability in aviation, military flight operations, and nuclear energy
- A similar level of success has been achieved in the field of anesthesia, where adverse events have been significantly reduced over the past 25 years through standardization of monitoring and medication use

ACOG: Clinical Guidelines and Standardization of Practice to Improve Outcomes

"The adoption by the clinical care team of one appropriate specific management plan will, by virtue of standardization alone, yield results superior to those achieved by random application of several individually equivalent approaches."

Are Protocols Still Necessary for Family Planning Clinicians?

In the old days

- Necessary for independent practice of NPs
- Rules varied by state nursing licensing boards

Currently

- Maximizes evidence-based clinical practice
- Standardizes care among all types of clinicians by minimizing variation in care
- A “play-book" for new clinicians *in your system*, written by clinicians who practice in your system

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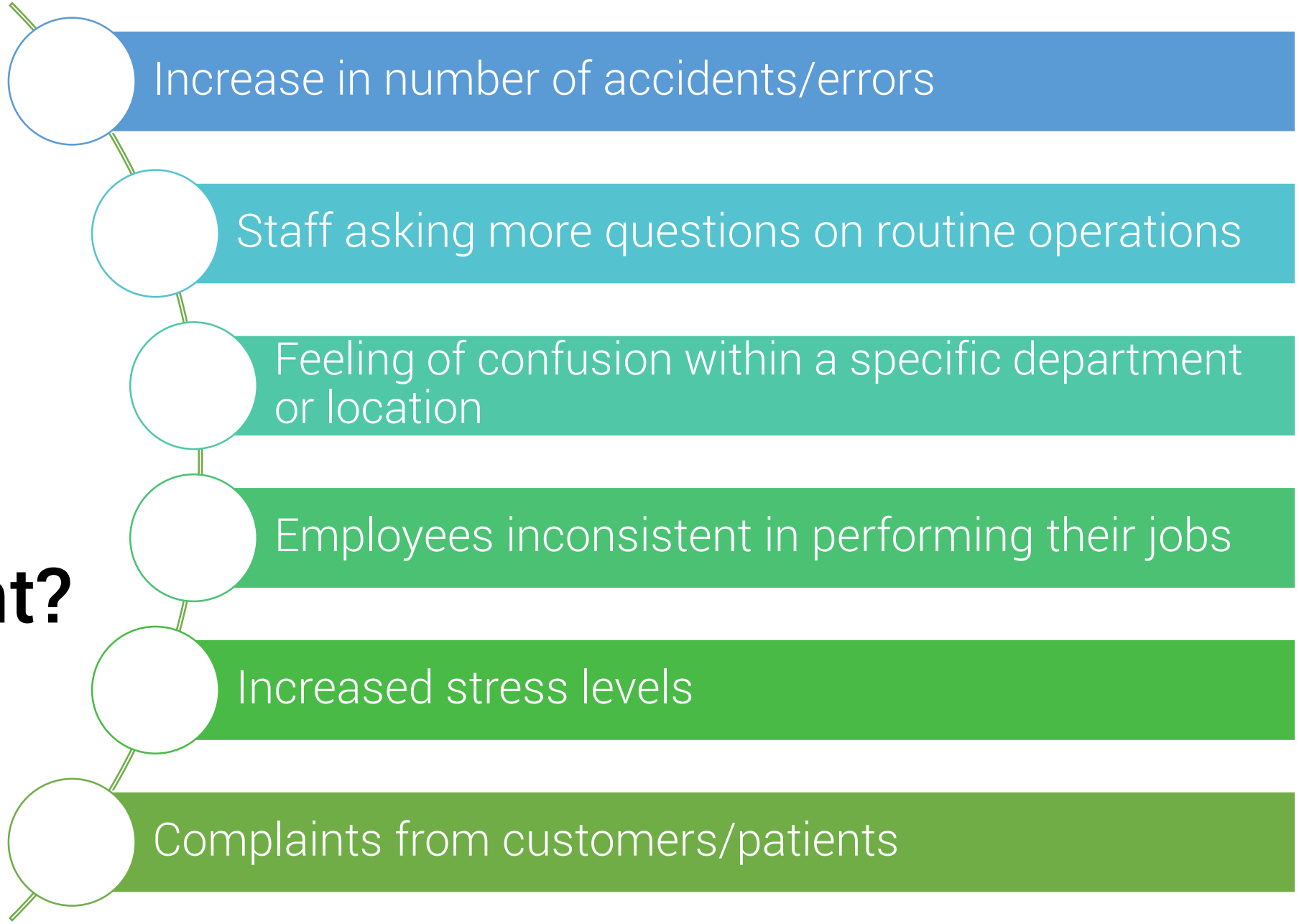
Are there signs that your PPP need improvement?



Why are PPP important to you?

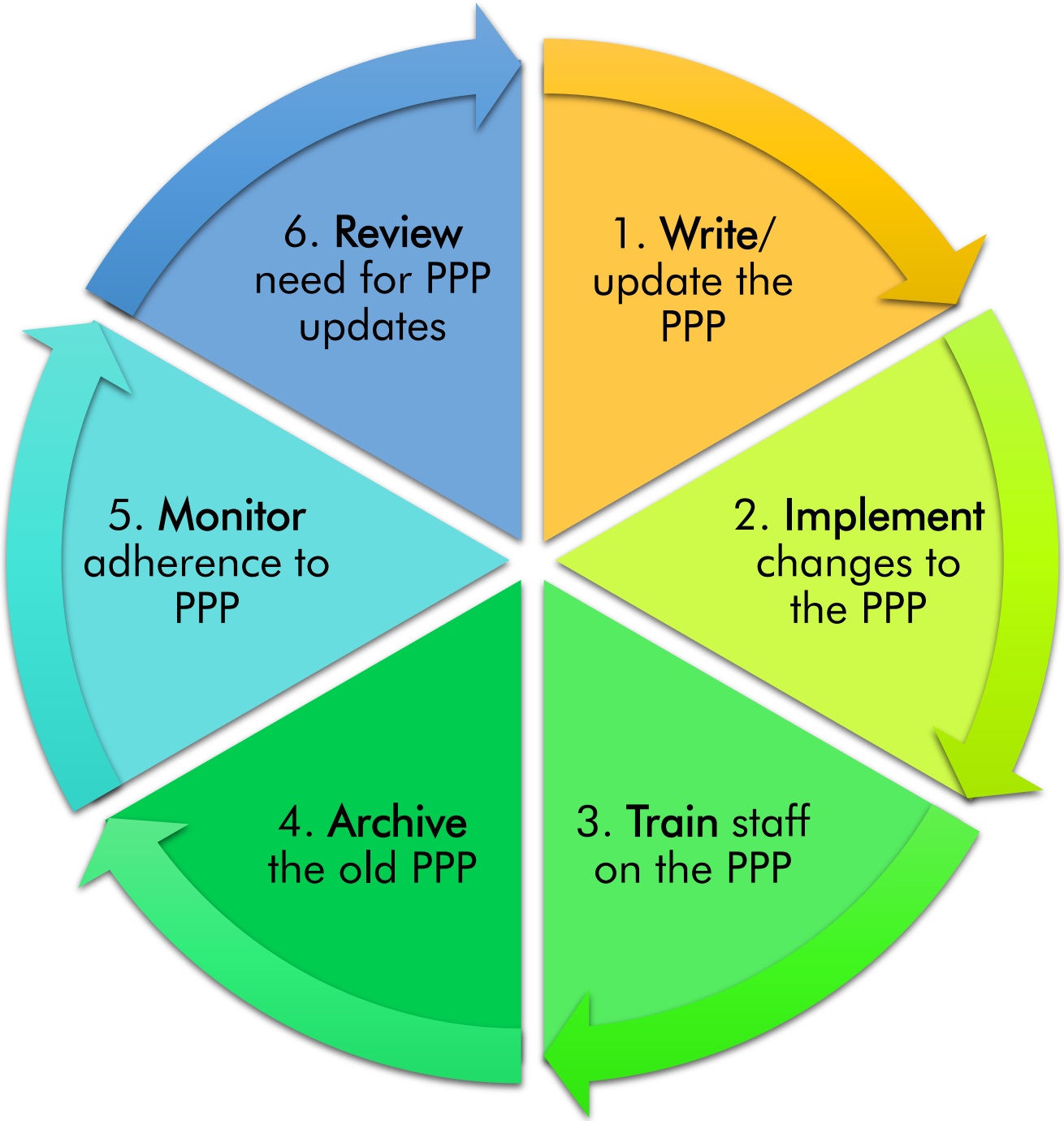
What brought you here today?

Best Practices

PPP Management: Standardized System

- Base on the PPP Maintenance Cycle
- Establish process for developing and maintaining documents/manuals
- Establish timelines/calendars for each phase
- Maintain documentation throughout each phase
- Ensure transparency throughout each phase
- Ensure accountability at all levels

Components of a maintenance cycle



PPP Development Best Practices

- Policy vs procedure vs protocol
- Document creation and editing
- Format/essential elements
- References/laws/regulations
- Responsibility/accountability/transparency
- Storage and access
- Archive, retention, and destruction plan

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DEVELOPMENT GUIDE

DEVELOPING AND MAINTAINING POLICIES AND PROCEDURES

This guide is intended to assist organizations in creating easy-to-use policies and procedures, as well as implementing an effective policy and procedure maintenance cycle.

An organizational **policy** is a statement of principles, rules, and guidelines that an organization follows in order to achieve a desired outcome. It exists to communicate an organization's point of view to its employees and to ensure that actions carried out at the organization take place within the policy's defined boundaries.

A **procedure** is a set of actions that an employee takes to complete an activity within the confines of an organizational policy. It exists as a reference for employees to understand their roles and responsibilities.

All policies and procedures (P&P) written by an organization are combined into one document called a **P&P Manual**. Maintaining a P&P Manual – the act of writing or revising documents within it – is an ongoing effort. It must be reviewed periodically in order to ensure continued accuracy.

P & P Management: Put it in Writing

- Write a draft PPP
- Review by stakeholders
- Incorporate edits
- Final review
- Final approval

P & P Management: Implementation

- Establish / publish schedule
- Develop / conduct / document training
- Implement changes
- Assess adherence
- Monitor / reinforce / retrain
- Review/update

P & P Management: Roll Out Considerations

All at once

- Small changes
- Minimal training needed
- Few locations

Phased in

- Significant changes
- Complex training or requires skills check-off
- Multiple locations

P & P Management: Training & Implementation Schedule

- Establish / publish schedule
  - Training dates
  - Training format
  - Training location
  - Implementation date/s
  - Review / audit dates

P & P Management: Training & Documentation

- Develop and conduct training
  - Same trainer/s for all staff preferable
  - Determine training format
  - Highlight changes/rationale
  - Elicit and respond to questions / feedback
  - Assess staff understanding
- Document training
  - Name of training and presenters
  - Date, location, format
  - Outline and documents used
  - Obtain staff acknowledgment
    - For EACH policy
    - Signed and dated

P & P Management: Assess Adherence

- Check back
  - Ask questions
  - Observe behavior
- Conduct audits
- Identify challenges
- Encourage feedback
- Support change process

P & P Management: Ensure Sustained Adherence

- Monitor progress
- Reinforce purpose
- Retrain if needed
- Review / update document if adaptation is needed
- Repercussions if necessary

P & P Management: Ongoing Review/Update

- Schedule reviews and revisions
- Review process includes:
  - On cycle
  - Off cycle
- Identify responsible person/s
- Include laws / regs / references

P & P Management: Archive Retired Documents

- Legal protection vs. point of reference
- Important to know dates document was in force
- May need to demonstrate
  - Previous actions consistent with policy
  - Specific individual trained

P & P Management: Archive Process

- Develop procedure for storage, retrieval, and destruction
- Retire discontinued documents
- Place in long-term/quasi-permanent file
- Ensure retrievable in future periods
  - Electronic
  - Hard copy

P & P Management: Archive Process

- Preserve in archive at time of implementation
- Add documentation of training and staff sign-off
- When document is retired – add date discontinued

Best Practices for Protocols

ACOG: Clinical Guidelines and Standardization of Practice to Improve Outcomes

- When checklists or protocols are developed at a national level, it is advisable to adapt them to individual practice settings
- Local practice conditions should be taken into account when these tools are introduced in any institution.
- It is important that physicians are informed whenever checklists or protocols are to be initiated.
- Encouraging input from physicians in the review and distribution of checklists and protocols will help foster buy-in from physicians for their use.

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DEVELOPMENT GUIDE

DEVELOPING CLINICAL PROTOCOLS FOR FAMILY PLANNING SERVICES

This guide is intended to assist organizations in identifying the clinical protocols necessary for a family planning provider.

WHAT ARE CLINICAL PROTOCOLS?

Clinical protocols are:

- Site-specific policies for the provision of high-quality health care to patients.
- The scope of care that can be provided by clinicians and care team members (e.g., nurse practitioners, physician assistants, certified nurse midwives, physicians, registered nurses, health educators, lab technicians), consistent with state regulations.
- Explicit processes regarding when a patient should be referred or transferred to another source of care, and how (and how quickly) this should be accomplished.
- The objective criteria by which clinicians can be evaluated and audited regarding the quality of care provided.

Creating a Clinical Protocol

- BEST PRACTICE #1: Always write or revise a protocol with the supervision of the medical director
- BEST PRACTICE #2: If a clinical protocol manual is provided to staff in an electronic format only, include a hyperlink directly to any clinical recommendations
  - Has most current version of recommendations
  - Lessens the burden on staff to update the protocol each time recommendations change

Creating a Clinical Protocol

- BEST PRACTICE #3: Include the right level of detail when drafting a clinical protocol.
  - Someone new to the organization may do things differently, or someone who has not performed a service or procedure in several months or years may need a refresher

Local Clinic Protocols: What They Are

1. Guidance for clinicians that describes the policies, procedures, and practices of this clinic system for the provision of consistently high-quality care
2. Policies of this clinic system regarding scope of care that can be provided by each category of health professionals, consistent with state regulations
   - APC: NP, PA, CNM
   - Physician: MD/DO
   - Nurses: RN, LVN, PHN
   - Health educators, counselors
   - Medical assistants

Local Clinic Protocols: What They Are

3. Policies for client referral, consults, and transfers
   - Where to refer, based on contracts or MOUs
   - How to refer (e-referral, written, phone call)
   - How quickly (emergent, urgent, routine)
4. The objective criteria by which clinicians can be evaluated and audited for quality of care provided
   - Ideally, at least semi-annually
   - By medical director, QI director, or colleague (not self)
   - Separate from "focused" QI (PDSA) audit
   - Often expected in health plan contracts

Local Clinic Protocols: What They Are

5. Derived from, and consistent with, current national clinical practice guidelines
   - CDC contraceptive, STD, pre-pregnancy guidelines
   - US Preventive Services Task Force
   - American College of Ob-Gyns (ACOG)
   - American Cancer Society
   - Specialty: ASRM (fertility), ASCCP (cervical pathology)

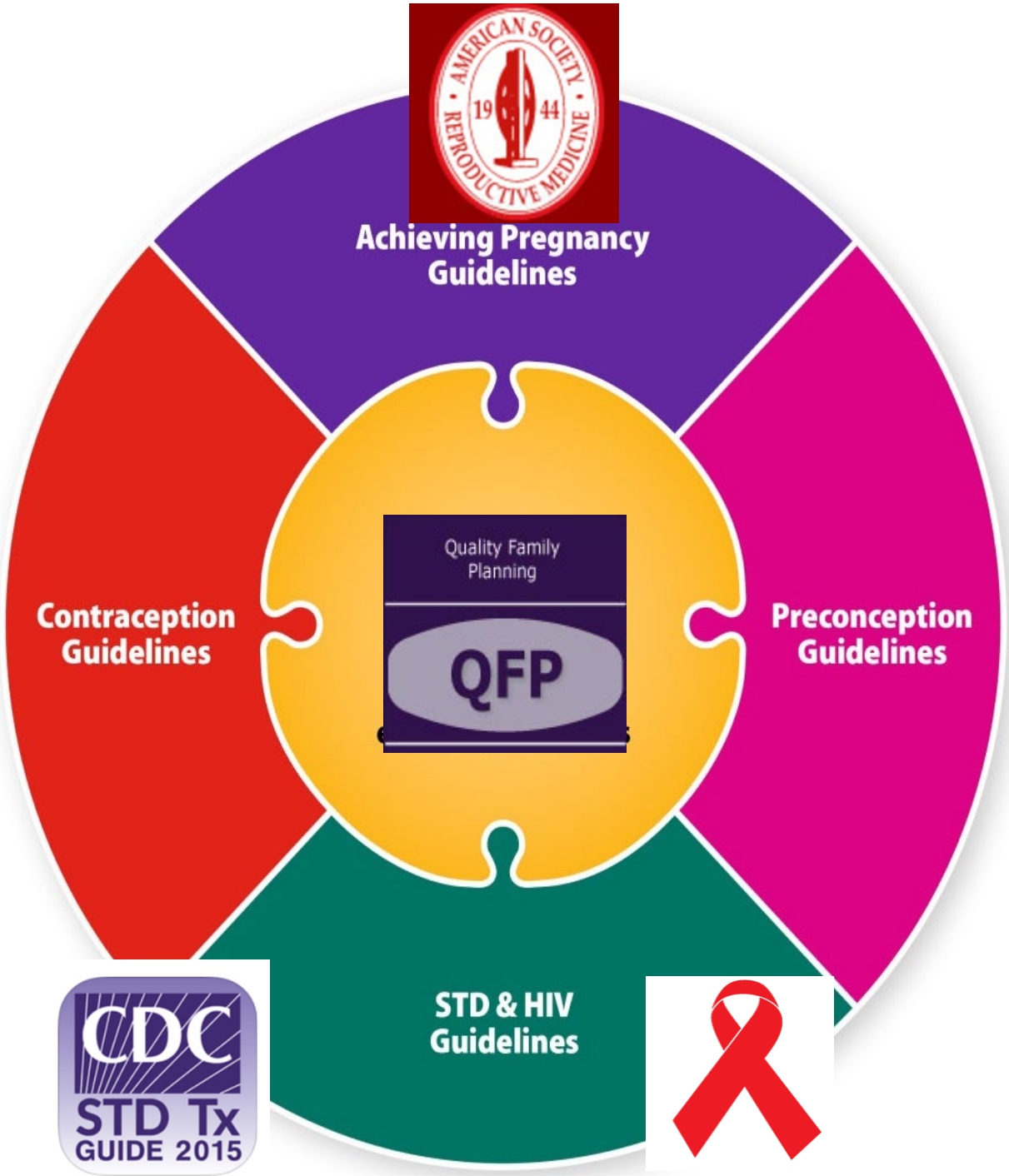
CDC "Suite" of Family Planning Recommendations

United States Medical Eligibility Criteria for Contraceptive Use

US MEC

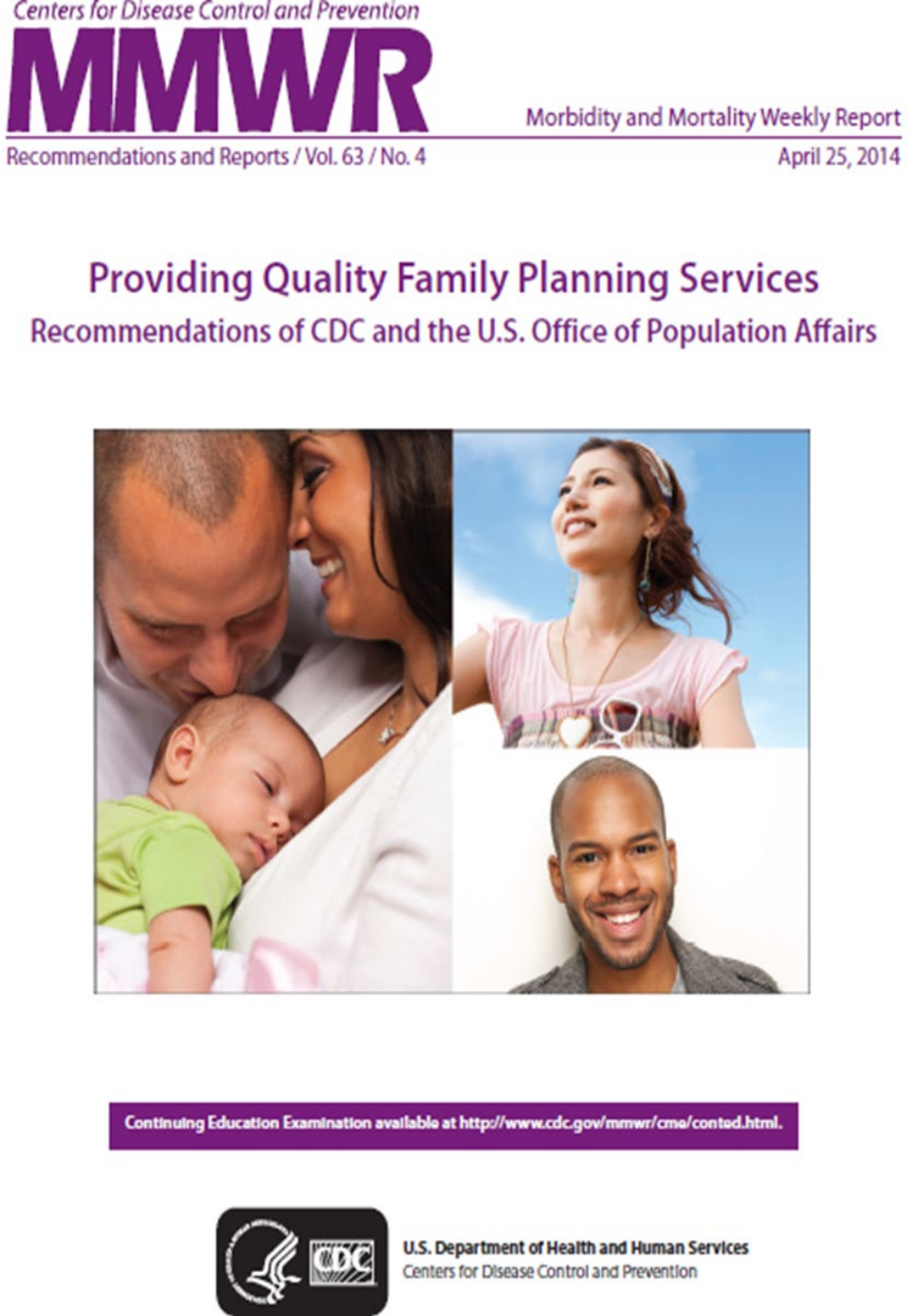
United States Selected Practice Recommendations for Contraceptive Use

US SPR



CDC STD Tx GUIDE 2015

Show Your Love Preconception Health



Filling The "Gaps"

- Pregnancy testing and counseling
- Achieving pregnancy
- Basic infertility
- Preconception health
- Preventive health screening of women and men
- Contraceptive counseling, incl reproductive life plan

My opinion: use by clinicians should be a quality metric!!

Local Clinic Protocols: What They Are

6. Are consistent with the standards, guidelines, and policies of contracted payers
   - State Medicaid program
   - State family planning program
   - Title X grantees and sub-grantees
   - Commercial health plans, if contracted
7. Written by, or developed under the supervision of, the medical director of the clinic system
   - Review by, and integration of input from, clinical staff members who will be subject to the protocol is critical

Local Clinic Protocols: What They Are

8. Updated on a regular schedule
   - Usually annually
   - Often on a rotating schedule
   - As needed, based on the issuance updated national guidelines or payer policies

Refer to NFPRHA's resource, Developing and Maintaining Policies and Procedures, for guidance on implementing a review cycle for organizational documents.

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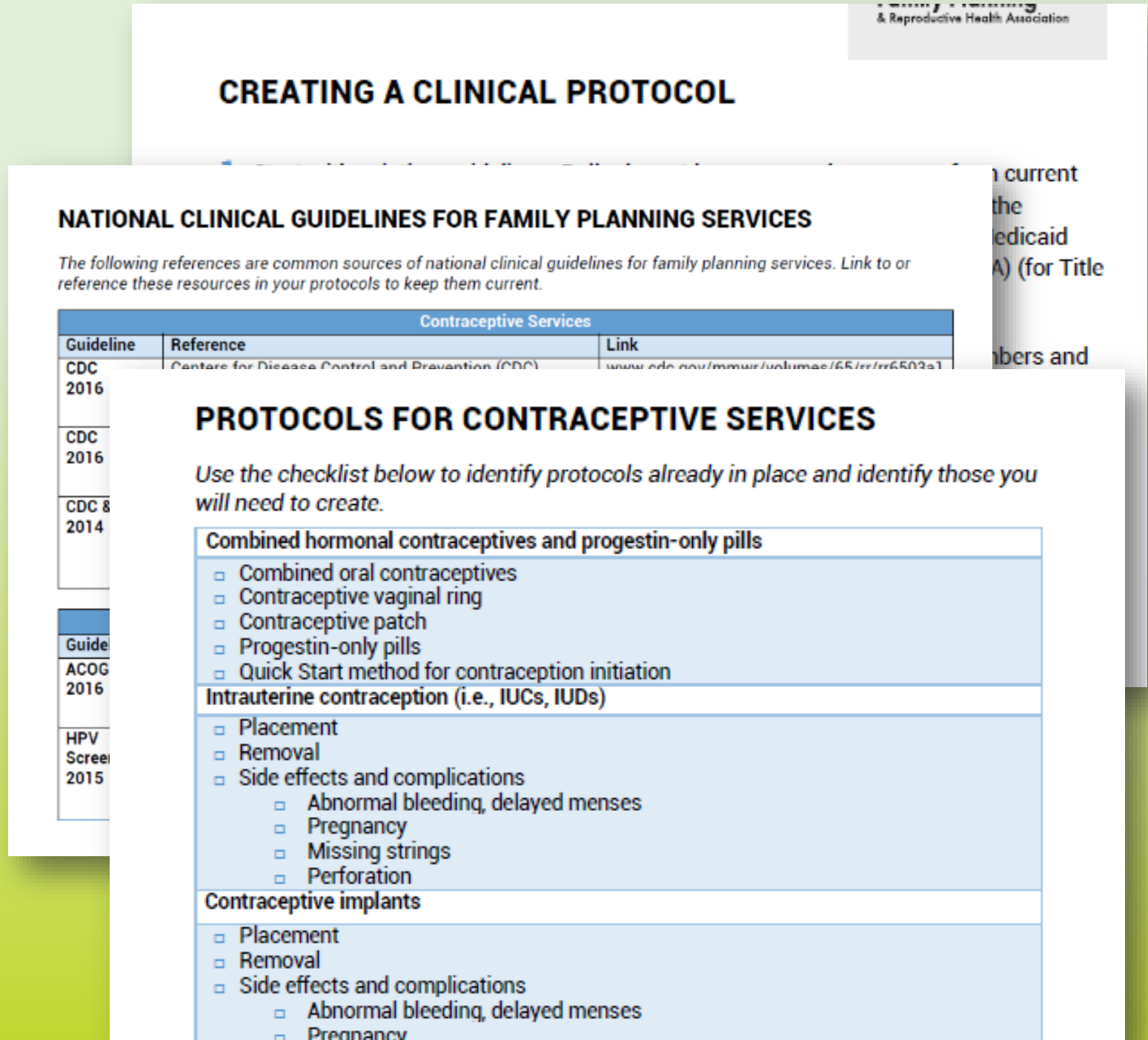
Local Clinic Protocols: What They Are NOT

- X A “cut-and-paste” duplication of the content of a health care textbook or a national guideline
- X A “cook-book” for clinicians to direct the provision of care
- X Boiler-plate content borrowed from a different clinic system, but not adapted to constitute the policies of this system
- X Standing orders for RNs who furnish contraceptive methods (this should be a separate document)

NFPRHA Protocol Guide includes:

- Best practices in protocol development
- Current national benchmark guidelines
- Protocol topic lists



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CREATING A CLINICAL PROTOCOL

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NATIONAL CLINICAL GUIDELINES FOR FAMILY PLANNING SERVICES

The following references are common sources of national clinical guidelines for family planning services. Link to or reference these resources in your protocols to keep them current.

Contraceptive Services		
Guideline	Reference	Link
CDC 2016	Centers for Disease Control and Prevention (CDC)	www.cdc.gov/mmwr/volumes/65/rr/rr6503a1
CDC 2016		
CDC & 2014		

Guide	
ACOG 2016	
HPV Scree 2015	

PROTOCOLS FOR CONTRACEPTIVE SERVICES

Use the checklist below to identify protocols already in place and identify those you will need to create.

Combined hormonal contraceptives and progestin-only pills

- ☐ Combined oral contraceptives
- ☐ Contraceptive vaginal ring
- ☐ Contraceptive patch
- ☐ Progestin-only pills
- ☐ Quick Start method for contraception initiation

Intrauterine contraception (i.e., IUCs, IUDs)

- ☐ Placement
- ☐ Removal
- ☐ Side effects and complications
  - ☐ Abnormal bleeding, delayed menses
  - ☐ Pregnancy
  - ☐ Missing strings
  - ☐ Perforation

Contraceptive implants

- ☐ Placement
- ☐ Removal
- ☐ Side effects and complications
  - ☐ Abnormal bleeding, delayed menses
  - ☐ Pregnancy

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CLINICAL PROTOCOL TEMPLATE

SYPHILLIS TESTING & TREATMENT

This template protocol is intended to assist family planning providers in developing local protocols for testing and treatment of syphilis.

A clinical protocol is a site-specific policy for the provision of high-quality health care to patients. It clarifies the scope of care that can be provided by clinicians and care team members, consistent with state regulations. Clinical protocols from one organization should never be adopted intact by another organization without first revising them, since these protocols will not include an accurate description of the adopting organization's policies and procedures nor will they account for other organizational considerations.

Refer to NFPRHA's resource, **Developing Clinical Protocols for Family Planning Services,** for more information on clinical protocols, including best practices for development.

How To Use a NFPRHA Template Protocol

- Each template protocol is written with several decision points that must be addressed before the protocol is ready for use
- The author tailors the template protocol to their own organization and creates a draft local protocol

How To Use a NFPRHA Template Protocol

- Decision points are listed in blue in the template
- The writer includes only the option that reflects their organization's current practices
- If the organization has policies, procedures, or practices that are not listed as an option, they should be inserted into the draft local protocol
- When formatting the draft local protocol, options that do not apply should be deleted

INTRODUCTION

[Name of health center or system] offers targeted screening, diagnosis, [treatment of syphilis in females [and males]] and [treatment of male and female sexual partners]. This protocol does not include guidance related to the diagnosis and management of tertiary syphilis or neurosyphilis; patients suspected of having either of these conditions should be referred to an expert in the management of these infections. [If your health center or system manages these patients, explain management here. If not, list where patients should be referred internally or in the community.] Screening and treatment of syphilis in pregnant women is not addressed in this protocol document. [If your system offers antenatal care, you should have a separate protocol for this service and reference that protocol here.]

	Point of Care Lab Tests
Objective (Lab Testing) NOTE: Testing for other STDs, including HIV, should be recommended in persons infected with syphilis.	• Darkfield microscopy [The special microscopes used for darkfield evaluation are available only in some sexually transmitted disease clinics, public health departments, and a few emergency departments. Do not list this test unless it is available in your health center or system. If so, describe where it is located, how to use it, and who is authorized to perform this evaluation.] • Rapid serology test (Syphilis Health Check (SHC)) [The SHC is performed on fingerstick whole blood and detects treponemal antibodies only. It cannot distinguish between old syphilis and recent infection; it should not be used in patients with a known history of syphilis. Additional testing must be performed at the clinical laboratory to obtain a nontreponemal titer (Venereal Disease Research Laboratory [VDRL] or rapid plasma reagin [RPR] test). The test is CLIA-waived and has a 10-minute turn-around time.]

How To Use a NFPRHA Template Protocol

- The draft should be reviewed and edited by select clinicians who will provide care to patients under the guidance of the final version of the local protocol
  - Serves as a "reality test" of whether the draft accurately reflects what currently is practiced within the organization
  - Gives clinicians an opportunity to provide feedback regarding new policies and procedures
- Much more likely that all clinicians will have a sense of "buy-in" to the new protocol once implemented

Considerations for the Future

- Local policies, procedures, and protocols (PPP) documents will be accessed on-line, or even app-based
- State-of-the art electronic medical records (EMR) systems will accommodate links to local PPPs, as well as source national guidelines and recommendations
- Auditing of clinician adherence to protocols will be on the basis of EMR data, rather than printed information
- As pay-for-performance strategies proliferate, adherence to protocols will pay economic dividends

Examples

Before: Specific Guidance on EPT in Idaho

For chlamydia:

- Partners of patients with chlamydia should be treated with azithromycin 1gram orally in a single dose, unless the partner is allergic to macrolide antibiotics. In this situation, consult the MMWR STD Treatment Guidelines 2015 or contact a consulting physician for further instructions. Empiric co-treatment for gonorrhea is not recommended[3].

For gonorrhea:

- Partners of patients with gonorrhea should be treated with cefixime 400 mg orally in a single dose AND azithromycin 1 gram orally in a single dose at the same time as cefixime, unless the partner is allergic to cephalosporins or macrolide antibiotics. If the partner is allergic to either class of antibiotics, EPT is discouraged; the partner should be advised to seek timely evaluation and treatment in-person. Patients with gonorrhea and their partners who are seen in-person should be treated with the first-line recommended treatment: ceftriaxone (250 mg intramuscularly) in addition to azithromycin. The second-line treatment, cefixime, is used for EPT because of the convenience that it can be taken orally.

- The Idaho HIV, STD, and Hepatitis Section does not recommend doxycycline in the use for EPT for several reasons. The use of doxycycline for EPT has not been studied. In addition, partner treatment of chlamydia or gonorrhea infection with doxycycline requires a multi-dose, multi-day regimen compared with single-dose treatment with azithromycin, and completion of EPT would be expected to be reduced. Doxycycline also has the potential to cause more frequent and more significant adverse events than azithromycin, including fetal risks in the event of inadvertent treatment during pregnancy.

After: Specific Guidance on EPT in Idaho

EPT drug regimens:

- Partners of patients diagnosed with **chlamydia**:
  - Azithromycin (*Zithromax*) 1 gram (4 x 250 mg, 2 x 500 mg, or 1 x 1000 mg) orally, once
- Partners of patients diagnosed with **gonorrhea**:
  - Cefixime (*Suprax*) 400 mg (4 x 100 mg, 2x 200 mg or 1 x 400 mg) orally, once AND
  - Azithromycin (*Zithromax*) 1 gram (4 x 250 mg, 2 x 500 mg, or 1 x 1000 mg) orally, once

- **Patients with gonorrhea and their partners who are seen in-person should be treated with the first-line recommended treatment:** ceftriaxone (*Rocephin*) 250 mg intramuscularly in addition to azithromycin. The second-line treatment, cefixime, is recommended for EPT because of the convenience that it can be taken orally.
- **Partner(s) in the previous 60 days may be receive EPT** (or most recent sex partner if none in the previous 60 days).

Personal Cell Phones and Devices – Policy Statement

Before

It is the policy of FPS to prohibit staff from use of personal cell phones and other electronic devices during work hours. FPS patients are prohibited from using cell phones and other electronic devices in clinical areas, and from use of phones/devices for photography, video, and voice calls while in the waiting area.

After

It is the policy of FPS to limit the use of personal cell phones and devices (Devices) on its premises.

Personal Cell Phones and Devices – Rationale

Before

FPS recognizes the need to have a cell phone/device policy both for workplace professionalism and patient safety and privacy. Use of personal cell phones and electronic devices during the workday for personal business is a distraction from paid duties and a disruption of official business. Patient use of cell phones/devices in public areas of the clinic can be disruptive and distracts from assigned tasks (e.g. completing paperwork, participating in interview/exam process, etc.).

After

This policy is to assist employees and patients in understanding the appropriate times and uses for devices to ensure a professional environment at FPS, while seeking to minimize distractions, inefficiencies, errors and possible confidentiality/HIPAA breaches that can result from improper use.

Personal Cell Phones and Devices – Patient

Before

- Signs will be prominently posted in the FPS clinics noting the prohibition of the use of cell phones and devices in the clinical area.
- Staff will enforce this by politely reminding patients when they check in that their cell phones/devices should be turned off once they enter the clinical area.
- Patients may use their devices while in the waiting area to watch videos, listen to music, and read, but may not take photos or video footage.

After

- Photo, video and audio recording is prohibited on the premises.
- Devices cannot be used in the patient care area and must turned off before they are escorted to the back.
- Patients may stream music, watch video and read while in the waiting area.
- Signs will be prominently posted in FSP clinics noting the allowed use and specific restrictions that apply to use of personal devices.
- Staff will enforce this by politely reminding patients when they check in that their devices must be turned off prior to entering the clinical area.

Small-Group Activity

Small-Group Activity

Instructions

1. Choose from:
    1. Policies and Procedures
    2. Protocols
2. Head to the designated area of the room
3. 40 minutes of group time
4. Return to large group

Discussion and Q&A

Time for Discussion and Q/A

- What has worked well regarding your process for maintaining your PPPs?
- After hearing the information discussed today, what gaps have you identified in your processes?
- What more could NFPRHA do to assist your work?
  - Any template PPP that you'd like "fast-tracked"?

What to do when you're back at the office

Initiating Change at Your Organization

Challenges

- Don't know where to start
- Not the decision maker
- Resistance from staff
- Skillsets (formatting, etc.)
- No time to develop/implement
- Limited fiscal resources
- Technology/IT support
- Geography

Strengths

- Have support of C-suite
- Have support of key staff
- Have already begun making changes
- Have technology
- Minimal change is needed

Plan Your Own Adventure

Specific PPP Document

- Format
- Review/revise timeframe
- Wording
- Resources
- Implementation timeline
- Training options
- Documentation/sign-offs
- Audit/follow-up

PPP System

- Components of current system
- Components missing
- Components in need of improvement
- Identify system changes
- Determine best options for employing new strategies at home


We’re here to help you!

Find resources at:
www.nationalfamilyplanning.org

Thank you!

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