2024 NFPRHA NATIONAL CONFERENCE

WASHINGTON, DC
MAY 19-22

ANCHORING YOUR PRACTICE WITH CLINICAL POLICIES, PROCEDURES, & PROTOCOLS

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Disclosures

- Michael Policar has nothing to disclose
- Jane Lose has nothing to disclose

Learning Objectives

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

- Define clinical policy, procedure, and protocol
- Critique sample formats for policies, procedures, and protocols
- Develop a plan for updating old and integrating new clinical policies, procedures, and protocols
- Identify resources for developing, updating, and archiving policies, procedures, and clinical protocols

Learning Objectives

- **Differentiate**
  - Policies, Procedures, and Protocols
- **Describe**
  - Development, maintenance, and implementation processes needed for effective and useable policies, procedures, and clinical protocols.
- **Review**
  - Strategies for troubleshooting common problems in the development of policies, procedures, and protocols
- **Identify resources for developing, updating, and archiving policies, procedures, and clinical protocols**

Outline: Part 1

- Define policies, procedures, and protocols
- Traits of an effective system
- Why standardize practice?
- Policy and procedure best practices
- Clinical protocol best practices
- Use of template protocols
- Clinical Site Visits with the Family Planning Program
- Audience discussion and Q/A

Outline: Part 2

- **Critique of a protocol**
- **Case studies**
  - Credentials and privileges
  - Fitness for duty
  - Incident reporting
  - Focus studies using CQI (continuous quality improvement)
- **Audience discussion and Q&A**

Poll Question: How would you rate your level of expertise in the development of PPP's?

1. Highly experienced
2. Moderate level of experience
3. Minimal level of experience
4. I haven't done this before

The 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

Clinical Standard and Guidelines

Standards

- Minimum level of quality (floor)
- Established by experts
- “Musts”

Guidelines

- Best practices for high quality care
- “Shoulds”

Comments

- “You may want to do it this way”

Why Are These Documents 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
- Frees up time to do more important/rewarding work
- Allows management by exception
- Clarity in expectations

Organizational Impact

- Improves overall effectiveness and efficiency
- Minimizes potential liability
- Protects reputation and brand
- Provides legal protection
- Sends the signal that “we want employees to be successful”

Effective Policies, Procedures and Protocols

- Clarity
- Standardization
- End-user involvement
- Prioritize equity
- Dedication to implementation and monitoring
- Consistent reviewing and updating
- Includes a defined process for retiring documents

Are there signs that your PPPs need improvement?

- Increase in number of accidents/errors
- Staff asking more questions on routine operations
- Feeling of confusion within a specific department or location
- Employees inconsistent in performing their jobs
- Increased stress levels
- Complaints from customers/patients

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

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
- **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

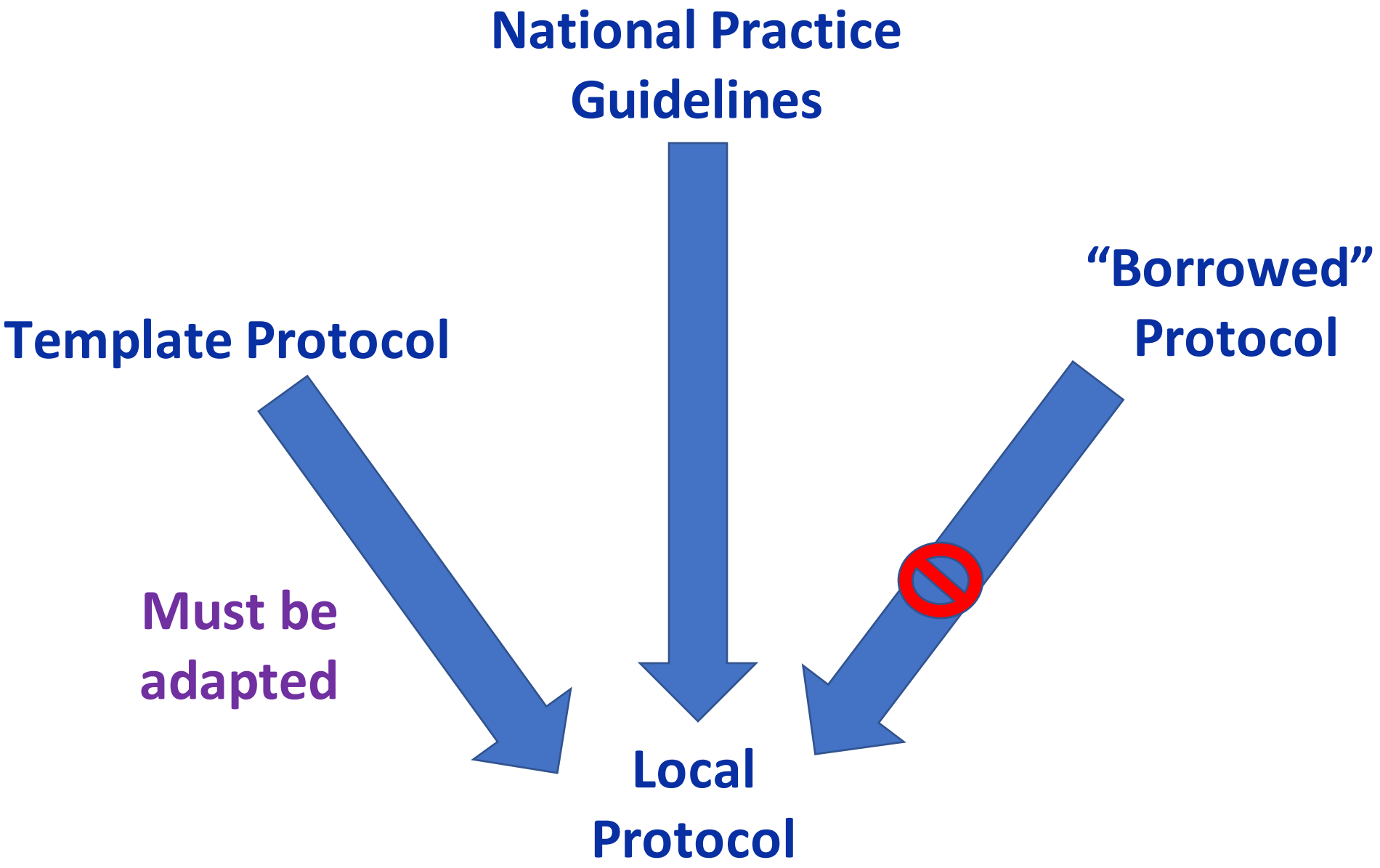
- **Elimination of variation in processes has been a cornerstone of improved performance and reliability in aviation, military flight operations, and nuclear energy**
- **A similar level of success has been achieved in the field of anesthesia, where adverse events have been significantly reduced over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

ACOG: Clinical Guidelines and Standardization of Practice to Improve Outcomes

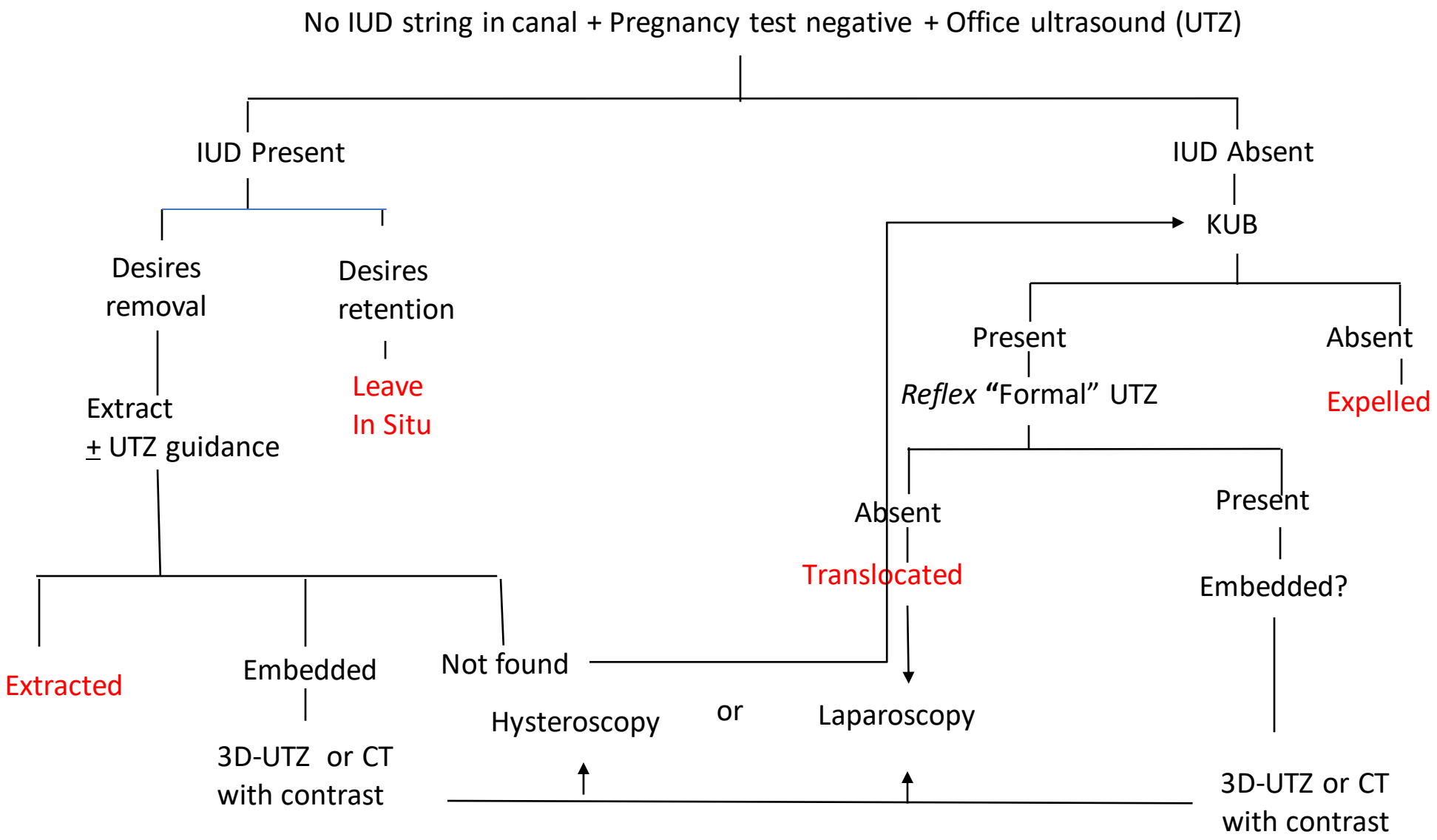
"The adoption by the *clinical care team* of one appropriate specific management plan will, by virtue of standardization alone, yield results superior to those achieved by random application of several individually equivalent approaches."

ACOG: Clinical Guidelines and Standardization of Practice to Improve Outcomes

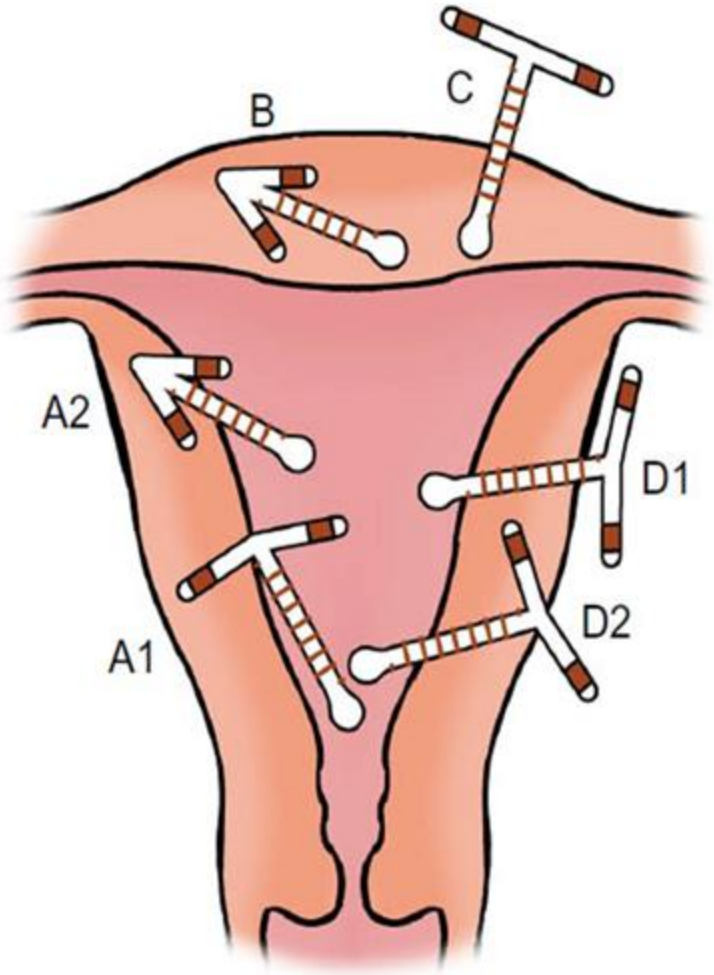
- When checklists or protocols are developed at a national level, it is advisable to adapt them to individual practice settings
- Local practice conditions should be taken into account when these tools are introduced in any institution
- It is important that clinicians are informed whenever checklists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


National Practice Guidelines
Template Protocol
"Borrowed" Protocol
Must be adapted
Local Protocol

Missing IUD String: Office Ultrasound Available



CT or 3-D Ultrasound



A: Hysteroscopy

B: Laparotomy

C: Laparoscopy

D_1: Laparoscopy

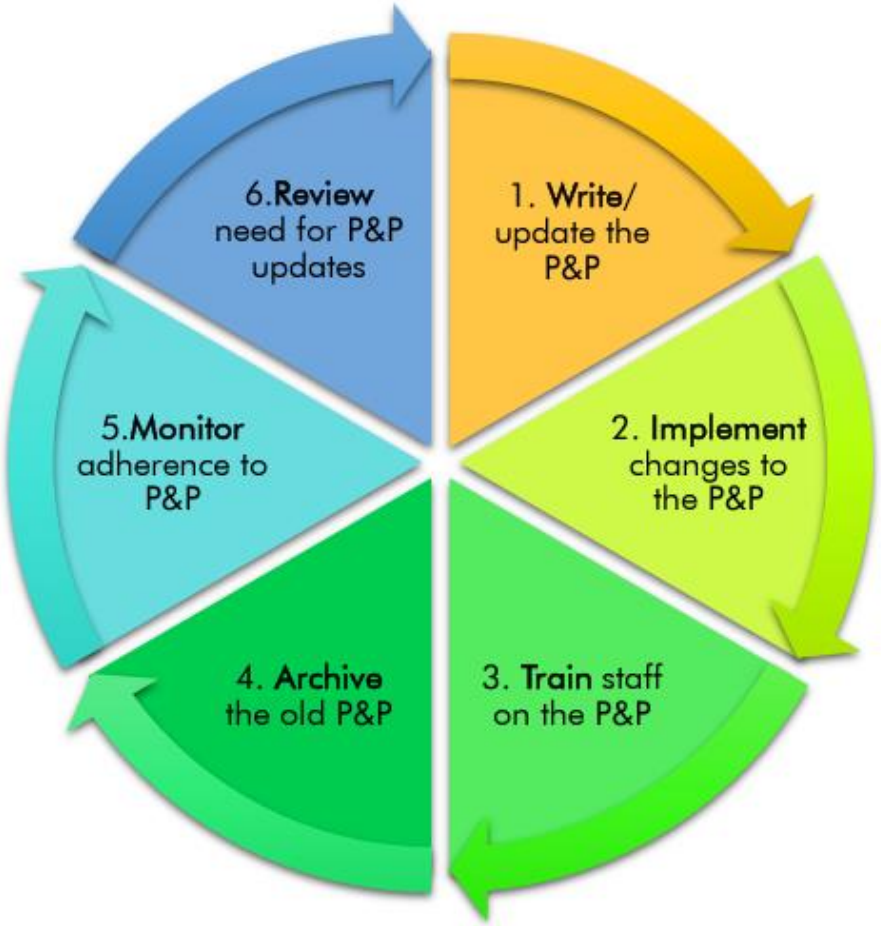
D_2: Hysteroscopy

Checklist: Extraction of IUD with Missing Strings

- ❑ Patient wants removal of IUD
- ❑ Pregnancy test negative
- ❑ Attempt to tease strings with brush unsuccessful
- ❑ Office ultrasound shows IUD within uterine cavity
- ❑ Assessment of pain tolerance re: need for cervical block
- ❑ Sterile alligator forceps available in clinic
- ❑ Sterile IUD hook available in clinic

Best Practices for Policies, Procedures, and Protocols

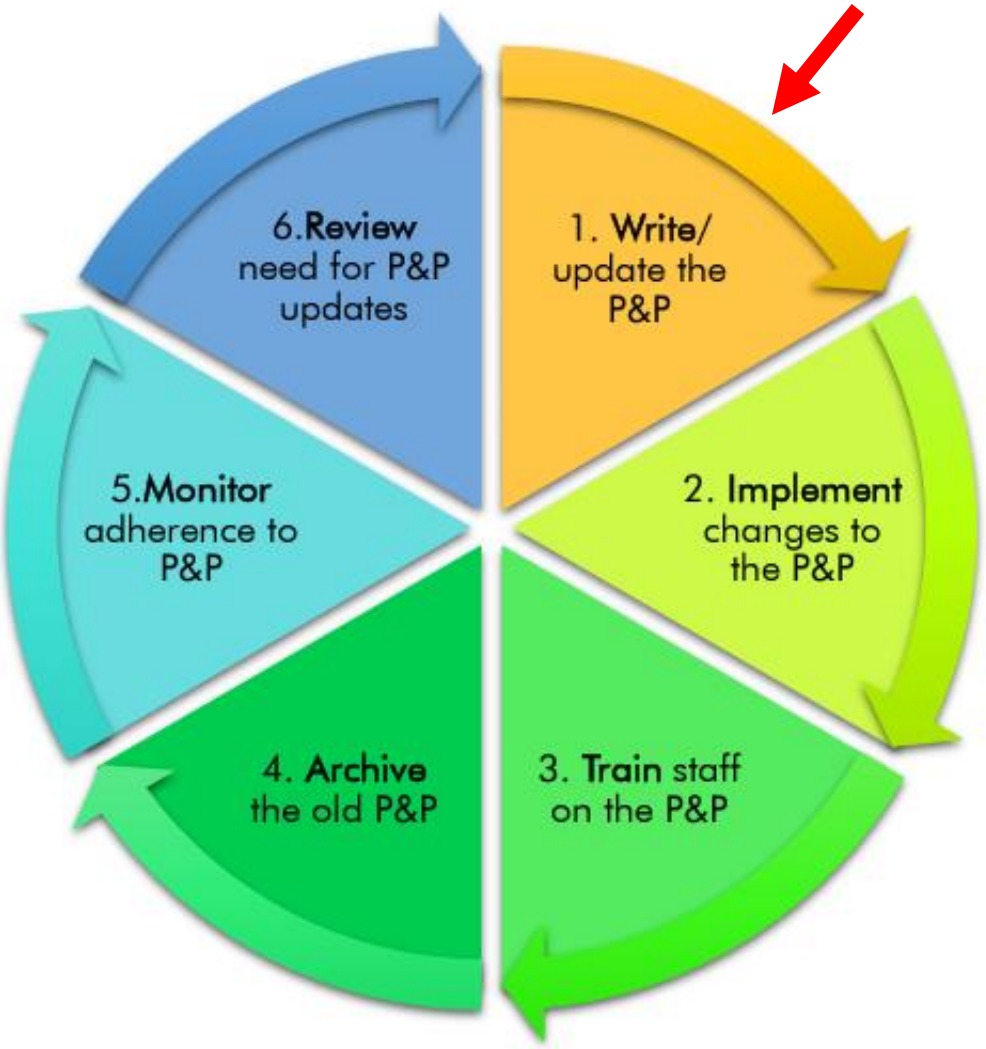
Components of a Maintenance Cycle



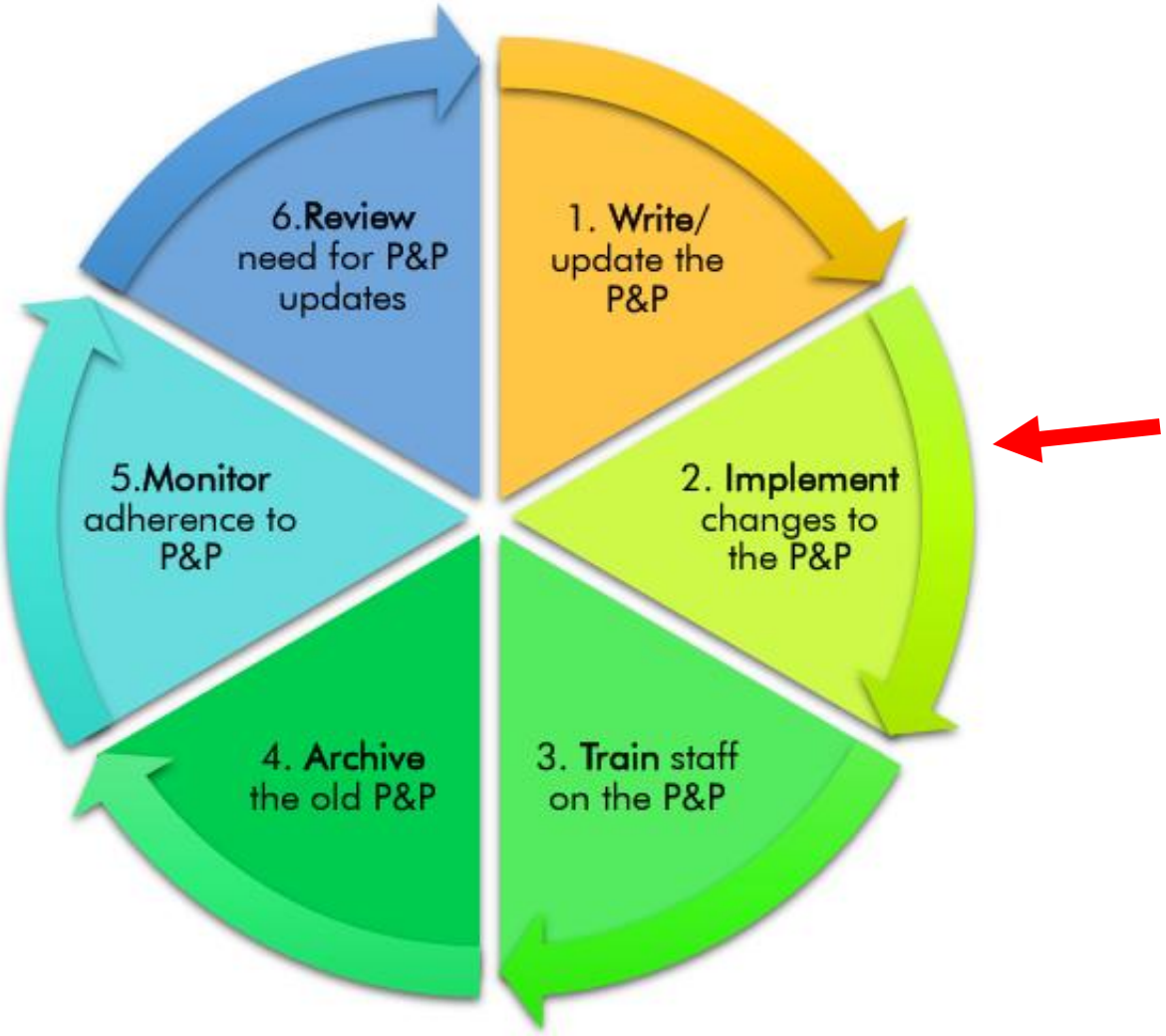
The P&P Maintenance Cycle

NFPRHA: Developing and Maintaining Policies and Procedures

Write


1. Write/ update the P&P
2. Implement changes to the P&P
3. Train staff on the P&P
4. Archive the old P&P
5.Monitor adherence to P&P
6.Review need for P&P updates

Implement


6.Review need for P&P updates
1. Write/ update the P&P
2. Implement changes to the P&P
3. Train staff on the P&P
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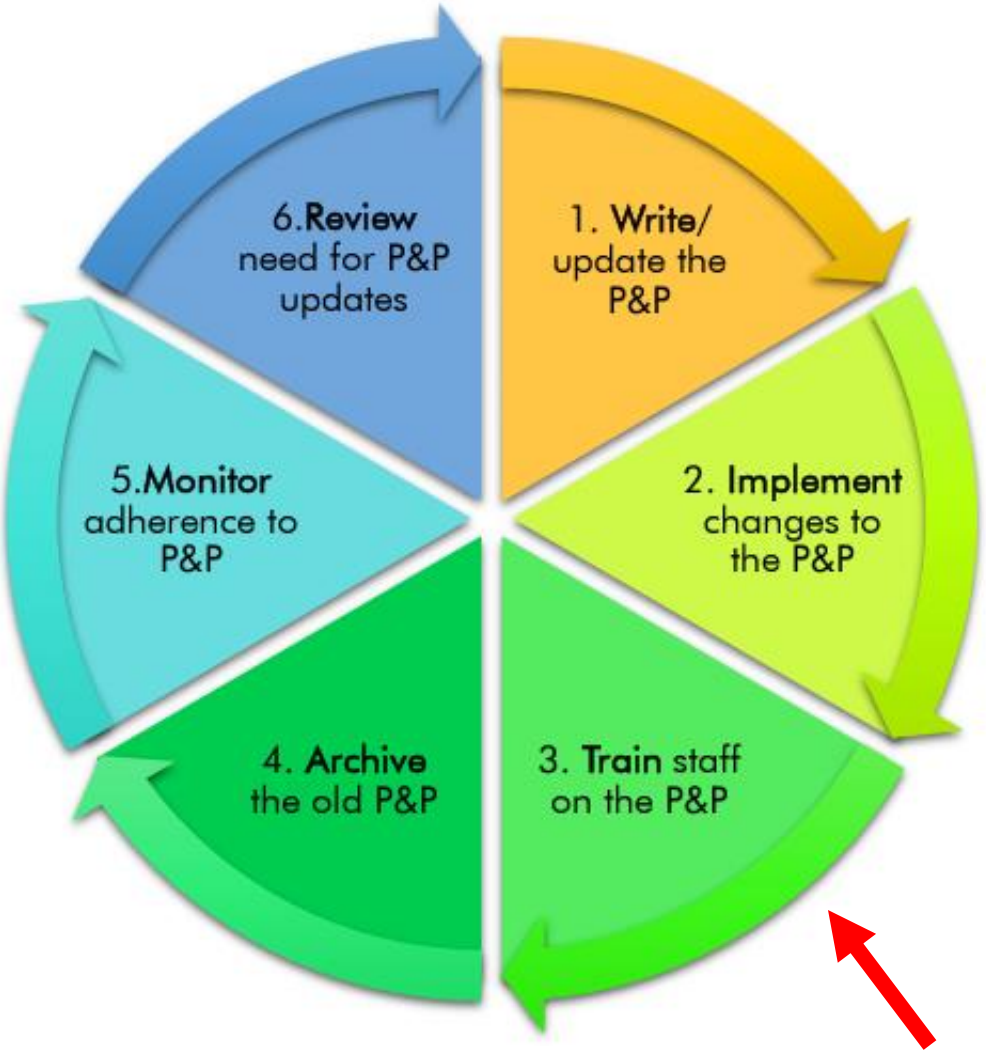
Train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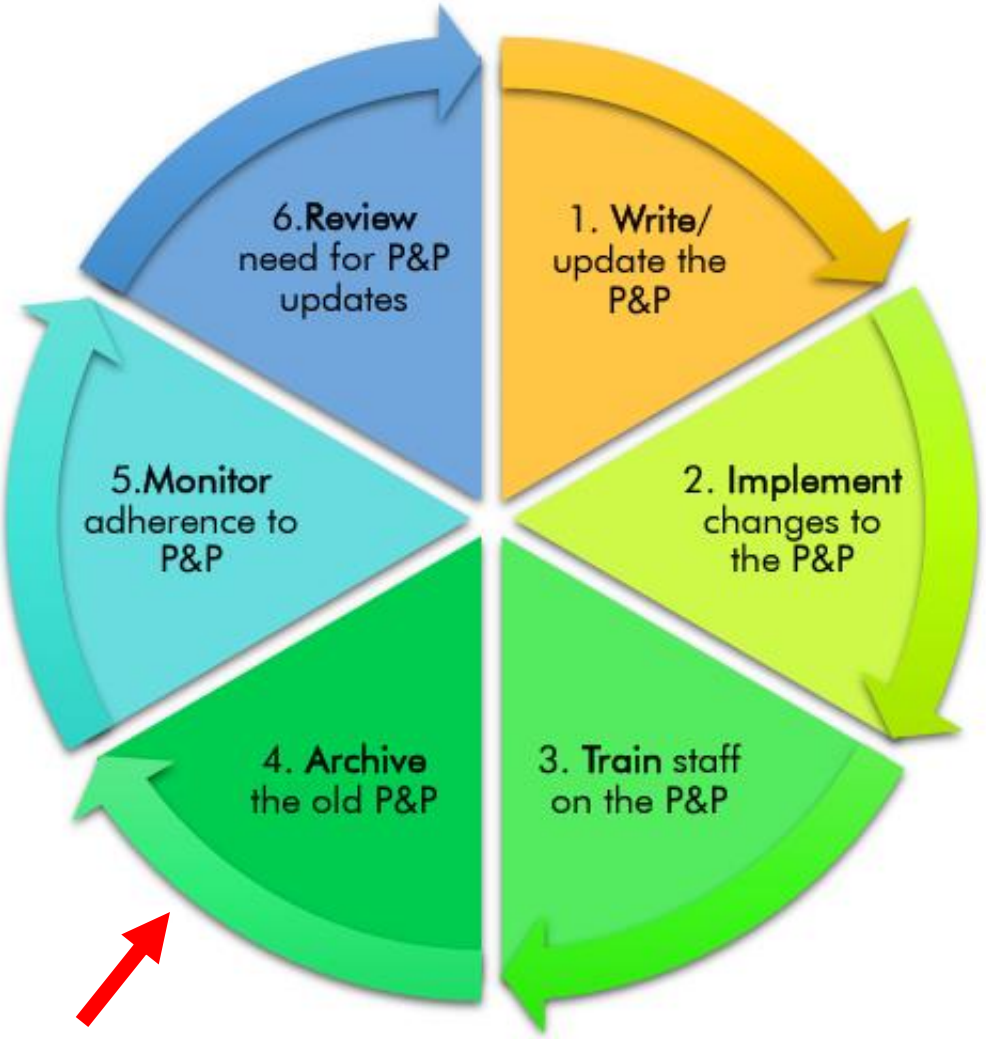
4. Archive the old P&P
5.Monitor adherence to P&P
6.Review need for P&P updates

Archive


6.Review need for P&P updates
1. Write/ update the P&P
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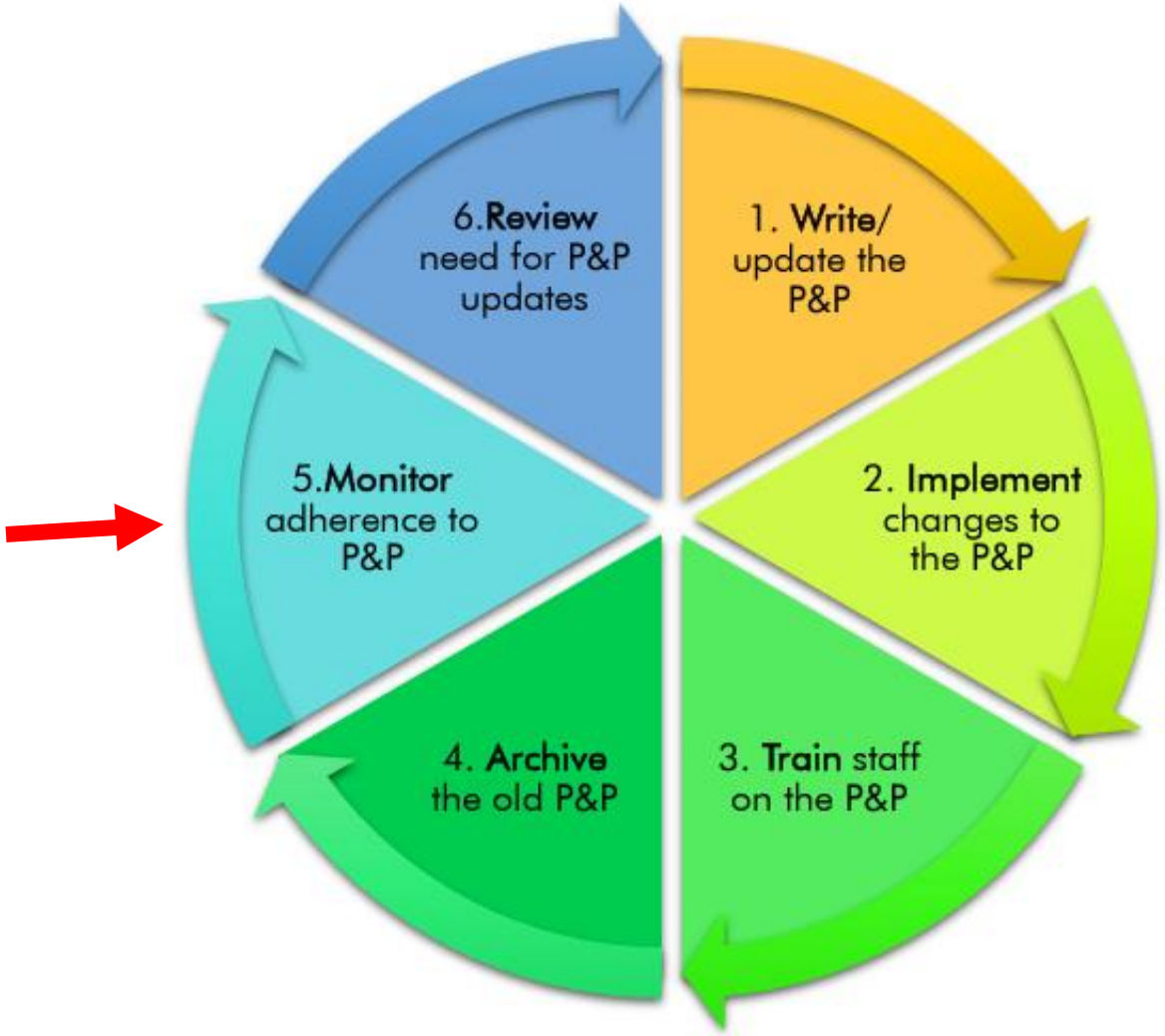
Monitor


6.Review need for P&P updates
1. Write/ update the P&P
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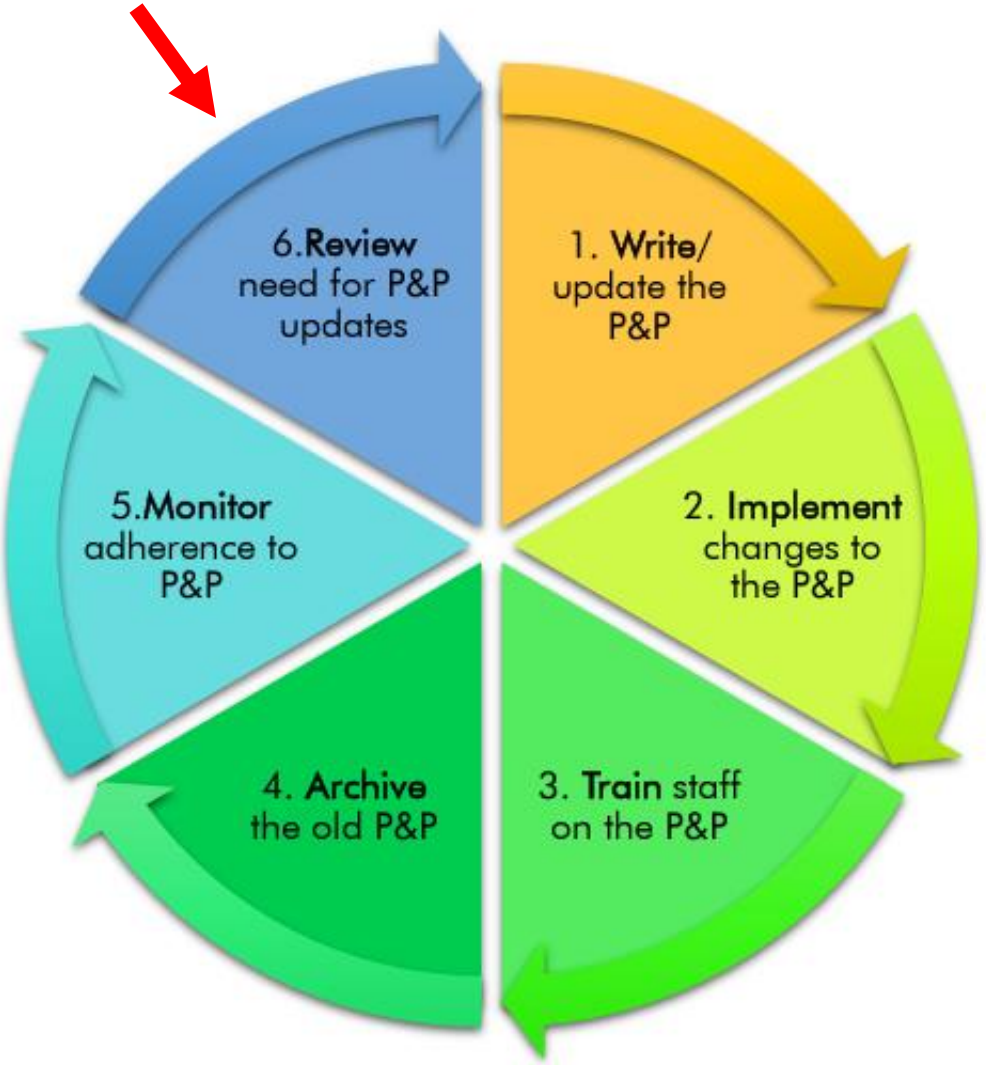
Review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PPP Management: Standardized System

- Establish process for developing and maintaining documents and manuals
- Establish timelines/calendars for each phase
- Maintain documentation throughout each phase
- Ensure transparency throughout each phase
- Ensure accountability at all levels

Elements to Include in a Policy or Procedure

- **Purpose**
- **Policy statement**
- **Rationale**
- **Background**

Header/Footer

- Organization name
- Title of the document
- Tracking number
- Date of implementation
- Date of revision
- Date of next scheduled review

Write Policies Based on Quality Indicators

Adolescent Services, Expectation #5:

Ensure that all applicants for Title X funds certify that they provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities. (Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 466 (2022), OPA Expectation #5)

Write Policies Based on Quality Indicators

[INSERT AGENCY NAME AND LOGO]

FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

Adolescent Services #3, #4, #5: Required Adolescent Counseling

The purpose of this policy is to describe ***(insert Agency Name)*** process for ensuring compliance (including the recipient, subrecipient, and service sites, as appropriate) with adolescent counseling requirements. To the extent practical, Title X projects shall encourage family participation. However, Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services. (Section 1001, PHS Act; 42 CFR § 59.10(b))

Projects must ensure that all applicants for Title X funds certify that they encourage family participation in the decision of minors to seek family planning services. (Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 466 (2022))

Projects must ensure that all applicants for Title X funds certify that they provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities. (Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 466 (2022))

Write Policies Based on Quality Indicators

Policy Information	Description
Title	**Required Adolescent Counseling**
Effective Date	
Revision Dates	
Review Due Date	
References	Title X Program Handbook, Section 3, Adolescent Services, #3, #4, #5 (https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2022-508-updated.pdf#page=20) Section 1001, Public Health Service (PHS) Act (https://opa.hhs.gov/sites/default/files/2020-07/title-x-statute-attachment-a_0.pdf) 2021 Title X Final Rule 42 CFR § 59.10(b) (https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A/section-59.10) Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 444 (2022) (https://www.congress.gov/117/plaws/publ103/PLAW-117publ103.pdf)
Approval Signature	
Approved Date	

Write Policies Based on Quality Indicators

Policy: *[Agency may want to include the following]*

- To the extent practical, minors seeking care receive counseling to encourage family participation in the decision to seek family planning services.
- Minors seeking care receive counseling on how to resist attempts to coerce minors into engaging in sexual activities.
- Staff are trained on these requirements upon hiring and again on an annual basis.
- Counseling regarding encouragement of family participation in adolescent clients' decisions to seek family planning services, and how to resist attempts to be coerced into engaging in sexual activities is documented in the medical record.

Write Policies Based on Quality Indicators

Procedure: *[Agency may want to include the following]*

- Process for ensuring minors are encouraged regarding family participation in their decision to seek family planning services and counseled on how to resist attempts to be coerced into engaging in sexual activities.
- Process for ensuring and documenting (e.g., staff circulars, training curricula) that all project staff have been formally trained on: 1) encouraging family participation in the decision of minors to seek FP services, and 2) counseling minors on how to resist attempts to coerce them into engaging in sexual activities.
- Process for including language in sub-recipient contracts and conducting monitoring activities related to the legislative mandates.
- Recipient's process for monitoring sub-recipients and service sites to ensure compliance with this expectation.
- Process for notifying staff about this policy.
- Where staff notification is documented (e.g., statement signed by employee, staff circulars, training records, orientation checklist, etc.) at the recipient, sub-recipient, and service site levels.
- How staff are trained and updated on changes to this policy.
- How staff can access this policy (location of paper and/or electronic versions).

National Family Planning & Reproductive Health Association

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.

Best Practices for Clinical Protocols

Clinic Protocols: Potential Problems

- Non-existent or incomplete set of titles
- Out-of-date
- Little/ no focus on internal processes and referrals
- Cut-and-paste from national guidelines (only)
- Borrowed intact from another system

Clinic Protocols: What They Are NOT

- X **Boiler-plate content borrowed from a different clinic system, but not adapted to constitute the policies of this system**
- 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 **Standing orders for RNs who furnish contraceptive methods (this should be a separate document)**

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 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/LPN, PHN
   - Health educators, counselors
   - Medical assistants

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)

Clinic Protocols: What They Are

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 (Plan-Do-Study-Act, or PDSA) audit
   - Often expected in health plan contracts

Clinic Protocols: What They Are

5. **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
   - Ideally, reviewed and approved by your health system "Medical Advisory Committee"

Local Clinic Protocols: What They Are

6. **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

Local Clinic Protocols: What They Are

7. **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)

The 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

Show Your Love Preconception Health

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Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 63 / No. 4
April 25, 2014

Providing Quality Family Planning Services

Recommendations of CDC and the U.S. Office of Population Affairs

Continuing Education Examination available at http://www.cdc.gov/mmwr/cme/contad.html.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Filling The "Gaps"

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

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

Benchmark National Clinical Practice Guidelines
FOR FAMILY PLANNING CLINICS

National Family Planning & Reproductive Health Association

CONTRACEPTIVE SERVICES	SOURCE	REFERENCE	LINK
US Medical Eligibility Criteria (MEC)	Centers for Disease Control and Prevention (CDC), 2016	Curtis KM, Tepper NK, et.al. United States Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2016. *MMWR* 2016; 65(3): 1-103.	https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6503.pdf
US Selected Practice Recommendations (SPR)	CDC, 2016	CDC, U.S. Selected Practice Recommendations for Contraceptive Use (US SPR), 2016. *MMWR* 2016; 65(4) 1-66.	https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf
Quality Family Planning Guidelines (QFP)	CDC & Office of Population Affairs, 2014	Gavin L, Moskosky S, Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs (OPA). *MMWR* 2014; 63(RR-04): 1-54.	https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf
Adolescents and LARC Use	American College of Obstetrics and Gynecologists 2018	ACOG Committee Opinion No. 735: Adolescents and Long-Acting Reversible Contraception: Implants and Intrauterine Devices. *Obstet Gynecol* 2018;131(5):e130-e139.	https://pubmed.ncbi.nlm.nih.gov/29683910/
Adolescent Pregnancy, Contraception, and Sexual Activity	ACOG, 2017	ACOG Committee Opinion No 699: Adolescent Pregnancy, Contraception, and Sexual Activity. Committee on Adolescent Health Care. *Obstet Gynecol* 2017 May;129(5):e142-e149.	https://pubmed.ncbi.nlm.nih.gov/28426620/
Immediate Postpartum LARC	ACOG, 2016	ACOG Committee Opinion No. 670: Immediate Postpartum Long-Acting Reversible Contraception. ACOG Committee on Obstetric Practice. *Obstet Gynecol* 2016 Aug;128(2):e32-7.	https://pubmed.ncbi.nlm.nih.gov/27454734/
Female Contraceptive Sterilization	ACOG, 2019	ACOG Practice Bulletin No. 208: Benefits and Risks of Sterilization. *Obstet Gyneco* 2019 Mar;133(3):e194-e207.	https://pubmed.ncbi.nlm.nih.gov/30640233/
Vasectomy	American Urological Association, 2012 (ALLA)	Sharlip ID, Belker AM, et. al. Vasectomy: AUA guideline. American Urological Association. *J Urol* 2012 Dec;188(6 Suppl):2482-91.	https://pubmed.ncbi.nlm.nih.gov/23098786/

https://www.nationalfamilyplanning.org/file/Clinical-Practice-Guidelines-Family-Planning-Clinics-10222021.pdf?erid=2636361&trid=aa7dc273-85dc-4a02-b997-85d4cf6a1496

Consensus Guidelines for Facilities Performing Outpatient Procedures

Evidence Over Ideology

Barbara S. Levy, MD, Debra L. Ness, MS, and Steven E. Weinberger, MD

February 2019

In policy and law, regulation of abortion is frequently treated differently from other health services. The safety of abortion is similar to that of other types of office- and clinic-based procedures, and facility requirements should be based on assuring high-quality, safe performance of all such procedures. False concerns for patient safety are being used as a justification for promoting regulations that specifically target abortion. The Project on Facility Guidelines for the Safe Performance of Primary Care and Gynecology Procedures in Offices and Clinics was undertaken by clinicians, consumers, and representatives from accrediting bodies to review the available evidence and guidelines that inform safe delivery of outpatient care. Our overall objective was to develop evidence-informed consensus guidelines to promote health care quality, safety, and accessibility. Our consensus determined that requiring facilities performing office-based procedures, including abortion, to meet standards beyond those currently in effect for all general medical offices and clinics is unjustified based on an analysis of available evidence. No safety concerns were identified.

(Obstet Gynecol 2019;133:255–60)
DOI: 10.1097/AOG.0000000000003058

Endorsing Organizations

www.SocietyFP.org

Outpatient Procedures: Scope of Project

- **Only facility factors (e.g., physical environment, office and clinic operations) covered**
  - Not clinical practice or scope of practice
- **The Working Group considered only offices and clinics providing procedures within primary care or gynecology**
- **Did not seek to articulate guidelines and accepted practices for the provision of sedation and anesthesia**
  - American Society of Anesthesiologists guidelines accepted

Facility Guidelines: Categories

- **Emergency preparedness**
- **Biological material handling**
- **Physical plant specifications**
- **Facility accreditation and licensing**
- **Clinician qualifications beyond licensing**
- **Other *policies and procedures***
  - Infection control
  - Quality improvement plan
  - Checking equipment functioning
  - Medication inventory

The Bottom Line

- **The new "benchmark" for all clinics and offices performing reproductive health procedures**
  - IUDs and implants
  - Biopsies (e.g., vulvar, endometrial, cervical)
  - Miscarriage management
  - Surgical abortion
- **Ensure that your policies, procedures, and clinical protocols are consistent with these guidelines**
  - If you don't have written PPPs in each of the topics in the guideline, create them!

Local Clinic Protocols: What They Are

- **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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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.

NFPRHA: Syphilis Testing & Treatment

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

How To Use a NFPRHA Template Protocol

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.]

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**

Aspirations 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

Preparation for a Site Visit

It’s almost never too early to start!

Colorado Department of Public Health and Environment (CDPHE)

Administrative + Fiscal & Clinical Site Visits

Site Visit Process for Subrecipients

This document outlines what you can expect during the administrative + fiscal and clinical site visit processes and provides links to the documents that will be used during the process.

Site Visit Agendas

- Administrative and Fiscal Site Visit Meeting Agenda
- Clinical Visit Meeting Site Agenda

These sample agendas demonstrate the general topics that will be discussed during the site visit meeting. The FPP team will work with your agency to finalize the agenda in preparation for your site visit meeting.

Site Visit Document Lists

- Administrative and Fiscal Site Visit Document List
- Clinical Site Visit Document List

These document lists outline all of the required documents that your agency will submit for review by the FPP team before the site visit meeting. The lists describe what staff will be reviewing and looking for in each document based on the site visit tools (below). This is the primary document you will use to prepare for your site visit.

Site Visit Tools

- Administrative and Fiscal Site Visit Tool
- Clinical Site Visit Tool

These tools were developed to align with the federal Title X program review tools used by the Office of Population Affairs (OPA) to monitor compliance with Title X requirements. The FPP team will indicate whether each requirement was met or not met and record what evidence supports the determination. These tools are provided for informational purposes and you are not required to review or use this document prior to the site visit.

CDPHE- Family Planning Program- Site Visits Page

Preparing for a Site Visit

- Map regulatory agency's requirements to your organization's policies and procedures
- Identify gaps and assign roles and responsibilities to fill them
- Synthesize into information to be shared with all organizational staff
- Practice with mock site visits
- Debrief after the site visit is completed

Mapping Quality Indicators to Policies and Supporting Evidence

Adolescent Services, Expectation #5

Ensure that all applicants for Title X funds certify that they provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities. (Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 466 (2022), OPA Expectation #5)

Suggested Evidence to Submit for Program Review

- Documentation of staff training
- Adolescent counseling and education protocol
- Medical records review
- Observations and staff interviews
- Recipient and sub-recipient policies and procedures state to provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities
- Monitoring/audit reports

Benchmark National Clinical Practice Guidelines
FOR FAMILY PLANNING CLINICS

National Family Planning & Reproductive Health Association

CONTRACEPTIVE SERVICES	SOURCE	REFERENCE	LINK
US Medical Eligibility Criteria (MEC)	Centers for Disease Control and Prevention (CDC), 2016	Curtis KM, Tepper NK, et.al. United States Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2016. *MMWR* 2016; 65(3): 1-103.	https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6503.pdf
US Selected Practice Recommendations (SPR)	CDC, 2016	CDC, U.S. Selected Practice Recommendations for Contraceptive Use (US SPR), 2016. *MMWR* 2016; 65(4) 1-66.	https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf
Quality Family Planning Guidelines (QFP)	CDC & Office of Population Affairs, 2014	Gavin L, Moskosky S, Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs (OPA). *MMWR* 2014; 63(RR-04): 1-54.	https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf
Adolescents and LARC Use	American College of Obstetrics and Gynecologists 2018	ACOG Committee Opinion No. 735: Adolescents and Long-Acting Reversible Contraception: Implants and Intrauterine Devices. *Obstet Gynecol* 2018;131(5):e130-e139.	https://pubmed.ncbi.nlm.nih.gov/29683910/
Adolescent Pregnancy, Contraception, and Sexual Activity	ACOG, 2017	ACOG Committee Opinion No 699: Adolescent Pregnancy, Contraception, and Sexual Activity. Committee on Adolescent Health Care. *Obstet Gynecol* 2017 May;129(5):e142-e149.	https://pubmed.ncbi.nlm.nih.gov/28426620/
Immediate Postpartum LARC	ACOG, 2016	ACOG Committee Opinion No. 670: Immediate Postpartum Long-Acting Reversible Contraception. ACOG Committee on Obstetric Practice. *Obstet Gynecol* 2016 Aug;128(2):e32-7.	https://pubmed.ncbi.nlm.nih.gov/27454734/
Female Contraceptive Sterilization	ACOG, 2019	ACOG Practice Bulletin No. 208: Benefits and Risks of Sterilization. *Obstet Gyneco* 2019 Mar;133(3):e194-e207.	https://pubmed.ncbi.nlm.nih.gov/30640233/
Vasectomy	American Urological Association, 2012 (ALLA)	Sharlip ID, Belker AM, et. al. Vasectomy: AUA guideline. American Urological Association. *J Urol* 2012 Dec;188(6 Suppl):2482-91.	https://pubmed.ncbi.nlm.nih.gov/23098786/

https://www.nationalfamilyplanning.org/file/Clinical-Practice-Guidelines-Family-Planning-Clinics-10222021.pdf?erid=2636361&trid=aa7dc273-85dc-4a02-b997-85d4cf6a1496

Staff Interview Guide

Our organization **provides counseling to adolescents about how to resist sexual coercion**

- We have an adolescent care policy that addresses this
- All direct care staff receive annual training
- Use of this framework is audited in peer review chart audits
- We have patient handouts to support this practice

Practice Makes Perfect

- **Provide interview guides to staff with enough time to familiarize themselves with the content**
- **Perform mock site visits**
  - Identify growth areas
  - Give staff the opportunity to practice in a low stakes setting
  - Reduces anxiety for the real review

Debrief After the Visit

- **Where did we perform well?**
- **What surprised us?**
- **Feedback provided in real-time?**
- **What could be have been better prepared for?**
- **Are there immediate corrective actions that need to be implemented?**
  - Who is taking responsibility for implementing corrective actions?

Critique of a Borrowed Protocol

- **“We have a site visit coming up and just realized that we don’t have an OC, contraceptive patch, and vaginal ring protocol”**
- **“A friend in Montana sent me the one that they use”**
- **“Given the time frame, is it OK to re-label it as ours ‘as-is’ or are modifications necessary?”**
- **“How do we decide which modifications to make?”**

3.0 COMBINED HORMONAL CONTRACEPTIVES

TITLE	DESCRIPTION
DEFINITION:	Combined contraceptives contain both an estrogen and a progestin and through the combined actions, reduce the risk of pregnancy primarily by suppressing ovulation and thickening cervical mucus. Combined oral contraceptives, vaginal ring delivery system, and transdermal patch are all combined contraceptives.
SUBJECTIVE:	**Must Include:** 1. LMP. **Should Include:** 1. Comprehensive medical, sexual, and contraceptive use history (initial or update) as appropriate.
OBJECTIVE:	**Must Include:** 1. BP. **Should Include:** 2. Height, weight, BMI. 3. Age-appropriate physical exam as indicated.
LABORATORY:	**May Include:** 1. Pap smear, as indicated. 2. STD screening, as indicated. 3. Sensitive urine pregnancy test, as indicated. 4. Other lab work, as indicated.

ASSESSMENT:	Client is candidate for CHCs as evidence by: No condition that represents an unacceptable risk for the use of CHCs (US Medical Eligibility Criteria for Contraceptive Use Category 4). If client has condition that represents a theoretical or proven risk that usually outweighs the advantages of using CHCs (US Medical Eligibility Criteria for Contraceptive Use Category 3), may be a candidate if clinic protocols support use and/or with consultation with medical provider. RN dispensing: RNs dispensing hormonal contraceptives may dispense Category 1 [no restrictions] methods. RNs may dispense Category 2 [advantages generally outweigh theoretical or proven risks] methods **with the following exceptions:** undiagnosed breast mass; history of a DVT/PE in a first degree relative; inflammatory bowel disease; and unexplained vaginal bleeding. **RNs may not dispense Category 3 or 4 contraceptive methods**
PLAN:	1. Counsel about the full range of methods they are medically eligible to use to identify the optimal method. 2. Discuss potential barriers of using the method(s) under consideration. 3. Prescribe the CHC, including dosage, # of cycles and directions for use. 4. Develop a plan with the client for using the method correctly and consistently.

TITLE	DESCRIPTION
	5. Client can start the CHC anytime if the provider is reasonably sure she is not pregnant. 6. Discuss the benefits of shortening the hormone-free interval from 7 days to 3-4 days. 7. Instruct the client her cycle will be 25 days instead of 28 days. 8. Advise back-up method per information in the current Selected Practices Recommendations for Contraceptive Use. 9. Postpartum client wanting to start CHCs: a. Category 4: <21 days status post vaginal delivery. b. Category 3: 21 to 42 days status post vaginal delivery with other risk factors for VTE (such as ≥35 years or age, previous VTE, thrombophilia, immobility, transfusion at delivery, BMI ≥30, postpartum hemorrhage, post-cesarean delivery, preeclampsia, or smoking). c. Category 2: 21 to 42 days status post vaginal delivery without risk factors for VTE. d. Category 1: >42 days status post vaginal delivery. 10. Discuss method benefits (contraceptive and non-contraceptive), mechanism of action, effectiveness, correct use of method, possible side effects, STI protection and danger signs and document in the chart. 11. Discuss emergency contraception (EC) and how to obtain it either through Title X services or OTC. Consider sending a cycle of (EC) home with client especially if just starting BC, is an adolescent, has transportation issues or lives in a rural area. 12. Ensure client understanding.

EDUCATION:

1. Instruct client to report any pill warning signs:

PILL WARNING SIGNALS -ACHES	
Abdominal pain	Blood clot in liver or pelvis Gall bladder disease
Chest pain	Blood clot in the lungs Heart attack Angina (heart pain)
Headaches	Stoke Migraine headache with neurological problems (blurred vision, spots, zigzag lines, weakness, difficulty speaking) New onset or worsening headache High blood pressure
Eye problems	Stroke Blurred vision, double vision, or loss of vision Migraine headache with neurological problems (blurred vision, spots, zigzag lines) Blood clots in the eyes Change in shape of cornea (e.g. contacts don't fit)
Severe leg pain	Inflammation and blood clots of a vein in the leg

2. Instruct client regarding management of missed pills: See recommendations for missed pills in the Selected Practices Recommendations for Contraceptive Use, 2016, page 28.
3. Data show conflicting reports related to the risk of venous thromboembolism (VTE) with transdermal patch use (See Reference 1). Regardless, the risk of

TITLE	DESCRIPTION
	VTE with patch use is still far below the risk of VTE during pregnancy. 4. The risk of blood clots may be higher in pills containing greater than 35mcg of estrogen (See Reference 2). 5. Educate client of clinical trials suggesting that transdermal patches may be less effective in women with body weight > 198 lbs. than in women with lower body weights. 6. Review safer sex education, if appropriate. 7. Counsel women 35 years of age and older that tobacco use is considered an absolute contraindication per the MT Family Planning Medical Standards Committee. Women 35 years and older that use tobacco are not eligible for CHC use. 8. Recommend to client to RTC annually, PRN for problems or as indicated per individual plan.
REFERRAL TO MEDICAL PROVIDER:	Any client with prescribing precautions in categories 3 or 4 for combined contraceptives (see current U.S. Medical Eligibility Criteria for Contraceptive Use).
REFERENCES:	1. *Hatcher RA, Trussell J, Nelson A, Cates W, Kowal D, Policar M. Contraceptive Technology. 20 edition. Atlanta GA: Ardent Media, Inc., 2015. Pp. 249-369.* 2. *Centers for Disease Control and Prevention. US Medical Eligibility Criteria for Contraceptive Use. MMWR 2016;65(3):55-80. (www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm). (Retrieved 1/30/2017).* 3. *Centers for Disease Control and Prevention. U.S. Selected Practice Recommendations for Contraceptive Use, 2016, MMWR Vol. 65. No. 4.* 4. *Greziottin A, The shorter, the better: A review of the evidence for a shorter contraceptive hormone-free interval.Eur J Contracept Report Health Care. 2016;21(2): 93-105.* 5. *Sulak PJ, Continuous oral contraception: changing times. Best Practice & Research Clinical Obstetrics & Gynaecology 2008 Apr; 22(2):355-74.* 6. *Willis SA, Kuehl TJ, Spiekerman AM, Sulak PJ. Greater inhibition of the pituitary-ovarian axis in oral contraceptive regimens with a shortened hormone-free interval. Contraception, 2006 Aug:74(2):100-3.*

Questions

- Was it a good idea for this protocol to include all combined hormonal contraceptives or would you have written 3 separate protocols (i.e., for oral contraception, patch, vaginal ring)?
- Is it protocol up-to-date?
- What is its value as a “template protocol”?
- Is there enough detail regarding scope of care that can be provided by each category of health professionals?
- Is there enough detail regarding client referral, consults, and transfers?
- Are there objective criteria by which clinicians can be evaluated and audited for quality of care provided?

Questions

- Is the protocol derived from, and consistent with, current national clinical practice guidelines?
- Is it consistent with the standards, guidelines, and policies of contracted payers?
- Is there information on how to update the protocol on a regular schedule?

3.0 COMBINED HORMONAL CONTRACEPTIVES

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TITLE	DESCRIPTION
Agree?	5. Client can start the CHC anytime if the provider is reasonably sure she is not pregnant. 6. Discuss the benefits of shortening the hormone-free interval from 7 days to 3-4 days. 7. Instruct the client her cycle will be 25 days instead of 28 days. 8. Advise back-up method per information in the current Selected Practices Recommendations for Contraceptive Use. 9. Postpartum client wanting to start CHCs: a. Category 4: <21 days status post vaginal delivery. b. Category 3: 21 to 42 days status post vaginal delivery with other risk factors for VTE (such as ≥35 years or age, previous VTE, thrombophilia, immobility, transfusion at delivery, BMI ≥30, postpartum hemorrhage, post-cesarean delivery, preeclampsia, or smoking). c. Category 2: 21 to 42 days status post vaginal delivery without risk factors for VTE. d. Category 1: >42 days status post vaginal delivery.
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EDUCATION:

Necessary?

Agree?

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Necessary?

Agree?

Who?

Agree?

Additional QI Activities

Quality Improvement Committee

Peer Review Committee

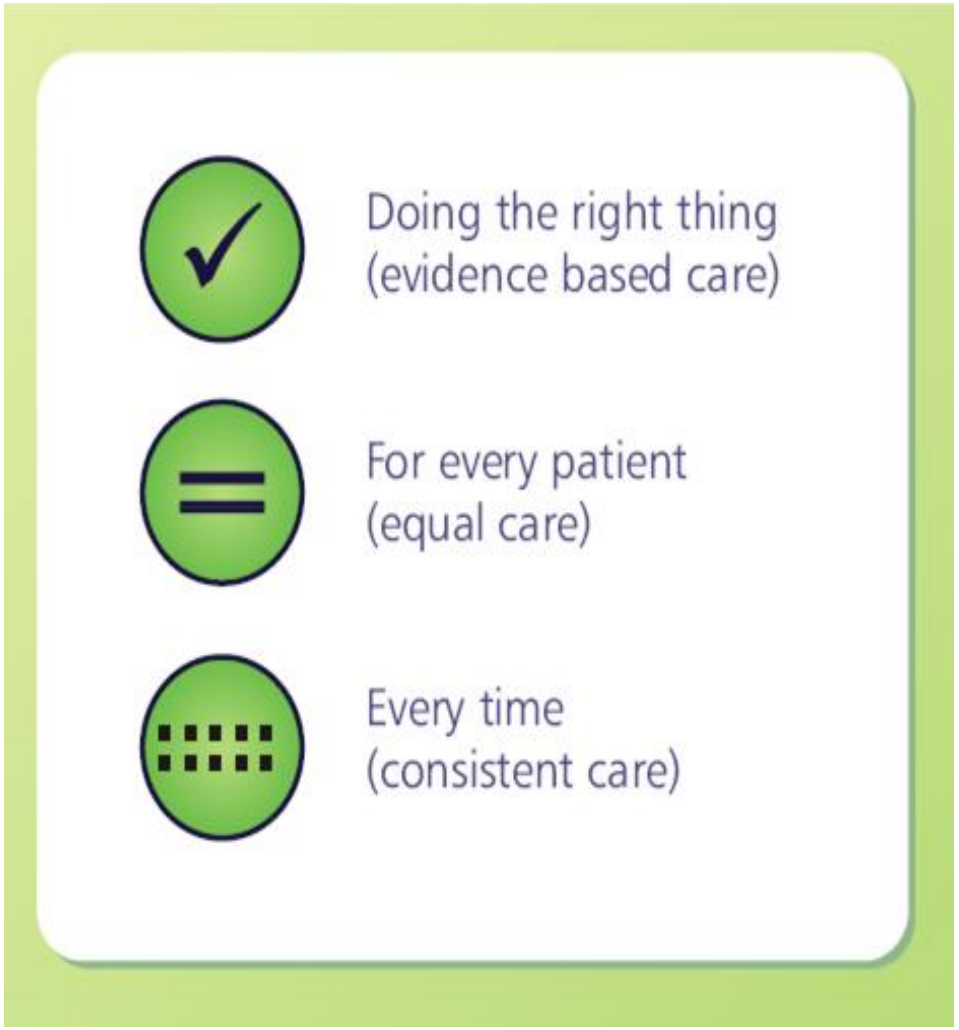
Morbidity and Mortality Conferences

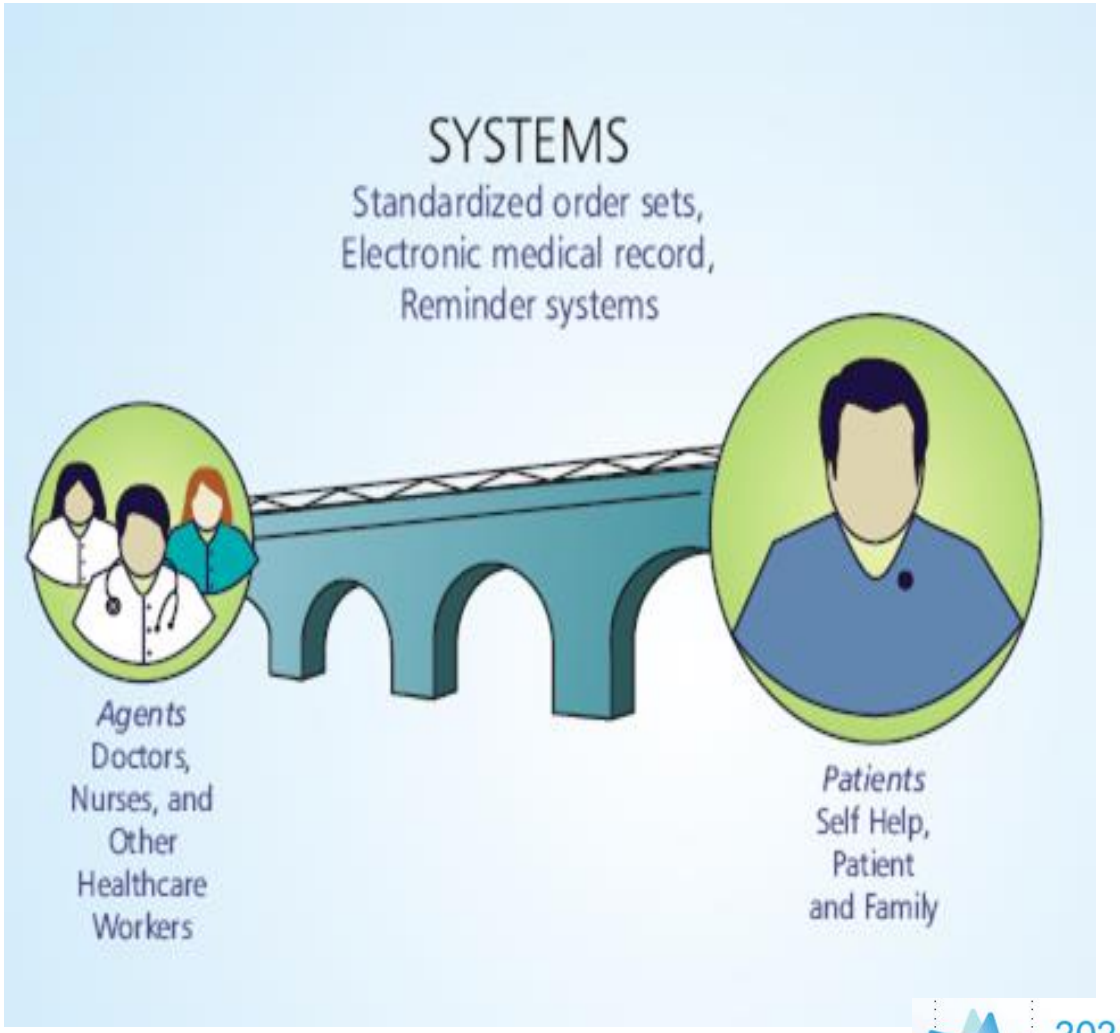
Focus studies

Clinical staff credentials and privileges

(Clinical) Care pathways

Goals of Quality Improvement





Transformation to a CULTURE of Quality

Variations → Uniformity

Paper records → Electronic Medical Records

System

A focus on quality will lead to a change in our culture just as patient's rights and confidentiality have changed our practice with informed consent and new regulations.

In a quality culture, systems are designed to reduce unwarranted variations, yet they permit clinically necessary and patient-desired variations. For example, systems using information technology such as electronic medical records can help in bringing about changes and reducing variation.

Financial Focus → Quality Focus

Restricted → Transparent

Administration

Autocratic → Team

Practice focus → Patient centered

Doctors

In a quality culture, administrators increase their focus on quality. Transparency of all quality data is the rule rather than the exception. For example, at hospital administrators' meetings, reports on quality need to be given at least the same amount of time and attention as the census or the financial report. Also, quality data should be shared between departments and among facilities.

In a quality culture, doctors take teamwork seriously. Team decision-making lessens the burden and shares the responsibility of complex and critically ill patients. For example, multi-disciplinary team rounds in the ICU lead to significant improvement in quality.

Quality improvement creates patient-centered care. Quality improvement is the right thing to do.

Case Study #1

- Your clinic has decided to “expand our business line” by offering hormone therapy for transgender individuals
- Two clinicians (one NP, one MD) are interested in providing this service
- **Questions:**
  - **What steps are necessary to add new privileges?**
  - **How can competence be demonstrated?**

Goals and Objectives of Credentialing

- **“Protect our patients” from unqualified clinicians**
  - The “family member” test
  - The “60 Minutes” test
- **Objectives:**
  - Consistently applied
  - Fair
  - Non-bureaucratic
  - Meets requirements of state and accreditors
  - Legal protection of patients and health systems

The End Point of Credentialing

“Permission from the health care organization’s *Board of Directors* for the member to diagnose and treat patients in the organization’s facility or under the auspices of the organization.”

Medical Staff 101: Definitions

- **Credentialing (Appointment)**
  - Granting of citizenship on the medical staff
  - Assignment of a MS category and department
- **Privileges**
  - Permission to provide general or specific services by an individual member of the medical staff
- **Proctoring**
  - Observation of the actual practice of a clinician in determination of privileges

Additional Privileges: New Procedure

- **Request to add new procedure addressed to Medical Director and/or Board of Directors**
  - Criteria set for training and supervision is developed
  - Clinical protocol developed
- **First clinician privileged may need “external” proctor**
  - Can serve as proctor for subsequent cases

Case Study #2

- Several complaints have been lodged by nurses that a clinician has had several bad outcomes in implant removals
- She is a very senior clinician who has been with the agency for 20 years and supervises other clinicians
- The clinician is known to have worsening spinal stenosis and is using 24/7 fentanyl patches
- **Question:**
  - **What should be done to evaluate the clinician's "fitness for duty"**

Peer Review Committee

- **Clinician behavior can be evaluated and judged only by other similar clinicians**
- **Meetings confidential; protected by Section 1157**
- **Complaints/concerns about**
  - Clinical practices or patterns of practice
  - Interactions with patients (abuse, neglect)
  - Interactions with staff (abuse, harassment)
  - Malpractice, criminal, or licensing issues

Peer Review Committee

- **Can "peers" in the same system really judge each other?**
  - Conflicts of interest are almost impossible to avoid (e.g., she's my partner, needed for call)
  - May require "outside" reviewer(s) for impartial review
- **Interventions:**
  - Additional CME, privilege restrictions, suspension
  - Fitness for duty evaluation
  - Appeal rights detailed in agency policies

Case Study #3

- At a colposcopy visit, a clinician realizes that he has placed trichloroacetic acid (TCA) 80% into the vagina instead of vinegar
- He notified the supervising nurse practitioner immediately
- The patient has no complaints at this time
- **Question:**
  - **What should be done next?**

Areas of Concern

- Patient safety
- Medication management
- Medication error – although no harm reported
- Education of team in charge of discharge

Incident Reporting

- All healthcare organizations must have a mechanism to report errors or near misses
- Usually there is an easy and reliable way to report an incident
- An incident report is not a tattle tale move!
- Incident reports can help provide information to conduct root cause analysis

What Happens After You Report?

- Oversight and review
- Root cause analysis to find system errors
- Identify problems and then problem solve
- Involve the team
- Educate providers and ancillary staff on new system to reduce errors in the future
- Possibly create a best practice

More Reporting Leads to More Improvement

- **Less reporting leads to “burying” errors**
- **Errors happen – it is how you handle them that will impact future care**

How Will It Affect Credentialing?

- Sentinel events and incident reporting are different
- Acuity and regulatory agencies will define a sentinel (or adverse) event
- The Credentialing Committee determines which incidents will be considered in the credentialing process
- Usually near misses are not considered (but these incidents uncover system failures)

Case Study #4

- Upon review of clinic quality indicators, the rate of incident reports for colposcopy procedures doubled
- **Questions:**
  - **What else do to want to know in order to decide what the next step should be?**
  - **If the decision was made to explore this in more depth, how would you go about doing it?**
  - **What are the "standard" steps necessary to fix it?**

Continuous Quality Improvement (CQI)

PDSA :
"Plan, Do, Study, Act"

Sigma Six: (DMAIC)

- Define
- Measure
- Analyze
- Improve
- Control

Continuous Quality Improvement (CQI)

- **Plan:** Set objectives; plan the new process
- **Do:** Implement the new process
- **Check (Study):** Monitor and evaluate the processes and results against objectives
- **Act:** Modify the process to improve it before its next implementation

Continuous Quality Improvement (CQI)

- Rather than enter "analysis paralysis" to get it perfect the first time, **it is better to be approximately right than exactly wrong**
- Apply in repetitive upward spirals that converge on the ultimate goal

Note the “circle” – the cycle is repeated for CQI

Wheels in Motion:
Continuous Quality Improvement

Quality Improvements of the Future

- Industrial strength QI principles in health care
- Electronic health records (EHRs) and computerized physician order entry (CPOE) as QI tools
- Standardized (but tailored) order sets
- Real time prompts for missing, dangerous entries
- Integrated evidence based clinical practice guidelines
- Proliferation of decision analysis tools
- Expect more pay for performance
- Expect more (and better) report cards
- (Hope for) more evidence-based practice guidelines

2024 NFPRHA NATIONAL CONFERENCE

WASHINGTON, DC
MAY 19-22

GROUP DISCUSSION & Q & A

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