Policies, Procedures and Clinical Protocols Toolkit

A Toolkit for Developing and Maintaining Policies, Procedures, and Clinical Protocols for Sexual and Reproductive Health Clinicians and Managers

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Overview

This toolkit is intended to be a resource for administrators, quality managers, and clinicians for developing and maintaining **policies, procedures, and clinical protocols** for the provision of sexual and reproductive health within a health care system. While this toolkit was developed for Title X clinic staff, it will be helpful for other health care systems that provide sexual and reproductive health care services.

The goal of the PPP Toolkit is to assist health care systems in adopting best practices, training clinical and non-clinical staff, and assessing quality of care provided by individual clinicians.

The toolkit does not have to be used sequentially and any topic can be accessed according to your needs and interests. Each section provides step-by-step guidance, followed by resources relevant to that section. Resources are hyperlinked to external websites and PDF files.

The use of **clinical protocols** allows health care providers to offer appropriate screening, diagnostic, management/treatment, health education, and referral services to clients, and high-quality, evidence-based training to clinical staff. Such protocols provide a locally agreed upon standard to which clinicians and the organization can work and against which they can be audited. The use of protocols may help to tackle other issues successfully, such as the reduction in clinical services providers' hours, and the facilitation of shared or team-based care. It may also bolster the medico-legal robustness of the health care delivered. If the protocols are sufficiently detailed, costing, coding, and other resource usage information can flow directly from the clinical records. Such benefits may be maximized by using **clinical protocols** within the framework of an electronic client record system.

Policies and procedures are closely related to **clinical protocols**. They also provide standardization, but for daily clinic operational activities. All three are essential in providing clarity when dealing with issues and activities that are critical to health, including client outcomes, safety, legal liabilities, and regulatory requirements.

Objectives

This toolkit will help you:

1. **Differentiate** between policies, procedures, protocols, standards, and guidelines.
2. **Describe** the development, maintenance, and implementation processes needed for effective and useable policies, procedures, and clinical protocols.
3. **Discuss** common problems and strategies for troubleshooting when developing policies, procedures, and clinical protocols.
4. **Identify** resources for developing, updating, and archiving policies, procedures, and clinical protocols.

Definitions

Before using this toolkit, familiarize yourself with definitions, descriptions, and other background information about the development and maintenance of **policies**, **procedures**, and **clinical protocols**. The following table provides definitions of frequently used terms in this toolkit.

Document	Definition/Description	Example(s)
Policy	An organizational policy is a statement of principles, rules, and guidelines that an organization follows 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.	• Dress code policy • Cell phone policy • Policy for discharge from clinic after an office procedure
Procedure	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. It details sequential steps to achieve a specific result, based on the policy.	Step-by-step procedures or instructions for entering data, managing cash, or expense reporting at the organization or health care system
Clinical Protocol	A clinical document which incorporates standards and guidelines to provide clear expectations and instructions about how medical care is provided to clients in an organization or health care system.	• Provision of combined hormonal contraceptive pills • Sexually transmitted infection screening • Pregnancy testing and options counseling
Standard	A standard establishes a basic level of quality (i.e., a floor). National standards are developed by expert panels and represent criteria against which individual and system performance can be measured.	Documenting a negative pregnancy test before extracting an intrauterine device with a missing string
Guideline	A guideline outlines best practices (i.e., operations that represent the most efficient or prudent course of action) for high quality care and denote a recommended, but not required, practice. A guideline should not be used as an indicator against which individual and system performance is measured, but can be seen as "value added" criteria.	Performing a pelvic ultrasound before extracting an IUD with a missing string
Health Care System	In this document, the term health care system refers to the entity which develops and uses	• Single family planning clinic

Document	Definition/Description	Example(s)
	policies, procedures, and clinical protocols (PPP). This includes: • A single clinic or practice site • An entity with multiple clinical sites • A single-specialty or multi-specialty medical group • An integrated delivery system that includes a multispecialty group and hospital(s)	• Planned Parenthood affiliate • Kaiser Permanente Medical Group

Overview of Policies and Procedures

These two documents– policies and procedures (P&P)– usually are combined in a single document.

A policy defines an objective or desired outcome, while the procedure describes the steps that are expected in carrying out the policy.

As an example, the **policy** states that your health care system will not charge clients at or below 100% of the federal poverty level (FPL) for family planning services. The **procedure** tells staff exactly how to determine whether a client is at 100% FPL, what documentation needs to be collected, which form(s) need to be completed, what data must be entered, and where it is stored.

All 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 information within it — is an ongoing effort. It must be reviewed periodically to ensure continued accuracy and applicability.

Beyond writing P&Ps, an organization must take additional steps to ensure that the guidance reflected in the documents is effectively implemented throughout the organization. Additionally, P&Ps should be retired and archived in a timely fashion to ensure staff have ready access to retired documents in the event of a regulatory or legal inquiry. All these activities combined make up a **P&P Maintenance Cycle**, which will be discussed later in this document.

P&Ps, as well as clinical protocols, take into consideration federal laws, state regulations, and industry best practices.

Importance of Policies and Procedures

Clarification

Clarifies roles and responsibilities. Enables the workforce to clearly understand individual and team responsibilities. Everyone is working from the same page! When effectively developed, implemented, and managed, it sends employees, at all levels, the message that administration cares about them and their success. Employees don't need to guess or bumble their way through a process; they know what to do and when to ask questions.

Guidance

Guides managers in health system operations so that their leadership and personnel oversight is provided objectively, consistently, and fairly.

Protection

Protects clients, staff, volunteers, and the health care system as a consequence of the application of clearly written, well thought out, and evidence-based instructions for clinic operation.

Improvement

Improves quality of care and helps create a successful risk management system. P&Ps provide objective criteria against which individual and system performance can be evaluated. When P&Ps are in existence and followed by staff members, the likelihood of a bad outcome or low patient satisfaction is reduced or eliminated.

Traits of an Effective Policy and Procedure System

Clearly written and standardized policies and procedures provide:

Clarity

Straightforward language that is easily understood helps avoid confusion. Beware of organization-specific jargon, which may not make sense to a new staff person. Consider the end-user when writing, to ensure that the final product is written to their level of understanding

Standardization

Establish a standardized format, including all the essential components that each document must have. In addition, standardize where and how P&Ps are organized.

End-user involvement

It's critical to involve the end-user during the drafting and revision process of P&Ps as a means of achieving universal buy-in.

Dedication to implementation and monitoring

Make sure staff training on the documents is scheduled, completed, consistent, documented, and that there is an opportunity for staff to ask questions and receive answers. To ensure adherence, check in with staff, conduct on-site visits, audit regularly, retrain as needed, and clarify the ramifications of non-compliance. Ensure that all staff sign off on each P&P to document that they've received training.

Consistent reviewing and updating

This process is an ongoing cycle, not a one-time activity. Make sure that there is a review cycle built in with dates to review documents regularly, and consider the need for off-cycle additions. Have a defined process for storage, retention, retrieval, archiving, and destruction.

Relevance

The management team of the organization is responsible for ensuring that a P&P exists for all of the major, and most of the minor, operational issues that employees need to know about. In addition, there are external influences on health care system operations that must be accounted for in the policies and procedures. These include P&Ps required by state or federal law (for example, non-discrimination laws that apply to employees and clients and physical accommodations required by the Americans with Disabilities Act).

Impact of Well-Developed Policies and Procedures

Employee Impact

- Improves confidence, consistency, accuracy, and employee satisfaction.
- P&Ps establish predefined limits:
    - Employees know what is expected and can feel more confident in their ability to be successful in their job.
    - Avoids extra work.
- If staff members feel well versed and fully trained, have ready access to information, and know where to go for questions:
    - Employee frustrations are minimized.

- Overall satisfaction is improved.

Manager Impact

- Provides a guide for decision making, diminishes the need for micro-managing, and allows management by exception. This minimizes the need for constant supervision so that managers spend more time supporting staff.
- Since managers also are employees, the same principles apply— clarity in what is expected leads to improved performance and overall job and professional satisfaction.
- Having expectations and limits established, managers can confidently guide their employees, letting employees do their jobs and managers do their jobs better.

Organizational Impact

- Improves overall effectiveness and efficiency, protects reputation and brand, and provides legal protection, which in turn minimizes potential legal liability.
- Clearly written policies and procedures, if followed, make errors less likely. If outsiders can understand what is written, the organization has better legal footing if challenged in court.
- When everyone is working from the same "official" information, employees know what they are supposed to be doing and are better able to do the job, with few or no errors.
- Individual and team responsibilities are made clear, saving time and resources.
- Sends the message that we want employees to be successful, resulting in better job satisfaction, and consequently, a high level of employee retention.

Developing Individual Policies and Procedures

Elements to Include in a P&P

Using a consistent format across organizational P&Ps increases the ease of use for the end user. It also ensures that newly drafted P&Ps include all necessary sections.

- Purpose of the document
- Policy statement to support rationale for document
- Background, if applicable
- References related to:
  - P&P and protocols
  - Tools, resources, forms, etc.
- Citations to legal, regulatory, and professional references
- Header or footer with
  - Organization name
  - Title of document
  - Tracking number or identification (ID) (a combination of numbers and/or letters that uniquely identifies this particular policy and procedure)
  - Date of implementation
  - Date of revision
  - Date of next scheduled review
  - Page number within each policy

This PDF from NFPRHA's development guide is a great starting point. That resource and more can be found on the interactive, accessible, online version of this document (Policies, Procedures, and Clinical Protocols Toolkit).

Creating and Maintaining a P&P Manual

Best Practice #1

Create a standard template for a P&P Manual that includes the following elements to ensure consistency:

- Title page indicating:
  - Type of manual
  - Purpose of the manual
  - Date of initial publication
  - Date of revisions
  - Date of next review
  - Timeframe for approved use
- Table of contents, including title of each section and the P&Ps included within
- The name, title, date, and signature of the individual providing final approval for use
- Credit to the authors, including names and titles
- Each current policy or procedure

Best Practice #2

Format the manual to allow for updating of individual pages, individual documents, and entire sections. For example, format page numbers so that individual documents can be removed or revised without having to renumber pages in the entire document.

Best Practice #3

Create a numerical tracking system to improve the manual's ease of use. For example, file financial policies in Section 100, clinical policies in Section 200, etc. Give each document in the section a corresponding reference number (e.g., 100-001 Income Determination Policy, 100-002 Schedule of Discounts Policy, etc.)

Best Practice #4

Consider providing staff with the organization's P&P manual solely in an electronic format. Doing so ensures that staff always refer to the current version. If paper copies of a P&P manual remain in use, designate a staff person to archive old copies and distribute new copies each time a change occurs.

Best Practice #5

If the manual is used in an electronic format, create hyperlinks in the table of contents to send users directly to the referenced document within the manual. Note that confirming hyperlinks to correct pages will be important when changes are made to the document.

The P&P Maintenance Cycle

Best Practice #1

Create a P&P Maintenance Cycle based on the following steps:

1. Write or update the P&P

- Write a new P&P or update an existing P&P to reflect any changes to recommendations included in the document or based on the P&P review process
- Write to the level of detail for clear understanding for the end user
- Get approval from the final authority before implementation

2. Implement changes to the P&P

- Replace and archive outdated policies in printed and electronic P&P manuals
- Create or update and distribute/implement supplementary materials [e.g., forms, documentation, electronic health record (EHR) templates]

- Create a written summary of the P&P change and disseminate to all affected staff

3. Train staff on the P&P

- Refer staff to P&P changes and answer any questions
- Assess staff understanding during and after the training or in-service
- Create a training documentation system to track when and to whom training on P&Ps was provided. Document training in your training documentation system, including:
    - Date of training
    - Specific P&Ps covered by the training
    - How training was provided
    - Who conducted the training
    - Individual staff acknowledgement of receipt of training
- Create a recognition system for staff who will need to adopt and adhere to new P&Ps

4. Archive the old P&P

- Create an electronic repository to store P&Ps that are no longer in effect
- Move outdated P&Ps and related documents to the P&P archive. Related documents include:
    - Title pages, referenced materials, authorizing signature page, training materials, training documentation, memos, audit reports
- Add a discontinued date to indicate when the document is retired
- Seek legal advice to clarify how long P&Ps should be retained and when it is acceptable to destroy archived documents

5. Monitor adherence to P&P

- Set dates and times for formal check-ins with applicable supervisors on staff implementation and adherence to the new P&P
- Conduct formal reviews and audits to assess ongoing compliance
- Use audit results to identify problem areas, P&Ps that require additional detail, and retraining needs

6. Review need for P&P updates

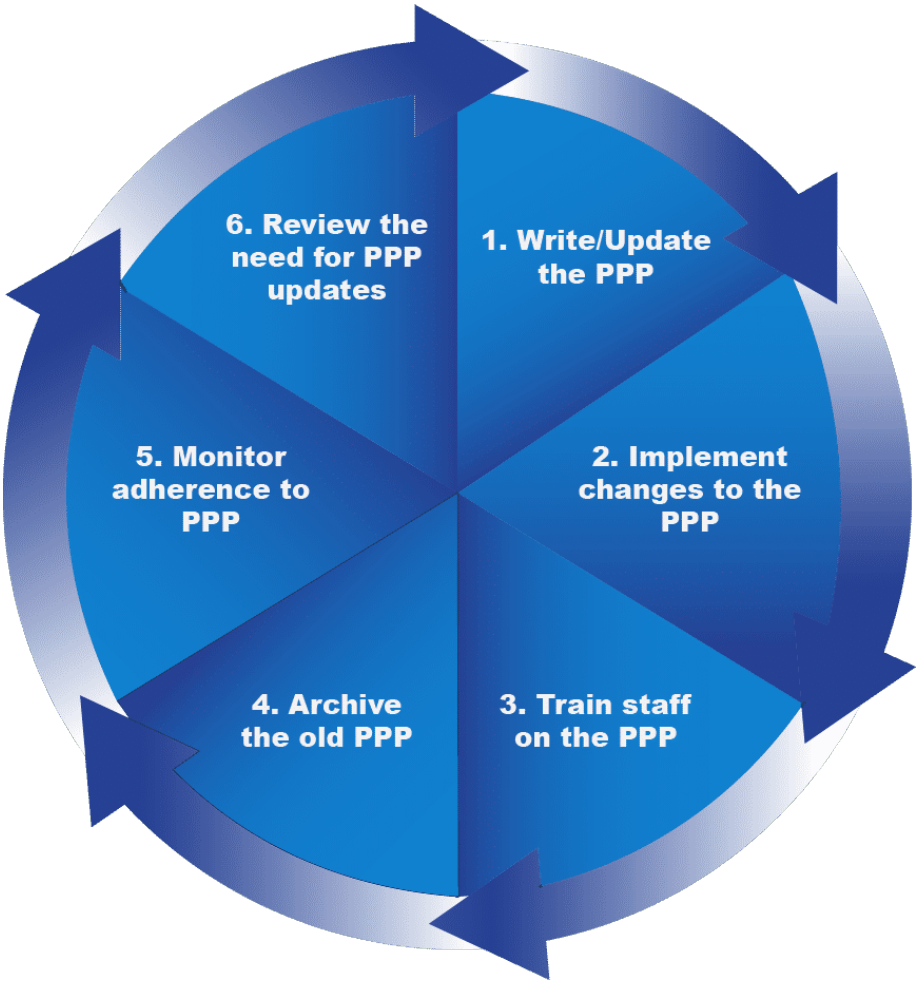
- Review P&Ps at least annually or whenever there are changes needed based on:
    - Federal/state/local regulation changes
    - New clinical guidance
    - Staff feedback
    - Patient feedback
- Make recommendations for P&P updates
- Involve collaborators and partners throughout review process
- Establish a process to elicit staff questions and feedback on P&Ps

P&P Maintenance Cycle Best Practice #2

Identify the staff members responsible for each step of the P&P Maintenance Cycle, including who has the final authority to approve implementation of new or updated policies.

P&P Maintenance Cycle Best Practice #3

Develop a written procedure for each step of the P&P Maintenance Cycle and include these documents in the appropriate P&P Manual within the organization.



The above is a representation of the maintenance cycle for organizations' PPP internal documents. It is in a blue circle to represent its cyclical nature. The steps are:

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

And then the cycle begins again at the first point, Write/Update the PPP.

The maintenance activities for an organization's PPP (Policy, Procedure, and Protocol) internal documents are represented by a continuous cycle because the job is never over!

Reproductive Healthcare Examples

NFPRHA has developed documents with samples of the P&P process in reproductive health care. Resources can be found on the interactive, accessible, online version of this document (Policies, Procedures, and Clinical Protocols Toolkit).

Triggers for "Off-Cycle" Updating Policies and Procedures

- Some critical signs that a particular P&P needs to be reviewed and updated include:
- An increase in the number of accidents or 'near misses'
- More staff questions on what "normal operations" should be
- A feeling of general confusion within a department or division

- An increase in the number of employees who demonstrate inconsistency in their job performance
- An increase in workforce's stress levels
- More complaints from customers

Overview of Clinical Protocols

Origins of Clinical Protocols

The origin of the use of clinical protocols for reproductive health care services occurred in the 1970s with the advent of registered nurses being trained and practicing as nurse practitioners (NPs).

In these early days, most states required the use of written clinical protocols by NPs in addition to varying degrees of supervision by physicians. The scope of practice permitted of NPs and other practice requirements were developed by state nursing licensing boards, sometimes with input from the state medical board. Conversely, most states did not require the use of clinical protocols by certified nurse midwifes (CNMs). Over the ensuing decades, most states have loosened the requirements for NP practice, including the adoption of independent NP practice and billing policies.

A Playbook for Clinicians

A helpful way to think about a collection of clinical protocols is as a "playbook" for all of the clinicians in your health system, written by the very clinicians who practice there. Well written clinical protocols indicate to newly hired clinicians the approach to care that is unique to this particular health system and the health system's expectations of how all the clinicians in the system will provide care to clients. In addition, they are valuable to clinicians who have practiced in the system for years, or even decades, since they should be frequently updated to include new developments in care, based on the periodic modifications to national practice guidelines. Clinical protocols provide a foundation to ensure clinical care is rooted in the most up to date practices.

Why is Standardization Important?

The rationale for clinical protocols and checklists has evolved since the 1970s, with the objective of standardizing care provided by all clinicians, including physicians, to maximize evidence-based clinical practice and to minimize variation in care within a health system. Standardization is an important goal because of the wide variation in clinical practice that exists within a health system, as well as variations in the geographic location of the health system. There are two types of clinical variation:

- **Necessary variation** is dictated by individual client factors, such as their medical history or age or body parts, and the client's goals for care.
- **Unexplained variation**, which usually arises from differences in the training and practice styles of individual clinicians. This type of variation is problematic because it may lead to increased rates of error.

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

"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, Obstetrics and Gynecology 2019; 134: e122-125)

Developing Clinical Protocols

You may be reading this document because of your concern regarding the status of the clinical protocols in your own health care system. Experienced providers of site-visit reviews (i.e., surveyors, auditors) have identified several potential problems related to clinical protocols:

1. an incomplete set of protocols relative to the range of services provided,
2. protocols that are out-of-date,
3. protocols that have little or no focus on internal processes and referrals,
4. protocols that are entirely "cut-and-paste" from national guidelines,
5. and those that are borrowed intact from another health care system but have not been adapted to this particular system.

Before describing what high quality clinical protocols should be, here is a listing of what they are not:

- Boiler plate content borrowed from a different health care system, but not adapted to constitute the policies of a specific health care system
- A "cut-and-paste" collection of the contents of a medical textbook or national guidelines
- A "cookbook" (rigid directions for how to provide care) for clinicians to direct and simplify the provision of healthcare
- Standing orders for Registered Nurses (RNs) (these should be included in a document that is separate from a clinical protocol)

Clinical protocols provide the clinicians in a health care system with the necessary tools for the provision of up-to-date and consistently high-quality care. The draft clinical protocol should be written by, or developed under the supervision of, the Medical or Clinical Director* (physician, physician assistant, nurse practitioner, certified nurse midwife, or expanded scope registered nurse) of the health care system. Following this, it's critical that the draft protocol is reviewed by clinical staff members who will be subject to the protocol, including integration of suggested modifications and edits. Next, draft protocols should be reviewed and approved by the health care system Medical Advisory Committee if there is one.

(**Title X recipients must**: Provide that family planning medical services will be performed under the direction of a clinical services provider (CSP)*. The CSP's direction must be within their scope of practice and allowable under State law, and with special training or experience in family planning. CSPs include physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health, and basic infertility care. (42 CFR § 59.5(b)(6) and 42 CFR § 59.2))

Components

When developing and implementing clinical protocols, several factors must be considered and integrated into each protocol. Each clinical protocol should contain:

1. Policies regarding the **scope of care** that can be provided by each category of health professional, consistent with state regulations, including
   - Advanced practice clinicians: nurse practitioners, certified nurse midwives and physician assistants
   - Physicians: MDs and DO, sometimes with specialty-specific guidance
   - Nurses: RN, LVN/LPN, and public health nurses (PHNs)
   - Health educators, counselors
   - Medical assistants (MAs)
2. Policies for **client referral**, **consults**, **and transfers**

- Where to send clients for consultations, transfers, or referrals based on contracts or memoranda of understanding (MOUs)
- How to initiate consultations, referrals or transfers (e-referral, written requests, or phone call)
- How quickly the consultation, transfer, or referral visit should occur (emergent, urgent, or routine) and when staff or follow-up team should check with the patient to see if the consultation, referral, or transfer visit occurred and the outcome

3. Guidance derived from, and consistent with, **current national clinical practice guidelines**, including
   - The US Preventive Services Task Force (USPSTF)
   - Centers for Disease Control (CDC): contraceptive, STI, pre-pregnancy guidelines
   - The American College of Obstetricians and Gynecologists (ACOG)
   - American Cancer Society (breast and cervical cancer screening guidelines)
   - American Society for Colposcopy and Cervical Pathology (ASCCP) (cervical cancer screening techniques and management of abnormal results)
   - American Society of Reproductive Medicine (ASRM; management of infertility)
4. Guidance consistent with the standards, guidelines, and policies of **governmental payers**
   - State Medicaid program
   - State family planning department or program
   - Office of Population Affairs (OPA) policies for Title X grantees, sub-grantees, and service sites
5. Clinical policies or guidance based upon contracts between **commercial health plans** and the health system (if contracted)
6. The **objective criteria** by which clinicians will be evaluated and audited for quality of care provided to clients (based on the "must" items in the protocol)
   - Ideally, at least semi-annually for new clinicians and annually for established clinicians
   - By medical director, QI director, or a clinician colleague (not by self-audits)
   - Separately from "focused" quality improvement (PDSA) audits
7. Reference to how often the protocol will be **updated**
   - Annually or every-other-year, depending on the topic
   - Often on a rotating schedule
   - As needed, based on the issuance of updated national guidelines or payer policies

Evidence-Based National Guidelines

The evidence-based national guidelines that should be the core of local protocols is the "suite" of Centers for Disease Control family planning and sexually transmitted infection guidelines, including:

- U.S. Medical Eligibility Criteria for Contraceptive Use (US-MEC; 2016)
- U.S. Selected Practice Recommendations for Contraceptive Use (US-SPR, 2016)
- Sexually Transmitted Infections Treatment Guidelines, 2021
- Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings
- Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update—A Clinical Practice Guideline: Use of pre-exposure prophylaxis (PrEP) to reduce the risk of acquiring HIV infection in adults and adolescents
- Recommendations to Improve Preconception Health and Health Care— United States (2006)

Be sure to adapt the content and recommendations from any national guideline that is used in the local protocol to the resources that are available in your health care system.

Quality Family Planning Guidance

In addition to the guidelines listed above, Title X grantees and sub-grantees are expected to adhere to the guidance contained in the "QFP," Providing Quality Family Planning Services: Recommendations of the CDC

and the U.S. Office of Population Affairs (MMWR April 25, 2014; 63(RR04);1-29). The QFP complements existing guidelines in two ways:

1. It integrates national existing guidelines that are appropriate for use in the family planning, sexual and reproductive health setting, including the suite of CDC family planning and genital tract infection guidelines.
2. It fills gaps in the CDC suite of guidelines.

For example, QFP provides recommendations about contraceptive counseling, and shows how this can be integrated with MEC and SPR. QFP also describes how to work with clients who produce sperm about pregnancy prevention, and how to address the special needs of adolescent clients. Other areas in which QFP makes unique contributions are in defining the range of services that should be offered in a family planning setting, emphasizing the role of helping clients achieve as well as prevent pregnancy, describing how to provide pregnancy testing and counseling services, and highlighting the role that quality improvement can play in improving health outcomes.

Which subjects/titles should be included in your collection of clinical protocols? The answer is "any unique clinical service" that the health care system offers. A list of potential topics is included in the Samples and Templates: Policies, Procedures, and Clinical Protocols section, with the understanding that your system may not be offering every service on the list, and conversely, that you may be offering unique services that are not listed.

Using Template Protocols

Several national family planning organizations, including National Family Planning and Reproductive Health Association (NFPRHA), the Reproductive Health National Training Center (RHNTC), the Clinical Training Center for Sexual and Reproductive Health (CTC-SRH), and others have developed "template" family planning and STI protocols to serve as a "**starting point**" for creating local protocols.

Each template protocol is written with the understanding that several decision points must be addressed by the health care system before the local protocol is ready for use. When an organization decides to use a template protocol, the author is expected to **tailor the contents** to their own health care system and to create a draft local protocol. It is recommended that, before organization-wide implementation, a draft of the revised template be reviewed by clinicians to allow them to weigh in on accuracy, completeness, and usability.

Features common to template protocols include:

- Decision points are highlighted in the template protocol. The writer includes only the option that reflects the individual organization's current practices or planned practices.
- Current practices or procedures that are not listed as an option, but are intended to be retained, should be inserted into the draft local protocol .
- When formatting the draft local protocol, options that do not apply should be deleted.
- 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. This serves as a "reality test" of whether the draft accurately reflects what currently is practiced within the organization and gives clinicians an opportunity to provide feedback regarding new content. Clinicians will have a sense of "buy-in" to the new protocol once implemented.
- Local practice conditions should be considered when these tools are introduced in the institution/organization.
- It is important that clinicians are informed whenever clinical protocols are to be initiated.

Resources

Oregon Health Authority; Reproductive and Sexual Health Provider Resources

Updating and Archiving Clinical Protocols

The process for updating and archiving clinical protocols is identical to the process described for Policies and Procedures.

Some aspects that are unique to updating and archiving clinical protocols include:

- Prompt (off-cycle) integration of the modifications **in updated benchmark national clinical practice guidelines**.
  - For example, the CDC publishes updated sexually transmitted infection treatment guidelines every few years based on newly published studies and expert panel consensus.
  - Typically, these modifications are **critical** for correct clinical management of clients, and consequently, local protocols must be modified to include these changes. Once the modifications in the local protocol are completed, clinical staff must go through an in-service training process.
- Occasionally, a new national guideline will be published on **a topic that should be integrated into existing protocols** or **a new protocol must be developed**.
  - An example is "Consensus Guidelines for Facilities Performing Outpatient Procedures" (including IUDs, implants, colposcopy, etc.), which was developed and/or endorsed by fifteen reproductive health organizations. It can be found at:

Levy BS, Ness DL, Weinberger SE. Consensus Guidelines for Facilities Performing Outpatient Procedures: Evidence Over Ideology. Obstet Gynecol 2019 Feb;133(2):255-260.

Implementing Clinical Protocols for New Clinical Services

From time to time, a health care system will decide to add a new clinical service, based on client needs or to take advantage of an opportunity to provide a service that is not available elsewhere in the community. In addition to the training and proctoring of clinician(s) who will provide the service to clients**, a new clinical protocol must be developed and approved before service provision commences**. If a template protocol is available for the service, it is an excellent starting point for the development of a local protocol. If one is not available, it may be possible to start with an existing protocol from another health system and then **adapt** it to your system.

An example is a health care system that decides to offer clinical services relating to gender affirming care. Other than locating clinicians who can competently provide these services, a necessary step is to decide upon the specific services that will be offered to clients; for example, counseling, hormone therapy, referral for gender affirming surgery, etc. In many situations, a companion P&P should be developed on the same topic that directs both clinical and non-clinical staff on issues such as patient confidentiality, health insurance coverage of transgender services, coding and billing for transgender services, etc. Note that this is an ideal opportunity to cross reference the non-clinical issues contained in the P&P with the clinical topics included in the protocol.

Step 1: Health Care System Decides to Offer New Service

Examples: Gender affirming services or permanent contraception (e.g., vasectomy)

Step 2: Decide on Specific Services

Other than locating clinicians who can competently provide these services (or providing training clinicians currently in the system), a necessary step is to decide upon the specific services that will be offered to clients. For the gender affirming care example, this might include counseling, hormone therapy, and referral for gender affirming surgery. For the vasectomy services example, this might include counseling, informed consent, pre-procedure care, performance of the sterilization procedure, and post-procedure care; conversely, it might

include counseling and obtaining informed consent, and referral to an external provider for pre-procedure care, the procedure, and post-procedure care.

Step 3: Develop a Companion P&P

In most situations, a companion P&P should be developed on the same topic that directs both clinical and non-clinical staff on issues such as staff roles and responsibilities, clinic work flows, patient confidentiality, informed consent requirements, health insurance coverage of transgender or sterilization services, and coding and billing for transgender or sterilization services.

Addressing Potential Problems with Clinical Protocols

This video provides viewers with recommendations for updating and improving clinical protocols. It presents a comprehensive critique of an existing protocol by Michael Policar, MD, MPH, by answering the following questions:

1. Was it a good idea for this protocol to include all combined hormonal contraceptives or would you have written three separate protocols (i.e., oral contraceptives, patch, vaginal ring)?
2. Is it up-to-date?
3. What is it's value as a 'template protocol' (i.e, can the format/structure be used to construct additional similar protocols?)
4. Is there enough detail regarding scope of care that can be provided by each category of health professional (e.g., registered nurse, advanced practice registered nurse)?
5. Is there enough detail regarding client referral, consultations, and transfers?
6. Are there objective criteria by which clinicians can be evaluated and audited for quality of care provided?

Samples and Templates: Policies and Procedures

This section includes samples or templates of policies and procedures from NFPRHA and RHNTC for you to use as you create or update your own policies and procedures. They can be found on the interactive, accessible, online version of this document (Policies, Procedures, and Clinical Protocols Toolkit).

Link to complete set of RHNTC template policies and procedures.