

Clinical Manual Committee

- 16 Mid-level providers and RNs volunteered to be committee members
- Met monthly July through October 2014 to review proposed changes and offer input
- Manual sections were edited and formatted by Lynda Saignaphone
- Sent to Stephanie Teal 11/12/2014 for review
- Put in page turning software by Kristina Green

Thank You Committee Members!

□ Brandy Mitchell	□ Melanie Reece
□ Deb Bell	□ Nettie Underwood
□ Kathy Brown	□ Pat Sullivan
□ Jane Heins	□ Stacy Herrera
□ Jane Lose	□ Susan Keithley
□ Terri Yelle	□ LiAnn Pemington
□ Lauren Mitchell	□ Molly Lee
□ Linda Johnson	□ Carmen Mora

Providing Quality Family Planning Services - QFP

- Briefly review QFP
- Overview of what's new in clinical manual
- Organization of manual
- Overview of sections – particularly health care services and contraceptive services
- Implementation

Providing Quality Family Planning Services

- Clinical Manual is based of the QFP
- The QFP encourages using a client centered approach to providing services.
- A client centered approach includes respecting the client's primary purpose for their visit;
- Providing confidential services;
- Offering a broad range of contraceptive methods; and

Providing Quality Family Planning Services

- Delivering services in a culturally competent manner to meet the need of all clients
- Including adolescents,
- Those with limited English proficiency,
- Racial and ethnic minorities,
- Those with disabilities and
- LGBTQ individuals

Providing Quality Family Planning Services

- Developed to:
 - Assure clients receive the care they need, while
 - Avoid unnecessary screening, and
 - Remove medical barriers as prerequisites for providing contraceptive services



Definition of Quality Family Planning Service Delivery

- **Safety** - use of US MEC and USPSTF recommendations
- **Effectiveness** - full range of FDA approved methods
- **Client centered approach**
- **Timeliness** - services provided in a timely manner
- **Efficiency** - focus on core services
- **Accessibility** - remove barriers to contraceptive use
- **Equity** - for all including teens, LGBTQ persons, racial and ethnic minorities, LEP, persons with disabilities
- **Value** - cost effective



Related Preventative Services

- Include breast and cervical cancer screening
- Services considered beneficial to reproductive health
- But do not contribute to achieving or preventing pregnancy
- Family planning service providers must be trained and equipped to offer all family planning and related preventative health services
- Refer for specialty care

Other Preventative Health Services

- Examples: screening for lipid disorders, skin cancer, colorectal cancer, or osteoporosis
- Should be available on site or by referral
- These services are not addressed in the QFP
- Refer to U.S. Preventative Services Taskforce for screening recommendations

What's New

- Clinical manual is arranged to mirror the QFP
- Providers are directed to source recommendations and guidelines instead of rewriting much of the material
- No longer divided in to Part 1 Policy and Part 2 Protocol
- One signature sheet for clinical
- Healthcare Services Section revisions
- Reversible contraceptive methods are listed by Tiers of effectiveness, starting with LARCs
 - Combined methods are group together

What's New

- New sections – same information
 - Introduction to contraceptive services
 - Achieving Pregnancy and Basic Infertility
 - Preconception Care
 - STI/HIV Services - combined
- References linked in each section
- Client consent section expanded to include adolescent consent resources
- Sections that were labeled as policies in past are moved behind the clinical care sections

What's New

- Revised laboratory section – individual testing information removed and replaced by general laboratory practices and requirements especially as relates to CLIA
- LGBTQ services and resources added to Healthcare Services section
- Updated menopause section by Jan Shepherd
- Clients Transferring, Infertility Prevention Project, UTI, Nutrition and Delayed Exam sections removed

What Hasn't Changed

- Following the same national evidenced based guidelines and recommendations for providing care
- Continue to provide basic preventative counseling and health care services with an emphasis on preventing or achieving pregnancy
- Continue to provide and document thorough contraceptive counseling
- Continue to discuss reproductive life plans with clients and provide preconception counseling as indicated

National Evidenced Based Guidelines

- Quality Family Planning Services (**QFP**)
- US Medical Eligibility Criteria (**US MEC**)
- US Selected Practice Recommendations (**US SPR**)
- **CDC** STD Treatment Guidelines
- American Society for Colposcopy and Cervical Pathology (**ASCCP**) Cervical Cancer Screening and Follow up Recommendations

National Evidenced Based Guidelines

- US Preventative Services Task Force (**USPSTF**)
- CDC and USPSTF HIV screening recommendations
- American College Obstetricians and Gynecologists (**ACOG**)
- National guidelines and recommendations do not replace clinical judgment based on individual circumstances of the client.

Organization of Clinical Manual

- Nine sections in the QFP and corresponding manual sections
 - Overview – Healthcare Services
 - Contraceptive services – reversible methods by tier
 - Pregnancy testing and counseling
 - Helping clients achieve pregnancy, combined with
 - Basic infertility services
 - Preconception health services
 - STI/HIV services
 - Related preventative health services –breast and cervical cancer screening
 - Conducting quality improvement

Section 1 - Healthcare Services

- Comprehensive history all clients
- Weight, height, BMI, BP. (High blood pressure and obesity screening)
- Reproductive life plan
- Staff to stress the importance of and provide for health maintenance screening exam if appropriate
- Comprehensive education regarding the chosen contraceptive method

Health Care Services

- Optimally, clients should see a provider and receive their desired contraceptive method, if no contraindications, on the day of their initial visit
- This is current practice
- Example: client sees provider, history, reproductive life plan, exam as indicated, and receives year's prescription for method (OCs, DMPA, etc.)
- Example: client requests LARC, there are no contraindications to chosen method and pregnancy ruled out

Health Care Services

- Comprehensive history, including reproductive life plan,
- BP, Wt., Ht., BMI
- Vaginal or urine CT/GC specimen
- LARC counseling and insertion
- If not enough time on day of visit, client can be rescheduled for exam, preventative health counseling, etc.

Healthcare Services-Physical Assessment

- Women: ACOG recommendations for periodic physical assessments
- Clinical breast exam starting at 20 and every 1 to 3 years. Starting at 40, annual breast exam
- Pelvic exam starting at 21. Shared decision between provider and client. Acknowledges no evidence to support
- American College of Physicians recommends against in asymptomatic, non-pregnant adult women

Healthcare Services-Physical Assessment

- Taking these two recommendations into consideration, clinicians may provide a pelvic exam at the time of cervical cancer screening for healthy, asymptomatic women.
- Cervical cancer screening according to ASCCP guidelines
- CT/GC screening for women 24 and younger once annually – USPSTF and CDC

Health Care Services-Express Visit

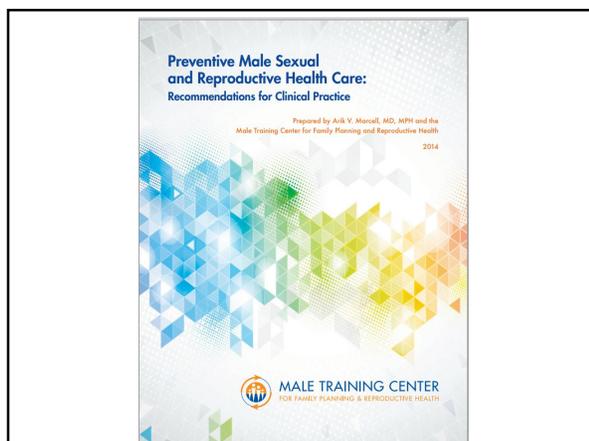
- Newer term instead of delayed exam
- Updated Express Visit form
- Components:
 - FPP program consent
 - Targeted history
 - Physical assessment - at minimum, BP, Wt, Ht, BMI
 - Pregnancy test if indicated

Health Care Services-Express Visit

- Components, con't
 - Method provided according to US MEC risk categories
 - Provide a minimum of 3 months of method
 - Method education
 - Consider CT/GC screening
 - Recommend client return to see provider for comprehensive history, physical assessment and lab work as indicated.

Healthcare Services

- Men: Preventative Male Sexual and Reproductive Health Care: Recommendations for Clinical Practice
- Developed by the Male Training Center
- Use as a resource
- Summarizes recommended services and services that are not recommended
- Ht., Wt., for BMI calculations, BP, physical exam as indicated



Section 2 - Contraceptive Services

- An introduction for all methods
- Method selection – use US MEC risk categories
- Counsel using a tiered approach – present most effective methods first
- General information about method use – US SPR
- Method education for all methods
- Information specific to each method addressed in the method section

Contraceptive Services

- Inform clients about all contraceptive methods that can be used safely – FP booklet
- Broad range of methods, including LARCs, should be available and discussed with all women and adolescents, if medically appropriate
- Use tiered approach to counselling – present most effective methods first
- If method not provided on site, must have established referral links and a written agreement to providers so client can obtain method

Contraception Services

- Assess reproductive life plan
- Assess client's contraceptive experiences and preferences
- Sexual health assessment
- Medical history – comprehensive health history required for both men and woman
 - Contraceptive safety for client
 - Use US MEC risk categories

Contraceptive Services

- Men
 - Assess condom use, partner contraceptive use, recent intercourse, partner's pregnancy history
 - Taking a medical history should not be a barrier to obtaining condoms - QFP
 - When appropriate, discuss female controlled methods including emergency contraception

Method Education

- Mechanism of Action
- Effectiveness
- Advantages and indications
- Possible side effects, complications and danger signs and symptoms
- Managing side effects and problems with method
- Managing missed pills, patch, ring, DMPA as indicated

Method Education

- User instructions for method
- Instructions on how to discontinue method
- Procedural instructions in case of an emergency
- Instruction to call or return to the clinic at any time to discuss side effects or other problems, if she wants to change the method being used and when it is time to remove or replace the contraceptive method

Method Education

- The contraceptive method (other than barrier methods) does not protect against STI-HIV and a barrier method should also be used for protection.
- Encourage partner communication about contraception

Provide Method

- Refer to the US Selected Practice Recommendations (US SPR) for information
 - How to initiate the chosen contraceptive method
 - Need for back up method
 - How to address problems and side effects the client may experience with their method and
 - Instructions for incorrect method use
 - Table – how to be reasonably sure client is not pregnant

US SPR

- A health-care provider can be reasonably certain that a woman is not pregnant if:
 - she has no symptoms or signs of pregnancy and meets any one of the following criteria:
 - is ≤ 7 days after the start of normal menses
 - has not had sexual intercourse since the start of last normal menses

US SPR

- has been correctly and consistently using a reliable method of contraception
- is ≤ 7 days after spontaneous or induced abortion
- is within 4 weeks postpartum
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [$\geq 85\%$] of feeds are breastfeeds), amenorrheic, and < 6 months PP

Provide Method

- Confirm client's understanding
- If providers assess client's understanding than a check box or written statement can be used in place of a written method specific informed consent form – QFP. Education must be documented.
- We no longer require method consents except for methods requiring procedure
- See method education information in the QFP, Clinical Manual, US SPR

Provide Method

- Onsite dispensing
- Begin at time of visit – quick start
- Provide or prescribe multiple cycles – ideally full years supply
- Provide condoms
- If client choses a method that is not onsite or the same day, provide another method to use until she can start the chosen method – bridge method
- Develop follow up plan

Contraceptive Services

- | | |
|--|--|
| □ Section 3 - IUCs | □ Section 8 – Barrier Methods |
| □ Section 4 - Implant | □ Section 9 – Natural Family Planning |
| □ Section 5 - DMPA | □ Section 10 – Emergency Contraception |
| □ Section 6 - Combined Hormonal Methods <ul style="list-style-type: none"> ■ OCs, Patch, Ring | □ Section 11 - Sterilization |
| □ Section 7 – Progestin Only Pills - POPs | |

Section 12 - Pregnancy Testing and Counseling

- Must be offered at all family planning clinic sites
- Client must sign FPP consent
- Updated pregnancy test request form
- Include discussion regarding reproductive life plan and medical history
- Options counseling in accordance with professional medical associations recommendations - QFP
 - ACOG/American Academy of Pediatrics (AAP)
 - Prenatal care, adoption, foster care, abortion

Pregnancy Testing and Counseling

- Options counseling must be non-directive and information must be neutral and factual
- Adoption information has been updated
- Appropriate referrals – referrals for all options
- Additional counseling based on test results
 - Contraceptive counseling – offer contraception/emergency contraception if negative test
 - Achieving pregnancy or basic infertility services

Section 13 - Achieving Pregnancy/Basic Infertility Services

- Advise clients who want to become pregnant according to professional guidelines such as
- American Society for Reproductive Medicine (ASRM)
- http://www.asrm.org/Guidelines_for_Practice/
- American Urological Association (AUA)
- <http://www.auanet.org/education/best-practice-statements.cfm>
- CDC
- <http://www.cdc.gov/reproductivehealth/infertility/>
- ACOG

Achieving Pregnancy/Basic Infertility Services

- Provide basic infertility services for men and women, including
 - History
 - Physical exam
 - Laboratory testing
 - Education and Counseling
- Referral resources available for those requiring more extensive assessment and treatment

Section 14 - Preconception Health Screening Services

- Emphasize importance of establishing a reproductive life plan with all clients
- One Key Question
 - Would you like to become pregnant in the next year?
 - Further discussion based on client's response
- Provide preconception counseling, as indicated
 - At high risk for unplanned pregnancy
 - Planning pregnancy
 - Seeking infertility services

Preconception Health Screening Services -QFP

- Reproductive life plan
- Medical history
 - Reproductive history
 - Medications
- Intimate partner violence
- Alcohol and other drug use
- Tobacco use
- Immunizations

Preconception Health Screening Services -QFP

- Depression
- Body mass index
- Blood pressure
- Sexual health assessment
- Chlamydia/gonorrhea/syphilis/HIV/AIDS
- Diabetes

Preconception Health Screening Services – General Education

- Importance of spacing pregnancies
- Healthy weight before pregnancy
- Folic acid – good nutrition
- Tobacco, ETOH and drug use warnings before and during pregnancy
- Importance of being up to date on immunizations prior to pregnancy
- HIV/STI screening prior to pregnancy
- Recommendations for stopping contraceptive methods

Preconception Health Screening Services

- Resources such as Before, Between and Beyond Pregnancy
<http://beforeandbeyond.org/>
- CDC
<http://www.cdc.gov/preconception/index.html>
- Provide or refer for care when health conditions are identified

Section 15 - STI/HIV Services

- Follow CDC STD Treatment Guidelines - 2015 Update planned
- CDC and USPSTF HIV screening guidelines

STI/HIV Services

- Each section of the CDC Treatment Guidelines includes:
 - Diagnostic considerations
 - Treatment, recommended and alternative regimens
 - Management of sex partners
 - Follow up
 - Special considerations such as pregnancy or HIV infection

STI/HIV Services

- Sexual Health Assessment includes 5 Ps
- Sexual practices (e.g. vaginal, anal, or oral sex)
- Pregnancy prevention
- Partners (number, gender, concurrency)
- Protection from sexually transmitted infections
 - Correct and consistent condoms use for those at risk for STIs
- Past STI history

STI/HIV Services

- STI/HIV risk assessment and risk reduction counseling required and may include
 - Abstinence and reduction of number of sex partners
 - Pre-exposure vaccination: HPV, Hepatitis A and B
 - Use of barrier methods: male and female condoms

STI/HIV Services

- Annual CT/GC screening in sexually active young woman - USPSTF 2014, CDC 2015
- CT/GC testing if at risk for infection for older women
- No specific screening criteria for men
- Screen men for CT/GC if high prevalence of CT/GC, MSM, or symptomatic males.
- Rescreen for reinfection in 3 months after treatment

STI/HIV Services

- HIV/AIDs
 - CDC/USPSTF recommendations:
 - Screen all clients 13-64, those at high risk should be rescreened at least annually
 - Client is informed that screening will be provided as part of general medical consent unless client opts out or otherwise prohibited by law

STI/HIV Services

- Each new family planning client must be offered HIV education and testing information
- HIV risk reduction counseling
- May test on site or by referral
- Many clinics are providing rapid HIV tests on site
- Many labs are moving to a 4th generation HIV test. Discuss the specifics of HIV testing with the lab the clinic uses
- HIV testing is not required to slide

STI/HIV Services

- Counseling for individuals considering pregnancy or pregnant
- PEP- Post exposure prophylaxis - use of antiretroviral drugs after a single high-risk event to prevent infection
- PrEP- Pre-exposure prophylaxis - prevention option, daily medication, for people at high risk for HIV infection

STI/HIV Services

- Next steps after testing positive for HIV
- Linkage to care for HIV positive individuals
- Treatment as prevention – reduces risk of transmission to others

STI/HIV Services

- Hepatitis C screening - CDC and USPSTF recommend one time testing for men and women born between 1945 and 1965
- Follow Advisory Committee on Immunization Practice's recommendations on reproductive health related immunizations
- HPV and Hepatitis B vaccinations
- Fees for vaccination services are not required to slide

Section 16 - Related Preventive Services-Breast Cancer Screening

- Screening for breast cancer – USPSTF update in progress
- USPSTF recommends biennial screening mammography for women aged 50 to 74
- Both the ACS and ACOG recommend annual screening mammograms starting at age 40
- Women in their 40's should have mammogram screening based on their individual risk and preferences. Mammography recommendations may also depend on physical exam findings or a radiologist's recommendations.
- Screening recommendations vary for women considered to be at moderate or high risk for breast cancer.

Section 17 - Related Preventive Services-Cervical Cancer Screening

- Cervical cancer screening – USPSTF or ASCCP guidelines
- “Providers should follow ACOG and AAP recommendations that a genital exam should accompany a cervical cancer screening to inspect for any suspicious lesions or other signs that might indicate an undiagnosed STI” – QFP

Related Preventative Services-Cervical Cancer Screening

- Cervical cancer screening starting at 21
- Every 3 year Pap testing 21-29
- 30 and older
 - Pap testing every three years, or
 - Pap with high risk HPV screening every 5 years
- Follow ASCCP guidelines for abnormal Pap/HPV follow up
- Primary HPV testing not addressed in manual

Primary HPV Testing

- FDA approved the cobas® HPV test as a “primary,” or first, test performed for cervical cancer screening – December 2014
- The test detects DNA from 14 high-risk HPV types, including types 16 and 18
- Society of Gynecologic Oncology (SGO) and the American Society for Colposcopy and Cervical Pathology (ASCCP)
- Issued Interim Guidance Report

Primary HPV Testing

- The Interim Guidance Report recommends:
- Primary HPV testing can be considered for women starting at age 25.
- Women under age 25 should continue to follow current guidelines that recommend cytology alone beginning at age 21.
- Women with a negative primary HPV test result should not be retested again for three years. This is the same screening interval recommended under current guidelines for a normal cytology test result.
- An HPV test positive for HPV 16 and 18 should be followed with colposcopy.
- A test that is positive for HPV types other than 16 and 18 should be followed by reflex cytology testing.

Section 18 - Adolescent Services

- Contraception counseling including that abstinence is effective in preventing pregnancy and STIs
- LARCs are safe and effective for nulliparous women, including adolescents
- Provide confidential services
 - Observe state reporting laws, etc.
- Encourage and promote family-teen communication about sexual health and reproductive health

Adolescent Services

- Avoiding sexual coercion counseling
- Referral services for pregnant and parenting teens – prevention of repeat pregnancies
- Take steps to make services youth friendly – QFP
- Document adolescent counseling

Additional Sections

- Section 19 - Menopause – updated by Dr. Shepherd
- Section 20 - Client Consent
 - Added adolescent consent information and resources
- Section 21 - Medical Emergencies
- Section 22 - Pharmaceuticals
- Section 23 - Referral and Follow up
 - Internal written abnormal lab and referral f/u procedures
- Section 24 - Common Gyn and Menstrual Disorders
 - Updated

Section 25 - Mandatory Reporting/Human Trafficking

- Must be compliant with all applicable state laws regarding the mandatory reporting of child abuse, child molestation, sexual abuse, rape, incest, or domestic violence.
- Agencies must have written procedures in place demonstrating compliance.

Mandatory Reporting/Human Trafficking

- Family Planning Coordinators must assure that all staff members are trained and familiar with Colorado law regarding mandatory reporting / human trafficking
- The Colorado Department of Human Services (CDHS) provides the Child Welfare On-line Training System at <http://www.colorado.gov/cs/Satellite/CDHS-Main/CBON/1251651932321>.

Additional Sections

- Section 26 - Medical Records
 - HIPAA information included
 - Colorado open records wording moved under HIPAA information
 - For state agency or a political subdivision of the state
 - Added some EMR wording
- Section 27 - Personnel Polices
 - Job descriptions – including consulting MD
 - Make sure you are following Colorado Nursing and Medical Board rules regarding delegation

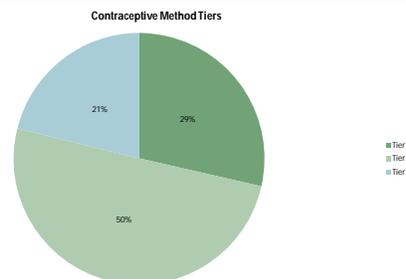
Section 28 - Risk Management/Quality Assurance

- Risk Management
 - Information and links for good laboratory practice and CLIA waived tests
 - Infection control measures
 - Blood borne pathogen exposure prevention and care after exposure
 - Quality assurance activities such as medical record audits and site visits

Quality Improvement

- Different than quality assurance
 - Which measures compliance against standard or the extent to which requirements are fulfilled
- Two dimensions of quality – provider (technical elements of provision of care) and client perceptions (experience as a service recipient)
- Definition - use of a deliberate and continuous effort to achieve measurable improvement in identified indications of quality care which improves the health of the community - QFP

State Wide Data 2014



State Wide Data 2014

- **Number of pregnancy tests**
 - Rate per 100 female encounters - 15
- **Chlamydia Screening Rate**
 - Females <=24 years old 61 %
 - Females >24 years old 31 %
- **Gonorrhea Screening Rate**
 - Females <=24 years old 55 %
 - Females >24 years old 28 %
- **Average number of encounters per client**
 - Males 1.5
 - Females 3.9

Section 29 - Laboratory

- CLIA Certificate of Waiver or Provider Performed Microscopy
- Guidance, resources and forms pertaining to CLIA waived and provider performed microscopy
- Each agency must have an internal lab manual
- Documentation of staff orientation and training
- The most recent package insert for each CLIA waived test must be available to staff

Laboratory

- Provider performed microscopy proficiency testing requirements - minimum biannually
- Documentation of the running of controls according to manufacturer instructions
- Documentation of instrument maintenance as directed by the manufacturer of the test or device (examples: devices used for CLIA waived tests, microscope, refrigerator including temperature log).

Plan for Implementation - OPA

- Developing crosswalk between old and new program requirements
- Job aids
- Provider training and resources to support implementation – plan for 2015
- http://fpntc.org/sites/default/files/resource-library-files/NTC_OFP_resources-Jan%202015.pdf
- Developing performance measures and new federal audit tools

Implementation

- Consulting physicians, providers providing care according to an MOU, and all FPP staff providing clinical care must review clinical manual and sign signature sheet
- Family planning coordinator will be asked in the quarterly report due the end of April if staff have reviewed the manual and signed the signature sheet
- Implement new clinical forms (see the Hub) by July 1, 2015

Summary

- Optimally a client's first visit will include a comprehensive history and provision of their chosen method
 - Other family planning services and related preventative services should be offered but can be provided at a later date
- Client centered care
- One Key Question for reproductive life plan
- Contact us with any questions