



Excellence of Care: Standards of Care for Providing Sonograms and Other Medical Services in a Pregnancy Medical Clinic

Clinical practice guidelines are common within the medical field, with over 1,500 issued in the past decade. Within the medical arm of the pregnancy center movement, there has been an increasing awareness of the need to provide guidance and standards to those performing sonographic examinations at their Pregnancy Medical Clinics (defined throughout this document as Clinic). The Physicians Resource Council of Focus on the Family has assisted in drafting, reviewing, and approving these evolving standards. The authors agree that if a Clinic follows these guidelines, they will be giving care within the medical scope of practice for pregnancy Clinics doing sonographic exams and providing other medical services.

GUIDELINES FOR PERFORMING SONOGRAPHIC EXAMINATIONS IN THE PREGNANCY MEDICAL CLINIC

General Standards

- A. The Clinic will operate under the supervision of a physician serving as the medical director. If the medical director does not have obstetrical experience, the Clinic will have a local physician with obstetrical training available for consultation.
- B. The Clinic should strive to have trained medical personnel on site whenever the Clinic is open. At those times when a physician or a nurse is not on site, one will be available by phone for consultation.
- C. A clinic services director or nurse manager (defined throughout this document as the Clinic Manager) who reports to the medical director will supervise the medical operations of the Clinic.
- D. Services will be provided for abortion-minded and abortion-vulnerable women to help them in the decision-making phase of their pregnancy. The provision of ultrasound services to women who are not abortion-minded or abortion-vulnerable is at the discretion of the medical director. A Sonographic exam in a pregnancy medical clinic is a medical procedure requiring a positive pregnancy test and a physician's order, supervision, and review. Sonograms will be performed only for appropriate medical indications by certified Allied Health Care Professionals as defined by the American Registry for Diagnostic Medical Sonography (ARDMS) Guidelines. Radiologic technologists may be allowed to perform limited ultrasound scans depending upon the scope of practice in the state.
- E. The Clinic will adhere to all applicable licensing requirements.
 1. All Allied Health Care Professionals will hold current state-appropriate licensure, certification, and/or registration.
 2. The Clinic will acquire any necessary state licensure.
 3. The Clinic will acquire a CLIA waived test status to do pregnancy tests in states that consider this necessary.
- F. The Clinic will obtain and maintain medical malpractice insurance.
- G. The Clinic will adhere to the standards set for medical clinics by the Occupational Safety and Health Administration (OSHA).

GUIDELINES FOR PERFORMING SONOGRAPHIC EXAMINATIONS IN THE PREGNANCY MEDICAL CLINIC

- A. The Clinic should follow the guidelines for obstetrical sonograms set forth by one of the nationally recognized organizations in the field: American College of Obstetricians and Gynecologists (ACOG), American Institute of Ultrasound in Medicine (AIUM), or Association of Women's Health, Obstetric and Neo Natal Nurses (AWHONN). The Clinic should not perform sonographic exams unless it has an established obstetrical referral mechanism.
- B. The Clinic will establish and follow a Medical Policy and Procedures Manual. It should be reviewed and updated annually.

Keys to Medical Excellence

- A. Role of the Medical Director
 - 1. Must possess a current license to practice medicine and function in accordance with the state's Board of Medical Examiners
 - 2. Agrees with the Clinic's Statement of Faith, Mission Statement, and Bylaws
 - 3. Adheres to a consistent pro-life medical position and practice
 - 4. Is reliable and respects confidentiality
 - 5. Oversees the nurse/medical services manager and meets with him/her on a regular basis
 - 6. Oversees the volunteer physicians in the Clinic
 - 7. Reviews and signs every sonogram chart or ensures this is completed by a physician designee; at his/her discretion, reviews and signs other medical charts (such as pregnancy tests) or ensures this is completed by a physician designee
 - 8. Reviews and approves Clinic medical policies and procedures and all medical literature distributed by the Clinic; establishes and signs Clinic standing orders for medical care
- B. Role of the Clinic Manager
 - 1. Must possess a current license in his/her medical profession and function in accordance with the licensing board of their state
 - 2. Agrees with the Clinic's Statement of Faith, Mission Statement, and Bylaws
 - 3. Adheres to a consistent pro-life medical position and practice
 - 4. Is reliable and respects confidentiality
 - 5. Operates from strengths but recognizes limitations
 - 6. According to the Nurses AWHONN Guidelines, the Clinic Manager shall obtain ongoing education pertinent to clinical practices. The Clinic Manager shall acquire competence and maintain competency in performing limited sonograms, through ongoing professional education that includes participating in reviews and clinical updates with competency assessments. He/she shall also keep documentation by which competency was gained and evidence that it has been maintained.
 - 7. Provides support, mentoring and medical back up to medical and non-medical volunteers
 - 8. Oversees adherence to all medical policies, procedures and protocols
- C. Role of the Sonographic Exam
 - 1. Sonograms should be performed under AIUM Practice Guidelines.
 - 2. Fetal sonography should be performed only when there is a valid medical reason, and the lowest possible ultrasonic exposure settings should be used to gain the necessary diagnostic information.
 - 3. A sonographic examination is performed when a specific question requires investigation and is indicated by a positive urine test as referenced in the physician's standing orders.
 - 4. In the case of a Clinic, the specific question to be answered should be, "confirmation of the presence of an intrauterine pregnancy, gestational age and determination of fetal cardiac activity, as indicated by a positive pregnancy test." A sonogram should not be given without the positive pregnancy test providing a medical indication of a pregnancy and thus justifying the sonogram exam.
 - 5. As with any medical procedure, the sonogram examination should be administered under a physician's order and using the highest standards of excellence and care.

6. Because imaging technology continues to advance, the Clinic should periodically determine that its ultrasound machine produces quality images comparable to accepted standards of care.
 7. The medical director will approve all protocols for screening and selection of clients for sonographic exams.
 8. Sonograms performed by medical personnel will be performed according to Clinic standing orders.
 9. The medical director may determine that certain medical conditions (i.e. pain or bleeding), gestational age of the pregnancy, or other parameters may exclude a client from a sonogram.
 10. Each Clinic will develop an informed consent form for clients to sign which specifically states the indications for the sonogram and what information the scan will and especially will not address.
 11. The Clinic must stress that the sonographic exam does not constitute ongoing prenatal care. Resources and referrals for prenatal care will be given to the client.
- D. Role of Medical Professional (Nurses and Radiologic Technologists) in Limited Ultrasound
1. Registered Nurses (and if allowed by the state, radiologic technologists) may perform sonographic exams.
 2. Medical professionals must possess a current license and function in accordance with the licensing board of their state. Radiologic technologists must be certified and function in accordance with the standards set by their state.
 3. They must possess the body of knowledge necessary to assess the significance of normal and abnormal findings.
 4. They must complete an ultrasound course that adheres to AWHONN, ACOG, or AIUM guidelines.
 5. They must have continual hands-on ultrasound training with a professional credentialed in ultrasound until they are deemed competent. This professional may be a competent registered diagnostic medical sonographer or physician. Competency should be established according to the written policies and procedures of the Clinic, AWHONN and the Society of Diagnostic Medical Sonographers (SDMS) guidelines.
 6. Prior to performing sonographic exams, the medical director or designee evaluates the competency of the medical professional (who is not credentialed in OB/GYN sonography), and a letter of competency from the medical director is placed in the individual's file.
 7. The Allied Health Care Professionals (i.e. nurse or radiologic technologists) will undergo ongoing assessment of competency.
- E. Documentation
1. Written sonogram reports accompanied by video/print pictures will be completed by the nurse or sonographer performing the scan. This is the minimum required documentation.
 2. Every sonogram will be read and signed in a timely fashion (to be determined by the medical director) by a physician qualified to read the ultrasound scan. It is recommended that sonograms be read within seven working days.
 3. Clients will be given pictures as determined by the medical director. Any pictures provided should not contain measurements or estimates of gestational age.
- F. Roles of Physician/Sonographer in Ultrasound
1. Licensed physicians, physician assistants, nurse practitioners, and registered sonographers will not practice beyond the level of their training.

KNOWLEDGE BASE FOR MEDICAL PERSONNEL

- A. Female Reproductive Anatomy and Physiology
 - 1. Normal/abnormal physiology
 - 2. Pregnancy physiology
 - a. Menstrual cycle
 - 1. Ovulation
 - 2. Conception and implantation
 - 3. Causes for amenorrhea (besides pregnancy)
 - b. HCG levels
 - 1. Normal levels
 - 2. Abnormal levels and possible causes
 - c. Ectopic pregnancy or miscarriage
 - 1. Signs/symptoms
 - 2. Assessment and instructions for patient
 - d. Rh factor- Rh negative
 - 1. What it is
 - 2. Why it is a risk factor in abortion or miscarriage
 - 3. Explanation/instructions for at-risk patients
 - e. Screening tests
 - 1. Knowledge of screening tests such as multiple marker screening, chorionic villus sampling, and amniocentesis
 - 2. Explanation to patient of what risk factors mean
 - 3. Ability to help patient access accurate/unbiased interpretation
 - 3. Contraception
 - a. Birth control pills
 - 1. Possible Causes for failure
 - 2. Action of drug
 - 3. Effect of long term use on menstrual cycle
 - 4. Depo-Provera
 - a. Effect on menstrual cycle
 - b. Side effects
 - c. Concerns if pregnant on Depo Provera
 - 5. Emergency contraceptives-morning after pill
 - a. Action of pill prior to and after ovulation
 - b. Handling of phone calls for ECP
 - 6. Mifeprex
 - 7. IUDs action and effects
 - 8. Other contraceptives (e.g. Nuvaring)—understand action/failure rate
 - 9. Understand and follow Clinic policy regarding birth control and unmarried women
- B. Sexually Transmitted Infections
 - 1. Know signs/symptoms
 - 2. STIs and testing related to abortion/future reproductive health
 - 3. STIs and ectopic pregnancy risk
- C. Abortion Techniques
 - 1. Which techniques are currently done in your area
 - 2. Medical resources in area to whom clients could be referred for laminaria removal
 - 3. Know the drugs used for chemical abortion
 - 4. Know complications (physical and emotional) of both chemical and surgical abortion
- D. Pregnancy Testing
 - 1. Understand action and accuracy of pregnancy test
 - 2. Know reasons for incorrect results
 - 3. Assess for accuracy of test result/need for retest

- E. Medical Risk Management
 - 1. Utilize trained medical personnel for phone inquiries to encourage patients to come to the Clinic where a full complement of services is available, rather than to give medical advice over the phone, as this incurs undue legal risks.
 - 2. Have charting guidelines and train all staff/volunteers in charting procedures; keep log of lab tests, including pregnancy tests.
 - 3. Maintain phone log for medical information given.
 - 4. Follow assessment tools to determine abortion vulnerability—refer women who are not your focus to appropriate resource providers.
 - 5. Train non-medical staff and volunteers in appropriate medical knowledge and clearly define what they should teach and tell clients, especially what is communicated over the telephone.
- F. Community Resources
 - 1. Know the resources and agencies in your area.
 - 2. Maintain current referral list
 - a. Life-affirming physicians for prenatal care or abortion after-care
 - b. Other life-affirming medical specialists
 - c. Churches with counseling/support group programs

SUGGESTIONS FOR MEDICAL POLICY AND PROCEDURE MANUAL

1. Scope of services
2. Hours of operation and opening/closing procedure for medical facility
3. Confidentiality
4. Advertising
5. Telephone call protocols/keeping a phone log
6. Insurance
7. Staffing
8. Personnel and personnel records
9. Medical staff peer review (should take place every six months)
10. Staff health, hepatitis B immunization and TB testing and any state-mandated testing
11. Medical Services Consent and Release Form
12. Scheduling of medical service appointments
13. Medical appointments without a physician on site
14. Pregnancy testing
15. Positive pregnancy test verifications
16. Pregnancy Confirmation
17. Selection and scanning of ultrasound clients
18. Assessment of fetal heart tones via Doppler
19. Prescription for prenatal vitamins (or recommendation for client to obtain over the counter folic acid and take 1mg daily until she can get a prenatal vitamin prescribed)
20. Definitions and criteria of abortion-minded/vulnerable clients
21. Sonograms
 - a. Standing orders by medical director, including medical indications for sonograms
 - b. Information for clients (Note: Clients should be offered neither videotapes nor pictures with measurements or estimates of gestational age.)
 - c. Information which will be obtained in a first trimester scan
 - d. Information which will be obtained in a second/third trimester scan
22. Policies and procedures addressing the event of sonographic disparities, i.e., non-viable fetus, multiple fetuses, suspected fetal anomalies, empty uterus, ectopic pregnancy, molar pregnancy, absence of fetal heart motion, etc.
23. STI Testing and Treatment
24. Infection control and universal precautions
25. Resources for referrals
26. Client follow-up
27. Client medical records, charting

28. Release of client medical records
29. Closing client files
30. Quality assurance
31. Reporting abuse (including sexual abuse, physical abuse, rape, statutory rape)
32. Services to minors
33. Suicide, assessing risk and reporting
34. Emergencies, transfer of patients
35. First aid kit
36. Safety and disaster plan

(This list is not exhaustive – please refer to NIFLA’s Medical Clinic Policies & Procedures List)

Focus on the Family’s Option Ultrasound™ Program (OUP) provides grants for qualifying pregnancy centers in high abortion areas to convert into medical clinics. OUP also provides grants for new ultrasound machines and sonography training to qualifying PMCs. *Visit Heartlink.org for more information.*

For more specifics regarding qualification, please contact:

Focus on the Family
 Robyn Chambers, OUP Manager
 8605 Explorer Drive
 Colorado Springs, CO 80920
 719/531-3474
Robyn.chambers@fotf.org

The following referral is provided to you by Focus on the Family’s Sanctity of Human Life Division as a source of information. If you would like to help your pregnancy resource center convert to a medical clinic, this organization has consulting, resources and training available that can assist with your conversion process.

National Institute of Family & Life Advocates (NIFLA)
 The Life Choice Project (TLC medical conversion program)
 PO Box 42060
 Fredericksburg, VA 22404
 Office: (540) 372-3930

Focus on the Family gratefully acknowledges the assistance of those who revised this document:

Connie Ambrecht, RT, RDMS, President,
 Sonography Now
 Las Vegas, NV

Beth Chase, CEO
 Chase Advancement Services
 East Wenatchee, WA

Kim Conroy, President
 S.M.A.R.T. Outcomes
 Consultant - Sanctity of Human Life Division, FOF
 Joplin, MO

Tom Glessner, J.D., President
 National Institute of Family & Life Advocates
 Fredericksburg, VA

Darlene Norberg, President
 Norberg Consulting Services
 Consultant - Sanctity of Human Life Division, FOF
 Dallas, TX

Audrey Stout, RN, RDMS, President
 Stout Ventures
 National Nurse Manager Consultant to NIFLA
 Gresham, OR

Byron Calhoun, M.D., National Medical Advisor
 National Institute of Family & Life Advocates
 Charleston, WV

Special thanks go to the following individuals who also helped initiate and draft the original version of the Standards of Excellence of Care:

Mary E. (Beth) Jewell, M.D.
Pat Sween, R.N.
Peggy Hartshorn, Ph.D.
Susan Rutherford, M.D., Perinatologist
Julie Parton, Ph.D.
William Stalter, M.D.

The following members of Focus on the Family's Physicians Resource Council helped draft and review these guidelines:

Brad Beck, M.D.
Marilyn Billingsly, M.D.
Byron Calhoun, M.D.
Margaret Cottle, M.D.
David Hager, M.D.
Jerry Hough, M.D.
Gaylen Kelton, M.D.
Walter Larimore, M.D.
Paul Mulzer, M.D.
Donald Nelson, M.D.
Mary Anne Nelson
Paul Reisser, M.D.
Roy Stringfellow, M.D.

 APPROVED BY THE
Physicians Resource Council

APPENDIX

THE PURPOSE(S) OF PROVIDING ULTRASOUND SERVICES TO CLIENTS

Pregnancy Medical Clinics (PMCs) provide ultrasound services for their clients in order to diagnose a viable, intrauterine pregnancy. Therefore, it is recommended that every pregnant woman have access to ultrasound through life-affirming PMCs reflecting medical best practices.

We recognize that every PMC desires to increase ultrasound hours available to patients. However, at times it may be necessary to prioritize accessibility of ultrasound, depending on the urgency of a patient's circumstances. When this occurs, the following definitions are offered to help client advocates assess a woman's need for intervention services in order provide positive options for challenging pregnancies. (The medical director and team will determine protocols for serving all medical patients.)

DEFINITION OF ABORTION-MINDED AND ABORTION-VULNERABLE

ABORTION-MINDED: The abortion-minded woman is one who appears to be planning or intending to obtain an abortion. Qualified Clinic personnel may recommend and schedule the client for a sonographic examination.

CRITERIA:

1. Client is seeking information as to how to obtain an abortion. For example, asking questions such as, "How much does an abortion cost?" "Can you give me a referral for an abortion?" "Do you do abortions here?"
2. She has an abortion scheduled, regardless of how tentative she seems.
3. The abortion procedure has been initiated, as in the introduction of laminaria.

ABORTION-VULNERABLE: The abortion-vulnerable woman is one who by continuing her pregnancy faces obstacles that she may feel incapable of handling or unwilling to experience. This category might also include women who state that they are pro-choice but are uninterested in aborting at this point. The counselor who detects the client's vulnerability for abortion shares this information with qualified Clinic personnel who will evaluate and may recommend and schedule the client for a sonographic examination.

CRITERIA:

1. Client has not eliminated the possibility of abortion.
2. Client lacks support from significant influencers (boyfriend, husband, parents) or is being pressured to have or consider an abortion.
3. Client is undecided. This may be expressed verbally or marked on the intake form.
4. Client is against abortion; however, she has a medical condition she thinks may affect the pregnancy.
5. Client is single (80% of women who abort are single, thus at a higher risk for abortion).

INTENDING TO CARRY TO TERM: This client does not meet criteria for abortion-minded or abortion-vulnerable, but meets the additional criteria noted below.

CRITERIA:

1. She does not believe abortion is right.
2. All indications reveal a healthy pregnancy.
3. She has support from all significant influences in her life.

NOTE: Clinic personnel and volunteers should be trained in assessment skills to evaluate the client's abortion risk utilizing the above factors and taking into consideration possible external influences.

Discussion concerning Limited versus More Comprehensive Sonograms:

There is some discussion among those involved in Clinics as to the extent of sonographic services that should be offered to pregnant women. Some suggest that pregnancy medical clinics should offer only a limited sonogram (a term which itself is not well defined) and should not perform scans of adnexa (the tissues and organs surrounding the uterus) routinely. Their rationale is that women being scanned are generally asymptomatic, and therefore Clinic resources would be expended unnecessarily. More importantly, legal liability issues exist if the scan or interpretation of the scan of the fetus and pelvic anatomy does not detect an existing medical problem. Women who go to these Clinics should be referred to other physicians for regular prenatal care, and should be referred immediately if they present with symptoms.

On the other hand, some Clinics are striving to expand their medical care. Their objective is not only to diagnose a viable intrauterine pregnancy and educate women who may be considering abortion, but also to provide a more comprehensive medical clinic, possibly involving complete prenatal care or help with adverse fetal diagnosis. In this case, the possibility of legal liability (and its implications for the Clinic) may not be as large as it might be with smaller Clinics, and comprehensive sonograms may be performed more routinely, provided personnel are well-qualified and the medical director has provided orders to do so.

The level of sonographic services offered by a Clinic should be determined by the mission of the Clinic, and at the discretion and direction of the Clinic's board and medical director. If the Clinic's mission is to provide medically accurate information to at-risk women regarding their pregnancy, the best sonographic option might be to perform limited scans while referring to other physicians and clinics for prenatal care. If the Clinic's mission is medically broader, the Clinic's board and medical director might deem it appropriate for that Clinic to offer more comprehensive scanning, as medically indicated.

Definition of a Pregnancy Medical Clinic:

A Pregnancy Medical Clinic is a facility which provides medical services under the direction and supervision of a licensed physician.

Defined and appropriate usage of the vaginal probe:

As the vaginal probe has become the standard of care for providing accurate resolution for early pregnancy ultrasound, the use of the vaginal probe is recommended.

LPNs or LVNs being trained for sonographic exams:

If PMCs are interested in training other health care professionals in sonography, they should consult ARDMS (www.ARDMS.org) prerequisites for who may be trained in performing sonograms. LPNs and LVNs do not meet their qualifications for training (unless they first become an RN), though the Medical Director may determine that they are able to scan. It is recommended that the Medical Director research the board of nursing for to determine possible limits of LPNs' or LVNs' training and whether they should be acting in an independent capacity in a medical clinic with no physician supervision on site.

 APPROVED BY THE
Physicians Resource Council

Revised 06/05/09