EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA
SOUTHWESTERN DIVISION

MKB MANAGEMENT CORP, D/B/A RED RIVER WOMEN'S CLINIC, AND KATHRYN L. EGGLESTON, M.D.,	)	Civil No: 1:13-CV-071
Plaintiffs,	)	
-vs-	)	
BIRCH BURDICK, in his official capacity as State Attorney for Cass County; WAYNE STENEHJEM, in his official capacity as Attorney General for the State of North Dakota; and LARRY JOHNSON, M.D.; ROBERT TANOUS, D.O.; KATE LARSON, P.A.C.; NORMAN BYERS, M.D.; CORY MILLER, M.D.; KAYLEEN WARDNER; GAYLORD KAVLIE, M.D.; KENT MARTIN, M.D.; KENT HOERAUF, M.D.; BURT RISKEDAHL; JOHNATHAN HAUG, M.D.; AND ROBERT J. OLSON, M.D., in their official capacities as members of the North Dakota Board of Medical Examiners,	)	
Defendants.		

D E P O S I T I O N

of

KATHRYN EGGLESTON M.D.

November 26, 2013

8:30 p.m.

Taken at: JOE TURMAN OFFICES
505 North Broadway, Suite 207
Fargo, North Dakota

REPORTER: KRISTEN M. KEEGAN

(PURSUANT TO NOTICE)

APPEARANCES

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Also Present: Tammi Kromenaker

INDEX

EXHIBITS

WHEREUPON,
the following proceedings were had to-wit:
KATHRYN L. EGGLESTON, a witness, called by the State Defendants, being first duly sworn, testified on her oath as follows:
BY MR. GAUSTAD: EXAMINATION

Q. Why don't you just state your name, please.
A. Kathryn Eggleston.
Q. Dr. Eggleston is that the way you want to be referred to?
A. Sure.
Q. My name is Dan Gaustad. I represent, what I refer to as, the state defendants.
A. Okay.
Q. I know that Birch Burdick is a defendant, but I don't represent him, okay. But basically all the other defendants in this case.
A. Okay.
Q. Okay. Have you ever been deposed before?
A. No, I have not.
Q. Okay. Couple of things that we need to probably make sure that we understand here today, some rules of engagement.

A. Okay.
Q. One is, you're doing very well so far, is, you need to enunciate your answers so that the court reporter can take them down. Nodding the head and hand gestures, just don't do it --
A. Okay.
Q. -- 'cause she can't get that down. Another rule is, and I know I'm gonna break this 'cause I -- sometimes I get so darn excited that I speak over people, but let's try not to speak over one another -- I -- 'cause it's hard for her to take down two people talking at once. So, I will try to finish my question, I'll hopefully allow you to finish your answer without talking over each other. I'm sure she'll let us know if we're violating that rule.
A. Okay.
Q. If, at any time, you need a break, let me know. Use the restroom, whatever you need just let me know and we can take a break at any time, okay? The other thing is, I'm not the best question formulator on the face of the earth. I'm gonna be candid with you on that. So, to the extent that you don't understand a question, let

Page 6

me know that --
A. Okay.
Q. -- and I'll try to rephrase it so that you do understand it. Okay? But to the extent that you answer the question, it will be assumed that you understood; is that fair?
A. Yes.
Q. Okay. Are you under any medical condition or medication that would preclude you from being able to answer fully and truthfully here today?
A. No.
Q. Okay. What did you do to prepare for today? Did you review anything?
A. No. Just talked with the -- my lawyers here.
Q. Okay. And I don't want to talk about your communication with your attorneys 'cause you're one of the named plaintiffs, correct?
A. Yes.
Q. Okay. Other than talking to your attorney, did you speak to anybody else in preparation for today's deposition?
A. No, I did not.
Q. Did you review any documents?

Page 7

A. No, I did not.
Q. Have you ever been involved in any prior litigation? Like a malpractice action?
A. I was involved in a malpractice action many years ago in Minnesota.
Q. In Minnesota?
A. Uh-huh.
Q. And were you a defendant? A plaintiff? What were you?
A. So, I would have been a defendant. I had a patient -- a patient's husband, essentially, had claimed that I had provided inadequate care and went through the process. It went to mediation, and I was found that I provided very good medical care and it was dropped.
Q. So when was this litigation roughly?
A. It would have been '98 I bet.
Q. And this was in Minnesota?
A. Yes. No, I'm sorry -- I'm sorry. This is Wisconsin. I was in my residency so this was in Wisconsin.
Q. Okay. And was there an actual lawsuit that was started then in Wisconsin? Do you know what I mean? Like you got a complaint

Page 8

that was handed to you or something like that?
A. Well, we went to -- I'm not familiar with -- I'm assuming -- when people ask me, "Have you been sued for malpractice?" My answer is yes.
Q. Okay.
A. It went to mediation, and I was found to provide good medicine, there was no -- you know, it was dropped.
Q. Okay.
A. So that's as far as it went.
Q. Okay. Do you know --
A. So I'm assuming they went through the pro- -- those legal maneuvers.
Q. Do you remember what the names of the parties were? The plaintiffs?
A. Yes. I don't know if I -- do I -- who sued me? My patient?
Q. Yes.
A. Yes. I'm assuming that I'm not breaking any HIPAA violations by talking about a patient's name?
Q. Well, that was the question. If they brought an action, did they actually serve? Did it get into a court system type situation?

Page 9

A. Yes.
Q. Okay. So tell me the --
A. So then it's public.
Q. -- name.
A. Platt, P-L-A-T-T.
Q. P-L-A-T-T?
A. I believe.
Q. Were you the only defendant?
A. The residency program was named.
Q. Which one? What was that called?
A. Eau Claire Family Medicine Residency.
Q. Anybody else?
A. I do not believe so.
Q. And that's the only other -- that's the only medical malpractice action you've been involved in?
A. That's the only medical malpractice I've been involved in.
Q. Even as a witness or anything like that?
A. I was involved in the medical -- the trial last year in April here.
Q. Okay. But that doesn't -- that didn't necessarily relate to a malpractice action?

Page 10

A. Exactly. This is the only malpractice.
Q. Okay. Even as a witness in any kind of --
A. Correct.
Q. Okay. The other litigation you've been involved in, you were in the case -- the state court case that's kinda still pending, right?
A. Yeah.
Q. Okay. Any other litigation that you've been involved in? Not just malpractice, anything else?
A. A divorce.
Q. When was that?
A. '99. I don't even -- I'm not even 100 percent sure.
Q. Okay. Are you single now?
A. No. I'm married.
Q. Okay. What's your husband's name?
A. I'm -- I don't feel comfortable answering that question.
Q. Well, what's your husband's name?
A. I don't feel comfortable answering that.

Page 11

Q. I understand that, but what's your husband's name?
MS. CREPPS: I --
MR. GAUSTAD: I'm just asking. I'm just trying to get some background information.
MS. CREPPS: I know, but that's completely irrelevant and I think well beyond the scope of what the Magistrate has authorized even as background. So I -- if she's not comfortable answering a question and we have other incidents like this, I think we should just make a list of the questions that we don't think she needs to answer and we can get the Magistrate on the phone towards the end and have him sort this out.
MR. GAUSTAD: It's just background information. I think he allowed context and background information. If you're not going to answer the question, just tell me that.
THE WITNESS: I'm not gonna answer the question.
Q. So you're divorced in '99. Any other litigation?
A. No.

Page 12

Q. And I'm not talking about whether you were a party to it, I'm talking as a witness. Anything?
A. No.
Q. Have you been involved in any type of complaints to like a medical board?
A. No.
Q. Do you serve on any professional boards?
A. Serve on professional boards? No.
Q. Are you a member of any type of -- and I don't know how to -- if you understand what I'm -- like professional --
A. I'm board certified --
Q. Yeah.
A. -- in American Board of Family Medicine.
Q. Okay.
A. I'm a member of the American Academy of Family Physicians, I'm a member of -- for Physicians of Reproduction Health.
Q. Okay. But do you see -- these must have some sort of overseeing board. Those, that you've just described, you don't serve on any of those boards, correct?

Page 13

A. No.
Q. How about any type of professional societies? Any maybe there's a distinction if you understand what I'm asking? Do you serve on any -- or a member of any type of professional society?
A. The ones I just listed.
Q. Okay. You're a member of it but you don't serve in any like leadership capacity; is that fair?
A. Correct.
MR. GAUSTAD: Would you mark this.
(Deposition Exhibit No. 1 was marked for identification.)
Q. Dr. Eggleston, I'm showing you what's been marked as Deposition Exhibit Number 1.
A. Okay.
Q. Do you have that in front of you?
A. I do.
Q. Okay. And it's about the, I guess, it's the fourth page in, it says Page 5 of 8 at the top.
A. Yes.
Q. Is that your signature?

Page 14

A. Yes.
Q. And, as I understand, this was a declaration that has been submitted to the Court for the Plaintiff's Summary Judgment Motion, and attached to it was your CV?
A. Yes.
Q. Are there any -- and I -- I don't want to go through, I mean, I think it speaks for itself. But, are there any changes since this thing was submitted? This CV.
A. The -- the only thing, I have been promoted to -- the first listing with Planned Parenthood. I'm the Medical Director of Family Planning in addition to the Associate Medical Director and that was since October of 2012. Other than that --
Q. What's the --
A. -- that's the only update.
Q. So there's some additional responsibilities then I presume as a Medical Director of Family Planning?
A. Yes.
Q. Okay. Can you tell me what they are in comparison to what I've got?
A. It's very -- very similar position

Page 15

there. It was more of a reorganization delineation of responsibilities. So, I still think the description is very accurate, and no significant changes in the description.
Q. But you serve in both capacities?
A. Correct.
Q. As the Associate Medical Director and Medical Director of Family Planning?
A. Correct.
Q. But the responsibilities are generally what's described?
A. Yes.
Q. In the CV?
A. Yes.
Q. Okay. Any other changes?
A. No.
Q. And I know I probably asked you this already and I apologize for that. These professional memberships, those are the ones you just described, the American Academy of Family Medicine?
A. Right. I listed -- when I listed it, the American -- the first one, the American Board of Family Medicine, that's under Licensure and Certification.

Page 16

Q. Okay.
A. So, it's a little different than the Professional Membership. That's why it's listed here separately.
Q. I see. And the American Board, you don't serve in any type of leadership position in that organization, correct?
A. Correct.
Q. And you don't serve in any leadership position with respect to American Academy of Family Medicine, correct?
A. Correct.
Q. And that's the same with Physicians for Reproductive Choice?
A. Yeah.
Q. Okay.
A. The Physicians for Reproductive Choice, it used to be Physicians for Reproductive Health and Choice. Now it's Physicians for Reproductive Health.
Q. Just changed the name?
A. I just saw that. Yeah. So, I just saw that correction.
Q. Oh, okay. So that should be changed to just the name --

Page 17

A. They just changed the name.
Q. Okay. How about with Abbott Northwestern, any leadership capacity there?
A. No.
Q. And as I understand, you're a family medicine physician?
A. Yes.
Q. And I'm trying to get a sense as to what that is in comparison to an OB/GYN. What distinctions are there? What can you -- well maybe it's -- an OB/GYN probably takes more years of education; is that fair --
A. No.
Q. -- or not?
A. No. It's a different residency program.
Q. Okay.
A. That's the main difference. And then who you're certified -- to be board certified in family medicine, you need to go to an approved family medicine residency to be board certified. With ACOG, you would need to go to an OB/GYN residency program.
Q. Okay. Are there things that an OB/GYN can do -- some procedures an OB/GYN can do

Page 18

that you can't do as a family medicine physician?
A. Not -- there isn't a list of things that can't be done. It's all about training and being able to provide those procedures safety to patients and have -- be able to prove you that you can do that.
Q. Have you ever been in a situation where you have been asked to perform a procedure and have not been able to because you don't have -- I'm not OB/GYN, and I'm not qualified to do that type of procedure?
A. No. The -- for instance C-sections, I don't -- I was never trained to do C-sections but some family medicines are -- physicians are. And when they're taking care of their labor and delivery patients, they could do their own C-section. And, when I was delivering and doing full, essentially, OB/GYN -- or full OB for my family medicine patients, I would consult or refer for an OB- -- an OB/GYN would do the C-section. I would not do that.
Q. Okay. But generally speaking then, an OB/GYN can do C-sections; is that fair? And a family medicine physician needs to be trained in that particular procedure?

Page 19

A. In that particular example, true. So, a lot of the focus for OB/GYN is more surgical based, you know, hysterectomy, you know, bladder slings, pelvic reconstructive surgery, that type of thing.
Q. Okay.
A. That is more -- that -- their scope is more surgical versus a lot of family medicine is, you know, outpatient procedures, more outpatient care.
Q. Okay. So, have you ever been trained to do a C-section?
A. I have never tried to do a C-section.
Q. What other surgical procedures then do you then refer to an OB/GYN?
A. Oh, I can't even --
Q. There's a number of them?
A. A number of them.
Q. Do you do any type of surgical procedures?
A. I do quite a few outpatient surgical procedures.
Q. Okay. Just give me some examples of, you know, patients that you have -- abortions I know you do --

Page 20

A. Uh-hum.
Q. -- that would be described as an outpatient surgical procedure?
A. Uh-hum. D&Cs, endometrial biopsies, colposcopy, wart removal, lesion --
Q. You might have to slow down for the court reporter.
A. Sure. Skin lesion, toenail removal, stitches, casting, I could -- I would need time, but I could probably keep going for some time.
Q. Okay. And, the C-section is something you would refer on to an OB/GYN. Can you give me another example of a surgical procedure that you would refer on to an OB/GYN?
A. For -- like -- so something that I'm -- first of all, when you do a referral, it's up to the physician to do the -- to make the decision whether that needs to be done. You know, so I'm not going to tell the OB/GYN, you know, this patient needs a C-section. I would say I suspect and it's going to be up to that physician to, essentially, give a second opinion and do the procedure that they think is appropriate.
Q. And that's fair. What I was asking

Page 21

was: You identified C-sections as something --
A. Oh, sure.
Q. -- you're not qualified to do.
A. Sure.
Q. I'm just trying to --
A. Tubal ligation.
Q. Okay. That would be something that, if the patient needed it, that would be something that --
A. Right.
Q. -- would be something you couldn't do?
A. Exactly. That's not an outpatient procedure. Well, there's a new procedure that's an outpatient procedure but typically the straight for- -- which has been done for many, many years tubal ligation is done in the OR. It is not an outpatient procedure.
Q. Okay. Are there different rules of standards that you have to follow versus an OB/GYN has to follow? You follow like -- your -- like the American Board of Family Medicine, if an OB/GYN is involved in that or your various licensing from various states, are there different rules for you as a family medicine

Page 22

physician?
A. No. I could be trained. I could be trained to do C-sections, I could be trained to do tubal ligations. If I lived in a very rural community, maybe that would be something that would be worth while but from where I have practiced and now, I don't need those skills, so I wouldn't do that. So, there's not a -- there's not a rule that a family physician can or cannot do this.
Q. Okay.
A. And typically, there are not rules from, you know, ACOG or other groups that say their physicians can or cannot do this.
Q. And I'm just talking, you know, I mean for example, the state board for North Dakota, I presume, issues rules and regulations that apply to the practice of medicine. Would that be a fair -- I mean generally?
A. They -- they licensed -- they are confirming that you are licensed to practice. And there are certain, you know, rules and regulations that are from the federal level and lots of them but they're not specific to you -- you as this specialty can or cannot do this, this

Page 23

specialty can or cannot do that.
Q. Okay. But what I'm trying to get at is: If a rule is say promulgated by the state board, for example, there are the -- you don't practice under a different set of, like, ethical rules or standards of care rules that an OB/GYN would -- would be practicing under --
A. Correct.
Q. -- with the exception that I might not be able to perform a certain procedure?
A. Correct. We're all under the same requirements of standard of care and ethical and HIPAA and all that.
Q. Okay. And I'm looking at your CV, it looks like, from what I can tell, you're -- you've been engaged in or performing either medical or surgical abortions since about 2000; is that about --
A. Yes. I was trained in 1999.
Q. Okay. So I was pretty good on my -- on my evaluation of your CV here. How much of your practice, percentage wise, is dealing with either medical or surgical abortion versus, you know, the stitching that you talked about earlier?

Page 24

A. The -- currently, my practice is 100 percent reproductive healthcare.
Q. Okay.
A. And of that, approximately 50 percent is directly related to medical and surgical abortion related.
Q. And when you -- and I'm trying to get a sense what you meant my directly related to. Are you actually --
A. Well, performing the procedure, follow-up appointments, that type of patient -- patient care.
Q. Okay. So when you say "directly related" it's performing the procedure and/or following up afterwards?
A. Yes.
Q. Okay. Anything else when you say 50 percent is directly related to medical or surgical abortions?
A. Continually, you know, continually, we are making sure that -- as you can see from my CV, I have a lot of medical director and associate medical director, so we work on protocols, we make sure things are up to date, but I think in general, still 50 percent is --

Page 25

it's hard for me to say if you're -- I guess are you asking patient contact or just time?
Q. Well, tell me --
A. It's very close -- I think it's very close to 50 percent. Most of that would be patient -- direct patient care.
Q. Okay.
A. And a small portion would be related to reviewing charts and reviewing blood test results, et cetera --
Q. And that's all --
A. -- related to abortion.
Q. -- and that's all related to the procedure itself --
A. Yes.
Q. Right? Okay. How much of your time then is spent for these protocols?
A. Different capacity with each -- each job. It's more of a continual. I feel like we're always working on wether it'd be protocols or improving patient flow, paperwork, and making sure that things are running efficiently whether it's the clinic or, you know, whether it's the clinic here or where I work in Minnesota and South Dakota.

Page 26

Q. Kind of management type of stuff?
A. Yeah. Exactly.
Q. How much is that? Do you -- you've got 50 percent actually involved in the procedure, how much is quote "management"?
A. Management. 30- --
Q. I'm not trying to --
A. Off the top of my head, 35 percent --
Q. Yeah, and I'm --
A. -- and probably 15 percent of other direct patient contact, family planning.
Q. That's not an abortion procedure or abortion protocol, right?
A. Right.
Q. The locations -- and I didn't -- the first one, this -- that you're now the Director of Family Planning, it says, "Planned Parenthood MN, ND, SD." Where is that? I mean is there a clinic -- for example in your second line of your CV, it says, "Medical Director present Women's Clinic in Fargo." I know where that's at.
A. Uh-hum.
Q. And then Women's Health Center, Duluth. So you've identified particular spots. I'm trying to figure out where this Planned

Page 27

Parenthood MN, ND, SD is?
A. Planned Parenthood has different affiliates. So, our Planned Parenthood affiliate involves Minnesota, North Dakota, South Dakota. We do not have a clinic in the State of North Dakota but an advocacy office, and there's two clinics in South Dakota and 20 clinics in the State of Minnesota. I'm not exact on the number of clinics in Minnesota. There's been a few changes.
Q. Do you then go to these two locations in South Dakota to perform abortions?
A. I have. Abortions are performed at the Sioux Falls Clinic not at the Rapid City, so I've been to both clinics.
Q. Okay.
A. But abortions are provided at Sioux Falls.
Q. Okay. And do you then go to -- are you the one that goes to the Sioux Falls Clinic to perform the abortions?
A. I'm one of the physicians.
Q. Okay. And there is no clinic in North Dakota for Planned Parenthood, correct?
A. There's no -- right.

Page 28

Q. But you mentioned a patient advocacy. What's that?
A. A med patient advocacy --
Q. I may have miss heard you. I'm sorry.
A. There's an office --
Q. Okay.
A. -- in -- in North Dakota.
Q. Okay. Are you involved in that office?
A. I'm not.
Q. What does that office do? Do you know?
A. That office works on -- for instance, the Planned Parenthood and, this is not my area of expertise, but Planned Parenthood and NDSU are working on teaching sex ed, and so that office helps promote that program or give support when needed.
Q. Okay. But your time isn't -- the time that was just gone through isn't committed to any of that, correct?
A. Correct.
Q. And then you're in the -- you're in the Fargo office. As I understand, you come here

Page 29

one day a week?
A. Approximately.
Q. Approximately. And how many days are you in Duluth?
A. One to two times per month.
Q. Okay. And when you're in the Fargo clinic, how many abortions are you performing when you're here on a daily basis? And I'm talking both medical and surgical.
A. And surgical. I don't -- I don't have the -- I can know approximately, but I don't -- I'm sure other people at this table know more about that number than I do.
Q. I don't though.
A. I would -- I would say probably right around 20 to 22.
Q. Okay. Are you the only one that performs the abortion procedure in the Fargo clinic?
A. I'm not -- when I -- physicians provide the abortion. I'm not the only physician.
Q. Okay. There are other physicians that perform abortions?
A. Correct.

Page 30

Q. Okay. I'm not asking just -- do you know how many?
A. Other physicians?
Q. Yeah.
A. There are three of us.
Q. Okay. Are they also located -- do they come from the Minneapolis -- or come from outside the Fargo area and --
A. They -- neither one of them live in North Dakota.
Q. Okay. And that's done once per week, correct? So all three of you come together one day a week or do each one of you come on different days?
A. Different days.
Q. Okay. Do you know how many abortions those other physicians are performing when they come?
A. I would believe it's very similar.
Q. 20 to 22?
A. Yes. And I -- I'm not saying that I know that number exact. That's my estimate.
Q. I'm not trying to lock you into a precise number --
A. Right.

Page 31

Q. -- I'm just trying to get a sense.
A. Okay.
Q. And are you -- what days do you come up?
A. I'm here typically on Wednesdays.
Q. Okay. Except for today, it's a Tuesday. What about the other physicians? Do you know what days they usually --
A. Their schedule is more variable.
Q. Okay. But they come up once a week too, correct?
A. No.
Q. Okay. How often?
A. So typically --
Q. Let me step back. You're coming up once a week, Wednesdays?
A. Not 100 percent, but generally.
Q. And I thought I read something it was like 50, 45 to 50 weeks per year?
A. Correct.
Q. Okay. These other physicians, how often do they come up then? Do they come up --
A. So, our clinic is typically opened one day a week for providing abortion services.
Q. Okay.

Page 32

A. And I'm the main -- I'm here the most.
Q. Okay.
A. And so they -- when they come, I'm not in the clinic, it's on at different day. Some days -- some weeks it does work out -- on occasion, it works out that we have two clinics in the same week but the majority of the time, it's one clinic.
Q. Okay. So those weeks that you're not here, one of these other physicians come in and kind of fill in for you. Is that kinda the way it works?
A. Yes.
Q. I probably should ask you this: Do you perform any type of, you know -- and I've read research upon research upon research and data in this case and, you know, have you done any type of research as far as reproductive -- published any type or articles or --
A. I've never published. I've -- I see patients. I'm not one of the -- the researchers, so I've not been published.
Q. Okay.
A. But I keep up to date on journal --

Page 33

you know, journal articles, that type -- attend conferences and speak with colleagues and speak with people who are researchers.
Q. Sure. Who -- what type of people -- do you have a name of a researcher that you speak to often?
A. No. But -- I mean at conferences. So, for instance, they would give a talk and if I had a question, I'd go up and talk to them afterwards type of thing.
Q. Are those conferences usually done by Planned Parenthood or --
A. There are some Planned Parenthood conferences. The National Abortion Federation has a conference a couple times a year.
Q. Do you go to that regularly?
A. Once a year usually.
Q. And do you -- you usually attend that?
A. Yes.
Q. Okay. Have you ever presented at the National Abortion Federation conference?
A. I have not.
Q. Have you ever been involved in any type of teaching?

Page 34

A. I teach medical students and residents on a regular basis.
Q. Is that -- is that teaching done in the Fargo clinic?
A. No.
Q. Where is that teaching done?
A. That's done at the -- when I work with Planned Parenthood either, essentially, at the Vandalia, the main clinic. It's in St. Paul.
Q. How long have you been doing that?
A. Ever since I started there. So, October of 2010.
Q. Oh, for the last about three years or so?
A. Yeah. And actually, I have worked -- when I was with Midwest Health Center for Women, we had students and residents come through us. And, at -- on occasion, the other two. But, essentially, I've always been involved with students and residents.
(A brief break was taken.)
Q. All right. Dr. Eggleston, we're back on the record. You understand you're still under oath?
A. Yes.

Page 35

Q. Okay. One of the things that I noted is: Under your -- in your CV, that you develop and implement clinical oversight of patient care and medical protocols, ensuring adherence to NAF standards of care. Do you see that?
A. Uh-hum.
Q. Is that the National Abortion Federation?
A. National Abortion Federation.
MR. GAUSTAD: Would you mark this.
(Deposition Exhibit No. 2 was marked for identification.)
Q. Showing you what has been marked as Exhibit Number 2, do you have that in front of you, Dr. Eggleston?
A. Yes.
Q. And it's the -- reads, "2013 Clinical Policy Guidelines, The National Abortion Federation?
A. Correct.
Q. Have you seen this document before?
A. Yes.
Q. Were you involved in preparing any of this?

Page 36

A. No.
Q. And referring back then to your CV, is this the type of standards of care that you're implementing or --
A. Correct.
Q. -- assuring adherences to this? Is this the standard of care that you're referring to in your CV?
A. Yeah. So, these are used as a guideline to help make sure that protocols at individual clinics are meeting the recommendations, policies, and requirements.
Q. Okay. And you use these as guidelines for protocols for the Fargo clinic, correct?
A. Correct.
Q. And, as I understand it, if there's a standard that's issued in these guidelines, that's something that is required to be incorporated within your protocols. Is that your understanding?
A. I can read the definition of the standards.
Q. Where are you referring to?
A. Three. The --

Page 37

Q. What page?
A. I, three I's.
MS. CREPPS: Three little I's.
THE WITNESS: Yeah.
Q. Okay.
A. "Standards are intended to be applied rigidly. They must be followed in virtually all cases. Exceptions will be rare and difficult to justify."
Q. And do your protocols then follow these standards?
A. Yes.
Q. And then the recommendations are quote "steering in nature," correct?
A. Correct.
Q. Is there -- so that gives you some discretion as to whether you're going to follow the recommendation or not?
A. Correct.
Q. Can you recall a recommendation that you haven't followed within this?
A. I would have to go through them individually.
Q. Okay.
A. I do not know the answer.

Q. But are there some? I'm not asking --
A. I'm not aware that we are out- -- I think we are -- we follow the standard of care, and I'm not aware off hand of an exception to that --
Q. Okay. You --
A. -- but I would need to go through them individually to be able to answer that question.
Q. Okay. You use the word "standard of care."
A. Yes.
Q. Is that different than standards that are in this clinic guideline?
A. So, when I say "standard of care," what I'm referring to is what -- any kind of medicine, what is typical for a disease or an illness, you know, for instance pneumonia, there's -- in certain areas of the nation, this is what they do. This is -- doesn't mean you have to do it but the majority of the time, that's what is recommended in the -- and people have agreed to that.
Q. Okay. But a standard would have to

be a standard of care, correct? A standard that's set forth in this National Abortion Federation?
A. Standards of care are not -- this is a very focused document --
Q. Uh-hum.
A. -- on standards related to NAF clinics or to be certified at a NAF clinic.
Q. Okay.
A. Standard of care is a much more broad definition that all of medicine uses.
Q. Sure.
A. And I wouldn't say is written down or defined like that.
Q. Okay. But if -- in -- and I'm just trying to get my mind around because it says, "standards are to be applied rigidly." Do you see that?
A. Uh-hum.
Q. And as I understand, your protocols follow those standards, correct?
A. Yes.
Q. Okay. So with respect to abortion procedures, wouldn't the standards be the standard of care?

A. I suspect, yes.
Q. Okay. And the recommendations are something then that you get to -- you guys have some discretion as to whether this is something we're going to follow or not?
A. Correct.
Q. And options are even more discretionary?
A. Correct.
Q. Okay. Are there any other guidelines or standards that you're referring to here in this adherence to NAF standards of care? Other than what's been marked as Exhibit Number 2?
A. No. That would be it.
Q. And this also deals with the clinical quality standards as well, correct? Exhibit Number 2?
A. Where are you?
Q. I'm looking at your CV. You're saying that part of your job duties with this Fargo clinic is to ensure adherence to NAF standards of care, correct?
A. Correct.
Q. And adherence to clinical quality standards?

A. Yes.
Q. Are -- let me ask the question.
A. Okay.
Q. As I understand, Exhibit Number 2 sets forth the standard -- NAF standards of care, correct?
A. Correct.
Q. Does Exhibit Number 2 also set forth the clinical quality standards?
A. True. I think this is part of that but there's more that goes into clinical quality standards. For instance, we have certain -- when you have a -- he have a hemoglobin machine that checks your blood level and there's -- it comes with expectation that this is how you're going to use it and it's gonna be, you know, evaluated on x many months, so those type of -- so there's more that goes into that.
Q. That's kind of like a manufacturer saying, hey, we can change --
A. True. But --
Q. -- batteries periodically, right?
A. True. But in lab and medicine, those are more important then just changing a battery.
Q. And it was an analogy, but it's a

Page 42

manufactures type of, here you've got this piece of equipment, these are the things you need to do to make sure it works properly?
A. We have a lab that goes through the proper evaluations. So, there is more standards related to that.
Q. Okay. And who does the lab evaluations?
A. We have a physician who's -- is the lab director.
Q. Of the clinic?
A. Yes.
Q. And that's not within the confines of your job duty?
A. Correct.
Q. You don't oversee -- is he your peer then? Or is it somebody that you oversee to make sure that they're meeting these quality standards?
A. More of a peer.
Q. Okay. He's not an outside consultant though, is he? And I refer to him as he, I don't know if it's a he or she?
A. It's a he. And I don't know the specifics of that arrangement, whether he's a

Page 43

consultant or salaried.
Q. Is he one of the physicians that performs the abortions?
A. No.
Q. Okay. And again I -- I'll have to apologize, I've got a few things on my mind, but I think I may have already asked you this: This Exhibit 2, is the NAF standards of care that you refer to in your CV?
A. That's what I was referring to.
Q. And the clinical quality standards you refer to, some may be in Exhibit Number 2 but there's some others that exist because of the -- the labs or equipment that you've got? Things like that.
A. Correct.
MR. GAUSTAD: Would you mark this.
(Deposition Exhibit No. 3 was marked for identification.)
Q. Dr. Eggleston, I'm showing you what's been marked as Deposition Exhibit Number 3. Do you have that in front of you?
A. Yes.
Q. Okay. And it's a, looks like a, four

Page 44

page document. As I understand, this was introduced as an exhibit during the State Court action that it must have occurred about in April of this year. Have you seen this document before?
A. Yes.
Q. Is this something -- the protocols that you prepare as part of your job duties with the clinic --
A. Yes.
Q. -- here in Fargo? Okay. And these protocols then meet the standard of care that's marked as Exhibit 2, correct?
A. Yes.
Q. And I should have asked you this: Other than Exhibit 2, are there other National Abortion Federation standards that you're aware of? Other than these clinical policy guidelines that you used to develop your protocols?
A. No. Not that I'm aware of.
Q. Okay. Exhibit 2 is what you use to prepare your protocols, correct?
A. Correct.
Q. And I didn't -- I don't have an abortion or surgical abortion protocol. This is

Page 45

for your medication abortions, correct? Exhibit Number 3.
A. Correct.
Q. Is there a surgical abortion protocol similar to Exhibit Number 3?
A. Yes.
Q. And you're the one that's charged with preparing these type of protocols like Exhibit Number 3, the surgical protocols?
A. Well, they were first developed prior to me being the medical director.
Q. Before you became medical director?
A. Right.
Q. Okay.
A. And so they were developed by somebody else and they are periodically reviewed and updated.
Q. Okay. And that's your job is to review them to make sure, geez, are we meeting the standard of care that the National Abortion Federation wants us to meet?
A. Right. And usually -- yeah. I'll just say yes.
Q. How often do you go through your protocols?

Page 46

A. We don't have a set schedule.
Q. Generally? I mean sometimes I've got books that I put on the shelf and I never look at again. I presume you look at these?
A. We -- because I attend conferences and involved with, whether it's a NAF conference or Planned Parenthood, we commonly learn new things and update our practice everyday, you know, I mean, regularly. Whether the paperwork is updated, there's definitely a lag and sometimes it -- we may change something and it's lag before the paperwork is updated.
Q. Okay. Is there -- in looking at Exhibit Number 3 -- is there a lag? Is there something in Exhibit Number 3 that's --
A. I've not looked at it since April and since that in detail, so I can read it right now.
Q. Sure.
A. (Reviewing document.)
MR. GAUSTAD: We can go off the record.
(A discussion was held off the record.)
Q. Dr. Eggleston, you understand you're still under oath?

Page 47

A. Correct.
Q. Okay. And you had an opportunity to review Exhibit Number 3?
A. Yes.
Q. Okay. And I think the question was: Is there something in here that is -- is there some procedure that's lag? That's not noted in Exhibit Number 3?
A. So, these are just the -- on the last page, it refers to a follow-up visit. There was something -- hold on a minute, sorry.
Q. You're reading under the conclusion of treatment?
A. And I'm just gonna scratch that. I don't have a comment, it was more of a typo and it's fine. There is a lot of reference in here to ultrasound, it's in a couple different locations and different type of wording is used. So, to make it -- I could make edits to this to make it a little bit more clear, but I feel overall this is accurate.
Q. Give me an example of where you would make an edit to make it more clear?
A. So, on 1B should have gestation no more than 63 days from the first day of the last

Page 48

menstrual period with concordant clinical examination. Conformation by ultrasound may be used routinely and conformation by ultrasound is used routinely. So, I wouldn't say it's an error, but that is what is routine in practice.
Q. Anything else?
A. The same thing. There was another reference to ultrasound. For instance, ultrasound examination will be used routinely.
Q. Where are you reading?
A. Under -- page 2, ultrasound examination.
Q. Okay.
A. So just to make sure that those two are consistent.
Q. But that's what it reads.
A. Right.
Q. It says, "ultrasound will be used to obtain," there shouldn't be a change with that?
A. Correct.
Q. Any other change that you would -- to make it more clear?
A. No. I believe that -- I believe that there was a few changes made to this within the last one year, and I can't pick them out, and I

Page 49

think they were small changes. It's hard for me to concentrate to read through it -- every -- but this, overall --
Q. Do you -- are you having difficulty concentrating? 'Cause if you are, let me know if you need a break or --
A. Well, in general, this document is correct.
Q. Okay. And there is a protocol for surgical procedures similar to what we've got here for medical abortions?
A. Similar, yes.
Q. Okay. And I want to kind of go through and make sure that conceptionally 'cause I don't have that document, and I apologize for that, and I'm trying to utilize your memory as best as you can for the surgical procedure to go through these.
Is there -- in the surgical abortion protocol, is there an eligibility section do you know? This one is pretty detailed as far as medical abortions are concerned. Is there an eligibility --
A. Yes. And I'm not -- I can't comment whether it is as detailed but there is an

Page 50

eligibility. Whether it's separated out under eligibility, I can't remember the layout.
Q. Sure. But there's an eligibility --
A. Correct.
Q. -- component to the surgical abortion?
A. Correct.
Q. Can you tell me what those eligibility components are for a surgical abortion?
A. I can tell you more what they are in practice. I can't verbatim give you our surgical --
Q. And I'm not asking -- that wouldn't be a fair question. I'm just -- generally from your knowledge what the eligibility components are?
A. So, we -- the eligibility that the women desires an abortion, has met -- is not being forced to be there, that the decision is her own, that she's been informed and consented to the procedure, we evaluate -- from an exam perspective, we evaluate their hemoglobin to make sure it's safe, vital signs, general nature, that they are, essentially, have stable vitals and are

Page 51

in good health. To -- essentially, to confirm that it's safe for them to have an outpatient surgical abortion. We use ultrasound to confirm an intrauterine pregnancy and evaluate the gestational age.
Q. How do you determine if they want -- first, that they desire to have an abortion and are not forced? How do you make that assessment?
A. By talking with the woman by herself without other people around and --
Q. Do you do that?
A. I do that at the time -- yes. When I speak with the patient, I confirm that, and it is also done -- that question is asked prior to them seeing me.
Q. And do you ask that question?
A. I'm sorry?
Q. Do you ask the question whether they desire to have an abortion?
A. Yes.
Q. And when does that -- when does that happen?
A. Prior to the abortion.
Q. Are they in the exam room then with you or is there a separate room?

Page 52

A. They're either in the exam room or a separate room.
Q. Generally, are you asking this question in the examination room or in the separate room?
A. Most of the time it is in the exam room.
Q. Who else is in the exam room?
A. Frequently there is another staff member.
Q. Anybody else? And the patient?
A. And the patient.
Q. And you?
A. Uh-hum.
Q. Anybody else?
A. No. Possibly an additional staff member but no other partner or family members are not present.
Q. Why?
A. A variety of reasons. Number one, to confirm this is her decision without feeling pressured by other friends, partners, family; second of all, we want to focus on the patient rather than having extra people that we need to focus on.

Page 53

Q. How do you determine whether this other staff person is going to be in the exam room when you're performing an abortion?
A. It just has to do with timing. So, the other staff member is in the room during the abortion. Whether they are in the room when I -- prior to the abortion, when I'm speaking with the patient.
Q. And then the informed consent, that's by state they have to sign off on something, correct?
A. Uh-hum.
Q. Anything else with the -- that you can recall as far as eligibility for a surgical abortion other than what we just went through? We went through I think seven of them. Is that you're not being forced, informed consent, you do their vital signs, hemoglobin, their general nature of their health.
A. So, similar -- there are medical -- if they have a bleeding disorder, it may or may not be safe for them to have an outpatient procedure so we would do, you know, further evaluation.
Q. You were referring to -- you're

Page 54

pointing to Exhibit Number 3. Is there something in Exhibit Number 3 that would --
A. Well, hemorrhagic --
Q. -- explain why?
A. -- Number 1, a hemorrhagic disorder, or concurrent anticoagulant therapy.
Q. Okay.
A. So that can be a contraindication to surgical or medical abortion.
Q. Okay. Anything else?
A. Very -- a very similar list. If they had a -- if we could not -- like I had told you before, we need to confirm it's an intrauterine pregnancy so that would -- that's in reference to Number 1.A.4.
Number 6 there, an IUD in place. That is a contraindication for medical abortion. That is not a contraindication for a surgical abortion.
Q. Okay.
A. And then Number 7: History of allergy to mifepristone, misoprostol or other prostaglandin. That would be not a contraindication to a surgical abortion.
Q. 6 and 7 are not issues with respect

Page 55

to surgical abortion?
A. Correct.
Q. Okay. And looking at the Counseling, Education, and Informed Consent in Exhibit Number 3.
A. Uh-hum.
Q. Is this generally what you go through with respect to a surgical abortion?
A. Number 1, yes. Number 2, so, that's not -- discussion of non-surgical and suction abortion alteratives; so, essentially when someone has a medical abortion, we also talk about if it does not work, we would need a surgical so would have to educate them both.
Q. Okay.
A. So that would limit the education portion. So we would not talk about the side effects of mife and miso, and so, that whole Number 3 section is not related. Number 4, that would not be discussed. Number 5, we do talk about what to expect afterwards and how long the procedure is. Number 6, we give the patient typically 800 milligrams of Ibuprofen before the procedure, so that's discussed. It's a little different -- the -- when you do a -- when they

Page 56

talk about Number 8, it's about what to expect at home.
Q. Number 7 is probably not something you discuss in a surgical abortion?
A. Only if the patient is receiving misoprostol.
Q. Okay.
A. So some surgical patients do receive misoprostol.
Q. Okay.
A. Number 8, what to expect at home after their -- after the surgical abortion. We review that. And there's not a medication guide, Number 9. Number 10, we're in compliance. I'm not sure how that's necessarily discussed but we're in compliance. And confidentiality is discussed and after care instructions, 24-hour emergency contact is discussed and contraception is discussed.
Q. How about under the Medical History and Physical Examination. Are these, the four items there listed, generally what is the protocol for a surgical abortion as well?
A. Correct. Once again, being consistent with ultrasound is used routinely.

Page 57

Q. Where are you referring?
A. So, Number 4. It says, "ultrasound exam when indicated."
Q. Okay. So when it said indicated it should say ultrasound examination routinely?
A. Yes.
Q. Is what it should read?
A. Right. And the sentence below it does say that.
Q. And so then my next question is: The ultrasound examination, does this, items 1 through 4 under that section -- I don't know why they're missing number two. Two is not missing and it is missing for some reason, but I got the same pages -- is the ultrasound examination -- there must be a misprint or something.
A. Yeah.
Q. Does that kind of set out the ultrasound examination for a surgical abortion as well?
A. Yes. The ultrasound examination is, essentially, the same whether you're having a surgical or a medical abortion.
Q. Okay. So what I'm showing here is marked as Exhibit Number 3 under Ultrasound

Examination, that's the protocol for a surgical abortion as well, correct?
A. Correct. There's just some reference to the mifepristone and misoprostol. Number 4 so -- Number 4 --
Q. With the exception of the -- those medications -- those references to the medication, I can't pronounce them very well so I'm not gonna try, but with respect to those references the rest of it, under the ultrasound section --
A. Correct. I'm sorry.
Q. -- is the same protocol for a surgical abortion?
A. Correct.
Q. And then the Laboratory Evaluation. Is that the same protocol that's used with respect to a surgical abortion as well?
A. Correct.
Q. And Medication and Follow-up. There must be some differences between the medication and the surgical abortion?
A. Yes.
Q. This sets out the follow up for medical abortion, correct? Medication abortion.

A. Correct.
Q. What's the follow up for a surgical abortion?
A. We offer patients a follow-up appointment but the follow-up appointment is not required.
Q. Not required by who?
A. Not required by us. By the clinic.
Q. How often do they come back? How often in your experience does an abortion patient come back?
A. If we have a -- so, on occasion we do recommend it or require it but typically it's not required. Of our surgical patients, I would say less than ten percent come back for a follow-up appointment.
Q. Out of the patients that you see that have either a medication or surgical abortion, how many come back to -- for further care by you?
A. For the follow-up appointment?
Q. Any type of -- any type of care.
A. I believe our follow-up -- our follow-up rate for medical abortion is around 75 percent or so and then the follow up for surgical, it's just a rough guesstimate because I

don't keep track of that, but less than ten percent and then a very rare patient do we see for -- at a later time for whether it's a physical or an IUD placement or other health care. Our clinic is mainly an abortion clinic and so those appointments are few and far between.
Q. When you're doing those examinations, when a woman has an abortion, is that the first time you've met the patient?
A. The day of their abortion is the first time I've met them, yes.
Q. Have they -- do you know do they come in before the abortion to kinda do some prep work and do any of this stuff as far as the desire and things like that?
A. Well, the -- their appointment is a few hours in length and during that time, they're receiving this care but it's all in one day.
Q. How many hours does it take?
A. For an --
Q. Do you know? From the time the woman walks in until the time she walks out.
A. I work at a couple different clinics and some of them quote different hours so I can't

quote you what Red River Women's Clinic tells the patient on the phone, but anywhere from three to six hours would be typical.
Q. Okay. And that's what you think they tell them, what actually happens? Do you know?
A. I think it's very -- very close to that.
Q. So you're between three and six hours -- you're -- the woman walks in, gets this -- all this testing that we just talked about, protocols, the examination, and there's a -- how long is she in a recovery room?
A. The recovery room is usually about 20 minutes.
Q. And then she's free to go?
A. Correct.
Q. Okay. The -- you talked about surgical abortions. You sometimes say we don't require but sometimes we do?
A. Require?
Q. A follow-up examination.
A. Correct.
Q. Tell me why that would be. Give me an example of why they would be required when generally it's not, correct?

Page 62

A. Sure. When we do an abortion, afterwards we examine the tissue, the pregnancy tissue, and if there's any concern whether we're concerned we may not see enough tissue and we want to make sure that she's fine. Or if a patient is in the recovery room having maybe more pain or more bleeding then we like, we would -- we may require that.

Q. But you still let her go?

A. If she's stable, uh-hum.

Q. And percentage wise, how many do you think you require to come back from a surgical abortion?

A. I would say maybe one or two percent and usually it would be because of the tissue examination.

Q. And how many actually follow your directive?

A. Of those? Most. The majority. Because they want to make sure that the pregnancy is ended.

Q. And I probably should have asked this: The -- the Counseling component, the protocol, the education. I understand you do some of that when they get into the exam room,

Page 63

ask them whether they want to have this abortion. Who else does that type of counseling?

A. We have staff that meet individually with the patient and we also have group education in a variety of different ways we interact with the patient. There's also some education going on during the ultrasound, so it's sort of throughout the day.

Q. Is there like a counselor or somebody that's licensed -- licensed counselor on staff that does this -- this work?

A. No. It's more of a patient educator.

Q. Okay. And the -- in the Medical History and Physical Examination, do you do -- are you involved in any of that?

A. The patient completes that prior to meeting with me and then I review that --

Q. Okay.

A. -- prior to and ask questions and review it with the patient, essentially.

Q. Anybody else involved in this Medical History and Physical Examination we're talking about?

A. There -- when somebody makes an appointment, we ask them if they have a bleeding

Page 64

disorder and so those things can get flagged ahead of time or brought to my attention ahead of time, and so on occasion, it's brought to my attention ahead of time.

Q. And who does the ultrasound examination? Are you involved in that?

A. I'm -- occasionally I am when it's a -- if it's a difficult or there's a question, that type of thing.

Q. Would you have a staff person that takes care of that?

A. Correct.

Q. Is there -- 'cause my niece is thinking about becoming a sonographer. Is that the correct term that performs ultrasounds?

A. Lots of people perform ultrasounds.

Q. Okay. You don't have to have a particular license or --

A. Correct.

Q. Okay. Do you have to have a particular degree in anything?

A. No. Not that I'm aware of.

Q. All right. Well, I'm gonna tell her maybe she doesn't have to go on to school. The lab evaluations, who -- are you involved in --

Page 65

A. What lab evaluations are you referring to?

Q. Well, under your protocol here?

A. Like the hemoglobin?

Q. Any type of --

A. So, I review -- I review the lab results prior to performing an abortion.

Q. Okay. And who actually takes the or does the blood draw and things like this? Is there somebody on staff that does that?

A. Yes.

Q. Do they have any particular -- is there an RN or somebody like that?

A. I don't know that -- she is licensed to do that. Whether it's a lab technician or phlebotomist, I can't quote what -- but she has training.

Q. She has some licensing or training in doing the lab work that's required -- that's necessary?

A. Right. And sometimes RNs can do it also, and I can do it. So --

Q. How many RNs do you have on staff? Do you know?

A. Quite a few. I don't -- I don't know

Page 66

the number.
Q. During this counseling, does some women that come in decide not to have an abortion?
A. True.
Q. What's the percentage of that?
A. Less than five percent.
Q. Do you know why?
A. A variety of reasons.
Q. Can you give me some examples of why.
A. They may decide after the ultrasound that maybe they thought they were earlier and they're father then they thought they were, they may have been somewhat undecided and came in and decided that they needed more time, or may have just changed their mind, and we also, maybe someone was forcing them to have an abortion and we talked with them and asked, you know, do you want to be -- do you want to have an abortion and they said no someone is forcing me to be here, we would send those patients home.
Q. Do you -- I mean, when you do this counseling, I presume you take records and take notes of the communications that occur, correct?
A. Not verbatim.

Page 67

Q. Sure.
A. But the -- there's a form that the patients complete and if there's anything unusual or outstanding, we would write that down, yes.
Q. Okay. But with respect to these protocols, as you go through, you must keep some record of yes, we went through this protocol and this is how we did it and this was the result of what we found?
A. What are you in reference -- referencing to?
Q. Well, I'm trying to, you know, for example, you go through your protocols. It says Counseling, Education, and Informed Consent --
A. Yes.
Q. -- right? And so I -- what I'm trying to get a sense of: You must keep some records of we went through this protocol with this particular patient?
A. Correct. We have -- for instance, when they sign the consent for a surgical or medical abortion, that is laid out and that's reviewed with them and then they sign it and I sign it.
Q. Okay. I just want to briefly just

Page 68

talk about, because I'm not that familiar with the procedure itself, the medication procedure, just -- if you could briefly describe to me medication abortion?
A. So --
Q. I don't need you to go through each of the protocols. I'm just tying to get a sense of what happens.
A. So day one they take the mifepristone and that's the pill that stops the pregnancy from growing. 24 to 48 hours later, they take the misoprostol which causes the pregnancy to expel. That's when they have the heavy bleeding, and we review when to call and what's normal and what's not normal. There's antibiotics given whether it's before, after, during that's in flux a little bit, and then a follow-up appointment is made to confirm that the pregnancy is passed and that is done usually anywhere from one to three weeks --
Q. Is that some sort of --
A. -- after.
Q. -- vaginal examination then?
A. It is a vaginal ultrasound.
Q. Okay. Is it the vaginal ultrasound

Page 69

that you use? Maybe I misheard you.
A. We use a vaginal ultrasound for the follow-up on medication abortion I would say 99 percent of the time.
Q. And so they take the first medication at your facility the day they come in?
A. Correct.
Q. And they take the second medication 24 hours later?
A. 24 to 48 hours later.
Q. Okay. And do they then call you? Is that kind of the procedure? Hey, I have expelled this unborn child. Is that what happens?
A. No. We tell them what to expect as far as bleeding and cramping. And if anything is unusual, then they should contact us and they have our number, 24 contact, you know, that kind of thing.
Q. Okay. So the next time that you -- unless there's something that they -- happens during that expelling, the next time you see them is that follow-up visit?
A. Correct.
Q. Assuming that they show up?
A. Correct.

Page 70

Q. Surgical abortion. Walk me through that process.
A. So --
Q. Not the -- I don't need the protocol. Just when you're in that examination room.
A. So, the procedure itself takes usually about five to ten minutes. After my review of their history and discussion and asking all -- making sure that they're confident in their decision, the next step is a pelvic exam. Then, speculum is placed in the vagina to view the cervix, local anesthetic is given around the cervix, and the cervix is dilated and the pregnancy is removed by, it's called, suction, and the whole procedure is usually five to ten minutes and then it's confirmed that -- the equipment is taken out and confirmed that the pregnancy has been removed.
Q. And then they go into the exam room -- do the medication abortions, do they go into a recovery room?
A. The way our facility works, they do actually go to the recovery room to kind of get a final -- antibiotics, contraceptive prescriptions, that's where those are given at

Page 71

that point. So, they are in the recovery room but it could easily have been done in a different room. It just logistically works out.
Q. Just -- this just happens to be the room we use for the --
A. Correct.
Q. So there -- the surgical abortion takes about five to ten minutes and that's for the -- is that for the entire time they're in that examination room with you?
A. It's probably closer to 15 minutes would be typical.
Q. So anywhere from 5 to 15 minutes?
A. That they're --
Q. Is 15 minutes the top end?
A. The 15 -- I'm in the room with them, I would say very close to 15 minutes.
Q. Okay.
A. The procedure, itself, is five to ten.
Q. Okay. And then once they're done with the procedure, itself, do you stay in the room with them or do you just move on to the next patient?
A. We have a staff member stay in with

Page 72

them. I make sure they're stable before I leave and they're helped to get dressed and brought to the recovery room.
Q. Okay. And so -- but you're -- once the procedure is done, then you leave the examination room; is that fair?
A. Yes.
Q. Do you ever see them again unless they come back?
A. I frequently -- the way our clinic is set up, the recovery room is very convenient so -- and I'm walking by it throughout the day, so I'm frequently popping my head in and probably, most of the time, end up communicating with the patient again just how are you doing or see them in the hallway.
Q. And how long is that interchange usually per patient in the recovery room?
A. So, they're in the recovery room with a nurse for 20 minutes.
Q. Okay.
A. And then just a very brief -- unless there's a concern, then I'm called to the recovery room.
Q. How often does that happen?

Page 73

A. Not very often at all. Typically, it's more like this patient needs a work note can you sign this work note or, you know, that type of --
Q. What's a work note?
A. For instance, if they -- were -- miss that day of work --
Q. Oh.
A. -- and needed doctor verification.
Q. Okay. It's not something internal with you? They just had to take time off?
A. Right.
Q. Okay.
MR. GAUSTAD: I've finished off quite a bit of water here. I need to -- I need to take a break to use the restroom.
MS. CREPPS: No. No. It's good. Okay. How long would you like?
MR. GAUSTAD: Doesn't take me very long to use the restroom. Maybe five or ten minutes?
MS. CREPPS: Okay.
(A brief break was taken.)
Q. All right. Dr. Eggleston, you understand you're still under oath?

Page 74

A. Yes.
Q. And am I pronouncing your name right? Eggleston?
A. Yes.
Q. If you could pull out Exhibit Number 1, it should be your declaration. Do you have that in front -- yeah, Exhibit Number 1. Do you have that?
A. Yes.
Q. Okay. And as I understand, and I'm looking at paragraph 8, where it says, "the protocols include an ultrasound for all abortion patients, which is important for dating the pregnancy and determining where the pregnancy is located within the uterus." And those are the protocols we just went through --
A. Correct.
Q. -- correct? And you go on to say, "A physician needs to confirm an intrauterine pregnancy and gestational age in order to safely provide an abortion." Do you see that?
A. Yes.
Q. Okay. And you use the term "pregnancy." What do you mean by that? In this declaration? You say, "determining where the

Page 75

pregnancy is located." What do you mean when you use the word "pregnancy"?
A. The gestational sac where it is located to confirm it's not an atopic or --
Q. What do you mean "it"? What do you mean by "where it is located"? What are you referring to?
A. So the --the sac, the gestational sac, is a fluid filled sac and the -- depending on gestational age, the embryo or fetus is inside that sac.
Q. Okay.
A. So it depends on what we're looking -- depending on the gestational age, is what we're looking at to confirm where the pregnancy is.
Q. Okay. And that's the purpose of the ultrasound, right? You need to find out that it's not -- that it's a normal intrauterine pregnancy and you need to know the age of this unborn child, correct?
A. We need to know the location -- yes, of the pregnancy and the gestational age.
Q. And those are the two things that you need to know in order to perform an abortion,

Page 76

right? From the ultrasound?
A. Correct. That's the point of the ultrasound.
Q. Precisely. Okay. And as I understand, the gestational age -- if it's less then five weeks lmp -- am I saying that right?
A. Yes.
Q. They're not eligible for an abortion?
A. Correct.
Q. Okay. And --
A. That's not a hard-and-fast rule, but in general, that is correct.
Q. Okay. And in general, what's the latest that the Fargo clinic performs an abortion as far as gestational age?
A. We go through 16 weeks.
Q. And so as long as it's an intrauterine pregnancy and it's within those perimeters, the gestational age perimeters, they're eligible for an abortion aside from the health and the other aspects?
A. The only exception to that is at the beginning because five weeks we may or may not see a gestational sac. We may or may not see a yoke sac. So, some women are eligible to have an

Page 77

abortion as early as five weeks but it depends on what we see on ultrasound.
Q. Sure. And depending on what you see on ultrasound, as long as it's an intrauterine pregnancy and you, in your medical judgement, has determined the gestational age fits within those perimeters, they're eligible for an abortion?
A. Correct.
Q. And one of the by-products is -- of the ultrasound is also you detect a heartbeat too, correct?
A. If we see an embryo or fetus, we evaluate whether we see cardiac motion.
Q. But that's not necessary to determine whether they're eligible for an abortion, correct?
A. It is necessary --
Q. Go ahead. I'm sorry. I didn't mean to interrupt.
A. Can you ask me the question again?
Q. Yeah. The detection of a heartbeat through the ultrasound, that doesn't -- does that affect where the -- whether it's an intrauterine pregnancy or not?
A. If we are -- if we are questioning

what we are seeing on the ultrasound, the cardiac motion can help us to confirm that it is an intrauterine pregnancy.

Q. Okay. And does the detection of a heartbeat, does that affect the gestational age? That component of --

A. It is typically seen about six weeks.

Q. Okay.

A. So when we determine gestational age, we can do different types of measurements, and if that's noted, then that can -- can influence in those very early gestational age -- that can influence whether we would call it five weeks or six weeks.

MR. GAUSTAD: Would you mark this for me.

(Deposition Exhibit No. 4 was marked for identification.)

Q. Dr. Eggleston, I'm showing you what has been marked as Deposition Exhibit Number 4. Do you have that in front of you?

A. Yes.

Q. And the last page of that, is that your signature?

A. Yes.

Q. Okay. And in turning to paragraph 10, of Exhibit Number 4, you made reference, "In early pregnancy, the location and gestational age of the embryo, as well as the presence or absence of cardiac activity is usually determined by vaginal ultrasound, rather than by any other method." Do you see that?

A. Yes.

Q. What is the percentage of vaginal ultrasound versus the other method of ultrasound that you maybe use? Do you know?

A. I don't know.

Q. Usually? I'm just trying to figure out --

A. In early pregnancy, that's what it's referring to.

Q. Okay.

A. It is used the majority of the time.

Q. More then 50 percent?

A. Well more, yes.

Q. More then 75 percent?

A. Yes.

Q. Is it used 100 percent of the time?

A. In early pregnancy -- no. It is not used 100 percent of the time.

Q. When you say "early pregnancy," what do you mean?

A. Well, I didn't define that in this. But, at the -- we were talking about cardiac motion at six weeks. At that gestational age, vaginal ultrasound, I suspect, is used 99 percent.

Q. Do you know or are you guessing?

A. I'm using my experience.

Q. And so the early pregnancy, you're referring to early pregnancy as somebody that comes in at a gestational age of six weeks? Six weeks lmp?

A. Six weeks lmp or earlier. I -- very close to 100 percent are going to be having a vaginal ultrasound done.

Q. Okay. When is it that you're beyond the early pregnancy period? I'm trying to figure out what you -- you said you didn't define it, so I'm trying to get you to tell me what you meant by early pregnancy? The timeline here. I get it's six weeks --

A. Everybody has a different opinion of what an early pregnancy --

Q. But you said that in your

declaration --

A. Yeah.

Q. -- doctor, so I want you to tell me what you meant by early pregnancy?

A. So I would say six weeks.

Q. Okay. And then anything after that six weeks is no longer an early pregnancy as you've defined it?

A. In reference to vaginal ultrasound, early pregnancy is right around six weeks.

Q. Okay.

A. But early pregnancy in other references, would be much more broad. For instance, first trimester.

Q. When you're using it in reference to this paragraph 10, what did you mean by early pregnancy, Dr. Eggleston?

A. I would say somewhere around six weeks gestational age.

Q. And so under this early pregnancy as you've just defined, it's 99 percent of the time we're using the vaginal ultrasound?

A. Correct.

Q. And how is it that you know they're at six weeks lmp before you do the ultrasound?

Page 82

A. Number one, we ask them their lmp when we make the appointment. We would hate for someone to drive and be 18 weeks, for instance. We need to make sure that we're letting them know our gestational age limits.
Q. Okay.
A. So, we have an idea of their lmp, gestational age. Then, the patient has the -- the typical patient, will have an ultrasound and that is initially done abdominally, and if we do not see -- we cannot confirm those things we've already discussed, then they would have a vaginal ultrasound.
Q. Okay. So even in early pregnancy, starts out with the abdominal. Is that what you're saying?
A. In most circumstances, yes.
Q. Okay. And then if you -- so what then prompts you to go to the next step and say geez, now we need to do a vaginal ultrasound?
A. Because of determining the location of the pregnancy and confirming it's an intrauterine pregnancy.
Q. Okay. Because the abdominal ultrasound doesn't confirm those or doesn't --

Page 83

A. It is much less clear. And so, at that gestational age, it's frequent that we don't see adequate visualization of the gestational sac or the yoke sac, so that's why we need to do vaginal.
Q. Okay. So you, as I understand then, you are, even in the early pregnancy, you're gonna start out with an abdominal ultrasound, correct?
A. Correct.
Q. And if you're able to locate the location and the gestational age on that, that's good enough? You don't -- you don't have to go on and do the vaginal ultrasound, right?
A. If we're able to confirm that it's an intrauterine pregnancy and confirm the gestational age by abdominal, we do not do a transvaginal ultrasound.
Q. So in those instances, well, let's start out with the early pregnancy. What's the percentage of just the abdominal ultrasound being -- whether you just -- you're able to figure out the location and the gestational age just the abdominal, in your experience?
A. So, six weeks -- that's what you're

Page 84

referring to?
Q. Early pregnancy. Yup.
A. I suspect 90 percent would need a vaginal.
Q. And how about for those that are beyond this early pregnancy stage?
A. Maybe 20 percent would require vaginal.
Q. In your experience?
A. In my experience.
Q. Okay. And, as I understand then, that if you don't detect cardiac activity, you inform the patient of that, correct?
A. If --
Q. Through this ultrasound process?
A. Sometimes we don't see the embryo. And so if we don't see the embryo, we're not going to see the cardiac motion. So in that instance, we would not necessarily inform the patient, but if the patient is eight weeks gestational age and there's an empty sac or an embryo without cardiac motion, we inform the patient of what the ultrasound find is.
Q. And why do you do that?
A. Because it's important to communicate

Page 85

with the patient. In this particular -- what we're discussing is likely a miscarriage, and so I want to make sure the patient is aware of that. It also gives them more options for more care.
Q. Getting back to the vaginal ultrasound, is that something that the National Abortion Federation -- is that required under these policy guidelines that are marked as Exhibit Number 2? Do you know?
A. I don't believe it is required, but I would have to --
Q. Probably wrong word. It should be: Is it a standard of care under their policy guidelines, right?
A. I -- so what's the question?
Q. Is a vaginal ultrasound, is that a standard set forth in --
A. I do not believe so.
Q. I'm looking for Exhibit Number 1, Dr. Eggleston. We can probably keep 1 and 4 close by. Exhibit Number 1, I'm looking at paragraph 11. You've got that in front of you?
A. Yes.
Q. Okay. And in that paragraph, you define viability "as the ability" and there's

Page 86

some words missing "to live outside the mother's womb albeit with artificial aid." Do you see that?
A. Yes.
Q. Okay. And then you cite to the Century Code Statute, right?
A. Yes.
Q. And I want to make sure because --
MR. GAUSTAD: Would you mark that.
(Deposition Exhibit No. 5 was marked for identification.)
Q. Dr. Eggleston, I'm showing you what's been marked as Exhibit Number 5.
A. Okay.
Q. You have that in front of you?
A. Yes.
Q. And I'll represent to you that this is the Century Code Statute that you've cited in your declaration.
A. Okay.
Q. 14-02.1-02.
A. Okay.
Q. And it's on page 3 subsection 14. You see that? It says "Viable means the ability

Page 87

of an unborn child to live outside the mother's womb, albeit with artificial aid."
A. Yes.
Q. Do -- is that -- I presume that's the same statute you are referring to in your declaration, correct?
A. Yes.
Q. Okay.
MR. GAUSTAD: Would you mark this also.
(Deposition Exhibit No. 6 was marked for identification.)
Q. And I'll represent to you that -- what's been marked, and I should have said this in advance, as Exhibit 5 is the Statute as through the 2011 session. And I just want to get clarity that kinda is to the current statute that exists.
You've got Exhibit Number 6 in front of you?
A. 6. Yeah.
Q. And I'll represent to you that is the same statute except it's through the 2013 session for North Dakota. And here, it's on page 3, again, and it defines -- under subsection 19 it

Page 88

defines viable and it has the same definition as the 2011 that you're referring to; is that correct?
A. Yes.
Q. Okay. In looking at paragraph number 11, again, Dr. Eggleston, after reciting the definition of -- you say viability but I think it's the definition viable, correct?
A. True. Yes.
Q. The statute says viable --
A. Viable.
Q. -- and you use the term viability.
A. Correct.
Q. Okay. And in the second sentence of paragraph 11 you say, "A fetus does not become viable until approximately twenty-four weeks lmp." Do you see that?
A. Yes.
Q. The term "viable" in that sentence, you're referring to that statutory definition, correct? When you say "fetus does not become viable," are you using the same definition that's in the statutes?
A. Correct.
Q. And, as I understand then, your

Page 89

opinion as to -- is the second sentence your opinion? "The fetus does not become viable until approximately twenty-four weeks lmp?
A. That's my opinion and my medical knowledge, yes.
Q. Okay. And that's based upon -- your medical knowledge based upon applying the definition of viable in the statutes, correct?
A. Correct.
Q. And I'm showing you it's Exhibit Number 4, in particular the paragraph 9. Do you see that?
A. Yes.
Q. And in there you use -- you say, "The presence of cardiac activity is an important indicator that a pregnancy retains potential for viability." Do you see that?
A. Uh-hum.
Q. The term "viability" when you use that in your declaration, is that the same as viable that's set out in the statues?
A. No.
Q. What is -- what do you mean by viability in that sentence then?
A. So, when we evaluate for cardiac

Page 90

motion, we're evaluating whether it is -- the term used there is a "viable pregnancy," that without intervention, it would continue -- the pregnancy would continue. So we -- the medical term for instance a "nonviable pregnancy" if the woman didn't have -- if the pregnancy didn't have the cardiac motion but you would expect it at eight weeks, then we would inform the woman that she has a nonviable pregnancy.

Q. And what would nonviable pregnancy -- would it be viable as the statute is defined it? Do you know? Is -- you said a non- -- if you don't have detectible cardiac activity, it's a nonviable pregnancy, correct?

A. If -- if the cardiac activity is expected at that gestational age and it is not present, then that is most likely a nonviable pregnancy, and I would have a discussion about that with the -- with the woman.

Q. Okay. And under those set of circumstances then, when it's a nonviable pregnancy, does it then have the ability to live outside the mother's womb albeit with artifical aid?

A. No.

Page 91

Q. So, then it would not be viable as the statutes defined it?

A. Correct.

Q. And then when it does have the presence of cardiac activity --

A. Uh-hum.

Q. -- then there is a potential for viability, correct?

A. No. That would be a viable pregnancy.

Q. Okay. And I'm referring to paragraph 9 of Exhibit Number 4. Where you say, "The presence of cardiac activity is an important indictor that a pregnancy retains the potential for viability."

A. Yes.

Q. Okay.

A. That's what it says.

Q. It does. And I'm trying to get a sense as to what you meant by then viability in that sentence?

A. So, viable pregnancy versus nonviable pregnancy means that the pregnancy will continue or at this point is continuing to grow and develop, versus a nonviable pregnancy is not

Page 92

continuing to grow and develop as expected.

Q. Okay.

A. And then -- yeah.

Q. And so the presence of cardiac activity may or may not then be viable as defined in the statute. Is that --

A. Right. When I'm referencing in Number 9, what I'm referencing is whether this is a viable pregnancy or nonviable pregnancy at that gestational age.

Q. And when you say viable pregnancy, you mean it will continue -- the unborn child will continue to grow?

A. The pregnancy will, without intervention, the pregnancy at this point is -- appears to be continuing to grow, a viable pregnancy.

Q. Okay. But that doesn't mean it's necessarily viable as the statute defines it?

A. Correct. Viable is used in different --

Q. Context?

A. Context, yes.

Q. Now turning to your opinion, and if you've got Exhibit Number 1 in front of you, do

Page 93

you have that in front of you?

A. Yep.

Q. And it's paragraph 11. Do you have that?

A. Number 11?

Q. Yes.

A. Yes.

Q. Okay. As I understand, your opinion is that a viability doesn't commence until approximately 24 weeks lmp, correct?

A. A fetus does not become viable until approximately 24 weeks lmp.

Q. In that context, you're using the definition of viable in the statute?

A. Correct.

Q. Okay. What attributes or characteristics does an unborn child have that is viable?

A. So --

Q. As your -- in your opinion?

A. So with medical intervention, at 24 weeks lmp, medical intervention is needed but the fetus would be able to survive after delivery.

Q. How long do they have to survive?

A. How long -- I don't -- I'm not sure

Page 94

your question.
Q. Well, you said they have to survive after delivery. How long? What's the length of time they have to survive to be viable?
A. Is -- I'm not sure if you're asking me from a medical/legal perspective or what --
Q. I'm asking from based upon your opinion that you say they're viable at 24 weeks.
A. So, the majority of -- well, most -- I'm not sure -- I'm not an expert at preterm delivery. If a woman was pregnant at 24 weeks and went into labor, the physician would, on that -- based on that individual pregnancy and her history, they would decide an individual nature how likely is it that this fetus can survive outside after delivery and use medical interventions to assist that.
Q. Okay. And, as I understand, this was -- this opinion that you rendered was based upon a reasonable degree of medical certainty, correct?
A. Correct.
Q. And so based upon that, Dr. Eggleston, I'm asking: How long does that fetus, for it to be viable, as you've opined here, at 24

Page 95

weeks, how long does that fetus have to survive after birth to be viable? Is it days? Years? What it is?
A. I -- it would be -- it could be -- unfortunately, it could be only minutes. But, there is a reasonable -- I mean, medical interventions have been successful that it's much longer. Hopefully a lifetime.
Q. Do you know what type of characteristics a viable child has? Do they have circulatory, respiratory functions? Does it -- viable --
A. Yeah.
Q. -- as you've defined it? Respiratory?
A. Yes.
Q. Circulatory function?
A. Yes.
Q. Does it have brain function?
A. Yes.
Q. How about pain? Is it capable of feeling pain?
A. The studies that I'm aware of, are -- the most recent studies that I've looked at, 26 to 28 weeks --

Page 96

Q. That's when a viable fetus or unborn child has to -- I'm asking what characteristics and you said a viable --
A. So with medical intervention, that the circulatory system is keeping the -- the brain alive, the heart alive, the lungs working, the kidneys, the liver, there has to be circulation to keep those organs working and alive.
Q. Okay. So all of those body functions need to -- those characteristics exist for a viable child, correct?
A. Correct.
Q. As you've defined it here --
A. Correct.
Q. -- at 24 weeks lmp, a viable unborn child of 24 weeks lmp, has a circulatory function, correct?
A. Yeah. I -- my --
Q. And I'm not asking about the -- I understand that it may require some artificial aid to -- but with that artificial aid, it would have circulatory function, correct?
A. That's my understanding.
Q. And is that your understanding when

Page 97

you issued this opinion, correct?
A. So my opinion is not based on my personal medical knowledge. I do not take care of kids in the neonate. Okay? This statement is in reference to my medical knowledge of what I read, of what I -- in the medical literature.
Q. Okay. So you don't know what functions -- your own personal experience, you don't know what functions a viable unborn child has to have? Unborn child has to have to be viable?
A. Other than some basic functions, that's all I can comment on.
Q. What basic functions does a viable unborn child have to have?
A. Circulation, oxygen --
Q. Respiratory, right?
A. Right. With medical intervention frequently.
Q. Anything else? Pain? Does a viable unborn child -- is it capable of feeling pain?
A. I have no medical knowledge.
Q. Don't know?
A. Don't know.
Q. Any other characteristics or

Page 98

functions or attributes of a viable unborn child?
A. I don't take care of those patients.
Q. Don't know?
A. So I don't feel comfortable answering.
Q. If you don't know, that's fine. Just don't know?
A. Personally, I don't know what you're asking.
Q. Fair.
A. And partially, I don't know the answer to that combination.
Q. This is where we get into if you don't understand, let me know. Okay? My -- what I'm trying to get at is: What type of characteristics, based upon your understanding, your knowledge, does a viable unborn child have? And you talked about brain function.
A. Yeah. I don't know the answer to that question.
Q. Okay. And what did you rely upon then to make your determination in paragraph 11 that viability commences at 24 weeks lmp?
A. Well, the literature and -- I'm involved in abortion care so you read lots of

Page 99

articles about limits and different state limits and frequently those articles are referencing what is the current medical expectation of fetal viability.
Q. Okay.
A. So --
Q. Is there -- is it a medical judgement call as to whether an unborn child is viable or not?
A. The physician would make that determination case by case. But in general, it is approximately 24 weeks lmp, my understanding.
Q. Does it take some medical judgement to determine whether or not a child is viable or not?
A. Yes.
Q. Okay. Is -- do you know whether -- if whether an unborn child is viable or not, does it actually have to survive?
A. I don't know.
Q. And in your paragraph 11, you pulled out the statute as far as what viable is and you say uses with artificial aid, right?
A. Uh-hum.
Q. Is there a time period that, you

Page 100

know, artificial aid -- if you're continuing to apply artifical aid, this unborn child won't be viable no matter how long -- as long as you keep the brain function going and the circulatory function going and the respiratory function going with artificial aid, it could be years. It is still a viable unborn child?
A. I don't know -- I don't know that answer.
MR. GAUSTAD: Would you mark this.
(Deposition Exhibit No. 7 was marked for identification.)
Q. Dr. Eggleston, I'm showing you what's been marked as Exhibit Number 7.
A. Okay.
Q. Have you seen this document before?
A. No.
Q. Then I won't ask you anything because you don't know anything about it, do you? You don't know anything about what's contained in Exhibit Number 7 if you've never reviewed it?
A. Right. I could review it now, but no, I've not reviewed it prior to this or not seen it.

Page 101

Q. Why don't you go ahead and review it.
A. Okay. Well --
Q. Go ahead.
A. Okay.
MS. CREPPS: We might as well go off the record.
MR. GAUSTAD: Sure.
MS. CREPPS: It will probably be 10 or 15 minutes.
(A brief break was taken.)
Q. Dr. Eggleston, you understand you're still under oath?
A. Yes.
Q. Have you had an opportunity to review Exhibit Number 7? Did you want --
A. Initial -- yes.
Q. Okay. And do you have any dispute with the findings that were made in this article?
A. I don't have anything -- no.
Q. Turning to Exhibit Number 1, Dr. Eggleston, it's paragraph 13. Do you have that in front of you?
A. Yes.
Q. Okay. You've already testified to this that abortions are performed only one day

Page 102

per week at the Fargo clinic, and "The bill will effectively limit women's ability to obtain an abortion to a single day during their pregnancy's fifth week." Do you see that?

A. Yes.

Q. Okay. And the bill you're referring to is the, I think, it's H.B. 1456, or Heartbeat Detection Statute?

A. Yes. That seems right.

Q. There's nothing in the statute though that precludes the clinic from being open -- doing abortions more then one day a week, is there?

A. Correct.

Q. And then turning to paragraph 14 of Exhibit Number 1. You made reference to, "Most of the women who currently receive abortions from the clinic at or after six weeks would probably be unable to schedule their abortions early enough to avoid the ban," due to a combination of a number of factors listed -- various -- it looks like about five factors here.

A. Uh-hum.

Q. Is this based -- I mean, is there some data that the clinic retains or you retain?

Page 103

Where would I look to find this type of data? Is there medical records or something like that that says this is the reasons why women wouldn't be able to get an abortion six weeks or later?

A. I think you could look at the clinics statistics on the percentage of patients we see that are earlier then six weeks.

Q. So they -- the clinic's stats?

A. Right. Stats.

Q. That would -- that's what you're relying upon for these statements?

A. No. That would be one factor.

Q. Okay. What are the other factors?

A. Talking to patients, and having knowledge of their -- difficult traveling, the work, like I had mentioned before, the notes for work, work release, medical, taking time off work.

Patients frequently share, you know, I have to be back by this time, I couldn't come last week because of this, you know, they share those experiences with us, so this is based on my experience, the stats, the -- the waiting, and delays imposed by the laws.

Q. The discussions you have with the

Page 104

patients, is that something you record then in some sort of record to say geez, the patient told me this, I should write this down in some fashion?

A. It may be when -- the patient completes some forms about why they're having an abortion, it may be in that, written down. But, when I have that discussion, I personally do not write that down.

Q. Okay. So to the extent that the patient completes that information, that would be with the medical records for that particular patient?

A. Correct. Sometimes we may elaborate and write additional notes.

Q. Okay. That's where I'd be looking for that type -- this type of information? Those medical records? Give me an example --

A. What type of information?

Q. The information about these factors that you've elicited in paragraph 14.

A. I wouldn't -- I think it could be in there on occasion but these are discussions we're having with women on the phone when we're making their appointment. I'm not on the phone, but I

Page 105

overhear. I hear patient concerns or staff discussing how can they get here and with my own discussion with the patients.

Q. What delays are you referring to -- you're referring to delays imposed by laws of the State of North Dakota. What are you referring to there?

A. They need to call and receive the information, the 24 hour reading at least 24 hours prior to the abortion.

Q. And then turning to paragraph 15, you made several references to factors women rely upon or utilize in deciding whether or not to have an abortion, and you've listed a number of them.

A. (Witness nods head.)

Q. Where would I look to -- I mean, I can read it on your Affidavit but is there somewhere else that would, a list of this information, medical records or the information the patient gives you?

A. When I have discussions with a patient, that frequently comes up, but there is a form that they complete and they may or may list their reasons for having an abortion.

Page 106

Also, I believe there's been some studies, I can't specifically mention them, but in -- seems to me I remember being at a conference and they discussed reasons why women had abortions and it was an actual study about it, but I don't know that study and can't name the conference. But in general, that type of material is discussed.

Q. Okay. So I'd look at these forms that the women fill out? May contain this type of information?

A. It may contain this.

Q. And then some studies that are out there is what you're relying upon to make this type of --

A. In my experience talking with women.

Q. Okay. Has there been a study done of this Fargo clinic?

A. Not that I'm aware of.

Q. Okay. And paragraph 14 and 15, really are directed at, as I understand, the harm that this statute would have on women, the patients for the clinic. Is -- your position on it anyway, is to the harm that this statue would have on women generally?

Page 107

A. So, what's the question?

Q. Poorly, poorly worded question. I'm sorry. What I'm trying to get at as: As I understand, paragraph 14 and 15 -- ah, strike that.

Do you know what -- I mean you've listed the factors as to why women have an abortion, do you know what factors women consider when they don't have an abortion? Or they come into your clinic and -- you've listed them as to why they'd have an abortion.

A. Uh-hum. You mean for the patients who come in and then leave?

Q. Yes.

A. They, I think we went over that earlier, but they changed their mind for a variety of reasons. I don't know that -- I think there's similar reasons and they may change their mind, maybe they were undecided and they changed their mind and that's the time -- that's when you have to make a decision is on that day, at least initially, women make a decision not to go ahead with an abortion, they may come back but there's some discussion and maybe they thought about something that they hadn't thought of before.

Page 108

Q. And do you have -- I mean, you listed the reasons why. Do you -- can you -- in your experience, in your discussion with those women that don't go forward with the abortion, do they describe to you why?

A. Some women may just leave and so we wouldn't know, some women may have a discussion with the front desk, some may have a discussion with me. And, typically, if they meet with me and I'm reviewing their history and ask them if they're confident in their decision, if they say no, I -- then we have discussion but I also document that.

Q. Okay. That would be in the medical records?

A. Yes. If I -- if at that point -- yes.

Q. Outside of those -- I resume you've talked with folks within the Fargo Clinic about this case?

A. Tammi Kromenaker, yes.

Q. And you've talked to others within the clinic about this case? I'm not asking for names. Just generally? Or not?

A. No.

Page 109

Q. How about -- and not your attorneys, have you talked to others outside of the clinic about this case?

A. Yes. Many people know I'm here today 'cause it changed my scheduled and a lot of people were involved.

Q. And I want to thank you for that --

A. That's fine.

Q. -- I apologize for having to reschedule, and I do appreciate it. But aside from having to reschedule, have you talked to anybody outside of the clinic about this case? And I'm not talking about your attorneys.

A. No. I've not talked to anyone.

Q. Looking at Exhibit Number 4, do you have it in front of you?

A. Yes.

Q. Okay. In paragraph 9, you say that, "no detectible cardiac activity after seven weeks can be a sign of a nonviable pregnancy or miscarriage." Do you see that?

A. Yes.

Q. And then you tell the patient or you inform them, as I understand it, about the fact that you can't locate a cardiac activity?

Page 110

A. Correct.
Q. Okay. And you're doing that, as I understand, because they may go out and find their own primary care physician, they may wait for the miscarriage, may not be -- the abortion is not necessary really, right?
A. Correct.
Q. What type of reaction do women have when they hear that there's no heartbeat?
A. They -- I think they're most interested in knowing, you know, what do I do from here, you know. So our discussion focuses on medical options. I think for some women, they feel a sense of relief. They don't have to go through with an abortion procedure.
Q. Why do they feel relief?
A. Well, they don't have to do anything, they can go home. They may be afraid of pain, this was -- if they're there for an abortion, at least at that point, they were considering terminating the pregnancy and didn't want to be pregnant. And so, by confirming that it's a nonviable pregnancy, they would not, essentially, be eligible for an abortion, technically an abortion.

Page 111

Q. What about when you detect a heartbeat, do you tell the women you detect a heartbeat?
A. No. Not routinely.
Q. Why not?
A. They may ask and we talk about it. But that is -- the women are coming in for an abortion and they're assuming that they have a normal pregnancy that will continue to grow and they choose to have an abortion. So, unless we see something different than that --
Q. So generally you don't tell them if you detect a heartbeat or not?
A. I don't believe so.
Q. And in those instances that you do tell them that you detect a heartbeat, what's the reaction of them?
A. I'm not -- I don't know that I can answer that question --
Q. Well, you talked about --
A. -- because I'm not having that discussion with every patient, you know, I'm not doing every patient's ultrasound.
Q. And I'm only asking about the patients that you talk to them about -- they've

Page 112

asked you -- you've detected a heartbeat, you've had this discussion. What's the reaction of the women?
A. I have not been present when a woman has asked that question. Usually, the discussion is this appears to be either a normal pregnancy or an abnormal pregnancy.
Q. And so you don't, as I'm -- If I'm hearing you correctly, you don't get into the discussion of whether there's a heartbeat detected or not with a patient?
A. Correct.
Q. And do you then tell them what you mean by an abnormal or a normal pregnancy?
A. Yes. If I'm brought in, I'm having that discussion with the patient.
Q. How often does that happen where you're brought in to talk about whether there's a normal or abnormal pregnancy?
A. Under five per- -- under five percent.
Q. And a normal is one that would be cardiac activity, correct?
A. There can be factors -- I'm brought in if there's a concern. So depending on the

Page 113

gestational age, there may or may not be expected cardiac motion.
Q. Flip it the other way then. If they don't have cardiac activity, that would be an abnormal pregnancy at seven weeks or more?
A. At seven weeks or more yes, we would expect to see cardiac motion.
Q. Okay. And if you don't have that then that, as you've defined it, is an abnormal pregnancy at that point?
A. When I use -- yeah, it would be -- there's a concern and that we need to have a discussion with the patient to make sure she understands and knows her options.
Q. Okay. And then when you detect cardiac activity at six weeks or seven weeks, that's, aside from the other, you know, the location and gestational age, that would be something that would be a normal pregnancy then, correct?
A. It's normal to have cardiac motion at six -- about six weeks gestational age and beyond.
Q. And, as I understand it, you don't have discussion with the patient whether there's

Page 114

cardiac activity or not? You just say there's either -- this is a normal pregnancy.
A. Correct.
Q. Okay. And then your statement that it says, "there's no detectible cardiac activity after seven weeks can be a sign of a nonviable pregnancy or miscarriage."
A. I'm sorry can you --
Q. I'm sorry.
A. -- tell me where you are?
Q. Exhibit Number 4 paragraph 9.
A. Okay.
Q. It's about halfway through. It says, "no detectable cardiac activity after seven weeks can be a sign of a nonviable pregnancy or miscarriage."
A. Uh-hum.
Q. Would the opposite be true then if there's a detectable cardiac activity after seven weeks can be a sign of a viable pregnancy?
A. Correct.
Q. Do you know who Stacey Burns is?
A. Yes.
Q. Who is she?
A. I know who she is.

Page 115

Q. And I'm showing you -- it's part of the plaintiffs discovery it's Bates number PL104 --
A. Okay.
Q. -- I don't use Twitter. I Facebook, but I don't use Twitter, and we got this from a Stacey Burns and it says @WentRogue.
A. Okay.
Q. Do you know what that means? @WentRogue?
A. No.
Q. Who is Stacey Burns?
A. She is a woman -- I know who she is, and I've met her. I do not know what her title is. I believe she did or does -- I believe she works for a pro choice organization, whether it's Pro Choice Resources, I'm not confident.
Q. Okay. Did she have any affiliation with the clinic?
A. Not that I'm aware of.
Q. Do you know if her stat is correct? 87 percent of the abortions done at the Fargo is, I don't know, @RRWomen'sClinic are at least six weeks gestation?
A. So six -- that seems pretty accurate.

Page 116

Q. And you don't know where she got her data from?
A. No, I don't not.
Q. Have you ever seen this?
A. I've never seen that.
Q. All right. There are several letters that we got as part of the discovery process. They are Bates Numbers PL624, and, I can't read the last number but I think it's gotta be, PL675 from women. Do you just want to -- so you can see them.
A. Uh-hum.
Q. Have you -- if you want to just look through them. The question I have is: Have you ever seen these before?
A. No. I'm assuming -- in our recovery room, there are notebooks for women to -- to write and this appears to be a photocopy of that notebook.
Q. Okay. You don't know?
A. I don't know.
Q. And do you have any idea how these things are created other than suspecting that they are done in this recovery room?
A. I don't know.

Page 117

Q. And do you have any idea who created them?
A. No. Create -- you mean who wrote them?
Q. Yes.
A. Oh, no.
Q. Do you know if they were actually patients that wrote them?
A. I would have no way to -- to know that. Like I said, it just looks like the notebook that's in our recovery room.
Q. But you don't know if an actual patient wrote any of those statements?
A. True.
MR. GAUSTAD: At this point, we've got a discovery dispute. We're in- -- we do intend to appeal the order. We're going to keep the deposition open to -- this is the -- I don't have any further questions today given the order, but we are going to keep the deposition open until the discovery dispute is resolved. We're limited as to the number or questions and the topics that we can discuss here today.
MS. CREPPS: So you're planning to appeal the Magistrate's order to Judge

Hovland?
MR. GAUSTAD: Yes.
MS. CREPPS: Okay.
MR. GAUSTAD: So that's it for -- for today, Dr. Eggleston. Thank you and thank you very much for rescheduling yesterday.
(The deposition was concluded at 11:20 a.m.)

NOTARY REPORTER'S CERTIFICATE
STATE OF NORTH DAKOTA
COUNTY OF CASS

I, Kristen M. Keegan, a Notary Public within and for the County of Cass and State of North Dakota do hereby certify: That the afore-named witness was by me sworn to testify the truth, the whole truth, and nothing but the truth.

That the foregoing one hundred nineteen (119) pages contain an accurate transcription of my shorthand notes then and there taken.

I further certify that I am neither related to any of the parties or counsel, nor interested in this matter directly or indirectly.

WITNESS my hand and seal this 4th day of December, 2013.

Kristen M. Keegan
Notary Public
Fargo, North Dakota

THE FOREGOING CERTIFICATION OF THIS TRANSCRIPT DOES NOT APPLY TO THE REPRODUCTION OF THE SAME BY ANY MEANS, UNLESS UNDER THE DIRECT CONTROL AND/OR DIRECTION OF THE CERTIFYING COURT REPORTER.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA
SOUTHWESTERN DIVISION

MKB MANAGEMENT CORP., et al.,

Plaintiffs,

vs.

BIRCH BURDICK, et al.,

Defendants.

Case No. 1:13-cv-071

DECLARATION OF KATHRYN L. EGGLESTON, M.D. IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Kathryn L. Eggleston, M.D., declares and states the following:

1. I am a physician licensed to practice in North Dakota, and a Plaintiff in this case.

2. I am a board-certified family medicine physician and have been providing reproductive health care for women, including abortion and family planning services, for over a decade. In addition, I have provided full-spectrum family medicine care, including obstetric and prenatal care and gynecologic services, to numerous patients. I graduated from the Medical College of Wisconsin with an M.D. in 1996 and from Colorado State University with a B.S. in Biological Science in 1991. I completed my residency at the University of Wisconsin's Eau Claire Family Medicine Residency Program in 1999. I have trained residents and medical students in reproductive health care methods, including medication and surgical abortion.

3. The opinions provided herein, which are held to a reasonable degree of medical certainty, are based upon my fourteen years of experience as a family medicine physician

and reproductive health care provider, and the knowledge I have obtained through my education, training, teaching experience, discussions with colleagues, attendance at conferences, and ongoing review of the relevant professional literature. A copy of my curriculum vitae, which summarizes my background, experience, and professional activities, is attached as Exhibit A.

4. I submit this affidavit in support of Plaintiffs' Motion for Summary Judgment.

Red River Women's Clinic

5. Since 2008, I have been the medical director of Red River Women's Clinic in Fargo, North Dakota.

6. Pregnancy is commonly measured by the number of days that have passed since the first day of a woman's last menstrual period ("lmp"). The Clinic provides abortions to women from about five weeks lmp through about sixteen weeks lmp.

7. I provide abortions at the Clinic one day a week, about forty-five to fifty weeks each year.

8. Red River Women's Clinic's protocols include an ultrasound for all abortion patients, which is important for dating the pregnancy and determining where the pregnancy is located within the uterus. A physician needs to confirm an intrauterine pregnancy and gestational age in order to safely provide an abortion.

9. The ultrasound is also used to detect fetal cardiac activity, which is detectible by about 6 weeks lmp on average, and sometimes a few days earlier.

10. The Clinic does not typically perform abortions before five weeks lmp because, due to the pregnancy's extremely small size, it may not be possible to confirm the

location of the pregnancy in the uterus, even using vaginal ultrasound. If the location of the pregnancy is not confirmed, it can be dangerous to perform an abortion. Also - most patients do not present to the clinic at this gestational age due to the fact not are not aware they are pregnant.

11. North Dakota law defines viability as "the ability . . . to live outside the mother's womb, albeit with artificial aid." N.D. Cent. Code. § 14-02.1-02(14). A fetus does not become viable until approximately twenty-four weeks lmp.

12. Many women do not know they are pregnant until after 6 weeks lmp. Typically, only women who have regular menstrual periods, keep close track of them, and take a pregnancy test promptly after missing a period at four weeks lmp will know they are pregnant by 6 weeks.

13. Since the Clinic only performs abortions one day per week, and cannot safely perform abortions before five weeks lmp, the bill will effectively limit women's ability to obtain an abortion to a single day during their pregnancy's fifth week.

14. Most of the women who currently receive abortions from the Clinic at or after 6 weeks lmp would probably be unable to schedule their abortions early enough to avoid the ban, due to a combination of some or all of the following reasons: they will not yet have realized that they are pregnant; they will be unable to gather the necessary funds or obtain transportation in sufficient time to reach the Clinic; they will be unable to take the necessary time off work with such short notice; they will be waiting through the delays imposed by the laws of the State of North Dakota; or they will need more time than the

few days allotted to them to make the important decision of whether or not to have an abortion.

15. In my experience, women often consider many factors in deciding whether or not to have an abortion. These can include, among other things, their ability to care for exiting children, the impact of parenthood on their educational goals, and the impact of parenthood on their ability to work and pursue a career. For most women, the risks associated with abortion and the relative risks of abortion compared to carrying a pregnancy to term, are only one factor among many that they consider.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on October 11th, 2013

KATHRYN L. EGGLESTON, M.D.

Exhibit A

Eggleston CV

KATHRYN L. EGGLESTON, M.D.

Associate Medical Director 10/2010 - present
Planned Parenthood MN, ND, SD
Coordinate patient care with and support mid level family planning clinicians. Review patient care and medical protocols. Provide reproductive health care for women including medical and surgical abortion, colposcopy services and family planning services including Implanon and IUD insertion and management.

Family Medicine Physician, 2004 – present
Medical Director, 7/2008 - present
Red River Women's Clinic, Fargo, ND
Provide reproductive health care for women including medical and surgical abortion in addition to family planning services including Implanon and IUD insertion and management. Additional responsibilities include development, implementation and clinical oversight of patient care and medical protocols, ensuring adherence to NAF standards of care and adherence of clinical quality standards. Provide oversight of medical staff including physicians and mid level clinicians.

Family Medicine Physician, 2003 – present
Women's Health Center, Duluth, MN
Provide reproductive health care for women including medical and surgical abortion and family planning services including Implanon and IUD insertion and management.

Family Medicine Physician, 2003 – 2/2012
Midwest Health Center for Women, Minneapolis, MN
Provided reproductive health care for women including medical and surgical abortion, colposcopy services and family planning services including Implanon and IUD insertion and management. Additional responsibilities included development and implementation of patient care protocols; coordinate patient care with and support mid level providers; train residents and medical students; train and coordinate physician volunteers.

Family Medicine Physician, 8/2007 – 5/2010
Volunteer Family Medicine Physician 5/2010 - 7/2010
Neighborhood Health Source, Sheridan Clinic, Minneapolis, MN
Practiced full spectrum outpatient family medicine in a community clinic. Additional responsibilities include colposcopy services, monitoring cervical cancer screening standards and adherence and family planning services including Implanon and IUD insertion and management.

Family Medicine Physician, 2/2004 – 7/2007
Indian Health Board of Minneapolis, Minneapolis, MN
Practice included full spectrum outpatient family medicine including prenatal care and gynecologic services in a community clinic. Clinic services provided to Native Americans and surrounding community, including many ethnic and minority populations. Responsibilities include medical director of Healthy Start program; coordinating new "open-access" office visit scheduling system; training and providing of first trimester OB ultrasound; supervising cervical

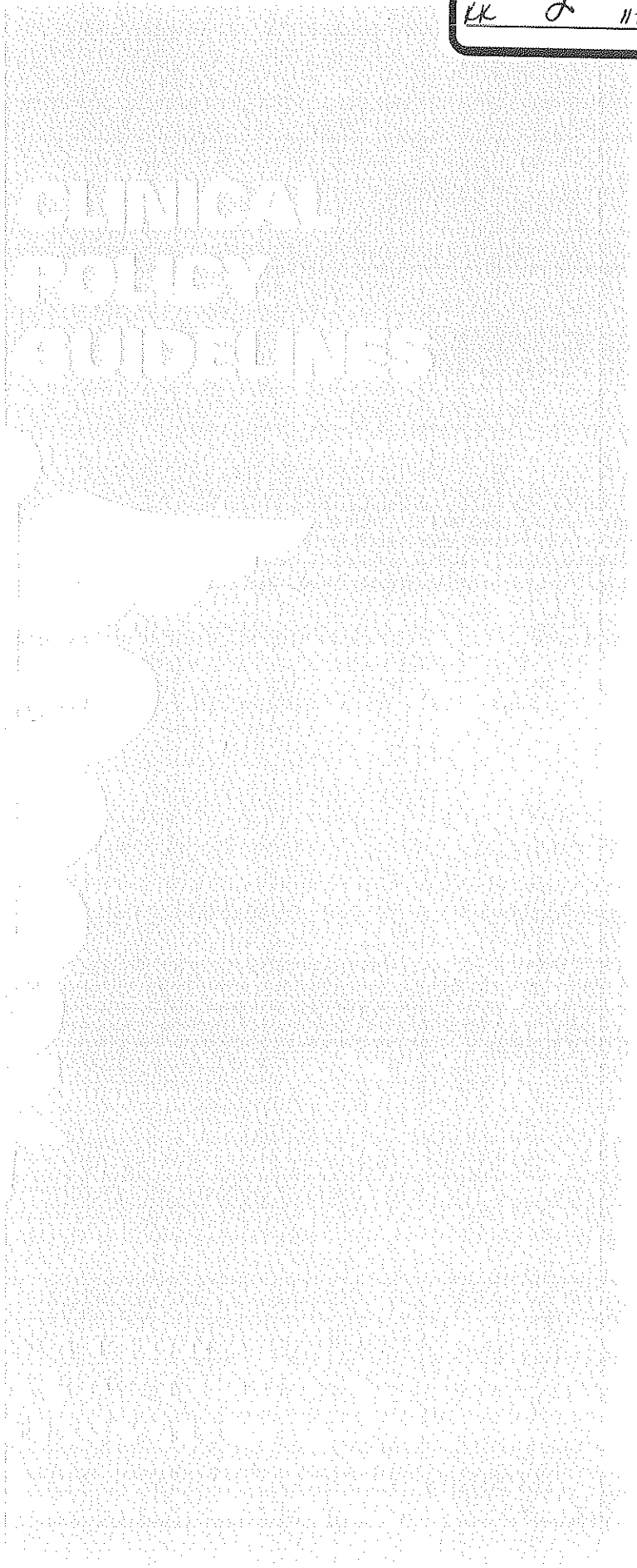
and breast cancer screening; colposcopy services; reproductive health care services including IUD insertion and management.

Family Medicine Physician, 2000 – 2003
Robbinsdale Clinic, P.A., Robbinsdale, MN
Practiced full spectrum family medicine including inpatient and outpatient medicine, reproductive health care including medical and surgical abortion.

Urgent Care Physician, 1999 - 2004
Marshfield Clinic, Eau Claire, WI
Acute care visits for all ages.

Family Medicine Physician, 1999 – 2000
Marshfield Clinic, Eau Claire, WI
Practiced full spectrum Family Medicine including inpatient medicine, outpatient medicine and obstetrics.

Education	University of Wisconsin, Eau Claire, Wisconsin Eau Claire Family Medicine Residency, June 1999 Medical College of Wisconsin, Milwaukee, Wisconsin Doctor of Medicine, May 1996 Colorado State University, Fort Collins, Colorado Bachelor of Science, Biological Science, December 1991
Licensure and Certification	Diplomate of the American Board of Family Medicine, 1999 – present State of Kansas, 2013-present State of Minnesota, 2000 - present State of North Dakota 2003 – present State of South Dakota 2010 - present State of Wisconsin, 1997 – present State of Alaska 2004 - 2010 Drug Enforcement Agency, 1998 - present Advanced Cardiac Life Support Provider, 1996 – present
Professional Memberships	American Academy of Family Medicine Physicians for Reproductive Choice
Hospital Privileges	Abbott Northwestern Hospital, Minneapolis, MN Regions Hospital, St. Paul, MN



NATIONAL ABORTION FEDERATION

2013 Clinical Policy Guidelines

1660 L Street, NW, Suite 450
Washington, DC 20036
www.prochoice.org

National Abortion Federation *Clinical Policy Guidelines* can be accessed on the Internet at www.guidelines.gov.

The National Abortion Federation is the professional association of abortion providers in North America. Our mission is to ensure safe, legal, and accessible abortion care, which promotes health and justice for women.

TABLE OF CONTENTS

National Abortion Federation

2013 CLINICAL POLICY GUIDELINES

INTRODUCTION

The mission of the National Abortion Federation (NAF) is to ensure safe, legal, and accessible abortion care, which promotes health and justice for women. An important part of this work is to develop and maintain evidence-based guidelines and standards as well as to educate providers in the latest technologies and techniques. NAF's programs make it possible for women to receive the highest quality abortion care.

Like its precursors, the 2013 edition of NAF's *Clinical Policy Guidelines* (CPGs) establishes clinical policy guidelines, which are developed by consensus, based on rigorous review of the relevant medical literature and known patient outcomes. These guidelines are intended to provide a basis for ongoing quality assurance, help reduce unnecessary care and costs, help protect providers in malpractice suits, provide ongoing medical education, and encourage research.

NAF's *Clinical Policy Guidelines*, first published in 1996 and revised annually, are based on the methodology described by David Eddy, MD, in *A Manual for Assessing Health Practices and Designing Practice Policies: The Explicit Approach.* Clinical policy guidelines are defined as a systematically developed series of statements which assist practitioners and patients in making decisions about appropriate health care. They represent an attempt to distill a large body of medical knowledge into a convenient and readily usable format.

When the outcomes of an intervention are known, practitioner choices are limited. But when the outcomes of an intervention are uncertain or variable, and/or when patients' preferences for those outcomes are uncertain or variable, practitioners must be given flexibility to tailor a policy to individual cases. This is addressed by having three types of practice policies according to their intended flexibility: standards, recommendations, and options.

1) STANDARDS are intended to be applied rigidly. They must be followed in virtually all cases. Exceptions will be rare and difficult to justify.

2) RECOMMENDATIONS are steering in nature. They do not have the force of standards, but when not adhered to, there should be documented, rational clinical justification. They allow some latitude in clinical management.

3) OPTIONS are neutral with respect to a treatment choice. They merely note that different interventions are available and that different people make different choices. They may contribute to the educational process, and they require no justification.

NAF's *Clinical Policy Guidelines* include an alphabetic list of bibliographic and cited references for each section when appropriate, and include discussion material in more controversial areas.

These guidelines are meant to be living documents, subject to revision every three years or sooner if new medical evidence should become available.

Note: The *Clinical Policy Guidelines* are not intended to educate members regarding legal and regulatory issues which may affect abortion practice. It is expected that administrators, staff, and clinicians will be aware of pertinent local, state/provincial/territorial, and national legislation as well as the requirements and limitations of their individual duties and scope of professional practice. NAF provider members should ensure that all employees have access to appropriate resources for information and support.

References:

1. Eddy, DM. Clinical decision making: From theory to practice. Designing a practice policy: Standards, guidelines, and options. *JAMA* 1990, 263:3077.
2. Eddy, DM. A Manual for Assessing Health Practices and Designing Practice Policies: The Explicit Approach. Philadelphia: American College of Physicians, 1992.
3. Field, M & Lohr, K (Eds). *Guidelines for Clinical Practice: From Development to Use*. Washington, DC: National Academy Press, 1992.
4. Garnick, D, *et al.* Can practice guidelines reduce the number and costs of malpractice claims? *JAMA* 1991, 266:2856.
5. Hadorn, D, *et al.* An annotated algorithm approach to clinical guideline development. *JAMA* 1992, 267:3311.
6. Hayward, RS, *et al.* Users' guide to the medical literature VIII: How to use clinical practice guidelines; A. Are the recommendations valid? *JAMA* 1995, 274:570.
7. James, BC. Implementing Practice Guidelines through Clinical Quality Improvement. *Frontiers of Health Services Management* 1993, 10: 1.
8. Leape, LL. Practice guidelines and standards: An overview. *Qual Rev Bull.* 1990, 161:42.
9. Meeker, CI. A consensus-based approach to practice parameters. *Obstet Gynecol* 1992, 79:790.
10. Walker, RD, *et al.* Medical Practice Guidelines. *West J Med* 1994, 161: 39.
11. Woolf, SH. Practice Guidelines: A New Reality in Medicine. I. Recent Developments. *Arch Intern Med* 1990, 150: 1811.
12. Woolf, SH. Practice Guidelines: A New Reality in Medicine. II. Methods of Developing Guidelines. *Arch Intern Med* 1992, 152: 946.
13. Woolf, SH. Practice Guidelines: A New Reality in Medicine. III. Impact on Patient Care. *Arch Intern Med* 1993, 153: 2646.

rev. October 2010

A NOTE ON FORMATTING

As presented here, Standards, Recommendations, and Options are hierarchical in nature. It is therefore expected that clinical practices will favor the highest level of guidance available on a given point. In order to clarify the relationships of Recommendations and/or Options that are subordinate to higher level Standards and/or Recommendations, NAF's guidelines are numbered and formatted according to the following scheme:

Within each main subject heading, Standards are numbered consecutively (e.g., Standard 1).

Recommendations are also numbered consecutively within each main subject heading, with numbers that are placed in the first position to the right of a decimal point (e.g., Recommendation 0.1). Where a recommendation follows from or is related to a Standard, it is indented below the Standard and the number of that Standard will be found to the left of the decimal point (e.g., Recommendation 1.1). Where the recommendation stands alone and is not related to a specific Standard, it is not indented in its placement on the page, and there will be a zero in the position to the left of the decimal point (e.g., Recommendation 0.1).

The consecutive numbers denoting Options within each main subject heading are placed in the second position to the right of a decimal point (e.g., Option 0.01). Where an option follows from or is related to a preceding Standard or Recommendation, it is indented below that Standard or Recommendation and the numbers identifying them will be found to the left of the decimal point and in the first position to the right of the decimal point respectively (e.g., Option 1.01 or Option 1.11, or Option 0.11). Where the Option stands alone and is not related to a specific Standard or Recommendation, it is not indented in its placement on the page, and there will be zeros in those positions (e.g., Option 0.01).

WHO CAN PROVIDE ABORTIONS

Policy Statement: Abortion is a safe procedure when provided by qualified practitioners.

Standard 1: Abortion will be provided by licensed[A] practitioners. This category is intended to include physicians from various specialties as well as nurse midwives, nurse practitioners, physician assistants, registered nurses, and other health professionals.

Recommendation 1.1: If required by law, documentation specifying privileges in accordance with each practitioner's scope of practice should be maintained.

Standard 2: All practitioners providing abortions must have received training to competency in abortion care, including the prevention, recognition, and management of complications.

Recommendation 0.1: Appropriate referrals should be available for patients who cannot be cared for by a practitioner at your facility.[B]

rev. December 2011

[A] The term "licensed" is used here to indicate that a person is lawfully entitled to practice their profession in the place in which the practice takes place. The laws are different throughout the United States, Canada, and Mexico City.

[B] This may include the NAF Referral Line.

PATIENT EDUCATION, COUNSELING, AND INFORMED CONSENT

Policy Statement: Obtaining informed consent and assessing that the decision to have an abortion is made freely by the patient are essential parts of the abortion process.

INFORMED CONSENT

Standard 1: The practitioner must ensure that appropriate personnel have a discussion with the patient in which accurate information is provided about the procedure and its alternatives, and the potential risks and benefits. The patient must have the opportunity to have any questions answered to her satisfaction prior to intervention.

Option 1.01: Information may be provided either on an individual basis or in group sessions.

Standard 2: There must be documentation that the patient affirms that she understands the procedure and its alternatives, and the potential risks and benefits; and that her decision is voluntary.

PATIENT EDUCATION AND/OR COUNSELING

Standard 3: Each patient must have a private opportunity to discuss issues and concerns about her abortion.

Standard 4: A patient must undergo the abortion as expeditiously as possible in accordance with good medical practice.

Standard 5: Information about clinical procedures, aftercare, and birth control must be available to patients at the facility.

Standard 6: All reasonable precautions must be taken to ensure the patient's confidentiality.

Discussion: Informed consent and abortion counseling are two different processes. The goal of informed consent is to assure that the patient's decision is voluntary and informed, and to obtain legal permission for an abortion.

Patient Education and/or Counseling is a discussion of the feelings and concerns expressed by the patient, which may include help with decision-making and contraceptive choices, values clarification, or referral to other professionals. A referral to community services should be

available if that becomes necessary or the needs of the patient are outside the scope of training of clinic staff.

When any third party is involved with payment for abortion, certain protected information will be given to that entity. Depending on applicable laws and regulations, the patient may need to be informed and authorization obtained for the communication of this information.

References:

1. Baker, A. *Abortion and Options Counseling: A Comprehensive Reference*. Granite City, Illinois: The Hope Clinic for Women, 1995.

2. Baker, A, *et al.* Informed Consent, Counseling and Patient Education. In Paul, M. *et al.* (Eds.), *A Clinician's Guide to Medical and Surgical Abortion.* Philadelphia: Churchill Livingstone, 1999.

3. Benson Gold, R. & Nash, E. State abortion counseling policies and the fundamental principles of informed consent, *Guttmacher Policy Review* 2007, 10(4), 8-13.

4. Needle, R. & Walker, L. *Abortion Counseling: A Clinician's Guide to Psychology, Legislation, Politics, and Competency*. Springer Publishing Co., 2008.

rev. October 2011

INFECTION PREVENTION

Policy Statement: Health care personnel and their patients are at risk for exposure to blood borne pathogens and other potentially infectious material. Infectious material may be transmitted to patients when proper engineering and work practice controls, which eliminate exposure are not followed.[A]

Standard 1: Exposure control plans must be established and observed, in compliance with applicable local, state/provincial/territorial, and federal regulations.

Discussion: Regulatory agency policies (see references) may be helpful in developing exposure plans that protect personnel and patients from potentially infectious material. Proper techniques for collection, labeling, and disposal of biohazardous material and for the processing of instruments are integral to any complete plan. Clinics should protect employees and patients from being inadvertently exposed to biohazardous material. Personal protective equipment, annual training programs, and Hepatitis B vaccine should be provided at no cost to the staff. Post exposure evaluation, prophylaxis (when indicated), and follow-up should be offered to exposed patients or staff for any potentially infectious agent, regardless of source.

References:

1. Canadian Centre for Occupational Health and Safety. Universal Precautions and Routine Practices (2011). Available at: http://www.ccohs.ca/oshanswers/prevention/universa.html.

2. Centers for Disease Control, U.S. Department of Health and Human Services (2003). Exposure to blood: What healthcare personnel need to know. Available at: http://www.cdc.gov/ncidod/dhqp/pdf/bbp/Exp_to_Blood.pdf.

3. Centers for Disease Control, U.S. Department of Health and Human Services (July 2011). Infection Prevention Checklist for Outpatient Settings: Minimal Expectations for Safe Care. Available at: http://www.cdc.gov/HAI/pdfs/guidelines/ambulatory-care-checklist-07-2011.pdf.

4. Claflin, N, Hayden, C (1998). *National Association for Healthcare Quality Guide To Quality Management*, Glenview, IL.

5. Occupational Safety and Health Administration, U.S. Department of Labor (last reviewed 2011). Blood borne pathogens and needlestick prevention. Available at: http://www.osha.gov/SLTC/bloodbornepathogens/index.html.

[A] Engineering control—available technology and devices that isolate or remove hazards from the work place, such as puncture-resistant sharps disposal containers.
Work practice control—an alteration in the way a task is performed that reduces the likelihood that an employee will be exposed to blood or other potentially infectious materials.

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rev. September 2012

Rh TESTING AND Rh IMMUNE GLOBULIN ADMINISTRATION

Policy Statement: Rh alloimmunization may jeopardize the health of a subsequent pregnancy.

Standard 1: Rh status must be documented in all women undergoing abortion.
a. This documentation may be obtained by on-site testing or outside medical source.
b. Du ("weak D") testing is not required. Testing for red blood cell antigens other than D (Rho) is not required.

Option 1.01: The use of approved slide/tube/spot methods is acceptable for on-site testing.

Standard 2: Additional testing for either sensitization or other antibodies is not required in patients undergoing pregnancy termination.

Standard 3: Rh immune globulin administration* must be offered to Rh(-) women and documented.

Standard 4: If Rh immune globulin is not administered in the facility, one of the following is required:
a. informed waiver signed by a patient who refuses Rh immune globulin; or
b. documentation of other arrangements for administration.

Discussion: There are as yet no data that support the safety of omitting the administration of Rh immune globulin in very early pregnancies (less than eight weeks), or that indicate any harm associated with its administration. Until/unless such data is available, the NAF Rh Testing Standards must be applied to pregnancies of any gestation.

*For Rh(-) patients, Rh immune globulin is administered by standard intramuscular injection; some practitioners inject it into the cervix.

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rev. December 2011

LIMITED SONOGRAPHY IN ABORTION CARE

Policy Statement: Proper use of ultrasound can inform clinical decision-making and enhance the safety and efficacy of abortion care.

Standard 1: Staff members who perform ultrasound exams and clinicians who interpret those exams must either show documentation that they have completed a program of training or must complete such a program developed by the facility. Training must include a period of direct supervision. Documentation of this training must be maintained. Following initial training, a system for evaluation of ongoing proficiency must be in place and documented.

Option 1.01: The *Ultrasound Training in Abortion Care* CD-ROM developed by ARMS, NAF, and CAPS is a good resource for training and may be utilized as part of a training program.[5]

Standard 2: A system of clinical privileging must be in place for staff members who perform ultrasound exams and clinicians who interpret those exams. This system must include periodic review and renewal of these privileges.

Standard 3: Patients must be informed of the purpose and limitations of the ultrasound exam in the abortion care setting.

Option 3.01: This information may be provided in writing and the patient may be asked to sign a form acknowledging receipt of this information.

Standard 4: The findings of all ultrasound exams and the interpretation of those findings must be documented in the medical record. Photos or another method of storing the ultrasound images must be included as part of the documentation.[3] This documentation must also include the name(s) of the staff members who performed and interpreted the exam.

Recommendation 4.1: A standard form for documenting findings and interpretation should be used.

Standard 5: In the first trimester, the ultrasound exam must include the following:

a. a full scan of the uterus in both the transverse and longitudinal planes;
b. measurements to document gestational age;
c. views to document the location of the pregnancy;
d. evaluation of fetal number; and
e. evaluation of the presence or absence of fetal cardiac activity.

Recommendation 5.1: When clinically indicated, evaluation of other pelvic structures (i.e., adnexal structures and the cul de sac) should be performed and documented.

Recommendation 5.2: Technology permitting both abdominal and transvaginal scanning should be available.

Standard 6: In the second trimester, the ultrasound exam must include the following:

a. fetal measurements to document gestational age;
b. views to document intrauterine location of the pregnancy;
c. evaluation of fetal number;
d. evaluation of the presence or absence of fetal cardiac activity; and
e. placental localization.

Recommendation 6.1: When placenta previa is suspected in a patient with a prior uterine scar, or when other placental abnormality is suspected, a referral for further diagnostic imaging should be made.

Standard 7: A procedure must be in place for further evaluation or referral of a patient in whom an intrauterine pregnancy has not been definitively identified or for whom an initial finding on the ultrasound may affect abortion management or future patient care.

Standard 8: Real-time ultrasound scanners must be used. Ultrasound equipment must be properly calibrated and maintained.

Standard 9: Ultrasound transducers must be disinfected between patients according to applicable infection control standards.[4] Adequate precautions must be taken to protect both staff members and patients from the potential toxicity of chemical agents.

Discussion: The use of ultrasound is not a requirement for the provision of first trimester abortion care. However, over the years, especially in higher resource settings, it has become widely used. Compliance with NAF standards for the use of limited ultrasound in abortion care will enhance the accuracy and reliability of ultrasound findings in this setting, thus improving the quality of care.

According to the American Institute of Ultrasound in Medicine (AIUM), in collaboration with the American College of Obstetrics and Gynecology (ACOG) and the American College of Radiology (ACR),[3] a "limited ultrasound examination" is performed when a specific question requires investigation. In addition to the determination of gestational age and location, limited

ultrasound examination may also be useful in intra-procedure and post-abortion care under certain circumstances.[A]

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December 2010

[A] See guidelines for "Early Medical Abortion," "Second Trimester Abortion by D&E," and "Evaluation of Evacuated Uterine Contents."

EARLY MEDICAL ABORTION

Policy Statement: Medical induction is an effective method for early abortion. Adequate counseling and follow-up care will enhance its safety and acceptability.

Standard 1: Pertinent medical history must be obtained and documented.

Standard 2: Confirmation of pregnancy must be documented.

Standard 3: The patient must be informed about the efficacy, side effects, and risks, especially excessive bleeding and infection.

Standard 4: The patient must be informed of the need to ensure that she is no longer pregnant and of the teratogenicity associated with the medications to be used.

Standard 5: Patient instructions must include written and oral information about use of medications at home and symptoms of abortion complications.

Standard 6: The patient must be informed that a surgical abortion will be recommended if medical abortion fails and this must be documented.

Standard 7: The facility must provide an emergency contact service on a 24-hour basis and must offer or assure referral for uterine aspiration if indicated.

Standard 8: Gestational age must be verified and documented.

Recommendation 8.1: Ultrasonography, using a consistent and published table of fetal measurement, should be used to confirm and document gestational age when physical exam and LMP are substantially discordant.

Option 8.01: Ultrasonography may be used routinely.

Standard 9: If intrauterine gestation has not been confirmed by ultrasound, ectopic pregnancy must be considered. At a minimum, evaluation will include history and physical exam and may also require serology, sonography, and examination of uterine aspirate, as well as documented follow-up through either clinical resolution or transfer of care.[A]

[A] See guidelines for "Management of Pregnancy of Uncertain Location."

Standard 10: Combined regimens are more effective than prostaglandin alone. Where mifepristone is available, an evidence-based mifepristone/misoprostol regimen must be used.[B]

Recommendation 10.1: When mifepristone and vaginal, buccal, or sublingual misoprostol are used, the regimen is recommended for gestations up to 70 days.[2, 9, 16, 24]

Recommendation 10.2: When mifepristone and oral misoprostol are used, the regimen is recommended for gestations up to 56 days.[24]

Recommendation 10.3: Where mifepristone is not available and methotrexate and misoprostol are used, a regimen using vaginal, buccal, or sublingual misoprostol is recommended for gestations up to 63 days.[1]

Recommendation 10.4: Where neither mifepristone or methotrexate are available and misoprostol alone is used, a regimen using vaginal, buccal, or sublingual misoprostol is recommended for gestations up to 63 days. [1, 11, 12]

Standard 11: Patient comfort level during the abortion procedure must be considered.

Option 11.01: Analgesia or other comfort measures may be used as needed unless there are contraindications.

Standard 12: Completion of the abortion must be documented by ultrasonography, hCG testing, or by clinical means. If the patient has failed to follow-up as planned, clinic staff must document attempts to reach the patient to ensure the abortion is complete. All attempts to contact the patient (phone calls and letters) must be documented in the patient's medical record.

Recommendation 12.1: Ultrasonography should be used to evaluate completion of the abortion when expected bleeding does not occur after medications.

Option 12.01: Ultrasonography may be used routinely.

Standard 13: Rh immune globulin must be offered in accordance with Rh Guidelines.[C]

[B] Abortifacients must only be used within established regimens under protocols which have been shown to be acceptable, safe, and efficacious in published clinical research. See NAF's *Protocol for Mifepristone /Misoprostol in Early Medical Abortion* for further resources.

[C] See guidelines for "Rh Testing and Rh Immune Globulin Administration."

Standard 14: *Clinical Policy Guidelines* Standards 6, 7, and 8 for Post-Procedure Care must be followed.[D]

Recommendation 0.1: Either hematocrit or hemoglobin screening should be obtained in women with a history of significant anemia or specific indication.

Recommendation 0.2: A complete blood count (CBC) should be considered for women receiving methotrexate.

Recommendation 0.3: Vital signs (e.g., blood pressure, pulse, and temperature) and physical exam should be done as indicated by medical history and patient symptoms.

Discussion: Many patients prefer pharmacological methods of terminating early pregnancies rather than suction curettage. Medical abortion has several advantages for patients. It avoids surgery and anesthesia and offers women more active participation and control over the abortion process. On the other hand, medical abortion is less effective than surgical abortion (90-98% versus 99% or greater). It also takes longer and may require more office visits.

Extensive research has established the safety and efficacy of mifepristone combined with misoprostol for early pregnancy termination. Methotrexate and misoprostol have also been found to be effective and are used in some services where mifepristone is not available. While misoprostol alone is inferior to combined methods for termination of pregnancy,[1, 11, 12] in areas where mifepristone or methotrexate are not available, it may be an acceptable alternative.[18]

Mifepristone is administered orally. Original trials involved a 600 mg dose, but an abundance of research indicates that 200 mg provides comparable efficacy. The best studied methotrexate regimen involves 50 mg/m^2 (body surface area) given intramuscularly, the same dose used in treating early unruptured ectopic pregnancy. Research also indicates acceptable efficacy when methotrexate is administered orally in doses of 25-50 mg.[5]

Information has also evolved on the types, doses, and routes of administration of the prostaglandin agents used in medical abortion regimens. Currently, misoprostol is the favored agent because it is efficacious, inexpensive, stable without refrigeration, and already FDA-approved for other indications.

Buccal administration of misoprostol has a similar physiological effect on the uterus as vaginal administration and is similarly highly effective for medical abortion. Sublingual administration of misoprostol is also highly effective for medical abortion with mifepristone, but is associated with a higher frequency of chills. One large retrospective study suggests that a change of route from vaginal to buccal administration of misoprostol after mifepristone was associated with a reduced incidence of serious infection, although absolute risk is extremely low.[8] The effectiveness of

[D] See guidelines for "Post-Procedure Care."

medical abortion declines very gradually with advancing gestational age. This decline is more evident with oral administration of misoprostol.[17,24]

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rev. September 2012

FIRST TRIMESTER SURGICAL ABORTION

Policy Statement: Legal abortion is one of the safest surgical procedures. The following guidelines enhance this safety.

PRE-PROCEDURE

Standard 1: Pertinent medical history must be obtained and documented.

Standard 2: Confirmation of pregnancy must be documented.

Standard 3: Gestational age must be verified and documented.

Option 3.01: Ultrasonography, using a consistent and published table of fetal measurements can be of clinical value in verifying intrauterine pregnancy and gestational age.

Standard 4: If intrauterine gestation has not been confirmed by ultrasound, providers should adhere to the guidelines for "Management of Pregnancy of Uncertain Location."

Standard 5: Baseline blood pressure and pulse must be obtained for all patients.

Recommendation 0.1: Hemoglobin or hematocrit and physical exam should be done as indicated by medical history and patient symptoms.[A]

Standard 6: Pain control options must be discussed with the patient.

PROCEDURE

Standard 7: Patient comfort during the procedure must be monitored. Analgesia or other comfort measures must be offered when needed.[B]

Standard 8: All instruments entering the uterine cavity must be sterile.

Option 8.01: The vagina may be cleansed with a bacteriocidal agent.

[A] By establishing a balance sheet of risks, costs, and outcomes, it was discovered that a pre-procedure Hct was of relatively questionable value statistically in preventing morbidity and mortality in a healthy woman in the first trimester with no history of anemia or major disease process.[1]

[B] See guidelines for "Analgesia and Sedation."

Recommendation 0.2: The cervix should be dilated gently and gradually.

Option 0.21: Cervical dilation may be facilitated through the use of osmotic dilators or misoprostol, particularly in adolescents or women at risk for cervical stenosis.

Option 0.22: Difficult cervical dilation at very early gestational age (less than seven weeks) may be facilitated by delaying the procedure. Alternatively medical abortion can be offered.[C]

Standard 9: Completion of the procedure must be verified and documented.[D]

Option 9.01: Intra-operative ultrasonography can be of value to locate fetal parts and aid in their extraction, to help verify an empty uterus, and to help verify an intact uterus.

Standard 10: Rh immune globulin must be offered per Rh policy guidelines.[E]

Standard 11: *Clinical Policy Guidelines* for Post-Procedure Care must be followed.[F]

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rev. December 2012

[C] See guidelines for "Early Medical Abortion."
[D] See guidelines for "Evaluation of Evacuated Uterine Contents."
[E] See guidelines for "Rh Testing and Rh Immune Globulin Administration."
[F] See guidelines for "Post-Procedure Care."

MANAGEMENT OF PREGNANCY OF UNCERTAIN LOCATION

Policy Statement: The early identification of ectopic pregnancy will reduce morbidity related to rupture and increase the likelihood of successful non-surgical management.

Standard 1: The patient's medical history and physical exam must be evaluated in order to assess for the risk of ectopic implantation in early pregnancy. Certain signs and symptoms, such as vaginal bleeding and/or pelvic pain, should alert providers to the importance of following policies and procedures for ruling out ectopic pregnancy.

Option 1.01: In addition to physical exam, evaluation may include:
- a. sonography;
- b. uterine aspiration; and
- c. serial quantitative hCGs.

Recommendation 1.1: Each provider site should have a written protocol to evaluate ectopic pregnancy.

Option 1.11: Clinical algorithms for the evaluation of possible ectopic pregnancy may be useful in developing practice protocols.[4, 10, 11]

Recommendation 1.2: All relevant staff at the site should be familiar with the protocol.

Standard 2: The patient must be evaluated for ectopic pregnancy if:
- a. transvaginal ultrasonography shows no intra-uterine pregnancy and serum quantitative hCG exceeds 2000 mIU/ml;[A] or
- b. abdominal ultrasonography shows no intra-uterine pregnancy and serum quantitative hCG exceeds 3600 mIU/ml; or
- c. a suspicious adnexal mass is found on ultrasound or pelvic exam; or
- d. no pre-abortion sonography demonstrating an IUP has been performed, and there is minimal or no bleeding in response to abortifacient medications OR there are no products of conception identified in the uterine aspirate.[B]

[A] All hCG values used in this document are based on the Third International Standard (originally referred to as the First International Reference Preparation).

[B] Intrauterine gestation is confirmed when an ultrasound demonstrates a gestational sac with a yolk sac or when chorionic villi are identified in the uterine aspirate. Sonographic or tissue confirmation of an intrauterine pregnancy makes concurrent ectopic pregnancy extremely unlikely in naturally conceived pregnancies (1/4,000 – 1/8,000).[5-6]

Standard 3: All patients with a pregnancy of uncertain location must be informed about the possibility of ectopic pregnancy, the symptoms and dangers associated with ectopic pregnancy, and have a plan for when and how to seek emergency medical attention. This should be documented in the medical record.

Recommendation 3.1: Each provider site should have a patient education handout describing ectopic warning signs and the medical record should reflect that the patient has received this handout.

Standard 4: The patient must not be released from follow-up care until either:
a. the diagnosis of ectopic pregnancy has been excluded;
b. clinical resolution of a possible ectopic pregnancy has been ensured; or
c. transfer of care to an appropriate provider has been made and documented.

Standard 5: Patients experiencing symptoms suspicious for rupturing ectopic pregnancy should be emergently evaluated for possible surgical management.

Standard 6: If either a medical or aspiration abortion is initiated for a patient with a pregnancy of uncertain location, resolution of the pregnancy must be verified and documented. This may be demonstrated by either the examination of aspirated tissue or by following serial BhCG levels according to evidence-based regimens.[c]

Discussion: A combination of clinical assessment, pelvic ultrasound, serum quantitative hCG, and examination of uterine aspirate is often needed to distinguish between an early intrauterine gestation, a miscarriage, and an ectopic pregnancy.[6] With early gestations, pre-procedure ultrasound may fail to identify an intrauterine pregnancy, leaving the clinician uncertain about the viability and location of the pregnancy. Although a gestational sac can usually be seen 4 to 5 weeks from LMP on transvaginal ultrasound, it may be confused with a pseudo-sac associated with an ectopic pregnancy.[1] Visualization of a yolk sac or embryo is therefore needed to definitely confirm an intrauterine pregnancy on ultrasound.

From seven to 20% of women with a pregnancy of uncertain location are subsequently found to have an ectopic pregnancy and approximately 25-50% of women with ectopic pregnancies initially present with pregnancy of uncertain location.[1] Although it is an important cause of pregnancy-related morbidity and mortality, ectopic implantation has been reported to occur in less than 1% of pregnancies in women presenting for induced abortion.[3,5]

[c] See guidelines for "Evaluation of Evacuated Uterine Contents."

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December 2010

SECOND TRIMESTER ABORTION BY D&E

Policy Statement: Second trimester[A] abortion by dilation and evacuation (D&E) is a safe outpatient surgical procedure when performed by appropriately trained clinicians in medical offices, freestanding clinics, and ambulatory surgery centers.

PRE-PROCEDURE

Standard 1: Pertinent medical history must be obtained and documented.

Recommendation 0.1: A patient with a suspected or actual placenta previa and prior uterine scarring should be evaluated for placental abnormality, such as accreta.

Recommendation 0.2: Physical examination should be done as indicated by medical history and patient symptoms.

Recommendation 0.3: A pre-operative Hgb or Hct should be done.

Standard 2: Gestational age must be verified by ultrasonography, using a consistent and published table of fetal measurements, prior to the termination of a pregnancy clinically estimated to be more than 14 weeks LMP.

Option 0.01: In later second trimester abortions, intra-amniotic or intra-fetal injection may be given to cause fetal demise in utero prior to abortion (see Discussion).

PROCEDURE

Standard 3: Patient comfort level during the abortion procedure must be addressed.[B]

Recommendation 3.1: Analgesic or other comfort measures should be offered unless there are contraindications. Such measures should be based on the woman's needs and the medical context.

Standard 4: Appropriate dilation of the cervix must be obtained.

Recommendation 4.1: Dilation should be achieved gently and gradually.

[A] For the purposes of these guidelines, second trimester begins at approximately 14 weeks LMP. (Cunningham, FG, *et al. Williams' Obstetrics; 22nd Ed.* Columbus OH: McGraw-Hill Inc., 2005: Chapter 4).

[B] See guidelines for "Analgesia and Sedation."

Recommendation 4.2: Osmotic dilators, misoprostol, and/or other cervical ripening agents should be used to facilitate adequate dilation.

Standard 5: When osmotic dilators, misoprostol, and/or other cervical ripening agents are used, a plan for emergency care prior to the scheduled procedure must be in place and communicated to the patient.

Recommendation 0.4: IV access should be established prior to evacuation.

Standard 6: All instruments entering uterine cavity must be sterile.

Standard 7: Uterotonics must be available to aid in control of uterine bleeding.

Option 0.02: Prophylactic vasopressin may be used intracervically or paracervically to reduce blood loss.

Option 0.03: Intra-operative ultrasonography can be of value to locate fetal parts and aid in their extraction, to aid in verifying an empty uterus, and to aid in diagnosis of uterine perforation.

POST-PROCEDURE

Standard 8: Completion of the procedure must be verified and documented by the operator.[c]

Standard 9: *Clinical Policy Guidelines* for Post-Procedure Care must be followed.

Option 0.04: Uterotonic agents may be prescribed at discharge.

Discussion: Second trimester procedures comprise approximately 10% of abortions in the United States today. The dilation and evacuation procedure requires special training, techniques, and equipment appropriate for gestational age. Dilation and evacuation (D&E) is now the predominant second trimester abortion procedure in the United States.

Clinicians who provide second trimester D&E procedures should provide the safest procedure possible for their patients. The United States Supreme Court has upheld a law banning some abortion procedures. Although the law does not require the use of fetocidal injections, some providers may choose to use them in order to avoid violating the law.

[c] See guidelines for "Evaluation of Evacuated Uterine Contents."

Clinicians must tailor surgical techniques to suit individual circumstances mindful of current legal implications and the need to maintain patient safety. As always, it is incumbent upon each clinician to be aware of the laws pertinent to their clinical practice.

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SECOND TRIMESTER ABORTION BY MEDICAL INDUCTION

Policy Statement: When performed in appropriate clinical settings by trained clinicians with appropriate medications, medical induction is a safe and effective method for termination of pregnancies beyond the first trimester.[A] As gestational age increases, complications and risks increase.

Standard 1: Personnel capable of surgical management and the necessary equipment must be available until post-abortion discharge. If surgical intervention is required, the NAF *Clinical Policy Guidelines* for Second Trimester Abortion by D&E must be followed.

Standard 2: A clinician must be available for emergency care from initiation of cervical pretreatment until post-abortion discharge.

Standard 3: Medical history must be obtained and physical examination performed as indicated by patient history and symptoms. These must be documented.

Standard 4: Gestational age must be verified by ultrasonography prior to the termination of a pregnancy clinically estimated to be more than 14 weeks LMP.[B]

Recommendation 0.1: When abnormal placentation[5] is suspected, diagnostic imaging should be obtained.

Recommendation 0.2: A pre-abortion Hgb or Hct should be done.

Standard 5: Patient comfort level during the abortion procedure must be addressed, and analgesia and other comfort measures offered. Such measures should be based on the woman's needs and the medical context.[C]

Option 0.02: Pretreatment with mifepristone 24-48 hours prior to misoprostol has been shown to reduce the induction-to-abortion interval (see Discussion).

Option 0.03: In later second trimester abortions, intra-amniotic or intra-fetal injection may be given to cause fetal demise in utero (see Discussion).

Option 0.04: Prostaglandins and/or oxytocin may be used to induce labor.

[A] For the purposes of these guidelines, second trimester begins at approximately 14 weeks LMP. (Cunningham, FG, *et al. Williams' Obstetrics; 22nd Ed.* Columbus OH: McGraw-Hill, Inc., 2005: Chapter 4).
[B] See guidelines for "Limited Sonography in Abortion Care."
[C] See guidelines for "Analgesia and Sedation."

Standard 6: Patients receiving prostaglandins or other priming and induction agents must be advised that administration of these medications may precipitate rapid onset of uterine contractions and expulsion.

Standard 7: Patients must be given detailed instructions for how to contact the health care facility. Patients must also be given detailed instructions on how to proceed when signs of labor are noted, including a plan for management of unscheduled feto-placental expulsion and recognition of related complications.

Standard 8: Once regular contractions have been confirmed, patients must be observed by a health care worker trained to monitor contractions and expulsion, and who can recognize emergent situations.

Recommendation 0.3: IV access should be established prior to expulsion.

Standard 9: Completion of the procedure must be verified and documented by the responsible clinician.[D]

Standard 10: Uterotonics should be available to aid in control of uterine bleeding.

Standard 11: *Clinical Policy Guidelines* for Post-Procedure Care must be followed.[E]

Recommendation 0.4: Evidence-based medication regimens should be used.

Option 0.41: Pretreatment with mifepristone 24-48 hours prior to misoprostol should be used to reduce the induction-to-abortion interval (see Discussion).

Option 0.42: In later second trimester abortions, intra-amniotic or intra-fetal injection may be given to cause fetal demise in utero (see Discussion).

Option 0.43: Prostaglandins and/or oxytocin may be used to induce contractions.

Discussion: In the setting of second trimester induction abortion, cervical preparation, drug regimens, a history of a scarred uterus, and issues of fetocidal injections are important clinical and pragmatic considerations. With respect to cervical preparation and related drug regimens, osmotic or mechanical dilators, prostaglandins, and/or mifepristone have all been used to achieve cervical preparation for induction and expulsion.

[D] See guidelines for "Evaluation of Evacuated Uterine Contents."
[E] See guidelines for "Post-Procedure Care."

Current published data provide support for the use of 200 mg oral mifepristone, followed 24-48 hours later by repeated doses of 200-400μg misoprostol every three hours by the sublingual or buccal routes. Thereafter, 400 μg oral, vaginal misoprostol may be utilized to a maximum of five doses.[4, 6, 14]

There is no evidence that the use of misoprostol increases the risk of uterine rupture in a previously scarred uterus in the second trimester compared to other induction agents. While the risk of uterine rupture during second trimester induction in a woman with a scarred uterus is unknown, there is a recognized risk at term and there have been case reports in the second trimester. At term, women with placenta previa and uterine scarring—especially multiple or vertical cesarean scars— are at increased risk for the rare occurrence of placenta accreta.[5]

In light of the relevant medical and legal context in which the abortion takes place, intra-fetal or intra-amniotic injection may be used to cause fetal demise in utero in later second trimester procedures. In addition to the references below, NAF Members may look to the *NAF Clinical Practice Bulletin for Digoxin Administration* for further information.

As always, it is incumbent upon each clinician to be aware of the laws pertinent to their clinical practice.

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rev. April 2012

ANALGESIA AND SEDATION

Policy Statement: Anxiolysis, analgesia, or anesthesia should be provided during abortion procedures for any patient in which the benefits outweigh the risks.

ON THE USE OF SEDATION IN GENERAL - All medications used in procedural sedation have the potential for serious risk. This risk may be reduced to a minimum by adherence to established practice guidelines. Guidelines developed by other organizations concern themselves with anesthesia and sedation delivered primarily in hospital settings and to patients varying widely in age and general health. Whether it be local anesthesia, oral analgesia, or procedural sedation, it is the degree of CNS depression rather than any type of modality *per se* that is the basis for the establishment of NAF guidelines.

NOTE: These guidelines do not address the use of deep or general anesthesia except to identify appropriate providers of such care, who are expected to follow their professional standards in the delivery of anesthesia services.

The promulgation of guidelines for the delivery and monitoring of anesthesia care issued by organizations such as the American Society of Anesthesiologists (ASA), the Canadian Anesthesiologists' Society (CSA), the American Dental Society of Anesthesiologists (ADSA), American Society of Gastrointestinal Endoscopists, and others have clarified many of the issues related to anesthesia care.

It is recognized that patient comfort and reduced anxiety are not dependent only on pharmacologic measures, but are significantly affected by patient counseling and by a supportive staff. It is also recognized that there is a wide range of alternative modalities (such as acupuncture, yoga, hypnosis) that are helpful for many patients. The focus of NAF guidelines for analgesia and sedation, however, is on the safe provision of pharmacologic methods generally used in outpatient abortion facilities.

DEFINITIONS[A]

1. Local Anesthesia - Elimination or reduction of sensation, especially pain, in one part of the body by topical application or local injection of a drug. In the context of abortion practice, this almost always signifies paracervical block.

[A] Based on *Continuum of Depth Sedation: Definition of General Anesthesia and levels of Sedation/Anesthesia*, 2009, of the American Society of Anesthesiologists. A copy of the full text can be obtained from ASA; 520 N. Northwest Highway; Park Ridge, Illinois 60068-2573.

2. Minimal Sedation (Anxiolysis) - is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, ventilatory, and cardiovascular functions are unaffected.

3. Moderate Sedation/Analgesia ("Conscious Sedation") - is a drug-induced depression of consciousness during which patients respond purposefully* to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained but may be impaired.

4. Deep Sedation/Analgesia - is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained but may be impaired.

5. General Anesthesia - is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce any level of sedation should be able to rescue** patients whose level of sedation becomes deeper than initially intended.

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.*

*** Rescue corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia, and hypotension) and returns the patient to the originally intended level of sedation.*

PERSONNEL AND MONITORING

Standard 1: When minimal, moderate, deep sedation, or general anesthesia is to be given patients must be given information about the risks, benefits, and side effects of the medications to be used.

Recommendation 1.1: Documentation of this education should include precautions relevant to transient mental impairment.

Standard 2: The supervising practitioner must be immediately available when sedation is administered.

Standard 3: When local anesthesia or sedation is provided, the practitioner responsible for the treatment of the patient and/or the administration of drugs must be appropriately trained.

Standard 4: The potential need for IV access must be considered prior to administering any level of sedation.

Recommendation 4.1: When more than minimal sedation is intended, IV access should be maintained.

Standard 5: When sedation is provided, monitoring must be adequate to detect the respiratory, cardiovascular, and neurological effects of the drugs being administered, and this monitoring must be documented.

Recommendation 5.1: Pulse oximetry should be available to enhance this monitoring.

Recommendation 5.2: The patient should be checked frequently for verbal responsiveness.

Recommendation 5.3: For patients in ASA P-3, P-4, and P-5 provision of care by an anesthesia professional should be considered. (see ASA "Physical Status Definition" in this document).

Standard 6: A person other than the clinician performing the procedure, and who is trained to monitor appropriate physiological parameters, must be present. This person must not be performing duties other than monitoring if the patient's responsiveness has declined from baseline and must be prepared to provide respiratory support.[B]

Standard 7: The practitioner administering **deep sedation** or **general anesthesia** must not be the practitioner performing the abortion.

Standard 8: The practitioner administering **deep sedation** or **general anesthesia** must be certified according to applicable regulations and adhere to established professional standards of care.

Standard 9: N2O/O2 must be self-administered by the patient.

[B] See guidelines for "Emergency Procedures for Facilities that Offer/Provide Minimal Sedation."

Standard 10: The provision of N2O/O2 must follow guidelines for patient monitoring, which are consistent with Standards 7 and 8 above, and requires dedicated monitoring personnel.

Standard 11: Equipment for the delivery of N2O/O2 must:

a. provide a concentration of N2O of no more than 70% inspired;
b. provide a maximum of 100% and minimum of 30% O2 conc.; and
c. be checked and calibrated regularly.

Recommendation 11.1: Equipment for the delivery of N2O/O2 should be outfitted with an oxygen analyzer.

Recommendation 11.2: Due to the potential for occupational exposure, room or personnel monitoring for levels of gases should be conducted (see Discussion below).

FACILITIES AND EQUIPMENT: See guidelines for "Emergency Procedures for Facilities that Offer/Provide Minimal Sedation."

DISCUSSION:

ON THE USE OF PULSE OXIMETRY - There have been no trials evaluating the benefit of pulse oximetry to young women undergoing outpatient abortion, who only rarely have respiratory or hemodynamic compromise. Given the low risk of morbidity and mortality associated with this procedure it is unlikely that there will be studies large enough to assess pulse oximetry on the basis of outcomes. The major correlation with prolonged oxygen desaturation is advancing age and cardiovascular function deficits; however, the use of pulse oximetry has become the standard of care for any patient who has received medication which alters the level of consciousness or the respiratory drive.

ON THE USE OF N2O/O2 - Nitrous oxide has a long history of use for analgesia and sedation, as well as an excellent safety record in the hands of both anesthesiologists and non-anesthesiologists. Attention must be paid to the level of sedation provided and the clinician must be prepared to recognize and care for changes in these levels. Occupational exposure to N2O has been associated with increased risks of neurologic impairment, spontaneous abortion, subfertility, and hepatic and renal disease. Although there is no OSHA standard for N2O, NIOSH recommends that airborne levels of N2O be kept below 25 ppm (1995) through well-designed scavenger systems and other engineering controls, equipment maintenance, exposure monitoring, and safe work practices.

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ANALGESIA AND SEDATION

American Society of Anesthesiologists

CONTINUUM OF DEPTHS OF SEDATION: DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA[c]

Committee of Origin: Quality Management and Departmental Administration
(Approved by the ASA House of Delegates on October 27, 2004, and amended on October 21, 2009)

	Minimal Sedation/ Anxiolysis	*Moderate Sedation/ Analgesia "Conscious Sedation"*	*Deep Sedation/ Analgesia*	*General Anesthesia*
Responsiveness	Normal response to verbal stimulation	Purposeful ** response to verbal or tactile stimulation	Purposeful** response following repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

[c] Excerpted from *Continuum of Depth of Sedation, Definitions of General Anesthesia and Levels of Sedation/Analgesia.* 2009, reprinted with the permission of the American Society of Anesthesiologists. A copy of the full text can be obtained from ASA; 520 N. Northwest Highway; Park Ridge, Illinois 60068-2573.

ANALGESIA AND SEDATION

American Society of Anesthesiologists

PHYSICAL STATUS DEFINITION[D]

The following represents the American Society of Anesthesiologists classification and should be used in evaluation of patients.

CLASSIFICATION OF PHYSICAL STATUS

P-1 - A normal healthy patient.
P-2 - A patient with mild systemic disease.
P-3 - A patient with severe systemic disease.
P-4 - A patient with severe systemic disease that is a constant threat to life.
P-5 - A moribund patient who is not expected to survive without the operation.
P-6 - A declared brain-dead patient whose organs are being removed for donor purposes.

[D] *ASA Relative Value Guide*. 2012. Reprinted with permission of the American Society of Anesthesiologists; 520 N. Northwest Highway; Park Ridge, Illinois 60068-2573.

USE OF ANTIBIOTICS IN ABORTION

Policy Statement: Prevention and treatment of infection will reduce post-abortion morbidity.

Recommendation 0.1: All women should receive antibiotics at the time of surgical abortion.

Option 0.01: Antibiotics may be given to women choosing medical abortion.

Recommendation 0.2: Empiric treatment of Chlamydia should be considered for patients at high risk for pre-existing infection.[A]

Recommendation 0.3: For documented infections of the reproductive tract, CDC guidelines should be followed.[3]

Option 0.02: Antibiotics may be initiated at the time of insertion of osmotic dilators.

Option 0.03: Patients with non-cardiac prostheses may be given peri-procedure antibiotics.[B]

Discussion: Our review of the literature supports universal antibiotic treatment of all women undergoing surgical abortion. There is one large retrospective analysis, which supports the use of antibiotics in medical abortion.[5]

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[A] Patients at high risk for Chlamydia are defined as those with any of the following:
a. age 25 or under;
b. new or multiple sexual partners;
c. mucopurulent discharge;
d. presence of any STD; or
e. history of pelvic inflammatory disease.

[B] "The statement concludes that antibiotic prophylaxis is not indicated for dental patients with pins, plates, or screws, nor is it routinely indicated for most dental patients with total joint replacements. However it is advisable to consider premedication in a small number of patients who may be at potential increased risk [1. All patients during first two years following joint replacement; 2. Immunocompromised/immunosuppresed patients; and 3. Patients with comorbidities (previous joint infections, malnourishment, hemophilia, HIV-infected, Insulin-dependent type-1 diabetes, malignancy)] of experiencing hematogenous total joint infections." [1]

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COMPLICATIONS: BLEEDING

Policy Statement: One of the most serious complications of an abortion procedure is hemorrhage. Early recognition of the source of bleeding can reduce morbidity and mortality.

PRE-PROCEDURE BLEEDING

Recommendation 0.1: An ectopic pregnancy or spontaneous abortion should be considered.

PERI-PROCEDURE BLEEDING

Standard 1: When there is excessive bleeding, the provider must institute measures to identify the etiology of the bleeding and control it.

Recommendation 1.1: IV access should be established.

Recommendation 1.2: The provider should consider incomplete procedure, atony, fibroids, lacerations, perforations, placenta accreta, cervical or cornual pregnancy, and coagulopathy.[A]

Option 1.21: Ultrasonography may be useful to determine whether the uterus is empty and to detect occult bleeding.

Option 1.22: When a cervical bleeding source is suspected, hemostasis may be achieved by compressing the cervix at the lateral fornices with ring forceps or placing a suture.

Option 1.23: When atony is suspected, uterine massage and uterotonics[B] may be useful.

Option 1.24: When coagulopathy is suspected, blood may be drawn for coagulation parameters and transfusion of blood or blood products may be necessary.

[A] See guidelines for "Complications: Perforation."

[B] methergine (intracervical or IM); oxytocin (intracervical, IM, or IV); prostaglandins (e.g. prostin, intracervical, or IM)

Recommendation 0.2: When excessive bleeding continues, the following measures should be instituted:

a. monitor and document blood pressure, pulse, clinical status;
b. uterotonics;
c. maintain IV access;
d. initiate appropriate volume replacement; and
e. prepare for transfer to a hospital facility if necessary.[C]

Standard 2: The patient must be transferred to a hospital facility when the bleeding does not respond to therapeutic measures or when the patient is hemodynamically unstable.[C]

DELAYED BLEEDING

Standard 3: When a patient reports excessive bleeding[D] after discharge from the abortion facility, she must be evaluated by that facility or an emergency contact service.

Discussion: Excessive bleeding in the peri-procedure and in the post-procedure period is almost always due to uterine atony, often complicated by incomplete emptying of the uterus. Therefore, the most important initial efforts should be directed at assuring complete evacuation of the uterus and at increasing uterine tone through uterotonics.

Problems arise when bleeding is ignored or its severity underestimated. Clinicians must always remember to do the simple things when confronted with a developing bleeding problem: continue assessment of the blood loss, measure and record blood pressure and pulse frequently, and assure intravenous access.

Many clinicians give uterotonics and vasoconstrictors as a preventive measure. Although there are data to support the routine use of vasopressin in the paracervical block, there is little evidence in the literature for other routine prophylactic strategies. However, experienced clinicians have found the following regimens useful:

In the paracervical block:

a. 2-6 units of vasopressin;
b. 4-8 units of oxytocin (e.g., 10 units in 50 cc of lidocaine, using 20 cc of the lidocaine for the block, or 4 units total dose);
c. epinephrine (20 cc of 1:200,000 in lidocaine, equivalent to 0.1 cc of 1:1,000); or
d. none of the above.

[C] See guidelines for "Emergency Procedures for Facilities that Offer/Provide Minimal Sedation."
[D] Saturation of more than one pad per hour for more than three hours.

Post-procedure, the following measures may be used for treatment of post-abortion hemorrhage:

a. methergine 0.2mg po, IM, intracervical, or IV;
b. oxytocin 10units IM or 10-40 units IV;
c. misoprostol 800-1000mcg pr or 800mcg sl (has been used for PPH);
d. hemabate 0.25mcg IM;
e. intrauterine pressure (e.g., Foley or Bakri balloon, or pack); or
f. vaginal pack.

When bleeding continues after assurance of complete uterine emptying and when there are no visible cervical or vaginal lacerations, the clinician must consider other complications such as perforation, coagulopathy, or placenta accreta.[E]

References:

1. Hakim-Elahi, E. & Tovell, H. Complications of first-trimester abortion: A report of 170,000 cases. *Obstet Gynecol* 1990, 76:129.

rev. October 2009

[E] See guidelines for "Complications: Perforation."

COMPLICATIONS: PERFORATION

Policy Statement: Uterine perforation is a complication of abortion that can lead to significant morbidity.

Standard 1: If, in the clinician's judgment, an instrument passes farther than expected, then uterine perforation must be considered.

Standard 2: If a perforation occurs, even if the patient is asymptomatic, close observation and follow-up must be done.

Option 2.01: Antibiotic coverage may be instituted.

Option 2.02: Uterotonics may be administered.

Option 2.03: The patient may be transferred to a hospital.

Option 2.04: If a perforation occurs and *the pregnancy has not been disrupted*, the completion of the procedure may occur immediately, after a delay, or by referral to another provider.

Recommendation 2.1: If a perforation occurs and *the pregnancy has been disrupted*, the abortion should be completed as soon as feasible.

Option 2.05: The uterine evacuation may be completed under direct ultrasonography.

Option 2.06: The abortion may be completed under laparoscopic visualization.

Standard 3: The patient must be hospitalized for definitive care if:

a. intra-abdominal viscera are detected in the uterine cavity, cervix, vagina, suction tubing, or on tissue examination;
b. fetal parts are detected in the abdominal cavity;
c. expanding intra-abdominal or retroperitoneal hematoma is detected; or
d. hemodynamic instability is present.

Standard 4: When uterine perforation is suspected and the cannula has been inserted into the uterine cavity, suction must be released immediately before the cannula is withdrawn.

Discussion: Perforations may be difficult to identify correctly. When a perforation is suspected, it is safest to proceed as if there has been a perforation until that possibility has been excluded.

Most perforations are midline and/or fundal in location, especially in the first trimester. Perforations are often occult and usually do not present a problem. In second trimester abortions there is an increased risk of serious perforations because the myometrium is more vascular and less resistant to damage by larger instruments. Lateral perforations are more likely to damage uterine vascularity. Perforations are more likely to occur in the following situations:

a. marked uterine anteflexion or retroflexion;
b. cervical internal os stenosis requiring more force to dilate;
c. uterine abnormalities; and
d. difficult and prolonged uterine evacuation.

Uterine perforation is likely if:

a. an instrument extends without resistance further into the uterine cavity than expected;
b. the patient experiences more than the expected amount of pain during the procedure; or
c. the patient experiences inordinate and persistent pain in the immediate recovery period.

Several factors may help prevent perforations:

a. accurate assessment of gestational age;
b. accurate assessment of uterine position;
c. straightening the axis of the uterus; and
d. cervical preparation beyond the first trimester.[A]

References:

1. Cervical preparation for second-trimester surgical abortion prior to 20 weeks of gestation. *Contraception* 2007, 76:486.

2. Cervical preparation for surgical abortion from 20-24 weeks' gestation. *Contraception* 2008, 77:308.

3. Elchalal, *et al.* Ultrasound-directed diagnosis and treatment of pelvic hematoma after therapeutic abortion. *J Clin Ultrasound* 1993, 21:55.

4. Freiman, SM & Wulff, GJ Jr. Management of uterine perforation following elective abortion. *J Obstet Gyn* 1977, 50:647.

5. Kaali, SG, *et al.* The frequency and management of uterine perforations during first-trimester abortions. *Am J Obstet Gynecol* 1989, 161:406.

6. Lajinian, S, *et al.* Sonographic appearance of suspected iatrogenic uterine perforation. *J Reprod Med* 1994, 39:911.

7. Lauersen, NH & Birnbaum, S. Laparoscopy as a diagnostic and therapeutic technique in uterine perforations during first-trimester abortions. *Am J Obstet Gynecol* 1973, 117:522.

8. White, MK, *et al.* A case-control study of uterine perforations documented at laparoscopy. *Am J Obstet Gynecol* 1977, 129:623.

rev. October 2009

[A] See guidelines for "Second Trimester Abortion by D&E."

POST-PROCEDURE CARE

Policy Statement: Most serious abortion complications are detectable in the immediate post-procedure period. Appropriate and accessible follow-up care is essential to patients' well-being.

Standard 1: Rh immune globulin must be offered in accordance with Rh guidelines.[A]

Standard 2: All patients must be observed during the recovery period by a health care worker trained in post-procedure care.

Standard 3: A clinician must remain in the facility until all patients are medically stable.[B]

Standard 4: The following criteria must be documented prior to discharge: the patient must be ambulatory with a stable blood pressure and pulse, and bleeding and pain must be controlled.

Standard 5: The patient must be given oral and written instructions outlining what to expect post-procedure, self-care, and signs and symptoms of complications.

Standard 6: The facility must provide an emergency contact service on a 24-hour basis, where calls are triaged in accordance with written policies and which conform to applicable regulations. A recorded message alone is unacceptable.

Standard 7: Any non-clinician involved with first-call triage must be trained to take a post-abortion health history and follow clear written guidelines indicating when immediate consultation with a clinician is indicated.

Standard 8: Any patient who gives a history suggestive of a post-procedure complication must have access to a clinician. The facility must establish a pathway for physician referral if indicated.

rev. December 2012

[A] See guidelines for "Rh Testing and Rh Immune Globulin Administration."
[B] Clinician is defined as a physician, nurse practitioner, physician assistant, or nurse midwife.

EVALUATION OF EVACUATED UTERINE CONTENTS

Policy Statement: Complete removal and identification of products of conception help prevent complications of abortion.

Standard 1: Completion of abortion must be confirmed prior to the woman leaving the facility.

a. When a fetal pole is not seen with pre-procedure ultrasound, evacuated uterine contents must be examined before the woman leaves the facility.
b. In other cases either tissue exam or ultrasound must be used to confirm evacuation.

Recommendation 1.1: Evacuated uterine contents should be examined before the woman leaves the facility.

Recommendation 1.2: In first trimester terminations, flotation of tissue with backlighting should be used to identify products of conception, including gestational sac.

Option 1.01: Pathological examination of evacuated uterine contents is not required.

Standard 2: When insufficient tissue or incomplete products of conception are obtained, or ultrasound findings unclear, the patient must be reevaluated.

Recommendation 2.1: Follow-up pelvic ultrasonographic examination should be considered.

Recommendation 2.2: Resuctioning should be considered.

Recommendation 2.3: Serial quantitative hCG or sensitive urine pregnancy tests should be considered.[A]

Standard 3: If insufficient tissue is present after adequate patient evaluation, a protocol to rule out ectopic pregnancy must be followed, and the patient must be informed of symptoms and dangers of ectopic pregnancy.

Recommendation 3.1: If the uterine cavity is determined to be empty, serial quantitative hCG tests should be measured.

[A] Sensitive urine pregnancy test is positive at 25 MIU of β-hCG.

Standard 4: The patient must not be released from follow-up care until the diagnosis of ectopic pregnancy has been excluded or an appropriate referral has been documented.

Recommendation 4.1: A 48-hour post-procedure serum quantitative hCG test should be done. If there is a decrease of 50% or more, no further ectopic follow up is necessary.[1]

Recommendation 4.2: If 48-hour post-procedure serum quantitative hCG testing shows no change, or a subnormal increase in value, ectopic pregnancy evaluation and definitive treatment should be instituted and documented, or a referral made and documented.

Standard 5: In second trimester abortions, placenta and all major fetal parts must be removed from the uterus.

Recommendation 5.1: If the above are not identified, ultrasonographic evaluation and repeat uterine exploration under ultrasound guidance should be considered.

Recommendation 5.2: The clinician should continue care of the patient until completion of the abortion has been determined.

References:

1. Creinin, MD. Change in serum beta-human chorionic gonadotropin after abortion with methotrexate and misoprostol. *Am J Obstet Gynecol* 1996 Feb; 174(2):776-8.

rev. October 2009

FETAL TISSUE HANDLING, STORAGE, AND DISPOSAL

Policy Statement: The improper handling, storage, and disposal of tissue can lead to spread of infectious disease, and can increase the risk of theft or misplacement of tissue. Because of the possible infectious nature of tissue removed during the abortion procedure, guidelines for proper fetal tissue handling, storage, and disposal are established.

Standard 1: All surgically removed tissue must be considered biohazardous and be handled, stored, and disposed of in accordance with applicable governmental regulations. A proper protocol for tissue handling, storage, and disposal must be in place.

Standard 2: Adequate engineering and work practice controls for handling potentially infectious materials must be observed.[A]

rev. October 2011

[A] Engineering control—available technology and devices that isolate or remove hazards from the work place, such as puncture-resistant sharps disposal containers.
Work practice control—an alteration in the way a task is performed that reduces the likelihood that an employee will be exposed to blood or other potentially infectious materials.

EMERGENCY PROCEDURES FOR FACILITIES THAT OFFER/PROVIDE MINIMAL SEDATION[A]

Policy Statement: Optimal management of abortion emergencies reduces morbidity.

Standard 1: When abortion procedures are being performed, a current health care provider level BLS-certified staff member trained and certified to the level equivalent to AHA health care provider level must be available on-site.

Recommendation 1.1: All medical staff should have current health care provider level BLS certification.

Standard 2: Functioning equipment and current medications must be available on-site to handle medical emergencies and must include: an oxygen delivery system; oral airways; uterotonics; vasopressors, including epinephrine; and antihistamines.

Recommendation 2.1: Facilities should have a specified area for emergency equipment, which includes oxygen, medications, and supplies. A protocol and time schedule for checking equipment and removing expired medications must be in place.

Standard 3: Protocols for the management of medical emergencies must be in place. These protocols must include indications for emergency transport and written, readily available directions for contacting external emergency assistance (i.e., an ambulance).

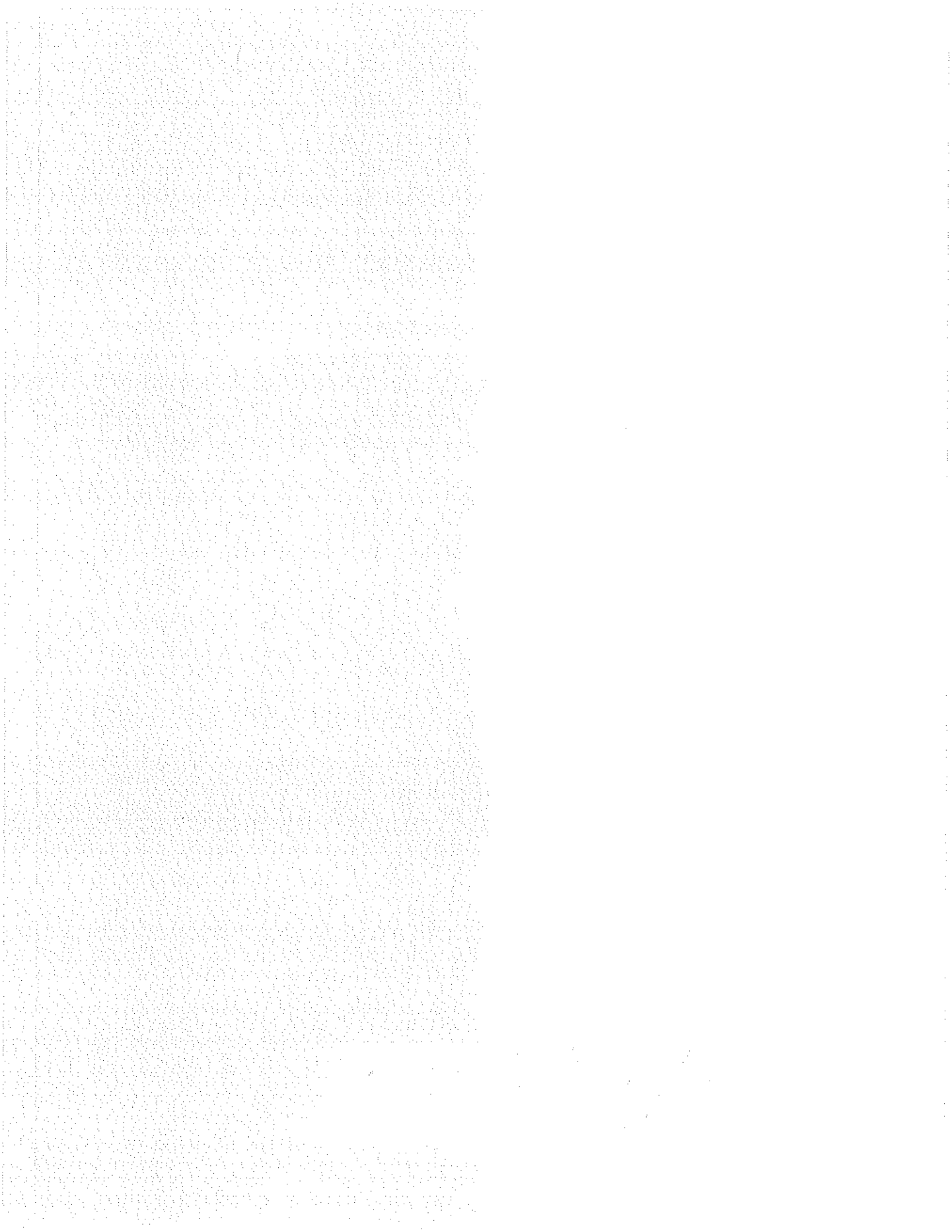
Recommendation 3.1: All staff should know their appropriate roles in the management of medical emergencies.

Recommendation 3.2: Clinics should consider developing a transfer agreement with a hospital outlining the means of communication and transport and the protocol for emergent transfer of care.

Standard 4: In settings where benzodiazepines and opioids are used, appropriate antagonists, bronchodilators, and ambu bags must be available.

rev. December 2012

[A] Where moderate or greater sedation is provided, a provider capable of handling associated emergencies must be present. See guidelines for "Analgesia and Sedation."



Red River Women's Clinic
512 First Avenue North
Fargo, ND 58102

PROTOCOL FOR MIFEPRISTONE AND MISOPROSTOL IN EARLY ABORTION

ELIGIBILITY:

1. Women considering medication abortion with mifepristone and misoprostol:
   a. Should not have any of the following:
      1) Hemorrhagic disorder, or concurrent anticoagulant therapy
      2) Chronic adrenal failure
      3) Concurrent long-term systemic corticosteroid therapy
      4) Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass
      5) Inherited porphyrias
      6) IUD in place (must remove before treatment)
      7) History of allergy to mifepristone, misoprostol or other prostaglandin
      8) Unwillingness to undergo a surgical abortion (if indicated);
   b. Should have gestation no more that 63 days from the first day of the last menstrual period (LMP) with concordant clinical examination. Confirmation by ultrasound may be used routinely, and is essential if the duration of the pregnancy is uncertain or if an ectopic pregnancy is suspected;
   c. Should be able to give informed consent, comply with treatment requirements, receive the mifepristone/Mifeprex™ Medication Guide, and sign the mifepristone/Mifeprex™ patient agreement; and
   d. Should have access to a telephone and transportation to a medical facility equipped to provide emergency treatment of incomplete abortion, blood transfusions and emergency resuscitation.
2. Special considerations:
   a. There are no data available on the effects of mifepristone or misoprostol while breastfeeding.
   b. Current severe anemia should be considered when assessing eligibility due to the bleeding involved in the process. Most research studies do not include women with a hemoglobin <10 gm/dl.
   c. Concurrent illness with significant diarrhea should be considered when assessing eligibility because of the diarrhea associated with misoprostol use.
   d. Any patient with serious systemic illness (e.g. severe liver disease, significant cardiac disease, renal failure, uncontrolled seizure disorder) should be evaluated individually to determine the safest method of pregnancy termination.

COUNSELING, EDUCATION, and INFORMED CONSENT should include:

1. Discussion of the decision to have an abortion and assurance that the decision is patient's own;
2. Discussion of non-surgical and suction abortion alternatives and the risks and benefits of each;
3. Discussion of known side effects and possible complications of mifepristone and misoprostol. This discussion should include:
   a. Information about what symptoms warrant contacting the on-call provider, for example:
      1) Soaking 2 or more maxipads per hour for 2 consecutive hours;
      2) Sustained fever or onset of fever > 24 hours after misoprostol;
      3) No bleeding within 24 hours after using misoprostol, as this may indicate failure of the

abortion and could be an indication of an ectopic pregnancy.
4) Cramping unrelieved by medications given and comfort measures

b. Explanation that mifepristone is not known to increase the risk of teratogenesis in humans, but that fetal malformations have been reported after first trimester use of misoprostol. Therefore, *women must he strong/v advised to complete the abortion, either medical/v or surgically, once the medications have been administered;*

4. Explanation that mifepristone combined with misoprostol has been approved by the FDA for induction of abortion; there is both a FDA approved regimen and an evidence based regimen. RRWC recommends the evidence based regimen
5. Discussion of the length of time involved in the medication abortion process, and the requirement of at least 2 visits. Onset of bleeding and likely expulsion are more consistent and more rapid in regimens using 800 µg vaginal misoprostol;
6. Discussion of amount of pain experienced by previous patients and the use of pain medications. The patient should have an appropriate supply and instructions for use of oral pain medications once treatment is initiated. Pain is typically described as cramping and is most intense during expulsion, most commonly over a 1-3 hour period, after which the pain usually subsides;
7. Instruction concerning the administration of misoprostol;
8. Discussion of the amount and quality of bleeding associated with the abortion process, including:
   a. bleeding is typically heavier than menses and may depend on the length of the pregnancy;
   b. likelihood of the passage of clots;
   c. an embryo is approximately the size of a grain of rice at the time when medical abortion is most commonly provided, and is not typically seen until 8½ to 9 weeks' gestation;
   d. while many women may start bleeding prior to using misoprostol, misoprostol is typically needed to complete the process;
   e. using maxi-pad sanitary napkins allows the clinician to assess the amount of bleeding;
9. A review of the Medication Guide given to the patient, the signed patient agreement, and consent form, specifying that our regimen differs from the FDA regimen and details the evidence-based regimen being used;
10. Compliance with additional applicable state and local laws, ordinances, regulations, and common law governing the consent process and standard of care for abortion procedures;
11. Discussion of issues of confidentiality;
12. Review of aftercare instructions, including 24-hour emergency contact information; and
13. Availability of contraception and contraceptive counseling. Contraception may be started within 5 days of the above regimen.

MEDICAL HISTORY and PHYSICAL EXAMINATION should include:

1. Pertinent medical and obstetrical history, including history of allergies and all current patient medications;
2. Pertinent physical examination, including vital signs;
3. Determination of gestational age by clinical assessment, with ultrasonography or with the aid of pregnancy tests ;
4. Ultrasonographic examination when indicated.

ULTRASOUND EXAMINATION:

1. Transvaginal probe or abdominal probe ultrasound will be used routinely to confirm gestational age and intrauterine gestation. Transvaginal probe ultrasound is preferable because it detects a pregnancy about 1 week earlier than abdominal probe ultrasound. Findings (gestational sac, yolk sac, embryonic pole, presence of cardiac activity) will be documented for the medical record

before administering mifepristone.

3. If an embryonic pole is visible, use this measurement instead of gestational sac measurement because it is more accurate for dating.
4. If an intrauterine sac is not present, this could indicate early intrauterine pregnancy, ectopic pregnancy, or an abnormal intrauterine pregnancy. After clinical assessment, further evaluation may be warranted. A quantitative serum β-Urine Pregnancy test of greater than 2000 mIU/ml with no intrauterine sac seen using transvaginal ultrasound, or greater than 3600 mIU/ml with no intrauterine sac seen using abdominal ultrasound, may indicate an ectopic pregnancy and warrants immediate further evaluation and/or treatment. Mifepristone should not be administered if ectopic pregnancy is suspected. The finding of abdominal pain and an adnexal mass or the absence of significant bleeding after using the mifepristone/misoprostol regimen may also indicate ectopic pregnancy.

LABORATORY EVALUATION:

1. Test to confirm pregnancy (urine Urine Pregnancy test, β-Urine Pregnancy test, or ultrasound).
2. Documentation of Rh factor.
3. Hemoglobin or hematocrit is recommended.
4. β-Urine Pregnancy test level is not required unless it is being used to monitor the completeness of the abortion or ectopic pregnancy is suspected.
5. Other tests as medically indicated.

MEDICATION and FOLLOW-UP:

FDA-APPROVED LABEL:

Medications must be administered by or under the supervision of a physician able to: assess the pregnancy's gestational age; diagnose ectopic pregnancies; provide surgical aspiration intervention or have plans in place to provide such care through others if needed; and assure patient access to emergency medical facilities equipped to provide blood transfusions and emergency resuscitation during the treatment procedure. Individual providers are not limited to the uses or regimens set forth in FDA-approved labeling. The FDA has consistently adhered to a policy that permits evidence-based use of approved medications. Red River Women's Clinic recommends the following evidence-based protocol:

DAY 1:

a. Mifepristone 200 mg (one 200 mg tablet) taken orally.
b. Rh immune globulin for Rh-negative patients (can be administered on Day I). Approximately 15% of women are Rh negative. For women having a medical abortion, and for women with pregnancies through 12 weeks gestation, the 50 mcg dose is prescribed.

DAY 2-3:

Unless abortion has occurred and has been confirmed by clinical examination or ultrasonography, 24 to 48 hours later, the patient inserts 800 µg misoprostol bucally at home. While onset of bleeding prior to misoprostol administration occurs in approximately 50% of patients, most women will need misoprostol to complete the process.

DAY 3-21:

Patient returns for a follow-up visit on approximately to be assessed for completion of abortion clinically, by ultrasonography, or by documenting a significant decrease in serum β-Urine Pregnancy test levels. Surgical abortion is recommended if a viable pregnancy is detected at this time by ultrasonography, because the pregnancy may continue and there is a risk of fetal malformation.

CONCLUSION OF TREATMENT:

When completion of the medication abortion is confirmed clinically or the absence of the gestational sac is noted on sonography, the patient should receive follow-up instructions including information about expected length of bleeding, signs and symptoms of incomplete abortion, and any other pertinent medical information. It is not uncommon for women to experience an episode of heavy bleeding or persistent bleeding requiring evaluation after the 14-21 day visit. Contraception of any type may be started immediately after confirmation of abortion.

SELECTED STUDIES ON REGIMENS WITH MIFEPRISTONE/MISOPROSTOL:

Allen RH, Westhoff C, DeNonno L, Fielding SL, Schaff SA. Curettage after mifepristone-induced abortion: frequency, timing, and indications. *Obstet Gynecol* 2001;98:101-106.

Fischer M, Bhatnagar J, Guarner J, et al. Fatal toxic shock syndrome associated with Clostridium sordelli after medical abortion. *New Engl J Med* 2005; 353:2352-2360.

Grimes DA. Medical abortion in early pregnancy: A review of the evidence. *Obstet Gynecol* 1997;89:790-6.

Kahn JG, Becker BJ, MacIsaac L, et al. The efficacy of medical abortion: A meta-analysis. *Contraception* 2000; 61: 29-40.

Middleton T, Schaff E, Fielding S, et al. Randomized trial of mifepristone and buccal or vaginal misoprostol for abortion through 56 days of last menstrual period. *Contraception* 2005; 72: 328-332.

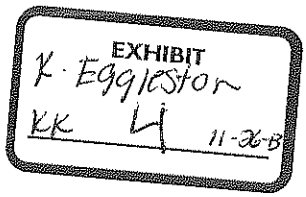
Paul M, Creinin MD (eds). Supplement on Early Medical Abortion. *Am J Obstet Gyn* 2000; 183: S1-S94.

Schaff EA, Eisinger SH, Stadalius LS, Franks P, Gore BZ, Poppema S. Low-dose mifepristone 200mg and vaginal misoprostol for abortion. *Contraception* 1999;59:1-6.

Schaff EA, Fielding SL, Eisenger SH, Stadalius LS, Fuller L. Low-dose mifepristone followed by vaginal misoprostol at 48 hours for abortion up to 63 days. *Contraception* 2000;61:41-46.

Schaff EA, Fielding SL, Westhoff C. Randomized trial of oral versus vaginal misoprostol at one day after mifepristone for early medical abortion. *Contraception* 2001; 64: 81-85.

Wiebe E, Dunn S, Guilbert E, Jacot F, Lugtig L. Comparison of abortions induced by methotrexate or mifepristone followed by misoprostol. *Obstet Gynecol* 2002; 99: 813-9.



IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA
SOUTHWESTERN DIVISION

MKB MANAGEMENT CORP., et al., Plaintiffs, vs. BIRCH BURDICK, et al., Defendants.	Case No.

DECLARATION OF KATHRYN L. EGGLESTON, M.D. IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELMINARY INJUNCTION

Kathryn L. Eggleston, M.D., declares and states the following:

1. I am a physician licensed to practice in North Dakota, and a Plaintiff in this case.

2. I am a board-certified family medicine physician and have been providing reproductive health care for women, including abortion, colposcopy services, and family planning services, for over a decade. In addition, I have provided full-spectrum family medicine care, including obstetric and prenatal care and gynecologic services, to numerous patients. I graduated from the Medical College of Wisconsin with an M.D. in 1996 and from Colorado State University with a B.S. in Biological Science in 1991. I completed my residency at the University of Wisconsin's Eau Claire Family Medicine Residency Program in 1999. I have trained residents and medical students in reproductive health care methods, including medication and surgical abortion.

3. The opinions provided herein, which are held to a reasonable degree of medical certainty, are based upon my fourteen years of experience as a family medicine physician and

reproductive health care provider, and the knowledge I have obtained through my education, training, teaching experience, discussions with colleagues, attendance at conferences, and ongoing review of the relevant professional literature. A copy of my curriculum vitae, which summarizes my background, experience, and professional activities, is attached as Exhibit A.

4. I submit this affidavit in support of Plaintiffs' motion for a preliminary injunction. It is my belief that enforcement of House Bill 1456 (the "ban"), which effectively bans the provision of most abortions in North Dakota, will harm the patients of Red River Women's Clinic ("the Clinic"), and force me to choose between the provision of abortions and the risk of criminal prosecution.

Red River Women's Clinic

5. Red River Women's Clinic is a women's reproductive health clinic located in downtown Fargo. The Clinic provides a range of medical services, including abortions, family planning services, including contraceptive education and prescribing, intrauterine contraception placement and removal, contraceptive implant placement and removal, cancer screening, testing and treatment for sexually-transmitted infections, pregnancy testing, and ultrasounds.

6. I have been the medical director of Red River Women's Clinic since 2008. I oversee the provision of all medical care at the Clinic.

7. I provide abortions at the Clinic one day a week, about forty-five to fifty weeks each year.

8. Pregnancy is commonly measured by the number of days that have passed since the first day of a woman's last menstrual period ("lmp"). The Clinic provides abortions to women from about five weeks lmp through about sixteen weeks lmp.

9. Red River Women's Clinic's protocols include an ultrasound for all abortion patients. This is important for several purposes. These include dating the pregnancy, determining whether the pregnancy is located inside the patient's uterus, and detecting cardiac activity. A physician needs to confirm an intrauterine pregnancy and gestational age in order to safely provide an abortion. The presence of cardiac activity is an important indicator that a pregnancy retains the potential for viability. Cardiac activity is detectible by about 6 weeks lmp on average, and sometimes a few days earlier. No detectible cardiac activity after seven weeks can be a sign of a nonviable pregnancy or miscarriage. Our patients need to be informed of this so that they can choose, if they wish, have a procedure in our clinic, seek care from their primary care physician, or await a miscarriage. For all these reasons, ultrasound, including for the purposes of checking for cardiac activity, is standard medical practice in abortion care.

10. In early pregnancy, the location and gestational age of the embryo, as well as the presence or absence of cardiac activity is usually determined by vaginal ultrasound, rather than by any other method. Vaginal ultrasound uses a higher frequency of sound waves and is inserted directly into the vagina, creating a clearer image to confirm whether the pregnancy is in the uterus and whether cardiac activity is present.

11. The Clinic does not typically perform abortions before five weeks lmp because, due to the pregnancy's extremely small size, it may not be possible to confirm the location of the pregnancy in the uterus, even using vaginal ultrasound. If the location of the pregnancy is not confirmed, it can be dangerous to perform an abortion.

12. Using vaginal ultrasound, some of the structures of pregnancy – principally, the yolk sac – can be reliably detected beginning at about five weeks lmp. Visualization of cardiac activity around 6 weeks lmp is possible even though the embryo itself is still extremely small

(only about four to five millimeters in length) because the cells that will unite to form the heart later in development have already begun moving, and this motion can be visible on the ultrasound.

13. North Dakota law defines viability as "the ability . . . to live outside the mother's womb, albeit with artificial aid." N.D. Cent. Code. § 14-02.1-02(14). A fetus does not become viable until approximately twenty-four weeks lmp.

The Impact of the Ban on Red River Women's Clinic's Patients

14. Many women do not know they are pregnant until after 6 weeks lmp. Typically, only women who have regular menstrual periods, keep close track of them, and take a pregnancy test promptly after missing a period at four weeks lmp will know they are pregnant by 6 weeks.

15. House Bill 1456 will ban virtually all abortions performed at the Clinic beginning around 6 weeks lmp, which encompasses almost all of the abortions we currently perform.

16. Since the Clinic only performs abortions one day per week, and cannot safely perform abortions before five weeks lmp, the bill will effectively limit women's ability to obtain an abortion to a single day during their pregnancy's fifth week.

17. Most of the women who currently receive abortions from the Clinic at or after 6 weeks lmp would probably be unable to schedule their abortions early enough to avoid the ban, due to a combination of some or all of the following reasons: they will not yet have realized that they are pregnant; they will be unable to gather the necessary funds or obtain transportation in sufficient time to reach the Clinic; they will be unable to take the necessary time off work with such short notice; they will be waiting through the delays imposed by the laws of the State of North Dakota; or they will need more time than the few days allotted to them to make the important decision of whether or not to have an abortion.

18. Abortion is a common medical procedure. About one in three American women will have an abortion over their lifetime. About twenty-two percent of all pregnancies, excluding miscarriages, end in abortion.

19. Abortion is one of the safest medical procedures in the United States. A recent large study found that the prevalence of any complication of first-trimester surgical abortion performed by physicians was 0.89%; the prevalence of major complications requiring treatment at a hospital was 0.05%. Carrying a pregnancy to term carries much higher risks of both morbidity and mortality than does obtaining an abortion through around twenty weeks lmp. The mortality rate associated with continuing a pregnancy in the United States is approximately fifteen times higher than that associated with abortion.

20. Access to safe and legal abortion benefits the health and wellbeing of women and their families. The availability of abortion enables women not to forego educational and economic opportunities due to unplanned childbirth, to avoid raising children with an absent or unwilling partner, and to prevent medical harms that arise from carrying risky or non-viable pregnancies to term. I have seen all of these benefits in the lives of my patients.

21. I provide my patients with abortions because they have determined that an abortion is the right choice for them. Pregnant women are capable of deciding for themselves whether to terminate a pregnancy, taking into account all relevant factors. When a woman has made that decision, it is important that she have a safe, high-quality, caring option for undertaking it. I and the rest of the staff at the Red River Women's Clinic provide that option. The ban presents me with an impossible choice: to face criminal prosecution or professional discipline for continuing to safely provide abortion care in accordance with my patients'

strongly-held desire and my own best medical judgment, or to stop providing my patients the care they seek.

I declare under penalty of perjury that the foregoing is true and correct.

Dated this 20th day of June, 2013.

Kathryn L. Eggleston, M.D.

West's North Dakota Century Code Annotated
Title 14. Domestic Relations and Persons
Chapter 14-02.1. Abortion Control Act

NDCC, 14-02.1-02

§ 14-02.1-02. Definitions

Currentness

As used in this chapter:

1. "Abortion" means the act of using or prescribing any instrument, medicine, drug, or any other substance, device, or means with the intent to terminate the clinically diagnosable intrauterine pregnancy of a woman, including the elimination of one or more unborn children in a multifetal pregnancy, with knowledge that the termination by those means will with reasonable likelihood cause the death of the unborn child. Such use, prescription, or means is not an abortion if done with the intent to:

a. Save the life or preserve the health of the unborn child;

b. Remove a dead unborn child caused by spontaneous abortion; or

c. Treat a woman for an ectopic pregnancy.

2. "Abortion-inducing drug" means a medicine, drug, or any other substance prescribed or dispensed with the intent of causing an abortion.

3. "Abortion facility" means a clinic, ambulatory surgical center, physician's office, or any other place or facility in which abortions are performed or prescribed, other than a hospital.

4. "Drug label" means the pamphlet accompanying an abortion-inducing drug which outlines the protocol tested and authorized by the federal food and drug administration and agreed upon by the drug company applying for the federal food and drug administration authorization of that drug. Also known as "final printing labeling instructions", drug label is the federal food and drug administration document that delineates how a drug is to be used according to the federal food and drug administration approval.

5. "Hospital" means an institution licensed by the state department of health under chapter 23-16 and any hospital operated by the United States or this state.

6. "Human being" means an individual living member of the species of homo sapiens, including the unborn human being during the entire embryonic and fetal ages from fertilization to full gestation.

7. "Infant born alive" means a born child which exhibits either heartbeat, spontaneous respiratory activity,

spontaneous movement of voluntary muscles or pulsation of the umbilical cord if still attached to the child.

8. "Informed consent" means voluntary consent to abortion by the woman upon whom the abortion is to be performed or induced provided that:

a. The woman is told the following by the physician who is to perform the abortion, by the referring physician, or by the physician's agent, at least twenty-four hours before the abortion:

(1) The name of the physician who will perform the abortion;

(2) The abortion will terminate the life of a whole, separate, unique, living human being;

(3) The particular medical risks associated with the particular abortion procedure to be employed including, when medically accurate, the risks of infection, hemorrhage, danger to subsequent pregnancies, and infertility;

(4) The probable gestational age of the unborn child at the time the abortion is to be performed; and

(5) The medical risks associated with carrying her child to term.

b. The woman is informed, by the physician or the physician's agent, at least twenty-four hours before the abortion:

(1) That medical assistance benefits may be available for prenatal care, childbirth, and neonatal care and that more detailed information on the availability of that assistance is contained in the printed materials given to her as described in section 14-02.1-02.1;

(2) That the printed materials given to her and described in section 14-02.1-02.1 describe the unborn child and list agencies that offer alternatives to abortion;

(3) That the father is liable to assist in the support of her child, even in instances in which the father has offered to pay for the abortion; and

(4) That she is free to withhold or withdraw her consent to the abortion at any time without affecting her right to future care or treatment and without the loss of any state or federally funded benefits to which she might otherwise be entitled.

c. The woman certifies in writing, prior to the abortion, that the information described in subdivisions a and b has been furnished to her.

d. Before the performance of the abortion, the physician who is to perform or induce the abortion or the physician's agent receives a copy of the written certification prescribed by subdivision c.

e. The physician has not received or obtained payment for a service provided to a patient who has inquired about an abortion or has scheduled an abortion before the twenty-four-hour period required by this section.

9. "Medical emergency" means a condition that, in reasonable medical judgment, so complicates the medical condition of the pregnant woman that it necessitates an immediate abortion to avert her death or for which the twenty-four-hour delay will create serious risk of substantial and irreversible physical impairment of a major bodily function. A condition may not be deemed a medical emergency if based on a claim or diagnosis that the woman will engage in conduct that would result in her death or in substantial and irreversible physical impairment of a major bodily function.

10. "Physician" means an individual who is licensed to practice medicine or osteopathy under chapter 43-17 or a physician who practices in the armed services of the United States or in the employ of the United States.

11. "Probable gestational age of the unborn child" means what, in reasonable medical judgment, will with reasonable probability be the gestational age of the unborn child at the time the abortion is planned to be performed.

12. "Reasonable medical judgment" means a medical judgment that would be made by a reasonably prudent physician, knowledgeable about the case and the treatment possibilities with respect to the medical conditions involved.

13. "Unborn child" means the offspring of human beings from conception until birth.

14. "Viable" means the ability of an unborn child to live outside the mother's womb, albeit with artificial aid.

Credits

S.L. 1975, ch. 124, § 1; S.L. 1979, ch. 191, §§ 1, 2; S.L. 1991, ch. 141, §§ 1, 2; S.L. 1995, ch. 243, § 2; S.L. 2009, ch. 142, § 1, eff. Aug. 1, 2009; S.L. 2011, ch. 109, § 1, eff. Aug. 1, 2011.

HISTORICAL AND STATUTORY NOTES

S.L. 2009, ch. 142, § 1, inserted the definition of "Human being" as subsec. 4; redesignated former subsecs. 4 to 9 as subsecs. 5 to 10; and in subsec. 6 a, inserted par. (2) and redesignated former pars. 2 to 4 as pars. 3 to 5.

S.L. 2011, ch. 109, § 1, rewrote the section, which previously read:

"As used in this chapter:

"1. 'Abortion' means the termination of human pregnancy with an intention other than to produce a live birth or to remove a dead embryo or fetus.

"2. 'Abortion facility' means a clinic, ambulatory surgical center, physician's office, or any other place or facility in which abortions are performed, other than a hospital.

"3. 'Hospital' means an institution licensed by the state department of health under chapter 23-16 and any hospital operated by the United States or this state.

"4. 'Human being' means an individual living member of the species of homo sapiens, including the unborn human being during the entire embryonic and fetal ages from fertilization to full gestation.

"5. 'Infant born alive' or 'live born child' means a born child which exhibits either heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles or pulsation of the umbilical cord if still attached to the child.

"6. 'Informed consent' means voluntary consent to abortion by the woman upon whom the abortion is to be performed provided that:

"a. The woman is told the following by the physician who is to perform the abortion, by the referring physician, or by the physician's agent, at least twenty-four hours before the abortion:

"(1) The name of the physician who will perform the abortion;

"(2) The abortion will terminate the life of a whole, separate, unique, living human being;

"(3) The particular medical risks associated with the particular abortion procedure to be employed including, when medically accurate, the risks of infection, hemorrhage, danger to subsequent pregnancies, and infertility;

"(4) The probable gestational age of the unborn child at the time the abortion is to be performed; and

"(5) The medical risks associated with carrying her child to term.

"b. The woman is informed, by the physician or the physician's agent, at least twenty-four hours before the abortion:

"(1) That medical assistance benefits may be available for prenatal care, childbirth, and neonatal care;

"(2) That the father is liable to assist in the support of her child, even in instances in which the father has offered to pay for the abortion; and

"(3) That she has the right to review the printed materials described in section 14-02.1-02.1. The physician or the physician's agent shall orally inform the woman the materials have been provided by the state of North Dakota and that they describe the unborn child and list agencies that offer alternatives to abortion. If the woman chooses to view the materials, copies of them must be furnished to her. The physician and the physician's agent may disassociate themselves from the materials and may comment or refrain from comment on them, as they choose.

"c. The woman certifies in writing, prior to the abortion, that the information described in subdivisions a and b has been furnished to her and that she has been informed of her opportunity to review the information referred to in paragraph 3 of subdivision b.

"d. Prior to the performance of the abortion, the physician who is to perform or induce the abortion or the physician's agent receives a copy of the written certification prescribed by subdivision c.

"7. 'Licensed physician' means a person who is licensed to practice medicine or osteopathy under chapter 43-17 or a physician practicing in the armed services of the United States or in the employ of the United States.

"8. 'Medical emergency' means that condition which, on the basis of the physician's best clinical judgment, so complicates a pregnancy as to necessitate an immediate abortion to avert the death of the mother or for which a twenty-four-hour delay will create grave peril of immediate and irreversible loss of major bodily function.

"9. 'Probable gestational age of the unborn child' means what, in the judgment of the attending physician, will with reasonable probability be the gestational age of the unborn child at the time the abortion is planned to be performed.

"10. 'Viable' means the ability of a fetus to live outside the mother's womb, albeit with artificial aid."

LIBRARY REFERENCES
Abortion and Birth Control ⚿103.
Westlaw Topic No. 4k103.

NOTES OF DECISIONS

Validity [1]

Viability [2]

[1] Validity

North Dakota Abortion Control Act section defining abortion as termination of human pregnancy with intention other than to produce live birth or to remove dead embryo or fetus was not void for vagueness, despite claim that definition would subject certain medical procedures such as amniocentesis to informed consent provisions, given that criminal penalties were imposed on physicians only if they willfully terminated pregnancy without obtaining necessary informed consent. NDCC 14-02.1-02, subd. 1. Fargo Women's Health Organization v. Schafer, 1994, 18 F.3d 526. Abortion And Birth Control ⚿ 144

[2] Viability

The term "quickening" cannot be construed to mean "viable" as used in state abortion statutes proscribing the killing and destruction of a "quick child" and providing punishment therefor in order to save statute's constitutionality, notwithstanding fact that strong public policy has clearly indicated that abortion is to be regulated in North Dakota. U.S.C.A.Const. Amend. 14; NDCC 12-25-02, 12-25-03. Leigh v. Olson, 1974, 385 F.Supp. 255. Abortion And Birth Control ⚿ 156

NDCC 14-02.1-02, ND ST 14-02.1-02

Current through the 2011 Regular Session

End of Document

West's North Dakota Century Code Annotated
Title 14. Domestic Relations and Persons
Chapter 14-02.1. Abortion Control Act

NDCC, 14-02.1-02

§ 14-02.1-02. Definitions

Currentness

As used in this chapter:

1. "Abortion" means the act of using or prescribing any instrument, medicine, drug, or any other substance, device, or means with the intent to terminate the clinically diagnosable intrauterine pregnancy of a woman, including the elimination of one or more unborn children in a multifetal pregnancy, with knowledge that the termination by those means will with reasonable likelihood cause the death of the unborn child. Such use, prescription, or means is not an abortion if done with the intent to:

a. Save the life or preserve the health of the unborn child;

b. Remove a dead unborn child caused by spontaneous abortion; or

c. Treat a woman for an ectopic pregnancy.

2. "Abortion facility" means a clinic, ambulatory surgical center, physician's office, or any other place or facility in which abortions are performed or prescribed, other than a hospital.

3. "Abortion-inducing drug" means a medicine, drug, or any other substance prescribed or dispensed with the intent of causing an abortion.

4. "Down syndrome" refers to a chromosome disorder associated with an extra chromosome twenty-one, in whole or in part, or an effective trisomy for chromosome twenty-one.

5. "Drug label" means the pamphlet accompanying an abortion-inducing drug which outlines the protocol tested and authorized by the federal food and drug administration and agreed upon by the drug company applying for the federal food and drug administration authorization of that drug. Also known as "final printing labeling instructions", drug label is the federal food and drug administration document that delineates how a drug is to be used according to the federal food and drug administration approval.

6. "Fertilization" means the fusion of a human spermatozoon with a human ovum.

7. "Genetic abnormality" means any defect, disease, or disorder that is inherited genetically. The term includes any physical disfigurement, scoliosis, dwarfism, Down syndrome, albinism, amelia, or any other

type of physical or mental disability, abnormality, or disease.

8. "Hospital" means an institution licensed by the state department of health under chapter 23-16 and any hospital operated by the United States or this state.

9. "Human being" means an individual living member of the species of homo sapiens, including the unborn human being during the entire embryonic and fetal ages from fertilization to full gestation.

10. "Infant born alive" means a born child which exhibits either heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles or pulsation of the umbilical cord if still attached to the child.

11. "Informed consent" means voluntary consent to abortion by the woman upon whom the abortion is to be performed or induced provided that:

a. The woman is told the following by the physician who is to perform the abortion, by the referring physician, or by the physician's agent, at least twenty-four hours before the abortion:

(1) The name of the physician who will perform the abortion;

(2) The abortion will terminate the life of a whole, separate, unique, living human being;

(3) The particular medical risks associated with the particular abortion procedure to be employed including, when medically accurate, the risks of infection, hemorrhage, danger to subsequent pregnancies, and infertility;

(4) The probable gestational age of the unborn child at the time the abortion is to be performed; and

(5) The medical risks associated with carrying her child to term.

b. The woman is informed, by the physician or the physician's agent, at least twenty-four hours before the abortion:

(1) That medical assistance benefits may be available for prenatal care, childbirth, and neonatal care and that more detailed information on the availability of that assistance is contained in the printed materials given to her as described in section 14-02.1-02.1;

(2) That the printed materials given to her and described in section 14-02.1-02.1 describe the unborn child and list agencies that offer alternatives to abortion;

(3) That the father is liable to assist in the support of her child, even in instances in which the father has offered to pay for the abortion; and

(4) That she is free to withhold or withdraw her consent to the abortion at any time without affecting her right to future care or treatment and without the loss of any state or federally funded benefits to which she might otherwise be entitled.

c. The woman certifies in writing, prior to the abortion, that the information described in subdivisions a and b has been furnished to her.

d. Before the performance of the abortion, the physician who is to perform or induce the abortion or the physician's agent receives a copy of the written certification prescribed by subdivision c.

e. The physician has not received or obtained payment for a service provided to a patient who has inquired about an abortion or has scheduled an abortion before the twenty-four-hour period required by this section.

12. "Medical emergency" means a condition that, in reasonable medical judgment, so complicates the medical condition of the pregnant woman that it necessitates an immediate abortion of her pregnancy without first determining postfertilization age to avert her death or for which the delay necessary to determine postfertilization age will create serious risk of substantial and irreversible physical impairment of a major bodily function, not including psychological or emotional conditions. A condition may not be deemed a medical emergency if based on a claim or diagnosis that the woman will engage in conduct that she intends to result in her death or in substantial and irreversible physical impairment of a major bodily function.

13. "Physician" means an individual who is licensed to practice medicine or osteopathy under chapter 43-17 or a physician who practices in the armed services of the United States or in the employ of the United States.

14. "Postfertilization age" means the age of the unborn child as calculated from fertilization.

15. "Probable gestational age of the unborn child" means what, in reasonable medical judgment, will with reasonable probability be the gestational age of the unborn child at the time the abortion is planned to be performed.

16. "Probable postfertilization age of the unborn child" means what, in reasonable medical judgment, will with reasonable probability be the postfertilization age of the unborn child at the time the abortion is planned to be performed or induced.

17. "Reasonable medical judgment" means a medical judgment that would be made by a reasonably prudent physician, knowledgeable about the case and the treatment possibilities with respect to the medical conditions involved.

18. "Unborn child" means the offspring of human beings from conception until birth.

19. "Viable" means the ability of an unborn child to live outside the mother's womb, albeit with artificial aid.

Credits

S.L. 1975, ch. 124, § 1; S.L. 1979, ch. 191, §§ 1, 2; S.L. 1991, ch. 141, §§ 1, 2; S.L. 1995, ch. 243, § 2; S.L. 2009, ch. 142, § 1, eff. Aug. 1, 2009; S.L. 2011, ch. 109, § 1, eff. Aug. 1, 2011; S.L. 2013, ch. 116, § 2, eff. Aug. 1, 2013; S.L. 2013, ch. 117, § 1, eff. Aug. 1, 2013.

Notes of Decisions (2)

NDCC 14-02.1-02, ND ST 14-02.1-02
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REPRODUCTIVE ENDOCRINOLOGY

Predictive value of the presence of an embryonic heartbeat for live birth: comparison of women with and without recurrent pregnancy loss

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Objective: To determine the predictive value of an embryonic heart rate (EHR) for a live birth in women with and without a history of recurrent pregnancy loss (RPL).

Design: Prospective cohort study with concurrent controls.

Setting: A subspecialty clinic for couples with RPL.

Patient(s): Three hundred pregnant women who previously had been diagnosed with RPL, followed prospectively compared with 300 age-, race-, and gestational age–matched pregnant control women.

Intervention(s): Transvaginal sonography between 6 to 8 weeks of gestation.

Main Outcome Measure(s): The EHR was determined between 6 and 8 weeks of gestation by transvaginal sonography. Obstetrical history and current pregnancy outcome were evaluated.

Result(s): Data were analyzed by using the two-tailed *t* test and Fisher's exact test. In women with RPL, an EHR predicted a successful live birth in 246 (82%) of 300, compared with 294 (98%) of 300 in control women. The mean (± SD) EHR from successful pregnancies in the control group (143.2 ± 20.8 beats per minute) was significantly higher than the mean in women with a history of RPL (131.4 ± 22.9 beats per minute).

Conclusion(s): An EHR in women with RPL is associated with a live birth rate of 82% and is significantly lower than EHR in controls. Clinicians should use this information to counsel patients with RPL. (Fertil Steril® 2004;82:1369–73. ©2004 by American Society for Reproductive Medicine.)

Key Words: Recurrent pregnancy loss, embryonic heart rate, ultrasonography

Ultrasound documentation of a live embryo at 8 to 10 weeks of gestation or of a viable fetus at 10 to 12 weeks of gestation is associated with a survival rate of 98% in the general obstetrical population (1, 2). Many clinicians use these same reassuring statistics to counsel pregnant women with a history of RPL when they most commonly present for ultrasonography, at 6 to 8 gestational weeks.

Recurrent pregnancy loss (RPL) has classically been defined as the occurrence of three or more consecutive, spontaneous losses before 20 gestational weeks. Recent studies and policy statements have suggested that this definition should be extended to include women with two or more consecutive losses (3). Recurrent pregnancy loss is reported to affect between 1% and 3% of women (4). The most common causes of RPL are genetic, anatomic, endocrinologic, immunologic, and microbiologic (5). A complete evaluation will identify the cause of RPL in approximately two thirds of patients. Maternal age, the number of previous miscarriages, the suspected etiology of RPL, and the history of a previous live birth affect the risk of RPL.

In patients with idiopathic RPL, the reported loss rates after the appearance of fetal heart activity in the first trimester range from 3% to 25% (4, 6–8). In one study of 67 women with a history of RPL, the presence of a heart rate on ultrasonography was associated with a live birth rate of only 75% (7). Another study of pregnant women with RPL reported that the presence of a heartbeat at 5 to 6 gestational weeks was associated with a live birth in 78% of patients (8).

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In addition to the detection of a heartbeat, it is important to document the embryonic heart rate (EHR) (9). Tezuka et al. (10) reported the development of the EHR in the first trimester and described the correlation between the heart rate and gestational age. It has been reported that pregnancies in general obstetrical patients that are complicated by so-called slow EHR have a decreased survival rate (11). A similar observation was made in previous studies of women with RPL, in which most failing pregnancies were associated with a slow EHR (6, 7). In most studies, a slow EHR was defined as below 100 beats per minute (bpm) before 6.3 gestational weeks or below 120 bpm between 6.3 and 7.0 gestational weeks (9).

This purpose of this investigation was to determine the predictive value of an EHR for a successful live birth in a large group of women with a history of RPL and to compare this to the EHR in a matched group of pregnant women with normal obstetrical histories. We included women at 6 to 8 gestational weeks, during the time that they were most likely to present to their provider for ultrasound evaluation. Furthermore, we extended previous studies to determine the average EHR by gestational age in women with a history of RPL. This information is important for the clinician to know to appropriately counsel couples about the probability of a successful pregnancy.

MATERIALS AND METHODS

Women With RPL

Women seen at a specialty clinic for the evaluation of RPL affiliated with the division of Reproductive Endocrinology and Infertility at the University of Tennessee, Memphis, were diagnosed with RPL and recruited for this study. Entry criteria included a history of three or more consecutive, spontaneous losses with the same partner before 20 weeks who were currently pregnant at 6 to 8 gestational weeks based on the first day of the last menstrual period; a current pregnancy with a measurable heart rate; a gestational age by ultrasound that agreed with dates within 3 days; and a willingness to participate in the study.

All women with RPL underwent a complete evaluation that included karyotypes on both partners; hysterosalpingogram or sonohysterography; midluteal serum progesterone, serum thyroid-stimulating hormone, serum prolactin, fasting insulin, and glucose; antiphospholiplid antibody panel (lupus anticoagulant [dilute Russell viper venom test and partial thromboplastin time-lupus anticoagulant (PTT-LA)], IgG, IgM, and IgA anticardiolipin and antiphosphatidyl serine antibodies); and cervical cultures for mycoplasma, ureaplasma, and chlamydia.

Any treatable etiology for RPL was corrected or treated before enrollment in the study. Exclusion criteria were ectopic pregnancies, multiple gestations, genetic abnormalities, conceptions before the complete workup of RPL, infertility, and refusal to participate.

Women With Normal Obstetrical Histories (Controls)

Normal control patients included pregnant women being seen through the private obstetrical service who were matched to the study patients based on age (within 1 year), race, and gestational age at presentation for their first ultrasound (within 3 days based on the first day of their last menstrual period). Control women were excluded if they had a history of pregnancy loss (more than one), a prior adverse pregnancy outcome, a multiple gestation, no measurable heart rate on ultrasound examination, or a designation of a high-risk pregnancy. Pregnancy outcome was confirmed via telephone interviews and medical record review.

Ultrasonography

Ultrasound examinations were overseen by the same clinician (W.H.K.). One certified ultrasonographer performed all examinations. Once a viable fetal pole was verified with the presence of cardiac activity, the transvaginal ultrasound findings between 6 to 8 weeks of gestation were recorded. Transvaginal ultrasound findings that were recorded included three-dimensional measurements of the gestational sac, three-dimensional measurements of the yolk sac, measurement of the crown to rump length, and cardiac activity measured in bpm. Many patients in this study had multiple ultrasound examinations during their first trimester. To maintain accuracy, their first examination with a measured EHR was used for data analysis. All study patients and controls had data from only one examination entered into this study.

Statistical Analysis

The null hypothesis was that there were no differences in the predictive value of an EHR for a live birth when comparing pregnancies in women with a history of RPL vs. control women. Data were analyzed by Graph Pad Instat, version number 3.05 for Windows 2000 (Graph Pad Software, San Diego, CA). Pregnancy outcome data were evaluated by the two-tailed Fisher's exact test. Demographic and heart rate data were analyzed by using the two-tailed unpaired *t* test with Welch's correction for populations with unequal standard deviations. Significance was defined as a *P* value of $<.01$. The study was designed to have a power of 95% to detect an 8% difference in heart rate, with a *P* value $<.01$ (alpha) requiring a sample size of 300 in each group.

RESULTS

Patient Demographics

A total of 600 patients were evaluated (Table 1). The pregnant women in the control group were matched to the study group on the basis of chronological age, race, and gestational age at the time of sonar. The control group included 300 women with a mean ($\pm$ SD) age of 33.2 $\pm$ 4.5

TABLE 1

Demographics of pregnant women with a normal obstetrical history (controls) and women with a history of RPL.

Demographic variable	Control (n = 300)	RPL (n = 300)	*P* value
Age (y)	33.2 ± 4.5	32.9 ± 4.4	1.0
Race (%)			
Caucasian	78	78	1.0
African American	18	18	1.0
Other	4	4	1.0
Gestational age at entry (d)			
42–45	49	49	1.0
46–49	109	109	1.0
50–53	81	81	1.0
54–57	61	61	1.0
Obstetrical history at entry (mean ± SD)			
Gravity	1.8 ± 1.0	4.9 ± 1.7	<.01
Parity	1.3 ± 0.8	0.8 ± 0.7	<.01
Miscarriages	0.4 ± 0.6	3.9 ± 0.8	<.01

Hyer. Heart rate and pregnancy loss. Fertil Steril 2004.

years, whereas the RPL group included 300 women with a mean age of 32.9 ± 4.4 years. The racial composition of each group included Caucasians (78%), African Americans (18%), and others (4%).

The two groups were similar in racial composition to reduce any potential bias secondary to socioeconomic factors. Women entered into the study were also categorized into four groups based on the gestational age of their pregnancy: 49 women at 42–45 days, 109 women at 46–49 days, 81 women at 50–53 days, and 61 women at 54–57 days. Thus, by study design, there were no differences in the demographics of women in the two groups.

The mean number of prior miscarriages in the RPL group was 3.9 ± 0.8, compared with 0.4 ± 0.6 in the control group. As expected by the study design, the difference between both the number of gestations and previous miscarriages of the two groups were significantly different ($P<.01$).

Presence of Cardiac Activity

A total of 643 women were screened by ultrasound examination to obtain the 600 women for inclusion in the study (Table 2). Approximately 11% of women with RPL presented and were found to have no cardiac activity (34 of 334). This was significantly more than the number of pregnancies in the control women that were found to have no cardiac activity (9 of 309 or 3%). The presence of an EHR correlated with a live birth in 98% of the control pregnancies, compared with in only 82% of the pregnancies in women with RPL ($P<.01$).

Comparison of the EHR

The mean EHR for pregnancies in the control group and for women with a history of RPL were compared as shown in Table 3. The mean EHR in the control population was 138.2 ± 29.4 bpm (range, 96–170 bpm) compared with an EHR of 115.6 ± 42.4 bpm (range, 72–164 bpm) in pregnancies from women with a history of RPL ($P<.01$). These differences persisted when we excluded the heart rates from pregnancies that ultimately failed and recalculated the average EHR in both groups ($P<.01$)

The EHR in pregnancies from women with RPL was slower than the EHR in pregnancies from control women when evaluated by gestational age (Table 4). For example, at gestational age of 50 to 53 days, EHR in women with RPL

TABLE 2

Pregnancy outcome in women with a normal obstetrical history (controls) compared with women with a history of RPL.

Group	Control	RPL	*P* value
Total no. screened	309	334	<.01
Total no. with a positive EHR	300	300	—
Total no. live births (%)	294 (98)	246 (82)	<.01
Total no. miscarriages (%)	6 (2)	54 (18)	<.01

Hyer. Heart rate and pregnancy loss. Fertil Steril 2004.

TABLE 3

Average EHR in pregnant women with a normal obstetrical history (controls) and in women with a history of RPL.

Variable	Control (bpm),	RPL (bpm)	*P* value
Mean EHR in all pregnancies	138.2 ± 29.4	115.6 ± 42.4	<.01
Mean EHR in births	143.2 ± 20.8	131.4 ± 22.9	<.01
Mean EHR in spontaneous abortions	63.8 ± 72.7	67.9 ± 64.7	.90

Note: Data are mean ± SD.

Hyer. Heart rate and pregnancy loss. Fertil Steril 2004.

was 132.5 ± 17.5 bpm, compared with 143.8 ± 15.7 bpm in controls (P=.01). The results in Table 4 are for all pregnancies, including those that resulted in spontaneous abortion despite evidence of cardiac activity.

No absolute heart rates could be identified that would accurately predict pregnancies that were ultimately determined to be nonviable. However, embryonic heart rates below 90 bpm at 45 gestational days, below 105 bpm at 49 gestational days, and below 120 bpm at 56 gestational days were generally associated with an unfavorable outcome in pregnancies from women with RPL (data not shown).

DISCUSSION

The presence of an EHR in pregnancies from women with a history of RPL was found to predict a viable pregnancy in 82% of women included in this study. This outcome was compared with a successful outcome of 98% in the control group of women without a prior history of an adverse pregnancy outcome. The data from the control group in the present study compare favorably with several studies that investigated the live birth rate in the general obstetrical population after the detection of an embryonic or fetal heartbeat (1, 2, 9, 10). For example, in a study of 489 patients with fetal cardiac motion present in the first trimester, the risk of spontaneous abortion before 20 gestational weeks was 2%, in agreement with the data in our study (1). However, we were concerned by the wide discrepancies that have been reported in the literature concerning the predictive value of a heart rate for a live birth in women with a history of RPL. Some of these studies suggested that the live birth rates in women with RPL were identical to those from the general obstetrical population, whereas others suggested much lower live birth rates (4, 6–8).

Embryonic heart rate should progressively increase with gestation. Tezuka et al. (10) described a correlation between EHR and gestational age that corresponds to an embryonic heart rate rise of about 4 bpm every day until 8 weeks' gestation. In the present study, the mean EHR of control patients was consistent with the regression equation reported by Tezuka et al. (10). Thus, results of this study, which suggest a 98% predictive value for pregnancy outcome in the control group, are supported by the control EHR when applied to the regression equation.

A previous study found that in approximately three fourths of pregnancies in patients with RPL, the rate of pregnancy loss after the demonstration of a live embryo was four to five times higher than the all-series rate of loss (<4%). However, their results were based on only 67 pregnancies, and the gestational ages at the time of sonography were not clearly detailed. Another study of 185 women with a history of multiple spontaneous abortions found a correlation between ultrasound documentation of fetal cardiac activity and pregnancy outcome (8). Those investigators reported that in women with a history of multiple spontaneous

TABLE 4

Embryonic heart rate in pregnant women with a normal obstetrical history (controls) compared with women with a history of RPL, by gestational age.

Gestational age (d)	No. of pregnancies	Mean EHR (bpm)		*P* value
		Controls	RPL	
42–45	49	117.6 ± 14.2	108.6 ± 15.9	<.01
46–49	109	135.3 ± 14.1	123.4 ± 18.1	<.01
50–53	81	143.8 ± 15.7	132.5 ± 17.5	<.01
54–57	61	162.4 ± 13.1	146.0 ± 18.6	<.01

Note: Data are mean ± SD.

Hyer. Heart rate and pregnancy loss. Fertil Steril 2004.

abortions, the rate of subsequent spontaneous abortion after ultrasound documentation of fetal cardiac activity was 22.7%. The control group in this study showed a pregnancy loss of 3.3%, which is consistent with the general population. Their study was restricted to women with pregnancies between 5–6 weeks' gestation. Our larger study expands their observation to include women who present for an ultrasound at 6 to 8 gestational weeks, at the time most commonly encountered by clinicians.

With the known differences in spontaneous abortion rates among patients with RPL and women without a history of pregnancy loss, clinicians should not assume that the predictive values for pregnancy outcome are the same in both groups. The importance of using EHR tables that correspond to the study population has been demonstrated in a group of women diagnosed with infertility. Qasim et al. (12) reported that infertility patients with EHR outside the reference range for viable pregnancies at corresponding gestational ages might be at risk for eventual pregnancy loss. Although their study was not exclusive to RPL patients, the patient population being studied is an important variable in using EHR as a predictor of eventual outcome.

Our study extends these previous reports in that it establishes an average EHR for pregnant women with a history of RPL. Our data suggest that the normal EHR may be 10 to 15 beats slower at each gestational age range in women with a history of RPL, compared with in those pregnancies in women without any prior obstetrical complication.

In conclusion, our data document significant EHR differences in early pregnancy in women with and without a history of RPL. After documentation of a heartbeat, the data from this study allow the physician to predict a successful delivery rate of 82% in patients with a history of RPL.

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