



Assessing hospital policies & practices regarding ectopic pregnancy & miscarriage management

**Results of a national qualitative study conducted by
Ibis Reproductive Health for the National Women's Law Center**

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About Ibis Reproductive Health

Ibis Reproductive Health aims to improve women's reproductive autonomy, choices, and health worldwide. We accomplish our mission by conducting original clinical and social science research, leveraging existing research, producing educational resources, and promoting policies and practices that support sexual and reproductive rights and health.

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Acronyms & abbreviations

ACGME	Accreditation Council on Graduate Medical Education
ACOG	American College of Obstetrics and Gynecology
AHA	American Hospital Association
βhCG	beta human chorionic gonadotropin
<i>Directives</i>	The Ethical and Religious Directives for Catholic Health Care Services
ED	Emergency department
EM	Emergency medicine
IRB	Institutional Review Board
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
NCQA	National Committee on Quality Assurance
Ob/Gyn	Obstetrician-gynecologist
OR	Operating room

Background

In the United States, it is estimated that 2% of all pregnancies are ectopic, over 97% of which are located in the fallopian tube [1]. This relatively common condition has historically been associated with significant maternal morbidity and mortality. Indeed, from 1979 to 1986, 13% of pregnancy-related deaths were associated with ectopic pregnancy [2]. Further, women who have experienced ectopic pregnancy are at increased risk of repeat ectopic pregnancy and of subsequent infertility [2]. Over the past 30 years there has been rise in the incidence of ectopic pregnancy [1]. In fact, 6-16% of women who present at the emergency department with first trimester pain and/or bleeding are subsequently diagnosed with an extrauterine or heterotopic pregnancy [3]. Concurrent improvements in diagnostic techniques, including the use of ultrasound and more sensitive and specific beta subunit of human chorionic gonadotropin (β hCG) assays, have allowed for earlier detection and treatment of ectopic pregnancies, thereby decreasing the rate of rupture and the consequent maternal morbidity and mortality. However, hemorrhage from extra-uterine pregnancies remains the leading cause of pregnancy-related death in the first trimester and accounts for 4-10% of all pregnancy-related deaths in the US [4].

Management of ectopic pregnancies has changed dramatically over the last several decades and the guiding principle has become a conservative approach that attempts to preserve the fallopian tube and prevent tubal rupture [5]. Management options for tubal ectopic pregnancy include use of methotrexate (medical therapy), removal of the embryo from the fallopian tube (salpingostomy), removal of the section of the fallopian tube containing the embryo (salpingectomy), and “expectant management.” Salpingostomy and salpingectomy are surgical procedures performed either by laparoscopy or laparotomy (open surgery); the former has been shown to be less costly and result in improved clinical outcomes [6]. Use of methotrexate and salpingostomy are fertility-sparing procedures and are options for women who want to preserve future fertility. Salpingectomy is generally reserved for women with typical symptoms of ruptured tubal pregnancy, sudden and intense abdominal pain, and uncontrolled bleeding [7]. Expectant management, awaiting the natural progression of the ectopic pregnancy and intervening only after signs hemodynamic instability and/or rupture, has been used to avoid interventions that might be unnecessary. Although the natural history of an untreated tubal pregnancy includes tubal rupture, tubal abortion, or spontaneous regression, available evidence suggests that expectant management is only appropriate for carefully selected asymptomatic patients with low β hCG levels [8,9]. In other cases, expectant management is associated with a high risk of tubal rupture and the significant morbidities associated with this outcome. While these four treatment options are the common clinical recommendations, they are based on limited scientific evidence. A variety of factors influence the management option employed by physicians including the woman’s future childbearing preferences, co-morbidities, allergies, and hemodynamic stability as well as trends in β hCG levels and the size and gestational age of the ectopic pregnancy. However, treatment practices may also differ depending on physicians’ and hospitals’ legal, religious, or moral objection to removal of a tubal pregnancy, viewed by some in the medical community as an abortion.

The Ethical and Religious Directives for Catholic Health Care Services (the *Directives*) issued by the United States Conference of Catholic Bishops govern the provision of care in Catholic-affiliated hospitals [10]. The *Directives* prohibit abortion and prohibit health service providers from taking “direct” action against the embryo. Despite the fact that ectopic pregnancies are not viable and are legally and medically differentiated from intra-uterine pregnancies, anecdotal reports have suggested

that the *Directives* may preclude physicians at Catholic hospitals from managing tubal pregnancies with either the administration of methotrexate or the removal of the embryo from the fallopian tube, defining these procedures as “direct” action. Although salpingectomy and expectant management do not act directly against the embryo and are therefore permitted under the *Directives*, the use of these management techniques may subject women with ectopic pregnancies to unnecessary risks and serious long-term consequences, including infertility, unnecessary surgery, and tubal rupture. Anecdotal evidence also suggests that patients with ectopic pregnancies are sometimes transferred (without treatment) from Catholic hospitals to non-Catholic hospitals.

In a similar vein, anecdotal reports suggest that some patients presenting with incomplete/inevitable abortions at Catholic hospital emergency departments have been transferred to non-Catholic facilities without treatment or stabilization [11]. A study published in 2008 found a small number of cases in which clinicians at Catholic-owned hospitals were prevented from performing medically-indicated uterine evacuations when fetal heart tones were present [12]. Although the *Directives* prohibit abortion and direct interference with an embryo, termination of a pregnancy is permitted if the action is undertaken for the direct purpose of preserving the health of pregnant woman. As stated in *Directive 47*, “Operations, treatments, and medications that have as their direct purpose the cure of a proportionately serious pathological condition of a pregnant woman are permitted when they cannot be safely postponed until the unborn child is viable, even if they will result in the death of the unborn child”[10]. However, what constitutes a “proportionately serious pathological condition” has been variably interpreted [12]. Some evidence suggests that management decisions are being strongly influenced by the interpretation of the *Directives*, as evacuation of the uterus may be viewed as a violation of the *Directives* when fetal cardiac activity or fetal heart tones are detected.

The degree to which the *Directives* are influencing the management of ectopic pregnancies and miscarriages in Catholic facilities and the impact that these management decisions have on women’s health and lives has yet to be fully explored or rigorously and systematically evaluated.

Overall study objectives

To better understand the relationship between the *Directives*, hospital policies regarding management of ectopic pregnancies and miscarriages, and clinical practices, Ibis Reproductive Health proposed to conduct a national study of clinicians and hospital administrators in non-Catholic, Catholic, and recently merged facilities. By employing a combination of qualitative and quantitative methods, our aim was to investigate the degree to which these hospital policies are formalized and communicated, evaluate the impact of these policies and the interpretation of these policies on management decisions, and assess physician perceptions of the impact of these policies on standards of care. We anticipate that the results of this study will inform the National Women’s Law Center’s programmatic and policy activities as well as provide critical information for the larger medical field and to researchers and advocates working to increase women’s access to reproductive health services.

In this report we present the results from the national qualitative study. We begin by detailing the methods, sample, and recruitment strategies employed before turning to the results of the qualitative study where we present both key themes and illustrative participant narratives. We conclude with recommendations for future research and advocacy.

Qualitative study aims & objectives

In order to examine the relationship between the *Directives*, hospital policies regarding management of ectopic pregnancies and miscarriages, and the clinical practices and cultural norms of physicians working in these institutions, Ibis Reproductive Health conducted a qualitative study with practicing clinicians. Specifically, we aimed to:

- Investigate the degree to which hospital policies regarding ectopic pregnancy and miscarriage management are developed and communicated, informally and through formal institutional mechanisms;
- Evaluate the impact of these policies and the interpretation of these policies on management decisions;
- Assess physician perceptions of the impact of these policies on standards of care; and
- Inform the development of a national mailed survey dedicated to exploring the impact of the *Directives* on ectopic pregnancy and miscarriage management.

Methods

Although previous qualitative studies have yielded valuable information, these studies have drawn participants from convenience samples. In order to conduct a more systematic investigation, our objective was to recruit participants from a randomly selected sample of hospitals. Further, our aim was to recruit clinicians and administrators from different practice environments in different regions of the US. We used the hospital as the unit by which to generate our sampling frame for the national qualitative study.

Hospital sample

According to the American Hospital Association (AHA), in 2007 there were approximately 4,100 hospitals with emergency departments (ED) in the United States. For the purposes of this study, we excluded uniformed armed services facilities, Veterans' Affairs medical centers, Indian Health Service facilities, and hospitals with fewer than 100 ED visits each year (typically specialty hospitals). We assigned each hospital a regional code, based on the nine regional divisions established by the AHA. Through cross-referencing hospitals in the AHA database with information obtained from institutional websites, we then assigned each hospital to one of three categories (institution type): non-Catholic, longstanding Catholic, or recently merged. For the purposes of this study, we considered a hospital to be "recently merged" if it acquired a new affiliation on or after January 1, 2003. Our decision to identify recently merged facilities was based on a hypothesis that physicians practicing at the same facility both before and after a merger may be better placed to discuss the ways in which hospital policies (and specifically the *Directives*) influence clinical practices.

Of the 3,975 hospitals that met our inclusion criteria, we categorized 3,351 hospitals as non-Catholic, 595 hospitals as longstanding Catholic, and 31 recently merged facilities. These recently merged facilities were comprised of 21 Catholic-to-non-Catholic mergers, eight non-Catholic-to-Catholic mergers, and two "compromise" mergers. However, two of the recently merged hospitals had multiple "campuses" and thus we ultimately identified 29 unique recently merged facilities. We list the number of hospitals in our sample, by type and percentage, in Table 1.

Table 1: Type of hospitals in each region, by number and percentage

AHA Region	Total # Hospitals	Recently merged		Longstanding Catholic		Non-Catholic	
		#	% of total	#	% of total	#	% of total
1	162	0	0.0%	19	11.7%	143	88.3%
2	352	5	1.4%	63	17.9%	284	80.7%
3	635	3	0.5%	34	5.4%	598	94.2%
4	657	7	1.1%	167	25.4%	483	73.5%
5	325	3	0.9%	28	8.6%	294	90.5%
6	609	1	0.2%	110	18.1%	498	81.8%
7	582	4	0.7%	62	10.7%	516	88.7%
8	299	1	0.3%	32	10.7%	266	89.0%
9	354	5	1.4%	80	22.6%	269	76.0%
Total	3975	29	0.65%	595	15.0%	3351	84.3%

Qualitative study sampling frame

For the qualitative study, our aim was to conduct interviews with clinicians and administrators at 16 to 24 institutions, or roughly 0.4%-0.6% of US hospitals with EDs that met our other eligibility criteria. In order to achieve geographic diversity and representation from non-Catholic, longstanding Catholic, and recently merged hospitals, and to include participants from different state-level practice environments (e.g., some from states with a large proportion of Catholic hospitals and some from states with a small proportion of Catholic hospitals), we purposively chose to recruit participants from hospitals in the following states:

- Pennsylvania: A Region 2 state with three recently merged facilities
- Kentucky: A Region 5 state with three recently merged facilities
- Illinois: A Region 4 state with five recently merged facilities and a large proportion of Catholic hospitals
- California: A Region 9 state with two recently merged facilities and a large proportion of Catholic hospitals
- Rhode Island: A Region 1 state with no recently merged facilities and one Catholic hospital that is in the process of merging with a non-Catholic hospital
- North Carolina: A Region 6 state with no recently merged facilities and no Catholic hospitals

After selecting the states for inclusion in the study, we used a stratified random selection process to generate the sampling frame of clinicians at Catholic and non-Catholic hospitals. We randomly selected five Catholic and five non-Catholic hospitals in Pennsylvania, Kentucky, Illinois, and California, five non-Catholic hospitals in North Carolina, and three non-Catholic hospitals in Rhode Island for inclusion in the study. We also included the one Catholic facility in Rhode Island in the sample for a total of 28 non-Catholic hospitals and 21 Catholic hospitals. Finally, we included 20 recently merged facilities in the sample – 13 from Pennsylvania, Kentucky, Illinois, and California and seven from other states. We expected that this sample of hospitals would allow us to recruit participants from a minimum of five Catholic hospitals, six non-Catholic hospitals, and five recently merged facilities in a range of states.

After identifying our sample of hospitals, we collected contact information for all obstetrician-gynecologists (Ob/Gyns) and emergency medicine (EM) physicians affiliated with each institution.

This publicly available information (which included name, mailing address, and telephone number) was obtained from individual hospital websites. When a hospital in our sample did not make this information available on the website, we randomly selected a hospital of the same type and from the same state as a replacement (thus the availability of contact information served as a post-hoc eligibility criterion). If email addresses for physicians were available from the hospital website, we collected that information as well. We were unable to systematically identify hospital administrators from institutional websites and were thus unable to collect contact information for administrators.

Participant recruitment

Ob/Gyns and EM physicians from each selected institution were initially sent a letter of invitation to participate in an interview regarding the policies and practices related to ectopic pregnancy and miscarriage management at their hospital. We contacted more than 1,500 physicians at the 69 hospitals in our sample with invitation letters. Follow-up phone calls, emails (if applicable), and faxes (if requested by an administrator or receptionist) were sent to non-respondents. In order to obtain multiple perspectives about the same institutional policies and practices, we set out to conduct two to three interviews with physicians and one interview with an administrator from each institution. Thus, once a clinician participated in the interview, we invited her/him to refer us to additional clinicians and administrators at the same hospital. We followed up referrals with a combination of letters, phone calls, and emails.

Data collection

We provide a copy of our interview schedule in Appendix A and biographies of key study team members in Appendix B. We received feedback on draft interview schedules from clinicians and advocates prior to initiating the study and we asked early participants in the study to provide feedback on the questions. We made small adjustments to the interview schedule based on participant feedback and, after study team discussions, modified several of our probes. All interviews were conducted over the telephone and averaged 30 minutes in length. The majority of interviews were audio-recorded after permission was granted by the interviewee. As a token of our gratitude for participating in our study, we offered participants a \$25 gift certificate to Amazon. No other incentives were offered to participants.

Analysis

We conducted a content and thematic analysis of all completed interviews. The content of each interview was reviewed by at least two members of the study team. Initially, interview content was assessed using *a priori* (e.g., pre-determined) categories and codes. During this first analytic phase, interviewers captured key themes and ideas on an Excel spreadsheet upon completion of each interview. Subsequent interviews allowed us to further refine these categories. We also used inductive analysis techniques to identify themes and categories of content that emerged during the project. This iterative process was guided by a series of regular team meetings. In the results section of this report, we present the main themes that emerged in our analysis of the data and use quotes from individual interviews to illustrate key findings. Further, we present a series of narratives that showcase the ways in which key concepts and themes were revealed by participants. We structure the results section of this report around these key themes and participant narratives.

Informed consent

We received institutional review board (IRB) approval for this study from Allendale Investigational Review Board. As we did not seek personal information about individual respondents or

information about specific patients, and as participation conferred minimal risk, we received a waiver of written consent and instead obtained oral consent from participants at the beginning of the interview. We provided all participants with contact information regarding the study and their rights as participants, including the contact information for both the Principal Investigator and Allendale IRB. In order to protect the confidentiality of our participants we have used pseudonyms throughout the report and have removed personally identifying information. Further, we do not provide the names of individual hospitals and instead reference hospitals by institution type and state.

Results

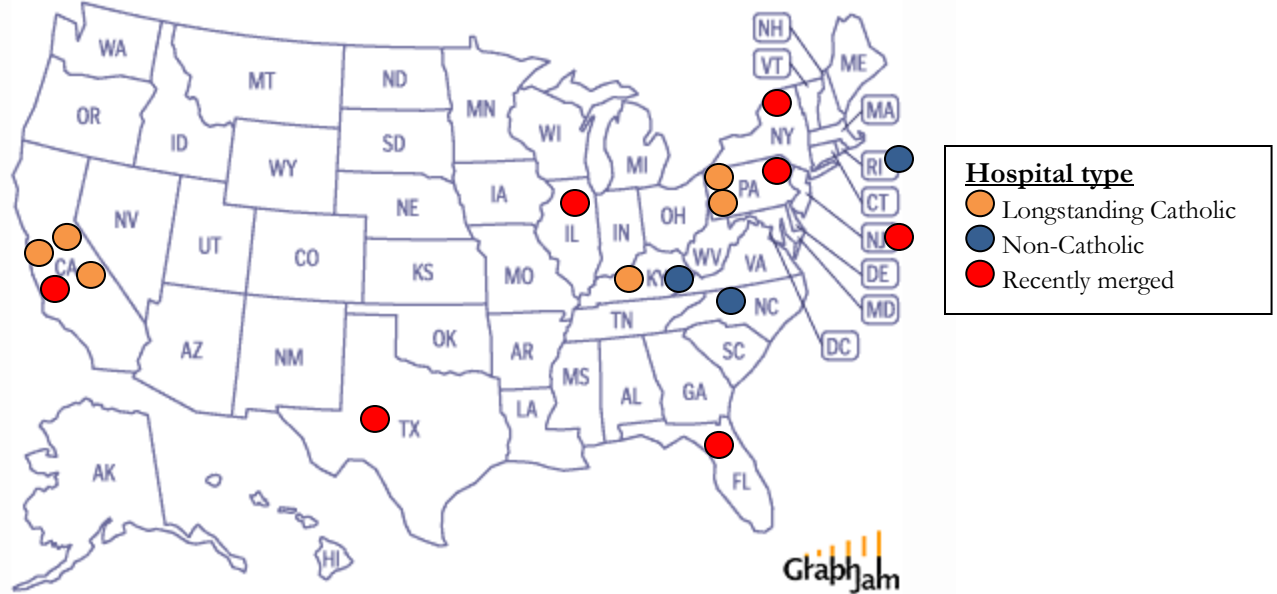
Participant & hospital characteristics

Our study team conducted 25 interviews with physicians (22), physician-administrators (2), and non-physician administrators (1) at 16 hospitals in ten states. Of our physician participants, 18 are Ob/Gyns and six are emergency medicine physicians. We completed eight interviews with clinicians and administrators at six longstanding Catholic hospitals, seven interviews with physicians and administrators from three non-Catholic hospitals, and ten interviews with physicians and administrators from seven recently merged facilities. Eight of the 16 hospitals in our sample operate under the Ethical and Religious Directives for Catholic Health Care Services (the *Directives*). Of the seven recently merged facilities in our sample, four were Catholic to non-Catholic mergers, two were non-Catholic to Catholic mergers, and one was a compromise merger. We present the location (by state) of the hospitals in our study on Figure 1.

Development & communication of hospital policies

All of our respondents reflected on the mechanisms by which hospital policies, in general, were developed. Many spoke about the multiple pathways for the creation of institutional policies and decision-making/treatment algorithms. A number of respondents spoke about how hospital policies were developed in diverse committees comprised of representatives from nursing, emergency medicine, and obstetrics and gynecology. In many cases, hospital policies were derived from national standards developed by professional medical societies, including the American College of Gynecology (ACOG), as well as regulatory bodies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Committee on Quality Assurance (NCQA). Several respondents discussed the influence of overarching health systems, health insurance companies, and corporate interests in shaping institutional policies as well. Multiple physicians at one recently merged hospital (a Catholic facility that had been acquired by a non-Catholic system) indicated that when the hospital was taken over, clinicians were given a package of policies and procedures from the corporation that severely affected their ability to treat patients in a timely manner. Finally, one participant spoke at length about the influence of state legislation on hospital practice guidelines and policies, particularly in the context of emergency contraception access in the ED.

Figure 1. Location of hospitals included in the study



Few physicians in our sample reported that hospital policies and guidelines, in general, were communicated “formally” through mechanisms such as training manuals, staff meetings, or presentations. A small number of providers indicated that their hospital guidelines were available on a shared server within the hospital or through posters throughout the department. However, one doctor reported that when she attempted to find the relevant guidelines, she was unable to locate them. Thus, while nearly all of our physician participants were confident that the hospital had written standardized guidelines on a number of Ob/Gyn-related conditions, most had never read or referred to them. Rather, most participants felt that norms were communicated in conversations between peers, by leaders within the department, or through implicit assumptions about what is acceptable in the department or facility.

Although all of our respondents discussed the generation of policies in general, nearly all reported that there were no specific policies and guidelines dedicated to the management of ectopic pregnancies and miscarriages. This finding held across hospital type, although most participants from institutions operating under the Catholic *Directives* discussed how reproductive health services, in general, were impacted by the *Directives*, as we detail in the following section.

Dr. S: Catholic hospital, Pennsylvania

Dr. S has been working as an emergency medicine physician for over 10 years. He is currently working at a large, urban, Catholic hospital in Pennsylvania. He has previously worked at other hospitals in the state and although every hospital has its own rules, regulations, and bylaws, 98% of the policies are the same. However, his current hospital operates under the Catholic *Directives* and because of the policy against abortion he feels that physicians do have to practice slightly differently.

Dr. S reports that policies and practice guidelines at his hospital are developed through several different pathways; sometimes they are derived from the requirements of external professional and accreditation bodies, sometimes from the overarching hospital system, and sometimes from internal corporate decisions and interests. His hospital also had to revise its standards of care guidelines after the state of Pennsylvania recently developed a policy regarding the provision of emergency contraception.

According to Dr. S the malpractice crisis in Pennsylvania has “chased out” all of the Ob/Gyns and, consequently, there are no longer Ob/Gyns practicing at his hospital. Approximately five women present each month at the emergency department with an ectopic pregnancy. The policy of the hospital is “identification, stabilization, and transfer.” Patients are routinely transferred to a neighboring hospital that has a full Gynecology service although expectant management (with a defined outpatient follow-up plan) is sometimes initiated if the patient meets specific clinical criteria. But because this is a Catholic hospital, methotrexate is never used “although many EDs across the country would consider methotrexate in [cases] without rupture.”

Dr. S believes that the *Directives* “absolutely” impact the management of ectopic pregnancies. “We had a case, [in the past] when we did have Ob/Gyns, where we had to transfer the patient out of the hospital in order to get [her] methotrexate because the hospital won’t provide methotrexate for the abortion of a baby even if it is an ectopic. We had a bit of an argument about that.” Dr. S reports that the patient did “absolutely fine,” but that he was none-the-less frustrated by the hospital’s policy.

Influence of the Catholic *Directives*

More than half of the physicians in our sample either currently work in facilities that operate under the Catholic *Directives* or have previously worked in hospitals operating under the *Directives*. Nearly all of these physicians reported that the *Directives* have not resulted in “policies” regarding the treatment of ectopic pregnancies and miscarriages. Indeed, most respondents initially indicated that the Catholic *Directives* “only” impacted policies related to elective terminations, tubal ligations, and contraceptive services. As one physician in a recently merged facility reported, the *Directives* “don’t apply” when methotrexate, salpingostomy, and uterine evacuation techniques are used to treat ectopic pregnancies or manage miscarriages because these “are not considered elective abortions because ectopic [pregnancies] and miscarriages were not intended nor were they the patient’s choice.” Another physician at a Catholic hospital reported that, “The senior managers are all senior nuns or priests, but their influence [on policy] is very subtle.”

Yet, upon further probing, physicians in our sample clearly feel the presence of the Catholic *Directives*, both directly and in the way that the *Directives* are interpreted by individual clinicians. One doctor recalled that when she first started practicing at a recently merged (non-Catholic to Catholic) facility, she was given an outline of treatment options in cases of incomplete or inevitable abortion in which a fetal heart beat was present. However, she reported that she never read the guidelines and “didn’t know what they were.” Participants from three different Catholic facilities explained that methotrexate was not offered for the treatment of ectopic pregnancies because the hospitals are Catholic, as illustrated in Dr. S’s interview above. Several physicians expressed frustration at this limitation and noted that methotrexate, in specific circumstances, would otherwise be their preferred treatment modality. Indeed, one physician noted that physicians in Catholic facilities often use expectant management because they are restricted from administering other treatments.

But it is perhaps the interpretation of the *Directives* at the individual clinician and department levels that most impacts treatment decisions regarding ectopic pregnancies and miscarriages. Although most physicians practicing in Catholic facilities reported that they had neither read the *Directives* nor had a formal conversation about the application of the *Directives* in cases of ectopic pregnancies or pregnancy loss, many physicians felt that it was clear that certain practices would violate the *Directives*. As one clinician at a longstanding Catholic hospital stated (hyperbolically) when asked about performing a uterine evacuation in the presence of fetal cardiac activity or heart tones, “Yes, we would be shot. I don’t know if it’s written, but clearly that is against the *Ethical Directives* of the Catholic Church.” Another physician stated that a primary difference between treating patients at Catholic and non-Catholic facilities is that if a physician takes a patient to the operating room at a Catholic hospital, the physician must be “100% sure that the pregnancy isn’t viable.” This physician reported that obtaining this certainty often requires additional paperwork and clinical tests including serial β hCGs and/or additional ultrasounds. She felt that these additional requirements would not be required at a non-Catholic hospital and, given that ultrasonography is often inconclusive, physicians are often unclear as to what their options are. As another physician at a different Catholic hospital reported, “If we were worried enough [that the pregnancy would be viable] we might take them to surgery because you can do a diagnostic surgery and if they don’t have an ectopic, you can stop the surgery. We would talk to the anesthesia folks first so they don’t give anything that is contra-indicated in pregnancy.” One physician reported that she has seen “some” ruptures because of these delays in treatment, but this outcome was not reported by other physicians in our sample. Several physicians did report that the limitations and the lack of clarity were frustrating and unnecessary but did not believe that it impacted patients.

Enforcement of institutional policies & the *Directives*

In the absence of formal policies and guidelines regarding the management of ectopic pregnancies and miscarriages, it is hardly surprising that few of our respondents reported knowing of any formal institutional enforcement mechanisms. Indeed, most respondents stated that they have never heard of a case in which a hospital ethics committee or department chair had intervened in a treatment decision regarding an ectopic pregnancy or miscarriage. This was true across all hospital types included in the sample. A notable exception was the story related by Dr. S (box, above), in which a patient was transferred to another facility in order to receive treatment with methotrexate.

Yet a number of physicians at Catholic facilities expressed concern that they would face consequences if they acted outside of the *Directives*. As one physician explained, “I knew it when I started working there. The OR [operating room] makes it clear that they are [checking that doctors are following the rules of the Catholic *Directives*]. The nurses are instructed to ask questions to be sure that [we are abiding by the *Directives*].” Although none of the physicians or administrators in our study reported direct knowledge of a case in which a physician received a reprimand for a treatment decision involving ectopic or miscarriage management, several physicians “had heard” about such cases. Indeed, one respondent reported that he “had heard” about a previous physician who had chosen to administer methotrexate in a Catholic hospital and was reprimanded by the hospital’s board. However, as we detail below, several physicians discussed cases in which colleagues were reprimanded or demoted for violating the *Directives* by providing women with tubal ligations.

Dr. Y: Catholic hospital, California

Dr. Y is an osteopathic Ob/Gyn at a Catholic hospital in California and has been practicing for over three years. Her primary position is at a small community hospital located an hour away from a major urban area. She also has a private practice as well as privileges at two other hospitals that do not operate under the Catholic *Directives*. The Catholic hospital has just over 100 beds and most of the cases they see are deemed low risk. The hospital has been run by a Catholic administration for the last seven years; a local health care district owns the land that the hospital is on.

Despite being located in a rural community, there are many resources available to the hospital – it is within close proximity to “a lot of major research institutes where research is done.” Dr. Y reports that specialists from local research centers visit the hospital to discuss recent findings with the doctors and the administration in order to inform department protocols. These discussions sometimes spark periodic reviews of hospital policies, although these reviews are all discussed within the Catholic guidelines.

Although Dr. Y sees only a small number of ectopic pregnancies every year, she often finds treating them to be difficult under the Catholic *Directives*. When asked what treatment options would be considered for a patient with an unruptured ectopic pregnancy at her hospital, she stated that if she is unable to definitively diagnose the patient as ectopic, there are few options available to the patient: “Probably she will be discharged and if she goes to me [at my private practice] or the health center, she’ll get methotrexate. But, again, it depends on how far along she is. It’s more likely that it won’t be clear and she gets sent home. If the patient hadn’t planned the pregnancy and doesn’t want the pregnancy, it would make sense just to terminate it without having to wait to diagnose it.”

In cases where an ectopic pregnancy diagnosis is definitive, Dr. Y notes she faces additional challenges in providing patients with her preferred treatment option. The hospital does not keep methotrexate in house, so a carrier must be sent to pick up the medication. The doctor suspects that the hospital does not keep the medication on hand because they don’t want physicians using it. In order to navigate around these barriers, Dr. Y often takes patients aside and reviews all of their treatment options, even though this level of disclosure is not permitted in the hospital. She notes that she knows of a few other physicians at the hospital who offer referrals and information “under the radar” as well. Dr. Y adds that she sometimes provides medication to patients surreptitiously, “Because I maintain the drugs in my office, I’ve gotten the drugs from my office and given them to the patients off the record because the diagnosis was unclear and I wasn’t allowed to tell the patient [all of her treatment options].” Dr. Y worries that the restrictions on treatment options impact the health and welfare of women. In cases of ectopic pregnancies, she feels that the practice guidelines at the Catholic hospital increase the risk of tubal ruptures since ectopic pregnancies are often not diagnosed in a timely manner. In terms of miscarriage treatment, patients are often bleeding very heavily before a dilation and curettage is allowed.

In addition to frustration over how to treat ectopic pregnancies and miscarriages, Dr. Y notes that the Ob/Gyns at the hospital are at odds with the Catholic administration over not being allowed to perform terminations or tubal ligations. In the offices of her private practice, Dr. Y performs both medication and surgical terminations up to 12 weeks’ gestational age. However, she’d prefer to be able to perform procedures in a hospital operating room.

Factors influencing clinical practices

Although hospital policies, and specifically the *Directives*, appear to both influence the treatment options available to women and shape clinical practices, respondents reported that a number of additional factors played a significant role in clinician decision making. Indeed, several physicians noted that while a hospital may have guidelines for actual procedures, these policies and guidelines should not trump the decisions of individual physicians. As one physician practicing at a recently merged (Catholic to non-Catholic) hospital noted, “Administrators know that doctors will do what they think is appropriate and [the administrators] are smart enough to stick their noses out of our business! They know we would be mad, ignore them, and just do what we think is right.”

Physicians reported on a range of factors that influenced their clinical decisions. Facility-level resource constraints were referred to by several physicians practicing at small and/or rural hospitals, irrespective of institution type. The absence of laboratory facilities at night or the absence of Ob/Gyns on staff influenced treatment and transfer protocols, not just in cases of ectopic pregnancy or pregnancy loss but other conditions as well. In these settings, physicians reported that there were well-defined consultation protocols such that off-site specialists were involved in treatment and transfer decisions.

But in the absence of resource constraints, respondents reported a great deal of uniformity in clinical assessment and decision making. With respect to ectopic pregnancies, nearly all of the physicians in our study reported that they used the same set of clinical criteria (patient history, blood pressure, β hCG, size, gestational age, pain, bleeding, etc.) to determine the optimal treatment plan. In general, methotrexate was reported as the preferred treatment for a hemodynamically stable woman with an unruptured ectopic pregnancy, even among physicians who were unable to offer this modality of treatment within the Catholic hospital setting. Physicians also discussed the relative benefits of salpingostomy, which most viewed as the preferred treatment modality for patients who were hemodynamically unstable with an unruptured ectopic and wanted to preserve future fertility

Physicians had a range of opinions about the relative merits of salpingectomy. Although many physicians reported that they generally prefer to treat ectopic pregnancies with tube-sparing procedures, physicians across institution types noted that they would consider salpingectomy in cases where the woman does not want (additional) children or when a woman has an ectopic pregnancy after a previous tubal ligation. Interestingly, several physicians at Catholic institutions reported that use of salpingectomy allowed them to perform a tubal ligation which would otherwise be prohibited under the *Directives*.

In my population, many patients are dealing with unplanned pregnancies already. I talk to them before I take them to the OR to determine if future fertility is an issue. If it's not an issue I would tend to take out the tube...The hospital has never said anything about it one way or another.

- Ob/Gyn, Catholic hospital

Few respondents felt comfortable using expectant management for ectopic pregnancies unless the patient refused methotrexate or surgical intervention. As one respondent at a recently merged (Catholic to non-Catholic) facility stated, "I have heard of Ob/Gyns in the community doing that, but that is crazy. If the patient is in the ER then it is an emergency and something needs to be done." Another respondent at a non-Catholic hospital reported that expectant management fell out of favor after a case went before peer review – a patient who was being expectantly managed experienced rupture and the review board found the physician at fault for failing to treat the patient "quickly."

With respect to pregnancy loss, clinicians at all institutions reported treating miscarriages much more frequently than ectopic pregnancies. All participants reported that management decisions were based on a number of clinical factors (history, gestational age, pain, bleeding, blood pressure, etc.). Most reported that they generally preferred to manage pregnancy loss expectantly (with referral for out-patient follow-up). Most physicians reported that they would recommend expectant management over uterine evacuation if the woman was hemodynamically stable and fetal cardiac activity/heart tones were present. This finding held true with physicians across institution type.

Nearly all physicians indicated that transferring a patient for either ectopic pregnancy or miscarriage management was extremely rare. As one physician practicing at a Level I, non-Catholic hospital stated, “We are here 24/7 and this has never happened. The hospital would have to be on fire or something...a nuclear explosion. It would just absolutely never happen.” For those that did discuss transferring patients, it was largely in the context of resource constraints. However, several physicians at hospitals operating under the *Directives* reported that they had, on occasion, arranged for women to be transferred to other facilities to receive treatment options (e.g., methotrexate or uterine evacuation) that were not provided by the Catholic hospital.

If we have a patient less than 24 weeks with no chance to reach 24 weeks and [there is] no chance of viability, I think they should be induced for delivery. If we still have a heartbeat, we can't do that, so I transfer them to another hospital.

- Ob/Gyn, Catholic hospital

A number of physicians made reference to personal factors that influenced their clinical decision making. Several of the more recently trained physicians indicated it was their residency training that most influenced their clinical decision making, not the policies or guidelines at the current hospital. Indeed, a few younger doctors asserted the graduates of their residency program would use the same standards, regardless of where they currently work. Several physicians also indicated that their personal religious beliefs influenced their clinical practices and the reproductive health services offered to patients. As in the example below, a few physicians explained that because they identified as Christian, they would not provide certain reproductive health services.

Influence of patient characteristics on clinical practices

Many clinicians mentioned how patient characteristics (both actual and presumptive) affected their clinical decision making. In addition to using “objective” clinical measures to determine optimal treatment strategies, many clinicians in our sample also mentioned that several subjective measures influenced their treatment recommendations. Patient reliability and assessment of likely compliance emerged as a significant theme among physicians across hospital types. Physicians repeatedly reported that if a patient “appeared” unreliable, they would often discuss treatment options differently and make different recommendations to the patient. For example, several physicians working with large Medicaid-enrolled and/or immigrant/migrant populations indicated that they would never offer expectant management to these populations due to concerns that patients would not return for outpatient follow-up. That the patient presented at the ED was also interpreted by some physicians as a marker for unreliability. As one physician at a non-Catholic hospital reported, “[In cases of pregnancy loss] people who show up at the ER are usually much further along in the pregnancy and have a belly full of blood and are in more pain.” Thus expectant management would not be the recommended course of treatment for both clinical reasons and concerns about patient reliability. Further, a number of physicians reported that they would not recommend expectant management to patients who, in their judgment, would not be able to tolerate pain or bleeding and would therefore be at risk of “bouncing back” to the ED.

Alternatively, “reliable” patients were consistently characterized by physicians as patients with whom the doctor had a previous relationship. As one physician in a Catholic hospital noted, “someone who comes to your office, you know her or her family, she’s more trustable [*sic*] than someone who shows up in the ER who you don’t have prior knowledge of.”

The assessment of reliability appears to impact the ways in which many physicians discuss options with their patients. Some physicians indicated that they told patients about every option for miscarriage and ectopic pregnancy management. However, a number of others reported “filtering” information based on patient characteristics. As one physician reported, “Sometimes when you have an unstable patient, you don’t give them all their choices, you just tell them what you recommend. If there is someone that you are very comfortable with and her medical condition and reliability indicates that she is eligible for [a] non-surgical [intervention], then you are going to give her all the options.”

Most physicians reported that patient involvement in the decision-making process depended on both the acuity of the situation and the communication preferences of the physician. Some physicians noted that their preferred method of treatment was by default the patient’s preferred method of treatment and hence the patient had a very small role in determining her treatment. All respondents said that they presented the options verbally first, and then obtained written consent for surgical interventions.

Impact of mergers on clinical practices

Ten of the physicians in our sample currently work at recently merged hospitals. Knowledge about and reactions to the merger ranged widely among this subset of respondents. Two respondents at a Catholic facility that had recently been “taken over” by a non-Catholic hospital system indicated that there was both extensive discussion among physicians about the merger and considerable concern that the resultant cost-cutting measures were significantly impacting the quality of care. An EM physician practicing in a different state reported that similar concerns were expressed when his Catholic hospital was acquired by a non-Catholic for-profit hospital system. However, none of these respondents reported that there were specific concerns raised by the Ob/Gyn department. Another respondent reported that when his Catholic hospital was acquired by a non-Catholic health system the only change involved the provision of abortion. “The religious hospital would not provide abortions in any circumstance... [The new system] will, but it does it very quietly.”

None of our respondents reported that they changed their practice patterns with respect to ectopic pregnancy and miscarriage management after a hospital merger. However, concerns were expressed by several physicians that the merger between a non-Catholic and a Catholic facility would impact the scope of reproductive health services, particularly the availability of abortion and tubal ligation services. One Ob/Gyn respondent described the dynamics of the recent merger at his hospital, which was acquired by a non-Catholic system that also acquired a Catholic hospital as part of a three facility merger. “Initially that was a big issue. The Ob doctors, all of us, wanted comprehensive reproductive health services and no discrimination on any procedures... This was a big reason that [the Catholic hospital] lost the bid to maintain their facility.” Although this physician reported that this Catholic hospital had historically been “generally lax” when it came to the management of ectopic pregnancies, the hospital operated under the *Directives* and prohibited abortions and tubal ligations and thus there was concern that those services would be “compromised” under the new system. These concerns were not limited to situations where a non-Catholic hospital was acquired by a Catholic health system, but also situations where the Catholic hospital merged with or was acquired by a non-Catholic system.

Dr. B: Catholic hospital, Kentucky

Dr. B is an emergency medicine physician at a Catholic hospital in Kentucky. He completed his residency in the early 1990s and worked in a university hospital and a not-for-profit hospital in Kentucky before joining his current hospital 13 years ago. His current position requires that he rotate through three network hospitals: an urban hospital, a suburban hospital, and a rural facility that were acquired by the Catholic system more than a decade ago. In combination, these facilities treat more than 100,000 patients each year through their respective emergency departments and roughly half of all patients are on Medicare, on Medicaid, or uninsured.

Although hospital committees develop policies on a range of health issues, Dr. B is not aware of any policies related to ectopic pregnancy or miscarriage management within this network. When patients present in the emergency department with either condition they are typically referred to the Gynecology service and are managed by Ob/Gyns. All treatment options are available to women with ectopic pregnancies who present at this hospital system, although methotrexate is rarely used and would never be used if cardiac activity was detected. Because of the Catholic *Directives*, the hospital does not offer tubal ligations – women requesting tubal ligations would need to be seen by another physician and go to a different facility. However, the hospitals differentiate surgical interventions for ectopic pregnancy from tubal ligation and abortion – interventions in cases of ectopic pregnancy are seen as necessary lifesaving interventions “for the mother.”

With respect to miscarriage management, Dr. B treats a “handful” of women in the emergency department each month, the majority of whom have pregnancies of less than 15 weeks’ gestational age. The decision to evacuate the uterus in cases where there is cardiac activity or fetal heart tones is made by Ob/Gyns. Sometimes women who are 20-26 weeks’ pregnant will be transferred to a Level I facility with a neo-natal unit, but only if the woman is stable. Dr. B doesn’t know of any other cases of transfer.

Dr. B doesn’t believe that the Catholic *Directives* impact his practice. As he stated, “I have patients that come in that would like information about birth control, or tubal ligation, and I politely tell them that first of all it is not within the scope of my practice and second that that may be done by somebody somewhere else. And there are plenty of physicians who do do that, family physicians who do provide birth control.” As a Christian physician, he doesn’t feel that the limitations imposed by the *Directives* are a problem.

Dr. B explained that the Catholic health system that he works for owns three of the five hospitals in this region of Kentucky and will soon be taking over the other two. “Our hospital...will be taking them over and they currently have “reproductive services” available. But [our] Board is going to basically not allow anyone under the umbrella of [this health system] to do tubal ligations or reproductive health, as it were. And so that’s probably a plus for a lot of physicians, the Christian physicians, the majority of them I think, but some of the physicians think this is a service that should be available and they are concerned that patients will have to actually go across the river to Ohio to get the service that they are getting in Kentucky now... That is going to be one of the greatest stumbling blocks to the merger of the two hospitals, the issue of sterilization procedures, and the reproductive health and pregnancy prevention issues. I know it is a big area of concern.”

Impact of the *Directives* on other reproductive health services

Although our interviews specifically focused on ectopic pregnancy and miscarriage management, many clinicians at Catholic hospitals and recently merged facilities used this opportunity to share their thoughts on the impact of the *Directives* on other reproductive health services. Indeed, many physicians working at Catholic facilities voiced frustration, not over ectopic pregnancy treatment or miscarriage management, but over an inability to provide women with desired tubal ligations. As one doctor said, “They do [operate under the Catholic *Directives*] and they make no exceptions and that is occasionally frustrating for me. We don’t do tubals here and I’d like to be able to offer some tubals, but we talk to patients about that early in the pregnancy so that if they want that [post-partum] they could transfer to another hospital where they can do that. We can refer for tubals, but not elective terminations of pregnancy.”

In addition to not being able to provide tubal ligations, concerns about not being able to provide comprehensive contraceptive and pregnancy termination services emerged as an important theme. As an Ob/Gyn at a Catholic hospital reported, “I’m not Catholic. I don’t agree with all of the issues on this. I’ve done elective [abortions] in previous jobs. I’m not opposed to them. My biggest concern is that I wanted to be able to give birth control. We can do pills, patch, condoms, ring, depo shot... can’t do implants, IUDs, tubals, but I can refer for those. We can’t buy condoms, but if we get them for free, we can hand them out. We are not supposed to talk openly about that because it is behind closed doors and that is between physicians and patients. That argument [of discussing things behind closed doors] would not hold water if I talked to a patient about elective termination.”

A number of physicians reported concern that they would be reprimanded for providing patients with comprehensive reproductive health services in the Catholic hospital setting. As one physician noted, “If I had done something outside of the guidelines, I certainly would have heard about it. I heard of a doctor once who operated outside of the guidelines, he was demoted, but did not lose his privileges. I would probably lose my job if that happened. I don’t blame them for that because I am aware that I can’t do a tubal.”

A physician who violates the policy if he does tubal ligations knowingly [and] not by accident in [this system] the consequences are pretty severe. I have heard a rumor that this happened once and the physician... they wanted to suspend him and terminate his privileges and all that sort of thing and a lot of high level meetings went on.

- Emergency medicine physician, Catholic hospital

Limitations & challenges

Qualitative methods provide an excellent mechanism for in-depth exploration of respondents’ experiences, beliefs, and behaviors. The robustness of the data raises a number of questions that merit further exploration and provides important guideposts for future research and advocacy priorities. However, as is true of all qualitative studies, the method is not intended to yield representative and generalizable results. Although recruiting physicians from a random (but purposive) sample of hospitals gives us confidence that the themes that we have identified are significant, we are unable to access the degree to which these experiences represent broader trends. Finally, results might be affected by social desirability biases as participants may have altered their responses based on their desire to provide interviewers with politically, medically, or socially acceptable responses.

The most significant challenge in undertaking this project is intertwined with one of the greatest strengths of the study: the sampling. In order to strengthen the results of the study we chose to move beyond convenience samples and, rather than recruit participants from our professional, training, and personal networks, we recruited participants through a (predominately) randomly selected sample of hospitals. However, the limitations of available databases resulted in an extremely time-intensive process of collecting physician contact information and we were unable to systematically obtain information about hospital administrators. Consequently, we were unable to complete the “sets” of interviews that we had originally aimed to complete at each facility. Further, our multi-modal recruitment process (that included letters, phone calls, emails, and faxes) necessitated a significant investment of time, personnel, and resources. Unfortunately, we suspect that many of the physicians in our sample never received our letters or messages as our invitations were often filtered by “gatekeepers.” Finally, physicians are a notoriously difficult population to

recruit for study participation both in terms of scheduling and incentive structure. However, in obtaining a diverse sample with respect to both US region and institutional type, we believe that we have been able to accomplish the original aims of the study.

Summary & discussion

We undertook this national qualitative study to better understand the relationship between the *Directives*, hospital policies regarding management of ectopic pregnancies and miscarriages, and clinical practices. We conducted 25 interviews with physicians and administrators at 16 hospitals in ten US states. The content and thematic analysis reveals a number of key results that address our original study aims. We summarize and discuss these main findings below.

Specific aim #1. Investigate the degree to which hospital policies regarding ectopic pregnancy and miscarriage management are developed and communicated, informally and through formal institutional mechanisms.

Our participants described a number of different pathways by which policies and guidelines are created. However, few reported that there were specific hospital policies regarding the treatment of ectopic pregnancies and miscarriages. Physicians based in hospitals operating under the *Directives* were often quick to point out that the *Directives* impact tubal ligation and abortion services but do not determine policies regarding ectopics and miscarriages. While policies regarding abortion and contraception were often formally communicated and discussed, the impact of the *Directives* on other areas of reproductive health was generally not communicated through formal channels.

Yet, upon further probing, it appears that the *Directives* are both directly and indirectly impacting the clinical practices at a number of the Catholic facilities in our sample. Interestingly, although some Catholic hospitals do not offer methotrexate because they are Catholic, many of our participants did not immediately attribute this to the *Directives* nor did they describe this as a “policy.” Although several physicians expressed frustration at not being able to offer patients methotrexate as an option (within the facility), most of these physicians seemed “resigned” to the situation. Although physicians from all institution types described methotrexate as their preferred line of treatment, it appears that some physicians in Catholic hospitals are not directly associating the lack of availability of methotrexate as a policy governed by the *Directives*.

Specific aim #2. Evaluate the impact of these policies and the interpretation of these policies on management decisions.

Although few hospital have “formal” policies that address ectopic pregnancy and miscarriage management, the results of our study leave no doubt that institutional norms do influence clinical decision making. The lack of availability of methotrexate in some Catholic hospitals within our sample is a clear indication that the *Directives* influence the treatment options available to women experiencing ectopic pregnancies. However, another interesting finding involves the use of salpingectomy. Although generally not a preferred mode of treatment by physicians (from all institution types), several physicians at Catholic facilities (both recently merged and longstanding) spoke about using an ectopic pregnancy as an opportunity to provide a service (in this case, tubal ligation) that is clearly prohibited under the *Directives*. This mechanism of navigating around the *Directives* to perform a desired sterilization procedure that is prohibited within the facility suggests

that some physicians are attempting to provide patients with a more comprehensive range of reproductive health services while still adhering to official institutional policies (or their interpretation of those policies). Other clinicians described the ways in which they provide comprehensive reproductive health services “under the radar” through a combination of referral to an outside practice, early information and counseling, and one-on-one interactions with patients “behind closed doors.” That some of these activities may violate the *Directives* was noted by several of our participants.

With respect to the management of miscarriages, a number of our study participants reported having to order additional tests and/or perform diagnostic surgery in order to definitively ascertain that a pregnancy was not viable. Several physicians reported that presence of fetal cardiac activity/heart tones/heart beat complicated management decisions at Catholic institutions. Some physicians expressed confusion as to what was required regarding assessment of viability within the Catholic hospital setting and many appear to be practicing conservatively in order to avoid censure or reprimand.

Indeed, the results of our study suggest that interpretation of the *Directives*, stories and rumors about the experiences of other physicians (particularly in the context of reprimand), and informal communications about institutional norms influence clinical practices. Although few participants reported knowledge of cases in which an ethics committee had intervened in an ectopic pregnancy or miscarriage management decision, some physicians did suspect that their behaviors were being carefully watched by other members of the health team and by administrators. Indeed, one physician reported that nurses in the operating room were monitoring physician actions to ensure that they were abiding by the *Directives*. It is difficult to imagine that this “splitting” of the health team does not impact trust between members of the team and the care that patients receive.

Many physicians in our sample discussed at length the degree to which the *Directives* impact their ability to provide comprehensive reproductive health services, specifically tubal ligation and abortion services. These limitations on physician practices were unquestionably more concerning to a number of physicians than the limitations imposed by the *Directives* on ectopic pregnancy and miscarriage management.

Specific aim #3. Assess physician perceptions as to the impact of these policies on standards of care.

The degree to which adherence to the *Directives* influences standards of care and ultimately patient outcomes are difficult to assess. Most physicians in our study that expressed frustration with not being able to use methotrexate, having to perform unnecessary tests to determine viability, or transferring (on occasion) a patient to an outside facility to receive care not offered within the Catholic hospital, went on to state that patient outcomes were not affected. One physician at a Catholic hospital reported that as a result of delaying treatment for ectopic pregnancies she had observed several cases of rupture. A physician from a non-Catholic facility reported a similar experience. The difference between these cases appears to be the way in which the institutional norms and treatment expectations changed (or didn't) as a result. In the case of the non-Catholic hospital, the respondent reported that expectant management quickly fell “out of favor” and is now rarely employed in the hospital. In contrast, according to the physician practicing at the Catholic hospital, practice patterns did not change as a result of these events.

In the context of hospital mergers, it is notable that none of our respondents reported that they changed their practice patterns with respect to ectopic pregnancy and miscarriage management after a hospital merger. However, concerns were expressed by several physicians that the merger between a non-Catholic and a Catholic facility (regardless of ultimate ownership) would impact the scope of reproductive health services, particularly the availability of abortion and tubal ligation services. These physicians appear to view these limitations as a problem both from the perspective of clinicians (particularly with respect to autonomy and decision making) and patients.

Physicians also discussed a number of non-policy factors that influence clinical decision making. In addition to a generally consistent set of clinical indicators and criteria, several physicians also discussed how their religious and personal beliefs influence the care that they provide and the way in which options are discussed with patients. A number of physicians (at all hospital types) discussed how perceptions of patient reliability and ability to comply with follow-up influenced both their recommended course of treatment and the ways in which options were discussed with patients. Finally, recently trained physicians referenced their residency experiences as an influential factor in their current practice decisions.

Specific aim #4. Inform the development of a national mailed survey dedicated to exploring the impact of the *Directives* on ectopic pregnancy and miscarriage management.

Although we conducted the national qualitative study as a rigorous, stand-alone study, we also used this opportunity to inform the development of a proposed national mailed survey. The study has provided us valuable information about the sampling, administration, content, and potential yield of a mailed survey.

The results of the qualitative study suggest that it will be difficult to capture information about the impact of the *Directives* on ectopic pregnancy and miscarriage management in a survey format. As we note throughout this report, we were able to obtain rich information about the ways in which the policies and interpretation of policies impact clinical decision making only after considerable probing. Few respondents initially tied limitations in ectopic pregnancy and miscarriage management care to the *Directives*. We are concerned that without the ability to draw out participants we will be unable to capture the ways in which hospital policies directly or indirectly impact clinical care. But perhaps more fundamentally, we are concerned that a mailed survey will not yield a high enough response rate for our results to be either representative or generalizable. The challenges that we experienced in recruiting participants for the qualitative study will likely only be more considerable with a mailed survey. Indeed, when discussing the mailed survey with interviewees many stated that only by offering considerable financial incentives (incentives well beyond the budget of this project) would we be able to obtain participation from busy clinicians. We suspect (and several participants confirmed) that these standards for incentives have been at least partially influenced by the amount of funding offered to physicians by pharmaceutical companies for participation in studies. As we discuss in our recommendations section, we believe that it would be more feasible and valuable to pursue additional qualitative research than to implement a national mailed survey.

However, in parallel with the qualitative study, our study team developed a revised study design, a draft instrument, and a preliminary analysis plan for a mailed survey. Based on the qualitative study, we substantially altered the design of the mailed survey from the one that we initially put forth in our

proposal. Below we outline our recommendations for the sampling, administration, and content of a mailed survey, should there be interest in proceeding in that direction.

Sampling for a mailed survey

Despite the challenges in recruiting for the qualitative study, we believe that the hospital should continue to be the unit by which to generate the sampling frame. Our experience with the qualitative study confirms the importance of including hospitals from different regions and of different institutional types. We believe that the sample should include all 29 recently merged facilities as well as random selection of both non-Catholic facilities and longstanding Catholic hospitals, with over-sampling of the latter group. Using a stratified random selection process we recommend selecting Catholic and non-Catholic hospitals that are “matched” to recently merged facilities in nine US states. We detail this sampling strategy in Appendix C. The 100 hospitals included in the sample would be comprised of 29 recently merged facilities (100% of recently merged facilities in the US), 41 longstanding Catholic facilities (6.9% of all Catholic hospitals in the US), and 40 non-Catholic hospitals (1.2% of all non-Catholic hospitals in the US). This sample would represent all recently merged facilities, 25% of all Catholic hospitals, and 5% of all non-Catholic hospitals in these nine “matched” states (as well as 11 additional recently merged facilities).

In generating the sampling frame for the qualitative study we learned a great deal about what information is (and is not) publically available. Notably, information about hospital administrators is not systematically available on databases or hospital websites and thus a survey would need to focus exclusively on physicians. Our results indicate that both Ob/Gyns and EM physicians offer important perspectives and we believe that a mailed survey should include both types of physicians. Finally, email addresses are not routinely available and thus any survey would need to be a standard mailed (e.g., paper and pencil) survey. Based on this sampling strategy, we have selected the 100 hospitals for the mailed survey and have collected information from Ob/Gyns and EM physicians at these facilities. We would recommend randomly selecting ten physicians at each institution (five Ob/Gyns and five EMs) for participation in the mailed survey, which would yield an ultimate sample size of 1,000 clinicians.

Survey administration

As noted above, one of our greatest concerns about conducting the survey is the probability of obtaining a low response rate. Indeed, based on our qualitative study, we believe that achieving a 10% response rate, even after multiple contacts, will be difficult. However, informed by discussions with the qualitative study participants, we believe that a mixed incentive structure (e.g., a small incentive for all completed surveys coupled with a high-value item offered through a lottery at the end of the project) may increase the response rate. We believe that a two-contact approach, such that non-respondents would be sent a second survey packet approximately three weeks after the initial administration, would be optimal, given time and resource constraints.

Survey content

Our study team incorporated the information provided during the qualitative study into a draft instrument. Unquestionably, the survey needs to be extremely short. Thus, in addition to a number of closed-category questions, we believe that offering respondents the opportunity to “freely respond” to several open-ended questions would allow us to uncover more substantive information from participants who are interested in taking time to write detailed responses. We received

feedback on the draft instrument from several clinicians, and if we decide to move forward with a mailed survey we will conduct a targeted pilot prior to survey administration.

Recommendations

The findings from our qualitative study highlight a number of priority areas for further research, exploration, and advocacy. We outline below a number of recommendations for moving forward.

1) Disseminating the results of the qualitative study

We believe that the results of the qualitative study are sufficiently robust to warrant a multi-tiered dissemination plan. In addition to this detailed report, we have developed a short “digested” summary of the results which could potentially be distributed to a wider audience of researchers and advocates. We look forward to working with the National Women’s Law Center to finalize the dissemination strategy and priorities. Should we decide disseminate the results of the study to advocacy groups, we could consider providing the summary document to colleague organizations through professional networks, such as the Training and Access Working Group, posting the document on the Ibis website, and formally presenting the results to advocates as opportunities arise.

We also believe that these results should be presented and published in academic fora. To that end, we would like to submit an abstract for presentation at the 2009 National Abortion Federation annual meeting and hope to develop a manuscript for submission to a peer-reviewed journal. Possible venues for submission include *Social Science & Medicine*, *Contraception*, and *Women’s Health Issues*. We believe that disseminating the results to a research audience will support the recommendations we list in this report.

2) Conducting additional qualitative research with clinicians and administrators at Catholic and non-Catholic facilities

The results from our study suggest several priority areas for further examination which would be best approached through additional qualitative research. Further exploration of the ways in which institutional norms are created and the ways in which religious beliefs and personal biases influence clinical practices appears warranted. That most treatment guidelines were not communicated through formal mechanisms suggests that additional research is required to understand how institutional norms are created and to ascertain how expectations are communicated and enforced through informal peer and social networks, as well as through institutional responses to adverse events. Our results raise a number of questions about how clinicians learn about an unspoken consensus regarding which procedures are preferred and which are prohibited. The dynamic suggested by one participant that members of the health team are monitoring the behavior and actions of physicians also merits further exploration.

However, beyond institutional policies and norms, individual clinician biases and religious beliefs appear to also shape both the range of services provided by clinicians as well as the options presented to patients (and the way in which those options are presented). These types of clinician biases, and specifically “religious refusals” and “conscious clauses,” have certainly been explored in other areas of reproductive health but have yet to be rigorously assessed in the context of ectopic

pregnancy and miscarriage management. It would be especially valuable to explore the ways in which religious beliefs influence clinician decision making at non-Catholic facilities. We believe that by conducting a “phase 2” qualitative study with a targeted sample of clinicians at additional hospitals, we would be able to shed light on a number of these questions.

3) Highlighting the role of the *Directives* in limiting an array of reproductive health services

Although participants in our study demonstrated considerable awareness that the *Directives* prohibit the provision of comprehensive contraception and abortion services, far fewer drew an explicit connection between the *Directives* and ectopic pregnancy and miscarriage management. Highlighting this link to clinicians may help raise awareness about the impact of mergers on their professional autonomy regarding a wider array of reproductive health issues. Further, incorporating these results into broader advocacy efforts may prove a strategic way to discuss the consequences of hospital mergers and draw attention to the challenges that women face when obtaining care at Catholic facilities.

4) Policies regarding ectopic pregnancy and miscarriage management

Our qualitative study reveals that few institutions have formal, articulated policies about the management of ectopic pregnancies and miscarriages. Working with and supporting efforts by professional societies, medical associations, and state-level stakeholders to develop policies and guidelines that specify standards of care may be a proactive way of addressing the lack of clarity expressed by a number of physicians. Further, as several younger physicians discussed the importance of residency training on shaping their clinical decision making (irrespective of hospital guidelines), our results suggest that residency education may be a vehicle for shaping standards of care and practice. A number of efforts have been undertaken and are underway to improve residency education and training in abortion care. However, exploring the Accreditation Council for Graduate Medical Education (ACGME) training requirements for ectopic pregnancy and miscarriage management and, if applicable and feasible, identifying ways of strengthening those residency requirements such that experience in providing a full range of services (in the context of ectopic pregnancy management) is expected, may serve to ultimately influence clinical practices. Providing organizations like Physicians for Reproductive Choice and Health and Medical Students for Choice with the results of this study may aid their efforts in promoting comprehensive training at the undergraduate and graduate levels.

5) Perspectives of women

Although our study reveals important information from the perspective of clinicians and (to a certain degree) administrators, the experiences and perspectives of women have not been explored. Physicians in our study that expressed frustration with not being able to use methotrexate, having to perform unnecessary tests to determine viability, or transferring a patient to an outside facility to receive care not offered within the Catholic hospital generally did not believe that this impacted patients. Yet women who are not offered a full range of options, transferred to another facility, and required to undergo unnecessary and time-consuming tests that delay care likely view those experiences very differently from physicians. Further, exploring the ways in which physician biases impact ectopic pregnancy and miscarriage management from the perspective of women themselves should be a priority moving forward.

Conclusion

We thank the National Women's Law Center for affording us the opportunity to complete this important work. We believe that the results of this study provide critical information for the larger medical field and to researchers and advocates working to increase women's access to reproductive health services. We look forward to continuing our collaboration with the National Women's Law Center to both disseminate the findings of this study and to develop and implement strategies for further understanding the impact of the *Directives* on a range of reproductive health services.

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Appendix A: In-depth interview schedule with clinicians

General information

Thank you for taking the time to speak with me today. I'd like to begin by asking you some general questions about yourself and the hospital(s) in which you work and have privileges:

1. Please introduce yourself (specialty, number of years of experience).
2. Please tell me a little bit about the hospital
 - a. Probe: rural/urban, percent Medicaid population, bed size, ownership
3. Has the hospital been recently merged with or been acquired by a Catholic hospital or health system?
 - a. If yes, were there any discussions among physicians/clinicians regarding the impact of the merger [Probe: concerns by Ob/Gyn department, association with advocacy groups, etc.]
4. How are policies/guidelines regarding standards of care [or decision-making algorithms] developed at your hospital? [Probe: ACOG or other professional body guidelines, internal hospital guidelines, department/ethics committees]
5. [If it is a Catholic hospital] Does your hospital operate under the *Catholic Religious and Ethical Directives*?
6. Do you practice at more than one hospital?
 - a. If yes, at what other hospitals do you practice?
 - b. Are any of them Catholic operated facilities?
 - c. If yes, do you practice differently at the Catholic hospital? [Explore responses]
[Questions should be repeated for each hospital/facility that the clinician has privileges at]

Management of ectopic pregnancies

I'd now like to ask you some questions regarding policies and practices surrounding the management of ectopic pregnancies:

1. Approximately how many ectopic pregnancies are treated in your hospital by month or year?
2. Approximately how many ectopic pregnancies do you treat each month or year?
3. In your hospital, which clinicians manage women with ectopic pregnancies [Probe: ER physicians, family physicians, only Ob/Gyn, etc.]
4. Does the hospital have written guidelines regarding the management of ectopic pregnancy and miscarriages? [Probe: what factors influence decision-making algorithms]
5. For a woman who is hemodynamically stable and/or with an unruptured ectopic pregnancy, what are the treatment options that might be considered at your hospital?
6. Please describe the situations when methotrexate is used.
7. Please describe the situations when salpingectomy is used.
8. Please describe the situations when salpingostomy is used.
9. Please describe the situations when expectant management is used.
10. How do you decide to use one method over another?
11. How are the different treatment options presented to the patient, and what is their role in choosing the treatment?
 - a. How are the relative benefits and risks presented? [Probe: Verbally, in writing.]
12. [For physicians that practice at more than one hospital] Do you feel that there are some treatment options available to you at one hospital that are not options at another hospital at which you work?
13. If operating under the *Catholic Directives*
 - a. Do the *Directives* have any impact on how you manage ectopic pregnancies and miscarriages?
 - b. If yes, in what way has your management of ectopic pregnancies been impacted?
14. Has the hospital's ethics committee ever been involved in decision-making regarding an ectopic pregnancy? [If yes, explore further].
15. Under what conditions (if any) would a woman with an ectopic pregnancy be transferred to another facility, and why?

Management of miscarriage and incomplete abortion

Now I'd like to turn to some questions regarding policies and practices surrounding the pregnancy loss management and specifically the management of incomplete or inevitable abortions:

1. Approximately how many miscarriages/incomplete abortions are treated in your hospital by month or year? [Probe: type of SAB, gestational age]
2. Approximately how many miscarriages/incomplete abortions do you treat each month or year?
3. In your hospital, which clinicians manage women with miscarriages/incomplete abortions [Probe: ER physicians, family physicians, Ob/Gyns, etc.]
4. Does the hospital have written guidelines about uterine evacuation in cases of incomplete abortion or inevitable abortion if there is still a fetal heartbeat/fetal heart tones/cardiac activity?
5. In the case of incomplete abortion what are the treatment options that might be considered at your hospital?
6. In the case of an inevitable abortion what are the treatment options that might be considered at your hospital?
7. What are the clinical factors that guide you to intervene with evacuating the uterus?
8. How are the relative risks and benefits presented to patients and to what extent are patients involved in treatment decisions?
 - a. If certain treatments are not available at your facility, what is the process for providing information and referrals to patients who choose those options?
9. If operating under the *Directives*
 - a. Do the *Directives* have any impact on how you manage patients experiencing an incomplete/inevitable abortion?
 - b. If yes, in what way has your management of patients experiencing an incomplete/inevitable abortion been influenced by the *Directives*?
10. Has the hospital's ethics committee ever been involved in decision making for a patient experiencing an incomplete abortion? [If yes, explore further]
11. [If the clinician is practicing at a Catholic hospital] Have you ever received guidance regarding how to manage women with incomplete abortion with respect to the *Directives*?
 - a. If yes, who provided the guidance?
 - b. What did the guidance consist of?
12. Under what conditions (if any) would an incomplete abortion be transferred to another facility, and why?

Other

Thank you so much! I only have a few more questions:

1. We are planning to speak with hospital administrators to understand their perspective regarding policies related to the management of ectopic pregnancy and incomplete abortions. With whom would you suggest we speak (hospital medical director, ER administrator, head of OB/GYN department, other)?
2. Are there any other clinicians/physicians at your facility that you would recommend that I speak with? Would you be willing to facilitate that introduction?
3. As you know, these interviews will inform a national mailed survey which we intend to conduct later this year. We would like to offer physicians a small incentive to participate in the survey – do you have any recommendations as to what incentive would be appropriate?
4. Is there anything that you would like to add?
5. Do you have any questions for me?

Appendix B: Biographies of key study team personnel

Angel M. Foster, DPhil, MD, AM, is a Senior Associate at Ibis Reproductive Health and joined the organization in 2002. A 1996 Rhodes Scholar from Oregon, she received her Doctor of Philosophy degree (DPhil) in Middle Eastern studies from Oxford University. Dr. Foster also holds a Doctor of Medicine (MD) degree from Harvard Medical School and both a Master's degree (AM) in international policy studies and a Bachelor's degree (BAS) from Stanford University. Dr. Foster has extensive experience in designing and implementing both qualitative and quantitative research projects, including a number of studies dedicated to health professions training, and has authored or co-authored over three dozen articles, book chapters, and reports on sexual and reproductive health. Dr. Foster also has extensive abortion and reproductive health advocacy experience. She has previously served on the Physicians for Reproductive Choice and Health (PRCH) Board of Directors and as the 2003-2004 President of the board of directors of Medical Students for Choice. A longstanding member of the Conference Planning Committee of the Training and Access Working Group, Dr. Foster currently serves on several PRCH committees and is a member of the ARHP's Curriculum on Reproductive Health Education initiative advisory committee. In 2004 she was named one of Choice USA's "30 Under-30 Activists for Reproductive Freedom." As Principal Investigator of the project, Dr. Foster was responsible for all aspects of the study, including study design, data collection and analysis, and presentation and dissemination of the results.

Amanda Dennis, MBE, is a Project Manager at Ibis Reproductive Health and joined the organization in 2007. Ms. Dennis holds a Master's of Bioethics from the University of Pennsylvania and a Bachelor's Degree in Liberal Arts from Hampshire College. Prior to joining Ibis, she worked as a counselor at an ambulatory surgery center specializing in second trimester abortion care and as a counselor at a domestic violence shelter. Her most recent research has focused on the juncture of disability rights and reproductive health and the role of male partners in abortion services. She is also leading a qualitative study to determine how frequently abortion providers have been able to successfully obtain Medicaid funds to cover termination costs, and to document their experiences, challenges, and successes with attempting to obtain Medicaid coverage for abortion. She is presently pursuing her Doctorate in Public Health, specializing in social and behavioral aspects of health care, at Boston University. Ms. Dennis served as a Co-Investigator on this study and was responsible for conducting interviews, analyzing the interview content, and contributing to the dissemination plan.

Fiona Smith, MPH, has more than ten years experience in conducting both qualitative and quantitative research with health service professionals. She received her Master's in Public Health degree from Tulane University and serves as a long-term consultant at Ibis Reproductive Health. As a Co-Investigator on this project, Ms. Smith was responsible for conducting interviews with clinicians and administrators, analyzing the interview content, and contributing to the dissemination plan.

Appendix C: Proposed quantitative study sample

Table of hospital types for inclusion in the national mailed survey

AHA Region	Recently merged		Longstanding Catholic			Non-Catholic		
	Sample (region)	% of total (region)	Sample	Total # (region)	% of total (region)	Sample	Total # (region)	% of total (region)
1	0	100%	1	19	5.3%	2	143	1.4%
2	5	100%	3	63	6.3%	6	284	2.1%
3	3	100%	2	34	5.9%	6	598	1.0%
4	7	100%	12	167	7.2%	6	483	1.2%
5	3	100%	3	28	10.7%	3	294	1.0%
6	1	100%	3	110	2.7%	3	498	0.6%
7	4	100%	2	62	3.2%	3	516	0.6%
8	1	100%	2	32	6.3%	2	266	0.8%
9	5	100%	12	80	15.0%	9	269	3.3%
Total	29	100%	41	595	6.9%	40	3351	1.2%

State breakdown of sample

AHA Region	Recently merged		Longstanding Catholic			Non-Catholic		
	Sample (State)	% of total (State)	Sample	Total # (State)	% of total (State)	Sample	Total # (State)	% of total (State)
1	0	100%	1-RI	RI-1	100.0%	2-RI	RI-20	10.0%
2	3-PA* 1-NJ* 1-NY	100%	4-PA	PA-17	23.5%	6-PA	PA-128	4.7%
3	2-FL* 1-VA*	100%	2-FL	FL-8	25.0%	6-FL	FL-120	5.0%
4	5-IL* 2-OH*	100%	12-IL	IL-46	26.1%	6-IL	IL-113	5.3%
5	3-KY*	100%	3-KY	KY-15	20.0%	3-KY	KY-71	4.2%
6	1-NE	100%	3-NE	NE-14	21.4%	3-NE	NE-56	5.4%
7	1-LA* 1-OK 2-TX	100%	2-LA	LA-11	18.2%	3-LA	LA-60	5.0%
8	1-NM	100%	2-AZ†	AZ-5†	40.0%	2-NM	NM-25	8.0%
9	2-CA 1-HI 2-WA	100%	12-CA	C-46	26.1%	9-CA	CA-204	4.4%
Total	29	100%	41	163	25.2%	41	797	5.0%

* Indicates states where there is at least one non-Catholic to Catholic merger or “compromise” merger

† As there are no longstanding Catholic hospitals in New Mexico that meet our other eligibility criteria, we have matched the only recently merged facility in Region 8 to Catholic hospitals in another Region 8 state.

NB: All recently merged facilities will be included in the study. However, only one state from each region will be matched with longstanding Catholic and non-Catholic facilities.

All matched hospitals			
State	# hospitals in sample	Total # hospitals in state	% of all hospitals in state
RI	3	21	14.3%
PA	13	148	8.8%
FL	10	130	7.7%
IL	23	164	14.0%
KY	9	89	10.1%
NE	7	71	9.9%
LA	6	72	8.3%
NM	3	26	11.5%
CA	23	252	9.1%