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Vasectomy provider decision-making rationales: balancing autonomy and non-maleficence

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Vasectomy provider decision-making rationales: balancing autonomy and non-maleficence

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An abstract of a thesis submitted to the Faculty of the Rollins School of Public Health of Emory University in partial fulfillment of the requirements for the degree of Master of Public Health in Global Health, 2021.

Abstract

Vasectomy provider decision-making rationales: balancing autonomy and non-maleficence

By: Alison T. Hoover

Background: Male sterilization, or vasectomy, is 99.9% effective at preventing pregnancy with less than a 2% risk of complications. Engaging men in contraception through vasectomy also contributes to driving more equitable gender norms. Despite the high efficacy, low risk, low cost, and gender equity benefits of vasectomy, just 2% of women reported that they and their partners relied on vasectomy as their contraceptive method in 2019. The contributing factors to low global vasectomy uptake are interrelated and span policy, demand, and supply barriers. The evidence is sparse on supply barriers for vasectomies, and particularly absent on how vasectomy providers evaluate patient candidacy.

Objective: The purpose of this study was to describe the decision-making rationales of experienced vasectomy providers that belong to the global Vasectomy Network google group when evaluating patient candidacy in complex vasectomy cases.

Methods: Fifteen vasectomy providers from seven countries participated in hour-long interviews over Zoom using a semi-structured in-depth interview guide. Providers were asked about their training in vasectomy provision, their reasons for getting involved in vasectomy provision, challenging cases they have faced in their career, and the approaches they use to handle challenging cases. Vignettes were used to help further elicit decision-making rationale. Thematic analysis was conducted using MAXQDA20 (VERBI GMBH, Berlin).

Results: Provider decision-making relied heavily upon ensuring that patients were well-informed, able to consent, and certain about their decisions. Once those conditions were met, providers filtered patient characteristics through their training, laws and guidelines, sociocultural norms, experience, and mission and values in order to evaluate the cost-benefit breakdown for particular patients. Based on that cost-benefit analysis, providers then determined whether or not they weighed autonomy or non-maleficence more heavily when evaluating patient candidacy for vasectomy provision.

Discussion: Despite clinical best practices promoting the prioritization of patient autonomy over non-maleficence, some providers continue to emphasize non-maleficence over autonomy, particularly in cases they deem to be at high risk of regret. The findings of this study suggest future trainings of vasectomy providers should focus on evidence-based medicine, shared decision-making, and patient-centered care to facilitate vasectomy provision that honors patient autonomy and rights.

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Chapter 1: Introduction

Contraceptives play a key role in meeting the right of all persons to plan if, when, and how many children they will have toward attaining the highest standard of sexual and reproductive health (United Nations Department of Economic and Social Affairs, 2019b). The global availability of contraceptives has halved fertility rates around the world, from 4.98 births per woman in 1960 to 2.42 in 2018 (World Bank, 2018). Sterilizations—both male and female—are the most effective contraceptive methods currently available, and male sterilization, or vasectomy, is the only authorized contraceptive method for men besides condoms. A vasectomy is a safe, simple, and highly effective permanent procedure that involves disrupting the flow of semen into the seminal fluid by severing each vas deferens through a small opening in the scrotum (Shih, Zhang, Bukowski, & Chen, 2014). Vasectomies are 99.9% effective at preventing pregnancy, with less than a 2% risk of complications, including infections, hematomas, or chronic pain (Shih, Zhang, Bukowski, & Chen, 2014). Beyond the clinical benefits of vasectomies, engaging men in contraception through vasectomy contributes to driving more equitable gender norms (Stern, Pascoe, Shand, & Richmond, 2015).

Despite the high efficacy, low risk, and low cost of vasectomy, just 2% of women reported that they and their partners relied on vasectomy as their contraceptive method in 2019, making it one of the least-used form of contraception globally (United Nations Department of Economic and Social Affairs, 2019a). The unmet potential for vasectomy uptake is particularly clear when comparing directly to female sterilization (tubal ligations). Compared with a vasectomy, a tubal ligation is 20 times more likely to have major complications, 10 to 37 times more likely to fail, and costs three times as much on average (Hendrix, 1999). Despite this, female sterilization is the most common contraceptive method worldwide, accounting for 24% of

women using contraceptives (219 million women). Global vasectomy uptake is also decreasing over time, having dropped from 3% in 1994 to 0.8% in 2019 (United Nations Department of Economic and Social Affairs, 2019a).

The contributing factors to low global vasectomy uptake are multifactorial and interrelated, but are best understood as policy, demand, and supply barriers. Policy barriers are primarily structural barriers to vasectomy, including limited public funding and mandatory waiting periods. Persistent low demand for vasectomy continues to be a major hurdle to vasectomy uptake, driven by low awareness of the method entirely among potential clients, followed by myths and misconceptions about the procedure, and gendered norms surrounding contraceptive use (Shattuck, Perry, Packer, and Quee, 2016; Shelton & Jacobstein, 2016; Shih et al., 2014; Shih, Dubé, Sheinbein, Borrero, & Dehlendorf, 2013). Supply barriers to vasectomy uptake include vasectomy provider-imposed eligibility limitations, lack of knowledge among general non-vasectomy providers, bias among both vasectomy and non-vasectomy providers, and low vasectomy provider availability.

Notably, the evidence is sparse on supply barriers for vasectomies. There is limited information on the mitigating factors for when non-vasectomy providers decide to discuss vasectomies with their patients, and even less available on how vasectomy providers evaluate patient candidacy. Although it has been suggested that the supply is not the issue (Shelton & Jacobstein, 2016), concerns have been raised about biases and knowledge among non-vasectomy providers. However, to date, there is very little data on how vasectomy providers evaluate patient candidacy. To sufficiently understand this barrier to supply, and to design appropriate interventions to support vasectomy uptake at the provider level, there is a need to understand the decision-making rationales of vasectomy providers. The purpose of this study was to describe the

decision-making rationales of experienced vasectomy providers that belong to the global Vasectomy Network google group when evaluating patient candidacy in complex vasectomy cases. The findings can be used to design trainings and policies that address supply gaps in vasectomy access that will, in turn, address persistent demand gaps.

Chapter 2: Literature Review

Contraceptives

The US Centers for Disease Control and Prevention (CDC) named contraception one of the 10 greatest public health achievements of the 20th century (CDC, 1999). Contraceptives are devices (e.g. IUDs, implants, condoms), practices (e.g. abstinence, rhythm method), pharmaceuticals (e.g. oral contraceptives), or procedures (e.g. sterilization) that are used to prevent pregnancy (Kavanaugh, 2013). The global availability of contraceptives has halved fertility rates around the world, from 4.98 births per woman in 1960 to 2.42 in 2018 (World Bank, 2018). Reductions in the fertility rate have in turn created more educational and economic opportunities for women, contributed to improved maternal and infant health and survival, reduced the spread of sexually transmitted infections including HIV, and reduced the need for abortions (Barot, 2008; Kavanaugh & Anderson, 2013). Contraception can also reduce the risk of developing reproductive cancers and can help treat menstrual-related symptoms and disorders (e.g. dysmenorrhea, menorrhagia) (Kavanaugh & Anderson, 2013).

In addition to their efficacy, contraceptives have had such a large global impact in part due to their scale of use; of the 1.9 billion women of reproductive age (15-49) worldwide in 2019, 842 million were using contraceptive methods (Kantorova, 2020; United Nations Department of Economic and Social Affairs, 2019b). Additionally, contraceptives play a key role

in meeting the right of all persons to plan if, when, and how many children they will have toward attaining the highest standard of sexual and reproductive health (United Nations Department of Economic and Social Affairs, 2019b).

Vasectomy

Sterilizations—both male and female—are the most effective contraceptive methods currently available, and male sterilization, or vasectomy, is the only authorized contraceptive method for men besides condoms. A vasectomy is a safe, simple, and highly effective permanent procedure that involves disrupting the flow of semen into the seminal fluid by severing each vas deferens through a small opening in the scrotum (Shih, Zhang, Bukowski, & Chen, 2014). Although there is a procedure to reverse the vasectomy procedure, called a vasovasostomy, the success rate varies greatly depending on the years between the vasectomy and the reversal, the age of the patient at the time of the procedure, and the skill of the provider (Patel & Smith, 2016). Given the variability of the reversal rate, the procedure is considered to be a permanent method.

The no-scalpel vasectomy (NSV) method is one of the most common methods for isolating and accessing the vas deferens during a vasectomy, where a small puncture is made instead of a short incision with a scalpel in a traditional vasectomy. Most vasectomies, both NSV and traditional, are done under local anesthesia and the procedure duration is commonly around 15 minutes. Vasectomies are 99.9% effective at preventing pregnancy, with less than a 2% risk of complications, including infections, hematomas, or chronic pain (Shih, Zhang, Bukowski, & Chen, 2014).

Beyond the clinical benefits of vasectomies, engaging men in contraception through vasectomy contributes to driving more equitable gender norms (Stern, Pascoe, Shand, & Richmond, 2015). A review of 58 evaluations of programs that worked with men and boys on sexual and reproductive health showed evidence of positive clinical changes in maternal, newborn and child health. Engaging men also led to positive attitudes and behaviors related to sexual and reproductive health, including interactions with their children; use of violence against women and with other men; and general health-seeking behavior (Barker, Ricardo, Nascimento, Olukoya, & Santos, 2009).

Global Uptake of Vasectomy

Despite the high efficacy, low risk, and low cost of vasectomy, just 2% of women reported that they and their partners relied on vasectomy as their contraceptive method in 2019, making it the second to last used form of contraception globally (United Nations Department of Economic and Social Affairs, 2019a). Rates vary dramatically by country. In Canada, 22% of men use vasectomy compared to 0.7% in South Africa. South Africa's rate is the highest in the African continent (Jacobstein, 2015). The unmet potential for vasectomy uptake is particularly clear when comparing directly to female sterilization (tubal ligations). Compared with a vasectomy, a tubal ligation is 20 times more likely to have major complications, 10 to 37 times more likely to fail, and costs three times as much on average (Hendrix, 1999). Despite this, female sterilization is the most common contraceptive method worldwide, accounting for 24% of women using contraceptives (219 million women). Global vasectomy uptake is also decreasing over time, having dropped from 3% in 1994 to 0.8% in 2019 (United Nations Department of Economic and Social Affairs, 2019a). The contributing factors to low global vasectomy uptake

are multifactorial and interrelated, but are best understood as policy, demand, and supply barriers.

Policy barriers

Policy barriers are primarily structural barriers to vasectomy, including limited public funding and mandatory waiting periods. These policy barriers are particularly evident in the US, where people with incomes less than 149% of the federal poverty line are five times less likely to get a vasectomy than those with incomes that are greater than 300% of the federal poverty line (Anderson, 2012). Of the procedures done in the US, 80.1% are covered through private insurance, and just 0.5% are covered by Medicaid, a stark comparison with 40.1% of tubal ligations covered by Medicaid. Vasectomies are covered by Medicaid in most states but are not covered under the Affordable Care Act. Conversely, tubal ligations are covered under the Affordable Care Act (Anderson, 2012; Shih et al., 2014). Vasectomy services generally are not available where minority and low-income men receive health care with fewer than 25% of publicly funded clinics offering vasectomies and less than 20% providing external referrals (Barone, 2004; Shih et al., 2014). The limited availability of vasectomy at publicly funded clinics has been attributed to a perceived lack of demand, a lack of adequately trained staff, insufficient funding, inadequate infrastructure, and clinics viewing vasectomy as beyond their scope and mission (Anderson 2012; Shih, Turok, & Parker, 2011; White, Campbell, Hopkins, Grossman, Potter, 2017). However, there is evidence to suggest the limited availability of vasectomy in publicly funded clinics in the US may also be a supply-side issue. White et al., noted that some clinics struggled to offer vasectomies because they could not find providers willing to accept the low reimbursement rate for the procedure (2017).

Mandatory waiting periods are also a major policy barrier to vasectomy uptake. In the US, any federally funded vasectomies, including through Title X or Medicaid, are subject to a 30-day waiting period between collecting informed consent and offering the procedure. The state of New York has an identical provision for all sterilizations, no matter the funding source. In addition to ethical concerns about differentiated care based on the ability to pay (Moaddab, McCullough, Chervenak, Fox, Aagaard, Salmanian, Raine, Shamshirsaz, 2015), it also has significant implications for maternal health and state health costs. Borrero et al. estimates that a revised sterilization policy with fewer logistical barriers would avert 29,000 unintended pregnancies and reduce costs by $215 million annually (2013). Concerns about the mandatory waiting period have only grown during the COVID-19 pandemic, as there have been no clear guidelines on telehealth consultations and sharp reductions in the availability of elective procedures (Evans, Qasba, Arora, 2021).

The mandatory waiting period was initially instated to counteract instances of coerced or forced sterilization among low-income women. Numerous countries around the world have a legacy of forced sterilization that continues to shape public perception and government willingness to promote sterilization (Largent, 2011; Sheynkin, 2009; Vicziany, 1982). In India, almost 7% of all Indian couples were sterilized from 1975-77 (Sheynkin, 2009). Coercive sterilization policies are still found today, such as those found at a jail in Tennessee, US, that offered reductions in jail time in exchange for undergoing sterilization procedures (Ockerman, 2019). While policies protecting against forced sterilization are essential, policy reforms are needed to promote timely, voluntary access with appropriate insurance coverage to vasectomies as an effective contraceptive method. In addition, understanding barriers related to both demand and supply will advance the evidence-base for policy reforms.

Demand barriers

Persistent low demand for vasectomy continues to be a major hurdle to vasectomy uptake. The primary driver of low demand is a lack of awareness of the method entirely among potential clients, followed by myths and misconceptions about the procedure, and gendered norms surrounding contraceptive use (Shattuck, Perry, Packer, and Quee, 2016; Shelton & Jacobstein, 2016; Shih et al., 2014; Shih, Dubé, Sheinbein, Borrero, & Dehlendorf, 2013). Only 30.9% of married men were aware of vasectomy as a family planning method in Turkey (Sahin, Gungor, Karabulutlu, & Demirci, 2008), with a comparable 37.5% of men aware of the method in Nigeria (Onasoga, Edoni, & Ekanem, 2013). Less educated individuals are less likely to seek vasectomy (Barone, Hutchinson, Johnson, Hsia, and Wheeler, 2006). Among those that do have basic familiarity with the procedure itself, there are rampant misconceptions and erroneous assumptions about vasectomies, such as the perceived ease of reversibility of tubal ligations (Shih et al., 2013). Other misconceptions have included concerns about erectile dysfunction, libido, and vasectomy leading to more promiscuous behavior (Shongwe, Ntuli, and Madiba, 2019). Other common misconceptions are that vasectomy is synonymous with castration or leads to physical weakness (Shattuck et al., 2016; Shelton & Jacobstein, 2016). There are also pervasive challenges with social norms around the gendered responsibility for contraception and viewing it as the woman's responsibility to manage (Shelton & Jacobstein, 2016), as well as social stigma against vasectomy (Shih et al., 2013). Gendered norms may be reinforced by men's less-frequent touchpoints with medical care, particularly for sexual and reproductive health. Men are rarely counseled to consider a vasectomy, compared to women's relatively frequent OB-

GYN consultations where they may be counseled on tubal ligations (Shelton & Jacobstein, 2016).

Although there are persistent demand-related barriers to vasectomy uptake, there are proven approaches to improving vasectomy uptake among potential clients. Evidence suggests community-based and mass media communications are effective in increasing demand for vasectomy, including radio advertisements, posters, and television broadcasts (Shattuck et al., 2016). Contact with a health worker was also a key driver in vasectomy uptake (Shattuck et al., 2016). Additional research is needed to determine the best health promotion messaging for campaigns to increase vasectomy uptake. Furthermore, there is a critical need to understand the role of health care providers in vasectomy uptake, including the direct barriers and facilitators to health worker promotion of vasectomy.

Supply barriers

Supply barriers to vasectomy uptake include vasectomy provider-imposed eligibility limitations, lack of knowledge among general non-vasectomy providers, bias among both vasectomy and non-vasectomy providers, and low vasectomy provider availability. Eligibility limitations include active policy limitations in some countries, and lingering vasectomy provider impositions based on past policies, including minimum age, minimum number of children, marital status, and spousal consent (Rizvi, Naqvi, & Hussain, 1995; Uhlman, 1974; Urquhart-Hay, 1975). The most common vasectomy provider-imposed eligibility limitations are age and parity restrictions (Bryk, Murthy, DeWitt-Foy, Sun, Parekh, Sabanegh, & Vij, 2020; Masterson, Avalos, Santomauro, Walters, Marguet, L'Esperance, & Crain, 2012; McQueen, 2017; Najari, Persily, Peterson, Wells, & Goldstein, 2021).

Lack of non-vasectomy provider knowledge of vasectomy, or inaccurate knowledge, has been identified as a major service delivery barrier (Shattuck et al., 2016). One study in Nigeria revealed erroneous beliefs among general physicians that vasectomy would impair a man's ability to ejaculate or increase his risk of prostate cancer (Ebeigbe, Igberase, & Eigbefoh, 2011). Some non-vasectomy providers report they perceive there to be low interest among their clients, leading them to not discuss the procedure, causing a cyclical barrier to low uptake (Shelton & Jacobstein, 2016; White, Campbell, Hopkins, Grossman, Potter, 2017). In one study in the US, only 2.5% of men who reported not desiring any additional children received sterilization counseling (Borrero, Moore, Creinin, & Ibrahim, 2010).

These restrictions and failure to provide accurate information to clients have also been described as forms of provider bias (McQueen, 2017; Shelton & Jacobstein 2016; Solo & Festin, 2019; Vieitez & Ramos, 2018). Ironically, Solo & Festin (2019) noted "the issue of bias regarding vasectomy does not arise frequently in the provider bias literature, likely in part due to the bias toward the method, its limited use in many programs, and the focus in bias literature around youth populations." As stated above in the policy barriers section, some clinics do not offer vasectomies because they cannot find providers willing to accept the low reimbursement rate for the procedure (White et al., 2017).

Notably, the evidence is sparse on supply barriers for vasectomies. There is limited information on the mitigating factors for when non-vasectomy providers decide to discuss vasectomies with their patients, and even less available on how vasectomy providers evaluate patient candidacy. However, there is evidence that training providers to provide client-centered counseling improves contraceptive uptake (IPPF & IMAP, 1994). In one program in Ghana,

training on providing "male-friendly" health services doubled awareness of vasectomy and tripled vasectomy uptake (Subramanian, Cisek, Kanlisi, & Pile, 2010).

Considerable work has been done to characterize the relative contribution of policy, demand, and supply barriers and facilitators to vasectomy. Although it has been suggested that the supply is not the issue (Shelton & Jacobstein, 2016), concerns have been raised about biases and knowledge among non-vasectomy providers. However, to date, there is very little data on how vasectomy providers evaluate patient candidacy. To sufficiently understand this barrier to supply, and to design appropriate interventions to support vasectomy uptake at the provider level, there is a need to understand the decision-making rationales of vasectomy providers. Addressing barriers pertaining to supply is the first step toward maximizing the ability of vasectomies to meet critical gaps in contraceptive coverage. Following this, health education campaigns and promotion by providers can start to address gaps in demand.

Contraceptive gains have stagnated in recent decades. With few new contraceptive technologies on the horizon, expanding access to existing and underutilized contraceptive methods will be key to meeting 2030 global contraceptive coverage goals, including unmet need for contraceptives. Addressing the untapped potential for vasectomies to provide a highly efficacious, low risk, and low-cost procedure has the potential to reap significant gains not just in contraceptive coverage, but also in gender equity (Stern, Pascoe, Shand, & Richmond, 2015). The 1994 International Conference on Population and Development[1] and the Sustainable

[1] "Special efforts should be made to emphasize men's shared responsibility and promote their active involvement in responsible parenthood, sexual and reproductive behaviour," (ICPD, 1994)

Development Goals[2] have both called for involving men in reproductive health programs to address gender inequities and to improve overall population health and wellbeing.

Despite the numerous benefits of engaging men in contraception through expanding vasectomy services, the echo of histories of forced sterilizations has fostered a reticence among governments and patients alike. Key to addressing this hesitation will be understanding provider decision-making rationales in a way that can inform responsive policies and provider trainings.

Chapter 3: Methods

Study Design

This study used a cross-sectional study design with in-depth interviews. The data are comprised of qualitative in-depth interviews with vasectomy providers to describe the decision-making rationales for vasectomy service provision. In-depth interviews were chosen for data collection to facilitate a detailed exploration into the various factors that inform their decision-making process. Understanding the complicated and nuanced experiences, beliefs, and perspectives of the providers was essential for capturing providers' decision-making pathways.

Participant Recruitment

To be eligible for this study, providers needed to members of the Vasectomy Network Google Group and to have provided vasectomies for five continuous years. Providers from any country were eligible to participate. Providers needed to have conducted vasectomies for at least

[2] "Ensure universal access to sexual and reproductive health and reproductive rights as agreed in accordance with the Programme of Action of the International Conference on Population and Development and the Beijing Platform for Action and the outcome documents of their review conferences" (SDG Goal 5, Target 6)

five continuous years in order to ensure they had a breadth of experience with different case contexts that would inform their decision-making process. Requiring five years of experience was also designed to ensure they were drawing on actual experience and not hypothetical decision-making, known to be subject to bias.

Participants were recruited through the Vasectomy Network Google Group, which, at the time of recruitment, had 535 members from 30 different countries. An email was sent to all participating members describing the study and its objectives, and inviting those interested to fill out an online screening form. The screening form queried their name, email, primary country of vasectomy provision, age, number of years continuously providing vasectomies, and availability for an interview. Twenty-two providers completed the screener, and one provider completed the screener twice for 23 total responses. Of the 22 that completed the screener, 20 were eligible; two providers had not provided vasectomies for five or more continuous years.

Twenty were subsequently contacted to schedule an interview via email. The email repeated the description and objectives of the study, and included a copy of the consent form to optionally review before the interview and to ensure participants had a copy to keep. Of the 20 that were subsequently contacted to set up an interview, one elected not to participate, two were too busy during the interview period in December 2020, three did not reply, and 14 were successfully scheduled. In order to reach saturation, one additional interview was scheduled in January 2021 of the two providers that had been unavailable for an interview in December 2020, resulting in 15 total interviews.

Data Collection

Interviews were conducted using Zoom video calls and lasted approximately one hour. At the outset of interviews, the interviewer went through the consent form and sought verbal consent. All interviews were audio and video recorded, with participants' consent.

Data were collected through semi-structured in-depth interviews to describe decision-making rationales of vasectomy providers. The interview guide began with close-ended questions to capture key demographic information, including age, gender, country performing vasectomies, years providing vasectomies and training background. Open-ended questions then followed about their training in vasectomy provision, their reasons for getting involved in vasectomy provision, challenging cases they have faced in their career, and the approaches they use to handle such challenging cases. Vignettes were used to help further elicit decision-making rationale. The study was approved by the Emory University Institutional Review Board (#00001730, see Appendix A).

Interviews were conducted principally in English, with one interview conducted in Spanish. An IRB-approved Spanish consent form was used with this participant. The principal investigator speaks Spanish and carried out an identical consent and interview process. Interviews were conducted in December 2020 and January 2021 by the principal investigator. A Rollins School of Public Health professor advised the researcher during data collection. Fifteen providers were interviewed, ranging in age from 41-71 (see Table 1 for descriptive statistics). Four were urologists, 5 were general practitioners, and 6 were family medicine doctors. Because there was not a meaningful distinction between family medicine providers and general practitioners in training, providers will be presented as urologist and non-urologists for the purpose of this analysis. The interviewer reviewed notes and transcripts after each interview to identify emerging themes and area for additional probing. After 15 interviews with providers

from 7 different countries, the themes in the data were repetitive and the researcher felt data saturation had been reached, concluding data collection.

Table 1: Demographic Characteristics

	Overall (N=15)
Gender	
Female	1 (6.7%)
Male	14 (93.3%)
Age	
Median [Min, Max]	65.0 [41.0, 71.0]
Years providing vasectomies	
Median [Min, Max]	30.0 [6.00, 43.0]
Average number of vasectomies performed each month	
Median [Min, Max]	27.0 [10.0, 275]
Medical specialization	
Family Medicine	6 (40.0%)
General Practicioner	5 (33.3%)
Urology	4 (26.7%)
Country where they perform the majority of vasectomies	
Australia	1 (6.7%)
Canada	1 (6.7%)
Ireland	1 (6.7%)
Mexico	1 (6.7%)
Spain	1 (6.7%)
UK	3 (20.0%)
USA	7 (46.7%)

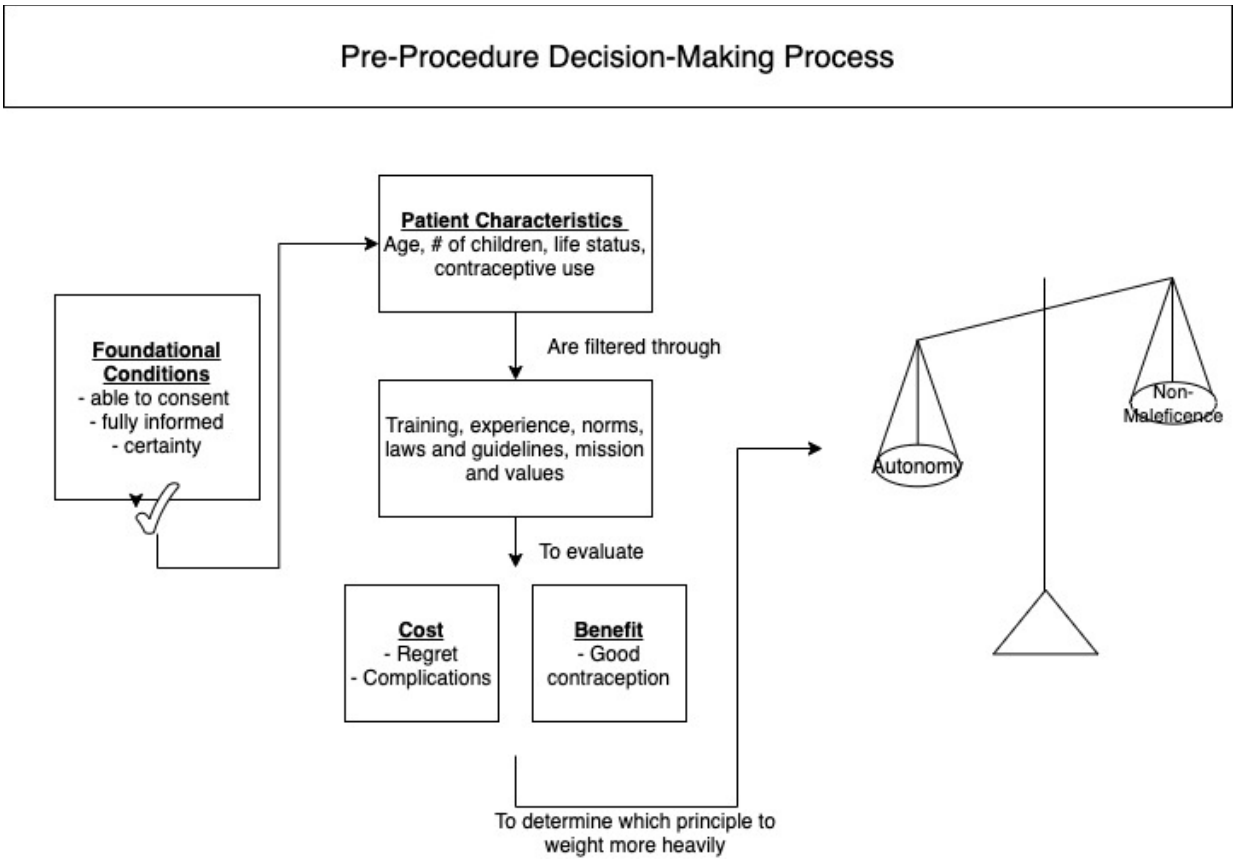
Data Analysis

All interviews were transcribed verbatim. Audio files were uploaded into the otter.ai transcription platform and edited and verified by the principal investigator. The Spanish transcript was transcribed in Spanish and then translated into English for analysis. Transcripts were then uploaded into MAXQDA20, a software package for qualitative data analysis (VERBI GMBH, Berlin). Data analysis involved reading transcripts multiple times and memoing data to identify core themes, which were then developed into a codebook. The principal investigator and the faculty advisor iterated the codebook, the final version of which was used to code all fifteen transcripts.

Thematic analysis involved drafting detailed summaries for each code, examining properties, dimensions, and variation across and within participants. This resulted in a rich description of the factors involved in provider decision-making. Results were compared across age, gender, country, medical specialty, years providing vasectomies, and average number of vasectomies performed each month. No clear distinctions were uncovered among these characteristics. Most of the providers factored similar considerations into their ultimate decision-making, which is described in the results. The full transcripts were frequently referred to in order to verify and expand upon results.

Chapter 4: Results

Foundational to provider decision-making was ensuring patients were well-informed, able to consent, and certain about their decisions. Once those conditions were met, providers filtered patient characteristics through their training, laws and guidelines, sociocultural norms, experience, and mission and values in order to evaluate the cost-benefit breakdown for particular patients. Based on that cost-benefit analysis, providers then determined whether or not they weighed autonomy or non-maleficence more heavily during the pre-procedure decision-making process.



Counseling

Informed consent is a process…about finding out who the patient is so that you know what they need to know. – Participant 2

Pre-procedure counseling discussions were a critical component of provider decision-making. It is where providers ensured patients were well-informed, able to consent, and certain about their decisions, forming the foundational elements of decision making. Notably, pre-procedure counseling also includes taking a medical history and a physical exam as part of determining a patient's clinical candidacy for a vasectomy. However, this analysis specifically and exclusively focuses on non-clinical elements of the pre-counseling and consent process.

Providers described the counseling process for vasectomy as including a thorough overview of the procedure itself, spanning descriptions of the technique itself, how it works to

prevent pregnancy, recovery and care instructions, and the need for a post-vasectomy semen analysis after 3 months to confirm sterility. Providers also emphasize the need to see the vasectomy procedure as permanent. Even though there is a reversal procedure, success rates vary between 50-90% depending on the age of the patient at the time of the vasectomy, the vasectomy technique used, the time between vasectomy and reversal, and the skill of the reversal provider. Reversals are also not commonly covered by insurance and can be expensive. Providers described reviewing other non-permanent contraceptive alternatives as part of ensuring vasectomy is the right choice for each patient's circumstances, and specifically recognizing that vasectomy alone does not protect against sexually transmitted infections. Some providers discuss sperm storage options with patients if it is available in their country, particularly for younger patients or those with a high potential for regret as an option to preserve some ability to have children.

The pre-counseling process also includes discussions of the risks of the procedure such as infection, hematoma, and chronic pain, though the extent to which the risks are discussed depends on the country. Some places use informed consent, where all possible risks must be discussed with the patient, while others emphasize valid consent, where only the risks that are deemed materially significant to the patient are discussed. In addition to the direct risks of the procedure, most providers counseled on possible indirect outcomes of the procedure, particularly those that might lead to vasectomy regret, such as breaking up or divorcing from the current partner, losing a child, or simply changing one's mind. Some described this as "putting [the decision] in perspective," or "checking in," and many considered this a critical step in avoiding patient regret. For example, one provider asks patients with pregnant partners if they would be ok if they could not have any more children and they lost this pregnancy in an unlikely obstetric

disaster. It is not to dissuade them from the procedure, but to ask questions to facilitate discussion and support informed decision-making.

> *my responsibility is to try to put things in perspective in case [the patient] has not put them in perspective, because of the permanent nature of this decision. – Participant 14*

From there, providers answer questions; some providers ask patients to repeat the process back to them to verify comprehension, and then providers document consent. Documenting consent entails both a form that patients sign, and the medical notes the provider takes about the consent discussion they have had.

Pre-procedure counseling functions to determine patient candidacy and to set patient expectations. It enables providers to build rapport, in addition to discerning patient mental status and ability to consent. It is an opportunity for providers to ensure patients understand what they have been told and are fully informed. Providers also use the encounter to evaluate patient rationale and certainty about their decision, while managing patient expectations of the procedure and the possibility of regret. However, providers disagreed on the extent to which patient expectations need to be managed. Some providers highlighted that patients are simply more likely to be unhappy if they did not consider possible outcomes during the decision-making process and considered it their due diligence to make sure patients thought through their decisions. Conversely, a few providers found it paternalistic to counsel patients on every possible outcome and assume patients had not put themselves through a complex decision-making process.

Pre-procedure counseling was also an opportunity to look for non-clinical red flags or signs of elevated risk of regret. Red flags included repeated misconceptions, such as an

expectation that having a vasectomy would resolve erectile dysfunction or premature ejaculation, or concerns that vasectomy would affect strength or masculinity. Providers also screened for patients who might be selecting vasectomy as a form of retaliation against an intimate partner, or as a form of self-harm. Signs of elevated regret risk potential included young age, recent changes in life status, and no or one child. Generally, patients with a perceived high risk of regret received additional and intensive counseling on the chance of regret and on possible outcomes that could lead to regret. One provider screened beyond regret risk to include patient characteristics that might deem a vasectomy to be unnecessary in their context, such as having a good working contraceptive method, or that would supersede some of the regret characteristics, such as a strong stance on abortion or their perceived ability to be a good parent.

Pre-procedure counseling was considered valuable for protecting patients from vasectomy regret or coerced procedures; one provider believes the practice of pre-procedure counseling is part of overcoming the legacy of forced sterilization. Some providers also highlighted the importance of pre-procedure counseling as malpractice lawsuit protection or medicolegal cases. A few providers considered the process of documenting consent to be just as important as the consent itself.

Providers' pre-procedure counseling approaches and steps are informed by their peers, local laws and guidelines, and their experiences. Some providers referenced consent checklists they use that came from the Vasectomy Network google group, and another said their consent process has improved over the years as they have gone about accrediting other providers and seeing their approaches. One provider uses the direct language set about in the American Urological Association guidelines, while all UK providers have set language and standards they must adhere to under their medical board, in part informed by a historic legal case, Montgomery

v Lanarkshire Health Board, regarding informed consent. Experiences of being sued, having complaints levied by the medical board, or serving as an expert witness in medicolegal cases also informed some providers' approaches to the consent process. Two providers who offer reversals noted that seeing who comes back for reversals has shaped how they counsel vasectomy patients with overlapping characteristics. And a number of other providers reflected that their approach to pre-procedure counseling is a transference of their other medical training.

Rapport

Providers described various strategies for and benefits to building rapport with patients, particularly during counseling. The strategies included listening to and validating patient concerns, giving permission to delay or cancel the procedure, using humor, avoiding judgment or applying humanism, retaining an internal sense of curiosity about the patient and their context, and being realistic with commitments. Some categorized their approach as "nurturing" or "babying" patients. The approach described for building rapport during follow-up similarly included being available for questions and validating concerns. Proactive follow-up was considered to be a particularly effective strategy.

One provider described the importance of creating an "experience" for the patient and connecting the vasectomy procedure to broader implications of male responsibility. This provider actively celebrates and praises the patient's decision to get a vasectomy as being an equitable partner and sharing the contraceptive burden. This link to the broader mission of vasectomy is designed to add significance and meaning to the process.

The benefits of building rapport had implications for providers, patients, and society as a whole. For providers, building rapport with patients offered protection. Some cited informal

protection, avoiding patients' anger or encouraging patient forgiveness with errors, while others noted the formal medicolegal protection that patient rapport offered them. Most noted that relationships with patients led to better counseling, whether it was through the patients being more forthcoming with pertinent medical details, or through knowing the patient well enough to be able to provide adequate counseling. Improved counseling through building patient rapport was also deemed essential to driving better overall health outcomes. Societal implications of patient rapport were described as improving the promotion of vasectomy through word-of-mouth recommendations from prior clients.

Patient Characteristics

Once the foundational conditions of ensuring patients were well-informed, able to consent, and certain about their decisions, providers closely examined patient characteristics as part of decision making. Providers described using a wide variety of patient characteristics to determine vasectomy eligibility. Some of the patient characteristics were indirectly related to the vasectomy and more about the individual's life stage, while other characteristics were directly related to the patient's rationale, thoughtfulness, and certainty about the vasectomy itself. Providers took these characteristics in conjunction with one another to determine the level of counseling needed, any non-binding recommendations they might make, and as part of decision-making. Providers detailed a number of technical and clinical contraindications with proceeding with a vasectomy such a genitourinary problems or hematomas, but this analysis only examines the socio-cultural characteristics used in provider decision-making.

<u>Indirect Patient Characteristics (Life Stage)</u>

Age: Among the indirect patient characteristics, age was the biggest predictor of additional counseling, followed by number of children, pregnancy status, and presence of psychiatric conditions. Younger and older patients were more likely to get additional counseling and potentially have their procedure delayed or denied. Younger patients were commonly considered to have the highest potential for regret, which led to providers doing additional counseling on regret as well as examining other patient characteristics to determine vasectomy eligibility. Other indirect patient characteristics that were more heavily examined with a young patient were number of living children, relationship or marital status, contraceptive alternatives, stance on abortion, and health history. Direct patient characteristics examined with young patients included rationale for pursuing the procedure, time spent considering it, expressed certainty around the decision, and whether or not they had stored sperm. The definition of "young" varied by provider, with some citing 21 as the age of full adulthood, others using what they called an arbitrary 27, and others considering anyone under 30 to be young and meriting additional counseling.

> *…like all of us, I would have a strong and detailed discussion with a young man who's requesting a vasectomy, emphasizing the fact that reversals are expensive, and don't always work. – Participant 8*

Older patients and those with older partners at or near menopause also received additional counseling. Some providers detailed that only two or three years of contraceptive protection did not seem worth the risks of complications from a vasectomy procedure and would encourage their patients to consider other contraceptive methods until their partner was in menopause. This rationale did not apply in instances where the patient was single or not in a committed

partnership with someone near menopause, such as if an older man was with a younger partner. Additional counseling was not applied in these circumstances.

Number of living children: Patients with no children received more counseling than patients with two or more children. Some providers would counsel those with only one child more intensively than if the patient had two or more children, while others only described doing additional counseling on those without children. Some providers sought out a psychologist to verify the patient's ability to give consent and make informed decisions if they did not have children. Providers also described examining the relationship or marital status of patients without children alongside contraceptive alternatives, time spent considering it, expressed certainty around the decision, ability to give valid and informed consent, and the patient's certainty about the procedure. One provider evaluated whether or not he thought patients would be good fathers as part of deciding whether or not to offer a vasectomy – childless men who were perceived as being poor caretakers were more likely to be offered a vasectomy.

Pregnant: For patients whose partner is currently pregnant, some providers said they would be sure to provide additional counseling about the risks of fetal or newborn demise. This also depended on how many living children the patient had, and whether this pregnancy was intended. One provider counseled patients to consider a tubal ligation if the birth is expected to be a cesarean section.

Marital or relationship status: Only one provider noted factoring marital or relationship status on its own into their decision-making on vasectomy eligibility. This provider was wary of providing vasectomies during or after any major life changes, such as a divorce. Others described using this indicator when other characteristics may have raised questions about vasectomy eligibility. Another provider felt that those who are of an older age and single may not be a good

candidate for vasectomy, as they may meet a partner who has already gone through menopause, and as such, any complications that could arise from a vasectomy procedure outweighed the benefits. Other providers used the length of time a patient had been with their partner or the partner's feeling about the vasectomy as supplementary factors in determining a patient's eligibility criteria, particularly if the patient was young and/or childless.

Contraceptive alternatives: A few providers examined contraceptive alternatives if there were lingering questions about patients without children or who were on either the younger or the older end of the age spectrum. This entailed whether or not there were viable contraceptive alternatives for the couple to use that are reversible or had a smaller risk of complications, such as an IUD. For one provider, this also included considering the couple's stance on abortion and whether methods with a higher failure rate would be deemed unacceptable.

Mental health conditions: Providers provide additional counseling to patients with mental health conditions. No providers said that mental health conditions were automatically excluded from vasectomy eligibility, but all said they would want to ensure the condition was well-controlled without recent depressive or manic episodes, and the patient was able to give fully informed and valid consent. Some providers were comfortable proceeding in instances where patients could not give fully informed and valid consent, as long as they had consent from a parent or guardian or a patient's primary care provider or psychologist. A few providers practice in countries or states where a court order is required before performing a vasectomy on someone unable to consent and as such did not need to evaluate an individual patient's candidacy on their own.

Family history: A couple providers described using family history as part of determining a patient's candidacy. One provider had a patient with an incurable hereditary disease he did not

want to pass on to his children, so though he was young and childless, this fact increased his eligibility for a vasectomy. Another provider had a young and childless patient with a family history of addiction and his own patterns of drug use, and the provider intended to move ahead with offering the procedure.

Fertility: Men who reported using testosterone were not generally considered candidates for vasectomy without a semen analysis indicating high levels of sperm concentrations, given sterility is a common side effect of testosterone use.

Ability to be a good father: Two providers mentioned analyzing patients to determine whether or not they had the potential to be good fathers as part of decision-making on vasectomy eligibility. Those with strong negative attitudes towards children or suffering from addiction were not considered likely to be good fathers, and thus these men were deemed stronger candidates for vasectomy.

Employment status: One provider used employment status as part of determining vasectomy eligibility. Patients with stable employment were less likely to be making an impulsive decision about vasectomy that they may come to regret and were considered to be better candidates for vasectomy than those with unstable employment.

Insurance status: One provider allowed that he would be more likely to provide the vasectomy if the patient's insurance would soon be expiring and they had a short window in which to pursue sterilization or contraceptive methods in general.

Direct Patient Characteristics (Vasectomy-Specific)

Informed consent: Providers all described needing to secure informed consent from their patients before proceeding with a vasectomy. For providers, fully informed consent entailed

understanding the permanence of the procedure, knowing and accepting the risks and their consequences, and patients listening and doing their due diligence on the procedure. Patients who were not fully informed and would not be candidates for a vasectomy would include those seeking a vasectomy because they think it will resolve their erectile dysfunction or premature ejaculation, those who are convinced they will have erectile dysfunction after the procedure, or those who did not listen during counseling. Once informed, patients needed to give consent free from coercion, duress, grief, major life changes, manic or depressive episodes, hesitation, or uncertainty. The patient also needed to be mature and capable of giving consent through their physical and mental age.

Certainty: Most providers also sought a sense of certainty from patients about their decision to pursue a vasectomy. Some described this phase of consent as asking patients to "convince" the providers of their decision. Patients that were considered certain about their decision were described as adamant and insisting on the procedure, while those who were uncertain asked repeatedly about sperm banking or the success rate of vasectomy reversals. Other characteristics that factored into perceived certainty included the time a patient spent considering a vasectomy, their motives and rationale for wanting a procedure, and their thoughtfulness on their potential to regret the decision in the future. The appropriate amount of time spent considering a vasectomy depended across the providers, and was also a reflection of some of the indirect patient characteristics; older patients did not need to consider the decision as long as younger patients to be considered appropriately thoughtful about the decision. Most providers wanted a minimum of one month considering the procedure. Many providers also asked patients directly, particularly young patients, about whether they had considered the potential of regretting the decision at a later point and if they had considered other contraceptive

alternatives for the time being. Patients that exhibited complex decision making, or acknowledged the potential for regret but still wanted the vasectomy, were more likely to be considered candidates for vasectomy than those who did not acknowledge the potential for regret.

> *Now, if they if they feel it's the best thing for them, and they've convinced me that they've thought about what they're doing, I'll move ahead. – Participant 15*

Training

Providers filtered patient characteristics through their training as part of evaluating the patient cost-benefit breakdown. The providers in this sample had various distinct vasectomy training pathways. Of the 15, four were urologists and 11 were non-urologists. All of the urologists received training on traditional vasectomy techniques during their residency, and then two sought additional training in the no-scalpel vasectomy (NSV) method that was introduced after they left medical school. The two who sought formal training on the method were trained by the inventor of the NSV technique. The other two used what they called a minimally invasive method and described being self-taught through reading and experience. The urologists in this study also had the highest number of years performing vasectomy, ranging from 27-41 years.

Only two of the family medicine doctors received their initial training on vasectomy during their residencies. One of these providers noted that it is becoming increasingly uncommon for family medicine providers to be trained on vasectomy, and that their training program was unique in its focus on procedures. The other provider was one of the older participants in the survey, and vasectomy training may have been more commonly included in medical residency at that time. This apparent reduction in availability for family medicine practitioners to be trained

in vasectomy was echoed by two other providers who described facing push back and significant challenges to being trained in vasectomies. Both ultimately sought private training.

Outside of residency, providers received training from private trainers, through on-the-job training, or were self-taught. The majority of providers were trained in the NSV technique through private trainers, including those that had originally received traditional vasectomy technique training during residency. Most of the UK providers were trained through government provided training sessions conducted as part of their jobs as general practitioners. Two general practitioners described observing procedures and then learning by doing without formal training. One of these providers went on to seek private training in the NSV technique, while the other watched a video to learn the technique. One urologist who had been trained in residency on the traditional technique read about the new technique and then began implementing it directly.

Private and on-the-job trainings were more likely to include elements of pre-counseling and consent than residency trainings. Most providers who received their vasectomy training during residency reported learning about how to conduct pre-counseling and collect consent through their general medical training or through experience and had not received vasectomy-specific counseling training. One provider expressed an explicit desire for medical ethics training as it related to vasectomy. Only three of the providers received formal and vasectomy-specific counseling training. The others learned either by observing their trainers, observing their peers, or by applying experience or other medical training. Training during observation was common during private trainings, where trainees often visited the trainer's existing practice and were able to observe all elements of vasectomy service provision over a number of days or weeks. The time spent in vasectomy training ranged from a few hours to a few months.

Most of the providers in this study also train new vasectomy providers. Some are private trainers, some are a national vasectomy trainer through the public health system, and others provide trainings during vasectomy missions to developing nations. Almost all noted that they include elements of training on pre-counseling and consent, even if it was not something they received in their own training.

Laws and Guidelines

Providers also filtered patient characteristics through local laws and guidelines as part of evaluating the patient cost-benefit breakdown. The cost of vasectomies varied across the different national health systems. Most countries have a hybrid system where vasectomies are available in both the public and private health system, with the exception of Canada, where even private clinic vasectomies are reimbursed by the government with no ultimate cost to the patient. Among the hybrid countries, some have predominantly out-of-pocket or private insurance coverage for vasectomies, like Australia, Ireland and the US, while others have predominantly publicly funded vasectomies, like Mexico and the UK. Vasovasostemies, or vasectomy reversals, are also covered under public health insurance in Mexico, Spain, and Canada, but are out of pocket or reliant on private insurance coverage in the other countries.

The UK was the only country that required a referral to see a vasectomy surgeon. Almost all the countries had a mix of general practitioners and urologists providing vasectomies, though the specialty that did the majority of vasectomies varied by country. Spain was unique in that only surgeons, urologists, or gynecologists can provide vasectomies; the vast majority are provided by urologists.

Providers described laws and guidelines in each country that governed consent, rights, and pre-procedure protocols. Providers mentioned a number of local laws that influenced their protocols. One such law was the Anti-Age Discrimination Act in Australia that outlaws discrimination against youth and the elderly. Another was the Official Standards for Family Planning in Mexico that decrees the right of an individual to decide when and how many children they want. The Mental Health Act of the UK was also discussed, which confers the ability to suspend personal liberties to a combined team of a psychiatrist and an independent assessor. There were also regulations around how to collect consent and who can give consent. In the US, these regulations for how to collect consent came from the American Urological Association guidelines and in the UK, the General Medical Council and the Faculty of Sexual and Reproductive Health Guidelines.

Providers reported various requirements for offering a vasectomy to someone who may not be able to provide full and informed consent, such as someone with intellectual disabilities. In Canada, Australia, and the UK, court orders are required before being able to offer a vasectomy to someone unable to consent. Some states in the US have a court order requirement, but it is not nationwide. Court orders are not required in Spain. The US and the UK also have waiting periods – the UK has a universal two-week waiting period between the pre-procedure counseling and the procedure. Any procedure that is federally funded in the US, through either Title X or Medicaid, is also subject to a 30-day waiting period between counseling and procedure. The state of New York has the same waiting period for privately funded vasectomies as well.

Providers described numerous ways in which laws and guidelines influenced their practice. One provider in the US noted that because of the 30-day waiting requirement for

Medicaid, they expect all their patients to have thought about the procedure for a month before feeling comfortable providing it. For that provider, the 30-day waiting period set a subconscious precedent even for those who are not subject to that regulation. Similarly, because the Medicaid age of consent is 21, another provider uses that as their age of consent for all vasectomies no matter how they are funded.

> *Now, what's magic about 21? There's nothing magic about 21, whether it comes to drinking or smoking or anything else. But the fact is that in order to get assistance through the United States government under either Medicaid or Title X, you have to be 21. So I'm just following sort of a guideline that is there. It's very random. – Participant 4*

Any experience with malpractice lawsuits or medical board infractions also affected how providers collect and document consent, including indirect exposure to medicolegal cases. Most providers acknowledged that the best way to protect themselves from litigation centers on communication with the patient – clearly explaining all the risks and verifying the patient's candidacy for the procedure – and documenting the full nature of the communication as such. A couple of providers talked about the importance of rapport, relationship-building and trust as key skills in preventing litigation. Some providers were indirectly influenced by high-profile litigation of other doctors. All of the UK providers discussed the role of the Montgomery case in shaping their consent process. The Montgomery case was an obstetrics case where a patient sued because not everything was clearly explained to her before her cesarean section. This subsequently informed how the providers discuss possible complications with their vasectomy patients. One provider serves as an expert witness in medicolegal cases and noted that exposure

has significantly affected the way they practice including how they collect consent and how they document consent.

Experience

Providers also filtered patient characteristics through their experiences as a vasectomy provider as part of evaluating the patient cost-benefit breakdown. Of those that highlighted experience providing vasectomies as shaping their practice and protocols, they highlighted lessons and adaptations across patient interactions as well as in acute decision-making. Most highlighted that experience had taught them to do better and more comprehensive counseling. The reasons providers changed their counseling style ranged from potential malpractice suits, joining a new surgical practice, and exposure to other methods of counseling and consent. A couple of the providers also noted that experience taught them to listen more acutely to the patient as part of building improved rapport and leading to overall improved patient care. This included honoring patient ambivalence and removing judgment from the counseling process.

While most providers felt that experience had led to improved decision-making, two categorized improved decision-making as becoming more conservative providers. One noted "experienced surgeons step back from more procedures than inexperienced surgeons," and having seen a young patient come back and seek a reversal, he had grown more cautious with decision-making. Another felt compelled by advances in science, such as cures for hereditary disorders, to be grounds for proceeding more carefully with cases.

Sociocultural Norms

It was somewhat uncommon for providers to highlight sociocultural norms as influential in their decision-making. Of those that did acknowledge the influence of sociocultural norms, they focused on social expectations of having children, political climates, and health justice issues.

All of those who highlighted the social expectation of having children having an influence on a patient's candidacy for vasectomy were US providers. They noted a potential double standard in themselves and in other providers that they felt a greater need to prevent regret around not having a child than they felt the need to prevent regret for having a child. They noted that US society is less comfortable with someone missing out on having a child instead of having one more child than they planned on. This includes age double-standards – it is generally considered ok for a 24-year-old to have kids but not for a 24-year-old to decide to get a vasectomy. One provider attributed this to primal procreative instincts to preserve the species. Concerns around the potential for future vasectomy regret were greatest among young and childless men, though what was considered "young" varied by provider. Some said anyone younger than 30 merited additional counseling, while others said 24 or 27. Most agreed that those above the age of 30 have likely had enough life experience to understand and be able to mitigate their own regret.

> *By saying no to him [denying a vasectomy], I'm forcing, in some ways, forcing him to be a father. Just because in our society or in ourselves, we feel bad for people if they accidentally miss out on the chance of becoming a parent. – Participant 1*

Providers also acknowledged their decision-making was influenced by the social attitudes of the countries they practice in. One non-US provider practices in a societally conservative

country that has been slow to implement a vasectomy program. This participant noted the tenuousness of the vasectomy program and what they felt was reluctant societal acceptance, resulting in an imperative to avoid bad vasectomy outcomes—such as regret—that could reflect poorly on the integrity of the program on the whole. Another provider in a more socially conservative context felt they were the most liberal provider in their private practice office despite having conservative approaches to decision making relative to others in the sample. Conversely, providers in two less conservative countries noted social attitudes about the importance of patient autonomy influenced their approaches to honoring patient autonomy in complex situations.

Many of the countries represented in this study have a history with forced or coerced sterilization. Some providers noted this history influenced their consent process, including through regulatory outcomes of historical legal adjudication. Others noted the influence on the inclusion or lack of the partner in decision-making and consent. One provider felt that in an effort to prioritize patient autonomy as a result of the history of forced and coerced sterilization, that not enough emphasis was being given socially on encouraging women to be involved in vasectomy decision-making. In this same vein, this provider and others noted that vasectomy can be a manifestation of broader efforts toward improving gender equality.

Two US providers highlighted the norms between general practitioners and urologists, underscoring that urologists do the majority of vasectomies and can be reluctant to train general practitioners to do vasectomies. One provider emphasized the importance of OB-GYNs as advocates for vasectomy instead of the higher risk and more invasive female equivalent, tubal ligations.

Lastly, there were some mentions of the role of sociocultural norms in decreeing which patient characteristics were relevant during consultations. One non-US provider noted that with the high rates of medication use for anxiety and depression in the nation, they did not feel a need to counsel those patients any differently. Another provider in the US felt that the national maternal and fetal mortality rates are low enough to not counsel pregnant couples to wait for their vasectomy.

Peer Influence

Many of the providers described calling on peers to support active case decision-making, improve upon their respective pre-counseling and consent protocols, and seek feedback on retrospective clinical and sociocultural approaches. Providers gave examples of a variety of peers, including psychiatrists, general practitioners, clinical assistants, online networks, medical missions, colleagues in their physical office, doctors they met at conferences, and doctors met through reaccreditation processes.

In challenging cases including young men or those with intellectual disabilities or mental health conditions, most providers mentioned they would seek out a second opinion. Some would contact a psychologist or psychiatrist, others would reach out to the general practitioner or primary care provider with an established relationship with the patient, and others still would ask colleagues in their office to provide a second opinion. Providers' reasons for soliciting a second opinion included for their own benefit—to build their confidence with their approach—as well as for legal coverage in the future if their decision-making was drawn into question. The second provider was commonly asked to verify the individual's ability to consent, their certainty of the procedure, if they were fully informed of the procedure and adequately counseled on

contraceptive alternatives. The providers generally felt that having a second provider evaluate a patient supported more robust decision-making.

Nearly every provider spoke positively of peer interactions with other vasectomists through the online google group used for recruiting the sample for this study, the Vasectomy Network google group. One provider noted the value of a checklist of questions to ask young patients they borrowed from another provider on the network. Another provider turned to the network after receiving a complaint letter to seek counsel and feedback from the other providers. Another provider mentioned intending to ask the network about their approaches to those with intellectual disabilities, as he is questioning his own country's default approach to such cases. Other providers noted the minimum age of consent they use in their office came from peer advice through the network. The cross-cultural exchange available to providers through the network was valuable to them in getting second opinions on their approaches, both clinical and non-technical. Other providers noted similar benefits from peer exchanges at conferences, through reaccreditation processes, and during medical missions organized by the leaders of the Vasectomy Network.

Opportunities for peer interaction, including cross-cultural exchange, were generally seen as useful in networking, skill-building, exposure to different approaches, and in receiving support during active or retrospective cases. The main advice a few providers gave to new vasectomists was to get support from other vasectomists, underscoring the importance of such relationships in being an effective provider.

Mission and Values

Providers also filtered patient characteristics through their own mission and values as part of evaluating the patient cost-benefit breakdown. Providers described logistic and philosophical reasons for getting involved in vasectomy provision. Logistically, some of the providers highlighted the demand for vasectomy for why they got involved, others noted they offered the service to round out their clinic's contraceptive offerings. A couple private practice providers mentioned that vasectomy was a good way to financially support themselves, while another provider in the public sector explicitly mentioned that finances were not a motivator because their health system only pays a flat rate no matter the quantity of vasectomies performed.

Most of the providers considered the procedure to be interesting, satisfying, and exciting. Many of them are proceduralists who described valuing the simplicity of the surgery and being able to readily and easily address a problem for the patient. Some also noted the freedom the procedure affords to the patient created a strong sense of personal satisfaction for them as providers.

Roughly half of the providers connected their reasons for getting involved in vasectomy provision to broader issues including the environment and gender equality. One noted the influence of prominent environmentalists on their view of population growth that led to a personal mission to prevent unintended pregnancies. This provider drew a great deal of satisfaction from making the procedure available to those under low-income programs who would otherwise not have had access to vasectomy services. Another described vasectomy as a way to support holistic health for the person, family, society, and environment. One provider reflected their own parents' decision to get a vasectomy and the way it empowered their mother, and has a core mission of providing vasectomy as part of advancing gender equality and addressing disparities in contraceptive burdens.

A few of the providers also described feeling passionate about training new providers and medical school students, particularly students who are enthusiastic, passionate themselves, and connected to the mission. Providers who felt strongly about training those who are connected to the mission were the same providers who expressed their own connection to the broader vision of vasectomy provision, either for the environment or for gender equality.

Other values the providers described that influenced either their decision to provide vasectomies or their approach to continued services included offering high-quality procedures, offering a good overall vasectomy experience, and minimizing harm wherever possible.

Responsibility

As part of conducting a cost-benefit analysis for vasectomy clients during decision making, providers reflected on their responsibility to their patients. Providers nearly universally described a sense of responsibility to what they deemed to be the right thing – but differed substantially on what they considered the right thing to be. Their responsibility to patients sat on a spectrum. Most considered their foremost responsibility to be to ensure the patient is able to give free and voluntary consent, or the proper steps have been taken for guardians to give consent instead. The "proper steps" required to transfer the ability to consent to a guardian depended on the provider's legal context. In instances where the patient might not be able to give full consent, such as intellectual disabilities or severe mental health conditions, providers would screen for acute instances of depression or mania. Some would also reach out to the patient's general practitioner to ascertain and verify the patient's ability to give consent.

Once the patient's ability to give consent was validated, providers then emphasized their responsibility to fully inform patients. This included the technical information about the

procedure and its risks, as well as the potential for regret and other outcomes. Some providers described this as "putting it into perspective" and translating the technical components into each patient's life circumstances. Most felt their key responsibility was in this step, of informing patients fully and in an actionable way.

Once it was established that a patient could consent and was fully informed, providers deemed their ultimate responsibility to be to the man himself. There were differences in the way providers translated the desire to do the right thing for the man into service provision. All providers felt a desire to avoid patient regret, but some felt their responsibility stopped after providing full information, including allowing a patient to make a decision they had a high likelihood of regretting. Other providers described it as an imperative to avoid regret, and as such, would not proceed or would try to talk patients out of the procedure if the risk of regret was deemed to be too high. These providers described the need to avoid regret as predicated on the high cost of reversals as well as to prevent the risk of complications for an elective procedure. They saw themselves as shared decision partners in the process, guiding patients toward reasonable decisions and operationalizing the "do no harm" principle.

> *my responsibility is to try to put things in perspective in case he has not put them in perspective, because of the permanent nature of this decision. – Participant 14*

Other providers described the man's decision-making authority and autonomy to be the central importance in deciding whether or not to provide a vasectomy. Honoring their autonomy included providing a vasectomy even if the provider felt the decision was wrong or had a high chance of regret. Providers who made decisions based on autonomy also felt it was their responsibility to care for patients even when they were uncomfortable with the situation, rather than refer them to another provider just to avoid the discomfort of a challenging case. Some

providers described a responsibility to challenge unequal gender balances in contraceptive provision that led them to provide vasectomies and informed their counseling approaches. These providers detailed wanting to offer patients a good experience, and focused on building trust and rapport as being a key part of vasectomy service provision.

Providers described their responsibilities as dictated by local guidelines and laws, their own internal moral code, the desire to provide high-quality procedures, a need to overcome the legacy of forced sterilizations, and medical oaths.

Regret and Reversals

The potential for regret was factored into every patient cost-benefit analysis for providers. All providers described feeling a responsibility to minimize or avoid regret, but that yielded different implications for decision-making across the providers. Though most providers felt responsible for mitigating regret through their position as providers, one provider thought of it more as a moral responsibility than a professional responsibility. Some providers deemed directly counseling patients about the possibility of regret to be the only mitigation needed to minimize regret. This group of providers emphasized ensuring the patient could be at peace with their decision even if they regretted it in the future. Conversely, other providers felt minimizing regret was insufficient and the imperative lied with avoiding regret entirely by not providing vasectomies that had a high likelihood of regret in the future.

The characteristics that were considered high-risk conditions for regret included young age, low numbers of children, hesitancy around the procedure, recently divorced, spontaneous decision-making, and other major recent life changes. The most commonly mentioned predictors of regret were being younger than 30 years old or having no children. Providers described being

particularly concerned when those two conditions cooccurred. One provider explained that they assume anyone over the age of 30 has experienced decision regret and is thereby capable of mitigating decision regret and doing their own calculus on their personal chance of regret. Almost all providers noted that they would not provide a vasectomy for someone who was repeatedly inquiring about reversals or sperm storage during their pre-procedure counseling, or otherwise expressing hesitation or uncertainty about the procedure. This also included those who did not understand or recognize the permanent nature of vasectomy, such as saying to the provider that they could just get it reversed in a few years if they changed their mind. Some providers felt that patients who were recently divorced and single had a high chance of meeting someone and wanting to have more children with the new partner. A few providers extended their concerns about regret to anyone who was single or without a partner at the time of seeking a vasectomy. Most providers were concerned about those who appeared to have made the decision to get a vasectomy or a vasectomy reversal recently, potentially spontaneously, and preferred to see certainty in the decision over a period of time. The span of time providers preferred patients to consider the procedure varied between a few weeks to a few years. Related to spontaneous decisions, providers also described being concerned about patients who were seeking vasectomies during or immediately following major life changes, such as a pregnancy, the loss of a child, or a change in relationship status.

Provider notions of high-risk conditions for regret were informed by both published data and personal experience. Among the providers that were concerned about young age and no children as predictors of regret, most cited literature as evidence of the increased rates of regret among those populations. Only one provider cited personal experience as informing his reticence with that population. But other providers did have personal instances of patients seeking

vasectomy reversals that influenced their decision-making in relation to how they counsel around regret. Notably, vasectomy providers that also offer reversals were more likely to report intensive regret counseling with their vasectomy patients, but overall, having patients come back and express regret even with providers that do not offer reversals was influential in how much those providers factored regret into their counseling.

> *He may not have thought about, like, what happens if I break up with this girlfriend or what if I meet someone who wants to have a child, and is the love of my life? You know, the way you think of things at 24 is different than you think of them at 34. So, you know, I think that's what the data suggests with respect to regret. Because you know, I do all the reversals, so I see them. I feel the regret. – Participant 15*

Interestingly, the reasons reversal providers described why patients seek reversals do not directly correlate with the characteristics deemed to be high-risk for regret. The reasons providers detailed included post-vasectomy complications like chronic pain, having a new partner and wanting to have a family with the new partner, changing their mind about the number of desired children without a partner change, and the loss of a child. One provider specifically noted that in their reversal practice, it is very uncommon for someone without children to seek a vasectomy reversal, though this is almost ubiquitously considered to be a high-risk characteristic for vasectomy regret.

Providers described their responsibility to avoid or minimize regret as grounded in the high cost, low access, low success rate, and invasive nature of reversals, particularly in light of the existence of good non-permanent contraceptive alternatives. Cost was a major concern everywhere except in Spain and Canada, where the procedure is available for free through the

public health system but does have a lengthy waitlist. Some providers described feeling a responsibility to participate in shared decision-making and guide the patient toward the best option for them. Conversely, other providers felt that regret was only a problematic outcome if the provider did not fully counsel and inform the patient of the risks of regret ahead of time. A few providers felt that regret suggested that they had missed something during pre-counseling, while other providers noted that circumstances change and that regret is not a failure of counseling or decision-making.

Providers mitigated the risk of regret by adjusting their counseling, imposing a waiting period, or not offering the procedure at all. Almost all providers described offering more intensive counseling to patients they considered to be at elevated risk of regret, including asking if the patients had thought through the potential scenarios that could cause them to regret a vasectomy, or asking outright if the patient thought they might come to regret their decision and using their answer to gauge their thoughtfulness and certainty about the decision. Providers would also underscore both the expense of reversals (in countries where cost was relevant) and the inconsistent success rates. The inconsistent success rates were particularly underscored for older patients, as evidence suggests those who get vasectomies later in life have lower reversal success rates than those who get a vasectomy at a younger age. One provider said they try to discern whether the regret of having a child would be greater than the regret of not having a child and factored that into their decision making. Another provider asks younger patients to write a letter to their future selves as a tool for helping the patient internalize and consider the possibilities of regret. Other strategies providers described using to mitigate regret included encouraging sperm storage pre-procedure – especially for older patients because of the low reversal success rate – and getting a second opinion from other providers, particularly early in

one's career. A couple of providers said they simply would not provide the procedure if they deemed the risk of regret to be too high. Occasionally this could be superseded if a patient was particularly adamant and remained adamant after a waiting period.

Autonomy

Providers commonly mentioned the concept of patient autonomy as a major factor in their decision-making processes. Most providers described honoring patient autonomy as a primary consideration. All providers felt a necessary condition to patient autonomy was that the patient was both fully informed and able and willing to demonstrate being well-informed. Providers were unwilling to honor autonomy for any patients that were uninformed and/or unable to demonstrate being informed. Many providers described their responsibility to fully inform patients and to put their decision into perspective, but felt that once that responsibility was met, the patient's choice should be the leading factor in decision-making, even if the provider felt the patient was making the wrong decision.

This also applied to those with mental health conditions and intellectual disabilities. Generally, if the mental health condition was controlled through medication or the intellectual disability did not prevent a person from being informed and able to demonstrate being informed, patient autonomy could be central in decision-making. Some providers qualified this with additional conditions, including if the patient's right to make decisions had not been stripped by the state at any point, if the patient lacked the capacity to be a good caretaker for children, or in instances of acute psychosis. The providers who mentioned these conditions felt non-maleficence should outweigh autonomy in these instances. A few providers were willing to provide vasectomies even when intellectual disabilities precluded a patient's ability to be fully informed

or to demonstrate being fully informed, as long as there was guardian approval or a court order. However, all providers expressed that they would not allow a guardian or court order to supersede direct patient requests not to have a vasectomy, thereby prioritizing patient autonomy. The provider from Mexico was the only one who mentioned a redress mechanism that legally stated a patient's right to autonomy that providers had to adhere to, or providers could open themselves to a lawsuit. Other providers in other legal contexts described prioritizing autonomy out of their own values, training and experience. They described honoring patient autonomy as part of being a respectful provider, or viewing it as their responsibility as a health care provider.

A few providers ascribed other conditions that needed to be met before autonomy could lead decision-making, including being of an age considered to have fully developed frontal cortexes and resulting decision-making capacity (24-25) and not experiencing grief or major life changes that could yield a sense of duress. In some cases, a waiting period was imposed between the request for the procedure and the procedure date to demonstrate consistent decision certainty on the part of the patient. Most providers felt that the patient wishes were more important than their partner's wishes, though a couple felt that the partner's wishes should have some bearing in decision-making.

The majority of providers interviewed felt that autonomy was more important than provider comfort with the decision, or providers agreeing with the decision, but a few felt that their responsibility as a provider was to prevent regret, and as a result, that the principle of "do no harm" outweighed patient autonomy. Instances where non-maleficence was considered more important than autonomy for these providers included patients considered to be at high risk of regret, such as young patients and patients with recent major life changes.

My responsibility is helping them to make the best decision. Most of the time, I'm not making the decision. But in some cases, I'm inclined to orient the patient... I think it's my responsibility to do some shared decision making on what is the best option. – Participant 9

Judgment

Providers described a tiered judgment system. There are certain foundational conditions all providers tacitly agreed must be met before a patient is deemed a vasectomy candidate. All providers described needing to verify a patient's ability to consent and ensure they are fully informed and that they have a demonstrable sense of certainty about the procedure. Any patients that did not meet that criteria were delayed or denied services by providers until those foundational conditions were met. For example, if a patient was in a hypomanic state of an otherwise controlled mental health condition, vasectomy services would be delayed until they were in a stable, non-hypomanic state of mind. Patients who repeated misinformation, such as expectations that vasectomy would help address premature ejaculation or erectile dysfunction, were also denied services as they were not fully informed of the procedure and its results. There were no exceptions to these foundational conditions to be deemed a vasectomy candidate among providers.

All providers expected some amount of thoughtfulness and certainty, though the levels and expressions of that certainty varied. Some described it as not expressing hesitancy, such as repeatedly asking about vasectomy reversal success rates. Others looked for a sense of thoughtfulness, which could include a protracted length of time thinking about the procedure, or concrete reasons for wanting a vasectomy, such as to avoid passing on a genetic condition or

because of a strong personal ethic to limit overpopulation. One provider described it as "insight," and having clearly considered the potential for regret or other unforeseen life circumstances that might lead to a renewed desire for children. Though providers defined the idea of certainty differently, all considered it a prerequisite for vasectomy service provision.

Once the foundational conditions of certainty and informed consent were met, providers filtered patient characteristics through their training, laws and guidelines, sociocultural norms, experience, and mission and values in order to evaluate the cost-benefit breakdown for particular patients. Based on that cost-benefit analysis, providers then determined whether or not they weighed autonomy or non-maleficence (do no harm) more heavily during the pre-procedure decision-making process.

While all providers felt recognizing patient autonomy was a pillar of medical service provision, some weighed the principle of non-maleficence more heavily than the principle of autonomy in particular circumstances. This centered around the provider's evaluation of harm. Specifically, a few providers felt that vasectomy regret was a substantial harm, and as such, patients with a high chance of regret were not good candidates for vasectomy. Patients considered to have a high chance of regret included young patients, patients without children, and patients undergoing major life changes including pregnancy or divorce. One provider explained the need to avoid patient regret as predicated on the high cost, low availability, and limited success rate of vasectomy reversal procedures, especially given the availability of well-functioning forms of non-permanent contraceptives. In that cost-benefit analysis, the provider deemed the cost of vasectomy regret to be greater than the benefit of vasectomy as compared to other contraceptive options.

You want to minimize regret. And you want to make sure people are in the frame of mind when they've thought about all the scenarios, where, if their life changed, that they could consider having all the options available. Not everyone can afford, you know, $15,000 for a reversal, or $20-25,000, for a sperm retrieval and IVF. So you want to make sure that you don't have them burn any bridges. It's like, measure twice, cut once, you know? – Participant 15

Two providers highlighted the non-zero risks of complications during vasectomies and the potential for physical harm compared to the elective, non-essential need for a vasectomy. These providers noted the low but present risk of infections, hematomas, and chronic pain, and felt that because a vasectomy is an elective, non-essential procedure, that the threshold where risk outweighs benefit should be low. As such, these providers did not consider patients with elevated chances of vasectomy regret or those with low benefits (e.g. men with partners near menopause) to be good vasectomy candidates.

The third provider that emphasized non-maleficence in decision-making was driven largely by sociocultural norms and the nascency of the vasectomy program. Given the desire to maintain a good reputation and not challenge the legitimacy of the relatively new national vasectomy program, this provider was highly reticent to take on complicated cases that could be result in patient regret or complaints. This provider was acutely concerned with individuals making decision under duress, including during major life changes such as a pregnancy or a divorce. The provider's only instance of regret came from a young patient, and the provider's experience with that case informed their preference to impose waiting periods for young patients.

There was also a group of providers that equally weighed concerns of non-maleficence against autonomy. Many of these providers had inclinations to delay patients who were young,

childless, or in the midst of major life changes, but would provide the vasectomy without a waiting period for those who were "insistent" or "adamant" or who had concrete rationales for needing the vasectomy now, such as expiring insurance coverage. This group of providers were similarly informed by experience, laws and guidelines, data around patient regret, and their sense of responsibility as providers.

The largest group of providers factored non-maleficence into their counseling but not into their judgment of vasectomy candidacy. These providers described viewing their responsibility as needing to educate patients and probe about possible life changes and outcomes that could lead to regret but felt that once patients were thoroughly counseled and able to demonstrate being fully informed, patient autonomy superseded provider concerns around regret. This group of providers were informed by experience, training, laws and guidelines, their mission and values, and their sense of responsibility as providers.

> *…with the underlying belief being that his autonomy, his ability to make his own decisions about his own reproductive destiny, should trump our concerns unless there's something very much impairing his ability to make those choices. – Participant 3*

Ultimately, provider judgment was multifaceted and reflected the contexts in which they work and how they were trained, in addition to more personal elements of their mission, values, and perceived responsibility as providers.

> *I'm a doctor, not a technician…Just because someone wants something doesn't mean it's the best thing for them. And it's my job to lay that out for them. Now, if they if they feel it's the best thing for them, and they've convinced me that they've thought about what they're doing, I'll move ahead. But if I'm not convinced, I'm*

not obligated to do something that I think is the wrong thing for the patient. – Participant 15

COVID-19

Traditional pathways to decision-making were somewhat disrupted during the COVID-19 pandemic. In addition to the complete cessation of vasectomy services during national lockdowns, providers described changing their consent, patient flow, and PPE protocols due to the ongoing COVID-19 pandemic. Many providers have shifted their pre-counseling process to telehealth and virtual consultations to reduce the duration of face-to-face time. Some providers felt the shift to telehealth prevented them from conducting the consultation process in a way that allowed them to build rapport; one called it less "satisfying" and another noted the challenges in being able to involve the partner in the counseling process. Some providers have instituted health screenings with symptom screeners and temperature checks at the door. Providers also detailed that they have had to stymie patient flow in order to allow for enough time between patients to ventilate the room and the general reduction in client volume. The provider in Spain was the only provider who mentioned an uptick in demand volume after the lockdown. Two providers in the US that work with Title X and federally funded patients also noted major declines in patients from those populations, which they attributed to the challenges of continuing with the group consultation model during COVID.

Chapter 5: Discussion

How vasectomy providers make decisions

Ultimately, vasectomy providers employed contextual factors, lived experiences, and personal values as part of prioritizing the principle of autonomy or the principle of non-

maleficence in decision making. Once the foundational conditions of patient certainty and fully informed patient consent were met, providers filtered patient characteristics through their training, experiences, laws and guidelines, norms, and mission and values. The result was a cost-benefit analysis for the individual patient, where the provider weighed the risk of regret and complications against the benefit of good contraception. This cost-benefit analysis then informed whether or not providers weighed the principle of autonomy or non-maleficence more highly in decision-making.

Based on the outcomes of this decision-making process, providers perform, delay, or deny procedures. Prioritizing autonomy commonly meant doing the procedure and emphasizing non-maleficence most often meant delaying or denying the procedure. For example, a young, unmarried and childless patient presenting for a vasectomy was deemed by most providers as being at a high risk of vasectomy regret. This likelihood was informed by literature, their personal experiences, and national vasectomy guidelines. Providers that prioritized autonomy after the cost-benefit analysis would proceed with the vasectomy. Providers that prioritized non-maleficence would either delay the procedure and impose a waiting period to make sure the patient was sure and had considered the chance of regret, or deny vasectomy candidacy until the patient was older.

Though emphasizing non-maleficence most commonly meant delaying or denying the procedure, there were instances where the opposite was true. Some providers offer vasectomy in countries where sterilization can be approved by court order, in cases where patients cannot exercise their own autonomy. In those instances, providers may do the vasectomy on the basis of prioritizing non-maleficence in relation to what having a child might mean for someone unable to exercise autonomy.

Many of the providers in this study prioritized autonomy. Some shifted their prioritization on a case-by-case basis, and a few predominantly prioritized non-maleficence. There were no clear patterns based on medical specialization, country of operation, years providing vasectomy, number of vasectomies provided per month or if they also provide reversals that predicted whether a provider would prioritize autonomy or non-maleficence.

How providers rationalize their decisions

Providers described different assumptions about the role of doctors in medical decision-making processes, which shaped their ultimate prioritization of autonomy or non-maleficence. Within this study, there were two distinct schools of thought about the role of doctors. The first group viewed doctors – and thus, themselves – as educators and a resource available to facilitate patient decision-making. The second group saw themselves as active and engaged gatekeepers of decision-making. These two operating paradigms are both appropriate and permissible within medical decision-making, but they do have distinct implications for patient care. This analysis will not attempt to evaluate the defensibility of these two paradigms, but rather evaluate their implications.

The first group, which will be referred to as the "educators", principally honor autonomy over non-maleficence. They see their role as educating, empowering, and facilitating the patient's own ultimate decision. The educators hold themselves at a distance in decision-making, describing their responsibility as providing information and offering their perspective. These providers feel their responsibility extends as far as providing full and complete information but goes no further. This is true even if the provider feels the patient is making a mistake with their decision. One provider offered a metaphor of seeing a patient running toward a cliff, and the

provider viewing it as their responsibility to shout, "there is a cliff up ahead!" but not to stop the person if they knowingly continue to run toward the cliff. Educators frequently commented that individuals have a right to make wrong or bad decisions.

The educator approach is strong in the way it honors patient autonomy and promotes patient-centered decision-making. It also limits opportunities for provider bias in determining vasectomy eligibility when the decision is led by the patient. A weakness of this approach is that access to vasectomy reversal services can be limited and costly, creating differential access to reversal services among those who can afford to pay out of pocket. This can result in down-stream discrimination for those who may wish to pursue reversals.

The second group, which will be referred to as the "gatekeepers," principally honor non-maleficence over autonomy, and see their role as extending beyond education. This group views the ultimate decision as one made in partnership, but where the provider has the ultimate say given the provider's distance from the emotion of the decision and their familiarity with vasectomy regret. The gatekeepers tended to emphasize the risks associated with vasectomy, including the risk of regret as well as the risk of rare complications including infection, hematoma, or post-vasectomy chronic pain. In light of these risks, gatekeeper providers were more cautious and conservative with their approaches. One provider described it as "measure twice, cut once," in reference to the challenges with reversal access and the desire for patients to be completely certain before pursuing vasectomy. Some gatekeeper providers described their lead role in decision-making as holding themselves to a higher standard as providers. The majority of the gatekeeper providers are from socially conservative countries.

The gatekeeper approach is strong in that it avoids complications in patients that may come to regret the procedure, and limits vasectomies that result in regret where reversals are

either not accessible or not affordable. As such, this approach reduces costs and overall utilization of health care resources. It also helps mitigate vasectomy regret. One provider also highlighted the role of cautious vasectomy provision as part of overcoming the legacy of forced sterilization and the importance of exceptional diligence in decision-making in light of this legacy.

However, a weakness of this approach is the opportunity to introduce provider bias in determining whether the risk of regret is too high. Recent research suggests childless men are no more likely to regret vasectomy and should not be counseled any differently than men with children (Bryk, Murthy, DeWitt-Foy, Sun, Parekh, Sabanegh, & Vij, 2020; Najari, Persily, Peterson, Wells, & Goldstein, 2021). Denying access to sterilization over the possibility of future regret has also been deemed unethical (Lalonde, 2018; McQueen, 2017; Mertes, 2017). Yet, childless men were considered at high risk of regret among both educator and gatekeeper providers, underscoring the potential for bias to shape vasectomy access when gatekeeper providers take an active role in decision making.

Current clinical best practices

Shared decision-making is considered a best practice in clinical decision-making and patient-centered care. Shared decision-making entails detailed information on the benefits and harms of the procedure provided by a health care professional as part of facilitating patients to arrive at informed preferences (Charles, Gafni, & Whelan, 1997; Elwyn, Frosch, & Kobrin, 2016). These informed preferences are then respected and integrated into decision-making as a way of respecting autonomy. Shared decision-making in contraceptive choice has been shown to increase satisfaction with both provider counseling and ultimate method uptake (Dehlendorf,

Grumbach, Schmittdiel, & Steinauer, 2017). Patients who engaged in shared decision-making were more satisfied with the process of decision making than patients who reported making the decision on their own or that providers made the decision for them (Dehlendorf, Grumbach, Schmittdiel, & Steinauer, 2017).

Patients appear to benefit from thorough education and moderate assistance in contraceptive decision-making. As such, the educator approach – with its emphasis on full information and assisting with choice through providing perspective – may be the best approach for driving patient satisfaction with their method of choice.

The gatekeeper approach, where the provider has the ultimate say in whether or not the procedure is being offered, may generate reduced patient satisfaction. The gatekeeper approach is essentially honoring the autonomy of the patient's future self more than the autonomy of the patient's current self as justified by avoiding harm. There is substantial merit to the need to minimize harm for sterilization procedures, particularly in light of the legacy of forced sterilization in many countries around the world. However, it may be time to reexamine the tradeoff between addressing that legacy through cautious provision and addressing it through honoring patient autonomy. Forced sterilization was fundamentally a lack of autonomy, and truly addressing this legacy may best be served by prioritizing patient autonomy.

Clinical decision-making around sterilization has been studied more extensively for tubal ligations (female sterilization) than vasectomy. There are many parallel barriers to access for tubal ligations – young and childless women are commonly turned away when seeking tubal ligations over the risk of regret (Lalonde, 2018; Richie, 2013). Notably, much of the current literature presumes regret is not factored into decision-making for men seeking vasectomies as it is for women seeking tubal ligations (Mertes, 2017; Richie, 2013), though the findings from this

study suggests otherwise. It is well-documented that regret is centrally factored into clinical decision-making for tubal ligation procedures (Lalonde, 2018; Mertes, 2017; Richie, 2013; Taylor 2020). Similarly, it is expected that age, number of children, and marital status are factored in as subsidiary characteristics as part of weighing a tubal ligation patient's chance of regret (Sobel & Gert, 1986).

Case studies and commentaries have also reflected female sterilization providers striving to find a balance between autonomy and non-maleficence (Goldrath & Smith, 2016). Commenting on a case study of a young and childless woman seeking a tubal ligation, Goldrath (2016) noted: "While it is the duty of the physician to "do no harm," it is preferable to provide extensive counseling and allow the patient to decide, rather than to refuse unilaterally, which would be paternalistic….Ultimately, it is the responsibility of the health care provider to have a substantive discussion, fully inform the patient, provide alternative treatment options, and allow the patient to decide." Smith countered with the value of a six-month or one-year waiting period to manage both honoring autonomy and mitigating the risk of "tubal regret" harm.

Ultimately there are greater parallels to clinical decision-making between tubal ligation providers and vasectomy providers than much of the literature currently suggests. There are educator approaches and gatekeeper approaches among both tubal ligation and vasectomy providers. Yet in both instances, the gatekeeper approach is challenged as paternalistic, unnecessarily regret cautious, and discriminatory. It is also worth noting that although providers appear to have similar approaches to counseling tubal ligations and vasectomies, tubal ligation procedures are significantly more invasive, riskier, and less reversible. It stands to reason that vasectomy providers can and should take a less cautious approach to non-maleficence in vasectomy provision, given the reduced level of risk compared to tubal ligations.

Implications

The findings of this study suggest an opportunity for vasectomy providers to examine the role of evidence in their decision-making, and to examine and mitigate opportunities for bias to shape decision-making. Providers only reported evidence as driving their decision-making when it came to patients at high risk of regret, and some of the criteria they described being as high-risk are not consistently supported in the literature nor in the lived experience of those who provide reversals (Najari, Persily, Peterson, Wells, & Goldstein, 2021). There is a need to examine what kind of evidence is used and the way evidence is used to guide decision-making, as well as a need to practice reflexivity on how bias may shape decision-making. Future trainings of vasectomy providers should focus on evidence-based medicine, shared decision-making, and patient-centered care to ensure vasectomy provision that honors patient autonomy and rights.

Improving access to existing contraceptive methods will be critically important to meeting Sustainable Development Goals on ensuring universal access to sexual and reproductive health and rights (Goal 5, Target 6). Within that, expanding access to non-hormonal male methods of contraception will be essential. As such, the educator method should be encouraged during provider trainings and in policymaking, and the gatekeeper approach should be actively discouraged. Future vasectomy trainings should also incorporate medical ethics training, including balancing the principles of autonomy and non-maleficence in decision-making, particularly as they relate to sterilization.

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Appendix A: Copy of IRB approval letter

IRB EXEMPT REVIEW

November 19, 2020

Alison Hoover

alison.hoover@emory.edu

Title:	Decision-making rationales of vasectomy service providers
Principal Investigator:	Alison Hoover
IRB ID:	STUDY00001730
Funding:	None
Documents Reviewed:	• Combined_Waiver_Consent_HIPAA_Elements_Hoover_Vasectomy.docx, Category: Other; • Hoover_Vasectomy_Interview Guide, Category: Surveys, Questionnaires, Interview Guides; • Hoover_Vasectomy_IRB_Protocol_Sociobehavioral, Category: IRB Protocol; • Hoover_Vasectomy_SaaSVerbal_Consent, Category: Consent Form; • Hoover_Vasectomy_Screener_Google Forms.pdf, Category: Recruitment Materials;

Dear Alison Hoover:

Thank you for submitting an application to the Emory IRB for the above-referenced project. Based on the information you have provided, we have determined on 11/19/2020 that although it is human subjects research, it is exempt from further IRB review and approval. This project meets the criteria for exemption under 45 CFR 46.104(d)(2ii). Specifically, you will conduct in-depth interviews to investigate vasectomy providers' interpretations of ethically challenging cases.

Please note the following in association with this exemption:

- Attached are stamped approved consent documents. Use copies of these documents to document consent.

This determination is good indefinitely unless substantive revisions to the study design (e.g., population or type of data to be obtained) occur which alter our analysis. Please consult the Emory IRB for clarification in case of such a change. Exempt projects do not require continuing renewal applications.

Please note that the Belmont Report principles apply to this research: respect for persons, beneficence, and justice. You should use the informed consent materials reviewed by the IRB, if applicable. CITI certification is required of all personnel conducting this research.

Unanticipated problems involving risk to subjects or others or violations of the HIPAA Privacy Rule must be reported promptly to the Emory IRB and the sponsoring agency (if any).

Sincerely,

Jessica Blackburn, MPH, CIP
Senior Education and QA Research Protocol Analyst

Now that your submission has been approved, please take a few moments to complete the Emory IRB Satisfaction Survey*. We will use your responses to improve our service to the Emory research community. We appreciate your feedback!*

Appendix B: Codebook

Code Names	Brief Description/Definition
Consent & pre-counseling	This code captures references to the consent process, including all pre-procedure counseling conversations and forms. It also includes consent and pre-counseling processes involving administrative or nursing staff, as well as barriers or facilitators to gathering consent.
Training	This code captures all references to the training the providers received (or did not receive) in the process of becoming vasectomy providers. It also captures any training they provide to other vasectomists.
Experience	This code captures the outcome of experience providing vasectomies, or the ways providers have changed their decision-making approaches over time. This does not include changes in consent, procedural technique, or other technical changes – only changes to decision-making approaches or mindsets.
Laws and guidelines	This code captures references to any laws, guidelines, or human rights codes that pertain to vasectomy provision. It can also include references to malpractice (hypothetical or actual) or insurance.
Socio-cultural norms	This code captures references to socio-cultural norms that influence decision-making, including religion.
Peer influence	This code captures references to the role of peers in decision-making, including peer recommendations, peer perception (actual or hypothetical), or peer interactions such as during a training or reaccreditation. This does not include peer influences in surgical techniques.
Mission and values	This code captures references to mission and value of providers. This includes reasons they are motivated to provide services and reasons for getting involved in vasectomy provision. It does not include any internal values that actively inform a specific case decision (see "Judgment" code)
Patient characteristics	This code captures all references to the various patient characteristics solicited during the pre-counseling and consent process that influence vasectomy candidacy, including age, relationship status, pregnancy status, # of children, contraceptive alternatives, stance on abortion, certainty and duration of decision to seek vasectomy, life stage, and ability to be good parents.
Responsibility	This code captures references to the responsibility a provider feels. The responsibility can be to their patient at any point in the consent, counseling, or procedure process; responsibility to society; responsibility to medical associations or certifying boards;

	responsibility to the patient's partner or parents; or responsibility to themselves.
Judgment	This code captures references to a provider's judgment, including how judgment is developed, the importance of a provider's judgment, or the application of a provider's judgment. (keywords: internal). Judgment as it specifically applies to decision-making, not counseling.
Rapport	This code captures references to rapport and trust between the patient and provider. This can include ways to build rapport/trust, ways to know rapport/trust is built, the result of rapport/trust, and the lack of rapport/trust.
Regret	This code captures references to regret, including the need to avoid regret, ways to avoid regret, data on regret, stories of regret, and the role of regret in decision-making.
Reversals	This code captures all references to vasectomy reversals, including hypothetical or actual reversals, training in reversals, counseling in reversals, or data on reversals.
Autonomy	This code captures any references to the patient's autonomy or lack thereof in decision-making, such as their right to a decision, or when their autonomy should be superseded by another concern.
COVID-19	This code captures all mentions of the impact of COVID-19 on their vasectomy services.