

Gaps in male infertility health services research

Andrew K. Leung, Mark A. Henry, Akanksha Mehta

Department of Urology, Emory University School of Medicine, Atlanta, GA, USA

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Correspondence to: Akanksha Mehta, MD, MS. Department of Urology, Emory University School of Medicine, 1365 Clifton Road, Building B, Suite 1400, Atlanta, GA 30322, USA. Email: akanksha.mehta@emory.edu.

Abstract: The field of male infertility remains a niche specialty within urology. Although a male factor is implicated in at least 50% of all cases of infertility, and male infertility is thought to be associated with overall male health and longevity, this subspecialty comprises a relatively small proportion of urologic training. There remains a large knowledge gap with regards to prevalence of male factor infertility, as well as the need for health services for the diagnosis and treatment of male infertility. Health services research is a multidisciplinary approach that combines both qualitative and quantitative methodologies to improve patient care and outcomes pertaining to male infertility. This review summarizes the current literature pertaining to health services for male infertility and identifies opportunities for future research to improve access to and outcomes of male infertility care, including improvements in costs of care, patient education, and health policy.

Keywords: Health services; male infertility; access to care

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Introduction

The diagnosis of male factor infertility has a tremendous impact on the physical and emotional health and quality of life of affected couples. Infertility, broadly defined as an inability to achieve a pregnancy following one year of unprotected intercourse (1), affects 15% of all couples (2,3). A male factor contributes in part or whole to 50% of cases of infertility (4-6). Determining the true prevalence of male infertility, however, remains elusive, as most estimates are based on couples pursuing assisted reproductive technology, which may underestimate the problem. Men are less likely to pursue medical evaluation than women, whether for social reasons, fear, cultural norms, or lack of health insurance coverage (6-8), which limits the opportunities for patient education about the etiology, diagnosis, and treatment of male infertility.

Health services research, defined by the Academy for Health Services Research and Health Policy as "...

the multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviors affect access to health care, the quality and cost of health care, and ultimately our health and well-being" (9), is a powerful instrument with the ability to shape the field of andrology and male infertility. More specifically, this is accomplished with a goal "...to identify the most effective ways to organize, manage, finance, and delivery high quality care; reduce medical errors; and improve patient safety" according to the Agency for Healthcare Research and Quality (10). The overall goal of health services research is to evaluate factors that impact the need for health services, access to care, costs, and outcomes of care, with intent to evaluate factors affecting both individuals and populations. Unlike clinical and basic science research, which rely primarily on quantitative data analyses, health services research frequently combines quantitative and qualitative analyses, referred to as "mixed methods research" (11).

The mixed methods approach allows researchers to comprehensively investigate study questions, and provides a more comprehensive understanding of study outcomes.

The goal of this manuscript is to review the current literature pertaining to health services for male infertility and identify opportunities for future research to improve access to and outcomes of male infertility care, including improvements in costs of care, patient education, and health policy.

Prevalence of male infertility

The true prevalence of male infertility, and thus, the true need for health services for male infertility, remains unknown. There is no national registry that systematically and specifically collects information about male reproductive health. While data pertaining to male infertility does exist within a variety of sources, it is often limited in detail and applicability. Some of these sources, such as the National Survey of Family Growth (NSFG), the National ART Surveillance System (NASS), and the National Survey of Ambulatory Surgery (NSAS), are maintained by the CDC. Information pertaining to fertility rates and family size is also collected by the U.S. Census Bureau, and by the U.S. Bureau of Labor Statistics, via the National Longitudinal Survey of Youth. This section summarizes the strengths and limitations of these data sources for estimating the true prevalence of male infertility.

NSFG gathers information on family life, marriage and divorce, pregnancy, infertility, use of contraception, and men's and women's health, in order to understand trends related to fertility, family structure, and demographics in the United States (12). Data from the 2002 NSFG cycle demonstrated that 7.5% of all sexually active men aged 15–44 visited a healthcare professional for assistance with having a child, translating to 3.3–4.7 million men reporting a lifetime visit, and 787,000 to 1.5 million men reporting a visit during the preceding year (13). However, a follow-up study utilizing NSFG data from the 1995, 2002, and 2006–2008 cycles, demonstrated that among couples actively seeking infertility care, 17.7–27.4% of male partners did not undergo an infertility evaluation (8). Although NSFG was designed to include a nationally representative sample, the number of men included in the earlier cycles of the survey was small, and the number of men who reported utilization of services for reproductive health was even smaller. Therefore, it is unclear to what extent NSFG is truly representative of the U.S. male population, with respect

to use of health services for male reproductive health in general, and male factor infertility in particular.

NASS was established under the 1992 Fertility Clinic Success Rate and Certification Act, and collects data pertaining to ART treatment cycles and outcomes (14). Although this is a robust national database with detailed cycle-level information about ART outcomes, it is lacking in demographic and clinical information for male partners. Thankfully, the CDC implemented a key change to NASS in 2016, to include information about male age, and etiology and severity of male infertility. These data are expected to be available for analysis later in 2018. Although this change will allow a more accurate characterization of the prevalence of male infertility amongst couples actively seeking infertility care, it is important to recognize that NASS still remains focused on the subset of infertile couples undergoing ART cycles, and thus, may not be representative of the general U.S. population.

NSAS, a survey of services provided at ambulatory surgical care in hospital-based and freestanding ambulatory surgery centers (ASCs), was conducted from 1994–1996, discontinued due to lack of resources, and then conducted a final time in 2006 (15). NSAS data demonstrated that the highest utilization for male infertility services is for men 25–34 of age (126/100,000); followed by men 35–44 years of age (83/100,000). However, the survey excluded information about reproductive health services provided at specialty facilities, such as family planning clinics, and included such services only provided at general facilities. Details about patient demographics and specific procedures were also frequently lacking, with many procedures related to male infertility being characterized as “operations on the male genital organs” only. The most recent iteration of the NSAS, the National Ambulatory Medical Care Survey, does not include details about infertility related services (16). Therefore, current estimates of surgical treatments for male factor infertility are not available.

Recent studies based on large institutional databases, or population-level databases have provided some insight and information pertaining to demographics, workup, and contemporary treatment of male infertility patients. However, Joyner *et al.* found the quality of fertility data of several large-scale databases to be lacking to various degrees. The authors compared male and female fertility rates from the 1979 and 1997 cohorts of the National Longitudinal Survey of Young (NLSY79 and NLSY97), along with the 2002 NSFG, to those reported by the U.S. Census Bureau and the National Vital Statistics System

(NVSS). They found statistically significant differences of each survey's reported age-specific male and female fertility rates when compared to fertility rates reported by the NVSS and Census Bureau. In particular, men aged 15–24 reported lower fertility rates in NLSY79, NLSY97, and NSFG, compared to the overall population, suggesting that even surveys with large numbers of respondents lack reliability in male fertility reporting (17). The cross-sectional design of the NSFG survey, as opposed to the longitudinal nature of the NLSY surveys, lends itself to a possible recall bias affecting NSFG data. In addition, NSFG excluded incarcerated men or those serving in the armed forces, which may also skew racial and socioeconomic demographics. The implications are not only on the quality of survey data regarding fertility and paternity, but also pitfalls/shortcomings of survey design.

A recent study assessed the possibility of utilizing claims to capture information regarding male-factor infertility on a population level. Khandwala *et al.* examined internal claims data of 11,068 male patients at a single institution to assess whether ICD-9 codes accurately identified men with abnormal semen analyses based on WHO 4th Edition parameters. Six different ICD-9 codes analyzed: 606.0 (azoospermia), 606.1 (oligospermia), 606.8 (infertility due to extra-testicular causes), 606.9 (unspecified male infertility), 606.x (male infertility), V26.21 (fertility testing). Specificity ranged from 92.3% to 99.7% and increased to 99.8% if three or more codes were analyzed in combination (18). However, sensitivity was not calculated as not all patients had a documented semen analysis. Given the high specificity, this study's findings could potentially be extrapolated to larger, de-identified databases such as MarketScan[®] Truven and provide further insight regarding prevalence of male infertility. This would allow for regional analysis of access to care and patient management by examining what potential male infertility etiologies are prevalent in what regions and what management patterns exist. However, further validation studies beyond a single institution are needed.

It is important to recognize the limitations in these current estimates of male infertility, because they directly impact estimates of the need for health services for male infertility. Additionally, these estimates are largely based on men actively seeking treatment for infertility, which may not be representative of the general population of subfertile men. Demographic and economic factors, for example, as well as availability of male reproductive specialists, may play a role in whether or not men seek infertility

treatment services. Current estimates of the prevalence of male factor infertility likely underestimate the true prevalence of this problem. In response to the limited data specifically addressing the prevalence, etiology, severity, and management of male infertility, clinicians and researchers have recently formed the Andrology Research Consortium (ARC), with support from the Society for the Study of Male Reproduction. Three years after its formation, a total of 14 centers specializing in male infertility across North America have contributed information to the database. Interestingly, only 9.8% of couples who had undergone IUI and only 28% of couples who had undergone an IVF cycle reported a prior male factor evaluation (19). Although this database is still in its infancy, the targeted focus on male infertility has already yielded great insight, and stands to greatly gain from expansion in the future.

Access to care

Access to care for infertility care relies on proximity to local and regional ART centers and, ideally, proximity to both male and female fertility specialists. Two studies have examined the geographic distribution and accessibility of infertility treatment centers and male infertility specialists, based on 2000 U.S. Census data. There is wide variability in the distribution of ART centers with respect to population density for men and women of reproductive age (women 20–44 years; men 20–49 years) (20). At the time of publication, over 1.5 million men and women in Kentucky were served by the single in-state ART center, compared to 65,000 men and women served per ART center in the District of Columbia (20). Not surprisingly, states with some form of mandated health insurance coverage for infertility treatment were more likely to have a higher median number of ART centers, and these centers were more likely to be located in proximity to areas of high-population density (20).

The same group of authors then analyzed the distribution of male reproductive urologists in relation to the male population aged 20–49 years, and found a disparity in the distribution of male reproductive specialists in the United States, with large areas of the country being under- or over-served (6,21). In 2010, only 197 male infertility specialists and 390 advanced reproductive technology centers were identified in the United States (21). At the time of publication, 13 states had no male reproductive urologist whatsoever, and many more ART centers did not have a male fertility specialist within a 60-minute driving distance.

In these scenarios, there may be no option but to reply on general urologists that do not have expertise or interest in male reproduction, which, in turn, affects the interaction between male and female fertility specialists, and potentially impacts outcomes from ART care.

The relative lack of male reproductive health specialists is partly explained by the limited number of training positions nationwide for urologists (319 in 2017) (22), and significantly fewer for fellowships in andrology/male infertility (23), compared to female reproductive endocrinology and infertility fellowships (24) (15–20 vs. 55–60, based on the number of training fellowship programs recognized by the Society for the Study of Male Reproduction and the Society for Reproductive Endocrinology and Infertility at the time of writing). With a deficit in ART centers and male infertility specialists, ever-use of ART by women aged 15–44 declined by 23% between 1995 and 2010 (7,25). North America was estimated to have an unmet demand of 365,000 cycles per year, meeting only 24% of demand in 2003 (26). Given the likely depth of undiagnosed male factor infertility, this number conceivably may be even lower.

Together, these results demonstrate clear geographic barriers in access to a male reproductive health evaluation. Not only do these barriers limit access to care for men with an established diagnosis of infertility, they also diminish the potential diagnosis of subfertility in men who are not actively seeking ART services. This gap in patient to physician ratio is likely to continue to grow. Levine *et al.* recently published a landmark study showing that sperm counts in the westernized world has declined by approximately 60% over the past 3 decades (27), which is undoubtedly a contributor to increasing rates of male infertility. The shortage of male reproductive health specialists has even broader implications for male reproductive health services research. Without an adequate physician work force, data on health services and delivery of care is weak at best, and is likely to be limited by selection bias, given underlying disparities in those who can access this limited care. An imperfect knowledge of where unmet demand exists makes it difficult to build or incentivize appropriate services for addressing these gaps.

Costs of care

One of the biggest challenges to evaluating health services for male infertility is the lack of mandated insurance coverage for the diagnosis and treatment of male factor

infertility. Only 15 states currently mandate insurance coverage for female infertility, and only eight states mandate male infertility evaluation or treatment (28). Even among those eight states, there are great differences in the degree of coverage for evaluation and management. Coverage by employer health plans is deficient as well. A survey of employers with at least 200 employees revealed only 63% covered evaluation of infertility (male or female), 39% covered drug therapy, and only 22% covered in-vitro fertilization (4,29). Lindgren *et al.* found that most patients in the United States with reproductive health disorders are not covered by their health insurance, as reproductive care is still considered a lifestyle choice by many insurance carriers (30). The financial burden associated with the evaluation and treatment of male infertility is significant. The cost of undergoing *in vitro* fertilization and intracytoplasmic sperm injection in the United States is estimated to be approximately \$12,500, which is considerably higher than any other country in the developed world (26). This estimate does not include the associated out-of-pocket infertility-related expenses for couples with male factor infertility, which can be as high as \$15,000 (31). The absence of insurance coverage not only limits access to infertility care for a large proportion of patients, but also limits the ability to track the use and outcomes of infertility-related services in population level databases, such as claims-based datasets.

Areas for improvement

There is much room for improvement in health services research for male infertility, in order to ultimately effect health policy change and enhance patient care and outcomes. Expanded use of both qualitative and quantitative data collection in the aforementioned databases, especially the ARC, can provide further insight into where patient care is lacking and whether improvement efforts are effective. Data collected via large-scale patient surveys can also give voice to certain demographics who are traditionally overlooked in healthcare based on level of formal education, income, religion, sexual orientation, ethnicity, or even patients with cancer who must face treatment options that may affect fertility (6).

Given the overall deficit of infertility specialists, much less those who specialize in male infertility, patients are likely both under-educated regarding male infertility and have not been receiving complete male infertility evaluations, as suggested by the ARC report (19). To

alleviate the sheer volume of patient burden on male infertility specialists, further measures may be taken in addition to increase fellowship positions. Primary care physicians, obstetricians/gynecologists, and reproductive endocrinologists may benefit from Continuing Medical Education training courses or seminars at conferences such as those held by the American Society for Reproductive Medicine and American College of Physicians in order to fill this need. Increasing the number providers capable of initiating a male fertility workup would allow specialists to further concentrate their resources on those with a current diagnosis. In addition, this would give a larger number of non-specialist providers the knowledge base and confidence to counsel patients. The medical and policy-making communities, however, must recognize and reconcile the modern pressures of seeing a larger volume of patients in shorter amounts of time if non-infertility specialists were to take on this new responsibility.

Even as the use of over-the-air and online media by the general population has risen over recent decades, this powerful tool has not been proportionately harnessed by the male infertility community. This is noteworthy because 80% of Americans currently utilize online resources to search for information regarding medical diagnoses, with similar trends for infertile couples (32,33). As ART centers maintain websites with the dual purpose to educate patients regarding infertility and to advertise services. However, they are often lacking information specific to male infertility with 20% of websites failing to mention male factor infertility completely and less than 25% of websites mentioning referral to a urologist (34). Furthermore, it is unknown how many patients view these websites and to what extent. These studies suggest couples seeking fertility may be uneducated regarding their possible etiologies and that the infertility community is not taking advantage of the current media resources. This compounds the lack of patients' knowledge about male factor infertility and male health overall, as one recent study demonstrated a dissonance between patients' expectations of risks and benefits of testosterone replacement therapy (35). Some encouraging signs are seen, however, with recent coverage in media and celebrities speaking freely about their own struggles with male infertility (36,37). Formalizing media campaigns with a large target audience may help to remove the stigma and push couples to seek appropriate care.

Male infertility also needs to be recognized as medical condition and a public health concern. A growing body of literature demonstrates that male infertility is

associated with impaired overall health (38-40), decreased life expectancy (41), and lower quality of life (42). A comprehensive evaluation of male infertility has the potential to uncover serious and potentially life-threatening underlying medical conditions (43). The CDC's National Public Health Action Plan for the Detection Prevention and Management of Infertility, and the American Society for Reproductive Medicine's focus on addressing barriers in access to care, are examples of recent efforts that urologists and male infertility specialists can support to promote awareness of male infertility as a public health concern.

Conclusions

Health services research is a multidisciplinary approach of scientific investigation that combining both qualitative and quantitative methods to investigate healthcare. It can be a powerful instrument in detailing the strengths and weaknesses of the male infertility field to effect change. To date, there exists incomplete data pertaining to male infertility with barriers in evaluation and treatment. Ultimately, this translates to a harmful cycle that precludes the ability to gain knowledge, affect patient care, and transform policy. Improvement of existing databases, education of non-male infertility specialists, and utilizing all types of media, are potential solutions to breaking this cycle.

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Footnote

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