## Infertility – What do we mean?

M.A. Fathimunissa<sup>1</sup>, Pandiyan Natarajan<sup>2</sup>, Radha Pandiyan<sup>3</sup>

<sup>1</sup>Consultant Reproductive Medicine/Obstetrician/Gynecologist, Dr. Fatima's Fertility & Women's Clinic, Chennai, India <sup>2</sup>Chief Consultant in Andrology and Reproductive Sciences, Professor Emeritus, The Tamil Nadu Dr MGR Medical University, Apollo 24/7, NOVA IVF FERTILITY, Chettinad Super Speciality Hospital (Retired), Chennai, India <sup>3</sup>Senior Consultant in Andrology and Reproductive Sciences, Chettinad Super Speciality Hospital (Retired), Chennai, India

Address for correspondence: Prof. Natarajan Pandiyan, Chief Consultant in Andrology and Reproductive Sciences, Professor Emeritus, The Tamil Nadu Dr MGR Medical University, Apollo 24/7, NOVA IVF FERTILITY, Chettinad Super Speciality Hospital (Retired), Chennai, India. E-mail: pandiyan1@yahoo.com.

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Infertility is a global problem. Global estimates suggest that nearly 72.4 million people experience fertility problems.<sup>[1]</sup> What do we mean by infertility? We still lack a consensus on when and how we label a couple as infertile, that is, the definition of infertility.

In the literature, there are several attempts to define infertility – clinical, epidemiological, and demographic, but all stand in disagreement with each other. Even within each approach, there is wide dissent.

The requirement of a proper and common clinical definition for infertility is essential. This is because it initiates a long list of investigations and expensive treatment for the couple. WHO-ICMART revised glossary, 2009, defines infertility as, "A disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse."<sup>[2]</sup> American Society for Reproductive Medicine (ASRM) states, "Infertility is a disease defined by the failure to achieve a successful pregnancy after 12 months or more of appropriate timed, unprotected sexual intercourse or therapeutic donor insemination."<sup>[3,4]</sup> Even though both these bodies have a similar perception of infertility, the length of trying for pregnancy is not adjusted for women's age (it is the same across all age groups) and

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neither of them failed to define what one means by regular sexual intercourse. The frequency of intercourse has a direct bearing on the chance of success. In their paper, Agarwal *et al.* state that frequency of at least several times every week is likely to result in coitus during ovulation. This increases the chances of pregnancy.<sup>[5]</sup> It appears that sexual activity is likely to result in conception only if it occurs during the 6 days leading up to ovulation. Briscoe *et al.* in their paper state that ovulation is highly variable, couples trying to conceive should have intercourse every 1 to 2 days. This will optimize their chances of pregnancy.<sup>[6]</sup>

There is also an ambiguity in the outcome measured – clinical pregnancy versus successful pregnancy. How does one define a successful pregnancy? – merely getting pregnant could be deemed as a success by some, others may consider crossing a viable gestational period as success. In contrast, many may choose only a live birth as success.

National Institute for Clinical Excellence guidelines (NICE) UK 2004 states that "Infertility is failure to conceive after regular unprotected sexual intercourse for two years in the absence of reproductive pathology."<sup>[7]</sup> This shows considerable heterogeneity in the duration of the infertility estimate, which forms the cornerstone of the definition.

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The National Institute of Child Health and Human Development (NICHD) describes infertility as the "Inability of a woman or a man to conceive a child or the inability of a woman to carry a pregnancy to term."<sup>[3,8]</sup> The usage of vague criteria and the numerous inconsistencies only add to the confusion. The current requirement would be a clinically meaningful definition sensitive enough to identify all couples who would benefit from an intervention. It would also be specific enough to eliminate overzealous investigation and premature treatment that may expose women unnecessarily to medical complications and expense.<sup>[9]</sup>

Demographic definitions are no exception. The literature search revealed numerous definitions used in various population studies. Demographic and Health Surveys (DHS) Comparative report No. 9 states that infertility is "An inability of a couple of reproductive age (15-49 years) to become or remain pregnant within five years of exposure to pregnancy."<sup>[10]</sup> Another recent systematic analysis says, "Infertility is the inability to become pregnant with live birth, within five years of exposure based upon a consistent union status, lack of contraceptive use, non-lactating and maintaining a desire for a child."<sup>[11]</sup> The former definition is extremely superficial as it does not specify if the couples are constantly trying to get pregnant and both have lengthened the duration to 5 years in stark contrast to 1 or 2 years used in clinical definitions. The main justification for this approach is that a longer duration makes it easier to collect data. However, WHO 2014 says that reducing the time frame from 5 to 2 years would increase the total number of infertile couples by two-anda-half fold.

Another caveat is the shifting of outcome measure from pregnancy to live birth by demographers simply because it is difficult to obtain data about conception in comparison to obtaining data about "live birth," which is relatively facile. A small difference exists whether "no live birth" was voluntary or involuntary. This ambiguity results in an erroneous estimation of the prevalence of infertility in the local or world population. This gives a false picture of the magnitude of the issue and makes it either too small to matter or out of proportion. Regions where fertility problems are rampant, and which require established Assisted Reproductive Technology (ART) services may be missed.

Epidemiologists are no different. Various studies show multiple values for prevalence based on the varying duration of trying such as 12, 24, and 60 months.<sup>[5]</sup>

They make it difficult to assess prevalence as the units of analysis vary widely as infertility is identified in "women," "couples," "people," or "individuals."<sup>[12]</sup>

It is crucial to have a clinically relevant definition of infertility because a thorough understanding of it will provide potentially useful insights. The goal cannot be met by merely scattering unclear terms and periods. In dissenting from it, we are more concerned with the difficulty of properly defining something and the effort involved. However, it is time for a refined definition of infertility. This would be more meaningful and effective.

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There are no conflicts of interest.

#### COMMENTARY

#### Why it is important to define infertility?

The paper published in the current issue by Fathimunissa *et al.* raises a very important issue of defining infertility.<sup>[13]</sup> The definition of infertility is very essential from a medical as well as a legal standpoint. The practitioners need guidance regarding when and how to initiate infertility investigations and treatment in couples anxious to conceive. In India, couples may come to the doctors' offices only after a few months of trying to worry about fertility because of social factors, late marriage, lack of awareness, or some self-correcting minor medical problems. Premature initiation of investigations may lead to a vicious chain of costly and invasive investigations. At the same time because of the lack of definition couples may need much-needed treatment and compromise their chances of successful treatment.

The International Committee for Monitoring Assisted Reproductive Technologies (ICMART) in partnership with several other international societies has provided the consensus definitions of various terms used in assisted reproduction.<sup>[14]</sup> The committee has defined infertility as, "A disease characterized by the failure to establish a clinical pregnancy after 12 months of regular, unprotected sexual intercourse or due to an impairment of a person's capacity to reproduce either as an individual or with his/her partner. Fertility interventions may be initiated in less than 1 year based on medical, sexual and reproductive history, age, physical findings, and diagnostic testing. Infertility is a disease, which generates disability as an impairment of function." The committee further advises using "subfertility" interchangeably with infertility. This definition is fairly comprehensive to cover all other medical factors which may lead to infertility, for example, the inadequacy of sexual intercourse, age, and other physical findings which may interfere with the conception.

The ART Regulation Act was passed by the Indian Parliament in December 2021.<sup>[15]</sup> The date of commencement is January 24, 2022. The Act defines infertility (section 2. [1] [/]) as "infertility" which means the inability to conceive after one year of unprotected coitus or other proven medical condition preventing a couple from conception. The law also allows providing ART services (section 21. [g]) only (i) to a woman above the age of 21 years and below the age of 50 years; (ii) to a man above the age of 21 years and below the age of 55 years.

Once defined by law any ART services provided to any couple outside the 1-year definition have to be on definite medical grounds. Similarly, the prohibition of ART services outside the age range may attract penal actions by the authorities.

Umesh N Jindal, Director, Jindal IVF & Sant Memorial Nursing Home, Chandigarh, India

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