Density of in-vitro fertilization centers and its correlation with socioeconomic factors in Maharashtra state, India

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INTRODUCTION

Infertility has become an important and increasing problem across the world. In India, also infertility has attracted obvious attention after the third District Level Health Survey (DLHS) carried out in 2007-08.1 Conversely, the Total Fertility Rate (TFR) is showing declining trend in many states. The decline in TFR is a desired status and is clearly expressed in most of the policy documents in India. Most of the couples opt to have a child within few years after marriage due to family pressure or own desire. It is well-known that, apart from bio-medical reasons like age, smoking, diabetes etc. socio-demographic factors like education, income, urbanization etc. are important determinants of infertility. The infertile couple particularly the woman is at receiver’s end of unwarranted and tormenting comments. She is believed to be an incomplete woman. The couple particularly the woman vehemently seeks treatment for infertility to avoid its social consequences like marital disruption and domestic violence perpetrated by husband and in-laws.2 The natural instinct of parenting is
responded by medical fraternity by providing Assisted Reproductive Techniques (ART). The number of in vitro fertilization (IVF) centers is enormously rising.

The newspapers, internet frequently have persuasive advertisements of such centers. This increase of IVF centers in the market is likely to be proportionate to the demand. Like a childless lady, woman having only daughters also receives unwarranted and tormenting comments. The son preference frequently results into daughter aversion. Neglect of girl children may reach to even their elimination which has been well documented since long period. The in-laws fervently try to convince the woman to try accepting all possible means to give birth to male child only. Ultrasound checkup is a non-invasive and comparatively affordable technique of sex detection of unborn child. It is also contended that with ultrasound machines capturing the market, the child sex ratio has declined. For addressing the problem of declining child sex ratio, Parliament of India enacted pre natal diagnostic act in 1994. Advancement in technology compelled the Parliament to amend the Act in 2003 to include pre conception techniques also under the ambit of the act. It is believed that families in connivances with doctors are going for sex selection. Maharashtra is one of the states which has shown drastic decline in child sex ratio during last couple of decades. It is feared that the increasing number of IVF centers may further decrease child sex ratio. Authors have conducted the study to find out socio-economic correlates of density of IVF centers and the effect IVF centers on sex ratio. The specific objectives of the study were to measure the correlation between number of IVF centers and following socio-economic factors; TFR, infertility, population density, decadal growth rate, female literacy, income, urbanization and to measure the correlation between number of IVF centers and various statistics of sex ratio.

METHODS

Study population and area

This study was carried out in 2014 using secondary data pertaining to Maharashtra State, which has 35 districts and 22 Municipal Corporations. Maharashtra is the second populous State in India. Population of Maharashtra is 112,374,333 which constitute about 10% of the population of India. Information about some socio-demographic factors is provided in Table 1. The literacy rate of the State is 82.95% and female literacy rate is 75.48% as per Census 2011. Maharashtra has well developed industrial area. Among larger states it occupies second rank next to Haryana in per capita income.

Compilation of IVF centers in Maharashtra

Internet search was carried out by using words IVF center, infertility treatment center, genetic clinic, genetic center or genetic counseling center. Similar search was carried out by using available online telephone directory services. The search was repeated for each district and each Municipal Corporation including Mumbai Municipal Corporation separately. Whenever IVF center/procedure was noticed on the internet, the center with its address was included in that district list. Ayurvedic and Homeopathy centers were usually not considered but six Ayurvedic centers and one homeopathy center proclaimed availability of IVF hence with the assumption that they may have appointed qualified technicians were included in the corresponding district list. Authors also collected list from State Appropriate Authority (AA) under PCPNDT Act, Indian Society for Assisted Reproduction and National Registry of ART Clinics and ART Banks in India maintained by Indian Council of Medical Research. Authors have not considered various procedures under assisted reproductive techniques separately and the word IVF center is used as a generic term. Genetic centers, genetic counseling centers and genetic laboratories were limited in number; hence no further analysis was carried out for such centers.

Infertility and fertility data

The state wise and district wise data about infertility was taken from DLHS 3. No distinction was made between primary and secondary infertility. The district wise information of TFR in Maharashtra state was obtained from the Survey of Causes of Death (SCD) for the year 2011, and sex ratio at birth from civil registration system. The SCD scheme collects information about vital events including TFR from rural areas of all the districts. State wise information of TFR was taken from sample registration system report for 2012.

Sex ratio data

The state wise as well as district wise information in Maharashtra state about population sex ratio and child sex ratio was obtained from Census 2011 report.6 Sex ratio at birth was obtained from available report of civil registration system.

Case study

One maternity home from Pune which was established before 50 years and started IVF services since last 20 years was visited. In depth interview was taken of the owner who is Obstetrician and Gynecologist.

Data analysis

Factor analysis was carried out using Software Package for Social Sciences. Correlation coefficients between number of IVF centers and infertility prevalence, sex ratio, child sex ratio, sex ratio at birth, per capita income and female literacy rate, decadal growth rate, density of population, urbanization were calculated with 95% confidence intervals.
The district wise status of TFR in Maharashtra is given in Table 1. The state wise correlation coefficient calculated between proportion of infertility (IIPS, 2010) and TFR (Office of the Registrar, 2013) showed that there is no correlation (r=0.95; C.I. 95%=-0.36 to 0.52). The correlation coefficient between TFR and infertility in Maharashtra is given in the Table 3.

**Sex ratio**

Population sex ratio, child sex ratio and sex ratio at birth in Maharashtra is given in Table 1. The trends in population sex ratio, child sex ratio in Maharashtra are shown in Figure 1.
Table 2: IVF centers in Maharashtra state.

| S. No. | District     | Population  | Centers | Center/ lakh |
|--------|--------------|-------------|---------|--------------|
| 1      | Ahmednagar   | 4543159     | 12      | 0.264        |
| 2      | Akola        | 1813906     | 1       | 0.055        |
| 3      | Amravati     | 2888445     | 3       | 0.104        |
| 4      | Aurangabad   | 3701282     | 16      | 0.432        |
| 5      | Beed         | 1200334     | 2       | 0.077        |
| 6      | Bhandara     | 2585049     | 0       | 0            |
| 7      | Buldhana     | 2586258     | 0       | 0            |
| 8      | Chandrapur   | 2204307     | 1       | 0.045        |
| 9      | Dhule        | 2050862     | 2       | 0.097        |
| 10     | Gadchiroli   | 1072942     | 0       | 0            |
| 11     | Gondia       | 1322507     | 2       | 0.151        |
| 12     | Hingoli      | 1177345     | 0       | 0            |
| 13     | Jalgaon      | 4229917     | 3       | 0.071        |
| 14     | Jalna        | 1959046     | 1       | 0.051        |
| 15     | Kolhapur     | 3876001     | 8       | 0.206        |
| 16     | Latur        | 2454196     | 2       | 0.081        |
| 17     | Mumbai       | 3085411     | 120     | 3.889        |
| 18     | Mumbai (Suburban) | 9356962 | 83 | 0.887 |
| 19     | Nagpur       | 4653570     | 17      | 0.365        |
| 20     | Nanded       | 3361292     | 5       | 0.149        |
| 21     | Nandurbar    | 1648295     | 0       | 0            |
| 22     | Nashik       | 6107187     | 14      | 0.229        |
| 23     | Osmanabad    | 1657576     | 0       | 0            |
| 24     | Parbhani     | 1836086     | 0       | 0            |
| 25     | Pune         | 9429408     | 135     | 1.432        |
| 26     | Raigad       | 2634200     | 8       | 0.304        |
| 27     | Ratnagiri    | 1615069     | 0       | 0            |
| 28     | Sangli       | 2822143     | 6       | 0.213        |
| 29     | Satara       | 3003741     | 8       | 0.266        |
| 30     | Sindhudurg   | 849651      | 0       | 0            |
| 31     | Solapur      | 4317756     | 6       | 0.139        |
| 32     | Thane        | 11060148    | 70      | 0.632        |
| 33     | Wardha       | 1300774     | 0       | 0            |
| 34     | Washim       | 1197160     | 0       | 0            |
| 35     | Yavatmal     | 2772348     | 0       | 0            |
| **Maharashtra** | 112,37,4333 | 525 | 0.465 |

Table 3: Correlation coefficients between variables, Maharashtra state.

|                      | IVF/ Lakh | Density (C.I. 95%) | Growth rate (C.I. 95%) | F. Lit. (C.I. 95%) | Rs. NDDP (C.I. 95%) | % Urban. | Infertility | TFR | PSR | CSR | SRB |
|----------------------|-----------|---------------------|------------------------|-------------------|---------------------|----------|-------------|-----|-----|-----|-----|
|                      | 0.76**    | (0.52 to 0.99)      | -0.19 (-0.53 to 0.16)  | 0.44** (0.12 to 0.77) | 0.65** (0.46 to 0.96) | 1        | -0.33 (-0.60 to -0.33) | -0.32 (-0.59 to -0.05) | 0.02 (-0.32 to 0.81) | 0.64** (0.39 to 0.80) | 1    |
|                      |           |                     |                        |                   |                     |          |              |     |     |     |     |
| Continued.           |           |                     |                        |                   |                     |          |              |     |     |     |     |
The world is estimated to be 3 to 5 percent of States. This group includes a core group of couples, a large group of couples, and a larger group of couples. About 40-50% (3600-4500) couples avail IVF services per year. The success rate is about 30%. Sex ratio at birth is 961. There is no clinical preference to any sex excepting in known person having hemophilia. The cost of one cycle is about Rs. 1.5 lakh. Most of the couples do not return after failure of first cycle. Intra-cytoplasmic sperm injection is comparatively delicate a technique.

**Factor analysis**

The results of analysis are given Table 4. Eigen value more than one was the extraction criterion.

**In-depth interview**

Intrauterine insemination is the easiest technique and carried out by almost all obstetricians. About 40-50% (3600-4500) couples avail IVF services per year. The success rate is about 30%. Sex ratio at birth is 961. There is no clinical preference to any sex excepting in known person having hemophilia. The cost of one cycle is about Rs. 1.5 lakh. Most of the couples do not return after failure of first cycle. Intra-cytoplasmic sperm injection is comparatively delicate a technique.

### DISCUSSION

In social construct a mother is synonymous with being a woman, and hence the failure to become a mother constitutes not fully achieving the status of ‘woman’. Any deviation is seriously considered in the family and community. Epidemiologists and demographers may define infertility differently in context to age groups but agree that the age at parenting is increasing. Globally prevalence of primary infertility is higher than secondary infertility among infertile couples. Prevalence of infertility across regions of the world is estimated about 9-10% and about 50-56% seek care. Impaired fecundity among married women aged 15-44 was estimated to be about 12% in 2006-2010, in United States. This group includes a core group of couples, estimated to be 3 to 5 per cent, who are infertile due to unknown or preventable conditions. In rest of the cases

| IVF/ Lakh | Density | Growth rate | F. Lit. | Rs. NDDP | % Urban. | Infertility | TFR | PSR | CSR | SRB |
|-----------|---------|-------------|--------|----------|----------|-------------|-----|-----|-----|-----|
| % Urban. (C.I. 95%) | 0.74** (0.50 to 0.98) | 0.76** (0.57 to 0.87) | 0.06 (-0.28 to 0.39) | 0.60** (0.33 to 0.78) | 0.87** (0.76 to 0.93) | -0.05 (-0.13 to -0.38) | 0.05 (-0.28 to 0.36) | -0.05 (-0.30) | 0.03 (-0.31) | 0.06 (0.29) | -0.08 (-0.40 to 0.26) |
| Intrauterine insemination | 0.30 (0.51) | 0.29 (0.76) | 0.75 (0.28 to 0.72) | -0.21 (-0.30) | -0.05 (-0.30) | -0.05 (-0.30) | 0.03 (-0.31) | 0.06 (-0.28 to 0.36) | 0.06 (0.29) | -0.08 (-0.40 to 0.26) |
| TFR (C.I. 95%) | -0.34* (-0.67 to -0.25) | -0.42* (-0.66 to -0.27) | 0.57** (-0.29 to 0.76) | -0.56** (-0.21) | -0.51** (-0.21) | -0.37* (-0.21) | -0.04 (-0.30) | -0.04 (-0.30) | -0.04 (-0.30) | -0.04 (-0.30) |
| PSR (C.I. 95%) | -0.54** (-0.84 to -0.25) | -0.55** (-0.75 to -0.27) | -0.37* (-0.63 to -0.04) | -0.23 (-0.11) | -0.45** (-0.04) | -0.65** (-0.14) | -0.41 (-0.30) | -0.41 (-0.30) | -0.41 (-0.30) | -0.41 (-0.30) |
| CSR (C.I. 95%) | 0.05 (-0.30 to 0.41) | 0.09 (-0.25 to 0.41) | -0.30 (-0.58 to 0.04) | 0.11 (-0.23 to 0.43) | 0.10 (-0.24 to 0.42) | 0.11 (-0.23 to 0.43) | 0.13 (-0.21 to 0.43) | 0.13 (-0.21 to 0.43) | 0.13 (-0.21 to 0.43) | 0.13 (-0.21 to 0.43) |
| SRB (C.I. 95%) | 0.11 (-0.24 to 0.46) | 0.16 (-0.18 to 0.47) | -0.31 (-0.58 to 0.03) | 0.53** (0.24 to 0.73) | 0.26 (0.43) | 0.18 (-0.08 to 0.55) | -0.05 (-0.30) | -0.05 (-0.30) | -0.05 (-0.30) | -0.05 (-0.30) |

**Correlation is significant at 0.01 level (2-tailed). * Correlation is significant at 0.05 level (2-tailed).**

**Table 4: Rotated component Matrix**

| Component Matrix | Variable | 1 | 2 | 3 | 4 |
|------------------|----------|---|---|---|---|
| IVF/lakh         | 0.86     | 0.08 | 0.14 | -0.07 |
| Density          | 0.84     | 0.13 | 0.24 | -0.30 |
| Growth rate      | 0.03     | -0.41 | -0.76 | 0.20 |
| F. Literacy rate | 0.49     | 0.72 | 0.05 | 0.11 |
| Rs. NDDP         | 0.84     | 0.34 | -0.02 | 0.22 |
| % Urban.         | 0.93     | 0.19 | -0.05 | 0.06 |
| Infertility      | -0.07    | 0.01 | 0.10 | 0.91 |
| TFR              | -0.31    | -0.66 | -0.44 | -0.01 |
| PSR              | -0.75    | 0.16 | 0.50 | 0.16 |
| CSR              | 0.07     | -0.07 | 0.78 | 0.25 |
| SRB              | -0.01    | 0.89 | 0.03 | -0.05 |

Extraction method: Principal component analysis; Rotation method: Varimax with Kaiser normalization; aRotation converged in 6 iterations.
there is some reason for infertility. Hence any prevalence of infertility above this level suggests preventable or treatable causes. In fact couples from both groups consult IVF centers. Smoking and alcohol consumption are leading to as the nozoospermia. The trend in India shows that sperm motility is decreasing. Advancing parental age decreases fertility particularly by dropping semen volume. Similarly azoospermia is becoming common and in such cases IVF is a boon. DLHS 3 conducted in 2007-08, revealed that about 8.2% women in India have some infertility problem alike other studies. Few studies have shown very high prevalence of infertility in India. In one survey called ‘Helping Families’ which may not be scientifically robust study, 2,562 participant couples and 100 infertility experts from nine cities including Mumbai were interviewed. It was observed that as many as 46% of young couples in the 31-40 year-age group surveyed were found to be infertile. But even in a scientific study in from south India high prevalence (50%) was observed in one district but low in another district. In the Mysore study, the prevalence of primary infertility was 12.6 percent. Such studies have generated concern at various levels resulting in redressal strategies including at primary health care settings. The medical fraternity is also promptly responding to the problem and demand of treatment. As a result of increased demand In Vitro Fertilization centers are mushrooming and probably selecting sex. Hence, Indian Council of Medical Research (ICMR) has disseminated guidelines about ART but they seem to be ineffective in curbing the prevalent malpractices in the field of IVF. In most cases infertility is treated with drugs or surgery and many times these treatments are combined. In some cases, ARTs are provided, based on the results of investigations of couples and other factors like paying capacity. One of the threats in few techniques particularly with pre-implantation genetic diagnosis (PGD) is the strong probability of sex selection of the baby to be born which is illegal in India. Under PCPNDT Act, it is expected that all institutions capable of detecting, selecting sex need registration with the AA. But it is feared that sex selection is happening rampantly although few condemn the act. Many rich families tour outside India to conceive the child of desired sex. AA had only 129 registered centers (24.43% of listed under this study). This indicates that The Appropriate Authorities are ignoring registration of IVF centers. Indian Council of Medical Research maintains National Registry of ART Clinics and ART Banks in India. Indian Society for Assisted Reproduction has also a short list of registered centers with it. No additional center was identified from those lists. Unless there is strict regulation, it’s difficult to obtain accurate information about functioning IVF centers. The density of IVF centers worldwide may range from 0.01 to 3.6 centers per million population. Our observation lies in the estimated range.

Conceptually infertility and fertility seem to be two sides of the same coin. Increase in infertility may theoretically contribute to decline in total fertility. It does not seem to be true at national level in India, as the correlation coefficient is less than 0.1 (derived from state wise data of these two variable from DLHS 3 and Sample Registration System), and in Maharashtra also (r=0.04). Weak negative correlation was reported in analysis of available NFHS data and census. Cities have high infertility and low TFR clearly illustrating negative correlation. TFR seems to be perfect proxy of family planning services rather than infertility.

The investigators studied correlation between number of IVF centers per hundred thousand population and prevalence of infertility, assuming that the supply may be proportionate to the need. There was no correlation between number of IVF centers and infertility in the community. The non-existence of correlation may be due to various factors. The foremost reason may be incomplete information about number of IVF centers. But it seems unlikely in present context because the information was compiled from multiple sources. A functioning center is most likely to be recorded from one source at least. Even if such un-noticed center exists, the number of beneficiaries is not likely to be very high to influence statistics. The number of centers is the result of interactions of at least three factors; need, demand and economic sustainability. Any condition affecting any of these factors may result in sparse scatter and also the poor correlation. The finding suggests that rather than need, limited demand and sustainability are responsible for absence of correlation.

In the social context, the perception about gender discrimination in the form of sex selective elimination was realized in the state as well in country prominently after 1981 census and glaringly after 2001 census. The poor child sex ratio was highlighted by one of the eye-catching article revealing the likely number of “India's lost daughters: Abortion toll in millions”, published in The New York Times January 9, 2006. The article had reference to low male to female sex ratio at birth. This has been incriminated to many reasons. Investigators also tried to assess the effect of IVF centers on three sex ratio indicators; sex ratio at birth, child sex ratio and population sex ratio, in that order of likely relationship. The district wise compiled information is given in Table 1. Excepting population sex ratio other two indicators did not reveal any correlation. The most likely reason may be the number of couples who are undergoing desired sex selection is small and insufficient to influence child sex ratio or sex ratio at birth in the population. Population sex ratio has a negative correlation with number of IVF centers. The observation is difficult to explain as the IVF centers have emerged only in last two decades and average age of Indian population is about 25 years. Hence high IVF density is unlikely to cause of poor population sex ratio. The change in sex ratio at birth is an earliest indicator of recent happenings hence the effects of sex selection may be first reflected in the sex ratio at birth. Fetal sex determining clinics first appeared in North and
North-Western states and about a decade later in Southern States. The decline in CSR followed the same trend.\textsuperscript{4} Generally sex ratio at birth favors females in adverse socio-environmental conditions.\textsuperscript{33} The sex ratio at birth is also affected by the different IVF laboratory techniques but overall it favors males.\textsuperscript{34,37} It has been attributed to excess female embryo mortality ratio.\textsuperscript{33} Similar observation was also reported from Japan. Only in China there was no difference in sex ratio at birth between children born normally and after IVF.\textsuperscript{38} We also received similar response from the interview. There is no clinical preference to any sex excepting where father is having hemophilia. The couple and service provider may opt for female sex. Review of such reports and articles is certainly essential because the number of children born through IVF is increasing. It is estimated that about 1% births in USA are through assisted reproductive techniques.\textsuperscript{35} It observed that only 1% couple seek services. Out of that 25% avail IVF services. The estimate of couples availing IVF services from India is about 65000. Considering present birth rate of 17.1/1000 and success rate about 30%; only 22000 births (0.02%) are product of IVF.\textsuperscript{39} In future in India also the number will considerably increase. It is estimated that infertility, couples seeking treatment and availing IVF services will increase substantially.\textsuperscript{39} In the present study sex ratio at birth is not showing correlation with number of IVF centers. The higher numbers of IVF centers is probably the result of factors operating since long time and same factors are responsible for decline of population sex ratio. Another reason may be differential distribution of availability of techniques which are capable of sex selection among existing IVF centers. Hence the theoretical reason could be proportion of IVF centers conducting procedure of sex selection among overall number which may be different in various districts. But there is no logical and convincing reason to presume unequal proportion. It was also noted that among the districts having IVF centers, Beed district has lowest population and the district is having the lowest child sex ratio.

The cost of IVF is very high.\textsuperscript{25,26} The respondent in the in-depth interview stated that one cycle can cost about Rs.0.1 to 0.2 million ($ 1,600-2,000). High cost rather than un-awareness was one the affecting factors for IVF utilization; it may be prohibitively expensive.\textsuperscript{14,40} Admitting the un-affordability and low probability of receiving any financial support from insurance, even modified techniques also have been suggested.\textsuperscript{41} The reason for absence of expected correlation between IVF centers and various factors may also be un-affordability of the procedure. Authors calculated correlation between per capita income in the form of Net District Domestic Product and IVF centers. The correlation between these two variables is significant. There is also significant correlation between number of IVF centers and female literacy rate. The correlation is strongest between IVF centers and proportion of urbanization. It seems that factors related to urbanization, income and education which are the most typical indicators of socio-economic status are playing major role in determining the density of IVF centers in the districts. Table 3 reveals that percentage of urbanization is directly proportional to income and female literacy and it is indirectly proportional to population sex ratio. The unexplainable relationship between IVF centers and population sex ratio may be clarified by correlation between urbanization and population sex ratio. The two districts of Mumbai Municipal Corporation are 100% urban and lowest two in population sex ratio. Table 4 clearly explains the relationships between variables. The number of IVF centers, density, income, urbanization, and population sex ratio form a group of interrelated variables. Similarly female literacy, TFR, and SRB form second group. Growth rate and CSR constitute third group whereas infertility behaves independently. The relationship or the effect of IVF on SRB can be clearly judged by mandating the ART providers to maintain and submit the record of the SRB after IVF. The sex ratio at birth after IVF is presently not available. It is generally accepted that unethical medical practices are existing and there is a need to regulate IVF centers.\textsuperscript{42}

**Limitations**

The source is information is internet and other secondary sources hence the completeness is uncertain. Various types of procedures under assisted reproductive technology were not differentiated as the information was not available. Although in some districts there were no IVF centers we have calculated correlation coefficient. We carried out Principle Component Analysis for ten variables to define inter-related variables.

**CONCLUSION**

The number of IVF centers is not dependent on magnitude of infertility. It is not affecting sex ratio at birth or child sex ratio. The number of couples seeking sex selection may be meager and cost may a prohibitive factor. The density is proportional to urbanization, income, female literacy rate and is negatively related to population sex ratio. The density of IVF centers in the districts seems to be an outcome of extent of urbanization and this explains its correlation with other variables.

**ACKNOWLEDGEMENTS**

We thank Aruna Deshpande for helping in analysis.

**Funding:** No funding sources  
**Conflict of interest:** None declared  
**Ethical approval:** Not required

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Cite this article as: Doke PP, Mangal DK, Gulati A. Density of in-vitro fertilization centers and its correlation with socioeconomic factors in Maharashtra state, India. Int J Community Med Public Health 2019;6:342-50.