Call for Action: Expanding IVF treatment in India

July, 2015

EY
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Foreword

Having a progeny is an aspiration that is shared universally across the world, though the sensitivities may vary in degree depending on the cultural and personal context. In India, of course, this is a matter of very high sensitivity and an inability can contribute to serious psychological, emotional and social distress to the family, irrespective of economic, educational or religious background. It is, therefore, a matter of great concern and alarm to witness an increasing incidence of infertility cases, much of it owing to changing lifestyles and its consequent effect on physiological and psychological health and also owing to genetic propensity in the case of female.

The good news is that advancement in medical science has achieved much success in the treatment of infertility with an impressive increase in success rate over the years, but it is also a sad reality that the actual beneficiaries are only a very small percentage of the needy owing to issues of awareness, affordability, access and assurance. With a very large and increasing population in child bearing age group and no hope for alleviation in risk factors, it is imperative for the stakeholders of Indian healthcare to address this issue that has serious implications for the individual and the society.

This report is a humble attempt to understand the current context of infertility treatment in India with a focus on IVF treatment option, with its complexities and constraints and comment on the possible future scenario along with key imperatives for effective management of the disease in the short to medium term. It has been an enriching experience for the team to work on this report and sincerely hope it further strengthens the mood, motivation and mandate for infertility management leveraging the IVF treatment option in India.

Executive summary (1/3)

Context - High disease burden of infertility in India

- Infertility, the inability to conceive by natural means, is a medical condition **with high prevalence affecting nearly 10-15% of married couples in India**. Nearly 27.5 million couples who are actively seeking children suffer from infertility
- It is estimated that while female factor accounts for 40-50% of infertility among couples, infertility attributable to male factors is on the rise and constitutes 30-40% of infertility
- While there is a rise in the proportion of women in the reproductive age of 20-44years (14% increase estimated between 2010 to 2020) the increase is skewed towards those aged between 30-44 years (20% increase estimated between 2010 to 2020), who typically display lower fertility rates. This shifting demographic trend coupled with increasing contraceptive use and risk factor exposure is likely to drive further rise in the burden of infertility in India
- The key risk factors that are leading to high prevalence of infertility include-
  - **Lifestyle factors:** Increasing marital age, increasing number of working women, rising alcohol and tobacco consumption and rising levels of obesity
  - **Clinical factors:** Increasing prevalence of medical conditions such as poly-cystic ovarian syndrome (PCOS), endometrial tuberculosis, and sexually transmitted infections (STIs). Studies also suggest that South Asian women have a poor ovarian reserve compared to Caucasian women, and are likely to suffer from earlier onset of infertility and poorer outcomes from infertility treatment

Executive summary (2/3)

Treatment landscape - Highly under-penetrated market with significantly low treatment rates

- Assisted reproductive technology (ART), which includes *in-vitro* fertilisation (IVF), is used primarily for treatment of infertility. In spite of increasing demand for infertility treatment, **only 1% of infertile couples in India seek treatment**
- The low penetration of infertility treatment in India is attributable to:
  - **High cost of treatment - at INR 150,000 – 200,000 per IVF cycle,** which often requires multiple treatment cycles, is largely unaffordable to nearly 80% of the population
  - Paucity of skilled IVF specialists and embryologists in India, with only about 3-4% (700-1,000) of the pool of gynaecologists performing IVF procedures. There is an urgent need to address the skill gap and technical expertise required to provide high quality treatment towards improving outcomes and patient safety
  - Significant geographical skew in the distribution of infertility centers with **~55% of IVF cycles being performed in the top eight metro cities** coupled with a highly fragmented market is affecting access to quality treatment
  - Absence of a regulatory framework for quality management of ART centers and patient safety resulting in mushrooming of IVF clinics with poor treatment outcomes and quality of patient care
  - Low awareness of fertility problems among couples despite the high need for parenthood and the importance of social status associated with parenthood
- It is estimated that the addressable demand in the key metro cities of Delhi, Mumbai and Bangalore is 9 to 12 times higher than the current market for IVF treatment

Executive summary (3/3)

Outlook for the treatment landscape: IVF treatment market has the potential to grow by ~20% as barriers to treatment are progressively addressed

- IVF cycles are estimated to increase from an estimated 1,00,000 cycles currently to 2,60,000 cycles by 2020 driven by an increase in number of infertile couples seeking treatment. Key imperatives that will enable improved penetration of effective treatment in the short to medium term are as follows:

Key themes	Future imperatives for assisted reproductive treatment delivery
A **Improve outcomes**	1. **Institution of a regulatory framework** at a national level for monitoring and surveillance of ART procedures
B **Expand care**	2. **Training and skill building of ART personnel (IVF specialists, embryologists, gynaecologists)** to improve treatment delivery and improve outcomes 3. **Improving financing options for ART** through expansion of government and private insurance schemes to include infertility treatment 4. **Adoption of innovative IVF treatments** to reduce cost of treatment
C **Build patient confidence**	5. **National educational programs for increasing the awareness** of the population regarding infertility causes, prevention and treatment 6. **Inclusion of infertility prevention in the national reproductive care program** and increasing awareness about the causes of infertility

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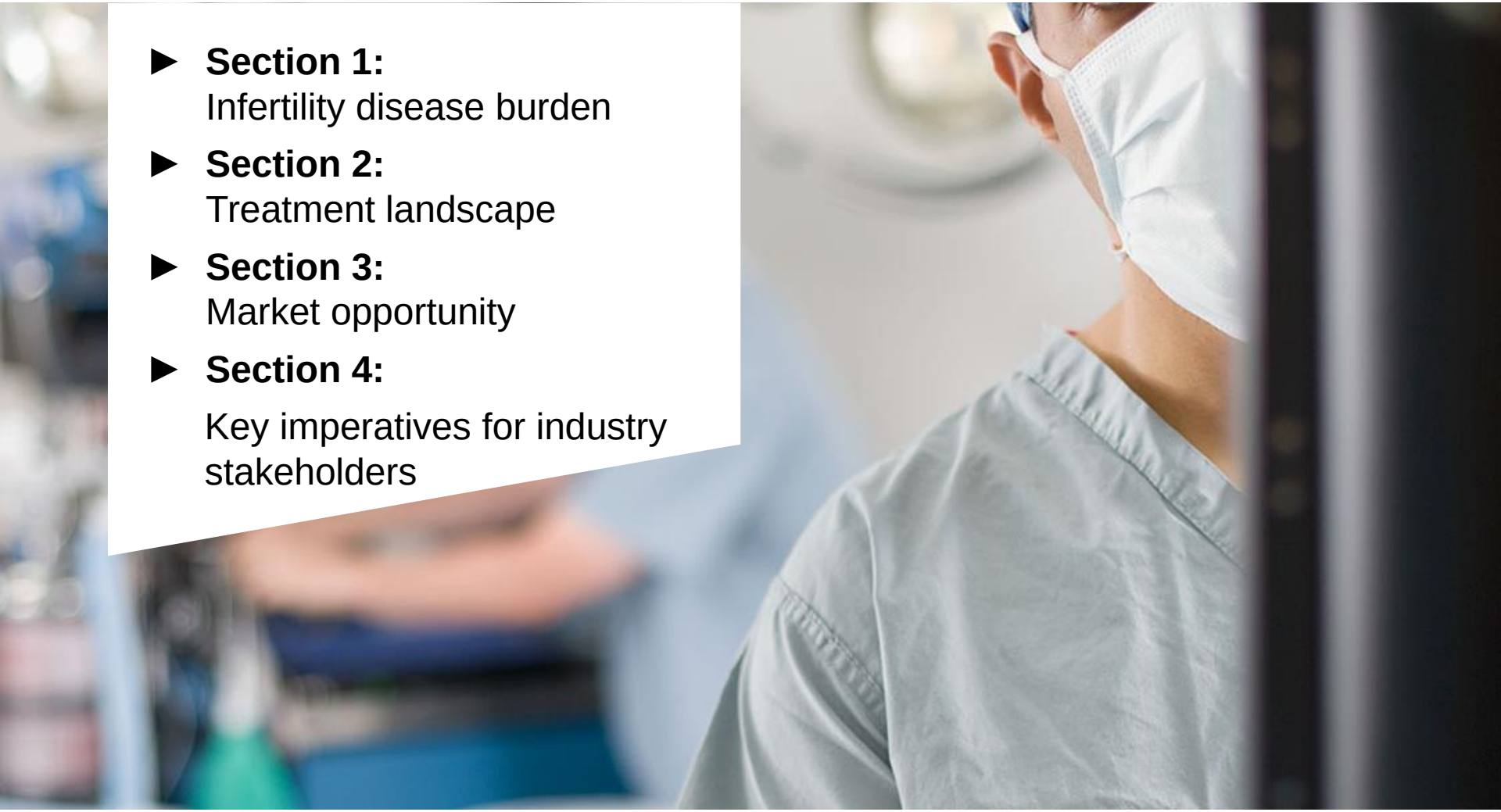

Section 1: Infertility disease burden

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1. India faces a high burden of infertility, with 22 to 33 million couples in the reproductive age suffering from lifetime infertility

2. Female factor accounts for 40%-50% of infertility among infertile couples, while male factor, which is on the rise in India, accounts for 30%-40%

3. India is exhibiting a deterioration of risk factors that are key drivers for the high burden of infertility

Section 1: Infertility disease burden

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India faces a high burden of infertility, with 22 to 33 million couples in the reproductive age suffering from lifetime infertility

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Female factor accounts for 40%-50% of infertility among infertile couples, while male factor, which is on the rise in India, accounts for 30%-40%

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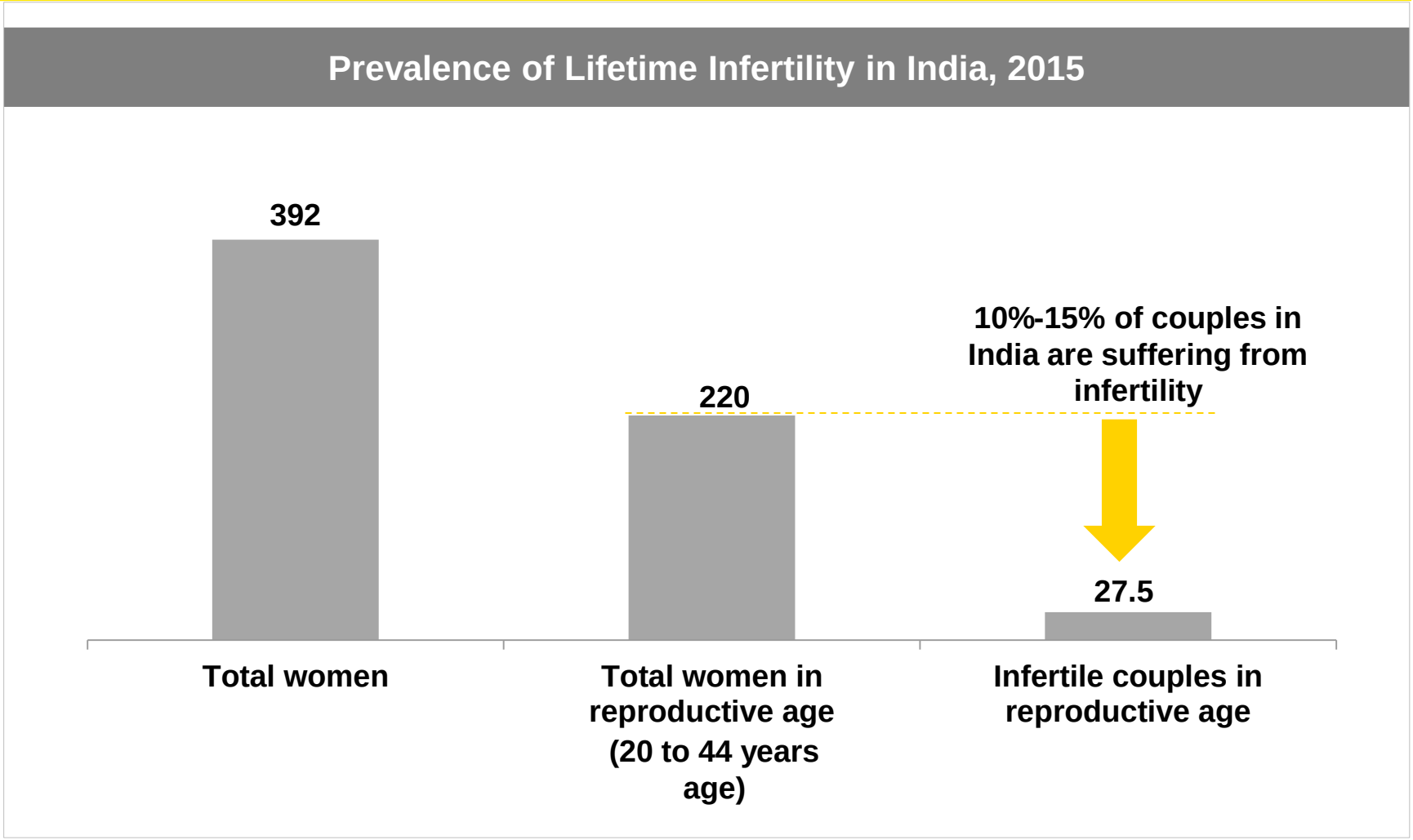
India is exhibiting a deterioration of risk factors that are key drivers for the high burden of infertility

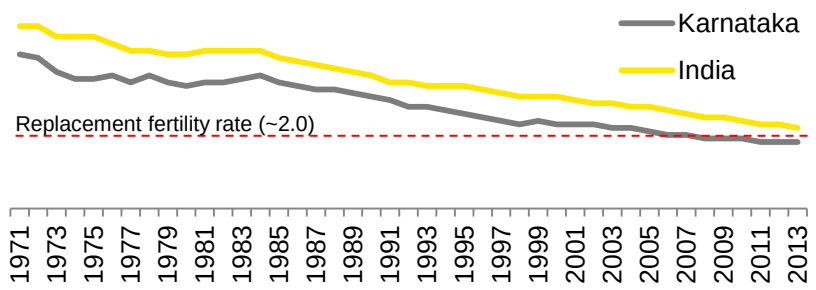
India is witnessing a high burden of infertility, with an estimated 22 to 33 million couples in the reproductive age suffering from lifetime infertility in 2015



Source: Primary interviews with KOLs and leading pharmaceutical companies, Census of India 2001 and 2011, EY analysis

Over the last few decades, a decline in fertility rates has been observed due to higher prevalence of contraceptive use and increasing effective age at marriage

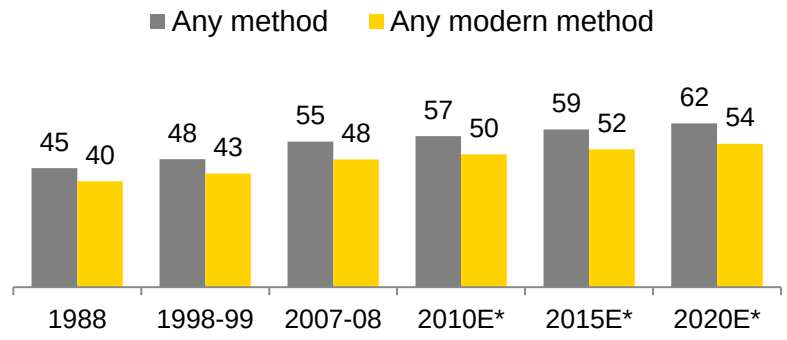
Total fertility rate
(Avg. number of births per woman, 15-49 years)



Source: Sample registration system, Statistical report (Registrar General, India)

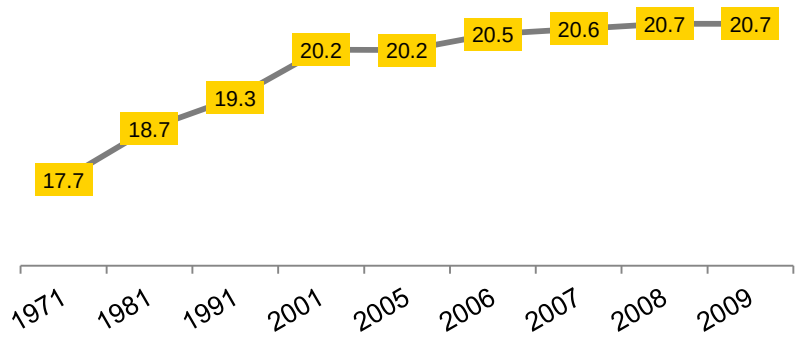
- Total fertility rate (TFR), the average number of children that would be born to a woman if she experiences the current fertility pattern throughout her reproductive span (15-49 years), has seen a steady decline from 3.9 in the 1990s to 2.3 in 2013.[1-3]
- The key factors that have contributed to this decline include:
  - Increasing prevalence of contraceptive use from 45% in 1988 to ~59% in 2015, which is expected to increase to ~62% by 2020[4]
  - Rising effective age at marriage, from 17.7 years in 1971 to 20.7 years in 2009[1,4,6]

Percentage of contraceptive prevalence
(both sexes, 15-49 years)



Source: Estimates and Projections of Family Planning Indicators 2014, United Nations Population Division

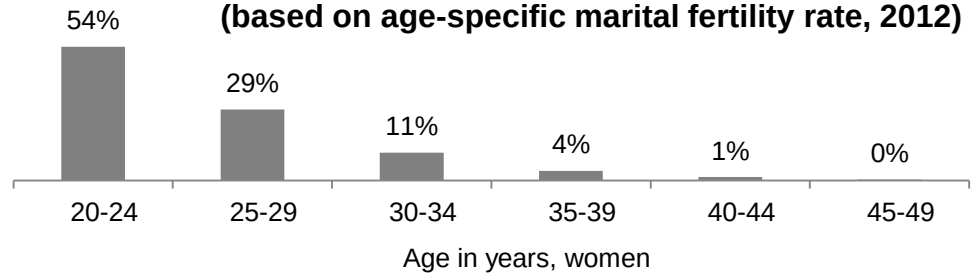
Effective age of women at marriage (years)



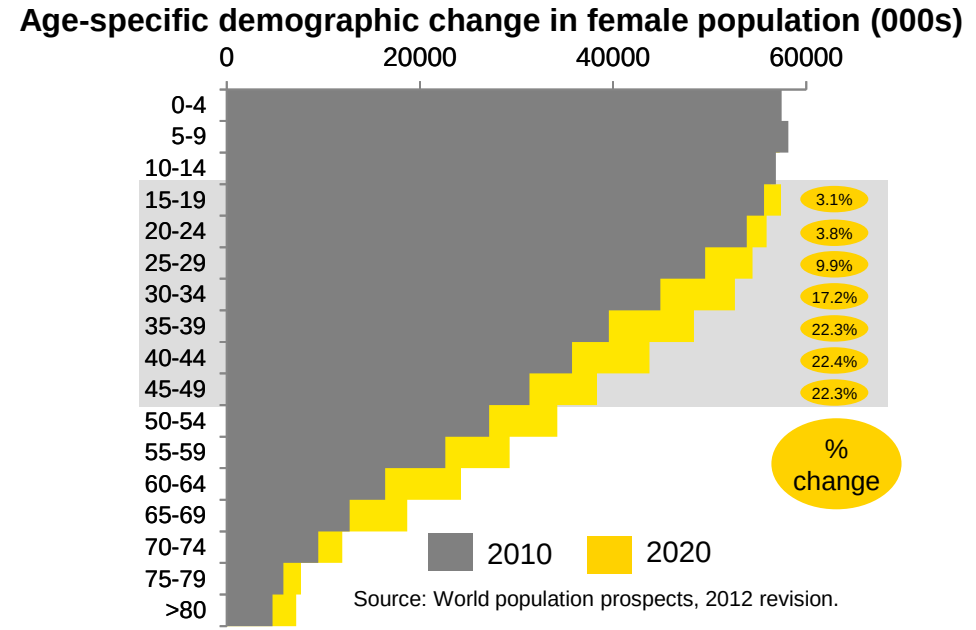
Source: World Fertility Report 2012-Country profiles, DHFS-3, Sample registration survey 2012

By 2020, an increase in the proportion of women in the reproductive age (20-44 years), coupled with a skew towards those aged between 30-44 years, is likely to result in an increase in infertility prevalence

- In 2012, ~83% of live births occurred among married women in the age-group between 20-29.[1]
  - Fertility rates in women aged 30-49 are significantly lower than that of women aged 20-29 years
- Demographic changes in the population are forecast to increase the percentage of women in the reproductive age (20-44 years) by ~14% between 2010 to 2020.[8,9]
  - The increase in the proportion of women is skewed towards those aged 30-44 years, and is forecast to increase by ~20% between 2010 to 2020. This shift is likely to increase the burden of infertility in India by 2020
- Assuming the marital rate in 2020 is similar to current rate, the number of couples is forecast to increase from *220 million* in 2015 to *244 million* by 2020.[8-10]



Source: Sample registration survey 2012, EY analysis



Source: World population prospects, 2012 revision.

Section 1: Infertility disease burden

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India faces a high burden of infertility, with 22 to 33 million couples in the reproductive age suffering from lifetime infertility

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Female factor accounts for 40%-50% of infertility among infertile couples, while male factor, which is on the rise in India, accounts for 30%-40%

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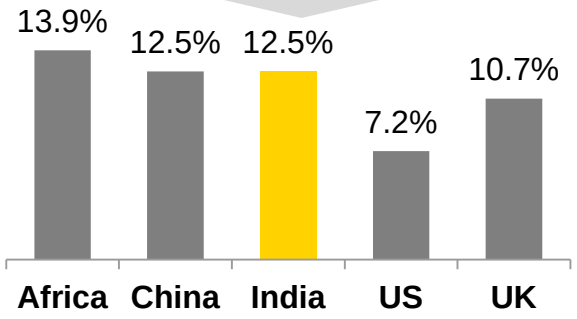
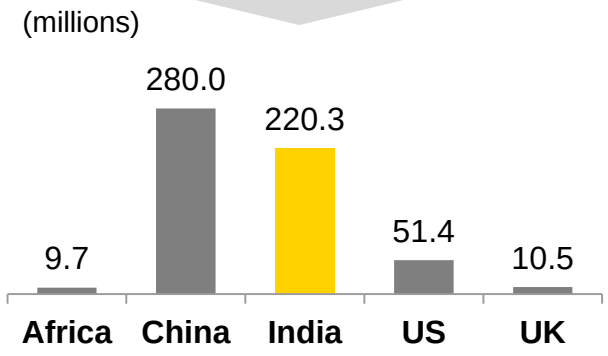
India is exhibiting a deterioration of risk factors that are key drivers for the high burden of infertility

Although the current prevalence of infertility in India is comparable to its peers, a skewed demographic profile towards a younger population and an increasing risk factor exposure is contributing to rising infertility

Prevalence of infertility in couples actively attempting reproduction, 2012[11-14]



Total women in reproductive age (20-44 years), 2015[10]

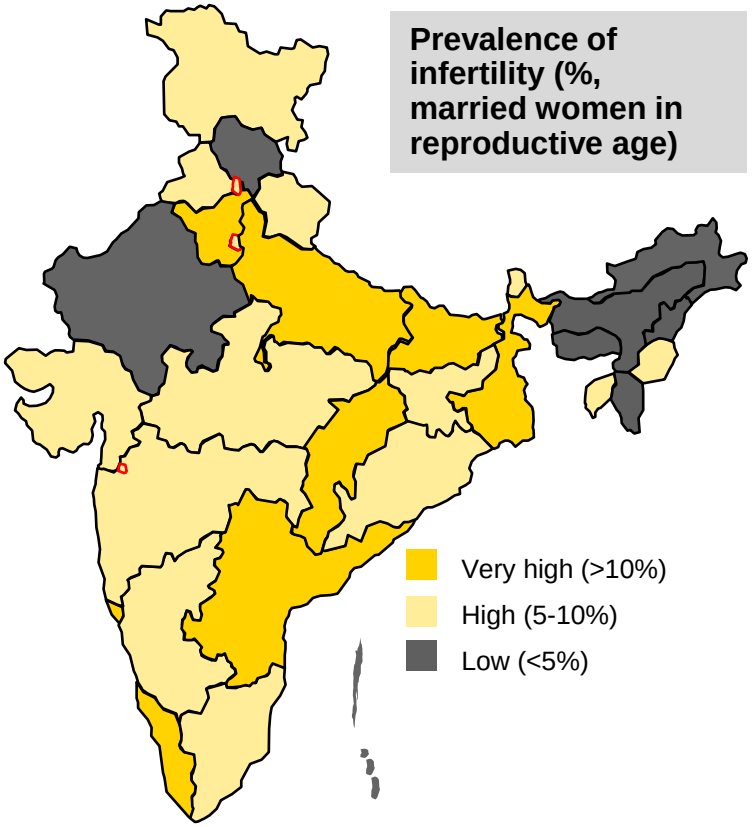


Source: Mascarenhas et al. 2012, 2013; Census of India 2011

Risk factors leading to high prevalence of infertility

Polycystic Ovarian Syndrome (PCOS)	▸ Studies have reported prevalence rates of PCOS in Indian women ranging from 3.7% to 22.5%, which is at par with the mean global prevalence rate of 5% to 10%[15-20]
Endometrial Tuberculosis	▸ Prevalence of genital TB (a risk factor that causes tubal blockage and endometrial damage resulting in infertility) is estimated to be 18% among infertile women in reproductive age in India vis-à-vis 1% in the USA (multiple studies 1997-2008)[21]
Obesity	▸ Prevalence of obesity in men (+18 years, BMI ≥25kg/m^2) has increased from 17.3% (2010) to 19.5% (2014), and from 10.6% (1998) to 24.7% (2014), in women[22,62]
Tobacco use	▸ The WHO 2015 estimate of prevalence of tobacco use in India (17%) is approaching the levels of use in the UK (21%) and the US (19%)[23,24]
Alcohol consumption	▸ Overall alcohol per capita consumption (adults +15 years) increased from 3.6 liters in 2005 to 4.3 liters in 2010, and is estimated to be 4.7 liters by 2020[25]
Sexually transmitted infections (STI)	▸ Prevalence of lab-diagnosed STIs was reported to be between 7% to 34% based on a large meta-analysis of 41 studies carried out between 2000-2012[26]

While prevalence varies across states, intensification of lifestyle risk factors is expected to result in an increasing prevalence of female infertility



Female factor has been attributed to 40%-50% of infertility among couples

Source: NHFS -3 survey, 2006; DLHS survey 2007-08; Census of India 2001 and 2011; GATS 2009-10; Sample registration survey 2002 and 2012; Primary sources

Key states		Lifestyle factors[1,2,28,29]			
	TFR	% BMI ≥25kg/m²	Mean age of marriage	Working women	Tobacco use
Haryana	2.17 ↓	17.4%	19.7	3.6% ↓	5.6%
Uttar Pradesh	2.95 ↓	9.2%	18.4	1.2% ↑	16.9%
Bihar	2.87 ↓	4.6%	17.6	0.7% ↓	40.1%
West Bengal	1.59 ↓	11.4%	18.5	0.1% ↓	19.3%
Chhattisgarh	1.78	5.6%	18.9	1.5% ↓	41.6%
Andhra Pradesh	1.73 ↓	15.6%	19.0	2.1% ↑	18.8%
Goa	1.77 ↓	20.2%	25.1	1.7% ↑	4.1%
Kerala	1.73 ↓	28.1%	22.1	1.5% ↑	8.5%
J&K	1.63 ↓	16.7%	22.2	2.3% ↓	10.3%
Punjab	1.88 ↓	29.9%	21.3	3.3% ↓	0.5%
Delhi	1.80 ↓	26.4%	21.6	1.2% ↑	3.7%
Gujarat	1.92 ↓	16.7%	19.6	1.5% ↓	11.3%
Madhya Pradesh	2.58 ↓	7.6%	18.5	0.7% ↑	18.9%
Maharashtra	1.91 ↓	14.5%	19.3	3.2% ↑	18.9%
Tamil Nadu	1.70 ↓	20.9%	21.3	0.9% ↑	8.4%
Karnataka	1.89 ↓	15.3%	19.8	2.3% ↑	16.3%

TFR - Total fertility rate (15-49 years)

Prevalence of medical factors that cause female infertility, such as PCOS, is high and increasing within certain Indian states

1

PCOS

Characterized by:[30]

- Infertility
- Insulin resistance
- Obesity
- Ovarian cysts
- Metabolic abnormalities
- Acne
- Hirsutism
- Skin pigmentation

- Global prevalence of PCOS in women of reproductive age is between 5-10%[30]
- While there is limited data on the prevalence of PCOS in India, few studies have demonstrated the **prevalence rates to range from 3.7% to 22.5%**[15-20]
  - A hospital-based study in South India demonstrated the PCOS prevalence of 11% in rural v. 25% in urban adolescent girls, aged 12-19 years[17]
- In a study on Indian subcontinent women residing in the UK, PCOS prevalence was reported to be as high as 52%[16]

Region	Sample size	Mean age (range/SD)	Prevalence[15,17,18,20] %	Year of study
Pondicherry, TN	238	20.5 (19-25)	11.76	2014
Mumbai, MH	**687**	**18.15 (±2.4)**	**22.50 (10.7)**	**2014**
Vellore, TN	**126**	**16 (12-19)**	**18.00**	**2015**
Anatapur, AP	460	15 -18	9.13	2011
Lucknow, UP	1520	18.96 (±1.73)	3.70	2012

Racial differences and ethnicity seem to have a significant role in fertility and outcomes after assisted reproductive technology (ART) treatment

2

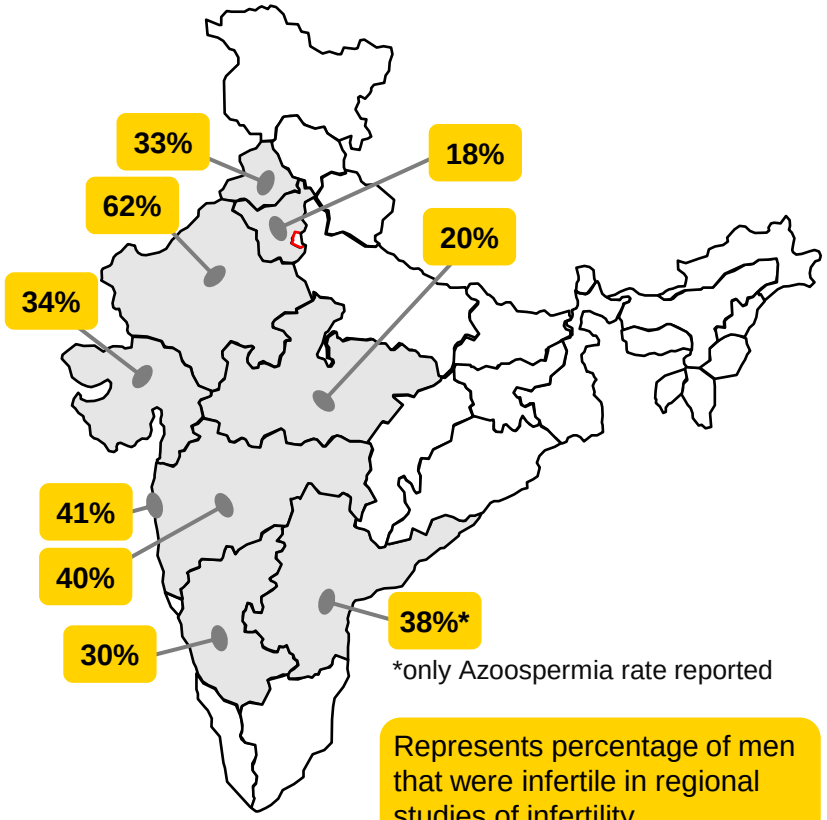
Racial factors and ethnicity

Ethnicity has been shown to adversely affect ART outcomes in Asian women, resulting in lower clinical pregnancy, lower live birth rates and higher miscarriage rates

- A study involving Spanish (n=229) and Indian women (n=236), in 2014, reported the following:[31]
  - Indian women had lower Anti-Mullerian Hormone levels (AMH), higher Follicular Stimulating Hormone (FSH) levels, and a longer duration of infertility despite being significantly younger
  - **Indian women had an earlier onset of decline in antral follicular counts (AFC),** nearly 6.3 years earlier than the Spanish cohort
  - **AFC in Indian women was lower by a factor of 2.3** times compared with the Spanish cohort
- Despite younger age and similar embryo quality, **Indian-American women had a significantly lower live birth rate following IVF than white American women (24% v. 41% respectively)** suggesting poorer ovarian reserve[32]
- In another study (2014), live birth rate in **South-East Asian women was 38%, in contrast to 43.8% in white European populations** implicating genetic factors affecting fertility[33]
- Mahmud *et al*. (1995) reported a **higher number of discontinued cycles (22.7% v. 9.1%) and lower live birth rate** during IVF, among South Asian women (n = 44) compared with Caucasians (n=88) [34]

Lower IVF success rates, longer duration of infertility, lower AFC and AMH levels in Indian and South Asian women, occurring at a younger age compared to Caucasians, suggests poor ovarian reserve and an earlier onset of infertility

Intensification of lifestyle risk factors among Indian men is expected to significantly increase the prevalence of male infertility, with some regional estimates varying between 20%-30%



*only Azoospermia rate reported

Represents percentage of men that were infertile in regional studies of infertility

Male factor infertility has been attributed to 30%-40% of infertility amongst infertile couples[35-39]

Source: NHFS -3 survey, 2006; DLHS survey 2007-08; Census of India 2001 and 2011; GATS 2009-10; Sample registration survey 2002 & 2012; Primary sources Refer **Annexure 1** for details of male infertility studies

Key States	Lifestyle factors[1,2,28,29]			
	BMI ≥25kg/ m^2	% male (>15-49 years) consuming alcohol	Self-reported STI (men >15-49 years)	Tobacco use (men, >15-49 years)
Haryana	10.8%	27.7	1.6%	39.4%
Uttar Pradesh	7.3%	25.5	4.1%	48.8%
Bihar	6.3%	54.9	4.7%	66.2%
West Bengal	5.5%	54.0	11.3%	52.3%
Chhattisgarh	4.9%	52.5	2.7%	63.9%
Andhra Pradesh	13.6%	47.2	1.7%	39.7%
Rajasthan	8.9%	19.1	7.0%	60.4
Kerala	17.8%	55.8	3.5%	35.5%
J&K	6.2%	12.5	4.3%	41.6%
Punjab	22.2%	45.4	1.7%	21.6%
Delhi	16.8%	55.1	4.5%	40.9%
Gujarat	11.3%	16.0	6.3%	46.2%
Madhya Pradesh	4.3%	50.8	6.1%	58.5%
Maharashtra	11.9%	24.0	2.6%	42.5%
Tamil Nadu	14.5%	41.5	1.1%	24.0%
Karnataka	10.9%	28.5	0.5%	39.8%

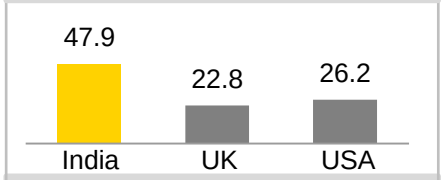
Rising levels of tobacco and alcohol use are risk factors that are strongly associated with male infertility

1 Tobacco consumption

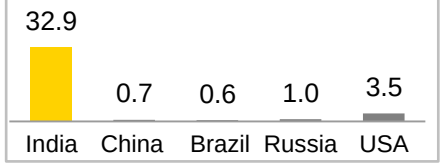
Tobacco use affects spermatogenesis and has been linked with low sperm count, abnormal morphology and altered motility due to oxidative damage. Higher estrogen and lower testosterone levels have been reported with tobacco use[40,41]

- Prevalence of smoking among men (>15 years of age) in India was estimated at 47.9% vis-à-vis 22.8% in the UK and 26.2% in the US, in 2010[22-24]
- Additionally, India had the highest percentage prevalence of smokeless tobacco use in men (>15 years of age) among 14 GATS countries at 32.9 % (<1% in China; 3.5% in the US), in 2010[29]

Any tobacco use, male +15 years (% prevalence)



Smokeless tobacco, male +15 years (% prevalence)



Source: WHO Global NCD report, 2014, Giovino et al, 2012, WHO GATS 2009-2010 report, EY analysis

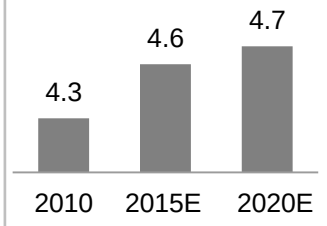
2 Alcohol consumption

FSH - Follicular Stimulating Hormone,
LH - Luteinizing Hormone,
E2 - Estradiol

Alcohol consumption has been shown to increase leukocyte counts in seminal fluid, reduce seminal quality and result in significantly high FSH, LH, and E2, and low testosterone levels[40]

- Significantly increased FSH, LH, and E2, and low testosterone levels were observed in chronic alcoholics (n=66) who had no tobacco or drug exposure[42]
  - Semen volume, sperm count and motility were also significantly decreased in these men
- India had the third-highest increase in alcohol per capita (APC) consumption (adults >15 years of age) between 1992 to 2012, among 34 OECD countries and its key partners[43]
- WHO estimates average per capita consumption of alcohol in India to increase from 4.3 liters in 2010 to 4.7 liters in 2020[25]

APC (liters), India



Source: WHO Global status report on alcohol and health, 2014

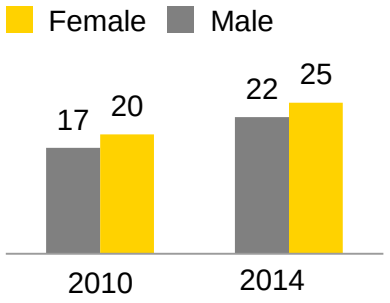
Increasing levels of obesity and high prevalence of sexually-transmitted infections in the Indian population have been linked with increased infertility in both genders

3 Obesity

High BMI has been associated with infertility due to low semen quality, hormonal imbalances leading to lower testosterone, inhibin B levels and increased plasma oestrogen in men, and low levels of AMH in women[40,44]

- India has the third-highest number of obese individuals in the world, after the US and China, with an estimated **198 million** people over 18 years having a BMI ≥25kg/m^2 in 2014[45]
- Prevalence of BMI ≥25 kg/m^2 in males (+18 years) increased from 17% in 2010 to 22% in 2014 and from 10.6% in 1998, to 20% in 2010, and to ~25% in 2014, in females[22]
- A significantly higher prevalence of BMI ≥25 kg/m^2 in men and women (+18 years), 41.1 & 45.2% respectively, has been reported in a study (n=6198 ; men=3426; women = 2772) carried out in 11 medium-sized Indian cities[46]

BMI ≥25 kg/m^2 in males and females +18 years (% prevalence)



Source: WHO Global NCD report 2014

4 Sexually transmitted infections (STI)

Infertility due to STIs such as gonorrhea, syphilis, chlamydia and trichomoniansis has been attributed to pelvic inflammatory disease and tubal infertility in women, and poor semen quality in men.

- A meta-analysis of 41 papers published between 2000-2012 reported the prevalence of STIs to be 7%-34% in studies where laboratory methods were used to confirm clinical diagnosis of STI in self-reported cases[26]
- Higher prevalence rates of STI symptoms have been reported in regional studies[2,28]
  - Around 42% was reported in a study in rural and urban Delhi (n=215), with 73% of urban cases, and only 45.6% of rural cases seeking treatment[47]
  - A 2013 study reported a 17.3% prevalence of STI-related symptoms in urban women aged 15-44 years (n=260)[48]

Section 2: Treatment landscape

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1. India faces a serious challenge of high infertility rate, coupled with significantly low treatment rates

2. The IVF market is highly under-penetrated with addressable demand being 9 to 12 times higher than the current market, even in large metro cities

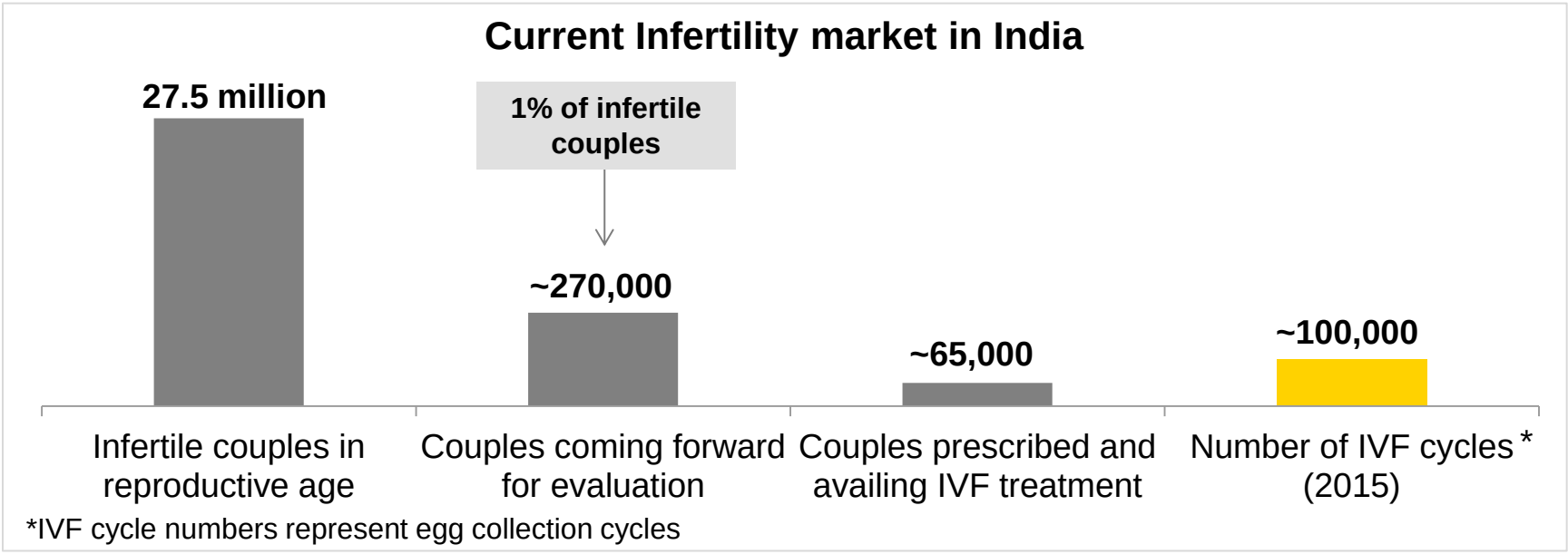
3. Affordability, access, awareness and assurance are the key barriers that limit the adequacy of diagnosis and treatment in India

1 **India faces a serious challenge of high infertility rate, coupled with significantly low treatment rates**

2 The IVF market is highly under-penetrated with addressable demand being 9 to 12 times higher than the current market, even in large metro cities

3 Affordability, access, awareness and assurance are the key barriers that limit the adequacy of diagnosis and treatment in India

The current treatment* market for infertility is estimated at ~100,000 *in-vitro* fertilization (IVF) cycles….



Basis

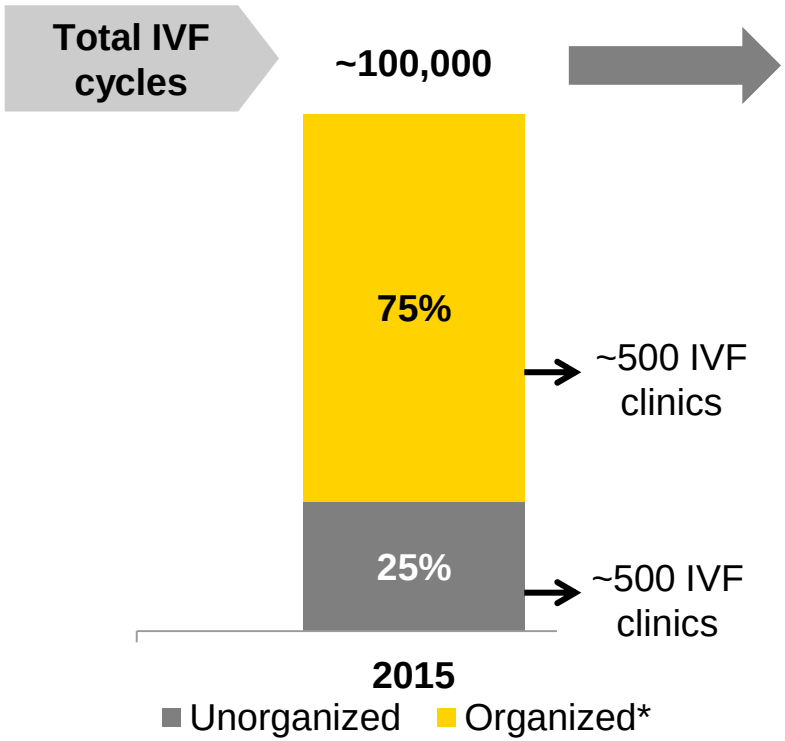
- **10%-15% prevalence** of infertility in India, in 2015[11,12,14]
- **20%-25%** of the total couples registering at an infertility center undergo IVF
- This **represents 1% of the total infertile couples seeking** infertility treatment
- Assuming **1.5 IVF cycles** per couple
- Estimates of market size based on **primary interviews with KOLs, pharmaceutical companies and clinicians**

*The primary assisted reproduction treatment options for infertility include intrauterine insemination (IUI) and in-vitro fertilization (IVF). Surgical procedures may also be required in certain patients. Certain assisted reproduction procedures may require a male (sperm) or female (egg) donor. Some cases may also require a gestational surrogate. Fertility preservation is an emerging field, and due to the rising incidence of cancer in patients of reproductive age, there is an increase in cryo-preservation of egg or fertilized embryo in cancer patients prior to commencement of cytotoxic treatment.

Source: Primary interviews with KOLs, leading pharmaceutical companies, IVF specialists, data analysis of a leading IVF center, EY analysis

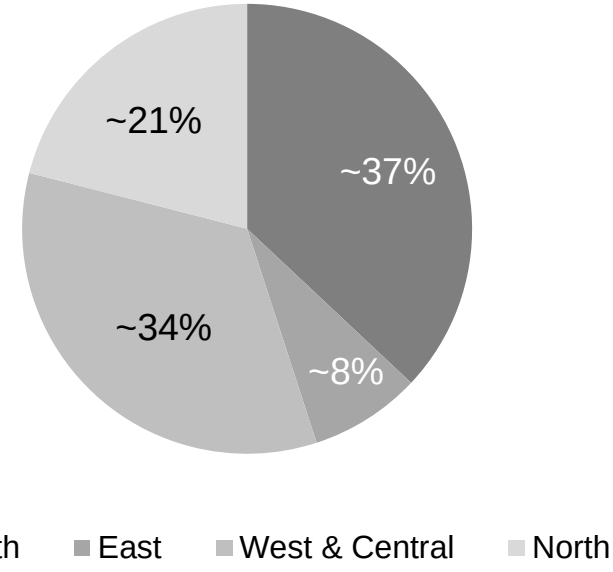
…being performed by ~1,000 centers, of which 50% are organized players who contribute three-fourths of the total number of cycles

Infertility treatment market in India



***Organized market**: includes corporate chains and stand-alone clinics of well known IVF specialists

Geographical distribution of IVF cycles performed



- **75% of the market is captured by the top 500 clinics, comprising of a few corporate chains and leading private clinics, as of 2015**[49]

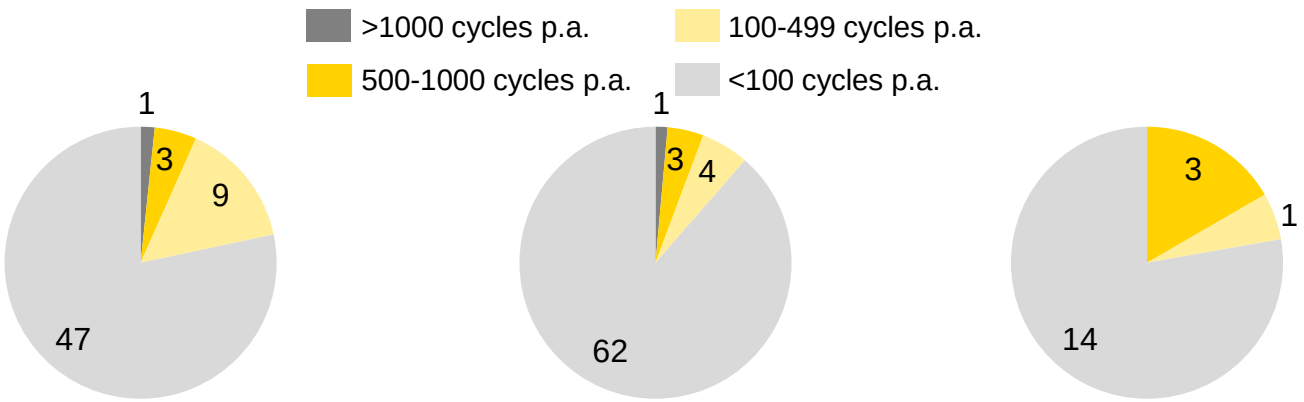
Source: Primary interviews with KOLs and leading pharmaceutical companies, EY analysis

The infertility market is highly fragmented with very few players performing more than 1000 cycles per annum across major metros (1/2)

- IVF centers may be broadly dissected into four groups performing >1000, 500-1000, 100-499 and <100 cycles per annum. The market is fragmented with <2-4 centers performing >1000 cycles per annum, and <5-7 centers performing 500-1000 cycles per annum, in each of the key metro cities respectively.

	Delhi- NCR	Mumbai	Hyderabad
# of doctors	90	100	26
# of centers	60	70	18
# of IVF cycles p.a.	11,800-12,000	8,800-10,000	6,450-6,650

Segmentation of centers based on number of cycles performed



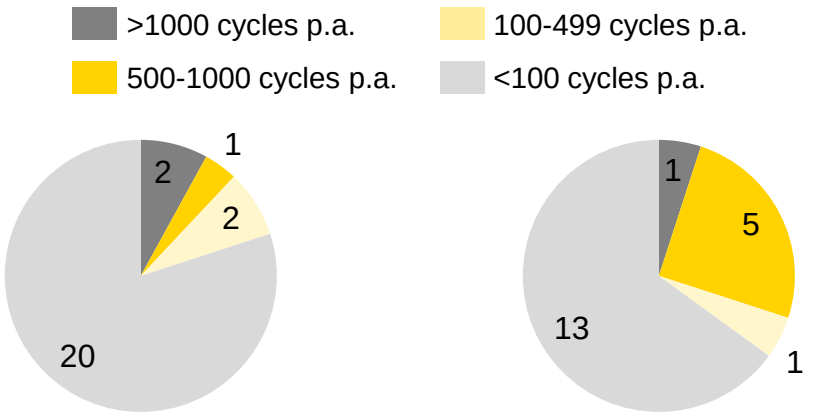
Data available for top centers performing high number of cycles only; centers with unavailable data were assumed to perform <100 cycles p.a.
Source: Primary interviews with KOLs and leading pharmaceutical companies, EY analysis

The infertility market is highly fragmented with very few players performing more than 1000 cycles per annum across major metros (2/2)

- IVF centers may be broadly dissected into four groups performing >1000, 500-1000, 100-499 and <100 cycles per annum. The market is fragmented with <2-4 centers performing >1000 cycles per annum, and <5-7 centers performing 500-1000 cycles per annum, in each of the key metro cities respectively.

	Chennai	Bangalore
# of doctors	30	30
# of centers	25	20
# of IVF cycles p.a.	7,700-7,800	4,100-4,250

Segmentation of centers based on number of cycles performed



Data available for top centers performing high number of cycles only; centers with unavailable data were assumed to perform <100 cycles p.a.
Source: Primary interviews with KOLs and leading pharmaceutical companies, EY analysis

Presence of very few chains further indicates the fragmented nature of the supply situation

	Leading chain across India - 1	Leading chain across India - 2	Leading chain across India - 3	Leading center in Bangalore	Leading center in Chennai
Geographic footprint	**18 centers** across North, West and South India	**14 centers** in South, Central and West India	**9 centers** across India	**3 centers** at Bangalore	**1 center** at Chennai
Estimated IVF cycles per annum	**1,500-1,800**	**1,600-1,800**	**4,000-4,500**	**1,200-1,400**	**1,100-1,200**

Source: Primary interviews with KOLs and leading pharmaceutical companies, EY analysis

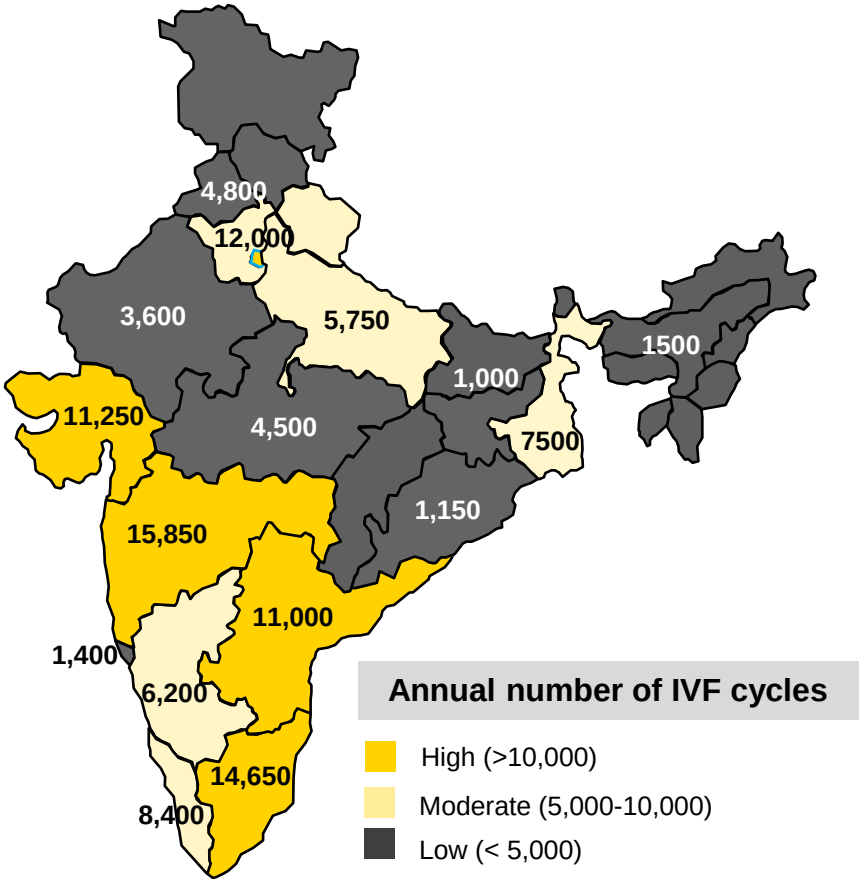
Please note the above list is indicative and not exhaustive

Key approaches by leading chains for driving growth:

- Strong focus on referral marketing
- Collaborating with young IVF specialists/gynecology department of other hospitals, for training of good gynecologists
- Educational marketing campaigns
- International protocols/state of the art technology

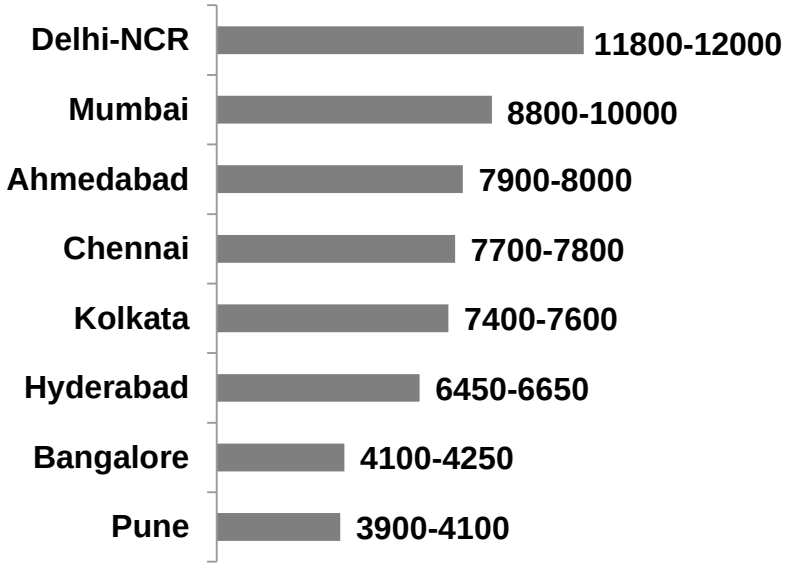
There is a significant geographic skew in access, with more than 50% of the cycles performed across the top eight metros

State-wise distribution of the number of IVF cycles performed per annum



Source: Primary interviews with KOLs and leading pharmaceutical companies

Market in key Indian metros based on the number of IVF cycles per annum

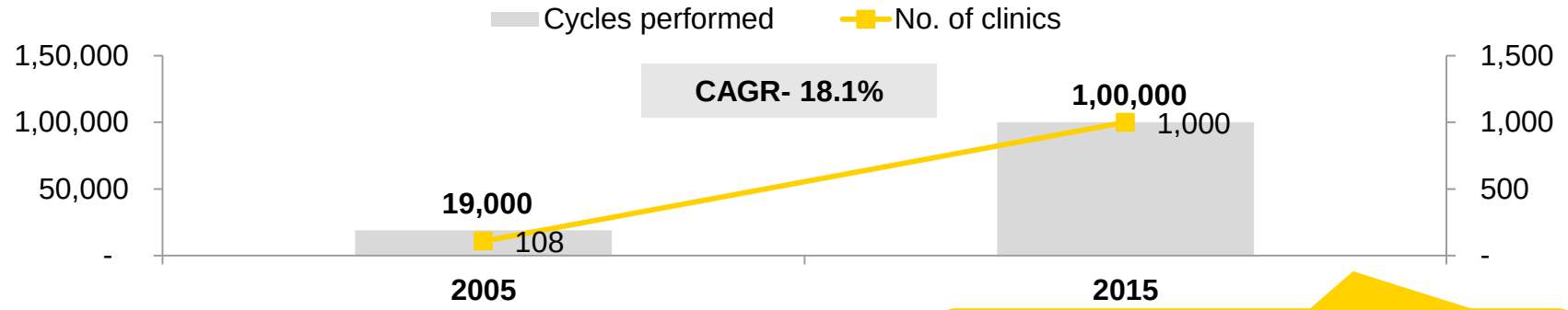


India performs ~ 100,000 IVF cycles annually, with a significant concentration of IVF cycles being performed in metro cities[49]

- The top eight metro cities account for **around 55%** of IVF cycles performed p.a.[49]
- Poor geographic distribution of infertility treatment facilities highlights the difficulty in accessing treatment options faced by patients

The IVF market in India is growing at a robust CAGR of ~18%, but the penetration is still very low compared to other global markets

Growth of IVF market in India



IVF Market penetration[50-53]

Country (reported year)	Women aged 20-44 years (millions)	IVF cycles	Cycles per million infertile women aged 20-44 years
Japan (2010)	1.8	242,000	134,444
UK (2013)	1.1	64,600	58,727
Germany (2010)	1.3	67,600	50,884
US* (2013)	3.8	174,960	46,042
China (2014)	30.8	200,000	6,494
India (2015)	35.9	100,000	2,786

*Reported by society for assisted reproductive technologies (SART) clinical summary report
Source: Primary interviews with KOLs and leading pharmaceutical companies, Census 2001,2011, WHO World population prospects, 2012 Revision, EY analysis

Additionally, ~30,000 frozen embryo transfers performed in 2015[40]

- The IVF market in India has grown at a fast pace, with IVF cycles growing at 18.1% CAGR.[49] Refer **Annexure 2** for the growth of IVF cycles in key international geographies
- The penetration of the IVF market is significantly low in India compared to other countries, with only **~2800 cycles/million infertile women in the reproductive age (20-44 years),** indicating further potential for growth[49]

Section 2: Treatment landscape

1

India faces a serious challenge of high infertility rate, coupled with significantly low treatment rates

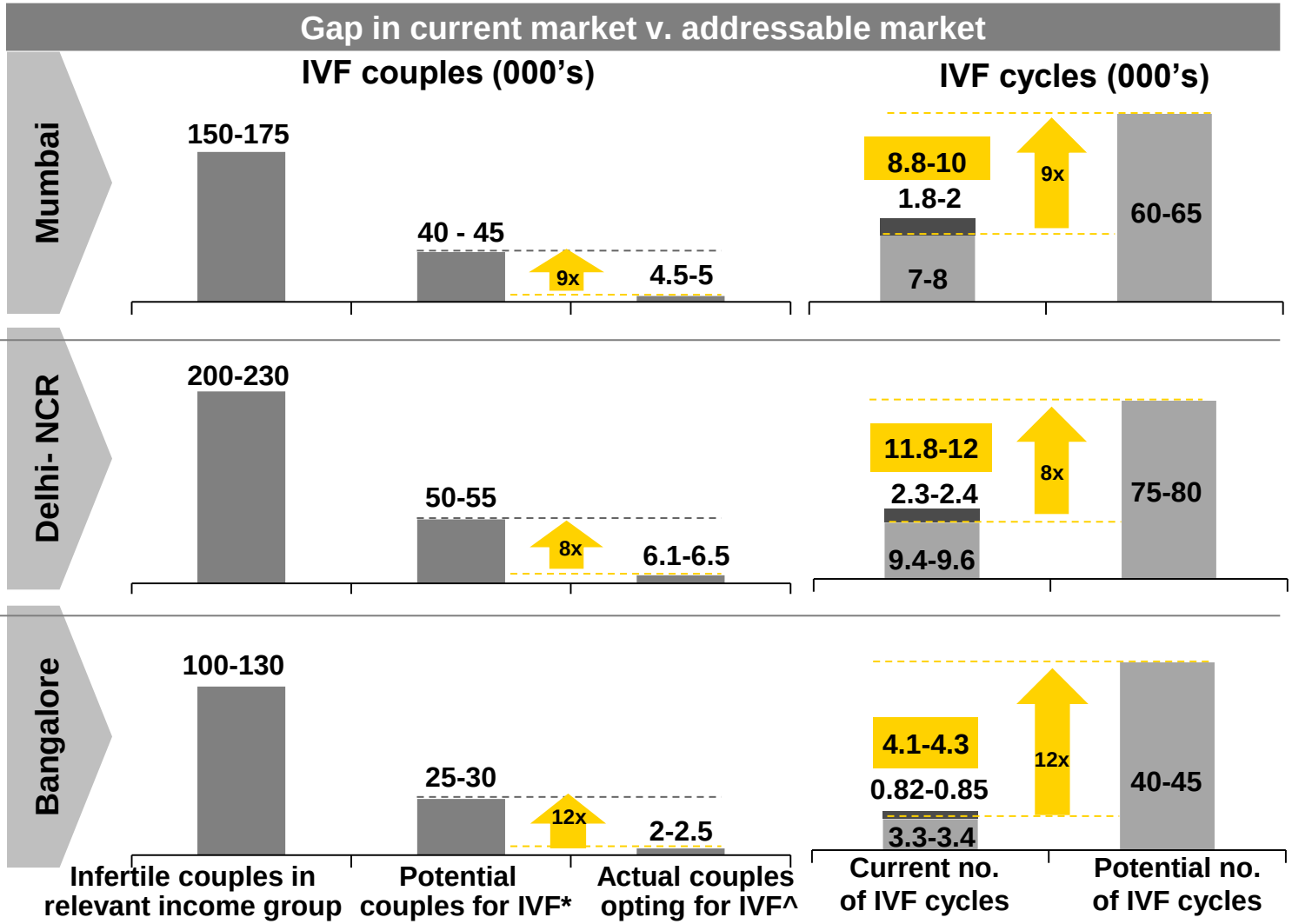
2

The IVF market is highly under-penetrated with addressable demand being 9 to 12 times higher than the current market, even in large metro cities

3

Affordability, access, awareness and assurance are the key barriers that limit the adequacy of diagnosis and treatment in India

This is further substantiated by the market-sizing analysis of the top three metros, where the addressable demand is estimated at 9 to 12 times the current market



*Assuming 25% of the total infertile couples opt for IVF
^Assuming 1-2 IVF cycles for each infertile couple opting for treatment

Drain-in from surrounding areas (15-20% of total)

Refer **Annexure 3** - Estimation of Infertile couples seeking treatment

Source: EY analysis

Section 2: Treatment landscape

1 India faces a serious challenge of high infertility rate, coupled with significantly low treatment rates

2 The IVF market is highly under-penetrated with addressable demand being 9 to 12 times higher than the current market, even in large metro cities

3 **Affordability, access, awareness and assurance are the key barriers that limit the adequacy of diagnosis and treatment in India**

Affordability, access, awareness and assurance are the key barriers limiting the adequacy of diagnosis and treatment in India

1 Affordability

- While the **cost of IVF treatment** in India is **3-4 times** lower than in the US, treatment is unaffordable for ~80% of population due to:
  - Low average household income levels with **~21% of households (~52.6 million households)** having an annual income **>INR 200,000**[49,54]
  - Majority of public and private insurance programs do not cover infertility, excluding ESI (Employee State Insurance) Corporation, which provides IVF treatment facilities to insured persons (~75 million beneficiaries)[55-58]

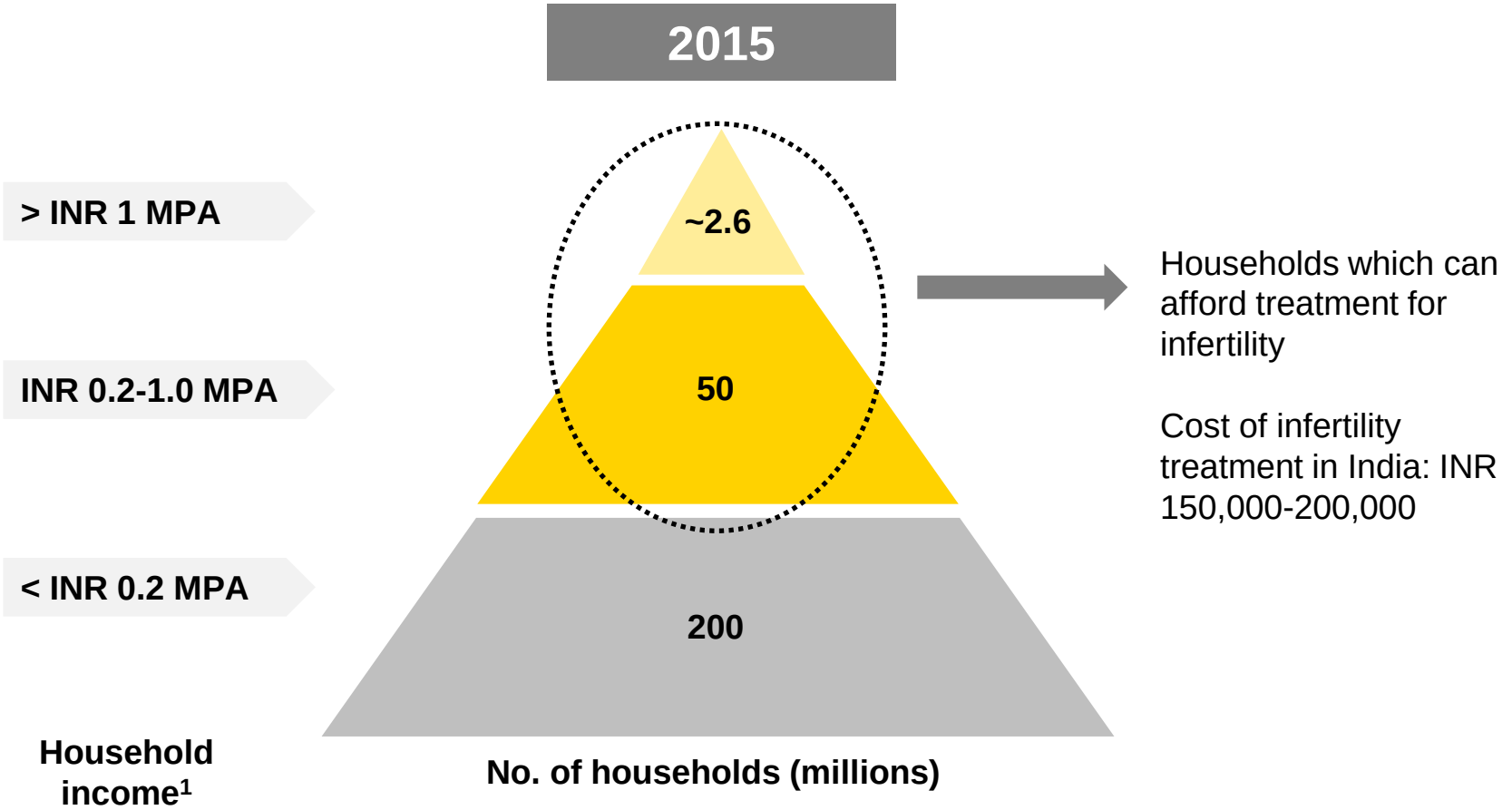
2 Access/ Awareness

- Poor access to **human infrastructure** (IVF specialists) and **physical infrastructure** (diagnostic and treatment facilities):
  - Small pool of senior IVF specialists in India with limited brand portability
    - Limited organized training or fellowship programs for building a pool of skilled IVF specialists and embryologists
  - Few specialized IVF chains with established brand equity
  - Lack of diagnostic offerings for infertility by public sector providers. A survey of 6,000 gynaecologists revealed that none of the public sector providers offered ARTs, such as IVF, and only 36% offered intrauterine insemination (IUI)[59]
- Propensity to seek fertility treatment is high, as the **need for parenthood** and **social status of parenthood** is more influential in India. However, the **awareness** of ART is a major barrier.[60]

3 Assurance

- Lack of **regulatory framework** for quality management of IVF centers and safety of patients
  - Compliance of ART banks with best practices is circumspect in the absence of any current legislation requiring formal legal registration of ART clinics and banks

1 Even though the cost of IVF treatment in India is significantly low, affordability is the major barrier

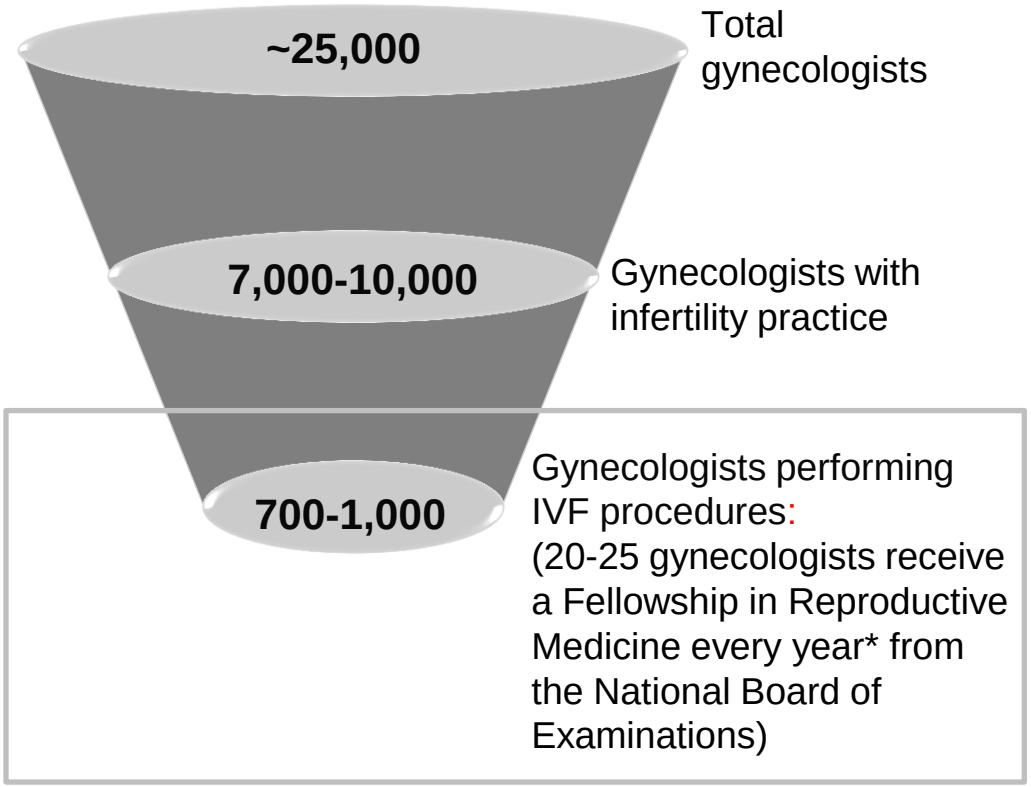


► **Only ~21% of the total households in India can afford treatment for infertility**[49]

Source: MGI, EY analysis

MPA- million per annum

2 Availability of capable IVF specialists and embryologists is a key challenge limiting the access to treatment



# of Embryologists registered with the Academy of Clinical Embryologists in India: 380

# of Embryologists in India (estimated total): 700-800

Yearly output of embryologists	
M.Sc. Embryology, Postgraduate Diploma in Clinical Embryology	15-20
M.Sc. in Clinical Embryology from abroad	~10-15

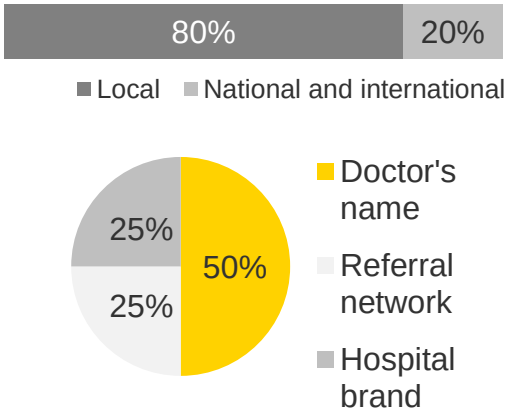
*Participating institutes : Sri Ganga Ram Hospital (Delhi), Pulse Women's Hospital (Ahmedabad), Lilavati Hospital (Mumbai), Milann (Bangalore), Ruby Hall Clinic (Pune), MMM Hospital (Chennai), Institute of Reproductive Medicine (Kolkata)

Source: Primary interviews, EY analysis

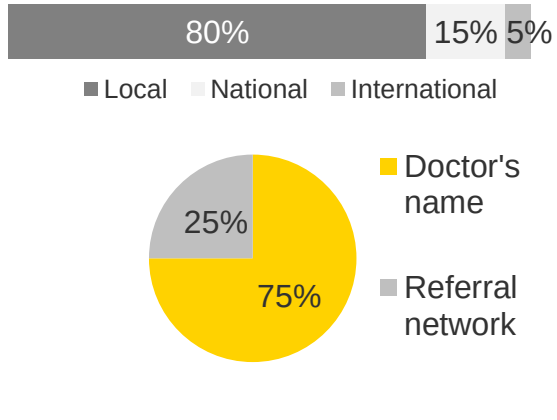
2 Doctor's reputation is a key pull-factor to build an infertility practice, but portability of personal brand is limited

Irrespective of the geographic location, the patient inflow to an IVF center is mainly governed by the popularity and credentials of the doctor

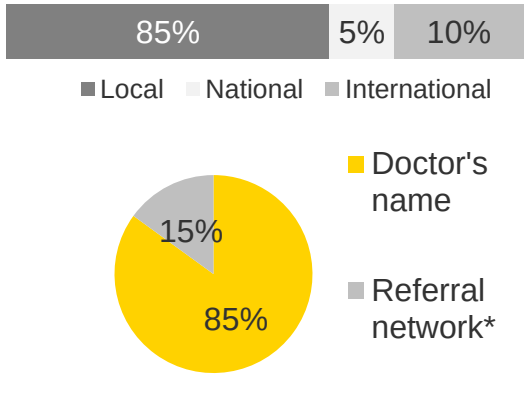
Patient inflow (Delhi)



Patient inflow (Mumbai)



Patient inflow (Bangalore)

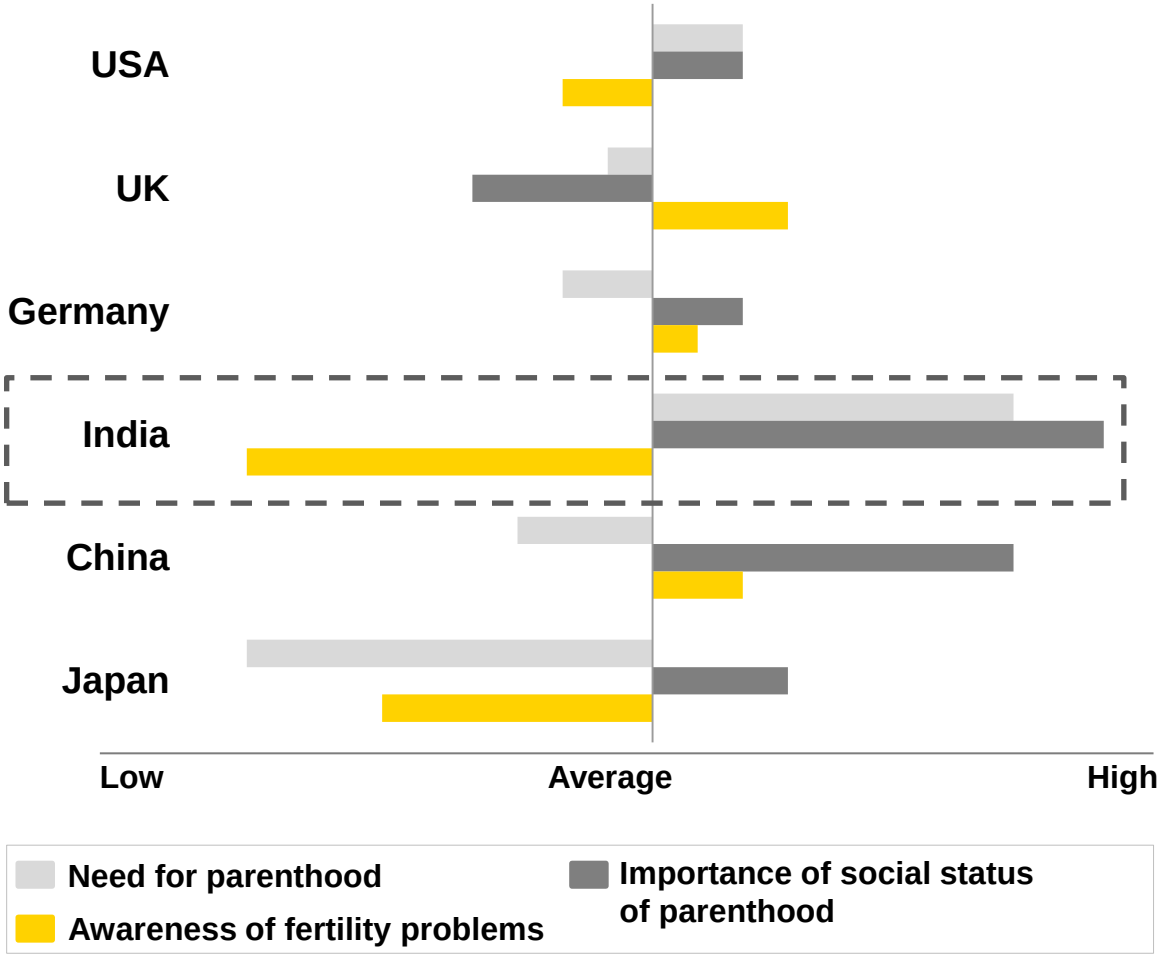


a) There are a limited number of IVF specialists in India and the brand portability of most doctors is limited to a small region

b) Some IVF specialists extend their brand value by consulting in several different cities - however this has limitations, as one IVF specialist can only travel to 3-4 cities to provide full cycle services and perform a maximum 75-80 IVF cycles/month

*Contribution of referral network has been increasing due to entry of corporate IVF chains
Source: Primary interviews with KOLs and leading pharmaceutical companies , EY analysis

2 A large international study demonstrated that Indians seem to have a high propensity to seek fertility treatment, but awareness is a major barrier



- **Need for parenthood** (the importance of having children) is **greatest in India** and lowest in Japan[60]
- Social **status of parenthood** is **more influential in India and China,** but is less valued in countries with a high level of economic development[60]
- **Awareness of fertility problems is lowest in India** compared to other countries[60]

- **Increasing awareness of infertility is a key imperative in India, as many couples do not suspect a potential problem when in fact, they should already be seeking treatment, which further reduces their chances of conceiving, over time**

Source: "Starting Families" study by Merck Serono and Cardiff University

3 Lack of a regulatory framework for quality management; safety is a key challenge

No legal registration is required for ART clinics and banks currently. Hence the compliance of ART banks with best practices are circumspect

Surrogacy	▸ Maintaining confidentiality ▸ Monitoring of surrogates at surrogate homes ▸ For cross border surrogacy, there are problems related to legal/political citizenship of children born from these procedures ▸ There is no provision of counseling and psychological screening of surrogate mothers
Gamete and embryo handling	▸ No regulatory guidelines or laws concerning management of embryo banks ▸ Lack of compliance and monitoring mechanisms to check malpractices at ART banks and clinics ▸ Unethical use of donor embryos/sperms/oocytes ▸ No regulatory laws or guidelines concerning the number of embryo transfers. Often, multiple embryos are transferred resulting in multiple birth, risking the life of the mother
Gender determination	▸ Pre-natal diagnosis of the gender of the baby by Pre-implantation Genetic Diagnosis (PGD)

ART Regulation[61]	▸ Currently, there is no ART regulation, although an ART bill has been drafted and submitted to the Government and is with the legislative department pending approval
	▸ The proposed ART bill seeks to address the following issues:
	  ▸ Number of pregnancies allowed for a surrogate mother
	  ▸ Rights of a child born through surrogacy
	  ▸ Age limit and compensation for surrogate mothers
	  ▸ Need of professional patient counselling by clinics regarding the implications and ART success rates
	  ▸ Prohibition of sex selection and Pre-implantation Genetic Diagnosis (PGD)
	  ▸ Regulations with respect to research on human embryos
	  ▸ Make it mandatory for all infertility clinics to register under National ART registry of India (NARI) (currently only 30% clinics are registered)
	  ▸ There exists no reliable data with respect to the total number of infertility clinics in India
	  ▸ In the US and the UK it is a legal requirement for all ART clinics to report details on quality and outcomes regarding ART procedures to the respective national registries whereas in India reporting to NARI is voluntary

NARI- National ART Registry of India

Refer **Annexure 4-** Assessment of regulatory landscape

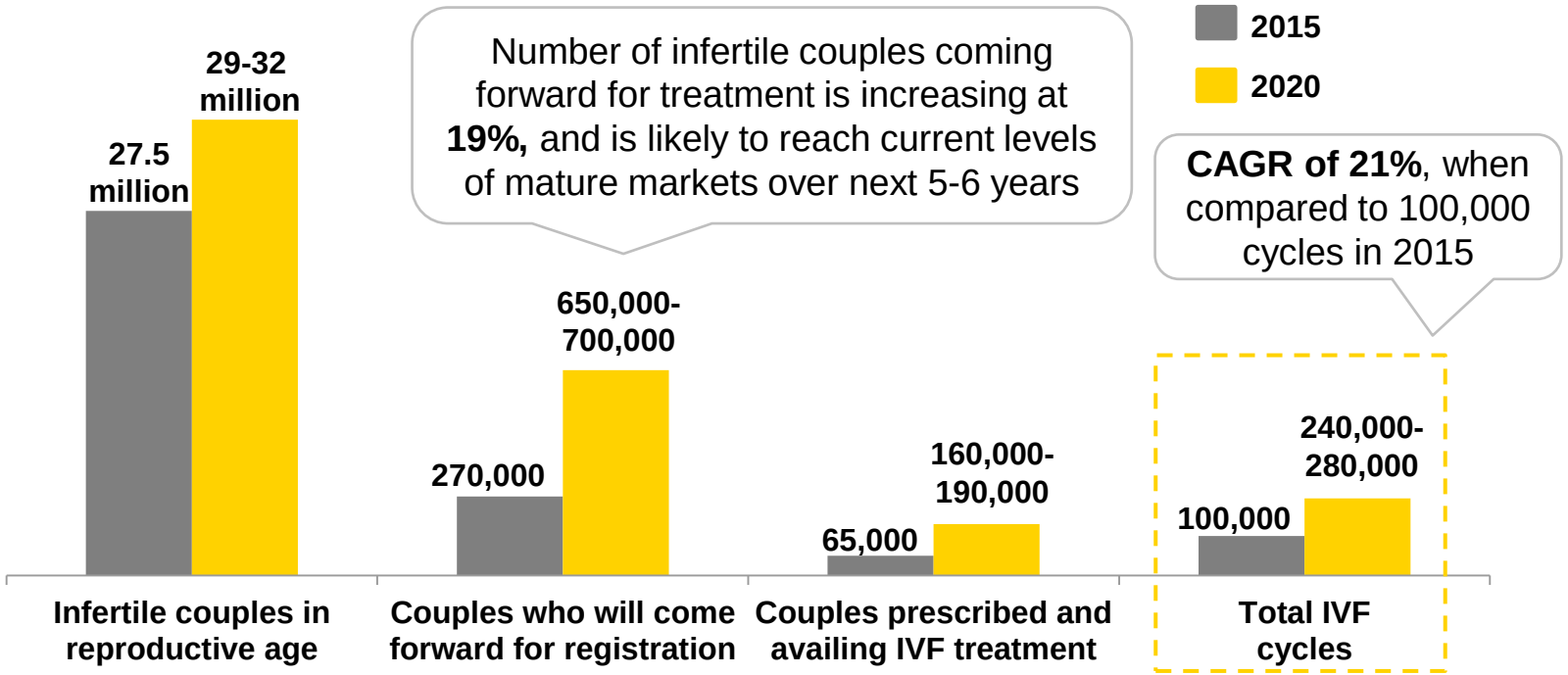
Section 3: Market opportunity

1

The market is expected to grow at a CAGR of ~20% from the current 100,000 cycles to 260,000 cycles in 2020 as barriers are progressively addressed

With more infertile couples coming forward for treatment, the IVF market is estimated to grow by ~20% to ~260,000 cycles by 2020

Potential IVF market in 2020



Growth drivers

- **10%-15%** prevalence of infertility
- Increase in the total number of women in the reproductive age-group (20-44 years) from 220 to 244 million in 2020

- Increasing number **of infertile couples coming forward for registration at infertility clinics**
- This represents ~2.3% of the total infertile couples seeking infertility treatment

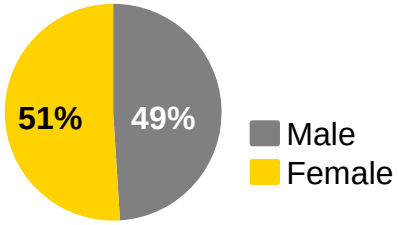
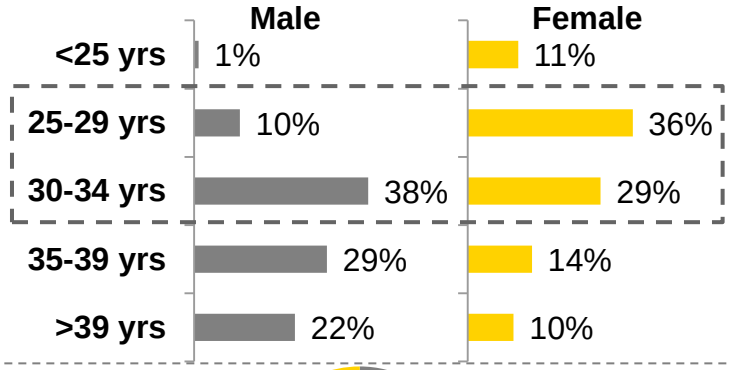
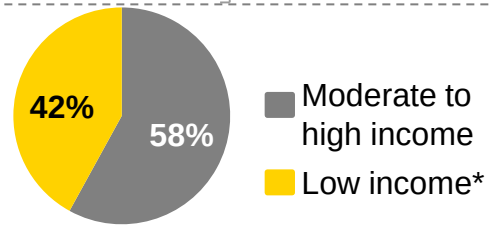
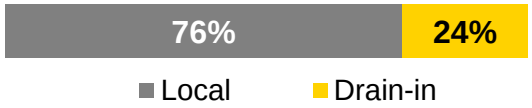
- **25%** of the total couples registering at infertility centers are availing IVF treatment

- Assuming **1.5 IVF cycles** per couple

Refer **Annexure 6** - % couples registering for treatment

Source: EY analysis

Study of patient flow, based on the representative data of leading center in a metro city, corroborates the patient segments that matter - young males and females across all income groups

Segments	Patient distribution	Key insights
Gender		1. Both males and females are key customer segments for infertility with an equal market share
Age		2. High percentage of young patients, with 65% females and 48% males within the age group of 25 to 34 years
Income levels		3. Low income group patients also form a significant share driven by societal pressures
Location		4. 24% drain-in of patients from outside the metro

*Note: Categorization into low income group based on high level assessment of the profession of the patient by a leading center in Bangalore

Source: EY analysis

Section 4: Key imperatives for industry stakeholders

Framework for future delivery of accessible, affordable and high-quality assisted reproductive treatment

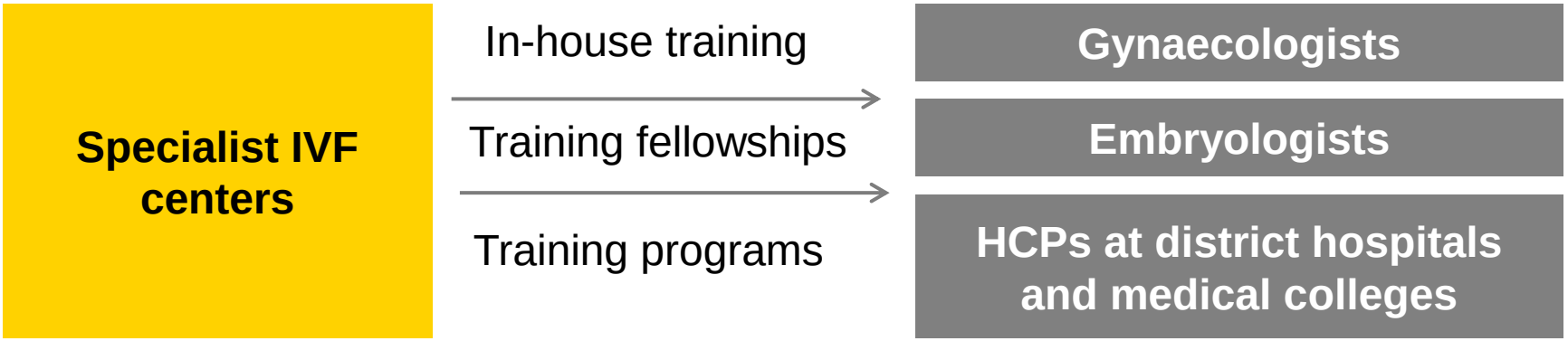
Key themes	Future imperatives for assisted reproductive treatment delivery
A **Improve outcomes**	1. **Institution of a regulatory framework** at a national level for monitoring and surveillance of ART procedures
B **Expand care**	2. **Training and skill building of ART personnel IVF specialists, embryologists, gynaecologists)** to improve treatment delivery and outcomes 3. **Improving financing options for ART** through expansion of government and private insurance schemes to include infertility treatment 4. **Adoption of innovative IVF treatments** to reduce cost of treatment
C **Build patient confidence**	5. **National educational programs for increasing awareness** of the population regarding infertility causes, prevention and treatment 6. **Inclusion of infertility prevention in the national reproductive care program** and increasing awareness about the causes of infertility

A. Improve outcomes
1. Institution of a regulatory framework for monitoring and surveillance

- **Institution of a regulatory framework** at a national level for monitoring and surveillance of ART procedures is a pressing need given the highly unregulated environment that results in unethical practices, poor outcomes and low quality of care for patients
  - **The government needs to ensure that the ART bill is enacted into law** to safeguard the rights of patients and surrogates, prohibit sex determination, and prescribe rules for procurement, storage and use of embryos for treatment and research
  - **All ART clinics must obtain a license from defined government regulatory authorities to conduct infertility treatments** and demonstrate the required expertise and technology to ensure patient safety and standard quality of care
  - **ART clinics must mandatorily report statistics** related to infertility treatments conducted and outcomes to the National ART registry of India (NARI). Annual publication of statistics of infertility treatments and outcomes should be published by NARI to ensure transparency and monitor outcomes

B. Expand care
2. Addressing skill gap in delivery of ART procedures

- **Training and skill building of ART personnel –** Infertility treatments such as IVF rely on technical expertise of a team of IVF specialists and skilled embryologist working in tandem, coupled with adequate infrastructure to ensure quality treatment outcomes. In order to bridge the skill-gap and technical expertise required for delivering high quality of care, it is imperative for the government to focus on capacity building in partnership with private players. The key models that may be explored includes-
  - **Provision of training fellowships** programs by nationally recognised and qualified ART clinics (including both private and public set ups such as district hospitals) to increase the pool of skilled IVF specialists. The training fellowship curriculum to also include courses on cost effective and simplified IVF treatment procedures
  - **Training of young gynecologists familiar with infertility** to start an IVF practice with robust technical support from qualified public and private ART clinics through resource and knowledge sharing schemes. In-house training by IVF specialists to early career gynecologists may also be undertaken at IVF specialist centers
  - **Training programs for health professionals** at district hospitals and medical colleges for treating common causes of infertility such as STIs, and provision of patient education for appropriate behaviours to prevent infertility



B. Expand care

3. Public financing, inclusion in private insurance schemes and adoption of cost effective treatment options

- **Improving financing options for ART–** Due to the high cost of treatment and poor outcomes coupled with the majority of public and private insurance programs not offering to cover or reimburse infertility treatment in India, it is unaffordable to ~80% of population currently. With the increasing burden of infertility, there is a need for public and private funding of infertility treatments which can be achieved in the following ways:
  - **Public funding for infertility treatments through a co-payment model –**several governments offer part-funding for infertility treatments (Australia, Japan, Korea, Germany), wherein couples may apply for capped income-based co-funding that covers a limited number of infertility treatments**. Provision of income based co-funding options for one cycle of infertility treatment through state health insurance schemes** to the poorer sections of the population who are childless, at designated facilities will ensure access to quality treatments
  - **Private insurance schemes to cover infertility treatments through partnerships –**innovative models, such as the Bharatiya Mahila Bank (BMB) insurance schemes, where BMB has partnered with private insurers to provide infertility treatment cover to its female account holders, may been explored
- **Adoption of innovative treatments** to reduce cost – public providers such as district hospitals that offer ART services to adopt cost saving measures throughout the treatment pathway from appropriate patient selection to use of simplified IVF procedures. In resource-poor scenarios, simplified IVF may be considered wherein cost savings are made through minimal stimulation, lower volumes of fertility drugs, and reduced risk of multiple pregnancies and ovarian hyperstimulation while offering comparable outcomes to traditional IVF procedures**.** These have been shown to nearly **halve the cost** of traditional IVF treatments. Some examples include natural IVF, minimal-stimulation IVF and ‘IVF Lite’ (a combination of minimal stimulation IVF, vitrification, accumulation of embryos, and remote embryo transfer)

C. Build patient confidence
4. Awareness programs to build patient confidence

- **National campaigns aimed** at increasing awareness of the population regarding infertility, causes of infertility, appropriate behaviours to prevent infertility and available treatments highlighting credentials of success rate needs to be driven by the government
- **Government reproductive care programs that focus on family planning and reproductive health should include measures to target causes of infertility** such as treatment of STIs, and primary health workers should receive training for provision of patient education and awareness regarding the causes of infertility

Annexures

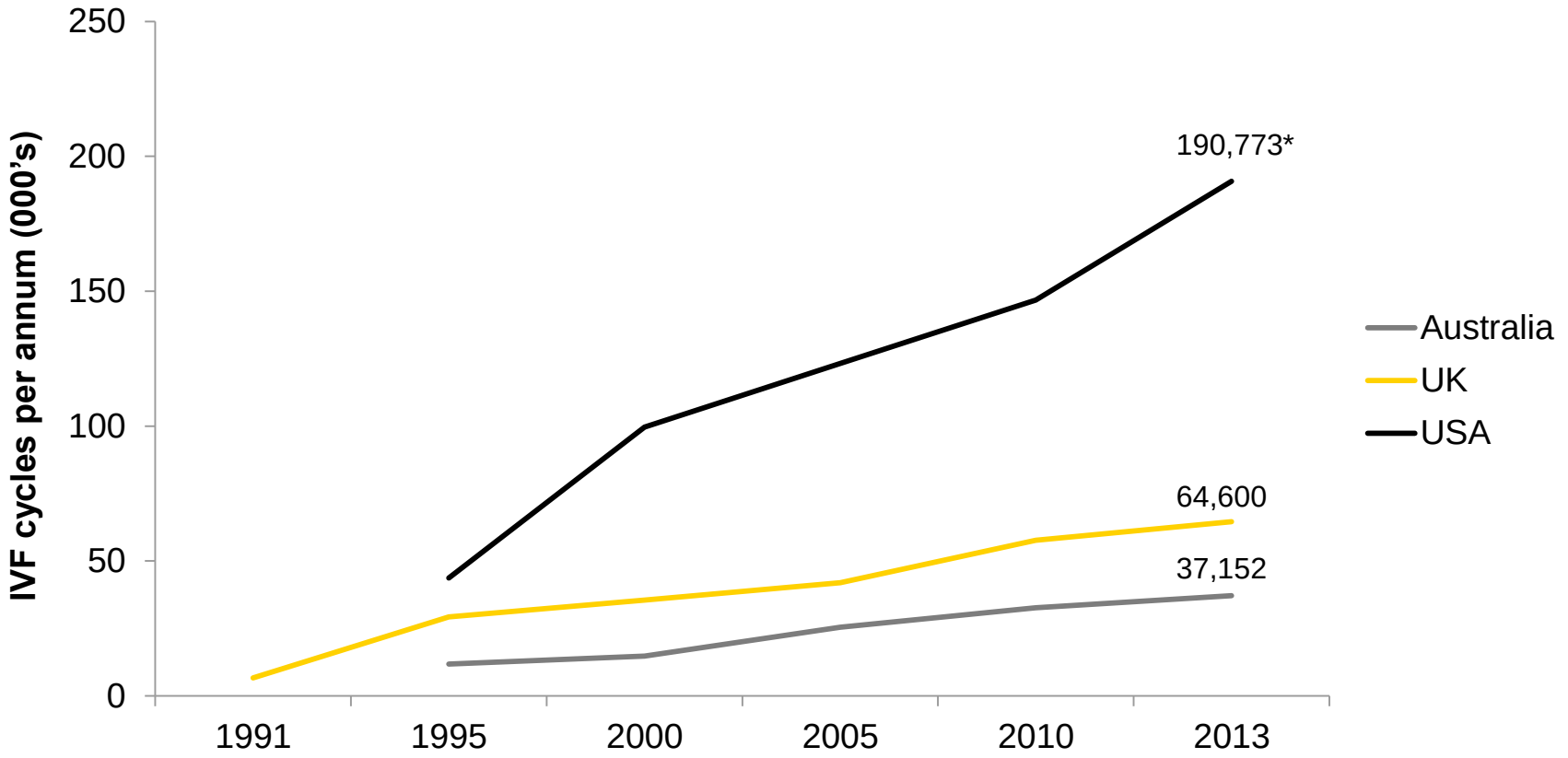
Annexure 1 - Male factor infertility studies

Reference	Location	Sample Size (N)	Analysis (n)	Male factor	Female factor	Combined	Unknown
Mittal et al, 2015 (IJIMS),Vol 2, No.4, 124-130	Ambala, Haryana	4,456	475	87 (18%)	169 (36%)	105 (22%)	114 (24%)
Mital et al, Research Journal of Recent Sciences, Vol. 1(ISC-2011), 207-211 (2012)	Indore, MP	1,000	1,000	20%	30%	13%	37%
Samal et al, Indian Medical Gazette — May 2012	Wardha, MH	3000	3,000	1200 (40%)	NA	NA	NA
Kumar et al. Indian J Med Res 140. 2014 pp 29-35	Ahmedabad, GJ	240	240	82 (34%)	NA	NA	NA

Reference	Location	Sample size	Prevalence (%)		
			Azoospermia	Oligospermia	Total
Mehta *et al.* Asian J Androl 2006; 8 (1): 89-93	Bangalore	1,627	10%	20%	30%
	Jalandhar	7,567	14.60%	18%	33%
	Jodhpur	1,341	37.30%	25%	62%
	Kurnool	2,723	38.20%	51%	89%
	Mumbai	3,456	10%	31%	41%

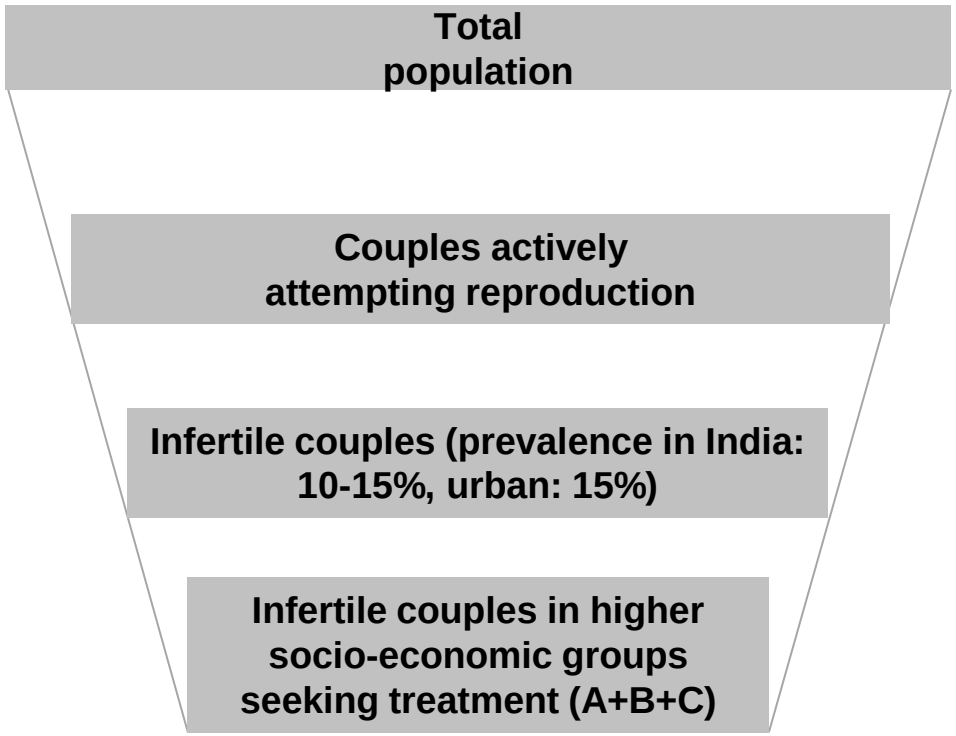
Source: Census of India 2011; HANSA 2012Q2 market research data

Annexure 2 - Growth of IVF cycles in key international geographies



*Includes 27,564 banking cycles but does not include 67 cycles in which a new treatment procedure was being evaluated
Source: CDC 2013 Fertility Clinic Success Rates Report; HEFA, UK; Australian Medicare Benefit Schedule Item Statistic Reports for items 13200, 13201

Annexure 3a - Illustration of potential couples for infertility



	Mumbai	Delhi	Bangalore
	All values in 000s		
Total population	13,297	17,480	9,875
Couples actively attempting reproduction	1,662	2,185	1,235
Infertile couples (prevalence in India: 10-15%, urban: 15%)	250	328	185
Infertile couples in higher socio-economic groups seeking treatment (A+B+C)	150-175	200-230	100-130

Most of the cities have a drain-in of 15-20% from surrounding areas

Annexure 3b - Illustration of the methodology for estimation of potential market for infertility in Bangalore city (1/3)

	Consultations	Cases	X	Visits/ cycles	=	Market size	Rationale
1	**First line consultation and diagnosis**						
	All couples opt for treatment	115,000	X	1 episode	=	**~ 115,000 episodes**	All patients would opt for first-line consultations (primary interviews)
	1st and 2nd line diagnosis and treatments						
a	**First line treatment: Ovulation induction**						
	70% of couples opting for treatment	~80,500	X	3-4 cycles	=	**~ 0.24-0.32 million cycles**	Includes ovulation induction treatment and andrology treatment for husband (primary interviews)
b	**Second line diagnosis and treatment of pre-existing disease**						
	30% of couples opting for treatment	~34,500	X	1 visit	=	**~34,500 visits**	Includes Diagnostic/curative LAP (primary interviews)

Annexure 3b - Illustration of the methodology for estimation of potential market for infertility in Bangalore city (2/3)

	Core infertility procedures		Cases		Cycles		Market Size	Rationale
1	**IUI**			**Total IUI cycles = ~0.1 million**				40% of cases opting for treatment Effective drop-out rate for 3-4 cycles = 20% (primary interviews)
	32% of couples opting for treatment		~37,000	X	3-4 cycles	=	**110,000 -150,000 cycles**	
2	**IVF**			**Total couples to be treated = 29,000 Cycles per couple = 1 to 2 Total IVF cycles = ~29,000 - 58,000**				
	25% of couples opting for treatment	**Type of IVF**	**% of total IVF**					
a		**IVF/ICSI/IMSI**	***75%***	~22,000	X	1-2	=	**22,000- 44,000 cycles**
b		**IVF with PESA /TESA**	***10%***	~2,900	X	1-2	=	**2,900-5,800 cycles**
c		**IVF with donor egg/embryo**	***15%***	~4,300	X	1-2	=	**4,300-8,600 cycles**
d		**Cryopreservation**	***70%***	~20,300	X	1	=	**20,300 cycles**

10% of cases opting for treatment
Effective drop-out rate for 2-3 cycles = 30% (primary interviews)

Annexure 3b - Illustration of the methodology for estimation of potential market for infertility in Bangalore city (3/3)

	Cases		Visits/ cycles		Market size	Rationale
Surrogacy						
	~2,900	**X**	1-2 cycles	**=**	**2,900-5,800 cycles**	~1-2% of cases opting for treatment (primary interviews)

Estimated market size for Bangalore city

Potential market size of the number of IVF cycles needed by target segment in Bangalore city is ~29,000-58,000

Current market size: Actual number of IVF cycles done ~ 4,100-4,250

Indicates unmet need in a market that is growing at ~20-25% p.a.

Annexure 4 - Assessment of regulatory landscape (1/3)

Assessment parameters	India	USA	UK	Comments
No. of registered ART clinics/centers	 318 enrolled ART clinics*	 467 reporting clinics in 2013	 131 treatment or research centers	► **India**: The ART (Regulation) Bill is in the final stages of drafting ► **USA**: No federal law to govern the practice of ART clinics. Each IVF clinic reports its success rate ► **UK**: Most regulated
Management of embryo banks (What happens to embryos that are not transferred?)	 No regulatory guidelines or laws concerning management of embryo banks	 1. Future reproduction 2. Donate to research or another couple 3. Freeze indefinitely 4. Destroy	 1. Donate the embryos to a research project or another couple 2. Ask the clinic to destroy them	► **India**: No regulatory guidelines ► **USA** and **UK**: The couples have options to either preserve, donate or destroy the embryo
Parentage and legitimacy of children born involving donor egg/surrogacy	 ► Commercial surrogacy is legal ► Birth certificate issued with the commissioning parents as legal parents	 ► Surrogacy is regulated at state level ► There are no federal laws, ASRM guidelines are followed	 ► Prohibits commercial surrogacy ► Prohibits donor anonymity	► **India**: No provision of psychological screening of surrogate mother. Cross border surrogacy leads to problems in citizenship ► **USA**: No federal laws. According to ASRM guidelines, recipient should take responsibility ► **UK**: Surrogate mother is the legal mother at the time of birth

* There is no data available for unregistered ART clinics in India

Annexure 4 - Assessment of regulatory landscape (2/3)

Assessment parameters	India	USA	UK	Comments
Transfer of multiple embryos	No regulatory laws or guidelines concerning the number of embryo transfer	No regulatory laws or guidelines concerning the number of embryo transfer	The transfer of **only two** embryos is permitted except in special circumstances	► **India and USA**: No regulatory laws resulting in multiple births ► **UK**: Transfer of only two embryos for women below 40 years of age and three for over 40 years of age.
Minimum physical requirements for an ART clinic	National Registry of ART Clinics and Banks in India by ICMR	SART strictly monitors member clinics for adherence of ASRM guidelines	HFEA issues three year's license and conducts regular inspections	► All three countries have strict regulations for clinics to operate. However, the UK has the most stringent laws

Assessment rating Very low | Low | Moderate | High | Very high

Source: Fertility Clinic Success Rate and Certification Act (FCSRCA, or Public Law 102-493), CDC, USA; Human fertilisation and embryo authority, UK ART regulator; The assisted reproductive technologies (regulation) bill – 2010 (DRAFT), ICMR www.icmr.nic.in

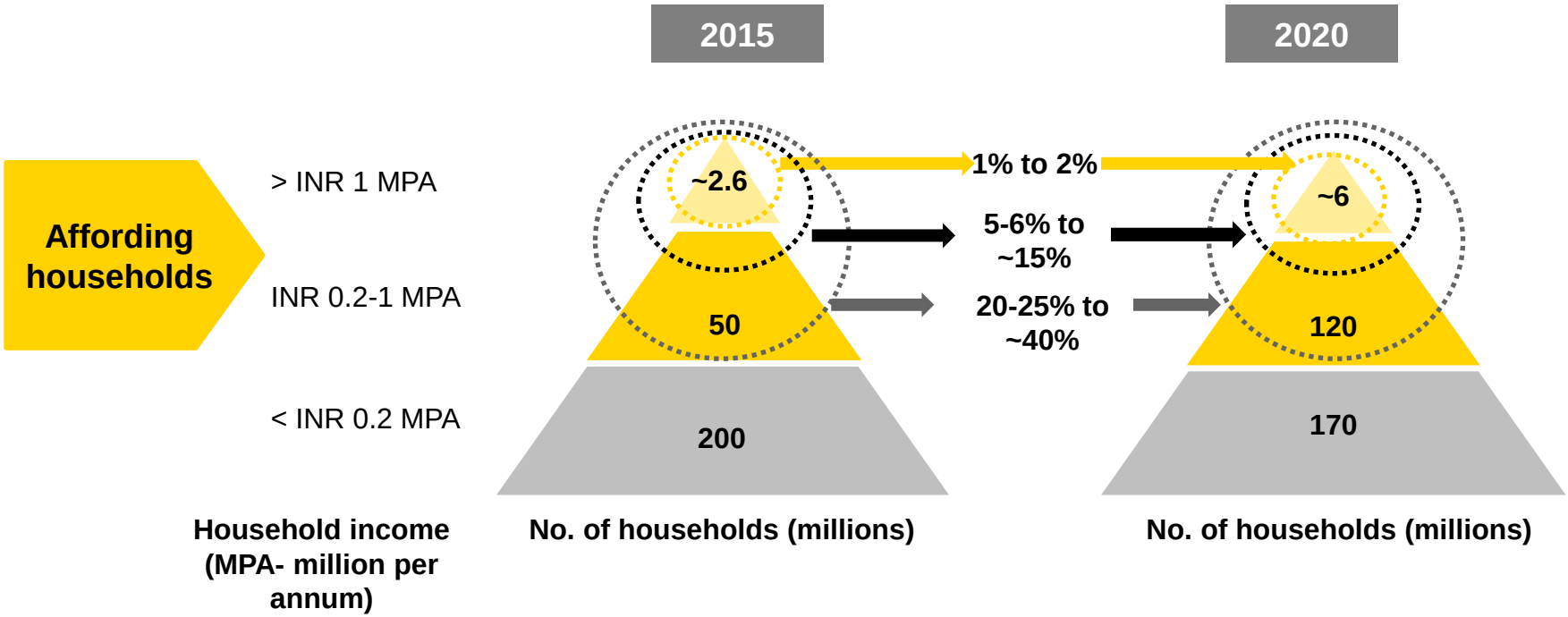
Annexure 4 - Assessment of regulatory landscape (3/3)

Current regulatory landscape in India

- The fertility treatment market in India is currently unregulated.
- There is no requirement to obtain any permission or have any specific qualifications to open infertility or assisted reproductive technology clinics in India. As a result, in the last 20 years, there has been an increase in the number of fertility clinics that use techniques requiring handling of spermatozoa or oocyte outside the body or the use of a surrogate mother.
- Assisted reproduction technologies not only require expertise but also open up many avenues for unethical practices, which can adversely affect the recipient of the treatment, medically, socially and legally.
- The Assisted Reproductive Technologies (Regulation) Bill 2013 ("ART Bill") is currently awaiting legislative approval in India.
- The ART Bill is intended to provide for a national framework for the accreditations, regulation and supervision of assisted reproductive technology clinics, for prevention of misuse of assisted reproductive technology, for safe and ethical practice of assisted reproductive technology services. In seeking to achieve these aims, the ART Bill will require ART clinics to disclose their rates of successful and unsuccessful IVF treatments and will subject such clinics to carry out audits of their results, whilst it will also impose greater qualification requirements and disclosure of such qualifications on practitioners.

Source: The assisted reproductive technologies (regulation) bill – 2010 (DRAFT)

Annexure 5a - By 2020, it is expected that with rising income levels, ~40-50% of population can potentially afford IVF treatment



► **Typically, IVF treatment in India cost's around INR1,50,000-2,50,000**

Source - MGI, 12th five year plan working group report , EY analysis

Annexure 5b - Key healthcare chains have adopted different strategic levers to deal with limited doctor portability

Key approaches identified in IVF Market to tackle the challenges of doctor portability			
	Approach 1	**Approach 2**	**Approach 3**
Lever	► **For volumes:** the patient base of partner hospital as well as brand of star doctors ► **For clinical success:** star doctors travel to multiple centers and also build a core team to travel to centers and provide services ► Core team does advanced procedures periodically and the stars visit all centers but less frequently. ► Consultation, counseling and embryo transfer are managed by the star doctors	► **For volumes:** Leverage corporate brand name, or international tie-ups to compensate for the lack of doctor's brand name ► **For clinical success:** In-house team of experts is built for each center with no particular doctor as the star	► **For volumes and clinical success :** IVF/infertility specialists are partnered/employed in order to capture their expertise and patient base to scale up faster ► IVF specialists with standing practices are taken as partners on revenue share for equipment and expertise/learning provided ► Infertility practitioners at secondary care level are also made partners, who refer complex IVF cases to the hubs
Time required	► Short term (1-2 years)	► Medium term (3-4 years)	► Short term (1-2 years)
Limitations	► Limited supply of stars ► Sizable upside sharing with partner hospitals ► Bandwidth challenge of key doctors limiting scale-up	► Brand value of international partners not established in India ► Not able to attract best talent because no skill-building opportunity for them	► Risk of brand dilution/reputational risk as less control on partners ► No focus on capacity building ► No Indian stalwart on board; hence clinical support & quality perception may be impacted

Marketing activities work parallel to build brand and develop in-house patient inflow

Annexure 6 - Estimation of the percentage of total number of infertile couples registering for treatment

Year	Prevalence	Married women 20 - 44 (million)	Infertile couples (million)	Total cycles	No. of couples for IVF	Actual couples who came for registration	% of infertile couples coming for registration
Calculation	A	B	C= A*B	D	E = D/2	F = E*100/25	G = F/C
Assumption	-	-	-	-	1.5 cycles per couple	25% of total couples opt for IVF	-
2001	12.5%	161.7	20.2	7,000	4,667	18,667	0.09%
2005		176.4	22.1	19,000	12,667	50,667	0.23%
2010		197.0	24.6	70,000	46,667	1,86,667	0.76%
2015		220.0	27.5	1,00,000	66,667	2,66,667	**0.97%**
CAGR (2001 - 2015)			**2.2%**				**20.9%**

Growth in registration due to increasing awareness, affordability and access = **20.9%** — **2.2%** = **18.7%**

% infertile couples coming for registration growing at CAGR of ~19%

Comparison of "% of total infertile couples coming for registration" with other countries:

Country	% age	Reasons (if any)
US	3.4%	-
UK	5.7%	(Significant role of the Government in the form of sponsorship, which may be leading to higher numbers)

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Abbreviations

AFC	Antral follicular count	**HEFA**	Human Fertilisation and Embryology Authority
AMH	Anti-Mullerian Hormone	**HPV**	Human papilloma virus
APC	Alcohol per capita	**ICMR**	Indian Council of Medical Research
BMI	Body mass index	**ICSI**	Intracytoplasmic sperm injection
CAGR	Compound annual growth rate	**IMSI**	Intracytoplasmic morphologically selected sperm injection
CGHS	Central government health scheme	**INR**	Indian rupee
Cr/cr	Crore	**IUI**	Intra-uterine insemination
DHFS	District Level Household and facility Survey	**IVF**	*In-vitro* fertilization
E2	Estradiol	**KOL**	Key opinion leader
ESHRE	European Society for Human Reproduction and Embryology	**LH**	Luteinizing Hormone
ESIC	Employees' State Insurance Corporation	**MPA**	Million per annum
FSH	Follicular Stimulating Hormone	**MSc**	Master of Science
GATS	Global adult tobacco survey	**NFHS**	National Family Health Survey

Abbreviations

NGO	Non-governmental organisation	**TESA**	Testicular sperm aspiration
NSSO	National Sample Survey Office	**TFR**	Total fertility rate
OECD	Organisation for Economic Co-operation and Development	**UK**	United Kingdom
p.a	Per annum	**UN**	United Nations
PCOS	Polycystic Ovarian Syndrome	**USA**	United States of America
PESA	Percutaneous epididymal sperm aspiration	**USD**	US dollar
RAS	Rajiv Arogyasri Scheme	**WHO**	World Health Organization
RSBY	Rashtriya Swasthya Bima Yojna		
RTI	Reproductive tract infection		
RTI	Reproductive tract infection		
SART	Society for Assisted Reproductive Techniques		
SRS	Sample registration survey		
STI	Sexually transmitted infection		

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