

ASSESSING AND ENHANCING FERTILITY SERVICES: A TERTIARY CARE CENTRE'S QUALITY IMPROVEMENT JOURNEY

Supriya Chaubey¹, Aruna Nigam²

¹Assistant Professor, Department of Obstetrics and Gynaecology, Hamdard Institute of Medical Sciences and Research, Jamia Hamdard, New Delhi, India.

²Professor & HOD, Department of Obstetrics and Gynaecology, Hamdard Institute of Medical Sciences and Research, Jamia Hamdard, New Delhi, India.

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Corresponding Author:
Dr. Supriya Chaubey,
Email: drsupriyachaubey@gmail.com

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Abstract

Background: In India, infertility is a social stigma and causes a significant stress to the infertile couples. Many couples can be benefitted by a good counselling about fertility period and ovulation induction with or without intrauterine insemination (IUI) that is level 1 ART services. Also, the new ART laws and its medicolegal implications has restricted the infertility treatment in institutions leading to lack of training of postgraduate students. Therefore, we decided to improvise and channelize the services in our institute using DMAIC methodology. **Materials and Methods:** This was a prospective study, conducted between July 2023 and June 2024 in this study targets were set for the five-phases of the DMAIC methodology. Multiple cycles of DMAIC, each targeting and eliminating one root cause at a time and lasting for a month, were applied for problem solving until all root causes were eliminated. The primary outcome analyzed was total number of women attending the infertility -OPD, and the average response of patients on the Patient Satisfaction Scale (PSS); secondary outcomes were the total number of follicular monitoring done and IUI performed in the department. **Result:** The average infertility OPD attendance rate per month during the study period was 47 ± 12.8 patients with an 78.7% increase compared to previous one year. The average rate of follicular monitoring was increased to of 40.2 ± 7.1 /month (+54.0% increase) during the study period. The highest average PSS score (3.7) was observed. Total IUI procedure done was 50 with an increase of 28.2% compared to previous 12 months. Out of these 50 IUI 9 patients conceived (pregnancy rate was 18%) and 2 patients delivered at term till date. **Conclusion:** An important lesson learned from the study was the importance of communication and consultation in improving procedural standards and satisfaction rates. Our study is the first of its kind to apply a novel Six Sigma methodology – The DMAIC process to address the deficiencies and areas of improvement associated with infertility treatment services.

INTRODUCTION

Infertility, a reproductive disease that results in the inability to conceive after 12 months of unprotected sex.^[1,2] Despite the immense number of individuals that are affected globally, the vast social, physical, and mental health implications of infertility have been largely unaddressed in the last 15 years.^[3] In India, where the fertility rate is extremely high individuals and couples with infertility face significant stress due to social and financial issues. Many couples can be treated with just a good counselling regarding timed intercourse or ovulation induction and intrauterine insemination (IUI) and very less number require invitro fertilization (IVF). Therefore, it's very important to have a dedicated

staff and gynecologist with level 1 ART (artificial reproduction treatment) facilities in the institutes. With new ART laws and medicolegal implications general gynecologists are not treating the cases. This is hampering the teaching of postgraduate students to this competency which is mentioned clearly at the levels of performance as per National Medical Commission (NMC) mandate. Therefore, we decided to improvise and channelize the services in our institute using DMAIC methodology.

MATERIALS AND METHODS

This was a prospective study, conducted between July 2023 and June 2024 in the Department of Obstetrics and Gynecology. This was a prospective

observational quality assurance study aimed at improving infertility treatment services using the 5-phase DMAIC methodology. The D in DMAIC stands for “Define the problem or the effect”; M stands for “Measure the Problem”; A stands for “Analyze cause”; I stand for “Improve things”; and C stands for “Control of the process and future performance through quality control” [Figure.1a,1b]. In our case, following targets were set for the five-phases of the DMAIC methodology:

- D – The Apparent effect/problem was defined as an ‘Improvement in infertility treatment services at the institute.’
- M – The performance of infertility treatment services was estimated using data for the last 12 months (from July 2022 to June 2023) on the number of patients attending the infertility clinic, no of follicular monitoring done in the department and no. of IUI performed in the department.
- A – The reasons for poor infertility treatment services were elaborated and represented figuratively using an Ishikawa or Fishbone or Cause-Effect diagram. This diagram is a visual aid to identify and categorize causes/solutions to a problem; the head of the fish on the far right represents the main problem for which a solution is desired. The branches and the subbranches represent the cause and the sub cause, respectively [Figure 2].
- I – In the Improvement phase, one root cause was specifically addressed and eliminated.
- C – The study team was led by a Quality Initiative (QI) team constituting of a professor who was also the head of the department, and an assistant professor from the same department along with a nursing staff. They have been tasked with maintaining quality controls during the Improvement phase.

Multiple cycles of DMAIC, each targeting and eliminating one root cause at a time and lasting for a month, were applied for problem solving until all root causes were eliminated. [Figure 1b]

At the end of each DMAIC cycle, the outcomes were recorded and tabulated in an Excel spreadsheet. The primary outcome analyzed was total number of women attending the infertility -OPD, and the average response of patients on the Patient Satisfaction Scale (PSS).; secondary outcomes were the total number of follicular monitoring done and IUI performed in the department. The PSS was based on a five-point Likert scale with score 1 corresponding to “very unsatisfactory” response, score 2 corresponding to “unsatisfactory” response, score 3 corresponding to “neutral” response, score 4 corresponding to “satisfactory” response, and score 5 corresponding to “very satisfactory” response.

Data analysis was performed using Microsoft Excel 2021 MSO (Version 2401 Build 16.0.17231.20236).

Problem Identification: To streamline the function of an infertility outpatient department (OPD), we

focused on optimizing each component of the system: People, Parts, Procedures, and Plants by using a structured approach.

We identified and improved the common issues faced in an infertility OPD like:

- Reducing patient waiting times by improving scheduling and resource allocation.
- Ensure clear communication between staff and patients.
- Minimizing mistakes by using digital records and standardizing documentation processes.
- Providing counseling and support to patients.

In this study we optimized the roles and responsibilities of the staff:

- Fertility specialists are available and up to date with the latest treatments and protocols.
- Training of postgraduate students and nurses, to handle both medical and emotional aspects of patient care.

We also started a set up for in-house IUI lab to ensure the quality of prepared semen. Diagnostic equipment was maintained and regularly calibrated like ultrasound machines, hormone testing kits, and other diagnostic tools. We also ensured a well-stocked inventory of medications, fertility aids, and laboratory supplies.

Improve: The study spanned 12 months between June 1, 2023, and May 31, 2024. In the first 11 months of the study, eleven DMAIC cycles were used to address twelve root causes. Each DMAIC cycle was completed in one month. In the last month of the study, all improvements were implemented together, and the outcomes were noted. Table.1 shows the improvements applied in each DMAIC cycle and the corresponding infertility -OPD attendance rates, number of follicular monitoring and PSS scores.

RESULTS

Define and Measure: We retrieved data on the number of follicular monitoring and IUI done in previous year along with infertility -OPD visits from the hospital's database system. The total number of patients attending the infertility OPD during the study period was 565: which corresponded to a monthly average of 47 ± 12.8 patient and an attendance rate of 14.2 patients per 1,000 women aged 15 years and above attending the general gynecology OPD. The total number of follicular monitoring done was 482. This is an average of 40.2 ± 7.1 scans per month and annual follicular monitoring rate of 12.1 per 1000 women aged 15 years and above who visited the general gynecology OPD. The total number of IUI procedures performed during our study was 50 which is 4.2 IUI per month and 8.8% of total patients attending the infertility OPD. Addressing any of the root causes resulted in improved infertility-OPD attendance and follicular monitoring rates.

Infertility OPD attendance counts: The average infertility OPD attendance rate per month during the study period was 47 ± 12.8 patients with an 78.7%

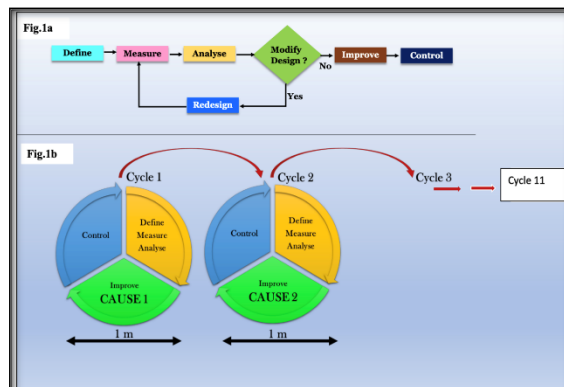
increase compared to previous one year. The baseline percentage increase in attendance rates during the entire study period remained above +10%. The highest increase in attendance rates was observed with the improvement of referral procedures to infertility clinic from general gynecology OPD (+121%). Whereas by improving communication and counselling (+100%) and by ensuring a robust IT support a +93% increase in attendance rates was noted. By eliminating all root causes, attendance rates increased dramatically by +219.2% (Table 1).

Follicular monitoring counts: The average rate increased to 40.2 ± 7.1 /month (+54.0% increase) during the study period. The baseline percent increase in the number of follicular monitoring during the study period remained above +14%. The largest increase in the number was after appointing a dedicated consultant trained in IUI and semen preparation for infertility clinic and IUI lab (+98.3%) followed by solving the administrative problems in procuring the essentials for IUI lab (+94.9%). After getting support from the IT department for maintaining and storing data of patients the rate increased to +81.5% and after eliminating all the problems the rate increased to +74.8% (Table 1).

Figure 3 shows trends in monthly infertility-OPD attendance rates and figure 4 shows monthly follicular monitoring rates during the study period.

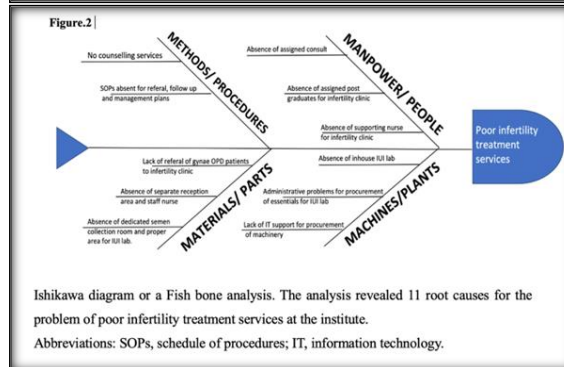
Average PSS Scores: The highest average PSS score (3.7) was observed for improvements in communication and counselling as well as proper referral of infertility patients from general gynecology OPD to infertility clinic. Improved IT support, the presence of a trained nurse to help in the smooth turnover of patients, assist in procedures and administrative support, appointing a postgraduate for assistance along with availability of an in-house IUI lab, were each associated with an average PSS score of 3.4. Table.1 lists the average PSS values for each DMAIC cycle.

Total IUI procedure done during study period was 50 with an increase of 28.2% compared to previous 12 months. Out of these 50 IUI 9 patients conceived, and 2 patients delivered at term till date. So, the pregnancy rate was 18% during study period.



Define-Measure-Analysis-Improve-Control or DMAIC process for problem solving (Fig 1a). Figure 1b depicts the flow of DMAIC cycles during the study period. One root cause was addressed and eliminated for one month period. The number of patients attending infertility OPD, number of follicular monitoring and patient satisfaction scores were recorded at the month's end. Eleven such cycles were performed over a 11-month period until all root causes were eliminated (see results section).

Abbreviation: m, month.

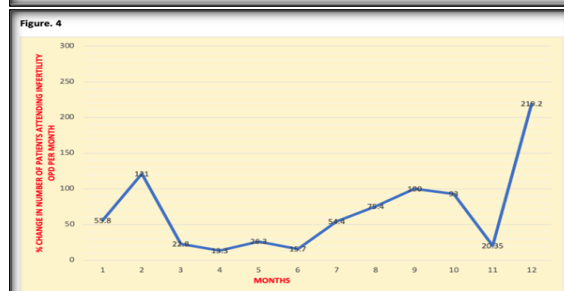


Ishikawa diagram or a Fish bone analysis. The analysis revealed 11 root causes for the problem of poor infertility treatment services at the institute.

Abbreviations: SOPs, schedule of procedures; IT, information technology.



Percentage change in number of follicular monitoring/months during study period



Percentage change in number of patients attending infertility OPD per month during study period. Abbreviations: SOPs, schedule of procedures; IT, information technology; OPD, outpatient department.

Table 1: Infertility-OPD attendance rates, follicular monitoring rate and PSS scores during the study.

DMAIC cycle number	Cause	Sub-cause	Improve	% Change in OPD attendance*	% changes in number of follicular monitoring	PSS scores (average)
Cycle 1	people	Lack of an assigned consultant for taking care of infertility treatment services	A consultant trained in IUI procedure and semen preparation was assigned for infertility OPD and IUI procedures	55.8	98.3	3.0
Cycle 2	Parts	Lack of referral of gynecology OPD patients to infertility clinic	Patients seeking infertility treatment were informed and being referred to infertility clinic from routine gynecology OPD.	121	44.5	3.7
Cycle 3	Plants	Absence of in-house IUI lab	An in-house IUI lab was set up to improve the quality of prepared semen and convenience of couples.	22.8	31.1	3.4
Cycle 4	Parts	Absence of dedicated semen collection room for IUI lab.	A dedicated semen collection room was allocated near the IUI lab.	13.2	37.8	3.3
Cycle 5	People	Absence of assigned postgraduate for infertility clinic and IUI	A postgraduate was posted along with the consultant to help and receive training in infertility clinic and IUI lab.	26.3	21	3.4
Cycle 6	Plants	Administrative problems for procurement of essentials for IUI lab		15.7	94.9	3.3
Cycle 7	Parts	Absence of a separate reception area and staff nurse to guide the patients	A dedicated reception and waiting area were set next to the infertility OPD.	54.4	34.5	3.2
Cycle 8	people	Absence of support nurse	A well-trained nursing officer was appointed to help in the smooth turnover of patients, assist in procedures and for administrative support.	75.4	22.8	3.4
Cycle 9	Procedure	No counselling services	A postgraduate was made available to elicit history, do preliminary examination and enter patient details into hospital software. He/she was also tasked with communicating reports to patients and advise on future management plans along with the consultant.	100	41.2	3.7
Cycle 10	Plants	Lack of IT support for procurement of machinery	Support from the institute's IT department was sought for setting up of high-speed wireless internet, printing, storage, and backup patient data, etc were ensured.	93	81.5	3.4
Cycle 11	Procedure	Absence of SOPs for management plan, follow-up, and referral	SOPs for management of patients undergoing infertility workup and treatment if required, referral to IVF clinics for additional services were laid down	20.4	14.3	3.3
Cycle 12	All causes eliminated			219.2	74.8	3.3

DISCUSSION

The total number of average monthly attendance rates at the infertility-OPD and follicular monitoring during the last year were of 47 ± 12.8 and 40.2 ± 7.1 /month respectively. We used the DMAIC model to improve infertility treatment services at the institute. Using the Ishikawa or fishbone diagram, we were able to identify twelve root causes of poor performance. The DMAIC methodology is like the four-step Plan-Do-Study-Act (PDSA) methodology. Both are used for problem solving in productivity and marketing areas, except that the DMAIC model is data-driven and more sophisticated than the PDSA model.

Most available infertility and fertility care indicators are outcomes indicators of effectiveness and efficiency dimensions. Most indicators fall into the domain of ART and are reported by fertility clinics. Indicators of safety, patient-centeredness, equity, and timeliness as well as non-clinical indicators are almost invisible.^[4]

Our study is the first of its kind to apply a novel Six Sigma methodology – The DMAIC process to address the deficiencies and areas of improvement associated with infertility treatment services.

Another advantage of this study was to improve training of postgraduates and exposure to the undergraduate students, although this was not assessed during the study period.

The major limitation of the study was its non-comparative design. Nevertheless, the study highlights the importance of quality assurance and controls in improving the treatment standards for couples attending the infertility clinic at our institute. An important lesson learned from the study was the importance of communication and consultation in

improving procedural standards and satisfaction rates.

CONCLUSION

While providing infertility treatment to the couple's high standards of care and auditing is very much needed for better satisfaction and outcome. Couples' satisfaction is very important for an effective infertility treatment which is influenced by quality and clinical success of treatment. Most of the time they face significant emotional and psychological stress during treatment and addressing their problems through counselling and information is vital. Counselling regarding their diagnosis, treatment options and expected outcome will make them a part in the decision making. Psychological support can assist patients in coping with stress of infertility, improving their overall well-being and satisfaction with the treatment received. In summary, the integration of quality assurance, auditing, and effective patient communication forms the backbone of a successful infertility treatment strategy.

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