**Indian uterine transplantation: Regulatory challenges and public confidence**

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**Abstract:**

In this article, uterus transplants in India are visited, considering the regulatory basis upon which three different institution have received approval to perform uterus transplants, and raising issues that need resolution in order to increase public and professional confidence.

**Main Article:**

Research on uterus transplants is gathering pace, with teams working worldwide to improve the safety and efficacy of this innovative reproductive procedure. The medical community has been working together to progress this field of research, by way of example, recent meetings organised by the International Society of Uterus Transplantation (ISUTx) have seen experiences shared, and discussions around how to advance [1]. Medical papers are regularly published, and media reports and press releases abound. To date, there have been 15 reported births, with further births expected soon [2].

Engagement with researchers and practitioners in the field is vital for research to develop safely, ethically and with public confidence; for the continuing professional development and education of practitioners, and for the best care for all patients involved. In contrast to this sharing approach, researchers from India, have demonstrated success with uterus transplants, apparently without significant collaboration with others working in the area. Some may question why there is a need to collaborate, when researchers in India have demonstrated the ability to perform uterus transplants with successful outcomes. Others have criticised the approach taken by not only the researchers, but also the regulatory bodies involved. Two years on from the first uterus transplant in India, there is still a lack of transparent, publicly available information. It is acknowledged that a few scientific publications have been published, but public facing information is limited to media reports. Whilst the author has more generally raised concerns about uterus transplants elsewhere, here concerns are raised about the particular regulatory circumstances in which the first Indian uterus transplants have gone ahead, and the need to increase public confidence that uterus transplants are progressing in India safely, ethically, and with appropriate oversight [3].

The Galaxy Care Laparoscopy Institute (GCLI) based in Pune, was the first Indian institution to conduct a uterus transplant. GCLI performed the first uterus transplant in India on the 18th May 2017 with a donation from a 41-year-old mother to her 21-year-old daughter. The following day, the Galaxy Care Hospital performed a second uterus transplant between a 45-year-old mother and her 24-year-old daughter. The first two recipients of a uterus transplant in India returned home, and it was confirmed in January 2018 that the donated uteri were still in situ [4,5]. In October 2018 the first recipient gave birth to a baby girl [6]. One news source reported that a third uterus transplant went ahead as planned on the 26th January 2018 and involved using the laparoscopic technique on a 23 yr old recipient and the recipient’ mother [7]. The GCLI was able to perform these uterus transplants as it was granted a five-year licence by the Directorate of Health Services of Maharashtra to perform uterus transplants on the basis that it is a clinical procedure.

The Milann International Institute of Training and Research in Reproductive Health, based in Bengaluru, is also on course to perform a uterus transplant in the near future. In contrast to the GCLI, the Milann International Institute received approval from the Indian Council of Medical Research (ICMR) to carry out two uterus transplants as part of a research project [8]. GCLI and the Milann International Institute have taken opposing approaches towards seeking approval to conduct uterus transplants; this difference in approval initially generated considerable debate in the mainstream Indian media following the announcement by GCLI of its intentions to go ahead with the planned transplants. The Director-General of ICMR, Dr Soumya Swaminathan, noted that ICMR permission was not required for established clinical procedures but that uterus transplantation was an experimental procedure [9]. Professor Mats Brännström, who leads the first team that successfully performed uterus transplants resulting in live births, has also said *“what is planned in Pune is a dangerous escapade of surgical cowboys wanting to the first in their country and to get (worldwide) publicity and fame easy.”[10]*

The lack of coherent regulation and oversight of uterus transplants in India has been criticised by Srinivasan as inadequate and flawed [11]. Srinivasan has criticised both the Directorate of Health Services for granting a licence to GCLI to conduct therapeutic uterus transplants, and the ICMR for granting the research approval to the Milann Institute. As Srinivasan clearly outlines, the Pune surgical team did not *‘…include a surgeon with the THOTA-specified “one-year training in the respective organ transplantation as an active member of team in an established transplant center”’* and the ICMR *‘…seem to violate key ethical and procedural requirements’* noting a lack of transparency, failure to submit the proposal to the ICMR central ethics committee, not demonstrating how uterus transplants was relevant to ‘national health priorities’, nor explaining why the Drugs Controller General of India (DCGI) would monitor the trial despite no authority to do so [11].

On the 5th January 2018, another hospital in India, the Sunrise Hospital in Kochi, Kerala was granted a licence by the Directorate of Medical Education to perform uterus transplants [12]. This is the third body to give approval for uterus transplants in India. Sunrise Hospital was the second Indian hospital to receive a licence to perform uterus transplants as a clinical procedure [13]. No further information has been released by Sunrise Hospital, although laparoscopic surgeon Dr Hafeez Rahman was quoted at the time as claiming that, *“In a month or two, we intend to do the uterine transplant. We will be selecting a patient with adenomyosis (a condition in which the inner lining of the uterus (the endometrium) breaks through the muscle wall of the uterus) as in most cases their ovary would be normal. The donor would be a mother or sister"* [14]. If Sunrise Hospital did perform uterus transplants in early 2018 as stated, nothing has been publicly reported, either in the press or medical journals.

As noted by Srinivasan, *“The ART industry in India has a well-documented history of unethical practice and a healthy dislike of regulation”* [11]. It now appears that at least one Indian team has been pushing ahead with uterus transplants, allegedly before they are truly ready to undertake such work. Uterus transplantation is an experimental research procedure and until relatively recently the only team to have successfully performed transplants that resulted in live births was the Swedish team. Members of the Swedish team have been working with other teams worldwide in order to share their experiences, and to try to ensure success in other clinical trials. This sharing of information is evident from the first birth outside of the Swedish trial, which involved doctors with strong links to the Swedish team [15,16]. In addition, the first International Congress of Uterus Transplantation was organised by the Swedish team and included information sharing sessions [17]. However, the GCLI team have not involved the Swedish team in their preparations. This raises questions around the ethics of performing uterus transplants without appropriate expert input.

There are concerns about uterus transplants taking place in India due to the poor record of treatment of women, with significant pressure upon women to reproduce. This pressure to reproduce results in women having poor marriage prospects if they do not menstruate, and served divorce notices when they are unable to gestate and reproduce [18]. There may be undue pressure upon Indian women to participate in uterine transplantation, either as a recipient or as a living donor; equally, there is a possibility of a market in uterus donations arising, in much the same way that there is reproductive tourism around surrogacy in India [19-21].

The donors in all three transplants performed by GCLI were the recipient’s mothers, the first two transplants involved mothers who were aged in their early 40’s. This is significantly younger than the women who were donors in the Swedish trial where the average age was 53 years old [20]. Due to the younger age of the donors, they are less likely to have gone through menopause; the hysterectomy will likely trigger this within 5 years, if an oophorectomy was also performed menopause will be triggered immediately [23]. The donor for the third uterine transplant was the 52 year old postmenopausal mother of the 27 year old recipient [5]. Inducing menopause was not an issue for this donor, although it must be acknowledged that the transplant surgery is not without its risks [24].

The media reported that the recipients would start treatment for conception around 7 to 9 months after the transplants; this was significantly quicker than the 1-year period that the Swedish team waited in their first uterus transplant clinical trial before undertaking the first embryo transfers to the recipients [25]. From the information available it is unclear why the GCLI team wished to start embryo transfer sooner than had occurred in the proof of concept Swedish trial. With regards to possible rejection of the donated uterus or pregnancy there does not appear to be a medical indication for starting embryo transfer sooner, although the risks of immunosuppressant drugs may be minimised somewhat if the time period for retaining and using the donated uterus is shortened. It has been reported that the recipients underwent IVF prior to the transplant, and that one recipient had four frozen embryos, the other had eight [5]. The UK eligibility criteria for uterus transplants requires at least ten frozen embryos; with fewer available frozen embryos it has not been stated what will happen if there is no successful pregnancy and birth [26]. The Indian teams have not made the eligibility criteria publicly available and there is limited information available. It is therefore difficult to assess the progress and processes of uterus transplants in India.

The lead doctor at GCLI, Dr Shailesh Puntambekar, is a surgeon in oncology and has said that he first practised by operating on human cadavers in Germany and also in the US [27]. This raises questions around the experience of this team undertaking uterus transplants with live donors, particularly as the Swedish team, that have had success with uterus transplants from live donors, have not been involved. As noted earlier, Professor Mats Brännström has publicly criticised the GCLI team questioning their experience in undertaking such complex and experimental surgery. According to one media report, *‘The minimum requirement in experience to carry out this procedure, as per the Human Organ Transplant Act, by a clinical team is not available in any group outside a Swedish group. Milann also obtained permission from the Medical council of India for the participation of Swedish doctors for the procedure which is yet another mandatory requirement.’* [28].So it appears that the ICMR would not have granted the GCLI approval to conduct uterus transplants without the involvement of the Swedish team; whilst the ICMR has said this uterus transplants should be done under a research protocol, the *‘ICMR does not have a mandate to interfere at this stage’* [29].

The discrepancy between the appropriate bodies to approve uterus transplants is one that needs urgent attention, whether it is a research, or a clinical practice body, is of importance due to the ethical controls, the consent procedures, and the application process involved. If uterus transplantation is to proceed then it needs to be ethical, carefully regulated, and clear which system of regulation applies and which body can give approval for uterus transplantation to proceed. At this stage in the journey of uterus transplantation it is still experimental and in the research stages, and approval should be sought accordingly, whether through a State body specialising in research, or through an institutional review body. Legal and ethical uterus transplantation is vital if this reproductive procedure is to progress with public confidence and support. Protection of the women involved as well as the future children is of paramount importance, and needs careful consideration by an appropriate ethical review body that is able to take into account the reproductive and societal cultures of the country, as well as the consent process, the scientific information about the proposed work, and the experience of the proposed medical team. The demand for uterus transplants in India is high, with 156 on the waiting list at GCLI reported as of June 2017 [30]. If uterine transplantation is to continue in India, there needs to be a resolution over which body has the authority to grant appropriate approval for uterus transplants, otherwise this risks undermining the positive work that has been done around the world through proceeding with cautious steps to the point of human uterus transplants trials [31].

On the whole the media reports around uterus transplantation have been positive, promoting the benefits that this procedure will bring to women who suffer from absolute uterine factor infertility and demonstrating that there is demand for this procedure. The negative press around uterus transplants in India focused on the discord between the GCLI, the Milann International Institute, and the ICMR. With strong opinions around start of life procedures, and the ethics of research trials, it is fundamental that this discord is resolved promptly in order to give confidence to women with absolute uterine factor infertility and their potential donors, that this work will be conducted ethically and professionally. The appropriate regulatory body to oversee uterus transplants within India must be clarified. Furthermore, reporting of trials, treatments and results must also be reported more widely in the medical journals and the press. Finally, greater collaboration between research teams worldwide is encouraged. When these issues are resolved, public and professional confidence in uterus transplants in India will increase.

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