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Informed consent in medical decision-making in commercial gestational surrogacy: a mixed methods study in New Delhi, India

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Key words

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Conflict of interest

Malene Tanderup, Sunita Reddy, Tulsi Patel and Birgitte Bruun Nielsen state explicitly that there are no conflicts of interest in connection with this article.

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Abstract

Objective. To investigate ethical issues in informed consent for decisions regarding embryo transfer and fetal reduction in commercial gestational surrogacy. *Design.* Mixed methods study employing observations, an interview-guide and semi-structured interviews. *Setting.* Fertility clinics and agencies in Delhi, India, between December 2011 and December 2012. *Population.* Doctors providing conceptive technologies to commissioning couples and carrying out surrogacy procedures; surrogate mothers; agents functioning as links for surrogacy. *Methods.* Interviews using semi-structured interview guides were carried out among 20 doctors in 18 fertility clinics, five agents from four agencies and 14 surrogate mothers. Surrogate mothers were interviewed both individually and in the presence of doctors and agents. Data on socio-economic context and experiences among and between various actors in the surrogacy process were coded to identify categories of ethical concern. Numerical and grounded theory-oriented analyses were used. *Main outcome measures.* Informed consent, number of embryos transferred, fetal reduction, conflict of interest among the involved parties. *Results.* None of the 14 surrogate mothers were able to explain the risks involved in embryo transfer and fetal reduction. The majority of the doctors took unilateral decisions about embryo transfer and fetal reduction. The commissioning parents were usually only indirectly involved. In the qualitative analysis, difficulties in explaining procedures, autonomy, self-payment of fertility treatment and conflicts of interest were the main themes. *Conclusions.* Clinical procedural decisions were primarily made by the doctors. Surrogate mothers were not adequately informed. There is a need for regulation on decision-making procedures to safeguard the interests of surrogate mothers.

Abbreviations: ART, assisted reproductive technology; CP, commissioning parent; FIGO, Federation of International Gynecology and Obstetrics; IVF, in vitro fertilization; SM, surrogate mother.

Introduction

The surrogate gestates genetically unrelated embryos fertilized via in vitro fertilization (IVF) techniques with gametes of the commissioning parents or gamete donors.

In April 1986, in the USA, the first child conceived by IVF and carried by a gestational surrogate was born (1). India has become one of the new global health tourism destinations with an expanding commercial gestational surrogacy market owing to low medical costs, high quality of and speedy access to treatment, widespread use of

the English language, and easy recruitment of surrogates (2–4). Furthermore, the Assisted Reproductive Technology (ART) Bill has been pending for five years and only the “non-binding” guidelines from the Indian Council of Medical Research regulate the running of clinics (5,6). The cost, laws and guidelines on surrogacy differ from country to country, facilitating cross border reproductive services. In India, Russia, Ukraine and some states of the USA both commercial and altruistic surrogacy are allowed. The UK and some states in Australia permit only altruistic surrogacy, and surrogacy is not legalized in Scandinavian countries and other countries such as Germany and Spain (7–9).

Commercial surrogacy attracts international interest because surrogacy and cross border reproductive services involve all countries, regardless of legal practices, and because infertile couples turn to the countries where the treatment is available or costs are low. The Federation of International Gynecology and Obstetrics (FIGO) has debated the ethical dilemmas of surrogacy and clinical practices, especially in cross border surrogacy (10). It raises medical ethical issues of conflict of interest, bodily integrity, and the rights and responsibilities of the various parties involved.

Informed consent is an integral part of medical decision-making for a patient accepting a specific treatment. To achieve informed consent, medical staff need to inform and discuss about potential effects and side effects of the treatment with the patient. Achieving informed consent among doctors and patients from the same socio-cultural background is challenging on many counts. This challenge is more complex when informed consent is sought for technical procedures from an uneducated, non-English-speaking surrogate (11). Medical terminology is too complex for patients without medical knowledge and training, and busy schedules and heavy patient load constrain clinicians from “translating” the medical terms to mainstream terminology. The lower socio-economic background of the surrogates tends to exacerbate language barriers, making the challenge even more complex. Furthermore, in India a self-assured attitude among doctors is the norm, hence the necessity of obtaining informed consent may not be felt as urgently as in other settings (12). Termed patriarchal, such an attitude is reflected in the Indian surrogate mother being counseled and trained as a “demure mother worker” (13). In more equal contexts, to become a surrogate may be viewed as an expression of a woman’s autonomy. Further, as an individual she should be free to make this decision based on comprehensive information. But given the authoritative medical context in India, to expect adequate counseling on medical risks leading to informed consent is farfetched (12,14–16).

The FIGO report recommends that healthcare providers should reduce the risk of multiple pregnancies to protect the surrogate and babies born out of surrogacy (10). Yet the number of embryos that should be transferred is highly dependent on laws or guidelines as well as ethics regarding risks and claims of success rates in infertility treatment (17,18). A high number of embryos transferred might increase the success rate of pregnancy but might also increase the risks of multiple pregnancy and thereby the risk of prematurity (18,19). In multiple pregnancies, fetal reduction is an option. The risk–benefit calculus of fetal reduction in multiple pregnancies demands ethical and medical assessment. Its complexity rests on the intention to sacrifice some fetuses for a better survival of the remaining ones (20).

Reproductive tourism in India is estimated to be worth US\$500 million to US\$2.3 billion annually (21). It brings together the different interests of the parties involved. Doctors in the business target high success rates and low costs to attract national as well as international clients. Infertile couples undergoing self-financed IVF treatment add to the pressure of achieving a pregnancy in their first attempt (22). Commissioning parents might see multiple pregnancies as a positive indicator and opt for clinics advertising higher success rates (23). The working class surrogates are attracted by the handsome payment. Many studies have explored the dilemmas and practice of surrogacy, but little attention has been paid to obtaining informed consent and medical decision-making. This study aims to investigate these two processes in commercial surrogacy, focusing on the number of embryos per transfer and fetal reductions, based on empirical data collected in Delhi, India.

Material and methods

The study was conducted in the National Capital Territory of Delhi, India, from December 2011 to December 2012. Through snowballing and internet search on clinics, hospitals and agencies involved in surrogacy, 35 clinics

Key Message

Adequate information regarding implications of medical procedures in surrogacy should be provided to commissioning parents and women undergoing surrogacy. Their autonomy and their voice should be respected in the decision-making process. Consideration should be given to conflicts of interest among fertility doctors, agents, commissioning parents and surrogate mothers.

and hospitals and 10 agencies were identified (Figure 1). The last internet search was performed in August 2012. Researching the sensitive topic of commercial surrogacy in India, it was problematic to get appointments with doctors, agents and, in particular, surrogate mothers (SMs). The authors did not succeed in getting an appointment with any of the commissioning parents (CPs). From the 18 clinics offering surrogacy services, eventually 16 doctors were interviewed once and four doctors were interviewed twice, resulting in 24 semi-structured interviews. Semi-structured interview guides were used in the first instance. All doctors were requested to grant a second interview which, being very busy, they were not inclined to do; those who agreed were interviewed to strengthen the contexts and content of the themes of informed consent and decision-making. The duration of the interviews ranged from 10 to 70 min, with an average of 35 min; the time varied because although all doctors answered the structured questions, some provided only brief answers whereas others provided long, full answers to the open-ended questions.

Five agents from four agencies were interviewed, resulting in seven interviews varying in duration from 15 to 90 min. Agents and a lawyer referred the 14 SMs who were interviewed. Using an interpreter in the interviews with the SMs limited the flow of the interview and some information may have been lost in translation.

Although some doctors expressed the possibility of interviewing SMs and CPs, it later turned out to be difficult to meet surrogates, and impossible to meet CPs.

According to the doctors, the SMs and CPs were unwilling to be interviewed as they had doubts concerning confidentiality or were nervous at the thought of meeting a foreign researcher. In some instances it was the day of embryo transfer or other medical interventions, raising ethical concerns in conducting interviews. Eventually we interviewed SMs through agents. In 11 of the 14 cases the agent or lawyer was present at the interviews. Interviews with the SMs were not as lengthy because they had to go for treatments or scans or had to leave, escorted by the agent. Subsequently, interviews with two SMs were conducted in a non-clinical setting (a park near the clinic) accompanied by one friend and a lawyer for two hours.

We used a mixed method design, with an interview guide combining structured and open-ended semi-structured questions. Numerical and grounded theory-oriented analyses were used (24). Data on socio-economic context and experiences of various actors in the surrogacy process were coded for teasing out categories of ethical concern. It required iterative reading and reflection on case comparisons for common patterns and themes in surrogacy practice to emerge. Comparable available studies were a constant reference during the research (4,13,14). Triangulation between the first and second interviews and among different respondents in the same category was contextualized to extract conceptual and theoretical pointers to salient features indicating how medical authority is the prime decision-maker. Triangulation enabled the researchers to segregate information on conflict of interest among various actors in the process.

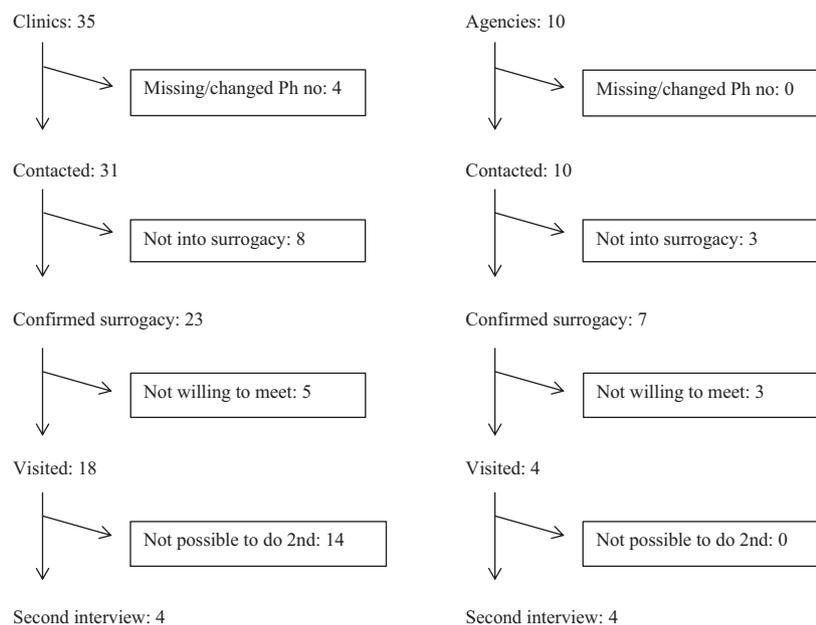


Figure 1. Flow chart of the visited fertility clinics and agencies working with commercial gestational surrogacy in New Delhi.

Oral consent was obtained from all participants after informing them of the purpose of the study. We chose oral consent as this was the most commonly used method in the Indian context, especially as the ethics review board had not started functioning at that time in the universities with which the authors were associated. The Declaration of Helsinki was followed to secure especially the interviewed surrogate mothers. If the agent or doctor required that specific questions were not raised in the interview of the surrogate mother this was respected so as to eliminate any adverse consequences to the surrogate from the interview. Participants were given pseudonyms to maintain confidentiality. All interviews were summarized with detailed notes and verbatim quotations. Permission to record was obtained in 11 interviews after getting consent. These were fully transcribed.

Results

Participants

Of the 14 surrogate mothers, five earned money from sewing, domestic work and checking goods in a company; five were unemployed and four did not answer. Nine of the surrogates' husbands worked as auto-rickshaw drivers, staff in office and fish salesmen; three of the surrogates did not provide information about their husband's employment (see Table 1).

All the 18 clinics were private; nine were smaller independent IVF clinics and nine were part of larger hospitals. The clinics had one to 15 cases of surrogate mothers per month and none of the clinics had an exclusive surrogacy business but had five to 100 cycles of ART a month. Characteristics of the doctors are given in Table 2.

One agency worked in cooperation with an IVF clinic. Three agencies were independent companies offering the clinics services such as recruiting women for surrogacy, corresponding with international clients and escorting surrogates to the clinic for treatment and scans. The agents had social networks in poorer enclaves, which were a potential source of surrogate women to clinics and agencies (Table 3).

The main themes of the qualitative analysis were informed consent, autonomy, profit-driven reproduction, provider-patient relationship, decision-making and conflict of interest.

Informed consent

In general the surrogates did not criticize the agency or clinic. Two surrogates in a clinic felt that they had been treated well; as one of them said: *"It is the agent who informs us. If he hadn't informed me good enough, I*

Table 1. Characteristics of the 14 interviewed surrogate mothers in New Delhi.

Ages (years)	
21–25	3
26–30	4
Unknown	7
Marital status	
Married	12
Widows	2
Parity	
1	6
2	6
3–4	0
5–6	2
Education	
Illiterate	1
1st–5th grade	5
6th–10th grade	4
Unknown	4
Monthly income in family (Rs)	
5000–9999	2
10 000–13 000	3
Unknown	9

Table 2. Characteristics of the 20 interviewed doctors working with gestational surrogacy (by performing fertilization, or being involved in antenatal and/or obstetric care) in New Delhi.

Sex	
Female	19
Male	1
Fertility experience (years)	
3–10	8
11–20	3
20–25	3
Unknown	6
Employment	
Owner	8
Employed	12
Presently working in	
One clinic	3
Two clinics	14
Unknown	3

wouldn't have become a surrogate again." Despite the fact that some of the SMs felt they had been adequately informed, none of the SMs was able to explain how many embryos had been transferred, or the possible complications in multiple pregnancies and fetal reduction. When asked if they required more detailed information on the medical procedures, for example, embryo transfer and fetal reduction, the SMs were less categorical in responding. Asking for elaboration of procedures for which the doctors are considered the experts is not seen as right;

Table 3. Characteristics of the five agents working in the field of gestational commercial surrogacy in New Delhi.

Sex	
Female	2
Male	3
Experience with surrogacy (years)	
0–2	2
3–4	2
5–6	1
Employment	
Owner	3
Employed	2

Table 4. Reported maximum number of embryos transferred to a surrogate mother by the 18 clinics in New Delhi.

Max no. of embryos per transfer	No. of clinics
2	3
3	7
4	4
5	3
7	1

indeed, it is a mark of the relationships between the authority-wielding doctors and near illiterate surrogates.

On the issue of giving SMs adequate information, Doctor A was asked what she told the SMs about number of embryos to transfer: “No, we never ask them and they are not even informed how many are going to be transferred. They are illiterate, uneducated girls. . . We do tell them that they are going to get embryos transferred into their womb and they are very happy when they are having twins because they are going to get more money.”

Decision-making in embryo transfer

Many of the interviewed doctors clearly expressed the need for legal restrictions on number of embryos to transfer. The guidelines from Indian Council of Medical Research prescribe the transfer of a maximum of three embryos. However, Table 4 shows other trends.

In 12 of the clinics the doctor made all the decisions. Four of the clinics would involve commissioning parents but not the surrogate mother, and only one clinic would involve all parties. Doctor B explained that with surrogates they never transfer more than two embryos because the surrogates are already proven fertile. This clinic preferred commissioning parents to be a part of the decision and if they wanted only one child, the clinic would only transfer one embryo.

Contrary to Doctor B, Doctor C clarified why, in her opinion, commissioning parents should not have any say

in the decision about number of embryos to transfer, “No, I decide. Because they may say, put six or put seven, and maybe sometimes they may carry triplets and say carry on with these triplets. So we can’t let them decide.” Doctor C normally transfers three embryos and reduces to two fetuses.

Doctor A emphasized the commissioning parents’ desperation to have a baby and thus the lack of focus on the medical aspects: “When a person is coming for surrogacy, it means all the doors have been closed, with no hopes. They are ready to accept anything. They just want a child. If they are twins, they are happier. So, most of the time they don’t say anything. . . As laymen, they don’t go into the nitty-gritties of the medical aspect of anything.”

Decision-making related to fetal reduction

In three clinics the decision to reduce the number of fetuses was made by doctors without involving any of the CPs or SMs. According to the doctors, the CPs were included in the decision-making in 10 clinics. Doctor D explained the clinic’s interest in decision-making for fetal reduction: “We do fetal reduction down to twins. It doesn’t look good for the clinic if we have too many multiple pregnancies. And there are more complications with triplets. The commissioning parents can influence the decision. If too many are reduced it ends up in abortion and the commissioning parents should know that. If they want triplets we counsel them as the surrogate mother should be able to carry triplets.” Doctors think they know the surrogate’s body’s capacity to carry multiplexes and often convince CPs to accept their expert advice.

Only three clinics explained fetal reduction as a joint decision between the doctor, CPs and SMs. It was mainly in the case of triplets that the surrogate could object, because of the increased risk to her health. In these clinics, surrogates learned of the number of fetuses they were carrying before fetal reduction. Doctor E explained decision-making in her clinic as: “The commissioning parents decide about the fetal reduction but we also ask the surrogate if she is willing to carry triplets. We have to do that because there are more complications connected to triplets. If she does not want triplets we convince the commissioning parents to go for fetal reduction.”

Conflict of interest

Surrogate A from an agency described the information she received when she signed the contract: “They [the medical doctors] were doing everything according to the madam’s [the agent’s] wishes and their own wishes”; she did not feel they listened to her. She had objected to carrying twins because, as she said, “There are so many

problems in having two kids. After having one kid of my own, I know how it is...I don't want two kids. Not the money but I have to care about my body, don't I?" Surrogate A did not know how many embryos had been transferred. All she knew was that she was carrying twins and the agent and doctor were not willing to reduce the fetuses. They offered her extra payment of 50,000 rupees (802 US\$) and a cesarean section, which she accepted.

From the physician's point of view the interest of the commissioning parents is different when they come from abroad, as compared with Indians; as Doctor F explained: *"When you have international commissioning parents you have to give them the best service; otherwise they will go another place and have it. The commissioning parents believe that ART is like 100% success [sic]. So they want to have children with them back [sic]"*. One clinic said that normal IVF would cost 1–1.5 lakhs (1604–2406 USD) and surrogacy about 12 lakhs (19 255 USD). Therefore the success rate had to be high to give the commissioning parents value for money.

The impact of cost considerations on decision-making was supported by Doctor A, *"It [the multiple pregnancy rate] is higher in my facility and in India than in the Western world. See over there, they are trying to reduce the multiple pregnancy rate, I don't get it over here because here IVF is self-financed. We have no insurances and we have no money to reimburse the IVF charges so...if they get twins it is two in one shot, they don't have to spend that money again."*

Discussion

This study illustrates the complexity of achieving informed consent and the difficulties in the decision-making process in commercial surrogacy. We found lack of adequate informed consent for all the 14 SMs. None was able to describe the risk implications of being a surrogate. Further, some doctors did not consider that the SMs were able to understand the more complex information. Shared decision-making was rare in embryo transfer and fetal reduction. Thereby the CPs and SMs had a minimal influence on how many children they could handle and carry respectively. Different interests were conflicting, with the SMs being paid a large amount of money compared with their normal income, the doctors not trying to lower the multiple pregnancy rate because of self-paid treatment and the CPs' interest in having a baby with minimum numbers of cycles.

In the course of our study some of the doctors acknowledged that the surrogates have a limited capacity to understand medical information and therefore the doctors have to simplify their explanations to the surrogates' level. Consequently, complexity of treatment, especially explanation of risks, gets left out. This might indicate

inadequate information provisioning, since none of the 14 surrogates were able to explain the medical procedures, especially the risks involved. This could be due to the doctors' authoritarian attitude and the doctors' assumption that the SMs would not, in any case, be able to understand the medical terminology. Doctors' explanations of the risks and implications of medical procedures should be tailored to the surrogate mothers so that complexity and precision are not lost in the 'translation' to the local language.

At fertility clinics, the first decision to surrogate is taken by the SMs, who seem in awe of doctors. The doctors think they know what is best (25) for SMs, who in turn avoid unnecessary questioning of doctors' decisions. However, the SMs do not submit to medical authority without question. For instance, poor pregnant women in Jaipur *bastis* (slums) indicate that they opt for suitable reproductive services (26). Having borne children, they are familiar with the natural processes of pregnancy and birthing. It is just that as SMs they are inadequately informed about the medical technological procedures for embryo transfer and fetal reduction. Their consent for various procedures is taken for granted once they commit to be surrogates. Undergoing ART procedures in plush surroundings, however, nuances the extant forms of authority between doctors and SMs. On the other extreme, Kekewich questions the value of excessive patient autonomy and consequent demands for inappropriate medical procedures in the West (27). We, on our part, argue for provision of appropriate information to SMs, even if they are quite confident of their proven fertility capacity.

The main limitation to our study was that the participants might not have spoken freely for fear of the consequences. This limited the interviews with the SMs, who were diffident and wary in front of agents and avoided revealing any negative aspects of the process. The surrogates interviewed in the non-clinical setting spoke more frankly about the situation than the surrogates interviewed in the presence of agents. The voices from different locations are important as they illustrate the power relationships between the agent and surrogates – the employer and employees, as it were. The limitation also affected the doctors and agents, as surrogacy is a matter of public debate in India as internationally, and to speak frankly might negatively affect their business. Yet, the majority of the doctors saw the importance of sharing their knowledge on the subject.

When the CPs and SMs are not a part of decision-making the doctor ignores their autonomy and assumes the power to decide. Only one clinic in our study practiced shared decision-making on number of embryos to transfer and three clinics practiced shared decision-making on

fetal reduction. Current practices could be due to great cultural, religious and socio-economic differences between CPs, SMs, agents and doctors. Similar conditions were found in another study from India on IVF treatment in which the infertile women underwent too many inseminations, encouraged by the doctors, without being informed of or involved in the decision (28). Rarely was decision-making on fetal reduction shared. This reflects the ethical dilemma that fetal reduction presents. The SMs and CPs could be apprehensive about reduction due to religion, culture or personal belief and this is not respected if they are not involved in deciding. The clinics should take steps to follow ethical standards by involving both SMs and CPs (10). The question is whether the doctors feel this is necessary.

This study illustrated the conflicts of interests between the involved parties in medical decision-making in surrogacy. The profit-driven, self-financed nature of IVF reproductive healthcare added to the pressure of achieving a pregnancy in the first attempt both for the doctors as well as commissioning parents (22). A similar practice of high number of embryos per transfer is reported from Taiwan, an East Asian country that also legalizes surrogacy and low cost medical treatments (29). The financial compensation offered to surrogate mother A for carrying twins was of such a size that it greatly influenced her consent and acceptance of the doctor's advice: in fact, the autonomy of the SMs is compromised when they are offered "enough" money. The interest of the doctors is focused on giving the commissioning parents the best possible success rates, disregarding the risk of complications related to a multiple pregnancy. High success rates would also attract foreign patients, as it would minimize the number of times they would have to travel to India (as Doctor A said, they would get "two in one shot"). However, a high number of embryos per transfer is unethical and needs regulation (10,22). This practice is similar to the profit-driven healthcare in the USA, which permits more embryos per transfer, in contrast to the partially public-funded IVF health care in Scandinavia, which favors single embryo transfer. This illustrates the complexity of reproductive care not only in surrogacy in India but worldwide, where social, political, cultural and economic contexts influence standardization of clinical procedures.

The above discussion shows how commercial interests join with medical authority in obtaining the unethical (uninformed) consent for certain procedures in gestational surrogacy in Delhi. The commercial considerations, with concomitant over-medicalization, such as multiple implantation and frequent fetal reduction, conflict with ethical medical practices based on FIGO guidelines (10). The self-regulated ART clinics have the freedom to prac-

tice without any clinical standardization, leaving surrogates at the mercy of the clinics.

Conclusion

There is a pressing need to explore the way risks are perceived by the surrogate mother and the commissioning parents and how clinical authorities make decisions. The doctors wield medical authority over surrogates, confident that the doctors know better. Kekewich, in contrast, shows how easily available medical information leads to several inappropriate procedures that consumers are increasingly demanding from doctors, in the West (27).

Conflicts of interest and lack of Indian ART laws make it easier for the clinics to cross ethical lines to convey high success rates. Indian clinics, with their advanced standards in science and medicine, should maintain equally high standards in ethical practices, regardless of complexities arising from the socio-cultural differences between all the players involved in the practice of surrogacy.

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