Sama
Resource Group for Women and Health

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To,
Prof. N.K. Ganguly
Director General,
Indian Council of Medical Research,
Ansari Nagar
New Delhi -29

Sub: Bringing to your attention our concerns on the ICMR National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, 2005.

Sir,

Sama- Resource Group for Women and Health is a Delhi based organisation working on women's health issues with a rights perspective to achieve equality and justice. We are currently carrying out a research on Assisted Reproductive Technologies, in the course of which we found it essential to refer the ICMR's National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, 2005.

At the outset, we are happy that ICMR has come out with a set of guidelines for the supervision and regulation of the ART clinics in India. We acknowledge the efforts of the members of the Indian Council of Medical Research for taking this initiative. However, as mentioned above, in the course of our field level interaction with users and the providers of the technologies several gaps between the guidelines and the ground realities were revealed. We, therefore, as members of a Women and Health group are writing to you to convey our concerns and suggestions with regard to the Guidelines.

In a society that places a premium on fertility, one needs to be aware of the fact that a potentially liberating technology to treat infertility cannot/does not exist in an apolitical vacuum. There are several issues that Assisted Reproductive Technologies raise at the interface of technology, health and society. The lucrative market and the powerful nexus between drug companies and providers of medical services cannot be undermined. In order to have a broader picture, it is significant to view the new reproductive technologies within this context of politics behind scientific research and perceived social pressures towards motherhood.

Moreover, in considering the area of assisted human reproduction and reproductive technologies now available, it is essential to take account of their health and social implications for women, and to recognize women's needs and experiences. Each of the technologies under the rubric of assisted reproductive technologies raise specific medical, ethical and social dilemmas.

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Unfortunately, at one level, we found several contradictions and inconsistencies in the document and at the other level there is enough space that can be manipulated according to the interests of the powerful groups associated with the technology.

Here, we endorse an overall critique of the Guidelines on Accreditation, Supervision and Regulation of ART clinics in India, 2005 and raise our concerns in relation to it. In the following sections, we examine and analyze the guidelines, it's assumption and also juxtapose with our observations in the field.

Though we believe ICMR has attempted to look into the issue of Assisted Reproductive Technologies to a certain extent, its limited understanding of the social and ethical implications of the technology is apparent. Apart from being gendered and moralistic, the contents endeavour to glorify the technologies at various junctures. To be precise, the guidelines revolve around the heterosexual and monogamous married couple. All over the document, terms like *'husband', 'wife' and in some places 'partner'* are used. Lesbians, gays, single women and their concerns are inconspicuous in the whole document.

This is quite disturbing as the ICMR guidelines, 2000 had a mention on the issues related to gays and lesbians, but strangely it finds no place in the present document. As Section 3.5.2 of the old draft guidelines read, *"There would be no bar to the use of ART techniques by single unmarried women or a lesbian couple or a gay couple who wish to have a child and no ART clinic may refuse to offer its services to the above, provided other criteria mentioned in this document are satisfied. The child thus born will have all the legal rights on the woman or the man.*

This exclusion of certain categories gives us enough evidence of the hetero normative structure, which the medical establishment tries to push forth.

Chapter 1

Introduction, brief history of ART and requirement of ART Clinics

The guidelines say under 1.1.1 that ART is an alternative to reversal of sterilisation. *"Infertility, consequent to use of terminal methods of contraception under the family Planning Programme, may sometimes need to be reversed for personal reasons such as having lost a child/children born prior to sterilisation...*

This makes it obvious that ART can be manipulated as another instrument in the hands of the population controllers to further their larger objective, providing justification for rampant sterilisations.

The guidelines construct infertility as a disease and the infertile as patients, which makes medical intervention not only a necessity, but also the only way out to deal with infertility.

It also says (1.6.4) *'IVF is a therapeutic option of reproductive medicine with the highest yield per attempt, coming close on many occasions to that achieved by fertile couples conceiving naturally'*. One needs to ask here what ICMR means by *'therapeutic option'*. The Oxford English Dictionary gives two meanings the word *'therapeutic'*. Firstly, it means *'curing of a disease'* and the other meaning is *'contributing to the relief'*. There is no clarity in which sense ICMR uses the word therapeutic, and on what basis does it claim IVF to have the highest yield per attempt, coming close to conceiving naturally. However, when the real take home baby rate with IVF is only between 15-20 percent,

such rhetoric will not only mislead the infertile people, but also lead to further invasion of women's bodies by the medical establishment.

National Advisory Committee (NAC)

Though there is a mention of the responsibilities and composition of the National Advisory Committee and the State Appropriate Authority, the scope of these committees and its modus operandi to implement its powers are not brought up comprehensively. Further, it is significant to state that the composition of the State Accreditation Committee finds no place in the document. Our other concern is whether the accreditation process has commenced, and whom do the clinics get accredited under i.e., the hospital registrations, Medical Councils, or any other body. Secondly, our concern is even if some or many of the clinics are registered, how would the users be aware of this top down formulation. How will ICMR ensure that the users go to authorised providers only?

1.6- ICMR says, *'it is hoped that the practitioners of ART in the country will bring to the notice of the committee on a continuing basis, any new procedure for the practice of which there would appear to be a sound scientific case'*. It is problematic to rely on the ART clinics and hope that they will be accountable to the National Accreditation Committee. Moreover, there are no details of the scope of the National Accreditation Committee and its responsibilities, whether it has any executive powers and what could be the qualifications of various members in this Committee.

How do we ensure whether the practitioners of ART are being accountable to the National accreditation committee?

Infrastructure

Physical settings

The document refers to categories of infertility care units, which includes primary level (1A), primary level (1B), secondary level and tertiary level. Our observations were quite contrary to what the guidelines say. We did not find any such categorisation in our study. Moreover, how will ICMR ensure that users go to level 1A and 1B initially and then to level 2 and 3?

The document says, *'level 1A clinics will ...maintain records, these records will be liable to inspection by an appropriate review committee'*. At the same time, it also says that a level 1A clinic will not require accreditation under these guidelines. The concern is, if the level 1A clinics are not accredited or officially recognised, how will the committee review the records of these clinics and ensure exactly what services these are providing?

1.3.1.3 A general purpose clinical laboratory

The draft guidelines say that the lab must be equipped to carry out simple procedures for screening for HIV, Hepatitis. However, the published guidelines are incomplete and does not say anything - Is it a printing error -? Then what is the purpose of 1.3.1.3?

The laboratory facilities should be such to include diagnosis of HIV, HBV, HCV, Syphillis, Gonorrhoea, Chlamydia etc., but should not be restricted to these. It should be possible to rule out any new, relevant infection. Similarly estimation of various hormones should be done at least with assays as sensitive and specific as immunoassays, not restricting the technology to immunoassays permanently. These details may be left to the discretion of a committee, perhaps under the NAC, and rules for the same formulated.

1.3.1.5 Record Room

"Any other.....for India"

It says ICMR shall make an effort to devise a form for basic data recording for possible adverse reaction to drugs"...but this form is not in the guidelines (published). What is the status now? How will they ensure?

Composition of the team in an ART clinic

'The practice of ART requires a well-orchestrated team work between the gynaecologist, the andrologist and the clinical embryologist supported by a counsellor and a programme coordinator/director', states ICMR.

In our sample of 25, 15 of them had a gynaecologist and 13 of them had an embryologist. Only 3 clinics had an andrologist and 3 clinics had a counsellor. One clinic had an urologist and a geneticist. Most of the clinics do not have their own team but they have an arrangement with other gynaecologists and andrologists.

1.5.4 Counsellors pg 22

"An individual may act as a counselor for more than one clinic.
A member of the staff of an ART clinic can act as a counselor" How do you ensure?
But our study revealed quite a dismal picture in this context. We were quite skeptical of the nature and content of the counselling provided, as some of the users did not know the technique being administered to them. These users stated that they had undergone a small operation and were on some drugs prescribed by the doctors

A counselor should be well versed with the complex issues and some of the ethical and legal dilemmas and as far as possible should not be influencing the decisions of the potential users of ART without explaining the positive and negative aspects of the issue.

One of the provider's pointed out that *'the professional counsellors would also add to the total cost of the treatment for the patients'*.

Another provider claimed, *"there is a serious dearth of qualified counsellors. In the absence of the counsellor, the workload of the doctor becomes double"*.

"We also have a house counsellor. However, in our country, the patient prefers to be counselled by the doctor. They don't believe much on the outside counsellor. In such situations, I counsel the patients. My time, in such cases, would be 20 minute," said a provider.

Counselling

The ICMR guidelines claim counselling to be a crucial component in the treatment process which would ensure that the users are thoroughly informed of the procedures and also consider other alternatives like adoption before going for ART. It says that a person who has a *'degree in social sciences, psychology, life sciences or medicine and a good knowledge of the various causes of infertility and its social and gender implications.... is qualified to occupy'* the position of a counsellor.

In most of the cases we found counselling is provided by the doctors themselves. There is quite a possibility that the providers will emphasize on ARTs rather than adoption, keeping in view their own self-interest. And adoption is advised only when the IVF fails.
It would not be erroneous on our part to assume that providers have their own vested interests and that would influence the counselling they provide.

AGE

ICMR holds an ambivalent stand regarding the maximum age of the woman going for ART. *'The endometrium of menopausal women has the ability to respond to sex hormones and provide a receptive environment for implantation of an embryo'*, points ICMR Though, it maintains that menopausal women can undergo these techniques there is no specification on the maximum age. Moreover, the health implications of ART on menopausal women is not spelt out anywhere in the document.

ICMR also maintains a considerable degree of ambiguity in relation to 'age' of the egg donor. Section 1.6.7.1 mentions that the egg donors should be within *'the age group of 18 to 35 years.'* Another section (3.7.4) maintains that the *'age of the of the oocyte donor must not be less than 21 or more 35 years.'* It is not comprehensible why ICMR maintains this contradiction over a crucial issue, which is likely to have implications on the egg donor's health.

As regards the issue of minimum age of a woman using ART, ICMR points out (3.14.1): *'Minimum age for ART: for a woman between 20 and 30 years, two years of cohabitation/marriage without the use of a contraceptive, excepting in cases where the man is infertile or the woman cannot physiologically conceive. For a woman over 30 years, one year of cohabitation/marriage without use of contraceptives. Normally, no ART procedure shall be used on a woman below 20 years.*

While this section of the guidelines articulates the minimum age for a woman using ART as 20, its stand on the maximum age is ambiguous.

ICMR also says that a *surrogate mother should not be over 45 years of age* and should belong to the same generation as the woman desiring the surrogate. However, our study evidenced certain contradictory facts. Most of the advertisements for surrogacy maintain an ambiguity with respect to the age requirement. The providers also shared that there are women above 45 years coming for Surrogacy. An advertisement says *"A childless couple in Mumbai looking for young, good looking female for surrogate mother. Suitable reward assured"*.

ART Procedures

1.6.2 Artificial Insemination with Donor Semen (AID)

"Only frozen sperm samples... should be used"

...screening/quarantining for infectious diseases should be open, not just limited to HIV, Hepatitis B and C, Syphilis, but there should be scope to include other infectious diseases.

1.6.8.8 Oocyte cryopreservation

What is the success rate with cryopreserved Oocyte? If it is poor then why it is allowed for further research?

1.6.11.2 Indiscriminate Use of ICSI

The guidelines clearly say *"There is a higher than normal frequency of sex chromosomes abnormalities in children born of ICSI procedure compared with the normal population"*

Any attempt to 'mature ' sperm in vitro or use sperm directly from epididymis or testis should not be prescribed as a legal ART, until adequate safety data about the use of such sperm becomes available.

Why should be ICSI used at all when there are so many studies establish the risk of transmitting defective fertility genes to the male progeny- no clear stand of ICMR on this

1.6.11.2 Possible misuse of ART - Sale of embryos and stem cells

The ICMR guidelines prohibit *the sale of human embryos to any party outside the country. However, within the country they are available to bonafide researchers only as a gift having no commercial interest.* How will ICMR monitor this?

Bonafide – who will identify their authentication? How do you ensure that there is no commercial transaction taking place when there is such growing interest in embryonic stem cells?

India has no appropriate stand on this issue. Embryos can be indiscriminately sold to other countries by providers, since there is no regulation. How will ICMR monitor this?

Chapter 2

Screening of Patient for ART: selection criteria and possible complications

Pg 39
2.1
Can only husband, wife/married couples go for ART? Why are single women, lesbian, gay couples and individuals excluded?

Chapter 3

Code of Practice, Ethical considerations and Legal issues

3.2.4 How do we know exactly what information is given about side effects, techniques involved and comparison with other available treatments. The information may be selective.

3.2.9 *The accreditation committee must approve all research that involves embryos created in vitro'* what does all research mean? It is problematic to say 'all' research without specifying what kind of research can be done, what can/should be the maximum age of embryos are contentious issues the world over. However, the ethical guidelines need not set out priorities for research in this document, but if one wishes to use the spare embryos for research, the name of the accreditation authority should be mentioned and principles of 'informed consent' mentioned above followed meticulously.

3.3.11 The consent forms in English and local languages are not found anywhere. Who and when will a body monitor all this? Though the guidelines claim to make the consent forms available in English and the local language (3.3.11), our study did not provide any evidence of the availability of the consent forms in the local language. The pertinent question in such instances is how one ensures whether the doctor has provided adequate and necessary information regarding the procedure involved? (In this case it was ICSI, which holds a high risk of genetic abnormality in the offspring) In the same instance, we interviewed the doctor who believed there was no risk to the progeny associated to ICSI, which made it quite clear that no such specific information was provided to the users.

ICMR emphasises on the informed consent of the users of Assisted Reproductive Technologies and maintains that treatment would be administered only after obtaining a written consent. It has devised a standard consent form for 'couples', and separate forms each for Artificial Insemination with Husband's Semen, Artificial Insemination with Donor Semen, consent for freezing of

embryos, consent for the procedure of PESA and TESA for ICSI, consent for oocyte retrieval and embryo transfer, consent for the donor of eggs, consent for the donor of sperms and a form to consent for surrogacy.

A minute scrutiny not only reveals several gaps between official rhetoric and ground realities, but also certain contradictions and inconsistencies inherent in the language used. There is too much emphasis on an optimistic scenario. The forms were not developed on the social, cultural and religious contexts, which may not allow free and voluntary choice. The language used in the consent forms which is similar to that used in the whole document seems quite problematic. It repeatedly uses expressions like 'husband' and 'wife' ignoring the possibility of other categories like gays, lesbians and single women who might desire to make use of these techniques.

The vital purpose of the consent form is to ensure that users have an ample knowledge of the procedures they use for treating infertility. However, 7 providers spoke about the nature of information provided to the "patient". 2 of the 7 providers said that they inform only about the success rate and side effects of the procedures. One provider said that he informs about the cost of treatment, efficacy and side effects.

On reviewing the sample consent forms we found that the potential risks of ovarian stimulation, oocyte collection, multiple pregnancies, ectopic pregnancies and miscarriage related to IUI and IVF had no mention. Though there is a separate consent form for PESA and TESA for ICSI, there is no mention of the risk of genetic abnormality inherent in the technique. How do participants take informed decision when information on efficacy, long-term safety and psycho-social implications are not adequate?

The form for surrogacy constructs the recipient couple as the 'biological' parent of the child, which is misleading. The couple/person hiring a surrogate may be the genetic parent(s) of the child in certain instances where they donate their own oocyte and sperms, but never the biological parent. It is only the surrogate mother who can rightly be addressed as the biological parent as she carries the child during pregnancy; hence, it is an imperative that ICMR replace the word 'biological' to 'prospective parents'.

The consent form for surrogacy demands the consent of the woman's husband, excluding the possibility of a single woman to be a surrogate. The other issue is *'AID without a husband's consent can be a ground for divorce or judicial separation'*. This again reiterates that a woman has no control over her own body and she requires authorization from her husband for every move.

3.4. 1 *ICMR says that a document containing the success rates... should be maintained by the couples and updated every 6 months.*
In our study we have not come across any such information given to couples No social audit was done in many clinics which can give the list of number of live children born.

3.5.2 *... there would be no bar to the use of ART by single woman. No ART clinic may refuse to offer its services to single women... provided other criteria mentioned in the document are satisfied...* What are the other criteria here?

3.5.3 *The ART clinic must not be a party to any commercial element in donor programmes or gestational surrogacy...*- Our study in some of the surrogates clearly mentioned the commercial transaction between the ART clinic and the couples who are hiring the surrogates.

3.5.4 *A surrogate mother register as a patient* ... Why should a surrogate mother register as a patient? This is problematic. Surrogacy is not any infection or disease which has to be treated.

3.5.9 & 3.5.10
Though 3.5.9 and 3.5.10 mentions about ART clinic not to offer sex selection through PGD or other wise, there is no surety that the providers are not doing sex-selection. A clear emphasis should be made to ban sex-selection by any procedure including PGD. Indian society is largely patriarchal and the preference to have a male child can be traced back to centuries. The practice of determining the sex of the foetus and aborting it in the case of female child is quite common. Thus, introducing a technique that makes sex selection before implantation possible in India provides the potential for its misuse.

3.5.13 & 3.5.14
ICMR says use of sperm donated by relative or a known friend of either the wife or the husband shall not be permitted. This is true also for oocyte donors.

But we found in certain cases oocyte donation was made by sisters. The doctors also claimed that there are less social complications in oocyte donation.

3.5.22
The guideline (3.5.22) says that *'the consent on the consent form must be a true consent witnessed by a person who is in no way associated with the clinic'*. Though this provision seems to be quite sound and reliable, the guideline contradicts itself, as the consent forms demand signature of a witness from the clinic. Moreover, in a country with dwindling literacy rates, how does one ensure whether the users read and comprehend the consent forms before adopting the Assisted Reproductive Technologies? This context makes the presence of a witness outside the clinic a priority. A social scientist or a social worker conversant with the social implications of ART can best suit the role.

3.6.1, 3.7.1, 3.9.1.6 should be futuristic in attitude i.e. should leave scope for inclusion/exclusion of more/different diseases and infections.

3.9.1.1 The reasons for permitting law firms to run semen banks are not clear.

3.9.1.8 pg 67
A semen bank may store a semen preparation for exclusive use on the donor's wife or on any other woman designated by the donor.
Can the donor designate? Does that mean the donor will know the identity of the person...?

3.9.2 pg 68
ICMR says, " the above organisations may appropriately charge the couple for providing an oocyte or a surrogate mother".
What is the appropriate charge?

3.10.3
The ART centre should not only be not involved in the negotiations of 'surrogacy' deals but should also not get monetary benefits from the deal. As mentioned earlier, some of surrogates mentioned that ART centres are actively involved in the deal.

3.10.7

Section 3.10.7 of ICMR says *"A prospective surrogate mother must be tested for HIV and shown to be seronegative for this virus just before embryo transfer. She must also provide a written certificate that...she and her husband have had no extramarital relationship in the last six months.*

This impinges on sexual life of a woman who would be a surrogate. Can't single women go for surrogacy? What about the sexual life of a single woman? How can ICMR assume that HIV can be acquired only through extramarital relationship?

3.11.2. pg 70
Section 3.11.2 says, *'this consent shall not be required if the couple defaults in payment of maintenance charges after two reminders sent by registered post'*. Here it is vital for ICMR to state the charges for maintenance. We need to ask what is done in circumstances where
the couple/person do not consent to use their stored embryos for other couples/person or research, but only because of lack of resources, they fail to make periodic payments.

3.14.11 Stem cell cloning and research on embryos (less than 15 days old) needs to be encouraged. Is it done with the consent of the woman whose embryos are being used for research? What about the issue of sale of embryos in case of couples who may not be in a position to provide the maintenance charges for embryos or for cryo preservation

3.15
Responsibilities of the accreditation authority need to be properly defined, as this becomes not only the accreditation authority but also the supervisory/regulatory authority in due course of time.

3.16.1
A child born through ART shall be presume to be the legitimate child of the couple, born within wedlock, with the consent of both the spouses, and with all the attendant rights of parentage, support and inheritance

This is premised on the notion that children born within the *"wedlock"* are only *"legitimate"*. This assumption is problematic as a child should not judged on the basis of her/his birth within or outside wedlock. This violates the rights of a child to live a life of dignity and respect. Moreover, this completely negates the fact that there are children born to single parent.

3.16.2 Adultery in the case of ART
The guidelines say under 3.16.2 *'ART used for married woman with the consent of the husband does not amount to adultery on part of the wife or the donor. AID without the husband's consent can, however, be a ground for divorce or judicial separation.* This reflects the reinforcing belief that wife's reproductive role is totally in the control of the husband. Hence, the same act of insemination gets interpreted differently if and when done with husband's consent or otherwise.

The law relating to "adultery" in IPC Section 497 is not only based on the husband's right to fidelity of his "wife" but also treats "wife" merely as a chattel of a husband. Such a gender discriminatory and proprietary oriented law of "adultery" is contrary to the spirit of equality guaranteed under the Constitution of India. The ICMR guidelines are also premised on a similar line of thought, which reiterates stereotypes and strengths the roots of unequal gender relations.

3.16.4 pg 75
Statements such as *" however AID be performed only on married 'women'* and that too with the written consent of her husband" and *"A child born to a single woman through AID would be deemed to be legitimate"* are objectionable. This will leave out single women (widows,

unmarried, separated, lesbians) out of these facilities if they wish to make use it. Similarly if gay couples wish to have a child using AID they should also not be prohibited from seeking help.

Chapter 4

Sample Consent Forms

We have certain reservations regarding the informed consent forms put forward in the guidelines. On reviewing the sample consent forms we found that the potential risks of ovarian stimulation, oocyte collection, multiple pregnancies, ectopic pregnancies and miscarriage related to IUI and IVF had no mention.

Though there is a separate form for PESA and TESA for ICSI, there is no mention of the risk of genetic abnormalities inherent in the technique.

The guidelines (3.5.22) say that 'the consent on the consent form must be a true consent witnessed by a person who is in no way associated with the clinic'. Though this provision seems to be quite sound and reliable, the guideline contradicts itself, as the consent forms demand a signature of the witness from the clinic.

The consent forms should use the language of partners/person rather than husband/wife.

The consent forms should include 'a child of desired sex cannot be asked for during the procedure'.

Pg 84 –
Consent for freezing.
How does one know whether the embryos have been destroyed after one's death?

4.5
Though there is a separate consent form for PESA and TESA for ICSI, there is no mention of the risk of genetic abnormality inherent in the technique.

4.6
Is there any way to know the number of oocytes retrieved?

Pg 92,
"I have however been also informed that there is a small risk of the mother or/and the father becoming seropositive..."
What does this mean?

Pg 95
Consent form for donor of eggs.
How does one know the number of eggs retrieved?

4.8
Health insurance of 10 years in specific HIV context should be included as a part and parcel of surrogacy contract

Other Concerns

Adoption

The guidelines state *'treatment for the unresponsive couples will then consist of counselling and an in-depth investigation, leading to the use of ART-failing which, adoption may be the only alternative'*. This makes it quite evident that ICMR considers adoption as a secondary option to be considered only

if the Assisted Reproductive Technologies fail to serve its purpose. This further gives justification to the providers to emphasise on Assisted Reproductive Technologies as a primary option.

Social Audit of the ART Clinics

Auditing and accountability of the ART clinics should be mandatory, which has been completely missed out in the entire document. The audit of the clinics should provide information on the costs (both actual and hidden), the number of live births with ARTs, along with sex-desegregated data on the children born with help of these techniques.

We sincerely hope that our concerns will be taken into consideration and ICMR will attempt to make some revisions in the existing document. Moreover, in the light of a new ART Regulation Bill 2006, that is yet to be passed in the Parliament, what will be the status of the published National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, 2005?

Please keep us informed about any further debate on the issue.

Sincerely,

Sarojini N.B.
(For Sama-Resource Group for Women and Health)