MISSION DIRECTOR, NATIONAL HEALTH MISSION, J&K00
Jammu Office: Regional Institute of Health & Family Welfare, Nagrota, Jammu.
Fax: 0191-2674114; Telephone: 2674244.Pin: 18122
Kashmir Office: Block A Ground Floor, Old Secretariat, Srinagar. Pin: 190001
Fax: 0194-2477309, 2470486 ; Telephone: 2477337; e-mail: mdnhmjk@gmail.com
NHM Help Line for Jammu Division 18001800104: Kashmir Division 18001800102

Chief Medical Officer,
(District Appropriate Authority PC&PNDT)
_____All_____

No: SHS/NHM/J&K 11238-64 **Dated:** 22/09/2021

Subject: Decision of Expert Committee constituted to devise suitable regulatory mechanism for introducing new technologies having potential for sex selection/determination-reg.

Madam/Sir,

With reference to the subject cited above, kindly find enclosed herewith communication No. V.11011/05/2021-PNDT Dated: 21st September 2021, forwarded by the PNDT Section, Ministry of Health & Family Welfare, Govt. of India along with minutes of meeting thereof, wherein the Expert Committee has decided that "all the labs/clinics/counsel centers etc. dealing in new diagnostic technologies like NIPT and other techniques needs to be mapped and registered under PC&PNDT Act, 1994".

Accordingly, you are directed to implement the above decision of the Expert Committee in letter and spirit within your respective jurisdictions and share the action taken report with this office at an earliest for onward submission to the Ministry of Health & Family Welfare, Govt. of India.

Matter may be treated as most urgent.

Enclosures: 6 pages.

Yours Sincerely,

Choudhary MohammedYasin (IAS)
Mission Director
National Health Mission, J&K

Copy for information to the:

1. Additional Chief Secretary, Health and Medical Education, Department, Civil Secretariat, Jammu/Srinagar.
2. Director, Health Services, Jammu/Kashmir.
3. Under Secretary, PNDT Section, Ministry of Health & Family Welfare, Govt. of India.
4. Programme Manager, PC&PNDT, SHS, NHM, J&K.
5. Law Officer, Jammu/Kashmir, SHS, NHM, J&K.
6. Office file.

(1)

No. V.11011/05/2021-PNDT
Government of India
Ministry of Health & Family Welfare
(PNDT Section)

Nirman Bhawan, New Delhi,
Dated the 21st September, 2021

To,

The Appropriate Authorities (PC&PNDT),
(All States/UTs)

Subject: Decision of Expert Committee constituted to devise suitable regulatory mechanism for introducing new technologies having potential for sex selection/ determination -reg.

Sir/Madam,

Please find enclosed herewith the minutes of the Meeting of the Expert Committee constituted to devise suitable regulatory mechanism for introducing new technologies having potential for sex selection/ determination held on 25/02/2021 through virtual mode, under the Chairpersonship of Joint Secretary (RCH).

2. The members of the Expert Committee have unanimously decided that all labs/clinics/counsel centres etc. dealing in new diagnostic technologies like NIPT and other techniques needs to be mapped and registered under PC&PNDT Act, 1994. The conventional and contemporary tools and techniques available having the potential for sex determination and sex selection at foetal or embryonic or gametic (only sperms) stages in a hospital/clinical (including ART clinics)/diagnostic/research settings are as follows:

A. Prenatal testing (in a variety of settings)

1. Using foetal tissues/cells obtained by CVS/Amniocentesis

2. Ultrasound and other imaging techniques-

- chromosomal
- biochemical
-molecular genetic tools (including PCR, Sanger sequencing, next generation sequencing (& single cell OMICS), DNA finger printing)

3. Using foetal DNA obtained from maternal blood (NIPT- non-invasive prenatal testing also at times referred to as non-invasive prenatal screening): - PCR- microarray
- microsatellite, marker genotyping
- sequencing tools

B. Pre-implantation testing (in ART clinics and associated research lab settings)

1. Using fertilised embryos

-chromosomal by Interphase FISH
-biochemical
-molecular genetic tools
(including PCR, Sanger sequencing, next generation sequencing (single cell OMICS), microsatellite marker genotyping)

2. Using sperm sorting and followed by IVF

C. Gene/genome editing

I. Using gametes (mostly sperms as of now though polar bodies from eggs are a possibility being explored)

II. Using embryos

3. You are, therefore, requested to take necessary steps required to map and register aforementioned technologies capable of sex selection and submit an action taken report to this Ministry at the earliest.

4. This issues with the approval of competent authority.

Encl - As above.

(Ajay Kumar)
Under Secretary to Govt. of India
Tel. 011-23061203

Copy to-

1. Nodal Officers (PNDT), All States/ UTs.

(3)

Minutes of the Meeting of the Expert Committee constituted to devise suitable regulatory mechanism for introducing new technologies having potential for sex selection/ determination, held on 25.02.2021 through Virtual mode, under the Chairpersonship of Joint Secretary (RCH)

The 1st Meeting of the Expert Committee to devise suitable regulatory mechanism for introducing new technologies having potential for sex selection/ determination was held on 25.02.2021 through virtual mode, under the Chairpersonship of Joint Secretary (RCH) (Ms. Preeti Pant)

The list of participants is as follows-

a. Ms. Preeti Pant, Joint Secretary (RCH), MoHFW - (In-Chair)

b. Dr. V.G. Somani, DCGI, Central Drug Standard Control Organization CDSCO.

c. Dr Reeta Rasaily, Scientist G.Head Division of RBMCH & N, ICMR, N. Delhi

d. Shri Rajiv Badhavan Director Drug Regulation MoHFW

e. Dr. Sudhir Gupta, Sr. CMO, DGHS. (MoHFW).

f. Dr. Asruddin, Director Health Services, PNDT O/o DGHS, Haryana

g. Dr. S. Gurunathan, M.S. State Appropriate Authority, Government of Tamil Nadu.

h. Prof. B.K Thelma, Dept. Of Genetics, University of Delhi South Campus, New Delhi

i. Dr. Rajesh Kapoor, Radiologist, New Delhi .

j. Smt. Vidushi Chaturvedi, Director PNDT

1. Joint Secretary (RCH) welcomed the participants and briefly dwelt on the purpose of the meeting, i.e. to devise suitable regulatory mechanism for introducing new technologies having potential for sex selection/ determination as per the decisions of the 28th CSB meeting.

2. It was brought to the notice of the Committee that under Section 18(1) of the PC&PNDT Act all facilities using technology capable of undertaking determination of sex of the foetus/sex selection are mandated to get registered.

3. It was further informed that neither the approvals for use of new technologies having potential for sex selection/determination nor methods to assess the viability of such technologies, comes under the purview of the PC&PNDT Act. Hence it becomes necessary to devise suitable regulatory mechanism for introduction of new technologies having potential for sex selection/ determination.

4. Regarding the availability of Non Invasive Pre-natal Tests (NIPT) in the market, representative from DCGI said that they do not provide license for the use of such tests. He informed that MoH&FW vide Notification No. 648(E) dated 11.02.2020, has notified all Medical Devices as Drugs under the Drugs & Cosmetics Act, 1940 w.e.f. 1st April 2020 as follows:

"All Medical Devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assisted in its intended function by such means for one or more of the specific purposes of,-

a) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;

b) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;

c) Investigation, replacement or modification or support of the anatomy or of a physiological process;

d) supporting or sustaining life;

e) disinfection of Medical Devices;

f) control of conception;''

5. In this regard representative form ICMR informed that ICMR also does not have mandate to grant permissions for the use of new technologies though it commissions academic and technical research projects on new technologies. Regarding the role of the Health Technology Assessment in India (HTAIn) it was stated that HTAIn is entrusted with the responsibility to collate and where needed, generate evidence related to the clinical effectiveness, cost-effectiveness, and safety of medicines, devices and health programs using the Health Technology Assessment (HTA) approach to facilitate the process of transparent and evidence informed decision making in the field of health.

6. It was further informed that the evaluation studies of newer technologies to assess their potential of misuse for sex selection from scientific point of view can be undertaken under HTAIN however; granting approval/ certification of the diagnostic technologies is not within the preview of HTAIn.

7. In view of the above discussions it was evident that there is a need for putting in place monitoring mechanisms while strengthening the existing ones. The medical audit of facilities using these technologies has to be stressed upon in terms of number of diagnostic tests performed, the outcomes recorded against each test/ procedure etc.

8. Dr Thelma K apprised the committee regarding conventional and contemporary tools and techniques available having the potential for sex determination and sex selection at foetal or embryonic or gametic (only sperms) stages in a hospital/clinical (including ART clinics)/diagnostic/research settings are as follows:

   A. Prenatal testing (in a variety of settings)

      i. Using foetal tissues/cells obtained by CVS/Amniocentesis

      ii. Ultrasound and other imaging techniques-

         - chromosomal
         - biochemical
         -molecular genetic tools (including PCR, Sanger sequencing, next generation sequencing (& single cell OMICS), DNA finger printing)

      iii. Using foetal DNA obtained from maternal blood (NIPT- non-invasive prenatal testing also at times referred to as non-invasive prenatal screening):- PCR- microarray

         - microsatellite, marker genotyping
         - sequencing tools

   B. Pre-implantation testing (in ART clinics and associated research lab settings)

      i. Using fertilised embryos

         -chromosomal by Interphase FISH
         -biochemical
         -molecular genetic tools
         (including PCR, Sanger sequencing, next generation sequencing (single
         cell OMICS), microsatellite marker genotyping)

      ii. Using sperm sorting and followed by IVF

   C. Gene/genome editing

      i. Using gametes (mostly sperms as of now though polar bodies from eggs are a possibility being explored)

      ii. Using embryos

9. Representatives from Ministry of Science and Technology and Law and Justice were unable to join the meeting hence their inputs in discussion could not be included. After the preliminary discussions Committee decided to deliberate further upon these very pertinent matters in the next meeting.

10. Ms. Vidushi Chaturvedi, Director PNDT concluding the meeting with a vote of thanks to chair and all the members of the Expert Committee.