



Ministry of Health and Family Welfare  
Government of India



# Guidelines

## On

### Use of Ultrasonography during Pregnancy





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Forward by the Joint Secretary, MOHFW

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**Arun Kumar Panda**  
Additional Secretary  
Tele : 23063155  
Telefax : 23063156  
E-mail : arun.panda@nic.in



भारत सरकार  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
स्वास्थ्य एवं परिवार कल्याण विभाग  
निर्माण भवन, नई दिल्ली - 110011  
Government of India  
Ministry of Health & Family Welfare  
Department of Health & Family Welfare  
Nirman Bhavan, New Delhi - 110011

## Preface

The progress made by India over the last two decades in the sector of health was significant. With the launch of NRHM in 2005 and its successor NHM in 2013, it is expected to make the pace even more rapid. True to its vision, NHM improved the availability of and access to quality healthcare by people, especially for those residing in rural areas, poor women and children. However, latest data and trends emerging from the national surveys demand a cohesive approach to manage child and maternal health care.

Several innovative strategies are being formulated to tackle the two major scourges of India – high maternal and child death rates. It is in this back ground that Govt has launched initiative like RMNCH+A strategy, India New Born Action Plan (INAP) etc. The guideline for the use of USG is another link in this chain.

Ultrasonography (USG) during pregnancy can detect high risk pregnancy, foetal anomaly and can provide significant information for decisions during pregnancy, appropriate treatment at birth, and prompt transfer to units specializing in the care of the new-born. The prenatal detection of congenital malformations should help to reduce perinatal mortality and morbidity.

I am confident that this well-conceived and effective framework for use of ultrasonography shall go a long way in helping pregnant mothers, the newborns and clinicians making the right decisions during the most important phase of a woman's gestation.

I need to emphasize here that the current guidelines on USG will not be a substitute to PC-PNDT Act but will facilitate better implementation of PC-PNDT Act & Guidelines. Laid down criteria in guidelines are in line with the current provisions in the PC & PNDT Act and will facilitate service providers to provide quality ANC services to the pregnant women.

I wish you all success in your endeavors and urge the states to take up the implementation of these guidelines to ensure improved maternal and child health.

  
**Dr. Arun Kumar Panda**  
AS & MD, NHM

**Healthy Village, Healthy Nation**



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Talking about AIDS is taking care of each other

वन्दना गुरनानी, भा.प्र.से.  
संयुक्त सचिव  
**VANDANA GURNANI, IAS**  
JOINT SECRETARY  
Tel : 011-23061706  
E-mail : vandana.g@ias.nic.in



भारत सरकार  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
निर्माण भवन, नई दिल्ली - 110011  
Government of India  
Ministry of Health & Family Welfare  
Nirman Bhavan, New Delhi - 110011

### Foreword

India has improved the maternal and neonatal mortality rates through its continuous and determined efforts in line of availability, accessibility and affordability of maternal and newborn healthcare all over the country. Public healthcare facilities are upgraded in terms of human resource, equipments and infrastructure to provide quality healthcare services. Technical & Operational Guidelines on "Use of Ultrasonography during Pregnancy" is an addition to these efforts to provide effective and efficient ante-natal care (ANC) during pregnancy. This initiative of the Ministry of Health and Family Welfare will strengthen the package of ANC services being provided at the public healthcare facilities.

"Guidelines on Use of Ultrasonography during Pregnancy" will restrict unnecessary use of USG in pregnancy and also strengthen the quality of Ante- Natal care for improved maternal and newborn care services in the country by detecting high risk pregnancy, fetal anomaly and provides significant information for decisions during pregnancy, appropriate treatment at birth and prompt transfer to units specializing in the care of the new-born. The prenatal detection of congenital malformations should help to reduce perinatal mortality and morbidity.

I compliment the efforts put by Maternal Health Division and contributing experts for developing these guidelines. I am confident that this well-conceived, effective framework for use of Ultrasonography shall go a long way in helping pregnant mothers, the newborns and clinicians making the right decisions during the most important phase of a woman's gestation and ensure improved maternal health.

(Vandana Gurnani)



**Dr. Dinesh Baswal**

Deputy Commissioner (Maternal Health)

Telephone : 011-23062830

E-mail : dinesh126@hotmail.com



सत्यमेव जयते

भारत सरकार  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
निर्माण भवन, नई दिल्ली - 110011  
Government of India  
Ministry of Health & Family Welfare  
Nirman Bhavan, New Delhi-110011

### Program Officer's Message

In spite of low prevalence of congenital anomalies, they account for nearly one fourth of the all perinatal deaths. Ultrasonography (USG) is an important tool of ante-natal care to detect the perinatal abnormalities and fetal growth and to reduce the perinatal mortality and morbidity. However in India, there are areas where women are not receiving even a single USG throughout their pregnancy while in other areas, pregnant women are exposed to USG more than required. Guideline on "Use of Ultrasonography during Pregnancy" is an attempt of Ministry of Health and Family Welfare to rationalize the use of USG and make uniform availability of services in the rural and urban areas of the country.

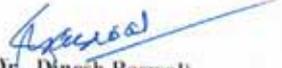
By the implementation of these Guidelines, it is envisaged that USG will be available as an essential part of ANC in the identified public healthcare facilities. Only experts and trained personnel's will be authorized to perform the USG, at appropriate gestational age and prepare a report accordingly.

This is to further emphasize that the current Guidelines will not be a substitute to the PC-PNDT Act but will facilitate better implementation of PC-PNDT Act & Guidelines. Laid down criteria in the Guidelines are in line with the current provisions in the PC & PNDT Act and will facilitate service providers to provide quality ANC services to pregnant women.

These Guidelines would not have been possible without the constant encouragement from Shri C.K Mishra, Secretary, Health & Family Welfare, Dr. Arun Kumar Panda AS&MD (NHM) and Ms., Vandana Gurnani, Joint Secretary (RCH) who gave the valuable inputs in framing the guidelines.

I thank all the members of the Expert Group for their contribution in developing the content of these technical and operational Guidelines. I sincerely thank Dr. Yaron Wolman, Chief of Health, UNICEF for their technical inputs; support in content development, and facilitating the process of guideline development. I would also like to thank Dr. Sudha Balakrishnana and Dr. Asheber Gaym, Health Specialist UNICEF, my colleague Dr. Veena Dhawan AC-MH, Dr. Tarun, Dr. Rajeev, Dr. Salima and Ms. Jenita Consultants, MoHFW for their valuable contributions.

This is an earnest request to all the States and District Programme Officers to implement and utilize these guidelines for placing the services as per the expectations of those who do not have accessibility and cannot afford the treatment.

  
(Dr. Dinesh Baswal)

### Healthy Village, Healthy Nation



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Talking about AIDS is taking care of each other

## List of Contributors

1.	Dr. Arun Kumar Panda	AS & MD (NHM), MoHFW
2.	Ms. VandanaGurnani	JS (RCH), MoHFW
3.	Dr. Rakesh Kumar	Senior DDG, ICMR
4.	Dr. Dinesh Baswal	DC (MH) Incharge, MoHFW
5.	Ms. Bindu Sharma	Director (RCH), MoHFW
6.	Dr. VeenaDhawan	AC (MH), MoHFW
7.	Dr. HimanshuBhushan	Advisor, NHSRC
8.	Dr. Yaron Wolman	Chief of Health, UNICEF
9.	Dr. Sudha Balakrishnan	Health Specialist, UNICEF
10.	Dr. Asheber Gaym	Maternal Health Specialist, UNICEF
11.	Dr. SuchitraPandit	Former President FOGSI
12.	Dr. Abha Singh	Prof&Head Department Of Obtetrics&Gynae LHMC
13.	Dr. Poonam Varma Shivkumar	HOD,Obstetrics &Gynaecology, MGIMS, Sevagram
14.	DrPratima Mittal	HOD, OBG, Safdarjung Hospital
15.	DrAchlaBatra	Consultant, OBG, Safdarjung Hospital
16.	Dr. M.K Mittal	Consultant & Associate Professor, Dept of Radiodiagnosis Safdarjung Hospital
17.	Dr. O.P Bansal	Secretary general Indian Radological&imaging association
18.	Dr Ashok Khurana	Consultant in Reproductive Ultrasound
19.	Dr. AnupamaTandon	Prof. Department of Radiology, GTB Hospital
20.	DrAnchitaPatil	NPO, UNFPA
21.	Dr. U.C Garg	Consultant & Head, Dept of Radiodiagnosis, RML Hospital
22.	Dr. Neelima Singh	Faculty, Indian Institute of Health & Family Welfare, Hyderabad
23.	Dr. Neelam Singh	Secretary/Chief Functionary, Vatsalyaa
24.	Mrs. Anita Shenoy	Advocate, Supreme Court
25.	Dr. Pushkar Kumar	Public Health Specialist, PHFI
26.	Dr. Gulfam Ahmed Hashmi	Health Specialist, UNICEF
27.	Dr. Tarun Singh Sodha	Consultant, Maternal Health, MoHFW
28.	Dr. Rajeev Agarwal	Sr. Consultant, Maternal Health, MoHFW
29.	Dr. Salima Bhatia	Sr. Consultant, Maternal Health, MoHFW
30.	Ms. JenitaKhawairakpam	Consultant, Maternal Health, MoHFW
31.	Ms. Ifat Hamid	Consultant, Gender,MoHFW

## I. INTRODUCTION AND RATIONALE

Maternal & neonatal morbidity and mortality are the two most important health indicators for a country. To ensure appropriate maternal and neonatal health, it is important that the quality of antenatal care is optimized based on current knowledge and available resources. Ultrasonography (USG) is now an established tool in the clinical management of pregnancy. It is beneficial in detection of congenital malformations, multiple pregnancies, placenta previa and for confirmation of period of gestation.

The prevalence of congenital anomalies ranges from 2% to 4% of all births, but they account for 20-25% of all perinatal deaths and an even higher percentage of perinatal morbidity. Diagnosis of malformations by routine USG provides early information and helps in making timely decisions during pregnancy for termination, appropriate treatment at birth and prompt transfer to units specialized in the care of the newborn. Thereby reducing perinatal mortality and morbidity. In the event of concurrent epidemic of infections, the effect of Chicken pox, Dengue, Zika virus etc can also be looked for.

Certain conditions such as ectopic pregnancy, multiple gestations, and placenta previa which may lead to potential life threatening complications can be identified earlier and appropriately managed with the help of USG.

Accurate gestational dating from ultrasound can assist in the management of abnormal foetal growth in pregnancies, which is a leading cause of perinatal morbidity & mortality in both developed and developing countries.

Crane et al in a meta-analysis of four randomized controlled trials of routine versus selective ultrasound scanning in pregnancy found a reduction in perinatal mortality in the routine screening group. Trials with high detection rates of diagnosis of congenital anomalies showed an increased rate of elective abortions and therefore reduced the number of perinatal deaths.

A Cochrane review of 11 randomized controlled trials including 37,505 women for outcome after routine early pregnancy ultrasound (before 24 weeks) versus selective ultrasound had revealed that, ultrasound in early pregnancy significantly increased detection of foetal abnormalities before 24 weeks of gestation. Routine ultrasound also increased the detection rate of multiple pregnancies and improved gestational dating which resulted in fewer inductions for post maturity.

## **Current status in India.**

India has the highest number of children with birth defects. They affect approximately 1 in 33 infants and result in approximately 3.2 million birth defect-related disabilities every year. The prevalence of high risk pregnancies in India is about 15% with only about 4% being diagnosed before delivery.

There are areas in India where a pregnant woman does not get even a single USG throughout pregnancy. High risk cases and foetal anomalies are only detected when women are delivering; thereby there is no preparedness for outcome and complications whereas in some places, tertiary facilities conduct ultrasound every week in the 9th month and in some private sectors frequency is even higher.

As per NFHS 3- data, ultrasound was performed in only 24 % of pregnancies. Out of these only 4% women in the lowest socioeconomic quintile had an ultrasound test compared with 62% among the highest wealth quintile.

Most of developed countries have guidelines for USG during pregnancy. European and Canadian guideline recommend two USGs as a part of standard prenatal care, first for dating at 8-14 wks and second to detect foetal abnormalities at 18-20 wks. A recent workshop of joint committee of American association of foetal imaging held in 2014 gave recommendations that in the absence of specific indications for a first trimester ultrasound, a single USG should be performed at 18-20 weeks of gestation.

At present in India there are no set standards for number of ultrasounds to be done in pregnancy, their interpretation and reporting. In view of the above evidence, GOI constituted an expert group to deliberate on use of USG in pregnancy in detail and formulate guidelines for India. The present guidelines have been prepared based on the recommendations of the experts and available national / international evidences.

Government of India has introduced Pradhan Mantri Surakshit Matritva Abhiyan (PMSMA) from June 2016 onwards, where on 9<sup>th</sup> of every month pregnant women ( in 2<sup>nd</sup>/3<sup>rd</sup> trimesters of pregnancy) will receive all essential ANC services by Medical Officer and /OBGY specialist including USG services. So these guidelines will also give states more clarity for implementing PMSMA programme.

## **II. Aim and Objectives**

### **Aim:**

Appropriate use of USG during pregnancy for reduction in maternal & perinatal mortality and morbidity

### **Objectives:**

- Number of USGs to be done in pregnancy
- Early detection of abnormal foetal conditions/ anomalies and also early detection of high risk pregnancies.
- Improving capacity of the health care providers in interpreting obstetric USG and making decisions about obstetric care.

**These guidelines have been developed for use by doctors working in government health facilities performing obstetric USG and are not a substitute to guidelines for implementing provisions of PC&PNDT Act and Rules.**

**Any doctor conducting obstetric USG has to work within defined parameters of PC&PNDT Act and Rules.**

## **III. Technical Guidelines for use of USG in Pregnancy**

Technical aspects will focus on the following:-

- a) Number of ultrasounds in pregnancy;
- b) Timing of obstetric ultrasound;
- c) Who will perform obstetric ultrasound;
- d) Purpose/ indication of obstetric ultrasound;
- e) Components of the routine obstetric ultrasound scan;
- f) Equipment and maintenance ;
- g) Consent forms and Reporting formats; and
- h) Follow-up action

**a) Number of Ultrasound in Pregnancy:** After reviewing the literature and considering available resources and feasibility, it has been decided that one obstetric ultrasound should be done during pregnancy between 18 and 19 weeks of pregnancy as part of routine Ante Natal Care (ANC) package. Additional ultrasound examinations can be done if clinically indicated.

**b) Timing of obstetric ultrasound.**

If a single scan is to be performed in pregnancy, ideally it should be done between 18 to 22 weeks of gestation. Routine USG in first trimester has not been able to provide any benefit in low risk pregnancies, except for the diagnosis of ectopic pregnancy. Clinically indicated ultrasound in the presence of risk factors or clinical suspicion based on history and physical examination, can correctly diagnose ectopic pregnancy in 80 to 100% of cases. If the USG is done before 18 weeks, many anomalies will be missed.

USG between 18 and 22 weeks provides some information about multiple aspects of pregnancy. It presents an opportunity to diagnose congenital anomalies and/or to detect soft markers of aneuploidy and to identify maternal pelvic pathology. Besides, it can confirm the number of fetuses present, the gestational age and the location of the placenta.

To allow for intervention after USG, if any anomaly is detected, an adequate period between gestational age for USG and the upper limit of gestational age at which MTP is permissible is required. Therefore the upper limit of gestational age for routine scan in second trimester varies from country to country depending on their MTP law. The law in our country permits MTP up to 20 weeks only; hence a single routine obstetric ultrasound should be performed between 18 and 19 weeks.

In the last two decades, the infant death rate from congenital anomalies has decreased by 50% in infants born after 24 weeks. This is probably partially related to early diagnosis of congenital anomalies leading to either pregnancy termination or better neonatal care. Second trimester diagnosis of congenital anomalies also provides the opportunity for foetal therapy.

Second trimester Ultrasound Examination can diagnose up to 94.4% twin pregnancies if done before 19-20 weeks. The occurrence of twins, undiagnosed at delivery is extremely rare when women have received a second trimester ultrasound. The likelihood of

unnecessary induction for post date pregnancy and intrauterine growth restriction also decreases significantly by second trimester USG.

However, it may be desirable for an ultrasound to be done earlier if there is some high risk factor. If the woman comes for the first time after 20 weeks, the USG should be done for clinical indications only.

The woman should be counseled before conducting ultrasound about the purpose of USG and after the ultrasound about the prognosis of foetal anomaly, if any anomaly is detected and options available. No prior preparation of the woman is required for the ultrasound examination. As far as possible, the day of ultrasound should coincide with ANC examination day and fixed days for USG should be avoided, as this may lead to multiple visits by the pregnant women.

### **c) Who will perform Obstetric USG?**

Medical practitioner qualified under the PCPNDT Act/ Rules to perform obstetric USG may be any of the following:-

- Radiologist who possesses a post graduate qualification in Ultrasonography/ Radiology/ Imaging Sciences.
- Gynecologist who possesses a post graduate qualification in Obs. / Gyn.
- Registered Medical practitioner with six months' training imparted in the manner prescribed in the "the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training) Rules, 2014.
- Registered Medical practitioner who are conducting ultrasound procedures, with one year experience in conducting Obs /Gyn USG or 6 month Obs /Gyn USG training at a government institute, before the implementation of six months training rules 2014, should have a certificate of clearing the competency based exam before Jan 1, 2017, as specified in the schedule II of the Six Months Training Rules, 2014.

In addition to the above requirement, for ensuring better quality of reporting USG, it is desirable for the Obstetrician and Registered Medical practitioners conducting obstetric USG in the Government health facility, to undergo a refresher course from Govt. recognized USG training centre

#### **d) Purpose/ indication for USG**

1. To detect chromosomal abnormalities, foetal structural defects and other abnormalities.
2. Estimation of gestational age which results in reduction of post term pregnancies
3. To detect number of foetuses and their chorionicity.
4. Evaluation of placental position and abnormalities
5. Assessment of cervical canal and diameter of internal Os to detect incompetent Os.

The above indications are as per “List of indications for Ultrasound during pregnancy under PC&PNDT Act, vide serial no x, ii, iii,xiv, and viirespectively”. **Annexure1 (Form F underPC&PNDTACT/RULES).**

#### **e) Components of the routine obstetric ultrasound scan**

The following systems are examined to assess for any congenital anomalies and screen for high risk pregnancy.

- foetal number, multiple gestations - chorionicity, amnionicity, comparison of foetal sizes, estimation of amniotic fluid volume (increased, decreased, or normal) in each gestational sac
- Qualitative or semi quantitative estimate of amniotic fluid
- Placental location, appearance, and relationship to the internal cervical Os
- Umbilical cord - number of vessels in the cord, and placental cord insertion site
- Measurements: Bi-parietal diameter, head circumference, abdominal circumference, and femoral diaphysis length.
- foetal anatomic survey:
  - Head, face, and neck:
  - Lateral cerebral ventricles, Choroid plexus, Midline falx, Cavumseptipellucidi, Cerebellum, Cistern magna, Upper lip
  - Chest: Shape/ Size of chest & Lungs
  - Heart:- Four-chamber view, Left ventricular outflow tract, Right ventricular outflow tract
  - Abdomen:- Stomach (visualization, size, and sites), Kidneys, Urinary bladder,
  - Umbilical cord insertion site into the foetal abdomen
  - Spine: Cervical, thoracic, lumbar, and sacral spine
  - Extremities: Legs and arms

- Maternal anatomy: Evaluation of the uterus, adnexal structures, and cervix should be performed when appropriate.

**f). Equipment and Maintenance**

The USG machine should be registered with the concerned Appropriate Authorities as per PC&PNDT Act and Rules.

**Specification of USG machine**

To provide quality services the specification for the USG machine at government health facilities, implementing use of USG in pregnancy, should be as follows-

Basic ultrasound unit having B mode & M Mode with multi frequency Curvilinear Transducer (3 to 7 M Hz) & Color Doppler facilities .Installation and three to five years AMC should be inbuilt for all new purchases.

**Maintenance**

Transducer is a very sensitive part of the machine and needs special care as it is repeatedly used, so it should be properly cleaned to prevent cross contamination.

**Cleaning of transducer**

Use of ultrasound transducers, like any instrument used on a woman, presents the possibility of microbial transmission if not properly cleaned after use on each PW. Trans-abdominal ultrasound transducers may be adequately cleansed between women simply by wiping with an antiseptic.

**Safety of USG**

There have been no reports of documented short term or long term adverse foetal effects for diagnostic ultrasound procedures, including duplex Doppler imaging. Still, foetal exposure time should be minimized using the lowest possible power output needed to obtain diagnostic information, following the ALARA principle (As Low as Reasonably Achievable).

**g) Consent forms and Reporting formats**

- (i) A written informed consent of the woman undergoing obstetric USG has to be taken in Form F as per PC&PNDT Act and Rules.**

All women should receive a clear explanation of the purposes of ultrasound scanning, the information that may be discovered, and the degree of certainty about the information. The implications of finding a FOETAL abnormality should be discussed with PW. Government health facility providing USG services will maintain a register showing, in serial order, the names and addresses of the women subjected to USG, the names of their spouses and the date on which they first reported for USG.

#### **(ii) Reporting Format**

**The USG report has to be entered in the Form F for the purpose of PC-PNDT Act and Rules**

For ensuring quality and completeness of reporting during the obstetric USG an additional form (**Annexure-2**) should be filled in at all government facilities which are implementing the use of USG program.

If any component of the ultrasound examination listed in the guideline is not visualized adequately, it should be documented in the report and serial scans suggested

#### **(iii) Record Keeping**

**All the records, forms and reports required to be maintained under the PC& PNDT Act and the rules have to be preserved for a period 2 years or for such period as may be prescribed from time to time.**

Therefore all scans should be carefully documented and archived for at least 2 years. The use of hard copy for routine normal scans has major cost implications. However, when abnormalities are found, or when specific structures are seen which may appear suspicious, hard copy is recommended.

#### **h) Follow up action**

The cases having any abnormalities should be referred to the nearest obstetricians for further management. If the ultrasound examination could not be completed as per Performa, PW should be referred to higher centre or second opinion should be obtained from an expert from the nearest teaching institutions.

## IV. Operational Guidelines

1. **Target Beneficiary:** 100% coverage of all pregnant women attending public health care facilities in India (in a phased manner).
2. **Roll out plan:**

### **Pre-requisites for routine USG in Pregnancy**

- Center should be recognized as per PC&PNDT Act, Rules and Regulations.
- The service providers should be trained as per PC&PNDT Act, Rules and regulations
- Additional orientation/exposure may be provided to Gynaecologist and Registered Medical Practitioner for detecting foetal anomaly scan.
- Availability of adequate number of USG machines and supplies depending upon the case load.
- In house facility for management of maternal and foetal risks which may be detected by USG.
- Appropriate referral linkages as and when required.
- Infrastructural and HR support for conducting USG.

### **3. Approach**

- USG should be linked with ANC days and PMSMA day so that the PW does not have to come twice just for getting USG done.
- All Medical Colleges, District Hospitals /District Women Hospitals (DH/DWH), Sub District Hospitals(SDH) and functional First Referral Units should have an in-house facility for conducting USG.
- Outside referral to private clinics after the reporting is not recommended since it may be time consuming and management may be delayed.
- This facility will be made available at all FRUs having existing USG machines, before expanding to other FRUs. Besides antenatal clinic days in these facilities, USG should also be done on all working days.
- The PW coming for USG at govt. health facility would be ensured USG including all the Janani Shishu Suraksha Karyakram (JSSK) entitlements.
- The capacity of the health facility would be upgraded to ensure that there is no waiting period for pregnant women coming for USG examination, as the window period for management after anomaly detection is very short.

- State needs to ensure availability of trained HR in place to expand the availability of USG.

#### **4. Selection of facility**

- a. The programme will be implemented at Medical College, DH/DWH, SDH and functional FRU level facilities in districts.
- b. A health facility chosen for implementation of the programme should have all the prerequisites in place.
- c. The service provider and the programme officer must be oriented and trained about the programme

#### **5. Level of Implementation:**

- All the medical colleges in the country must be involved in the programme and should be oriented on judicious use of USG as per the clinical indication. Only one routine USG should be done between 18 and 19 weeks of gestation.
- Initially, at least three facilities in each of the identified districts that are District hospital and two FRUs should be conducting routine USG provided availability of FRUs in place.
- It is not advisable to conduct USG below FRU, primarily because of non-availability of trained manpower and also if anomaly is diagnosed, in-house capacity for management of such cases may not be there.
- **The ultrasound to be undertaken only at places where facilities for second trimester abortion are available as per the MTP Act.**

#### **6. Health System Strengthening**

All the facilities which will be providing the USG services in the programme will be strengthened with respect to infrastructure, equipment and trained Human Resource.

##### **a) Infrastructure:**

- All the infrastructure requirements as indicated in the PC&PNDT Act and rules must be complied with.

For the convenience of PW coming for USG, it would be desirable to have the following facilities-

- A dedicated place in the health care facilities for providing USG to the PW, so as to maintain her privacy and dignity as well as to ensure confidentiality of the women.

- There should be a proper waiting area for the PW with facility for potable water and washroom nearby.
- The USGroom should be air-conditioned.
- Uninterrupted electricity supply including back up, hand wash facility, waste disposal facility needs to be ensured.

**b) Equipment:**

- The bulk of work in an anomalies scan can be achieved without high-end equipment
- Basic ultrasound unit having B mode & M Mode with multi frequency Curvilinear Transducer (3 to 7 M Hz) & Color doppler facilities should be used (**Annexure 3**).
- Additional equipment will be procured if work load is disproportionately high. Regular supply of all consumables like thermal paper and jelly should be ensured.
- AMC & routine maintenance should be an integral part of equipment maintenance.

**c) Human Resource:**

One ultrasonologist, certified under PC&PNDT Act with the minimum qualification as described under the heading “Who will perform Obstetric USG.”

**To manage a foetus diagnosed on USG to have substantial risk of suffering from physical or mental abnormality or to be seriously handicapped, it is desirable that the facility implementing use of USG should have following human resources:**

- Two MTP trained medical officers/ gynecologists. At least one of them should be EmOC trained.
- One Staff Nurse/ ANM for USG room for care and support to the PW.
- Other support staff required may be utilized from the existing HR. Where ever sufficient staff is not available, the same needs to be recruited / hired.

## **7. Trainings**

### **a) Organizing refresher course**

For the in service doctors permitted to do obstetric USG as per PC &PNDT Act and Rules, it is desirable that they undergo a refresher course in obstetric USG. Such course is for confidence building and improving the quality of reporting. For organizing the refresher course, the following guidelines have to be followed pertaining to the site of training, faculty for training and the doctors to be trained.

#### **Site**

**The refresher course may be organized at any of the following sites-**

- Centers of excellence established under an Act of Parliament.
- MCI recognized institutes offering post graduate programme in Obstetrics&Gynecology and Radiology.
- Institutes offering full time DNB course in Obstetrics&Gynaecology and Radiology.

#### **Faculty**

**Post graduate teachers in Obstetrics&Gynaecology and Radiology.**

#### **Trainee**

- Obstetrician with post graduate qualification
- Registered medical practitioner with 6 months' training or having a certificate of clearing the competency based exam as specified in schedule II of the six months training rules

#### **Duration**

The duration of course would be 2 weeks

### **b) Orientation and Training of Trainers(TOT)**

- Every state can organize a state level 2 days orientation/ TOT for Master Trainers of the medical college i.e radiologist and obstetrician along with state programme officers.

- State Master Trainers will be radiologist and obstetricians from the identified training sites
- Sensitization about the programme shall be done by GOI nominated official.

**Batch size:**

- For TOT, about 20-30 participants comprising of radiologists, obstetricians along with state programme officers.
- For refresher course in anomaly scan, trainer and trainee ratio shall be 1:2 and not more than two trainees should be posted at one medical college
- If number of trainees are more, the number of refresher course sites need to be increased

**Curriculum:**

TOT/ orientation will focus on:

- Orientation of guidelines “ Use of ultrasonography in pregnancy”
- Sensitization to the PC&PNDT Act and rules
- Standardized format of report writing
- Time bound management of cases as per the clinical decision of the obstetrician.
- Record keeping

**c) Refresher course will focus on**

- All the above
- Familiarizing them with different types of normal and abnormal findings of USG in a PW along with demonstrating USGs in few cases
- Making the trainee observe atleast 100 cases of obstetrical USG for evaluation of foetal anomalies.
- The trainee would maintain a log book of the cases observed every day and get it signed from the trainer. The certificate of attendance would be given only after observation of 100 anomaly scans.

#### **d) Record Keeping:**

Following records should be maintained at all the health facilities conducting Obstetric USG.

1. All relevant records as per the PC&PNDT Act, Rules and Regulations (Anexure1)
2. Mid trimester foetal Ultra sound scan report (Annexure 2)
4. Program related data as per monthly reporting form (Annexure 4).
5. All the referrals.

#### **e) Programme Indicators**

- a. Total number of USG conducted on PW
  - (i) Number of scans conducted between 18 and19 weeks.
  - (ii) Number of scans conducted other than at (i) above.
- b. Total number of foetal anomalies detected.
- c. Total number of maternal complications detected.
- d. Number of cases referred to higher facilities.

#### **f) Monitoring:**

Supervisor from Govt. Medical College will visit USG centre fromtime to time. He /she would be paid an honorarium of about Rs 1000/- per day besides transport.

- He/She would monitor by auditing records and onsite sampling of ongoing USG with focus on quality aspect.
- Any violation of PC&PNDT Act and the Rules shall be reported to the concerned state.
- Strict following of PCPNDT Act and Rule shall be ensured in the facility
- In cases of any deficiency detected, onsite mentoring or suggestions for retraining of the doctor would be made.
- Monitoring of record maintenance at facility level as per PC&PNDT Act/Rules and guidelines of this handbook.

#### **g) Community Sensitization and IEC**

- Health worker will make home visits to all pregnant women for ensuring registration within 12 weeks and counsel them for subsequent ANC.

- The counseling should explain that second ANC should be conducted during 18 and 19 weeks at an FRU & above since this is the time when foetal wellbeing can be observed by the doctor through an USG.
- The PW will be informed by ASHA/ANM about her designated health facility for second trimester ANC including USG.
- The PW will be informed by ASHA/ANM about the PMSMA programme where every pregnant woman (in 2<sup>nd</sup>/3<sup>rd</sup> trimester) will receive all essential ANC services including USG services.

## V. Role of health facilities and health personnel posted at the facilities

	Functionaries	Services/Districts
<b>Sub Centres</b>	ANM/ASHA	<ul style="list-style-type: none"> <li>• Sensitize &amp; motivate target women for early registration.</li> <li>• Counsel &amp; facilitate pregnant women for USG at 18-19 weeks by referring them to the identified centers. While referring it is to be ensured that she is in the defined timeline so that if anomaly is detected, appropriate management can be done.</li> </ul>
<b>PHC/CHC</b>	Medical Officer, Staff Nurse, ANM /ASHA	<ul style="list-style-type: none"> <li>• Sensitize &amp; motivate target women for early registration &amp; need for Routine ANC</li> <li>• Facilitate pregnant women for USG at 18-19 weeks by referring them to the identified centers.</li> <li>• While referring it is to be ensured that she is in the defined timeline so that if anomaly is detected, appropriate management can be done.</li> </ul>
<b>FRUs/District Hospital designated for USG</b>	Hospital In charge/Gynecologist/Radiologist	<ul style="list-style-type: none"> <li>• Ensure that regular and timely USG services are provided.</li> <li>• Ensure that USG of the PW following is as per the provision of PC&amp;PNDT</li> </ul>

		<p>Act/Rules.</p> <ul style="list-style-type: none"> <li>• Timely information of the result to the PW.</li> <li>• Ensure that PW comes in the defined timeline so that if the anomaly is detected, appropriate management should be done.</li> <li>• Record keeping and reporting for the activity as per the PCPNDT Act and guidelines.</li> </ul>
<b>Medical Colleges</b>	Medical Superintendent/Obstetrician & Gynecologists /dedicated Nurses	<ul style="list-style-type: none"> <li>• Ensure that regular and timely USG services are provided.</li> <li>• Ensure that PW comes in the defined timeline so that if anomaly is detected, appropriate management should be done.</li> <li>• Timely information of the result to the PW.</li> <li>• Appropriate management of referred cases.</li> <li>• Medical college will help the Radiologist/gynaecologist at District level in case of doubt in any of the USGs</li> <li>• Record Keeping&amp;reporting as per PC&amp;PNDT Act &amp; Rules and other relevant guidelines at para no. 12 of this handbook.</li> <li>• The identified centres to act as training institute for USG.</li> </ul>
• <b>State/District Head Quarter</b>	Program Officer incharge	<ul style="list-style-type: none"> <li>• Release budget on timely basis.</li> <li>• Identify the centers for providing USG services and ensure they are registered under PC&amp;PNDT Act.</li> <li>• Timely release of fund for the activity.</li> <li>• Identify the Obstetricians/ Radiologist for training.</li> <li>• Coordinate trainings.</li> <li>• Ensuring functionality of</li> </ul>

		<p>the identified site.</p> <ul style="list-style-type: none"> <li>• Record Keeping and reporting.</li> <li>• Supervision Monitoring &amp; evaluation of the implementation</li> <li>• Research &amp; up-gradation</li> </ul>
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## **Budget Write Up for the USG plan**

### **1. Facility up gradation Cost**

Facilities identified for doing USG will be given a onetime facility up gradation cost @ Rs. 50,000/- each. This amount is to be used for upgrading the room identified for USG in terms of logistics like curtain, table, chair, painting etc.

### **2. Training Budget**

#### **a. State level TOT**

i) The trainer to trainee ratio for this training will be 1:2.

ii) **Detailed budget for state level TOT a batch of 2 for 2 days is as below**

<b>Training of OBGY for foetal Anomaly Scan ( batch of 2 for 2 days)</b>					
<b>Sr. No</b>	<b>Head</b>	<b>Unit Cost(Rs.)</b>	<b>Number of Participants</b>	<b>Days</b>	<b>Total</b>
<b>1</b>	TA for Participants ( to and fro by Train)	As per state government rules	2	0	As per state government rules
<b>2</b>	DA to trainees	700	2	2	2800
<b>3</b>	Accommodation to trainees*	2000	2	2	8000
<b>4</b>	Lunch & tea	350	3	2	2100
<b>5</b>	Per Diem/ Honorarium for Trainers	1000	1	2	2000
<b>6</b>	Incidental expenses like study material, course material, photocopying, job aids, flip cart, LCD etc. ( Rate x Days of Training x number of participants)	300	2	2	1200
<b>7</b>	Contingency @15% of sub total				15% of the sub total
<p><b>*Note:</b> State should try and arrange for in house accommodation of trainees. However when this cannot be done the amount of accommodation will be reimbursed to the trainee on an actual basis on production of a valid original bill.</p>					

**iii) Detailed budget for training of 2 OBGY for 14 days on foetal anomaly**

<b>14 days training of OBGY for foetal Anomaly Scan, batch of 2</b>					
<b>Sr. No</b>	<b>Head</b>	<b>Unit Cost</b>	<b>Number of Participants</b>	<b>Days</b>	<b>Total</b>
<b>1</b>	TA for Participants ( to and fro by Train)	As per state government rules	2	0	As per state government rules
<b>2</b>	DA to trainees	700	2	14	19600
<b>3</b>	Accommodation to trainees*	2000	2	14	56000
<b>4</b>	Lunch & tea	350	3	14	14700
<b>5</b>	Per Diem/ Honorarium for Trainers**	1000	1	14	14000
<b>6</b>	Logistic expenses like study material, course material, photocopying, job aids, flip cart, LCD etc. ( Rate x Days of Training x number of participants)	300	2	14	8400
<b>7</b>	Incidental overhead ( 15% of sub-total)				15% of the sub total
<b>Note:</b>					
*State should try and arrange for inhouse accommodation of trainees. However when this cannot be done the amount of accommodation will be reimbursed to the trainee on an actual basis on production of a valid original bill.					
** In a scenario where both the trainers are involved in giving training. The amount to be distributed accordingly.					

**3. Logistics:**

Each center will need stationery for routine functioning like report writing, printing, maintaining records etc. The funds for these shall be sourced from the RKS/ Untied fund of the institute.

  
सत्यमेव जयते

# भारत का राजपत्र

## The Gazette of India

असाधारण

EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)

PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित

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स्वास्थ्य और परिवार कल्याण मंत्रालय

**अधिसूचना**

नई दिल्ली, 31 जनवरी, 2014

सा. का. नि. 77. (अ).—केन्द्रीय सरकार, गर्भधारणपूर्व और प्रसवपूर्व निदान-तकनीक (लिंग चयन प्रतिषेध) अधिनियम, 1994 (1994 का 57), की धारा 32 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, गर्भधारणपूर्व और प्रसवपूर्व निदान-तकनीक (लिंग चयन प्रतिषेध) नियम, 1996 का और संशोधन करने के लिए निम्नलिखित नियम बनाती है, अर्थात्: —

1. (1) इन नियमों का संक्षिप्त नाम गर्भधारणपूर्व और प्रसवपूर्व निदान-तकनीक (लिंग चयन प्रतिषेध) नियम, 2014 है।

(2) ये राजपत्र में उनके प्रकाशन की तारीख को प्रवृत्त होंगे।

2. गर्भधारणपूर्व और प्रसवपूर्व निदान-तकनीक (लिंग चयन प्रतिषेध) नियम के प्ररूप च के स्थान पर निम्नलिखित प्ररूप रखा जाएगा, अर्थात्: —

[धारा 4 (3) का परंतुक, नियम 9 (4) और नियम 10 (1क) देखें]

आनुवंशिक क्लिनिक/अल्ट्रासाउंड क्लिनिक/इमेजिंग केन्द्र द्वारा प्रसव पूर्व जांच की दशा में अभिलेख रखे जाने का प्रारूप

**भाग क : सभी नैदानिक प्रक्रियाओं/जांच के लिए भरे जाने के लिए**

1. आनुवंशिक क्लिनिक/अल्ट्रासाउंड क्लिनिक/इमेजिंग केन्द्र का नाम और पूरा पता
2. रजिस्ट्रीकरण संख्या (गर्भधारणपूर्व और प्रसवपूर्व निदान-तकनीक (लिंग चयन प्रतिषेध) अधिनियम, 1994 के अधीन)
3. रोगी का नाम आयु
4. कुल जीवित संतानों की संख्या
  - (क) जीवित पुत्रों की संख्या, प्रत्येक की आयु (वर्ष या मास में)
  - (ख) जीवित पुत्रियों की संख्या, प्रत्येक की आयु (वर्ष या मास में)
5. पति/पत्नी/पिता/माता का नाम
6. रोगी का पूरा पता, दूरभाष संख्या सहित, यदि कोई हो,
7. (क) चिकित्सक (चिकित्सक का पूरा नाम और पता/ आनुवंशिक परामर्शदाता केन्द्र) द्वारा निर्दिष्ट (निर्देश स्लीपों को प्रारूप च के साथ सावधानी-पूर्वक परिरक्षित रखना है)
- (ख) स्त्री रोग विशेषज्ञ/ विकिरणविज्ञानी/ रजिस्ट्रीकृत चिकित्सा व्यवसायी जो नैदानिक प्रक्रियाएं कर रहे हैं, द्वारा स्व-निर्देश (रोगी के निर्देश टिप्पण को मामले के कागज-पत्रों को प्रारूप च के साथ सावधानीपूर्वक परिरक्षित किया जाना है)
- (स्व-निर्देश से किसी ग्राहक द्वारा क्लिनिक में आना और जांच के लिए अनुरोध करना या गर्भवती महिला के नातेदारों) द्वारा जांच के लिए अनुरोध करना अभिप्रेत नहीं है)
8. पिछले रजोधर्म की अवधि या गर्भधारण के सप्ताह

**भाग ख :** केवल गैर-आक्रामक नैदानिक प्रक्रिया/जांच के लिए भरा जाना है

9. प्रक्रिया को करने वाले चिकित्सक का नाम

10. नैदानिक प्रक्रिया के लिए उपदर्शन

(निर्देश स्लिप या स्व-निर्देश टिप्पण में किए गए अनुरोध के संदर्भ में विनिर्दिष्ट करें।)

(अल्ट्रासोनोग्राफी प्रसवपूर्व निदान केवल तभी किया जाना चाहिए जब उपदर्शित किया गया हो। निम्नलिखित अल्ट्रासाउंड के लिए गर्भधारण के दौरान उपदर्शकों की प्रतिनिधित्वकारी सूची है) **(अल्ट्रासाउंड के लिए उपयुक्त उपदर्शक के सामने सही का निशान लगाएं)**

- i. अंतः गर्भाशय और/या अस्थानीय गर्भधारण और व्यवहार्यता का पता लगाने के लिए
- ii. गर्भधारण आयु का आकलन (तिथिकरण)
- iii. भ्रूणों की संख्या का पता लगाना और उनकी क्रमबद्धता
- iv. इनसीटू आई.यू.सी.डी. के साथ संभावित गर्भावस्था या गर्भनिरोधों की असफलता के परिणामस्वरूप संभावित गर्भधारण/ असफल गर्भ के चिकित्सीय समापन
- v. योनि रक्तस्राव/ रिसाव
- vi. गर्भपात के मामलों में अनुवर्ती प्रक्रिया
- vii. ग्रीवा नालिका का आकलन और आंतरिक ऑस का व्यास
- viii. गर्भाशय के आकार और मासिक धर्म की अवधि में भिन्नता
- ix. एडनेक्सल या गर्भाशय रोग-निदान की कोई संभावना/अनियमितता
- x. गुणसूत्र अनियमितताओं का पता लगाना, भ्रूण संरचना त्रुटियां और अन्य अनियमितताएं तथा उनका अनुवर्ती प्रक्रिया
- xi. भ्रूण और उसकी स्थिति का मूल्यांकन
- xii. लिकर अमनी का निर्धारण
- xiii. समयपूर्व प्रसव पीड़ा/ समयपूर्व झिल्ली का टूटना
- xiv. प्लेसेंटल प्रास्थिति, मोटाई ग्रेडिंग और अनियमितताओं (प्लेसेंटा प्रिविया, रेट्रोप्लेसेंटल रक्तस्राव, अनियमित अवलंबन, आदि) का मूल्यांकन
- xv. नाभि-रज्जु का मूल्यांकन - प्रस्तुतीकरण, सन्निवेश, नुक्कल एनसर्कलमेंट, वाहिकाओं की संख्या और टूनाट की उपस्थिति
- xvi. पूर्व के शल्यजन्य निशानों का मूल्यांकन

- xvii. भ्रूण की वृद्धि, भ्रूण के वजन और भ्रूण की कुशलता के मानकों का मूल्यांकन
- xviii. रंजक प्रवाह मापन और डूप्लेक्स डॉपलर अध्ययन
- xix. गर्भधारण का चिकित्सीय समापन, बाह्य सिफैलिक वर्सन आदि जैसी पराध्वनिनिदेशित प्रक्रियाएं और उनका अनुवर्ती प्रक्रिया
- xx. क्रमबद्ध अंकुर का नमूनाकरण (सीवीएस) उल्ववेधन, भ्रूण रक्त नमूनाकरण, भ्रूण चर्म वायोप्सी, अमनीयो इन्फ्युजन, इंटरायूटेराइन इन्फ्युजन, संटों आदि का अवस्थिकरण जैसे डायग्नोस्टिक और उपचारात्मक इन्वेसिव मध्यक्षेपों से अनुलग्नक
- xxi. इन्ट्रापार्टम घटनाओं का अवलोकन
- xxii. गर्भावस्था को जटिल बनाने वाली चिकित्सा/शल्यक्रिया स्थितियां
- xxiii. मान्यताप्राप्त संस्थाओं में अनुसंधान/वैज्ञानिक अध्ययन ।

11. की गई प्रक्रियाएं (गैर-आक्रामक) (समुचित प्रक्रिया पर सही का निशान लगाएं)

i. अल्ट्रासाउंड

**(महत्वपूर्ण टिप्पणः)** अल्ट्रासाउंड का परामर्श भ्रूण का लिंग उपदर्शित करने/ परामर्श देने के लिए नहीं दिया जाता है सिवाय डचेन मांसपेशी कूपोषण, अतिरक्तस्त्राव ए एवं बी आदि

ii. कोई अन्य (विनिर्दिष्ट करें)

12. वह तारीख जब गर्भवती महिला/व्यक्ति की घोषणा अभिप्राप्त की गई थी

13. वह तारीख जब प्रक्रियाएं की गई

14. की गई गैर-आक्रामक प्रक्रियाओं का परिणाम (किए गए अल्ट्रासाउंड सहित जांच की संक्षिप्त रिपोर्ट)

15. प्रसवपूर्व नैदानिक प्रक्रियाओं के परिणाम को ..... सूचित किया गया

16. नैदानिक प्रक्रियाओं/जांच में पता लगाई गई अनियमितता के आधार पर गर्भ के चिकित्सकीय समापन के लिए कोई उपदर्शन

तारीख :

स्त्री रोग विशेषज्ञ/विकिरण विज्ञानी/ रजिस्ट्रीकृत चिकित्सा व्यवसायी जो नैदानिक प्रक्रियाओं को कर रहा है, का नाम, हस्ताक्षर और रजिस्ट्रीकरण संख्या सहित मुहर

स्थान :

**भाग ग : केवल आक्रामक प्रक्रियाएं/जांच करने के लिए भरा जाना है**

17. प्रक्रियाओं को करने वाले चिकित्सक का नाम

18. कुटुंब में आनुवंशिक/आयुर्विज्ञान रोगों

का वृत्तान्त (विनिर्दिष्ट करें)

निदान का आधार (निदान के उचित आधार पर सही का निशान लगाएं)

(क) क्लिनिकल

(ख) जैव रसायनिक

(ग) कोशिका आनुवंशिकी

(घ) अन्य (उदाहरणार्थ विकिरण चिकित्सा विज्ञान, अल्ट्रासोनोग्राफी आदि - विनिर्दिष्ट करें)

19. नैदानिक प्रक्रिया के लिए उपदर्शन (उपयुक्त उपदर्शन पर सही का निशान लगाएं)

(क) निम्नलिखित सहित पूर्ववर्ती संतान

(i) गुणसूत्री विकार

(ii) उपापचयी विकार

(iii) जन्मजात विषमता

(iv) मानसिक निःशक्तता

(v) हीमोग्लोबिनोपैथी

(vi) यौन संबंधी विकार

(vii) एकल जीन विकार

(viii) कोई अन्य (विनिर्दिष्ट करें)

ख. अधिक मातृआयु (35 वर्ष)

ग. माता/पिता/ सहोदर भाई या बहन को आनुवंशिक रोग (विनिर्दिष्ट करें)

घ. अन्य (विनिर्दिष्ट करें)

20. वह तारीख जिसको गर्भधारणपूर्व और प्रसवपूर्व निदान तकनीक (लिंग चयन प्रतिषेध) अधिनियम, 1994 में विहित प्ररूप छ में गर्भवती महिला/व्यक्ति की सहमति अभिप्राप्त की गई है

21. की गई आक्रामक प्रक्रियाएं (समुचित पर सही का निशान लगाएं)

i. एम्नियोसेंटेसिस

ii. कोरिओनिक विल्ली एसपिरेशन

iii. भ्रूण बायोप्सी

iv. कोरडोसेंटेसिस

v. कोई अन्य (विनिर्दिष्ट करें)

22. आक्रामक प्रक्रिया की कोई जटिलताएं (विनिर्दिष्ट करें)

23. सिफारिश की गई अन्य जांच (कृपया वर्णन करें, यदि लागू हो)

i. गुणसूत्रीय अध्ययन

ii. जैव रसायनिक अध्ययन

iii. आणविक अध्ययन

iv. पूर्व प्रत्यारोपण लिंग निदान

v. कोई अन्य (विनिर्दिष्ट करें)

24. की गई प्रक्रियाओं/ जांचों का परिणाम (की गई आक्रामक जांच/प्रक्रियाओं की संक्षिप्त रिपोर्ट)

25. वह तारीख जब प्रक्रियाएं की गई

26. प्रसवपूर्व नैदानिक प्रक्रियाओं के परिणाम को..... सूचित किया गया

27. नैदानिक प्रक्रियाओं/जांच में पता लगाई गई किसी अनियमितता के आधार पर गर्भ के चिकित्सीय समापन का कोई उपदर्शन

तारीख :

स्त्री रोग विशेषज्ञ/विकिरण विज्ञानी/ रजिस्ट्रीकृत चिकित्सा व्यवसायी जो नैदानिक प्रक्रियाओं को कर रहा है, का नाम, हस्ताक्षर और रजिस्ट्रीकरण संख्या सहित मुहर

स्थान:

**भाग घ : घोषणा**

उस व्यक्ति द्वारा की जाने वाली घोषणा जिसकी प्रसवपूर्व नैदानिक जांच/ प्रक्रिया की जा रही है  
में श्रीमती/श्री ..... घोषणा करती हूँ/करता हूँ कि ..... नैदानिक जांच/ प्रक्रिया करवाने से  
मैं अपने भ्रूण का लिंग नहीं जानना चाहती/चाहता हूँ

तारीख : प्रसवपूर्व नैदानिक जांच/ प्रक्रिया करवाने वाले  
व्यक्ति का हस्ताक्षर/ अंगूठा निशान

अंगूठा निशान की दशा में:

नाम..... द्वारा पहचान ..... आयु ..... लिंग ...

संबंध (यदि कोई हो) ..... पता दूरभाष संख्या सहित .....

अभिप्रमाणित करने वाले व्यक्ति के हस्ताक्षर ..... तारीख

**प्रसवपूर्व नैदानिक जांच/ प्रक्रिया करने वाले चिकित्सक/व्यक्ति की घोषणा**

मैं ..... (अल्ट्रासोनोग्राफी/ छायाचित्रण करने वाले व्यक्ति का नाम) घोषणा करता/करती हूँ  
कि श्रीमती/श्री ..... (गर्भवती महिला या उस व्यक्ति जिसका प्रसवपूर्व नैदानिक प्रक्रिया/ जांच  
की जा रही है का नाम), का मैंने भ्रूण के लिंग की जांच की है ना ही उसका किसी व्यक्ति को किसी रीति में  
प्रकटन किया है।

तारीख :

**हस्ताक्षर**

**स्त्री रोग विशेषज्ञ/विकिरण विज्ञानी/रजिस्ट्रीकृत  
चिकित्सा व्यवसायी जो नैदानिक प्रक्रियाओं को  
कर रहा है, का नाम (बड़े अक्षरों में) और  
रजिस्ट्रीकरण संख्या सहित मुहर**

[फा.सं. वी.11011/6/2013-पीएनडीटी]

डा. राकेश कुमार, संयुक्त सचिव

टिप्पण : मूल अधिसूचना भारत के राजपत्र में सा.का.नि. 1(अ), तारीख 1 जनवरी, 1996 को प्रकाशित की गई  
थी और अधिसूचना सं. सा.का.नि. 109(अ) तारीख 14 फरवरी, 2003; सा.का.नि. 426(अ) तारीख  
31 मई, 2011; सा.का.नि. 80(अ) तारीख 7 फरवरी, 2012; सा.का.नि. 418(अ) तारीख  
4 जून, 2012 और सा.का.नि. 13 (अ) तारीख 9 जनवरी, 2014 द्वारा संशोधित की गई थी।

**MINISTRY OF HEALTH AND FAMILY WELFARE**

**NOTIFICATION**

New Delhi, the 31st January, 2014

**G.S.R. 77 (E).**—In exercise of the powers conferred by Section 32 of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994), the Central Government hereby makes the following rules further to amend the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996, namely :—

1. (1) These rules may be called the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Amendment Rules, 2014.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996, for Form F, the following Form shall be substituted:

[See Proviso to Section 4(3), rule 9(4) and rule 10(1A)]

**FORM FOR MAINTENANCE OF RECORD IN CASE OF PRENATAL DIAGNOSTIC TEST /PROCEDURE  
BY GENETIC CLINIC/ULTRASOUND CLINIC/IMAGING CENTRE**

**Section A: To be filled in for all Diagnostic Procedures/Tests**

1. Name and complete address of Genetic Clinic/Ultrasound Clinic/Imaging centre: \_\_\_\_\_

2. Registration No. (Under PC& PNDT Act, 1994) \_\_\_\_\_

3. Patient's name \_\_\_\_\_ Age \_\_\_\_\_

4. Total Number of living children : \_\_\_\_\_

(a) Number of living Sons with age of each living son (in years or months): \_\_\_\_\_

(b) Number of living Daughters with age of each living daughter (in years or months) : \_\_\_\_\_

5. Husband's /Wife's/ Father's / Mother's Name : \_\_\_\_\_

6. Full postal address of the patient with Contact Number, if any \_\_\_\_\_

7. (a) Referred by (Full name and address of Doctor(s)/ Genetic Counseling Centre): \_\_\_\_\_

(Referral slips to be preserved carefully with Form F)

(b) **Self-Referral** by Gynaecologist/Radiologist/Registered Medical Practitioner conducting the diagnostic procedures: \_\_\_\_\_

(Referral note with indications and case papers of the patient to be preserved with Form F)

**(Self-referral does not mean a client coming to a clinic and requesting for the test or the relative/s requesting for the test of a pregnant woman)**

8. Last menstrual period or weeks of pregnancy : \_\_\_\_\_

**Section B: To be filled in for performing non-invasive diagnostic Procedures/ Tests only**

9. Name of the doctor performing the procedure/s : \_\_\_\_\_

10. Indication/s for diagnosis procedure \_\_\_\_\_ (specify with reference to the request made in the referral slip or in a self-referral note)

(Ultrasonography prenatal diagnosis during pregnancy should only be performed when indicated. The following is the representative list of indications for ultrasound during pregnancy. **(Put a “Tick” against the appropriate indication/s for ultrasound)**)

- i. To diagnose intra-uterine and/or ectopic pregnancy and confirm viability.
- ii. Estimation of gestational age (dating).
- iii. Detection of number of fetuses and their chorionicity.
- iv. Suspected pregnancy with IUCD in-situ or suspected pregnancy following contraceptive failure/MTP failure.
- v. Vaginal bleeding/leaking.
- vi. Follow-up of cases of abortion.
- vii. Assessment of cervical canal and diameter of internal os.
- viii. Discrepancy between uterine size and period of amenorrhea.
- ix. Any suspected adnexal or uterine pathology/abnormality.
- x. Detection of chromosomal abnormalities, fetal structural defects and other abnormalities and their follow-up.
- xi. To evaluate fetal presentation and position.
- xii. Assessment of liquor amnii.
- xiii. Preterm labor / preterm premature rupture of membranes.
- xiv. Evaluation of placental position, thickness, grading and abnormalities (placenta praevia, retro placental hemorrhage, abnormal adherence etc.).
- xv. Evaluation of umbilical cord – presentation, insertion, nuchal encirclement, number of vessels and presence of true knot.
- xvi. Evaluation of previous Caesarean Section scars.
- xvii. Evaluation of fetal growth parameters, fetal weight and fetal well being.
- xviii. Color flow mapping and duplex Doppler studies.
- xix. Ultrasound guided procedures such as medical termination of pregnancy, external cephalic version etc. and their follow-up.
- xx. Adjunct to diagnostic and therapeutic invasive interventions such as chorionic villus sampling (CVS), amniocenteses, fetal blood sampling, fetal skin biopsy, amnio-infusion, intrauterine infusion, placement of shunts etc.
- xxi. Observation of intra-partum events.
- xxii. Medical/surgical conditions complicating pregnancy.
- xxiii. Research/scientific studies in recognized institutions.

11. Procedures carried out (Non-Invasive) (Put a “Tick” on the appropriate procedure)

i. Ultrasound

**(Important Note: Ultrasound is not indicated/advised/performed to determine the sex of fetus except for diagnosis of sex-linked diseases such as Duchene Muscular Dystrophy, Hemophilia A & B etc.)**

ii. Any other (specify) \_\_\_\_\_

12. Date on which declaration of pregnant woman/ person was obtained : \_\_\_\_\_

13. Date on which procedures carried out: \_\_\_\_\_
14. Result of the non-invasive procedure carried out (*report in brief of the test including ultrasound carried out*)  
\_\_\_\_\_
15. The result of pre-natal diagnostic procedures was conveyed to \_\_\_\_\_ on \_\_\_\_\_
16. Any indication for MTP as per the abnormality detected in the diagnostic procedures/  
tests \_\_\_\_\_

Date:

**Name, Signature and Registration Number with Seal of the  
Gynaecologist/Radiologist/Registered Medical Practitioner  
performing Diagnostic Procedure/s**

Place:

**SECTION C: To be filled for performing invasive Procedures/ Tests only**

17. Name of the doctor/s performing the procedure/s: \_\_\_\_\_
18. History of genetic/medical disease in the family (specify): \_\_\_\_\_ Basis of  
diagnosis ("Tick" on appropriate basis of diagnosis):  
(a) Clinical (b) Bio-chemical  
(c) Cytogenetic (d) other (e.g. radiological, ultrasonography etc.-specify)
19. Indication/s for the diagnosis procedure ("Tick" on appropriate indication/s):  
A. Previous child/children with:  
(i) Chromosomal disorders (ii) Metabolic disorders  
(iii) Congenital anomaly (iv) Mental Disability  
(v) Haemoglobinopathy (vi) Sex linked disorders  
(vii) Single gene disorder (viii) Any other (specify)  
B. Advanced maternal age (35 years)  
C. Mother/father/sibling has genetic disease (specify)  
D. Other (specify) \_\_\_\_\_
20. Date on which consent of pregnant woman / person was obtained in Form G prescribed in PC&PNDT Act,  
1994 : \_\_\_\_\_
21. Invasive procedures carried out ("Tick" on appropriate indication/s)  
i. Amniocentesis ii. Chorionic Villi aspiration  
iii. Fetal biopsy iv. Cordocentesis  
v. Any other (specify)
22. Any complication/s of invasive procedure (specify) \_\_\_\_\_  
\_\_\_\_\_
23. Additional tests recommended (Please mention if applicable)  
(i) Chromosomal studies (ii) Biochemical studies  
(iii) Molecular studies (iv) Pre-implantation gender diagnosis  
(v) Any other (specify)
24. Result of the Procedures/ Tests carried out (*report in brief of the invasive tests/ procedures carried  
out*) \_\_\_\_\_  
\_\_\_\_\_
25. Date on which procedures carried out: \_\_\_\_\_
26. The result of pre-natal diagnostic procedures was conveyed to \_\_\_\_\_ on \_\_\_\_\_

27. Any indication for MTP as per the abnormality detected in the diagnostic procedures/ tests \_\_\_\_\_

Date :  
Place

**Name, Signature and Registration Number with Seal of the  
Gynaecologist/Radiologist/Registered Medical Practitioner  
performing Diagnostic Procedure/s**

**SECTION D: Declaration**

**DECLARATION OF THE PERSON UNDERGOING  
PRENATAL DIAGNOSTIC TEST/ PROCEDURE**

I, Mrs./Mr. \_\_\_\_\_ declare that by undergoing \_\_\_\_\_ Prenatal Diagnostic Test/ Procedure. I do not want to know the sex of my foetus.

Date: \_\_\_\_\_ Signature/Thumb impression of the person undergoing the Prenatal Diagnostic Test/ Procedure

**In Case of thumb Impression:**

Identified by (Name) \_\_\_\_\_ Age: \_\_\_\_\_ Sex: \_\_\_\_\_

Relation (if any): \_\_\_\_\_ Address & Contact No.: \_\_\_\_\_

Signature of a person attesting thumb impression: \_\_\_\_\_ Date: \_\_\_\_\_

**DECLARATION OF DOCTOR/PERSON CONDUCTING  
PRE NATAL DIAGNOSTIC PROCEDURE/TEST**

I, \_\_\_\_\_ (name of the person conducting ultrasonography/image scanning) declare that while conducting ultrasonography/image scanning on Ms./ Mr. \_\_\_\_\_ (name of the pregnant woman or the person undergoing pre natal diagnostic procedure/ test), I have neither detected nor disclosed the sex of her fetus to anybody in any manner.

Date: \_\_\_\_\_ Signature: \_\_\_\_\_

\_\_\_\_\_  
Name in Capitals, Registration Number with Seal of the  
Gynaecologist /Radiologist/Registered Medical Practitioner  
Conducting Diagnostic procedure

[F No. V.11011/6/2013-PNDT]

Dr RAKESH KUMAR, Jt. Secy.

**Note :** The principal notification was published in the Gazette of India, *vide* G.S.R 1 (E), dated the 1st January, 1996 and amended *vide* notification numbers G.S.R 109 (E), dated the 14th February, 2003; G.S.R 426 (E), dated the 31st May, 2011; G.S.R 80 (E), dated the 7th February, 2012; G.S.R 418 (E), dated the 4th June, 2012 and G.S.R 13(E), dated the 9th January, 2014.

**The Checklist for the Anomalies Scan can be a combination of the following recommendations**

**Components of the Standard Fetal Examination at 18 to 20 Weeks of Gestation**

1. Fetal cardiac activity, fetal number, and presentation should be documented.
  - i. An abnormal heart rate and/or rhythm should be documented.
  - ii. Multiple gestations require the documentation of additional information: chorionicity, amnionicity, comparison of fetal sizes, estimation of amniotic fluid volume (increased, decreased, or normal) in each gestational sac, and fetal genitalia (when visualized).
2. A qualitative or semiquantitative estimate of amniotic fluid volume should be documented.
3. Placental location, appearance, and relationship to the internal cervical os should be documented. The umbilical cord should be imaged and the number of vessels in the cord documented. The placental cord insertion site should be documented when technically possible.
4. Measurements:
  - i. Biparietal diameter, head circumference, abdominal circumference, and femoral diaphysis length.
5. Fetal anatomic survey:
  - i. Head, face, and neck:
    - Lateral cerebral ventricles
    - Choroid plexus
    - Midline falx
    - Cavum septipellucidi
    - Cerebellum

- Cistern magna
  - Upper lip
  - Nuchal fold measurement may be helpful during a specific age interval to assess the risk of aneuploidy.
- ii. Chest: Heart:
- Four-chamber view
  - Left ventricular outflow tract
  - Right ventricular outflow tract
  - Three vessel view
- iii. Abdomen:
- Stomach (presence, size, and situs)
  - Kidneys
  - Urinary bladder
  - Umbilical cord insertion site into the fetal abdomen
  - Umbilical cord vessel number
- iv. Spine:
- Cervical, thoracic, lumbar, and sacral spine
- v. Extremities:
- Legs and arms
- vi. Gender:
- ONLY in circumstances permitted under PCPNDT Act w

6. Maternal anatomy: Evaluation of the uterus, adnexal structures, and cervix should be performed when appropriate.

Source: ACR-ACOG-AIUM-SRU Practice Guideline for the Performance of Obstetrical Ultrasound. Revised 2013 (Resolution 17). Permission for publication

granted by the American College of Radiology. Full document available at: <http://www.acr.org/~/media/F7BC35BD59264E7CBE648F6D1BB8B8E2.pdf>. Retrieved February 14, 2014.

## SOCIETY OF FETAL MEDICINE PROTOCOL FOR THE SECOND TRIMESTER ANOMALIES SCAN

The second trimester scan includes three components. These are a detailed anatomical evaluation of the fetus, fetal biometry, and, an evaluation of the fetal environment.

The use of high frequency transducers, transvaginal scanning, color and power Doppler studies and three dimensional and real-time three-dimensional scans enhances accuracy in several situations and is encouraged but not mandatory.

The study should document the following:

- Fetal number
- Chorionicity and amnionicity in case of multiple gestations,
- Fetal cardiac activity,
- Fetal biometry as recommended in the following sections,
- Estimation of fetal weight,
- A detailed fetal anatomic survey as recommended in the following sections, and,
- Evaluation of the fetal environment including the placenta, amniotic fluid, umbilical cord and maternal uterus, cervix and adnexa, as recommended in the following sections.

Fetal biometry should include the following measurements:

- Biparietal diameter (BPD) measured from the leading edge to the leading edge of the osseous margins of the cranium in an axial section that includes the cavum septum pellucidum and the thalami
- Head perimeter (HP) at the same level as the BPD, traced at the outer margin of the osseous skull vault,
- Occipito-frontal distance at the same level as the BPD, from the anterior edge of the osseous surface to the posterior edge of the osseous surface on the outer aspect,
- Abdominal perimeter (AP) measured in a transverse view of the abdomen at the level of the junction of the umbilical vein and portal vein anteriorly and the spine in a true transverse section posteriorly,
- Femur length includes the shaft only; vertical orientation of the bone is inappropriate. Measurements are to be taken end to end, and, if both femora are seen in the same plane, the bone in the near field is to be measured,

- The cerebellar transverse diameter at the maximum axial extent of the cerebellum.

Every effort must be made to obtain ideal planes for measurement. If these are not possible, several of the suboptimal planes described in literature may be used. However, the compromise on an ideal view should be mentioned in the report.

The following measurements are not mandatory but encouraged in appropriate clinical situations and serve the purpose of objectivity in anomalies detection:

- Humeral length
- Radial length, Ulnar length, tibial length, fibular length, foot length and clavicular length,
- Depth of the cisterna magna,
- Width of the atrium of the lateral ventricle,
- Nasal bone length
- Binocular distance, Interocular distance and orbital diameter
- Lung lengths, and,
- Kidney length.

The nuchal skin fold should be necessarily measured. This is ideally measured in an axial section showing the fold and including the cerebellum and cavum septum pellucidum.

Fetal weight estimates should be derived from customized charts, or in case these are not available, from standard charts. The chart used should be quoted in the report/report table. Measurements should include cranial measurements, abdominal perimeter and femoral length. Deviation of measurements from norm has traditionally been reported as equivalents in weeks and days. There is a recent trend of reporting deviations as centiles and this is encouraged.

Evaluation of the fetal environment includes assessment of the amniotic fluid, the umbilical cord, the placenta, the cervix and the myometrium and adnexa.

Evaluation of amniotic fluid includes assessing quantity and echogenicity. Measurements are not mandatory but encouraged to facilitate serial evaluation. Quantification may be done by assessing the amniotic fluid index or the maximum vertical pocket. The index is the sum of the deepest fluid pocket in each of four quadrants of the uterus. The pockets should be free of fetal limbs and the umbilical cord. In multifetal pregnancies the maximum vertical pocket should be measured in each amniotic sac. If the amniotic fluid is excessively echogenic this should be mentioned in the report.

The umbilical cord should be assessed for the number of vessels, its point of origin and its point of insertion. Masses in the umbilical cord, if any, should be noted. Cord length is unreliable to assess but a short cord if noted should be documented.

Placental evaluation should include location, echogenicity, thickness and the retroplacental area. Accessory lobes should be looked for and noted if present. Location includes a measurement of the distance of the inferior margin of the placenta from the internal os. Focal areas of altered echogenicity should be characterized if possible and noted. Assessment of placental thickness is subjective. Abnormally thin or thick placentas should be documented and maximum thickness should be measured in these situations. Although the sensitivity of ultrasound for assessing abnormal invasion of the myometrium by the placenta is poor, an attempt should be made to assess this.

The myometrium should be assessed for fibroids and any thinning of previous scars. Any maternal adnexal mass should be noted and characterized if possible.

The cervix should be assessed for its length and for a closed internal os. Emerging evidence suggests that a transvaginal scan is more accurate for this assessment and future direction is awaited.

The anomalies survey is the most significant component of the second trimester fetal study. A systematic and meticulous approach is necessary. This should not be limited by time constraints. Low-end equipment with its lower resolution is often inadequate for an adequate study. At the same time, very high-end technology is not necessary but encouraged.

The cranium should be assessed for shape, ossification and bony defects. The intracranial anatomic survey should include a subjective assessment of symmetry, the falx, cavum septum pellucidum, thalami, cerebellum, cisterna magna, the third ventricle, lateral ventricles and early sulcation of the cerebrum. Any focal abnormalities in the cerebrum should be noted. Deviations from norm should be reported.

The nuchal skin fold should be measured from the outer margin of skin to the surface of the occipital bone.

The anatomic survey of the face should include an assessment of the slope of the forehead, the orbit, eyelids, lens, nasal bone, nasal configuration, upper lip, lower lip, maxilla, mandible, cheek and chin. Location and configuration of the external ear is required only in specific clinical scenarios and does not form part of routine anomalies evaluation

The neck should be assessed for anterior, posterior or lateral masses.

The spine including the osseous components, soft tissues and skin should be assessed in longitudinal, coronal and axial sections.

The thorax should be systematically assessed for the chest wall, lungs, heart, mediastinum and diaphragm. The chest wall should include the ribs, scapula and clavicles. The cardiac survey should include cardiac situs, size, axis, rate, rhythm, four-chamber view, outflows and the three vessel / three vessel trachea view. The lungs should be assessed for extent and echogenicity. The mediastinum should be evaluated for masses and displacements. The diaphragm and interruptions should be looked for.

Anatomical assessment of the abdomen should include observing visceral situs, the anterior and posterior abdominal wall, filling and emptying of the stomach, bowel echogenicity, size and echogenicity of the liver and spleen, abnormal masses if any, kidney location, contour and echogenicity, urinary dilatation if any and the urinary bladder in a full and empty phase.

Evaluation of fetal genitalia should be considered only in the perspective of sex related disorders and in the context of local legislation.

The extremities should be assessed for the presence of bones and soft tissues in the proximal, middle and distal segments of both upper limbs and both lower limbs. Counting of the digits does not form part of the anomalies protocol. Clinodactyly and sandal-gap deformity should be looked for. Movements should be surveyed.

<b>Medium End Ultrasound Scanner for Anomalies Scan</b>
<b>TECHNICAL SPECIFICATIONS</b>
The system should be capable of performing 2D, Color Doppler and low end 3D/4D studies and have the following specifications
The system should have B mode, M mode, PW Doppler, High Pulse Repetition Frequency (HPRF), Color Flow Doppler, Power Doppler with bidirectional, current technique Tissue Harmonic Imaging (THI).
It should be able to display combined modes like B/Spectral Doppler, B/M-mode, B/Power Doppler, B/Color Doppler and Bidirectional Power Doppler and B/4 D mode.
The system shall have fully digital technology with minimum of 160000 channels per image frame for simultaneous formation, acquisition and display processing of multiple ultrasound beams and support dynamic focal length tuning
It should have minimum three active ports
A display of 15" high resolution TFT Flat Panel Screen with swivel and tilt facility.
Inbuilt image storage facility with not less than 500 GB HDD and DVD Writer facility. The image management must enable to rework on the volume files that are stored in the HDD.
Integrated DICOM interface, peripheral bay for B&W, Color and S-VHS.
The system dynamic range shall be not less than 255 Db and above
Intelligent Automatic Image Optimization function in B mode and Doppler
Transmission focus must be freely selectable in 1 to 5 focal zones and adjustable in minimum 6 different positions with a scan depth penetration of minimum 0 - 36 cm
Maximum zoom (read + write) upto 20 times having high resolution zoom with high definition worn
Extended field of view (panoramic imaging) with noise filter algorithm with measurements and individual frame display
The system shall have cine loop in the single/dual and quad formats upto 7000 frames in B-mode and atleast 60 seconds of flopper and M mode data
The system pulsed wave doppler should have Pulse Repetition Frequency (PRF) minimum 1.5 to 21.0 KHz with transmission frequency from 1 to 16 MHz with automatic doppler tracing and measurements
Real time spatial compounding with transmit compounding minimum 7 different angles in spatial compounding without decrease in frame rate volume
Image visualization and delineations of pathology with optimized contrast resolution with real time speckle management techniques even in color, the same should be applicable able to combine seamlessly with other applicational features in the system. Should be available with all the probes and should ensure that the frame rate is maintained high.

The system should be capable of the best 3D/4D imaging with newer techniques based on volume acquisition for better and optimized solutions in different diagnostic situations, apart from the basic multiplanar plane imaging with measurements in MPR possible, with other basic 3D features like 3D based volume calculations, 3D power doppler mode etc.
It should have dedicated 4D probes for convex, Transvaginal with description of applications as possible
The system should have a very good volume acquisition speed and should have the realtime 4D cine loop capable of editing at any time
The system should have the state of art Fetal Echo technique based on automatic volume acquisition and automatic plane identification
The system have the CT like slice distribution from the single acquired volume and should be able to acquire the other plane [A, B, C] at the touch of a button and should be able to combine with other applications for better diagnostic results
The system should have the technique for visualization of multiple cystic structures as well as to measure them instantly using the semi auto trace mode for a quick and precise estimation of volumes using the latest volume rendering modes
The 4D transvaginal probe should have the survey mode for imaging the complete details of female reproductive system
Dedicated software for breast imaging and vascular imaging may be provided alongwith other necessary software
All probes should have broad bandwidth with optimized application presets for better diagnostic results and have atleast 180 elements in the array.
System should have advanced features of 3D Static & 4 D Real time with single view facility.
System should mandatarly have the Sono NT and Sonorender start fetaure with Anatomical Model,
On board archive including Preview &PreSelection is a mandatarly.
<b>The system must be supplied with following minimum probes:</b>
One Convex probe for applications in abdomen, obstetrics and gynaecology with 2 to 5 MHz with separate selectable doppler frequency and harmonic frequency
One 9/11 MHz Linear Transducer with near focus
One volumetric convex probe with precision volume generation technology and light weight with FOV 70 degree and volume scan angle 80 degree with frequency of 4 to 8.5 MHz
One volumetric transvaginal probe with FOV of 145 degrees with 90 degree volume scan angle with 4 to 9 MHz frequency bandwidth
Standard accessories Viz: B/W thermal Printer and UPS with 30 minutes back of power is mandatarly and to be included in the Std. Scope of Supply.
<b>Safety conformance:</b> Should meet the standard norms
<b>Warranty:</b> It should be given for the system and accessories for a minimum period of 3 years from the date of successful commissioning of the system

**Annual Maintenance Contract (AMC):** The supplier must quote for service AMC charges and comprehensive AMC charges separately which shall become effective after the warranty period. The AMC shall include yearly calibration from reputed agency in a standard format. The supplier must give an undertaking to cover AMC for the Doppler Unit, Image Management Software including its upgradation for the lifetime of the system. The number of Preventive Maintenance Call and break down calls under AMC shall be indicated.

**Installation:** Delivery, installation and commissioning of the entire system at the DAE Hospital, Kalpakkam.

**User manual:** A printed operating manual in English must be supplied

The supplier shall indicate the conformity of the specification point wise and also furnish additional features of the system if any clearly. Rates must be quoted for the System and accessories separately.

## **VII. List of Abbreviation**

<b>ACOG</b>	AMERICAN COLLEGE OF GYNECOLOGIST
<b>ANC</b>	ANTENATAL CARE
<b>CHC</b>	COMMUNITY HEALTH CENTRE
<b>CPG</b>	CLINICAL PRACTICE GUIDELINES
<b>DH</b>	DISTRICT HOSPITAL
<b>FRU</b>	FIRST REFERRAL UNIT
<b>IEC</b>	INFORMATION EDUCATION COMMUNICATION
<b>JSSK</b>	JANANI –SHISHU SURAKSHA KARYAKRAM
<b>MTP ACT</b>	MEDICAL TERMINATION OF PREGNANCY ACT, 1971
<b>PC&amp;PNDT</b>	PRE- CONCEPTION AND PRE -NATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX SELECTION) ACT, 1994
<b>PHC</b>	PRIMARY HEALTH CENTRE
<b>PNDT</b>	PRE-NATAL DIAGNOSTIC TECHNIQUES
<b>PMSMA</b>	PRADHAN MANTRI SURAKSHIT MATRITVA ABHIYAN
<b>NFHS</b>	NATIONAL FAMILY HEALTH SURVEY
<b>PW</b>	PREGNANT WOMAN
<b>RKS</b>	ROGI KALYAN SAMITI
<b>SOGC</b>	THE SOCIETY OF OBSTETRICIAN AND GYNAECOLOGIST OF CANADA

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