



Process of Renewal of PC&PNDT License of a Large Tertiary Care Teaching Hospital of North India: How One Needs to Plan for it?

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Abstract

Background The Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act (PC&PNDT Act), 1994 was enacted to prevent sex determination and female feticide. As a mandatory statutory requirement, All India Institute of Medical Sciences, New Delhi, India has to renew its PC&PNDT license after every 5 years.

Aim The current study was undertaken with an objective to delineate in detail, the process of PC&PNDT license renewal, and the challenges dealt with while submitting the renewal application.

Methods and Material An observational descriptive study was conducted from February to July 2022. The renewal process was categorized into preapplication, application, and postapplication phases. The requisite documents and data were collected from the Hospital Establishment Section and Medical Records Department.

Results The preapplication phase involved obtaining details from 24 departments, with 20 responding initially. Challenges included incomplete documents and deficient details. The application phase required consolidation, affidavits, form filling, and fee payment. Postapplication, an inspection was conducted, and the renewal certification was obtained.

Conclusion The study highlights the complexities of renewal of PC&PNDT license of a large multispecialty tertiary care teaching hospital. Planning leads obtained during various phases could serve as a guiding template for other similar teaching hospitals. The study suggests the need for digitalization and streamlining of documentation process to ease out the renewal process and hence contribute to better patient care at large.

Keywords

- ▶ administrative challenges
- ▶ female feticide
- ▶ license renewal
- ▶ medical institutions
- ▶ PC&PNDT Act
- ▶ sex selection

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Introduction

A broad consensus on male child preference continues in India, despite the diversity of cultural, social, and religious backgrounds. As a result of which, female infanticide was used to eliminate girl child, which contributed majorly to the skewing of sex ratio of age group specifically under 6 years.¹

On September 20, 1994, the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) (PC&PNDT) Act was passed with the intention of prohibiting prenatal diagnostic techniques for determination of the sex of the fetus leading to female feticide and it was legislated in a manner that it could serve as a deterrent for those indulging in sex determination. The Act was amended from PNDT to PC&PNDT (The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act) in 2003 to accommodate preconception sex-selection techniques. Therefore, under the ambit of this Act, all the equipment and diagnostic techniques capable of detecting and selecting fetal sex are regulated to prevent female feticide or sex selection before or after conception, and all the prenatal diagnostic techniques for the purposes of detecting abnormalities or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex-linked disorders are regulated.²

As an apex institute of medical education and research in the country, with more than 2,500 beds, All India Institute of Medical Sciences (AIIMS), New Delhi, India has got a wide spectrum of equipment as well as users from across the disciplines. As per the statute, it is mandatory to hold a valid PC&PNDT license to render patient and prenatal health care. The renewal of PC&PNDT license after every 5 years poses a unique administrative challenge to timely collect and collate the required documents from the “user” departments and submit their details along with the application form to PC&PNDT Directorate. To seamlessly carry out this extensive exercise, a definite component of meticulous planning is required.

Methods

An observational descriptive study was undertaken at AIIMS, New Delhi with the objective to delineate in detail, the process of PC&PNDT license renewal, and the challenges dealt with while submitting the renewal application. The requisite

documents and data were collected from the Hospital Establishment Section and Medical Records Department. The study was conducted from February 2022 to July 2022.

Process of PC&PNDT License Renewal

The process of renewal of license can be broadly divided into three phases, namely:

1. Preapplication phase
2. Application phase
3. Postapplication phase

Preapplication Phase

To submit the application within the stipulated time limit, which is within 30 days prior to date of expiry of license, we started working on it a month prior to the actual date of submission. We drew a planning framework for it with timelines for each step, and factored in it the most plausible constraints. The steps entailed the following:

1. Collecting the details of organization and the applicant.
2. Sending a communication to all the user departments and centers for the required details and supporting documents.
3. Receiving and sorting replies, and sending reminder communications to furnish the deficient documents from the user departments.

Collecting the Details of Organization and Applicant

The details of the organization and applicant as mentioned in ►Tables 1 and 2 were collected apart from the number and types of facilities for which the license is required. The types of facilities are: (1) genetic counseling center, (2) genetic counseling laboratory, (3) genetic clinic, (4) ultrasound clinic, (5) imaging center, (6) echocardiography, and (7) in vitro fertilization clinic.

Sending a Communication to All the Departments and Centers for the Required Details and Documents

All the departments and centers were informed about the expiry of license of PC&PNDT. The requisite details of machines and users of their department were requested to be furnished to the office of Medical Superintendent to process the application. We sent standardized pro-forma separately for machines and users requesting the users to provide their information in the same (►Supplementary Material S1, online only). The details included are as mentioned in ►Table 3.

Table 1 Details of organization as per the format

SN	Details of	Particulars to be submitted	Additional documents ^{a,b}
1	Organization	a. Name b. Address c. Email ID d. Phone number	a. Organization address proof (electricity bill from the Engineering Department) b. Map of organization showing location of machines c. Present PC&PNDT certificate d. MTP registration certificate

Abbreviations: MTP, Medical Termination of Pregnancy; PC&PNDT, Pre-Conception and Pre-Natal Diagnostic Techniques.

^aLayout plan of Premises (for new registration).

^bFor private organization we need: (a) Memorandum of Understanding (MOU) and Certificate of Incorporation, (b) rent/lease agreement duly registered with competent authority valid for 5 years and copy of address proof of landlord, and (c) Nursing Home registration certificate.

Table 2 Details of the applicant as per the format

SN	Details of	Particulars to be submitted	Documents Needed (Copies)
1	Applicant ^a (Medical Superintendent)	a. Name b. Address (including S/D/W of) c. Email ID and phone number d. Date of birth e. Date of joining f. Qualification g. DMC Reg. No. and validity h. Bank details (account no., name and address of bank)	a. Registration and degree certificate b. Proof of address (either permanent or local) c. Aadhaar card d. Latest 6 months' bank account statement e. Two passport size photographs f. Declaration ^b g. Affidavits ^b

Abbreviations: DMC, Delhi Medical Council; S/D/W, son/daughter/wife.

^aApplicant in private organization can be owner or a representative of the owner.

^bDeclaration and affidavits - will be mentioned in separate declaration and affidavit section.

Table 3 Details of machines and users as per the format

SN	Details of	Particulars to be submitted	Documents needed (copies)
1	Machine	a. Type of machine (USG/MRI/Echo/CT/X-ray/B-scan) b. Make and model c. Serial number d. Date of installation e. Location (floor and room no.) f. Mobile or fixed	a. Invoice b. Installation report
2	User ^a	a. Name b. Address (including S/D/W of) c. Email ID and phone number d. Date of birth e. Date of joining f. Qualification g. Designation and department h. DMC Reg. No. and validity	a. Degree certificate b. DMC/State Medical Council registration certificate c. Experience Certificate d. Aadhaar Card e. Affidavit ^b f. Passport photographs (2 copies)

Abbreviations: CT, computed tomography; DMC, Delhi Medical Council; Echo, echocardiography; MRI, magnetic resonance imaging; S/D/W, son/daughter/wife; USG, ultrasound.

^aUser – Any doctor who advises or performs or reads the report of prenatal diagnostic tests/procedures.

^bAffidavits - will be mentioned in separate declaration and affidavit section.

Receiving and Sorting Replies and Sending Reminder Communications to Furnish the Deficient Documents from the User Departments

The documents sent by the various user departments were sorted and sequenced. Reminder communications were sent to the departments which failed to furnish the complete set of requisite documents.

Application Phase

The process of filing an application was divided in to the following:

1. Consolidation of data and documents received
2. Preparation of declarations and affidavits
3. Filling of application form and payment of fees
4. Finalizing application and its submission

Consolidation of Data and Documents Collected

Data pertaining to all the machines and users were collected and pooled onto a master Excel sheet in a standardized format that included the information listed in the tables. The serial numbers on the master sheet for each machine and user was matched to the individual number

assigned on their files for the convenience of pagination and archiving.

Preparation of Declaration and Affidavits

A declaration by the applicant was made on the letter head of organization which stated that "Hospital is completely furnished and all statutory requirements like examination table, notice board, signages, board of the center, etc., have been placed."

Two copies of the affidavits for the applicant were made which included the following as under:

- i. Statement of compliance to the rules of the PC&PNDT Act and no court case is pending related to the aforementioned Act.
- ii. Statement that we will make sure that the facilities and users comply with rules of the Act.

One copy of the affidavit per user was made.

The users were stratified in to two groups for the purpose of making affidavits:

Group I: Users from the Department of Radio-diagnostics and Obstetrics and Gynecology

Group II: Users from rest of the departments

For group I users: Stating that the legislation's regulations shall be followed, that records of prenatal diagnostic procedures shall be kept, that no test or method to discover the fetus' gender shall be ever performed, and that there was no court case pending related to the Act.

For group II users: Stating that the legislation's regulations shall be followed, no procedure/test related to detection of fetal gender shall be ever performed, and that there was no court case pending related to the Act.

For group I users, gynecologists, and all group II users, they have to write in the affidavit itself that they will be using the machines for ultrasound/Doppler/2D echocardiography/ORBIT for their field of patients only.

All the affidavits along with the user's documents were forwarded to the individual user's departments for their signatures and stamping. It is pertinent to note that all user's documents and photographs were self-attested, and certificates were countersigned and stamped by the applicant. Rest of the enclosures was self-attested and stamped by the applicant. The stamps which were used included: (1) seal of the organization with address, (2) seal of the applicant, and (3) seal of the users.

Filling of Application Form and Payment of Fees

After compiling all the necessary materials, we began filling the application form obtained from the Office of the Chief District Medical Officer, South District, Directorate of Health Services located at Malviya Nagar, New Delhi, India. The application form included a checklist and Form A. It was mandatory to submit the Form A (in duplicate).

A payment of 17,500 INR was made toward the renewal fee through NEFT (National Electronic Fund Transfer) as per the stipulated fee requirement under the desired category, the details of which are given in ► **Table 4**.

Finalizing Application and Submission

Checklist was filled and documents were double-checked for any missing signatures, stamps, or pagination. The application, completed in all the respects, was submitted to the appropriate authority (*by hand*) in the Office of the Chief District Medical Officer, South District, Directorate of Health Services located at Malviya Nagar, New Delhi.

Postapplication Phase

Appropriate authority from the Office of the Chief District Medical Officer after a due notice of intimation inspected departmental areas where the machines were located. The areas were inspected for the proper maintenance of records,

scan areas, and filling of Form F as per the guidelines stipulated in the Act. Form F with its data has to be mandatorily preserved for 2 years for inspection by the authorities as per the stipulations under the Act. The receipt of data of every month, which is to be submitted by 5th of every month, is also required to be mandatorily preserved for 2 years.

It is pertinent to highlight that all the fields in Form F are to be completely filled and the copies of following documents are to be preserved along with Form F; (1) copy of ID of pregnant woman self-attested (stating "self-attested for ultrasound scan"), (2) copy of referral slip with clear details of referring doctor, (3) copy of ultrasound report, (4) copy of thermal film, and (5) copy of outpatient department card clearly showing details of last menstrual period.

Challenges Faced in the Process of PC&PNDT License Renewal and Planning Leads Gathered

The renewal of license of PC&PNDT of such a large tertiary care teaching hospital was fraught with numerous challenges. Every stage described in the process of PC&PNDT license renewal had its own challenges due to a large number of machines and their locations, various departments spread across the main hospital and its centers, and most importantly the huge and wide spectrum of users. The challenges faced during various stages of its renewal and the planning leads gathered to deal with them are enumerated below.

Results

Under the preapplication phase, a total of 20 out of the 24 departments from which the details were sought reverted back with the requisite documents. Four departments reverted back with the following deficiencies (1) Delhi Medical Council registration certificate was not furnished, (2) insufficient details of users, and (3) few machines' invoices and installation reports. A total of three reminders were sent, in response to which two departments reverted on the first reminder in a time period of 5 days. Second and third reminders were sent to the remaining two departments which reverted back within a time period of 1 week. After the due submission of completed application with all the requisite documents, the officials from the office of the Chief District Medical Officer inspected the departmental areas of the hospital and the concerned premises and provided a copy of PC&PNDT Inspection Report. The renewal certification was received after a satisfactory inspection by the officials of PC&PNDT. The planning leads were gathered during each phase of application while encountering certain specific challenges relevant to that phase as described in ► **Fig. 1**.

Discussion

Collection of documents pertaining to the users and machines and preparation of requisite affidavits were the tedious exercise which can be attributable to the wide spectrum of machines and users across various disciplines.

Albeit the intent of the Act is laudable and the need of hour, however, tedious documentation involved in obtaining the

Table 4 Details of fee for the new license and its renewal

Number of facilities	New application	Renewal application
Single	25,000 INR	12,500 INR
More than One	35,000 INR	17,500 INR

Note: Mode of payment can be DD/NEFT/RTGS Transfer: DAA (Documents against acceptance - A/c no., Name and Address of Bank).

Stage of Renewal Process	Challenges	Planning leads gathered to handle the specific challenges
<p>Pre-application phase</p>	<p>Sending communications to all departments in possession of the machines or the users where the possibility of inadvertently missing out a department or a user is always there.</p>	<p>The process of collection of details and documents could be started three months prior to the expiry of existing license.</p>
	<p>Receiving and sorting of user details, departmental machine details and copies of documents of a large number of users.</p>	<p>Each detail and document have to be verified thoroughly; deficient details should be escalated to the concerned department well in time.</p>
	<p>A few users were on leave which caused delay in their detailed submission which eventually became a rate limiting step.</p>	<p>A clear and timely listing of such users with due reminders to their departments to make their submissions on the required details.</p>
<p>Application phase</p>	<p>Pagination of each set of documents in consonance with the details entered in their respective master sheets of machines and users.</p>	<p>Documents processing and pagination to be meticulously handled leaving no scope to error.</p>
	<p>Preparation of declarations and affidavits.</p>	<p>Preparation of affidavits of all the users is a tedious exercise, can be executed with the involvement of dedicated personnel from hospital store and establishment.</p>
	<p>Obtaining signatures of users on their individual affidavits made.</p>	<p>Multiple hospital and office attendants should be involved to timely get the user's signatures on their affidavits made.</p>
<p>Post-application phase</p>	<p>Maintaining compliance to the PC&PNDT Act in the premise of machines and complying with uniform standardized documentation across all the areas.</p>	<p>Monitoring, support and periodic training to all the staff on the maintenance of premise of machines and documentation in a uniform standardized manner.</p>

Fig. 1 Details of various phases and challenges in the renewal process and planning.

license and patient care metamorphosing in to insurmountable impediments in delivery of care. In consonance with digitization with advent of technology, it is imperative for the competent authority to take an environment-friendly green initiative of making a provision of e-filing of application similar to the initiative undertaken by the Government of Uttar Pradesh.³ Further, it is essential to pay heed to curb superfluous documentation.

As per the PC&PNDT Act, the validity of license is 5 years and is to be renewed within the prescribed time to avoid violation of the statutory rules and its dire consequences. The current study is an attempt to highlight and address the challenges involved in the renewal of PC&PNDT license of a large tertiary care teaching hospital and how the Department of Hospital Administration dealt with them through meticulous planning and a systematic effort as mentioned in **Fig. 1**, to get it renewed within the stipulated timeline and

to preclude duplication of work and an iota of deficiency in documentation. The most important takeaways are the planning leads gathered while going through different phases of application process and dealing with challenges specific to each phase.

*As per Rule 8(6) under the PNDT Rules - In the event of failure of the Appropriate Authority to renew the certificate of registration or to communicate rejection of application for renewal of registration within a period of ninety days from the date of receipt of application for renewal of registration, the certificate of registration shall be deemed to have been renewed.

Conclusion

A clear understanding of the various steps and stages with a component of good planning is essential for the renewal

process of a license like PC&PNDT of a large tertiary care teaching hospital. The planning leads gathered while encountering challenges at its various stages could be of immense help for other institutions who have to undertake this activity as statutorily mandated by law.

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None.

Conflict of Interest

None declared.

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