TITLE: Diagnostic ultrasonography access in rural India: a failure of the best intentions

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**ABSTRACT** (160 words)

The Pre-Conception and Pre-Natal Diagnostic Techniques Act was written to prevent societally unacceptable harms including intentional sex selection. The pragmatism required to enforce this law has profound effects on the ability of rural Indians to access diagnostic ultrasonography. In so doing, it may have inadvertently placed a heavier burden on the poorest and worsened health inequity in India creating serious ethical and justice concerns.

It is time to re-examine and update the law such that diagnostic ultrasonography can be widely available in even in the most peripheral primary health and community health centers. Shorter, more widely available ultrasonography training courses should be offered; collaboration between radiologists and rural practitioners and facilities should be encouraged. Finally, modern ultrasound machines can carefully record all images via a “silent observer” modality. With some modifications to previously used silent observer modalities, this technology allows both greater access but also better policing of potential misuse of ultrasound technology.

**MAIN ARTICLE**

**Introduction – Laws concerning sex selection**

In 1994, India passed the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act (PNDT). This law was a further extension of regional laws previously passed banning the use of amniocentesis or chorionic villus biopsy for sex selection in response to the skewed male: female sex ratios seen in many parts of India (1, 2) and later research which implicated the selective abortion of female fetuses as the most likely driver of “missing” annual female births (3). While this law did not ban the abortion of female fetuses, it banned sex determination of the fetus (1), required the registration of all facilities with sex determination capabilities, and penalized not only doctors for violating the law but also the pregnant woman’s family members for pressuring her to learn the sex of the fetus (4). The PNDT was revised in 2003 to the Pre-Conception and Pre-Natal Diagnostic Techniques Act (PCPNDT, “the law”) (1). The PCPNDT does not ban any specific technology but rather the discriminatory use of those technologies including ultrasound.

Despite good publicizing and serious penalties, the PCPNDT had little effect on sex at-birth ratios. In fact, from 1996 to 2016, India’s sex ratio *worsened* to 1,012 males:1,000 females at birth (1,5-8). Instead, the PCPDNT has created conditions that further disadvantages some marginalized populations. Some commentators have noted concerns about the law’s potential to catch women in a trap where giving birth to a girl results in remonstration at the hands of her husband and family while attempting sex selection invites prosecution by the government (1, 5).

**Unintended Consequences**

In this article, we will argue that current regulations have restricted access to a highly effective and appropriate technology (diagnostic ultrasonography) in Indian healthcare that especially disadvantages poor and rural patients, thus raising ethical and justice concerns. It is difficult to argue that one ethical imperative outweighs another, yet we believe revisions of some aspects of the PCPNDT can both improve access to diagnostic ultrasonography for medical care in rural India and also slow misuse of this technology for sex-selection.

**How did we get here? Non-maleficence and justice meet pragmatism**

The legislators who modified the PNDT in 2003 believed that the act of sex selection (and subsequent acts) was morally wrong. The ethical foundation of the PCPNDT is rooted in the principles of non-maleficence (the act of not doing harm) and justice. Even though the pregnant women herself is often not directly harmed at the time of a sex determination ultrasound, the law aimed to prevent harm to the unborn female fetus and societal ills that can emanate from skewed sex-ratios. Allowing sex selective practices predisposes to a future where women can be at greater risk of various forms of injustice – like sex trafficking or gender violence – due to their decreased numbers in the general population. India’s turn in this legislative direction mirrored that of other nations (1, 5, 6) including neighbors with similar cultural drivers like China (7-12) where concerns about ultrasound abuse have also been voiced (13).

However, enforcement of the law required a different approach, guided less by ethics and more by pragmatism. While data is not available about the conversations within the government about how this law moved from paper to action, we can conjecture based upon how it is enforced.

The Medical Termination of Pregnancy Act, 1971 law gives a woman the right to an abortion up to twenty weeks gestational age under a number of circumstances in India (14). Sex selective practices could not be curtailed in this way. Legal experts have long known the difficulty of obtaining convictions based upon a person’s motivations. The easiest, most direct way to limit sex selective abortion is prohibition of prenatal sex determination. Throughout India (and, indeed, the world) in-utero sex determination is largely performed by ultrasonography since the 1990’s. Thus, a pragmatic approach is to police the use of this technology. Regulation of the Law allowed only a small subset of medical professionals to perform ultrasound examinations: radiologists (the only group of doctors allowed to perform ultrasounds based solely on their degree qualifications) and obstetricians completing a six-month ultrasonography training course at selected training sites (15). The sale of all ultrasound machines was restricted through designated vendors and only to these qualified parties (1). The PCPDNT applies fully to all private, government and civic run hospitals (16, 17).

From a regulatory perspective, this decision was an absolute coup. The six-month training course was so long that it would be difficult for many full-time employed obstetricians to complete. Consultant radiologists are employed in diagnostic centers and hospitals generally found in urban areas. Within the government healthcare system, the smallest city that would offer a radiologist position is a district hospital. This would mean that one would only find radiologists in larger towns or cities and essentially eliminate the need to carefully police large swathes of rural regions of the country.

One can hardly fault legislators for taking a practical approach in turning this law into reality. Unfortunately, it was those large swathes of rural India that most stood to benefit from other aspects of diagnostic ultrasonography. In so doing, the PCPNDT created a pressing ethical and justice issue – access to an appropriate healthcare technology.

**Would ultrasound be beneficial in rural India?**

The entire ethical argument that there is a justice component to lack of access to ultrasound hinges on whether ultrasound is effective and beneficial in settings like rural India.

Diagnostic ultrasonography has the potential to benefit rural Indians in ways that may not have been fully appreciated in 2003. While ultrasound has long been an established medical imaging modality, since 2003 the medical community has made greater use of what is now termed “point of care ultrasonography” (POCUS). POCUS refers to a form of diagnostic ultrasonography that can be brought to the patient’s side – whether in emergency, outpatient (OPD), inpatient (IPD), intensive care (ICU), even in the back of an ambulance – and be used in real time to gather data and make meaningful clinical decisions.

POCUS has been shown to effectively diagnose and treat many medical conditions (**Table 1**) and has been used effectively in remote and low resource settings around the world (**Table 2**) (18). POCUS does require some expertise to appropriately use and interpret but these skills are not the sole province of the medical consultant and can be effectively taught to a variety of other medical professionals, including those with less education with brief trainings (**Table 3**). Multiple reviews have been published on POCUS use in remote and low resource settings (19-21) including disaster relief (22, 23).

Ultrasonography is an older medical imaging technology but one that has retained its role in the medical armamentarium due to its low costs, portability, ability to function on battery power without electricity, lack of pain, rapidity of results and lack of radiation exposure. In rural India, where patients often have limited funds, electricity is intermittent and long-term patient follow up is extremely difficult, ultrasound is clearly the imaging test of choice in a variety of circumstances.

This point is further elucidated by how POCUS is even making forays into higher resource settings where higher cost, higher resource imaging tests like computerized tomography (CT) scan or magnetic resonance imaging (MRI) are widely available. Emergency medicine and critical care physicians in the United States can now complete diagnostic ultrasonography fellowships (24) or certifications (25) as POCUS is so appropriate to emergency and ICU settings. If point-of-care / diagnostic ultrasonography is effective enough that settings with alternative diagnostic modalities are teaching, certifying and adopting it, there need to be unassailably strong arguments why it is not appropriate for rural India where such alternatives do not exist.

**Table 1**. Selected medical conditions that can be diagnosed and selected procedures that can be performed with POCUS / diagnostic ultrasonography.

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| **Medical Condition** | **Notes** |
| Congenital heart defects (26) | A neonatologist with only limited training was able to accurately diagnosis the presence of a patent ductus arteriosus (PDA). |
| Hydatid cysts (27) | Portable ultrasonography has proven of great benefit in diagnosis and monitoring treatment of echinococcal disease. |
| Deep venous thrombosis (28) | Bedside POCUS at two selected locations in each leg is nearly as good as longer, more complicated tests in their ability to detect deep venous thromboses. |
| Heart function (29) | During triage, POCUS of the heart was effective at both confirming clinical impression but also frequently altered clinical management rapidly at the bedside. |
| Lung function (30) | POCUS can be used to differentiate between different emergent pulmonary conditions including COPD exacerbations, pneumonia, pulmonary embolism and pulmonary edema. |
| Elevated intracranial pressure (31-33) | Ocular ultrasonography to measure ocular nerve sheath diameter can be used to detect elevated intracranial pressures including in pediatric cerebral malaria and those with hypertensive urgency or emergency. |
| Pain control (34) | Painful adhesive capsulitis (“frozen shoulder”) can be treated with ultrasound guided injection of the area around the suprascapular nerve. |
| Leprosy (35) | Ultrasonography can be used to monitor response to treatment in some types of leprosy. |
| Trauma and critical care (36-38) | POCUS can be used as a rapid and accurate technique to evaluate the critically ill including conditions ranging from life threatening trauma to shock. |
| Cardiac Arrest (39, 40) | Ultrasonography can be used to monitor presence or absence of cardiac function during cardiac arrest, to determine underlying etiology and monitor response (or lack of response) to cardiopulmonary resuscitation. |
| **Procedure** | **Notes** |
| Placement of intravascular access (41-47) | Ultrasound can be safely and effectively used to cannulate both the arterial and venous systems and is often safer with lower complication rates that attempting to place such intravascular devices blindly. |
| Lumbar puncture (48-53) | Ultrasound can be used to accurately find the necessary landmarks to safely perform lumbar puncture, especially in children. |
| Aspiration of fluid from various body compartments (54-58) | Ultrasound can be used to visualize fluid pockets in the lungs or abdomen and safely drain them for diagnostic or therapeutic reasons. Before inserting the needle, ultrasound can also be used to check that there are no major blood vessels near the planned site of needle insertion. |

**Table 2**. Selected remote and low resource settings where POCUS / diagnostic ultrasonography have been safely and successfully used.

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| --- | --- |
| **Setting** | **Brief Summary** |
| Lugufu refugee camp, Kigoma District, Tanzania (59) | After a four-day training, health care providers in this refugee camp made frequent use of ultrasound for diagnostic testing. |
| Trauma care after 2010 Haitian earthquake (60) | Access to ultrasound greatly benefitted the triage of trauma patients after the 2010 Haitian earthquake. |
| Ghanaian community (61) | Ultrasound was widely used in two separate primary care clinics in Ghana. |

**Table 3.** Successful training of non-medical specialists in use of POCUS / diagnostic ultrasonography.

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| --- | --- |
| **Non-Medical Specialists** | **Use of POCUS** |
| Briefly trained health workers (62) | Screening for rheumatic heart disease |
| Special forces medics (63) | Trauma |
| Internal Medicine residents (doctors-in-training) (64) | Cardiac echocardiography at bedside |
| Prehospital providers (65) | Long bone fractures |
| Emergency Nurses (66) | Long bone fractures |
| Dutch medical helicopter crew (67) | Chest ultrasound (heart and lungs) |
| Unclear (“minimally trained sonographers”) (68) | Pneumothorax |
| Medical students (brief training) (69) | Rheumatic heart disease with associated mitral valve injury |

**Justice concerns: unfairly shared burdens**

We believe the above demonstrate the potential benefits of POCUS and its natural fit for medical care in the realities of rural India. While never extensively studied, it is our contention that the unintended side effects of the PCPNDT and its regulation most heavily burden rural areas. India’s rural poor already suffer from multiple other substantial burdens including large barriers to accessing care (70) and (if and when care is accessed) a high risk of financial ruin (71).

In rural areas, many health centers have few (if any) physicians and they almost certainly will not have a consultant radiologist. Similarly, the time and expense that must be invested in the government mandated, six-month ultrasonography training course renders that option a non-starter for many rural obstetrician gynecologists. This means that many rural health clinics and hospitals cannot legally keep an ultrasound machine. It would be remarkable to find an ultrasound machine in our region of rural Chhattisgarh in a primary health center (PHC) and even many community health centers (CHC). We suspect the same to be true in other regions of rural India. While some rural practitioners will make do with the physical exam or a locally available X-ray, many rural patients will be referred for an ultrasound, CT or MRI at a distant urban facility. Even under the best of circumstances where the patient can find, pay for and perform the test, specialized expertise is needed to interpret CT and MRI images and can lead to delays in diagnosis. Delays in diagnosis are particularly burdensome in rural settings as patient follow up is often difficult because of structural barriers such as transportation and migrant labor. The realities of regulating and enforcing the PCPNDT function almost as a “poverty tax” where the poorest are made to shoulder a disproportionately large proportion of the unintended consequences of the PCPNDT. We have a clear ethical and justice issue on our hands when a rural Indian patient can be provided with actionable information about his or her condition with an ultrasound and be saved time, travel, money, radiation exposure (in the case of CT) and delay, yet such care is being denied by limiting access to a simple diagnostic tool.

**Possible solutions**

Several workable solutions exist and we would like to propose two: a modification of the existing six-month ultrasonography training course, and encouraging collaborative relationships between radiologists and rural health centers.

The current six-month training course for ultrasonography is logistically difficult for most individuals but the spirit of the idea seems correct. One can imagine a general certification available to medical professionals from primary care, general and emergency specialties such as Family Medicine, Pediatrics, Internal Medicine, Emergency Medicine, General Surgery and Anesthesiology. Much of this coursework could even be done close to home via online modules (where the internet is available) especially since many modern, portable ultrasounds interface with various other types of hand-held technologies (smart phones (72), jump drives) to securely store and transmit images. While such professionals would not have a radiologist’s skill set or breadth of knowledge, they certainly could make actionable clinical decisions. More advanced coursework could also be made available as one progressed through levels of certification. The Delhi high court opened this possibility in a February 17th, 2016 ruling whereby they could not adjudicate the difference between a “mere MBBS” and those individuals currently allowed to perform ultrasounds in a meaningful way. The Court further clarified how these laws were never intended to comment on who was qualified to perform ultrasound examinations (73, 74). There is now a legal precedent and way forward to make this suggestion reality. The Supreme Court also stated that the current restrictions “add no further to the person” in terms of ethical training (73, 74). We must note that our proposed solution cannot prevent nefarious use of ultrasound for prenatal sex determination any more than current coursework certifying practitioners in ultrasound diagnostics.

As noted previously, rural health care centers often lack the radiology specialist or trained obstetricians needed to register their own ultrasound machine(s). With the increasing connectivity of rural India and the safe, private transferring of ultrasound images from even remote locations (75), the PCPNDT could be modified to reward collaboration as a means to improvements in care in rural India. The first step in this process would be to allow radiologists to register additional machines at facilities where they are not physically present (ideally in areas with large unmet healthcare needs) if each radiologist can demonstrate ongoing, meaningful work with the rural clinic or hospital that now has an ultrasound machine. This radiologist can train local staff in the acquisition of whatever imaging types are most pertinent to their care setting and aid in image interpretation. Difficult cases can be shared in near real time via the proliferation of dissemination techniques available. The Tamil Nadu health system does something very similar whereby all primary health centers (PHC) are now connected to Chennai and its medical specialists and expertise. Over 250 Medical Officers at over 125 PHCs have been trained in basic obstetric ultrasound with the help of *MediScan* (76). A similar telemedicine model has been successfully tested in Nicaragua (77). While not without its flaws, such a system has multiple built in layers of protection against abuses and multiple potential whistleblowers: the consultant radiologist, the local practitioner making use of the ultrasound machine and the saved images documenting what was imaged (more below). Similarly, such rural health centers that are collaborating with ultrasonography specialists could legally purchase ultrasound machines through relaxation of the stringent laws dictating which person and facilities can purchase an ultrasound machine in India today.

It should be noted that we are certainly not the first to propose modifications to the PCPNDT. Cardiologists and anesthesiologists have previously filed court petitions requesting exemptions to perform ultrasound specific to their field in areas exempted from the PCPDNT and have been granted the same (78, 79). Ophthalmologists have already been exempted from the law’s statutes, probably because the probes used in ocular ultrasonography cannot be used for fetal sex determination (80). Radiologists in Pune have previously filed petitions against the draconian enforcement of the PCPDNT (81, 82). While we are sympathetic to these ideas and changes, we recommend larger, systemic changes to how the law is regulated as opposed to a more piecemeal, specialty by specialty approach. The former is more likely to be of benefit to rural Indian patients.

**Striking the balance**

The serious challenge in front of us is how best to increase the positive use of ultrasound for healthcare in rural India without simultaneously making it easier to perform antenatal sex determination for sex selection. We cannot simply move the dial on access to ultrasound and call it better, without considering potential rise in illegal use.

A potential for improved regulation is the use of the “silent observer” modality previously endorsed as feasible by the Supreme Court (83). In 2010, the silent observer was deployed in Kolhapur District in Maharashtra (16, 85). These silent observers were external, 250 GB hard drives that cost Rs. 39,5000. They intended to keep images of all ultrasounds to monitor sex determination and quality of antenatal maternal health (86). They were attached to all registered ultrasound machines in private, government and civic hospitals (87). The use of these silent observers raised cost and privacy issues (85) and made no difference in sex-at-birth ratios (84). They were ultimately not implemented long term or state wide despite the brief duration for which they were employed. Of note, these silent observer devices were easy to detach and key pieces of clinical information were easy to not record (86). Their brief trial period makes it difficult to conclude about the efficacy of this policing method.

Remote storage and transfer of imaging data has progressed substantially in the past eight years. Today, nearly all ultrasound machines (include those that can be purchased in India) have the ability to store or transfer images on internal, tamper-proof hard drives and, further, can be connected to wireless internet. As such, many can even be accessed remotely. Going forward, these tamper-proof, wireless connected machines should be the only ones available for purchase in India. This can realize a greater transparency than has previously been possible even with plugged in external hard drives. The revisions to the PCPNDT we propose above would also need to be coupled with clear rules regarding image storage. Every ultrasonography at every facility must have a mechanism whereby all images acquired with its use are stored for a designated period of time and must be available for review by regulators with ease. These images must not be editable or erasable by the person performing the ultrasound and this storage should not further burden the ultrasonographer or Radiologist with additional red tape. While it is not possible to know with certainty from looking at images of an antenatal ultrasound if that ultrasound was being performed for sex selection, there are tell-tale features that are highly suggestive of such behavior. Only certain probes can perform antenatal ultrasounds and, as such, only those images would need reviewing. Regulators could download randomly selected images of interest and monitor from afar. In lower resource settings, regulators could access the tamper-proof central drive where images are stored and review them in a similar manner. Those machines with consistent patterns of worrisome imaging findings (or those centers with consistent inability to play by the rules) could be placed under disciplinary action and, if ongoing worrisome patterns are observed, have their ultrasound privileges revoked. We have no illusions about how difficult curbing sex selection has been and will be. We also recognize these changes do nothing to address unregistered ultrasound machines. The above changes only allow for greater efficiency in monitoring registered ultrasound machines over larger geographic regions which will be necessary to allow for greater access in those same geographic regions.

The crux of improved regulation would lie with the immutability of image deletion or manipulation and a machine that looks no different externally from one without wireless and tamper proof drive monitoring. Policing for illegal use is better than restricting access and trusting that licensed practitioners will adhere to legal practice. Here the success or failure of maintaining the original spirit of the PNDT and PCPNDT would lie while also allowing greater access to ultrasonography.

**Conclusion**

The PCPNDT was written to prevent a number of societally unacceptable harms including the sex selection of unborn fetuses. To date it has yet to meaningfully deliver its stated non-maleficence aims (2) and, in that it has not changed skewed sex ratios, the original justice concerns of activists and legislators remain unaddressed. However, the pragmatism required to enforce this law has had profound effects on the ability of rural Indians to access a beneficial medical technology (POCUS / diagnostic ultrasonography) and may have even inadvertently placed a heavier burden on the poorest and worsened health inequity in India creating serious ethical and justice concerns. It is time to re-examine and update a law such that diagnostic ultrasonography can be widely available in rural India at all levels including in the public sector at PHCs and CHCs.

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