**Three important obligations of private practitioners can help in bringing down the scourge of TB in India**

**Abstract:**

Tuberculosis is a global public health crisis and India alone contributes 25% of the global TB burden. TB continues to be a devastating health crisis in India with more than 3, 00,000 deaths, 2.2 million new cases along with an economic damage of $23bn (£14.9bn;€20.3bn) each year. It has been observed that Indian population have a greater inclination toward private health facilities but surprisingly the TB care at private health facilities remain substandard and fuels the conversion of regular cases to Multi Drug Resistant /Extremely Drug Resistant-TB cases. This necessitates quality TB care (both diagnosis and treatment) at private health facilities which would invariably lead to a TB free society. There are a host of activities that the private practitioners need to be indulged with to provide quality diagnostic and treatment facilities however three important activities are of paramount importance at the present time. These activities include- adherence to STCI (Standards of TB care in India) guidelines, notification of TB cases to appropriate authority and advocate for ban on sero-diagnosis and restrain from carrying out such diagnostic tests which have limited value in clinical diagnosis of TB. This paper discusses these three important issues in relation to private practitioners in an Indian context.

**Key words:** Ban on sero-diagnosis, Standards of TB care in India, TB notification, Private health facilities, Private practitioners

**Introduction:**

Tuberculosis is a global public health crisis and India alone contributes 25% of global TB burden. TB continues to be a devastating health crisis in India with more than 3, 00,000 deaths, 2.2 million new cases along with an economic damage of $23bn (£14.9bn;€20.3bn) each year [1]. Currently, Govt. of India’s flagship TB control program known as Revised National Tuberculosis Control Program (RNTCP) is in operation to control TB at Public sector level. RNTCP has an objective of 85% cure rate among new sputum positive (NSP) cases and 70% case detection rate. RNTCP adopts a treatment strategy to provide treatment to the TB cases which is known as Directly Observed Treatment Short Course (DOTS) strategy. Noteworthy to mention here is that India has achieved this global target of 85% cure rate and 70% case detection rate since 2007 and DOTS has 100% coverage rate under RNTCP [2].

Despite the achievement of India’s flagship TB control program the country still struggles with the devastating crisis of TB and contributes to one fourth of global TB burden. Here the question arises; where does the problem lie? Are we really missing something huge? Yes, there is some problem in our control strategy and we are really missing something huge. The answer definitely lays with the huge private sector health systems which also provide services to TB patients in addition to public sector. The third question arises here; is it so huge that we really need to worry about? Yes the problem is huge and we really need to look in to it. Research in several Indian communities reveal that around 50-80% of Indian population seek medical care for TB at private health facilities leaving a substantially low proportion of population seeking medical care at public health facilities in India, some 20-50% [3]. This is further substantiated by the evidence that of the total market of USD 94 millions the public sector consumes USD 24 millions whereas the private sector consumes the rest USD 61 million [4]. Here further question arises; are the private sector health players relatively good or people are not aware of public health facilities for TB care? A study conducted at the P. D. Hinduja National Hospital and Medical Research Centre, Mumbai, India among TB patients not exposed to TB services offered in public sector revealed that 85% of the patients (n=200) are unaware of DOTS programme [5]. Furthermore, people access private health facilities owing to the confidentiality that the private sector offer to protect against social stigma, lack of trust for public health services, lack of attention offered at public health sector and the unhygienic conditions in public health institutions [4].

Given this situation an urgent attention is required to involve the private sector for the TB care in India. Several factors compel the involvement of private sector however the following three important obligations by the private practitioners require very urgent attention in order to bring down the scourge of TB in Indian communities.

**Adherence to standards of TB care by the private practitioners:**

It is a general consensus in the society that qualified medical practitioners would approach a medical condition as per their learning in medical schools or as per the guidance given in medical textbooks. This implies that a medical prescription for a hypothetical medical condition would be same for all the qualified practitioners and they would invariably be prescribing a common prescription for that hypothetical condition which may obviously vary if the medical practitioners physically examine the patient. However this is not the case in India as India is a land of pluralistic medical system where practitioners from different systems of medicine practice. Many a times cross prescription or cross-pathy is being observed among the practitioners of different systems of medicine which may be ethically wrong. Here cross prescription or cross-pathy refers to a condition where a medical practitioner prescribes medicines other than his own system of medicine. This condition sometimes makes the care and treatment of TB patients worse and leads to many disastrous outcomes such as Multi-Drug Resistant TB (MDR-TB), Extremely Drug Resistant TB (XDR-TB) or even the newly coined term-Totally Drug Resistant TB (TDR-TB).

Research during the last two-three decades shows that such type of prescription behavior of qualified private practitioners continues unabated. Different studies reveal the nature of treatment and prescription practices among a wide range of private practitioners treating TB patients. In a study in 1991 about the prescribing behavior of private practitioners, 100 doctors reported to have provided 80 different prescriptions [6]. A similar study undertaken in Mumbai and rural Pune published in 1998, reported 105 private practitioners giving 79 diverse prescriptions [7] and in a study in 2010 at P. D. Hinduja National Hospital and Medical Research Centre, Mumbai 106 doctors wrote 63 different prescriptions [8]. Poor prescribing practice is a major factor fuelling the MDR-TB epidemic. A report from Mumbai showed that about 10% of all MDR-TB cases were XDR-TB [9].

The way ahead to this problem is to introduce a uniform guideline for the treatment of TB in India among the qualified practitioners. With this backdrop a uniform TB guideline for the care and control of TB patients was developed which is known as Standards of TB care in India (STCI) guidelines. The standards for TB care is required in order to bring uniformity in TB care so that all the TB cases receive the same quality of TB care based on the best possible evidence available. The first such guideline known as the International Standards of TB Care (ISTC) was published in 2006 with two subsequent revisions in 2009 and 2014. Mimicking this some countries developed their own standards such as European Union Standards of TB Care including India. The STCI guideline in India is a result of a long process culminating in a 3 days long consultation workshop in Delhi organized by Central TB Division in December 2012 with the technical assistance from the WHO country Office, India with the presence of more than 120 technical experts in TB and allied areas. The STCI guideline delineates 26 guidelines which comprises of 1-6 guidelines for Diagnosis, 7-11 guidelines for Treatment, 12-21 guidelines for public health and 22-26 guidelines for social inclusion.

Despite the introduction of STCI guideline TB treatment in private sector remains substandard. A recent study in Pune, India reveals that of the 249 private practitioners interviewed 63% (158) of the practitioners’ responses were consistent with the ISTC diagnostic criteria, 34% (84) of practitioners’ responses were consistent with the ISTC treatment criteria. This indicates that the private practitioners needs to be sensitized with the standards of TB care which would help them in providing the quality diagnostics and treatment services universally and help in bringing down the scourge of TB in India.

**TB notification at private health facilities:**

TB is a notifiable disease in India as per the government order dated 7thMay, 2012 and requires that all healthcare providers that have diagnosed a case of TB through microbiological testing or clinically diagnosed and/or treated for TB must report to the District Nodal Officer for Notification. The main objective of making TB as a notifiable disease is to establish a surveillance system, to extend supportive mechanism for TB treatment adherence and standardized practices in the private sector. However the notification from the private sector is a big challenge in India owing to multiple factors [10]. In India TB notification among the private practitioners is a paradox; private practitioners know about TB notification, they know it is mandatory to do however many do not do notification. A recent study in 2015 among the private practitioners in Kerala revealed that 88% (n=169) of the private practitioners were aware of mandatory TB notification. It was further revealed that general practitioners are more aware of TB notification than the specialist practitioners (98% vs 84%). The study unfolded three important barriers to TB notification; (1) provider misconception, (2) lack of cohesion and coordination between public and private sector and (3) patient confidentiality, stigma and discrimination [11]. These barriers can be addressed with efforts through continuous and consistent dialogue with the private practitioners and with linkage between private and public sector.

Recently the new amendment in TB notification came in June 2015 which is more comprehensive and includes public sector involvement in follow up of the cases notified by the private sector. The above study also observed that almost two third of the private practitioners are not in favor of punitive action against failure to notify at private sector [11] however some strict legal enforcement can be mulled over if notification rate is poor. Mimicking the instances of other public health legislations, such as PCPNDT (Pre-Conception and Pre-Natal Diagnostic Test), would be worthwhile for consideration in the case of poor TB notification.

**Support the ban on Sero-diagnosis by the private practitioners:**

Serological tests are the kind of tests that are performed to detect the active TB based on the antibodies elicited by antigens of *Mycobacterium tuberculosis* recognized by the humoral immune response system. Most of these serological tests use ELISA (Enzyme Linked Immuno Sorbent Assay) formats while others use rapid tests such as immune-chromatographic and lateral flow analysis [12]. Thus the faster and rapid delivery of results by these serological tests make them attractive compared to sputum based diagnostic tests [13]. However one of the systematic reviews carried out on the commercial serological tests reveal that the results are inconsistent and of low quality [14]. Despite Govt. of India’s ban on sero-diagnosis these tests are being widely used by the private sector in India [15]. Furthermore none of the international guidelines support the use of serological tests for the diagnosis of active TB [16] but a rampant usage of these tests by the private sector is being observed in developing countries including India and 16 of 21 other high-burden countries in the world [17]. It is estimated that 1.5 million serological tests are being performed alone in India every year by the private sector for the diagnosis of active TB in India. The cost has been estimated at US $15 million (825 million INR) per year [17, 18]. According to the reports of a cost-effectiveness modeling study serological tests, if used in the place of sputum microscopy, would increase the costs of TB control program in India approximately by 4-fold and result in 102,000 fewer disability-adjusted life years (DALY) averted and 121,000 more false-positive diagnoses and 32,000 more secondary infections [19]. In 2011 WHO issued a policy statement mentioning that serological tests provide inconsistent and imprecise estimates of sensitivity and specificity. Further, there is no evidence that these commercial serological tests improve patient outcomes and high proportions of false-positive and false-negative results adversely impact patient safety [20]. As per the findings of different systematic reviews and Meta analysis no serological test can really match with the performance of sputum microscopy thus the usage of these tests at private sector should strongly be discouraged and the private practitioners should personally avert themselves in relying on these tests for the diagnosis of active TB cases. Most importantly these tests do more harm than benefit to the patient community by providing false positive or false negative results. Mimicking the steps taken by Indian Academy of Pediatrics which strongly discourages the usage of serological tests other professional bodies should also come forward to discourage the usage of serological tests for the diagnosis of active TB in India [21].

**Conclusion:**

It is undeniable that private sector in health care and the private practitioners have a major role to play in contributing their services for the control of TB in India as half of the TB patients visit private health facilities for seeking care. Distressingly the diagnostic and treatment services provided in private sector remains substandard. Irrational use of drugs, over reliance on chest X-ray, usage of serological tests, and non adherence to standard treatment protocols are still consistent in India. To overcome such situation Govt. of India has came up with its ambitious “National strategic plan 2012-2017” to include private sector for universal access to quality diagnostic and treatment services however the same will only be possible if the private sector come together and stop doing mal practice in TB diagnosis and treatment. The burden and economic damage due to TB can be averted if the private practitioners simply adhere to the above mentioned three important obligations; adherences to STCI guidelines, notification of TB cases and support and practice the ban on sero-diagnosis.

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