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Globally, the under-five mortality rate has dropped by 41%, from 87 deaths per 1000 live births in 1990 to 51 per 1000 live births in 2011. During this period, in the Member States of South-East Asia Region (SEAR), the under-five mortality rate reduced by about 50%, from 109 to 55 per 1000 live births.\[1\] In comparison to under-five mortality, the neonatal mortality has remained high. In SEAR, the neonatal mortality contributes to 52% under-five mortality, while, globally, it contributes to 40% of under-five mortality.

About one-third of newborn deaths worldwide are caused by pre-maturity; it is the second most common cause of child deaths, after pneumonia. About 1 million children die every year due to complications of pre-maturity. In addition, many survivors suffer a lifetime of disability, including learning disabilities and visual and hearing problems.

The World Health Organization (WHO) defines pre-maturity as birth before 37 weeks of gestation or fewer than 259 days since the first day of last menstrual period. The data and information on pre-term births in the SEAR remains a challenge. First of all, the birth registration rates are low in several countries. Second, assessing the gestational age is also a challenge as many women cannot recall the date of last menstrual period, birth weight is not recorded for all births, measurement of fundal height and neonatal examination for assessing maturity require skilled examiner and sonographic dating is not easily available.

Most pre-term births happen spontaneously and, in many cases, the exact cause of pre-term birth cannot be identified. Common causes include pregnancy among adolescents, pregnancies with narrow spacing, multiple pregnancies, maternal infections, chronic conditions like diabetes mellitus and pregnancy-induced hypertension, and exposure to tobacco, indoor air pollution and some environmental pollutants. Some pre-term births occur because of early induction of labour or caesarean section, owing to medical or non-medical reasons. It must be noted that births at 37-39 weeks still have suboptimal outcomes, and induction or caesarean birth should not be planned before 39 completed weeks, unless medically indicated.

The 'Born Too Soon' report has also highlighted several public health actions that are required to manage pre-term births. These have been considered in three broad areas: Preconception care, care during pregnancy and childbirth, and management of pre-term babies.

**Pre-conception care**

Early marriage of girls and early pregnancy in adolescence is common in Bangladesh, India, Indonesia and Nepal in the SEAR, which contributes to higher pre-term births. To reduce the pre-term birth rates, we need to focus on empowering adolescents to delay marriage and pregnancy, improve nutrition of girls and women and improve access to family planning and good quality of care during pregnancy. To address other causes, good control of gestational diabetes and prevention of use of and exposure to tobacco need to be ensured for all pregnancies.

**Care during pregnancy and childbirth**

Skilled care during pregnancy and childbirth would help in prevention and timely management of pre-term births. Health promotion during pregnancy to tackle maternal risk factors like intake of appropriate nutrition (including micronutrients), avoidance of exposure to smoke (tobacco and indoor air pollution) and alcohol, and gender-based violence would prevent pre-term births as well as intrauterine growth restriction. Use of antenatal steroids, tocolysis and prophylactic antibiotics for premature rupture of membranes in case of pre-term onset of labour improves neonatal outcomes.
Management of pre-term babies
Although neonatal intensive care may be required to save extremely pre-term babies, fortunately, deaths from pre-term birth complications can be reduced by over three quarters even without using high-tech care. About half the babies born at 32 weeks gestation could be saved with feasible, cost-effective, essential newborn care, such as provision of warmth (thermal care), breastfeeding support and basic care for infections and breathing difficulties.

Many of these interventions for prevention and management of pre-term births do not reach the populations that need them the most. Hence, efforts need to focus on high and equitable coverage of evidence-based life-saving interventions with good quality of services. Member states in SEAR are implementing adolescent health programmes, which include several pre-conception care interventions that need to be scaled-up. Fortunately, skilled care during pregnancy and at birth and the institutional deliveries are progressively increasing in these region, which would help improve prevention and management of pre-term labour and care of pre-term births. Countries in these region are strengthening home-based as well as facility-based newborn care to ensure essential care and timely referral of pre-term newborns. Investment in research is needed to understand the most efficient ways to reach people with preventive and curative interventions. Research is also needed to better understand the causes of pre-term births so that effective preventive interventions can be designed.

The recent commitments like the UN strategy for Women’s and Children’s Health and ‘Call for Survival-A Promise Renewed’ provide significant opportunities to expand efforts to address pre-term births towards overall neonatal and child survival.

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Spiritual health, the fourth dimension: a public health perspective

INTRODUCTION

Today the public health professionals are in the midst of the epidemic of non-communicable diseases, which are known to have their risk factors in the way how people live their lives. The major risk factors of lifestyle diseases identified are diet, physical inactivity and use of tobacco, alcohol and stress, among others.

A session of the United Nations (UN) Assembly, held recently, also focused on dealing with non-communicable diseases by combating ‘the globalisation of unhealthy lifestyles’. In fact, the behavioural aspects of an individual considerably influence one’s diet, interest in sedentary or active life and addictions to tobacco, alcohol and other substances. At the same time, an individual’s behaviour is influenced by the society’s value system and attitudes to which people subscribe to as acceptable. Spiritual principles of the world have always emphasized on certain cognitive and behavioural set for the individuals in pursuit of health and fulfilment in life.

Bringing changes in the cognitive, affective and behavioural domain is a long and a persistent process. Each individual responds to such change based on commitment and perception of the need for such change.

Lately, much thought and attention has been given in the academic and intellectual circles about the role of spirituality and health in the community. Formidable pressure is being felt to redefine the meaning and interventions in existing health systems in this regard. Health today cannot be conceived as balanced without including the dimension of spirituality in it. The spirituality and spiritual practices have been shown to have a positive impact on many of these lifestyle diseases. Until now, the scientific community of the world has successfully established the positive role of spiritual practices and spirituality concerning the treatment of cancer, hypertension, depression and smoking.

The relation between body, mind and social dimension is no longer a debatable issue. There is a need, therefore, to summon wisdom, to use the restructured cognitive-behavioural manifesto in health and disease before long. Certainly, a call has come to sweat our brows and marshal our strength to go beyond the existing health triangle of physical, mental and social dimensions in dealing with the health of communities. There is an impending necessity to reframe the statement in the direction of exploring the fourth dimension of health – the Spiritual Well Being of individuals. In a study on spiritual health – ‘defining and measuring the 4th dimension of health’, spiritual health has been defined as a state of being where an individual is able to deal with day-to-day life issues in a manner that leads to the realization of one’s full potential, meaning and purpose of life and fulfilment from within. Such a state of being is attainable through self-evolution, self-actualisation and transcendence. Existing literature reveals that spirituality broadly focuses on being deeply involved in day-to-day activities of the world, at the same time being detached, where there is a continuous effort for developing universality of love, compassion and equanimity to replace anger, jealousy, ego and hatred, resulting in utilization of one’s abilities to the fullest and even transcending beyond that. It unfolds the process of ‘Becoming’ to ‘Being’ and extending ‘Beyond’ to attain fullest positive health.

DISCUSSION

Rahul et al. in their cross-sectional study on ‘Spirituality and health: A knowledge, attitude and practice study among doctors of North India’, found that 65.65% had a strong or very strong belief in the spiritual dimension of health; 55.22% believed in the preventive role of spirituality; 80% believed in the curative role of spirituality and a similar proportion held the view that spirituality has an important role in day-to-day patient care and 92.5% wanted to know more about the scientific work being done in this field. Regarding the role of spiritual dimension of health in preventing and curing of diseases, 55.22% of the doctors opined that a spiritual person falls ill less frequently. A large majority (87.39%) also believed that a spiritual person copes better with illness, and 80% believed that they recover faster. The most significant finding was that 93.48% of the doctors believe that a spiritual person deals better with stress, and 81.74% felt that a spiritual person faces or deals better with death. Some of the physicians do consider these disease causing factors in their medical care practice. Subsequently, they have suggested spiritual health...
Assessment as a first step in including patients’ spirituality in medical care practice. A formal tool called HOPE has been designed for the purpose. In this acronym H stands for sources of hope, comfort, strength, meaning, peace and love connections. The O stands for role of organized spiritual or religious practices for patients. The P stands for personal spirituality and practices and E stands for effects on medical care.\textsuperscript{[4]} Spiritual health and its correlation with various lifestyle diseases strongly suggest designing interventions for corrective actions, which would likely go a long way in reducing the burden of lifestyle diseases.

Acceptable spiritual practices have a positive correlation with survival, reduction of high blood pressure, less remission time from depression, reduced number of cigarettes smoked per day per week and lowered severe medical illness. Instead, better quality of life, cooperativeness and lower inter-leukine-6 levels.\textsuperscript{[5]} King et al.,\textsuperscript{[6]} in a research study, revealed that people who possess good spiritual tendencies tend to cope with the death of a close relative or friend better and fully in comparison to non-believers. Spirituality dilutes the grieving process. Such beliefs, in spite of the fact whether one follows the religious practices or not, do help in recovering from tragedies. This is confirmed by the following quote ‘We are merely saying that spiritual beliefs appear to play a role in how people grieve and therefore should be taken into account in their overall care’. Such empirical evidences propel one to integrate physical, mental, social and spiritual dimensions for better health outcome for the patients. For the success of this unification and endeavour, it seems necessary to take note of some universally proclaimed practices termed as spiritual to create an integral transformation and lasting heightened sense of wellbeing.

Spirituality needs to be demystified by cultivating those desired spiritual practices and temperaments, which drives individuals to ensure optimum health, fulfilment, productivity and creativity.

It is a myth when people tend to associate spirituality with gloom and ‘kill-Joy’ approach. Based on the Sharpio\textsuperscript{[7]} study, spirituality is viewed as being cheerful, being authentically and meaningfully involved in day-to-day activities, appreciating mesmerizing poetry, music and art; natures’ exhilarating charm, which are the qualities beyond mundane. It echoes its voice for being away from comparisons, jealousy, ego, anger deceit and greed. It refers to exploring self in relation to outer world and, contributing to the flowing stream of human culture in whatever small way. For healing the self it is essential that jealousy, envy and hatred in the inner self be done away with. Instead, people need to embrace spiritual values of involvement with detachment, truth, love, forgiving themselves and others. Often the disease causing factors start within the mind, and they quickly manifest in the body, becoming a stiff shoulder, a sluggish liver, cancer or other illnesses. However, connection with one’s deeper self enables individuals to experience meaningful spirituality that in essence contributes to healing in the physical, mental and social dimensions.

One may contest that spiritual health does not cure a disease, but it surely helps taking control of one’s behaviours and lifestyle choices, which may act like an immunization in clinical science. It does help to make people feel better about them, assume the role of a preventive intervention. It acts as an invincible coping mechanism to deal with varied problems, challenges and lead a meaningful, creative and fulfilled life. According to Dossey,\textsuperscript{[8]} if modern medicine is truly to be a a healing art, it must embrace three ideas it has, too long, ignored. It must address not only people’s bodies, but also their minds and spirits as well. It must deal not only with the mechanism of illness, but also with its meaning to people’s daily lives. It must recognize that power to heal others and be healed need to extend beyond the physical dimension.\textsuperscript{[9]} The health professionals, however, must carve out a path for empirical investigations on spiritual health, its measurement and subsequently to be applied in various health and other settings.

CONCLUSIONS

Introspection and reflection are the invincible cognitive and behavioural tools. Today, public health professionals have hardly any choice but to use these, perhaps much more than ever before. The need of the hour is to think divergently, modify the self-talk, restructure the attitudes and be open. Time has come for a need to discern and manage health beyond the health triangle and be inclusive of the 4\textsuperscript{th} dimension of health, that is, the spiritual dimension.

Unrelenting efforts are required to take a journey within and catch the rhythm, melody and sparks of one’s inner self. Health professionals need to think out of the box and take a lead. An invincible pressure is there to adopt a proactive approach towards this 4\textsuperscript{th} dimension of health. Time has come when the health professionals globally need to delve into the matter more profusely and give a profound focus in the direction of introducing spiritual health for overall care. When an individual is tormented with stress, lifestyle syndromes, disorders and diseases; there is a profound need to integrate wholesome preventive, diagnostic and rehabilitative health interventions inclusive of spiritual health. This can be practiced by clinics, hospitals, psychotherapeutic centres, embracing good spiritual practices for better health outcome, higher quality of life and reduction of economic burden on governments.

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Influencing factors for household water quality improvement in reducing diarrhoea in resource-limited areas

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ABSTRACT

Background and Objectives: Water and sanitation are major public health issues exacerbated by rapid population growth, limited resources, disasters and environmental depletion. This study was undertaken to study the influencing factors for household water quality improvement for reducing diarrhoea in resource-limited areas.

Materials and Methods: Data were collected from articles and reviews from relevant randomized controlled trials, new articles, systematic reviews and meta-analyses from PubMed, World Health Organization (WHO), United Nations Children's Fund (UNICEF) and WELL Resource Centre For Water, Sanitation And Environmental Health.

Discussion: Water quality on diarrhoea prevention could be affected by contamination during storage, collection and even at point-of-use. Point-of-use water treatment (household-based) is the most cost-effective method for prevention of diarrhoea. Chemical disinfection, filtration, thermal disinfection, solar disinfection and flocculation and disinfection are five most promising household water treatment methodologies for resource-limited areas.

Conclusion: Promoting household water treatment is most essential for preventing diarrhoeal disease. In addition, the water should be of acceptable taste, appropriate for emergency and non-emergency use.

Key words: Diarrhoea, household water treatment, hygiene and sanitation, water quality

INTRODUCTION

Water and sanitation are the major public health concerns in developing countries. Safe water supplied together with good water management and hygienic sanitation are fundamental to health. Almost 10% of the global disease burden could be prevented by access to safe drinking water, sanitation, hygiene and appropriate water management to reduce risks of waterborne infectious diseases.¹ In addition, safer drinking water could prevent 1.4 million child deaths from diarrhoea and 860 000 child deaths from malnutrition annually.²

Diarrhoea is commonly linked to water and sanitation. About 4 billion cases annually account for 5.7% of the global burden of disease with diarrhoeal disease as the third highest cause of morbidity and sixth highest cause of mortality.³ Generally, safe water is important in preventing diarrhoeal diseases. For promoting safe water supply, the World Health Organization (WHO) sets guidelines for water quality, which express no detectable level of pathogenic organism in the water intended for human consumption.⁴ However, it is not always possible to follow standard guidelines for water quality. Furthermore, waterborne pathogens can also be
transmitted via ingestion of contaminated food and other beverages, by person-to-person contact and by direct or indirect contact with infected faeces.

United Nations Millennium Development Goal (MDG 7) ‘Environmental Sustainability’ includes use of improved drinking water source asking world leaders to support universal access to clean water. In 2010, the United Nations General Assembly declared that safe and clean drinking water and sanitation is a human right that is essential to the full enjoyment of life and all other human rights, voicing deep concern that almost 900 million people worldwide do not have access to clean water.[9] In 2008, 13% of the world’s population (884 million people) still rely on unimproved water sources (surface water from lakes, rivers, dams or unprotected dug wells or springs) for drinking, cooking, bathing and other domestic activities.[6]

MDG aims to halve by 2015 the proportion of people without sustainable access to safe drinking water; one-half of 1.5 billion people without sustainable access to improved water supply by the year 2015.[7] Providing safe piped disinfected water, to each household is the best solution to diarrhoea and waterborne disease. However, this solution would require an investment of tens of billions of dollars each year for infrastructure, which is not available in the developing world. Most of the developing world lacks sufficient conventional water supply infrastructure, and is home to substantial proportions (as high as 50%) of the total urban population and (nearly 90%) of the rural population.[8] Therefore, resource-limited areas especially rural populations need other immediate approaches in improving existing water quality. Interventions to treat and maintain the microbial quality of water at the point-of-use are among the most promising of these alternatives. The cost of treating water at the point-of-use can be dramatically less than the cost of conventional water treatment and distribution systems. It has been reported,[9] that developing countries will need US$42 billion for new coverage in water supply and US$322 billion for maintaining existing water supply services. Furthermore, only 57% of the global populations get their drinking water from a piped connection in the user’s dwelling, plot or yard.[9] Moreover, when demand exceeds supply in a piped water system due to intermittent and unreliable supply services, it results in inconvenience to users and increased risk of compromised water safety. This situation is most acute in Bangladesh, India and Nepal, which each have an average continuity of service of less than 10 hours a day compared with 22 hours in Latin America and in the Caribbean.[10]

There is an immediate need for resource poor communities to innovatively develop cost effective water treatment methodology before universal water supply and safe water pipe is provided.

This study reviewed the impact of different water sanitation programmes in reducing diarrhoea morbidity and mortality. Further analysis was extended to identify household water treatment in preventing diarrhoea and health impact.

**MATERIALS AND METHODS**

Relevant literature was obtained through a rigorous search from databases of the WHO, World Bank, UNICEF, Cochrane Library, PubMed, Medline, EMBASE, Water, Sanitation and Hygiene and WELL Resource Centre. All studies relating to water quality, diarrhoea, household water treatment, and hygiene and sanitation were searched. After reviewing titles, 316 studies between 1980 and 2011 were reviewed for abstract. Finally 31 articles were selected. Studies from developing countries were given priority in this review. All the studies collected were reviewed, collated, categorized and reported for all relevant and important findings.

**RESULTS**

Earlier studies about water and sanitation showed better results for sanitation and hygiene than water quality. Esrey et al.,[11] reported lower percentage of median reduction in diarrhoea morbidity by water quality intervention than sanitation and hygiene. The study reported that percentage of median reduction in diarrhoea morbidity as follows:

(i) Water quality and quantity (two rigorous studies) (17%); (ii) Water quality (four rigorous studies) (15%); (iii) Water quantity (five rigorous studies) (20%); (iv) Water and sanitation (two rigorous studies) (30%); (v) Hygiene (six rigorous studies) (33%) and (vi) Sanitation (five rigorous studies) (36%).

However, better evidence for water quality was found in the World Bank report [Table 1] indicating water supply with house connection has a 63% reduction in diarrhoea and 2.7 relative risk.

In another finding, water collection distance is also important for fullest use of water. In Figure 1, Caincross and Feachem[12] showed that household water consumption declined to less than half of connected households at more than 5 minutes water collection distance.

**DISCUSSION**

In this review, we explored and identified water quality including different water treatment methods affecting diarrhoea morbidity and mortality. Some findings show that household-based approaches to water treatment may
be more efficient and cost-effective means of preventing diarrhoeal disease than conventional treatment at the source.

Household-based chlorination is the most cost-effective method followed by solar disinfection, which is only slightly less cost-effective. Conventional source-based interventions have a mean cost per disability-adjusted life year (DALY) averted of about twice that of chlorination and solar disinfection. In Africa (high adult and high child mortality region), the cost per DALY averted by household chlorination is US$46, by household solar disinfection is US$54, by source-based interventions is US$106, by household ceramic filtration is US$125 and by household flocculation/disinfection is US$415 [Appendix 1]. However, the study reviewed endemic diarrhoea only and also could not include economic value of other benefits (including time savings) or diseases related to unsafe water such as typhoid, hepatitis A and E and polio. Those diseases are transmitted by the ingestion of unsafe water and food but their pathology does not consist of diarrhoea.

In addition, according to the Caincross model, household water consumption declined to less than half of connected households at more than 5 minutes water collection distance, no change between 5 and 30 minutes and reduced again after more than 30-minute distances. Calculating benefit and quality improvement of water; equity in access and social disparity are additional dimensions to be considered. In almost three-quarters of households without access to drinking water on premises, women and girls have the primary responsibility for collecting water; in some countries the proportion is more than 90%. This is a very significant burden for women, especially when the time taken to collect water is considerable.

Furthermore, the relation between water quality and diarrhoea was lower than sanitation and diarrhoea in most scientific publications during the late 20th century. Esrey et al.’s review on previous studies – interventions at the point of distribution, such as protected wells and springs – reported (15-17%) reduction in diarrhoeal disease. In contrast, improving microbial safety of water immediately before consumption (at point-of-use) could reduce 39% diarrhoea risk and water quality interventions, on average, effect a 42% relative reduction in child diarrhoea morbidity. WHO also estimated 45% reduction in diarrhoea morbidity from household water treatment and 65.9% reduction in diarrhoea morbidity (7.6 billion diarrhoea episodes) from universal piped and regulated water supply. Furthermore, it is well known that even uncontaminated source water becomes contaminated before use, that is, post-source contamination. Post-source contamination could be collection, transport, storage and drawing in the home. Moreover, additional studies about benefit of point-of-use treatment are: household-based chlorination is the most cost-effective method to prevent diarrhoea in the absence of universal piped and regulated water supply, and point-of-use treatment comprising disinfection, safe storage and community education reduce 44% diarrhoeal episodes. Moreover, better effectiveness of water supply was reported in the World Bank report; water supply with house connection is almost two times greater than sanitation in diarrhoeal reduction and also better than hygiene and greater cost-effectiveness.

Diarrhoea, acute or persistent, is a broad term and effect of household water treatment should be analysed in comprehensive health impact. Accordingly, health impact of treating water at the point of consumption is not absolute. Except in the case of *Vibrio cholerae*, point-of-use water quality or a reduction in waterborne pathogens is not clearly associated with a reduction in diarrhoea. Many studies could not produce consistent protective effect of water treatment; more than two dozen studies have shown

### Table 1a: Assumed reductions in diarrhoea attributable to water supply, sanitation and hygiene promotion

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Reduction in diarrhoea (%)</th>
<th>Corresponding relative risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water supply</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public source</td>
<td>17</td>
<td>1.20</td>
</tr>
<tr>
<td>Additional for house connection</td>
<td>63</td>
<td>2.70</td>
</tr>
<tr>
<td>Excreta disposal</td>
<td>36</td>
<td>1.56</td>
</tr>
<tr>
<td>Hygiene promotion to change hygiene behaviour</td>
<td>48</td>
<td>1.92</td>
</tr>
</tbody>
</table>

*Source: The World Bank [19]*

### Table 1b: Cost-effectiveness of water supply, sanitation and hygiene promotion (US$/DALY)

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Cost-effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water supply</td>
<td></td>
</tr>
<tr>
<td>Hand pump or stand post</td>
<td>94.00</td>
</tr>
<tr>
<td>House connection</td>
<td>223.00</td>
</tr>
<tr>
<td>Water sector regulation and advocacy</td>
<td>47.00</td>
</tr>
<tr>
<td>Basic sanitation</td>
<td></td>
</tr>
<tr>
<td>Construction and promotion</td>
<td>270.00</td>
</tr>
<tr>
<td>Promotion only</td>
<td>11.15</td>
</tr>
<tr>
<td>Hygiene promotion</td>
<td>3.35</td>
</tr>
</tbody>
</table>

*Source: The World Bank [19], DALY - Disability-adjusted life year*
household water treatment to be protective for diarrhoea but the range of effects is quite broad.\textsuperscript{[31]} Furthermore, one of the only blinded trials by Kirchoff et al.,\textsuperscript{[20]} has not demonstrated any statistically significant reduction in diarrhoea. Those heterogeneous results from various interventions may possibly be related to a wide range of conditions such as diverse risk settings, the different methodological rigour of the studies, negative externalities from unhygienic practices and other socioeconomic factors.

Lastly, microbial contamination of stored water has been influenced by many factors including storage times,\textsuperscript{[21‑23]} inadequate hand washing and higher temperatures.\textsuperscript{[24]} Storage duration of 1-2 days in rural Bangladesh has 10-fold higher cholera rate; however, storage duration of 4 hours in South Africa has no effect for increased diarrhoea and cholera, although it increased the coliform level. Storage containers are also important in improving water quality. Usually, containers with narrow opening or appropriate covers to prevent filling and containers designed for water treatment and directly stored for household use are preventive measures of microbial contamination. In contrast, increase faecal coliform and diarrhoea were found in following studies:

1. Rural Malaysia – higher diarrhoea rate in wide-neck container\textsuperscript{[25]}
2. Kolkata, India – four-fold increased cholera in wide mouth container\textsuperscript{[26]}
3. Trujillo, Peru – higher coliform and increase cholera risk in wide mouth storage container\textsuperscript{[27]}
4. Rural Trinidad – increased faecal coliform in open storage vessels\textsuperscript{[28]}

**Household water treatment for resource‑limited area**

Treating water at the point-of-use, household water treatment is the best option for the resource‑limited area. The WHO is exploring effectiveness in improving and maintaining microbial water quality, health impact, simplicity, accessibility, cost, acceptability, sustainability and potential for dissemination.\textsuperscript{[29]} The studies were further reviewed by Thomas,\textsuperscript{[3]} who reported the five most promising household water treatments.

**Chemical disinfection**

It is most common at the community level and in emergency. Liquid sodium hypochlorite or solid calcium hypochlorite is commonly used and mostly affordable methodology. At doses of a few milligrams/litre and contact time of about 30 minutes, free chlorine inactivates more than four logs of enteric pathogens, the notable exceptions being Cryptosporidium and Mycobacterium species.

**Filtration**

Household filters can operate at any temperature, pH and turbidity and have no effect upon taste and odour. There are three types:

2. Slow-sand filters.

**Thermal and solar disinfection**

Boiling or heat treatment of water is most effective against the full range of microbial pathogens. Similarly, solar disinfection by using thermal and ultra violet (UV) radiation reduce diarrhoeal morbidity of attributable risk fraction by 16% among children.\textsuperscript{[30]} Treatment of water with solar radiation was practiced in ancient India for more than 2000 years ago,\textsuperscript{[29]} which controls waterborne microbial contaminants by exposure to sunlight.

The ‘SODIS’ system, developed and promoted by the Swiss Federal Institute for Environmental Science and Technology treat low turbidity (<30 NTU) water in clear plastic bottles through aerating to increase oxygenation and exposing the bottles to the sun. Exposure times vary from 6 to 48 hours depending on the intensity of sunlight.\textsuperscript{[5]} Thermal and solar disinfection does not provide residual protection against recontamination.

**Combined flocculation and disinfection**

Turbidity, a common problem in household-based water treatment, can reduce by simple sedimentation or flocculation/coagulation using additives such as alum. Assisted sedimentation has been shown to reduce the levels of certain microbial pathogens, especially protozoa, which are resistant to chemical disinfectants. However, disinfection is still required in most cases for complete microbial protection. Field studies have demonstrated that use of home water treatment with flocculant-disinfectant decreased the incidence of diarrhoea.\textsuperscript{[31]}

However, prevalence of such appropriate household water treatment methodologies is not very common in developing countries. Generally, practices like straining water through a cloth or letting it stand and settle are not considered appropriate methods. There is a need for appropriate strategies to scale up to poorer households.

Beyond the importance of methodological complexity, additional factors are needed to achieve full utilization of household water treatments by communities. Accessibility, taste and quality of water are the most important factors. Public–private partnership (PPP) and social marketing will be further options for promoting household water treatment. Supporting private sector and local small and medium enterprise for the promotion of household water treatment could be the sustainable solution for resource‑limited communities.
RECOMMENDATIONS

Currently, five types of household water treatment methods are most effective and applicable to rural and resource-limited settings and areas where water is unable to be universally piped in. Regarding requirements of proper utility and storage methods related with human behaviour, we recommend further research about household water treatment among rural populations. While there is considerable research to support the microbiological effectiveness and promising, although not definitive health impact, there is relatively little evidence about the potential uptake of such interventions. Acceptability, affordability, long-term utilization and sustainability need further exploration, particularly in programmatic settings. Moreover, hardware development will have an exponential impact when there is software for changing people’s behaviour and acceptance. The possible policy option for promoting behaviour and acceptance among communities is social marketing through PPPs. The private sector has advantages in marketing and mobility to reach communities. Quality assurance by various research of the public sector can be assisted by private sector assistance in marketing and promotion of utility.

CONCLUSIONS

Promoting household water treatment is most essential in preventing diarrhoea disease and reducing diarrhoea death among patients. Although there are different methodologies so far, issues such as taste and quality (most acceptable), appropriateness to all situations (both emergency and non-emergency) and costing (affordability) will ultimately help to determine the potential role of household water treatment in preventing diarrhoea.

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How to cite this article: Zin T, Mudin KD, Myint T, Naing DK, Sein T, Shamsul BS. Influencing factors for household water quality improvement in reducing diarrhoea in resource-limited areas. WHO South-East Asia J Public Health 2013;2:6-11.

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### Appendix 1: WHO Cost-effectiveness Study (USD per DALY averted)

<table>
<thead>
<tr>
<th>WHO epidemiological sub-regions by mortality</th>
<th>Source-based interventions (stand post, bore hole, dug well)</th>
<th>Chlorination</th>
<th>Ceramic filtration</th>
<th>Solar disinfection</th>
<th>Flocculation disinfection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Africa (high adult, high child)</td>
<td>106</td>
<td>46</td>
<td>125</td>
<td>54</td>
<td>415</td>
</tr>
<tr>
<td>Africa (very high adult, high child)</td>
<td>123</td>
<td>53</td>
<td>142</td>
<td>61</td>
<td>94</td>
</tr>
<tr>
<td>America (low adult, low child)</td>
<td>1930</td>
<td>744</td>
<td>2005</td>
<td>861</td>
<td>6656</td>
</tr>
<tr>
<td>America (high adult, high child)</td>
<td>469</td>
<td>190</td>
<td>508</td>
<td>218</td>
<td>1687</td>
</tr>
<tr>
<td>Eastern Mediterranean (low adult, low child)</td>
<td>1511</td>
<td>510</td>
<td>1375</td>
<td>590</td>
<td>4565</td>
</tr>
<tr>
<td>Eastern Mediterranean (high adult, high child)</td>
<td>145</td>
<td>78</td>
<td>209</td>
<td>90</td>
<td>695</td>
</tr>
<tr>
<td>European (low adult, low child)</td>
<td>2254</td>
<td>978</td>
<td>2637</td>
<td>1132</td>
<td>8754</td>
</tr>
<tr>
<td>South-East Asia (high adult, high child)</td>
<td>1025</td>
<td>397</td>
<td>1069</td>
<td>459</td>
<td>3550</td>
</tr>
<tr>
<td>South-East Asia (low adult, low child)</td>
<td>143</td>
<td>125</td>
<td>336</td>
<td>144</td>
<td>1116</td>
</tr>
<tr>
<td>Western Pacific (low adult, low child)</td>
<td>1077</td>
<td>521</td>
<td>1405</td>
<td>603</td>
<td>4668</td>
</tr>
</tbody>
</table>

Source: Reference[13]; DALY - Disability-adjusted life year
Stigma related to HIV and AIDS as a barrier to accessing health care in Thailand: a review of recent literature

Sian Churcher

ABSTRACT

Background: Thailand has been recognized as a regional leader in its response to the human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) epidemic. However, low rates of voluntary testing, late entry into healthcare and delayed treatment continue to be major challenges. Stigma associated with HIV has been cited as a significant barrier preventing a successful and co-ordinated response. HIV-related stigma is known to exist among Thai communities. However, less is known about the attitudes of healthcare workers towards people living with HIV, and how this impacts health-seeking behaviours. This paper considers recent literature from Thailand (2007-2012), which discusses how HIV-related stigma affects health-seeking behaviour, as well as experiences of HIV-related stigma in healthcare settings.

Materials and Methods: Information was collected from electronic databases and websites using the search terms ‘HIV stigma healthcare’. Literature published in English, from 2007 onwards, discussing the relationship between HIV-related stigma and health-seeking behaviour, or HIV-related stigma in healthcare settings in Thailand was included in this review.

Results: There is scarcity of information assessing the forms of stigmatizing attitudes known to exist within the Thai healthcare sector. Literature highlights that key affected populations feel most stigmatized against. Interactions and negative experiences in government healthcare settings have contributed to a reduced engagement around seeking healthcare.

Discussion and Conclusions: More research is needed on HIV-related stigma in healthcare settings in Thailand. Evidence suggests that interventions at the policy, environmental and individual levels are required to address stigma and protect the health and rights of people living with HIV/AIDS.

Key words: AIDS, discrimination, HIV, health-seeking behaviour, healthcare settings, stigma, Thailand
The socio-cognitive approach to understanding stigma, recognizes the interaction of an individual's perceptions, within the broader social processes enabling and reinforcing continuums of acceptability for stigmatizing behaviours.[9‑19] A brief outline of key socio-cognitive approaches to understanding stigma is shown in Figure 1. Although this is not exhaustive, it does provide a snapshot of conceptualizations of stigma as described in other works.[9‑19]

At the macro-social level, factors influencing stigma such as cultural and religious values, social class and community understanding of the HIV virus is presented in the outer circle of Figure 1. At the inter-personal and intra-personal level, the inner circle presents manifestations of stigma, conceptually grouped as ‘enacted stigma’, ‘perceived stigma’, ‘internalized stigma’ and ‘vicarious stigma’. [9‑19] Literature describes ‘enacted stigma’ as experienced acts of discrimination, ‘perceived stigma’ as expectations that stigma is in the community or will occur during social interactions and ‘internalized stigma’ as the stigmatizing attitudes and beliefs of an individual.[9‑19] Steward et al., build on these categories, by defining ‘vicarious stigma’ as heard stories or witnessed events that provide evidence of how HIV has been treated.[10] These conceptualizations of stigma are mutually inclusive, with complex interrelationships, and relevance to those with stigmatizing behaviours and also those who feel stigmatized against.[9‑19]

HIV-related stigma, health-seeking behaviour and healthcare settings
Research has found that ramifications of HIV-related stigma on health-seeking behaviour may result in individuals fearing to get tested, and for people living with HIV/AIDS (PLWHA), responses include delaying or adhering to treatment and potentially not adopting preventative behaviours.[8,20,21]

Worldwide, there are a number of studies indicating the existence of HIV-related stigma in healthcare settings.[22‑32] Stigmatizing behaviours belonging to healthcare staff often stem from judgements associating HIV infection with immoral behaviours, fears related to contagion or an insufficient awareness of what stigma looks like and what the consequences of stigma are.[33,34]

To develop a better understanding of how HIV-related stigma manifests in Thai healthcare settings, and the affect of stigma on health-seeking behaviour, this review looked at recent studies from Thailand to identify common themes and priority areas for future research.

Epidemiological overview of HIV/AIDS in Thailand
UNAIDS estimates that there are around 490 000 [450 000-550 000] people living with HIV in Thailand.[35] More than 1 in 100 adults are infected with HIV, and AIDS is a leading cause of death and disability in the country.[36]
Modelling exercises predict that 43,040 new HIV infections will occur during 2012-2016, with around 9473 new infections in 2012 alone.[37] On average, that is approximately one infection every hour. In 2011, there were an estimated 27,650 AIDS-related deaths in Thailand, with similar projections at 26,829 for 2012.[38] Around one in three new HIV infections during 2012 will occur in intimate partnerships, while 6% of new infections will be among casual sex partners.[37,38]

HIV in Thailand is concentrated among sex workers (SWs) and their clients, people who inject drugs (PWID), men who have sex with men (MSM) and migrants.[37,38] During 2012-2016, 62% of new HIV infections are expected to occur among these key affected populations (KAPs), with 11% among SW and their clients; 10% among PWID and 41% among MSM.[37,38]

Testing and anti-retroviral treatment in Thailand
Voluntary HIV counselling and testing (VCT) rates are low. There is a limited availability across the country of quality sexually transmitted infection (STI) clinics and VCT services,[38,39] with most testing services still centralized within hospitals. Data of VCT rates among the general population from 'The National Household Survey' in 2006, found that 19% of people aged 15-49 knew their results from a HIV test in the past 12 months.[38] In 2010, around 51% of SW; 40.8% of PWID and 29.2% of MSM were tested for HIV in the past 12 months and knew the results.[37]

National treatment guidelines recommend the initiation of anti-retroviral therapy (ART) at CD4 levels of ≤350 cells/mm³.[38] However, late entry into care is the norm, with 60% of PLWHA initiating ART with CD4 levels of less than 100 cells/mm³, presenting challenges for immune system recovery and leading to poorer health outcomes.[38,40] In 2010, there was an estimated 430 000 PLWHA requiring treatment.[41] Data from 2011 shows that 225,272 people were reported to be receiving ART, representing 65% of the estimated total number of PLWHA in the country.[38] Provider initiated testing at antenatal clinics saw higher ART coverage among females at 82%, compared with males at 54%.[38] Furthermore, almost one-third of PLWHA in Thailand face the dual burden of HIV and tuberculosis (TB), as seen during 2011 when around 27.7% of PLWHA received treatment for TB.[38]

Policy approaches towards HIV-related stigma
The protection of the rights of PLWHA was a strategic objective of The National AIDS Plan for 2007-2011.[42] This plan supported the Thai Government’s provision to protect the rights, including anti-discriminatory measures, of the population under the Thai Constitution of 2007.[42]

Currently, the National AIDS Management Centre (NAMc) is responsible for ‘increasing awareness of adverse effects of stigma, discrimination and human rights violations on HIV prevention and care among communities and service providers’.37 Acts of discrimination and rights violations regarding PLWHA are dealt with by the NAMc and the Department for the Protection of Rights and Liberties, in conjunction with civil society.[37,42] Future plans of the NAMc, as outlined in the ‘Thailand National AIDS Strategy 2012-2016’, are to conduct a ‘training and sensitization programme’, followed by a survey on HIV-related stigma and discrimination for all HIV programmes and health services.[37] This strategy commits Thailand’s future response to improving the quality of life of PLWHA by identifying barriers to accessing healthcare caused by stigma, discrimination and human rights violations.[37,38]

MATERIALS AND METHODS

This review looked at original research published in English on HIV and AIDS stigma and discrimination with reference to Thailand. During May 2012, electronic databases namely, Medline, PubMed, the Social Sciences Citation Index, Social Sciences Index and Abstracts and the International Bibliography of the Social Sciences were searched. Initial searches were non-country specific, using the search terms 'HIV stigma healthcare', before narrowing down to literature based on Thailand, using the search terms ‘HIV stigma healthcare Thailand’. Only original qualitative research or descriptive analyses were included.

Experts working within Thailand on HIV/AIDS were consulted for recommendations on publicly available studies on HIV-related stigma. Websites belonging to several bilateral agencies and organizations such as World Health Organization (WHO), UNAIDS, Raks Thai Foundation, the Global Network of People Living with HIV (GNP+ and APN+) and the Global Fund to fight AIDS, TB and malaria (Global Fund) were also searched.

The criteria for inclusion in the review were articles containing information regarding HIV-related stigma affecting health-seeking behaviour, or HIV-related stigma in healthcare settings; published in 2007 or afterwards. This timeframe for inclusion was to take into account the national policy changes made in 2007, in relation to the Thai Constitution (2007), to include rights protection and anti-discrimination measures.

As this is a review, no ethical approval was sought. However, all personal communication was kept confidential.

RESULTS

Initially, 34 articles on HIV and AIDS stigma and discrimination with relevance to Thailand were identified. Studies prior to 2007, or those not containing a reference to HIV-related stigma affecting health-seeking behaviour or
stigma in healthcare settings were discarded. This resulted in a total of 15 articles to be reviewed [Figure 2]. In seven of the studies, HIV-related stigma was not a primary focus, however, was reported in healthcare settings or found to affect health-seeking behaviours. Two studies were publicly available from agencies working within Thailand, and 13 were published on the aforementioned electronic databases. Literature included in the review was based on case studies, surveys and descriptive analyses produced or translated to English.

Only one core study, examined the attitudes of Thai healthcare professionals. This study, by Chan et al., was a qualitative investigation using a sample of 20 nurses with results published in three different journals.[43-45] Other recent studies or reviews with a focus on examining attitudes of Thai healthcare staff could not be found, indicating a paucity of available information in this area.

The majority of studies were from the perspectives of PLWHA, with others based on, or including perspectives from the community or the perspectives of healthcare workers. All of these viewpoints touched on interpersonal and intrapersonal forms of HIV-related stigma – internalized; perceived; enacted and vicarious stigma. Stigmatizing attitudes towards PLWHA were commonly based on perceptions of immoral behaviours, or a lack of knowledge regarding disease transmission and progression. Across all of the studies, structural barriers in Thailand were discussed as having an effect on health-seeking behaviours or reinforcing HIV-related stigma. Therefore, a fair review needs to acknowledge the intersection of systemic or structural limitations in fostering or causing forms of HIV-related stigma and discrimination.

Applying the aforementioned socio-cognitive approach to understanding stigma, and how HIV-related stigma affects health behaviours, or manifests in healthcare settings, illustrating examples have been extrapolated from each study and organized under thematic headings in Tables 1-4. For example, internalized, perceived, enacted and vicarious forms of stigma arose across the studies as having an effect on health-seeking behaviour. So, using these conceptualizations, an illustrating example from each study has been linked to these theories. In the same way, negative attitudes towards KAP and a lack of knowledge or fear of transmission were common themes within the studies regarding HIV-related stigma in healthcare settings. Thus, an illustrating example from each study has been given as it corresponds to each theme. The intrinsic complexity and crossover of these ideas is also shown in Tables 1-4, with some examples applicable to several stigma concepts. The tables have been divided by the populations that were studied: PLWHA; sub-populations of PLWHA; Thai communities and healthcare workers. Organizing the tables in this way provides an overview of how HIV-related stigma manifests at the individual, community and healthcare levels. As previously mentioned, structural or policy issues have also been added to recognize the confluence of wider systemic factors.

Figure 2: Identification of articles for review

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![Figure 2: Identification of articles for review](image-url)
Fear of stigma, experiences of stigma in healthcare settings and acts of discrimination were recurring issues affecting the health-seeking behaviours of PLWHA, especially for those who also use drugs. For mobile populations, structural barriers relating to health insurance restrictions further compounded the effect of stigma on health-seeking behaviours. Ethnicity or nationality, co-infection with TB, sexual orientation, drug use and mental health issues were additional ‘layers’ of stigma on top of being HIV positive. \cite{15,60}

### Key crosscutting findings

#### Stigma exists in Thai healthcare settings

The study of 20 students, graduates and professional Thai Nurses found stigmatizing beliefs affected perceptions and hypothetical treatment scenarios for PLWHA.\cite{59} Chan et al. reported that participants considered PLWHA with co-characteristics of drug use and/or links to sex work, as less deserving of their sympathy and (professional/private)
### Table 3: Studies based on or including the perspectives of the community

<table>
<thead>
<tr>
<th>Study participants</th>
<th>Health-seeking behaviour</th>
<th>Healthcare settings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Illustrating examples</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Saether et al.</strong>[56]</td>
<td>74 HIV+ migrants, 13 NGO/health workers/PLWHA</td>
<td>Migrants feared workplace discrimination or arrest by police</td>
</tr>
<tr>
<td><strong>Ford et al.</strong>[56]</td>
<td>15 seafarers, 6 SW, 8 community members</td>
<td>Seafarers felt vulnerable to HIV infection</td>
</tr>
<tr>
<td><strong>Maman et al.</strong>[57]</td>
<td>Global study including 117 Thai people</td>
<td>Interviews revealed stigmatizing attitudes towards PLWHA with less tolerance for PWID</td>
</tr>
<tr>
<td><strong>Ti et al.</strong>[58]</td>
<td>244 Thai PWID in Bangkok</td>
<td>Some PWID were unaware of HIV risks and were therefore unlikely to adopt preventative behaviours</td>
</tr>
<tr>
<td><strong>UNESCO</strong>[59]</td>
<td>100 males: 61 gay, 31 TG, 4 bisexual</td>
<td>35 participants reported going for HIV testing, often due to perceived risk</td>
</tr>
</tbody>
</table>

PLWHA - People living with HIV/AIDS; ART - Anti-retroviral therapy; TG - Transgender; PWID - People who inject drugs

### Table 4: Studies based on the perspectives of the health care workers

<table>
<thead>
<tr>
<th>Study participants</th>
<th>Health-seeking behaviour</th>
<th>Health care settings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Illustrating examples</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Chan et al.</strong>[59]</td>
<td>20 student nurses from a Bangkok nursing college</td>
<td>Nurses believed they did not hold stigmatizing attitudes</td>
</tr>
</tbody>
</table>

*PLWHA - People living with HIV/AIDS; KAP - Key affected populations; PWID - People who inject drugs

Support. These co-characteristics or co-stigmas indicated a form of social or moral ordering. This ordering was expressed when discussing the utilization of commercial sex services, which was seen as ‘wrong’ but a ‘private matter within the realm of normal male behaviour’ and ‘generally better than drug use’. Attitudes towards HIV infection were associated with ‘immoral’ behaviours, with PWID seen as the lowest ‘immoral’ group. The physical scarring of opportunistic diseases such as Kaposi’s Sarcoma, was also viewed as being more ‘offensive’ and a reason for fear and avoidance of patients with AIDS. A key finding in the study of Thai nurses, was that most participants did not view themselves as having stigmatizing beliefs, despite expressing negative towards PLWHA. This finding suggests that some participants in the study had an insufficient awareness of what stigma looks like. While these findings are limited to a small sample of healthcare workers, they provide some correlation to findings from studies based on the experiences of PLWHA. For instance, The Index of Stigma and Discrimination by TNP+, reported cases of discrimination where PLWHA were refused health, dental or family planning services.

### Fear of stigma and criminalization affects the health behaviours of PWID

Fear of disclosure, mistrust in healthcare staff and concerns regarding patient confidentiality were frequently cited concerns of PWID. These issues resulted in cases of HIV-positive PWID fearing to seek healthcare or delaying treatment. The influence of perceived stigma on preventative behaviours was raised in the TNP + stigma index, which reported around 10% of HIV-positive PWID not disclosing their serostatus to friends sharing the same needle. A fear of disclosure to public health facilities, based on fear of criminalization or discrimination, also affected the ability of PWID to seek healthcare in several studies. Chan et al. suggest that the recent ‘zero tolerance’ and ‘war on drugs’ message run by the Thai
Stigma and mental health affects the health-seeking behaviours of PLWHA

The interaction between perceived and internalized forms of stigma, with the issue of mental health, was raised across several studies. Mental health issues, such as depression in PLWHA, had a flow on effect, resulting in issues such as changes in social support, social isolation, health-seeking behaviour and ART adherence. Li et al. call attention to the view that mental illness in Thailand is an issue, which is already stigmatized, resulting in PLWHA having to cope with a ‘double stigma’. 

DISCUSSION

Across the spectrum of interventions to manage HIV in Thailand, there are indications that HIV-related stigma is affecting the health-seeking behaviours of PLWHA. With HIV prevalence highest among MSM in Thailand, actions to scale-up coverage of STI and HIV prevention services for this group, are being thwarted by stigmatizing experiences at healthcare centres. Even among populations where Thailand has made significant progress, experiences with stigma in healthcare settings threatens to affect these results. This has been seen with interventions to prevent mother-to-child transmission of HIV. Vertical transmission rates of HIV from mother-to-child in Thailand have been reduced to approximately 3.59%. Yet, there have been recent cases of HIV-positive mothers not returning to antenatal clinics for care in subsequent pregnancies, or occasionally adopting mixed feeding practices, despite access to free formula milk. Across the country, recent figures suggest an 81% retention rate of HIV-positive patients known to be on ART 12 months after initiation; however, many are starting treatment too late. With a government supported healthcare scheme that is ART inclusive, the underlying question is – why are PLWHA, who know their serostatus, disconnecting from the healthcare system? There is no silver bullet answer to this question, as a number of possible factors underwrite this problem. Nevertheless, as studies have demonstrated in this review, HIV-related stigma and early impressions of health services has affected the health-seeking behaviours of PLWHA. A strategic approach to ameliorate the causes of HIV-related stigma in healthcare settings, would direct attention across three priority areas, with interventions focusing on policy reform, the healthcare environment and the individual.

Current policies that enable stigma and discrimination towards drug users and SWs in Thailand should undergo reform for current and future HIV interventions to be successful. A notable policy in this context has been the Thai Government’s recent ‘Harm Reduction Policy’, which has been part of the national ‘war on drugs’ discourse. Provisions in this policy included service categories for risk minimization, HIV, STI, TB diagnosis and treatment,
mental health support and drug rehabilitation. During 2012, the United Nations called for a closure of compulsory drug detention and rehabilitation centres enabled by this policy, based on issues such as human rights abuses, denial of healthcare and a vulnerability to HIV and TB infection. There is evidence to indicate that policies based on law-enforcement, and criminalization of drug use, prevent PWID from seeking care and getting tested, often due to fear of, or negative experiences within healthcare settings. The existence of such policies targeting drug users and also SWs, normalize the stigmatizing attitudes belonging to healthcare staff and the public generally. They also perpetuate a cycle of negatively stereotyping PLWHA, encumbering an effective response to the HIV/AIDS epidemic.

The Universal Coverage Scheme (UC) is another example of a policy shaping the way PLWHA are received by healthcare staff. While this antiretroviral (ARV) inclusive healthcare system has changed the country’s treatment landscape, current regulations for utilizing services covered by the scheme require patients to access health services at the local health facility where they registered. For mobile populations such as SWs and migrants, obtaining a referral can be difficult, especially under the Compulsory Migrant Health Insurance (CMHI) or the Social Security System (SSS). These regulatory barriers make it problematic for mobile populations to access treatment and care at their current location, if it is not where they initially registered. This inadvertently creates stigmatizing conditions, where PLWHA are refused treatment when they seek care for the management of their HIV infection.

Additionally, at the programme level, ART prescribing guidelines that are dependent on healthcare accessibility, and provider decisions regarding adherence, are affecting HIV-positive mobile populations. There is an absence of information regarding whether ART prescribing guidelines, and provider decision-making in Thailand is also impacting other KAPs. A recent study from North America found a significant proportion of providers were reluctant, or would not prescribe ART for PWID, based on opinions of drug use rather than CD4 counts. This often implicit, overriding process of provider-based decisions in the provision of ART could be an ethical consideration in Thailand. Particularly regarding mobile populations, where current policy decisions regarding rationing of ART are questionable, and reminiscent of the early days of rapid ART scale up witnessed with the WHO ‘3 by 5’ Initiative (2003). The interplay between economic rationale and internalized forms of stigma belonging to healthcare providers in Thailand, requires further investigation to establish whether or not provider-based decisions have had an impact on ART provision for SWs, MSM, PWID and migrants.

At the healthcare level in Thailand, current provisions for health service delivery also present a number of challenges. Issues include, prolonged gaps in CD4 testing from an initial HIV test, and healthcare providers who are not adequately trained to identify the clinical symptoms of HIV. Adding to these systemic issues are experiences with stigma and discrimination in the public system, resulting in multiple cases of PLWHA seeking healthcare in the private sector. Jittimanee et al. note that cases diagnosed by private health providers are often not reported, highlighting the need to improve linkages between the government and private healthcare sector. Fears relating to patient confidentiality are other reasons PLWHA, especially PWID, seek care in the private sector, and although the privacy of patient records is protected under Thailand’s National Health Act (2007), informing the community on patient privacy rights could go a long way in reducing some of the mistrust in the public health system. Adressing some of these systemic issues and policy implications, would create a more enabling environment at the healthcare level for focussed HIV-related stigma interventions.

Involving PLWHA in the planning, implementing and evaluating of programmes targeting HIV-related stigma in healthcare settings, is one way to improve service delivery. In their review of HIV-related stigma in healthcare settings, Nyblade et al. point out that it is important for healthcare workers to dissociate PLWHA from behaviours that are considered improper or immoral. They suggest that the involvement of PLWHA in training programmes provides a ‘human face’ and the opportunity to develop a better understanding of HIV as a disease that people live with. Involving PLWHA in care and stigma programmes has been attempted in Thailand, through previous initiatives such as the ‘Comprehensive and Continuous Care (CCC) Centres’, initially run under the supervision of Médecins Sans Frontières in 2001. Under this model, training was provided to PLWHA to work within the government hospital system to be co-providers of care. Yet despite the merits this model set out to achieve, over dependence on volunteerism and the stress of logistic demands in service provision, were expressed as key issues by participating PLWHA in the CCC centres. Future initiatives seeking to involve PLWHA need to consider the mutual benefit to those individuals, beyond the guise of inclusivity to reduce service delivery costs.

Providing a healthcare environment, which is accommodating and supportive of PLWHA, can provide a necessary form of respite from the wider community challenges of stigma and discrimination. A supportive health care setting can also assist PLWHA with coping strategies to manage their physical and mental health. Ensuring this environment exists, starts within training colleges and universities for health practitioners. Curricula
should cover an in-depth understanding of what stigma is, and what the consequences of stigma are. Studies from India\textsuperscript{[20]} and China\textsuperscript{[32]} have examined attitudes of healthcare workers across the sector, ranging from doctors through to laboratory technicians and cleaners. These studies have emphasized the importance of understanding social norms and personal attitudes to better understand the rationale behind stigmatizing behaviours. The concentration of the epidemic among KAP in Thailand, and indications from studies that PWID and mobile populations are among the most stigmatized, should inform the design of future interventions. Health-based training or workplace programmes need to provide health workers with fundamental information about stigma, discrimination and rights of PLWHA, along with basic information about how HIV is transmitted, appropriate precautions and the occupational risk of HIV infection as compared with other common highly transmissible diseases.\textsuperscript{[33]}

Interventions targeting HIV-related stigma within healthcare settings should also be reinforced by approaches at the community level. Communication messages to the public should be clear and unambiguous,\textsuperscript{[4]} targeting basic health literacy on HIV, dismissing HIV myths and emphasizing that HIV can be treated. An undercurrent in the literature in this review was the low level of HIV knowledge, regarding modes of transmission and disease progression, both among PLWHA and within the community.\textsuperscript{[38,46,52,55-57,59]} Fear of contracting HIV is a common reason driving the stigmatizing and discriminating behaviours of individuals, which can be abrogated through understanding the modes of transmission. Early prevention campaigns on HIV and AIDS in Thailand, along with localized community structures such as AIDS committees, have diminished as funding has focused towards increasing ARV provision.\textsuperscript{[60]} Complacency in improving community knowledge on HIV through education campaigns, not only stifles progress in reducing stigma, but could also result in younger generations lacking awareness on prevention strategies and the importance of HIV testing.

While this review has attempted to capture the key issues relating to HIV-related stigma in Thai healthcare settings, there have been several limitations. The most noteworthy was the availability of information regarding evaluations of stigma prevention approaches, and assessments of stigma in Thai health facilities. Secondly, several Thai studies within this review were limited in scope in terms of sampling and number of participants, particularly the study on Thai nurses and graduates. In addition, studies with a focus on measuring levels of HIV-related stigma employed varying methods of qualitative analysis and differing ‘stigma scales’. A ‘gold standard’ in stigma measurement, which is culturally and contextually appropriate, is needed if programmes are serious about evaluating their effectiveness in approaches to HIV-related stigma reduction. Efforts by international agencies such as USAID, to measure stigma in health facilities through their ‘Health Facility and Provider Stigma Measurement Tool’,\textsuperscript{[70]} is an example of a possible reference for future stigma assessment work in Thailand. Experiences from the TNP + report, should also inform future work, as well as prevent inconsistencies. A lack of timelines for experiences and participants’ understanding of survey questions was an issue in the TNP + index. For example, 24 of 233 participants wanted a cure for HIV, with the majority being concerned about issues associated with drug regimens and body image.\textsuperscript{[56]} Obscurity in questions or terminology producing such responses underlines the importance of participant understanding during research. Nevertheless, this review has highlighted that HIV-related stigma, especially within healthcare settings, has affected the health-seeking behaviours of PLWHA in Thailand.

If the programme targets in the ‘Thailand National AIDS Strategy 2012-2016’ are to be achieved, addressing the stigma directed at PLWHA should be a priority. Thailand has made substantial progress in the past, demonstrated by the in-country production of anti-retroviral generic medicines, and steps towards providing these through state healthcare, despite regional and country challenges. A strategic and committed approach is now needed, to address the pervasive and repudiating issue of HIV-related stigma, especially when perpetrated by healthcare staff.

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Changing epidemiology of dengue in South-East Asia

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ABSTRACT

The burden of dengue and its potential threat to global health are now globally recognized, with 2.5 billion people at risk worldwide. The pathogenesis of severe dengue is particularly intriguing with the involvement of different immune factors. Also, the epidemiology of dengue in South-East Asia is undergoing a change in the human host, the dengue virus and the vector bionomics. Shift in affected age groups, sex differences and expansion to rural areas are evident, while the virulence and genotype of the virus determine the severity and time interval between sequential infections. The *Aedes* mosquito, a potent and adaptive vector, has evolved in longevity and survival, affected by seasonality and climate variability, socio-cultural and economic factors of human habitation and development. This review provides insights into the changing epidemiology and its factors in South-East Asia, one of the most important epicentres of dengue in the world, highlighting the major factors influencing these rapid changes. Addressing the changes may help mitigate the challenges in the current dengue control and prevention efforts.

**Key words:** Dengue, epidemiology, human host, South-East Asia, vector, virus

INTRODUCTION

Dengue fever (DF) and its severe form, the dengue haemorrhagic fever (DHF), is a re-emerging arboviral disease of great public health importance, and it has spread to all tropical and sub-tropical countries in the world. Currently, an estimated 2.5 billion people in more than 100 countries are at risk. Globally, every year, an estimated 50 million dengue infections occur; half a million DHF cases require hospitalization with over 20 000 deaths.[¹] Most countries in South-East Asia bear a high burden of DF/DHF and experience frequent and cyclical epidemics.[²]

Dengue is caused by viruses belonging to genus *Flavivirus* (family *Flaviviridae*) with four known serotypes: DENV-1 through DENV-4. Infection with one serotype confers life-long immunity to that serotype and a few months cross-immunity to other serotypes. Sequential infection of two serotypes leads to more severe type of disease (e.g. DHF). All serotypes/genotypes are now circulating globally and maintaining hyperendemicity.[³,⁴]

*Aedes aegypti* is the primary vector and establishes its habitat between latitude 35°N and 35°S. This mosquito lives in proximity to human habitations in urban areas and breeds mostly in man-made containers. This vector is a day-time feeder, and its peak biting periods are early in the morning and before dusk. Female *Ae. aegypti* bites multiple people during each feeding period. *Ae albopictus* is considered a secondary vector, with characteristics of being highly adaptive, as it can survive in cooler climates and spread. Both species are sensitive to environmental conditions such as temperature, precipitation and humidity.

There is no specific treatment for DF, while several candidate vaccines are currently undergoing trials with varying progress.[⁵,⁶]

**Pathogenesis**

DHF occurs in a small proportion of dengue patients, mostly in those with secondary infection and is characterized by an increased vascular permeability that results in plasma
leakage, contracted intravascular volume and shock in severe cases. The leakage is unique as it is selective in pleural and peritoneal cavities with 24-48 h. Rapid recovery of shock without sequel and the absence of inflammation in the pleura and peritoneum indicate functional changes in the vascular integrity rather than in the structural damage of the endothelium as the underlying mechanism.

The pathogenesis of DHF and dengue shock syndrome (DSS) involves both the innate immunity (complement system and non-killer cells) and the adaptive immunity (humoural and cell-mediated immunity). Enhancement of immune activation, particularly during a secondary infection, leads to an exaggerated cytokine response, which results in changes in vascular permeability, generally referred to as antibody-dependent enhancement. Viral products such as NS1 may also play a role in regulating complement activation and vascular permeability.

Various cytokines with permeability enhancing effect have been implicated in the pathogenesis of DHF, albeit their relative importance is unknown. Studies have shown that the pattern of cytokine response may be related to the pattern of cross-recognition of dengue-specific T-cells. Cross-reactive T-cells appear to be functionally deficit in their cytolytic activity, but expresses enhanced cytokine production, including tumour necrosis factor (TNF-α), interferon (IFN)-γ and chemokines. TNF-α has also been implicated in some severe manifestations, including haemorrhage in some animal models. Increase in vascular permeability can also be mediated by the activation of the complement system, as elevated levels of complement fragments have been documented and some complement fragments such as C3a and C5a are known to have permeability enhancing effects.

Higher levels of viral load in DHF patients in comparison with DF patients have been demonstrated in many studies. The levels of NS1 viral protein were also higher. The degrees of viral load correlate with the measurements of disease severity such as the amount of pleural effusions and thrombocytopenia, suggesting that viral burden may be a key determinant of disease severity.

Dengue fever and dengue haemorrhagic fever epidemiological changes

The epidemiology of DF/DHF is complex and remains poorly understood. It involves host, viral and vector status that are further influenced by demographic, economic, behavioural and varied societal factors. Many field observations have raised questions against widely accepted epidemiological characteristics of dengue. It is thus imperative to properly understand the evolving pattern and trend of DF/DHF epidemiology, as it is crucial in determining the success of prevention and control programmes.

Changes in human host

Shift in affected-age group

In South-East Asian countries, where all the serotypes (DENV-1-4) are circulating, DF is typically acknowledged to be a disease of early childhood, while clinical DF in adults is rare. DHF/DSS in these areas occurs mostly in children aged 2-15 years. Older and many of the younger inhabitants are usually immune and escape DHF, as they have acquired immunity against primary infection.

However, there is an evidence of increase of dengue incidence in older age groups, and this age shift has been reported in Singapore, Indonesia, Bangladesh and Thailand. In Thailand, cases of DHF/DSS in small infants as young as 1-2 months and in adults have been reported with increasing frequency. In Nepal, during the first-ever outbreak in 2010 (virgin soil), majority of the cases occurred between the age of 16 and 45 years, and, in first DHF outbreak in Bangladesh, the age group of 18-33 years were the most affected. Sri Lanka with chronological overview shows that modal age group affected by dengue has shifted from <15 years of age to 15-34 years of age (MoH, Sri Lanka). In India, a legendary film maker died of DHF with multi-organ failure at the age of 80 years (Media Reports 21 October 2012) and older age group was significantly affected in the last major outbreaks in Delhi, India.

In Cuba, during an outbreak in 1981, DF and DHF caused by DENV-1 occurred both in children and adults. However, during the 1997 outbreak caused by DENV-2 (secondary infection) after 20 years, all cases of DHF were adults. It has been hypothesized that the time interval between two sequential infections could be the reason to explain this phenomenon.

Sex differences

There are many studies from South-East Asia region that suggest higher ratio of males than females in DF/DHF hospitalized cases (India, Bangladesh, Singapore and Malaysia), and only few studies suggest no difference in sexes. However, almost all of these studies were hospital-based, thus, probably only represent those who access healthcare rather than the infected population.
Gender bias is still abundant in many countries and health seeking behaviour is linked to this issue.

What could be interesting is the finding from studies that indicate the differences between sexes in term of severity of illness and case fatality ratio. Studies in Malaysia by Kabra et al.,[19] and in India by Shekhar et al.,[20] reported a higher rate of mortalities among females than males, suggesting different pathogenesis processes or immune response. Further research into determining the sex differences both in infection and severity of the disease is needed to capture both biological and societal factors that drive disease pattern in a community.

Rural expansion
According to study modelling the spatial-temporal wave of DHF occurrence in Thailand, it moves radially from Bangkok as an epicenter with the speed of 148 km a month.[21] In some countries, incidence of dengue is higher in rural than in urban areas.[14]

Changes in the dengue virus
Virulence affecting severity of the disease
Sequential infections or secondary infections are important to determine the severity of the disease. Studies in Thailand have revealed the following quantum of DHF risk with different sequences of dengue viruses with DENV-1/DENV-2: 500-fold, DENV-3/DENV-2: 150-fold and DENV-4/DENV-2 equals to 50-fold risk.[22] The infection enhancement contributes to the pattern of variable-sized outbreaks observed. Virulence of the circulating virus is hypothesized to play a role in disease severity, and small genotypic changes in dengue viruses could lead to DHF emergence, as reported from a Sri Lankan study.[23]

Genotype affecting time interval between sequential infections
There seems to be no time limit to sensitization after a primary infection. During 1997 in Cuba, DHF occurred after the introduction of Asian genotype DENV-2, 16-20 years after primary infection of DENV-1.[24,25] Singapore experienced the same situation: Years of successful vector control resulted in higher proportion of non-immune children and part-immune adults, in which infections lead to more severe cases of dengue. This long-interval secondary infection resulted in decreased neutralizing antibody from the primary infection, thus accounting for DHF/DSS in adults.[26] In South-East Asia, the higher age at DENV infection is linked to higher risk of clinical attack.[27] The interval between infections is linked to the fact that age plays a role as an important modulator of clinical dengue.

Changes in the vector bionomics
Rural spread
DF/DHF has been believed to be a primarily urban disease as the vectors are well-adapted to human habitation. The urbanization of South-East Asia that started after World War II for economic purpose has led to population growth that contributes to the increase of susceptible hosts. However, dengue has spread into rural areas from where it had not been reported before.

During the first half of the 21st century, piped water supply was restricted to urban towns, and now that supply system has been introduced into rural areas, water storage practices have changed. Modern transport system (cars and bikes) has also connected the rural areas better, and, finally, solid waste disposal also became a consequence from all this development. These are most cited reasons for rural dengue spread.[2,3] This expanding geographical distribution will pose new challenges in developing the most appropriate strategy for prevention and control.

Seasonality and climate variability
Dengue incidence, particularly dengue epidemics, has been currently associated with rainy season and the El-Nino phenomenon. Despite the number of studies, convincing data or models supporting this hypothesis is limited in small countries.[20] A study in Thailand found that climatic factors play a role in transmission cycle of DHF, but relative importance of these factors varied with geographical areas.[28]

Ecological studies related to Ae. aegypti have shown that Ae. aegypti is a hygrophilic (humidity-loving) species and is governed by microclimatic conditions to which it has adapted. It is independent of macro-level climatic conditions. However, it avails all available opportunities in the peri-domestic domain during this rainy season when temperature falls down and humidity increases. Further evidence and studies are needed to investigate vector behaviour.

Socio-cultural and socio-economic factors affecting vector longevity and survival
Socio-economic and cultural factors play a significant role in the variable incidence of dengue infection, albeit DF/DHF affects different level of income countries. Evidence indicates that this is more linked to behavioural practice and individual susceptibility. In dry and hot climatic region of India, desert cooler is a major source of Aedes mosquito species breeding, particularly, in lower socio-economic group (rich people use air conditioners). Sometimes, water storage is done in baked-soil containers that cannot be completely emptied, and, thus, Aedes breeding continues throughout the year.

Demographic transition, which eventually influences socio-economic development, including increase in population age also could predict the force of dengue infection.[29]
**Changing pattern of dengue transmission**

In Singapore, successful vector control programmes have brought down dengue incidence between 1974 and 1985, when the house index came below 2%. However, there was a major resurgence of dengue with more adult cases being reported. Serological studies indicated changes in the transmission sites and that the transmission was occurring in ‘work sites’ rather than in residential houses. [30]

**CONCLUSION**

Effective dengue prevention and control is a difficult effort today than ever before. However, first step would be recognizing it as a priority and understanding its characteristics. [31] The factors that may have contributed to rapid changing epidemiology of DF/DHF in South-East Asia region are the challenges that need to be addressed in designing operational research and implementation strategies. Operational research is needed to answer research questions on how the efficacy, cost-effectiveness, sustainability and scaling-up of existing and promising new control methods can be enhanced. Complementary to basic research, operational and implementation research are important in achieving progress. Dengue is a rising threat globally and requires actions of prevention and control in an urgent manner.

The major factors influencing changes in dengue epidemiology include: i) viral genotypes/subtypes with increased virulence; ii) lack of information on human population genetics and its relation with viral genome; iii) lack of information on vector ecology in micro-climatic conditions; iv) viral load injected by infected mosquito; v) post-infection natural immunity of the host and vi) time interval in sequential infection.

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Promoting tobacco cessation by integrating ‘brief advice’ in tuberculosis control programme

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ABSTRACT

Background: There is an enormous health burden caused by the co-prevalence of tuberculosis (TB) and tobacco use in India. This intervention study was undertaken in district Vadodara, Gujarat, India to promote tobacco cessation by integrating ‘brief advice’ for tobacco cessation in TB patients who were tobacco users and registered for treatment under TB control programme, based on the tested strategies advocated by World Health Organization (WHO) and the International Union against Tuberculosis and Lung Diseases (The Union).

Materials and Methods: Brief advice for tobacco cessation based on five A’s, advocated by the WHO and the UNION was incorporated into the on-going TB Control programme in India in the year 2010. The tools were developed for education, training and capturing data. All the registered TB patients receiving directly observed treatment short-course (DOTS) who used tobacco in any form were offered brief advice during routine interaction for treatment.

Results: A total of 46.3% of TB patients, predominantly males (89.6% males and 10.3% females) were current users of tobacco; 39.1% used smokeless tobacco, 35.9% were smokers and 25% were dual users, that is, smoked as well as used smokeless tobacco. At the end of treatment, of the 67.3% patients who were offered brief advice, quit tobacco use, 18.2% re-lapsed while 14.5% were lost to follow-up.

Conclusion: A significant numbers of TB patients use tobacco with adverse impact on TB control programmes. Our study shows that it is feasible to introduce ‘brief advice’ strategy as a cost effective intervention for tobacco cessation among TB patients with careful monitoring.

Key words: Brief advice, cessation, India, tuberculosis, tobacco

INTRODUCTION

Tuberculosis (TB) and tobacco smoking are currently two formidable public health concerns and independently pose a considerable threat to global health.1–3 The current estimates put the annual global mortality from the two epidemics at over 6 million.2,3 It is remarkable that TB and tobacco use are co-prevalent in many developing nations that are doubly burdened by the collision of the two epidemics.1–4

TB is among the most common causes of morbidity and mortality in the world especially in Asia and Africa. In 2006, 9.2 million new TB cases and 1.7 million deaths due to TB were reported globally.5
India is the highest TB burden country accounting for one-fifth (21%) of the global incidence. India is 17th among 22 High Burden Countries in terms of TB incidence rate. TB primarily affects people in their most productive years of life with almost 70% patients falling within the age group of 15-54 years and more than 50% of cases occurring before 34 years of age. Also, the disease is more common among the poor and marginalized sections of the community.[6]

TB accounts for 17.6% of deaths from communicable diseases and for 3.5% of all causes of mortality.[17] World Health Organization (WHO) estimated TB mortality in India as 280 000 (23/100 000) population in 2009. The Revised National Tuberculosis Control Programme (RNTCP), based on the internationally recommended directly observed treatment short-course (DOTS) strategy co-ordinates TB diagnostic and treatment services across the country through a decentralised primary healthcare system and more than 1.5 million patients are put on treatment every year.[8]

India is also the second largest consumer of tobacco products in the world with 35% of adults (15 years and above) consuming tobacco.[9] Overall tobacco use among males is 48% and among females is 20%. In the age group, 30 years and above, the proportion of deaths attributable to tobacco is almost 12% for men and 1% for women. Among those who die pre-maturely, almost one in every 28 deaths among those aged 30-44 years and one in 12 among those aged 45-59 years are attributable to tobacco use.[10]

There is ample evidence to demonstrate the adverse association between the global TB and tobacco epidemics. Active and passive exposure to tobacco smoke is associated with TB infection, disease and mortality. Various studies have concluded that smoking is associated with high prevalence of TB.[11,12] Smoking was the cause of half the male TB deaths in India, and of a quarter of all male deaths in middle age (plus smaller fractions of the deaths at other ages). At current death rates, about a quarter of cigarette or bidi smokers would be killed by tobacco at ages 25-69 years, those killed at these ages losing about 20 years of life expectancy.[13] In other words, one out of every five deaths due to TB could have been prevented if the patient was not a smoker.[13-15] The TB control programmes must involve those engaged in treatment in and outside the clinical setting.[16]

The convergence of the epidemics of smoking and TB, and their association, if causal, represents a modifiable risk factor, and a useful preventive adjunct to curative chemotherapy in further reducing the incidence of TB in India.[17] Therefore in India, where both smoking and TB are common conditions, preventing initiation of smoking and promoting quitting of smoking are important TB-preventive measures. Patients with TB who are tobacco users and wish to stop its use, need and should receive counselling and assistance in stopping tobacco use. Health professionals working in TB care can set up cessation counselling without elaborate or costly training; they can do this systematically within TB treatment services, and it should become as routinely performed as any of the other standard practices in patient management.[18]

Moreover, during a typical course of treatment TB patients are in regular contact with health professionals for at least 6 months. Patients are considered to be more receptive to health education messages and willing to modify their health behaviour when they are ill.[19]

This paper looks at the possibility and outcome of integrating ‘brief advice’ for tobacco cessation in tuberculosis patients who are registered for treatment under TB control programme and are tobacco users.

### MATERIALS AND METHODS

In the year 2010, Tobacco Control Division and Central TB Division in the Directorate General of Health Services, Ministry of Health and Family Welfare, India, discussed and decided to co-ordinate the potential of introducing tobacco cessation within RNTCP on a pilot basis. Two districts were chosen to undertake the project, Vadodara in Gujarat and Kamrup in Assam, where both RNTCP and National Tobacco Control Programme (NTCP) are under implementation. The project discontinued in the Kamrup district due to un-avoidable circumstances and hence this paper considered the project interventions in the Vadodara district of Gujarat only.

The RNTCP has well established infrastructure from national to the health centre at the grass root level, with comprehensive training material developed for all categories of staff and established tools for monitoring, supervision and evaluation of various components of the programme. The NTCP covers 42 districts all over the country and provides for tobacco cessation services at the district level.[20,21]

The Central Tobacco Control Cell developed training material for doctors and health workers. The tools used in the study included a Tobacco Cessation Intervention (TCI) Card, which was also developed to record information regarding tobacco use, exposure to second hand smoke (SHS), administration of brief advice and cessation status at the end of treatment. A patient information brochure containing information on TB–tobacco association and tips to quit tobacco use was prepared for educating TB patients. The TCI cards, brochures and training material were translated into Gujarati language. At the onset of the project, the State TB Cell of Gujarat organized a 2-day training of trainer’s workshop for state and district level programme officers under RNTCP and NTCP with technical support from the Ministry of Health and Family Welfare and the UNION. These trainers in turn trained...
109 doctors, 35 RNTCP staff and 1292 primary healthcare staff (total 1436) in basic counselling skills for brief advice for tobacco cessation both in rural and urban areas of the district, covering all DOTS providers in the Vadodara district between July and September 2010. Brief routine advice or brief advice to stop the use of tobacco by healthcare professionals is a behaviour intervention advocated for treatment of tobacco dependence. The brief advice can be offered by the medical staff in charge of managing TB patients in primary healthcare services.\textsuperscript{[16]}

Brief Advice on tobacco cessation takes less than 3 minutes and consists of five A’s:
- Asking if the patient uses tobacco in any form
- Advice on quitting tobacco
- Accessing readiness to quitting tobacco use
- Assisting with counselling and appropriate treatment
- Arranging for follow up.

All confirmed TB patients registered for DOTS in Vadodara district from October 2010 to June 2011 were included in the study. In addition to all TB-related information on TB treatment care; the tobacco use, both smoking and smokeless by the TB patients, types of tobacco products used, details of brief advice and the final outcome on the status of quitting smoking or tobacco use at the end of treatment was recorded in the TCI card, which was attached to each TB treatment card.

All patients who were current smokers and users of smokeless tobacco were offered brief advice on tobacco cessation by the DOTS provider and the same advice was repeated during each interaction with the TB patients during the treatment period. The tobacco users were assisted with counselling to quit tobacco use, emphasizing the association of TB and implications of continuing tobacco use on the disease and treatment outcomes. No pharmacological treatment was advised.

All the patients receiving DOTS were also given the patient information brochure to educate them on the harms of tobacco use, its association between their disease and treatment outcome and advantages of quitting tobacco.

The status at the end of TB treatment was taken as the outcome of intervention by ‘brief advice’. If the patients reported not using tobacco at the end of treatment period, it was taken as ‘quit’ status. If the patient stopped using tobacco during treatment at any point of time but was using tobacco at the end of TB treatment, it was taken as re-lapse. The patients who did not report their tobacco use status or the same was not recorded by the DOTS provider in the respective TCI card were considered lost to follow up.

The cost incurred on trainings, development of training material, data sheets and pamphlets was about US $ 7000 for the entire study duration and was borne by the RNTCP regular funds. No extra resources were provided for the project.

### RESULTS

A total of 2879 TB patients, 1986 males (69%) and 893 females (31%) registered for DOTS treatment during the study period-urban (51.5%) and rural (48.4%). Category wise, 68.9% patients were new cases of TB and 31% were previously treated.

Overall 81.7% patients suffered from pulmonary TB and rest 18.3% had extra-pulmonary TB. Of those who suffered from pulmonary TB, 71.2% were males and 28.8% were females. The extra-pulmonary group had 59% males and 41% females.

A total of 46.3% of TB patients were current users of tobacco (1333 out of 2879), 52.8% did not use any tobacco at the time of the study. Among the current tobacco users, 89.6% were males and 10.3% were females; 40.8% tobacco users belonged to urban areas and 52.2% were from the rural areas. In keeping with the general trend of tobacco use, the number of TB patients who used smokeless tobacco exceeded that of smokers. While 35.9% of the TB patients were smokers, 39.1% used smokeless tobacco. In fact almost one-fourth of them (25%) were dual users, that is, they smoked as well as used smokeless tobacco. Among the smokers, bidis were used predominantly (86.8%), followed by cigarettes (7.95%), others (3.77%) and hukka (water pipe, 1.46%). The smokeless tobacco users used gutkha (64.6%), followed by Paan with tobacco (betel quid, 18.75%), Khaini (15.6%) and others (9.0%).

Tobacco user TB patients were explained about link of use of tobacco and causation of TB. When asked about their willingness to quit tobacco use at the time of registering for anti-TB treatment, 61.9% males and 54.3% females expressed their willingness to quit.

Age wise distribution of those TB patients who were willing to quit tobacco use is shown in Figure 1.

All registered TB patients who used any form of tobacco (smoking and smokeless) patients were offered brief advice every time they came in contact with the DOTS provider.

The average number of times TB patients were offered brief advice before they quit tobacco use is shown in Figure 2.

At the end of 6 months, 67.3% patients who were offered brief advice quit tobacco, while 18.2% re-lapsed and 14.5% were lost to follow up.

Table 1 gives the age wise distribution of patients who quit, re-lapsed or were lost to follow up.
Highest number of patients who quit was in the age group 31-40 years while highest number who re-lapsed was in the age group 21-30 years.

Figure 3 shows age wise and gender wise distribution of patients who were tobacco users and quit tobacco use following 'brief advice' and remained quit at the end of treatment.

In all the age groups, the proportion of females who quit tobacco at the end of 6 months of treatment was higher compared with men, except in the age groups 41-50 years and above 61 years age group.

**DISCUSSION**

It is estimated that smoking will cause about 10 million adult deaths from all causes by 2030 and most of the increased tobacco-related deaths will take place in Asia, Africa and South America.[22]

Both smoking and TB are targeted by major international prevention and control efforts, and tobacco use in developing countries, where TB is most burdensome, is increasing. However, there has been little research on smoking cessation within TB treatment programmes. Outcome data on targeted smoking cessation interventions in countries where such interventions are available and

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**Table 1: Age-wise distribution of patients who quit, re-lapsed or were lost to follow up**

<table>
<thead>
<tr>
<th>Age group (years)</th>
<th>% Remained quit</th>
<th>% Re-lapsed</th>
<th>% Lost to follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-20</td>
<td>64.0</td>
<td>20.0</td>
<td>16.0</td>
</tr>
<tr>
<td>21-30</td>
<td>61.1</td>
<td>22.1</td>
<td>16.8</td>
</tr>
<tr>
<td>31-40</td>
<td>78.4</td>
<td>18.6</td>
<td>2.9</td>
</tr>
<tr>
<td>41-50</td>
<td>71.2</td>
<td>15.3</td>
<td>13.5</td>
</tr>
<tr>
<td>51-60</td>
<td>64.5</td>
<td>16.1</td>
<td>19.4</td>
</tr>
<tr>
<td>&gt;61</td>
<td>53.5</td>
<td>16.3</td>
<td>30.2</td>
</tr>
<tr>
<td>Total</td>
<td>67.3</td>
<td>18.2</td>
<td>14.5</td>
</tr>
</tbody>
</table>

(N=1333)
feasible provide policy directions on tobacco control for all low and middle-income countries.\textsuperscript{[23]}

Basu et al.,\textsuperscript{[24]} recently concluded that in spite of evidence that tobacco control may be highly relevant to the future control of TB, such control has not been integrated into most TB control programmes. Just as international TB control bodies have generated critical targets for TB control with specific measures to determine progress in TB case detection and treatment efforts, tobacco control should similarly be integrated with TB, with specific efforts to engage smoking as a critical risk factor for TB infection and mortality.\textsuperscript{[24]}

Even the existing evidence on the advantages of TCIs for TB patients and advocacy by the WHO and the UNION have not led to countries integrating brief advice for tobacco cessation in TB control programmes.

The potential salutary benefits of connecting smoking cessation to DOTS on improving TB therapeutic outcomes through an integrated approach including future lung health of TB patients who quit smoking have been reported.\textsuperscript{[25]}

It is also documented that the DOTS strategy offers access to smokers and guarantees regular patient–provider interaction.\textsuperscript{[23]} Physicians and DOTS providers should be actively involved in smoking cessation activities. Regular and repeated medical advices on smoking behaviours are recommended to be included in DOTS practice.\textsuperscript{[26]}

Promoting smoking cessation in TB patients can also increase patient’s compliance to treatment, improve their inter-personal and social communications, decrease their stress and control their risky behaviours.\textsuperscript{[27]}

Thus, there is ample evidence to suggest the larger advantages of offering brief advice to TB patients to improve the treatment outcome and decrease mortality from TB. The encouraging results of the present study provide a good model to extrapolate in TB control programme not only in India but also in other countries facing the challenge of high burden to tobacco and TB.

Moreover, as the use of smokeless tobacco is high in India, the opportunity was used to provide brief advice not only to TB patients who were smokers but also to those using smokeless tobacco. The same is evident from the results of the case study.

However, the feasibility of intervention used in this study must be confirmed by further research such as randomised controlled trials to test methods in various settings, and evaluation study to determine effects after widespread application of such practices, as recommended in earlier such studies.\textsuperscript{[28]}

**CONCLUSION**

Tobacco cessation must become an integral part of all TB control programmes.\textsuperscript{[29]}

Likewise, the recognition of association between TB and tobacco epidemics makes it imperative to carefully consider exposure to tobacco cessation in efforts to reduce
not only the risks of TB and overall mortality resulting from TB but also the decline in health cost burden. It is time that these cost effective interventions are integrated into routine and ongoing national TB control programmes. Training of DOTS providers in ‘Brief advice’ for tobacco cessation can easily be incorporated in the existing trainings under RNTCP.

An important aspect of the present case study is that no extra physical and financial resources were required for the intervention as the infrastructure of existing programmes was used optimally with remarkable co-ordination and collaboration of TB and tobacco control programmes at the national and state level.

Limitations of the study

The confirmation regarding quitting of tobacco use was subjective assessment based on the self-statement by the patients. It was not validated by performing tests such as urine cotinine or carbon monoxide analysis of breath.

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Annual risk of tuberculosis infection in Sri Lanka: a low prevalent country with a high BCG vaccination coverage in the South-East Asia Region

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ABSTRACT

Introduction: Despite its simplicity, efficiency and reliability, Sri Lanka has not used the Annual Risk of Tuberculosis Infection (ARTI) to assess the prevalence and efficiency of tuberculosis (TB) control. Hence, a national tuberculin survey was conducted to estimate the ARTI.

Materials and Methods: A school-based, cross-sectional tuberculin survey of 4352 children aged 10 years irrespective of their BCG vaccination or scar status was conducted. The sample was selected from urban, rural and estate strata using two-stage cluster sampling technique. In the first stage, sectors representing three strata were selected and, in the second stage, participants were selected from 120 clusters. Using the mode of the tuberculin reaction sizes (15 mm) and the mirror-image technique, the prevalence and the ARTI were estimated.

Results: The prevalence of TB estimated for urban, rural and estate sectors were 13.9%, 2.2% and 2.3%, respectively. The national estimate of the prevalence of TB was 4.2% (95% CI = 1.7-7.2%). ARTI for the urban, rural and estate sectors were 1.4%, 0.2% and 0.2%, respectively, and the national estimate was 0.4% (95% CI = 0.2-0.7%). The estimated annual burden of newly infected or re-infected TB cases with the potential of developing into the active disease (400/100 000 population) was nearly 10-fold higher than the national new case detection rate (48/100 000 population).

Conclusion: The national estimate of ARTI was lower than the estimates for many developing countries. The high-estimated risk for the urban sector reflected the need for intensified, sector-specific focus on TB control activities. This underscores the need to strengthen case detection. Repeat surveys are essential to determine the annual decline rate of infection.

Key words: Annual risk, prevalence, Sri Lanka, tuberculosis

INTRODUCTION

Annual Risk of Tuberculosis Infection (ARTI) is defined as the probability of acquiring new infection or re-infection over a period of 1 year. It is one of the simplest, most reliable, efficient and preferred indicators of the epidemiological situation of tuberculosis (TB).[1-3]

ARTI can be computed from the disease prevalence estimated through well-planned cross-sectional tuberculin
surveys in a representative sample of children. It provides required information with a sufficient degree of accuracy. Furthermore, practical World Health Organization (WHO) guidelines on conducting tuberculin surveys and estimating ARTI are readily available.\(^4\) In contrast to cross-sectional disease burden surveys, conducting tuberculin surveys is less cumbersome, cost-effective and requires minimal skilled staff.\(^4,5\) ARTI expresses the overall impact of multiple factors influencing transmission of TB and the effectiveness of disease control measures in a given community.\(^1\text{-}^3\)

Despite the feasibility and usefulness of estimating ARTI in low resource countries, this has not been conducted in Sri Lanka. Although Sri Lanka is considered as a low prevalent country in the South-East Asia region,\(^6\) around 9000 new TB cases are notified every year.\(^7\) Nearly 60% of these are smear-positive, pulmonary TB cases.\(^7\) Hence, conducting a nation-wide tuberculin survey to determine the prevalence of TB and the ARTI among Sri Lankan children, as an indicator of recent TB situation in the community, is timely and appropriate. This also helps determine whether there is an under-reporting of new cases through the routine disease surveillance system. Moreover, it would be a useful reference for future estimates, repeat tuberculin surveys to assess epidemiological trends and the impact of TB control activities in the country.

**MATERIALS AND METHODS**

**Study design**
A nation-wide, school-based, cross-sectional tuberculin survey.

**Study population and sampling**
Generally, un-vaccinated children or children without a BCG scar are enrolled for tuberculin surveys as BCG-induced tuberculin sensitivity could interfere with the interpretation of study results.\(^8\) However, given the very high BCG vaccination rates\(^9\) and the high rates of BCG scars among Sri Lankan children,\(^10\) enrolment of un-vaccinated children or children without a BCG scar in sufficient numbers is impracticable. Therefore, school-children aged 10 years (1999 birth cohort) irrespective of their BCG vaccination status and availability of a BCG scar enrolled in public and semi-public schools in Sri Lanka comprised the study population. All children with severe malnutrition, fever >38.5°C, known contraindications for tuberculin testing, immune-compromised conditions, skin rashes, eczema and those suffering from major viral infections, namely, measles, varicella, influenza and infectious mononucleosis at the time of tuberculin administration and those with exposure to live viral vaccines within 4 weeks preceding the date of tuberculin administration were excluded.\(^11\) The required sample size was estimated using the following formula:\(^12\):

\[
N = d (1.96)^2 \frac{(1-P)}{\hat{e}^2 P}
\]

where \(N\) = sample size, \(d\) = design effect, \(P\) = prevalence, \(\hat{e}\) = relative precision

We considered a prevalence of 10% based on the results of a south Indian study among children aged 10 years with a BCG scar\(^3\) as no estimates for Sri Lanka were available. For a relative precision of 10%, level of significance of 5% and a design effect of 1.5, the estimated sample size was 5186. This estimated sample size was distributed proportionately among urban, rural and estate strata based on 2001 population census data.\(^13\) Accordingly, the number of study participants required from urban, rural and estate sectors were 936, 3978 and 272, respectively.

A two-stage sampling procedure was used to select the study sample. In the first stage, we listed all urban, rural and estate sectors in the country separately. These sampling frames were used to sample urban, rural and estate sectors for the study. Urban and rural sectors in the Northern Province were excluded from this sampling frame due to inaccessibility. The sector-categorization used in the national census of 2001 formed the basis for categorization. Guided by the WHO recommendation to select 5-25% of the total geographical units in a stratum based on the operational convenience and sample size,\(^4\) we selected 6 (35%) out of 17 sectors listed in the urban stratum, 8 (40%) out of 20 sectors listed in the rural stratum and 3 (20%) out of 15 sectors listed in the estate stratum. Overall, 12 (48%) districts in the country were represented in sectors selected under urban, rural and estate strata in the study.

In the second stage, the required number of clusters was selected from three individual strata. A 'year 5' class in a school was considered as a cluster. All 'year 5' classes in selected sectors, the total number enrolled in a class and the cumulative number of 'year 5' school-children were listed separately for all three strata. The required number of clusters within the respective stratum was selected probability proportionate to the size (PPS). The required number of clusters from a stratum was determined by the cluster size that depended on the median number of children in clusters within a stratum. Based on this, the total number of clusters that was required to select the estimated sample size was 120. Within a selected cluster, school-children who were eligible for the study with the parental consent were enrolled. When the number of eligible children in a selected cluster exceeded the required cluster size, the required numbers of participants were selected randomly.
Field procedure

In a cluster, after explaining the purpose of the study and obtaining the written parental consent, a medical officer appraised the eligibility of students. The Public Health Nursing Sister (PHNS) noted down the availability of a BCG scar in an eligible child. Then, a trained nursing officer administered 0.1 ml of tuberculin I (1 TU of PPD RT 23 stabilized with Tween 80), according to the standard protocol. The PHNS recorded this procedure as ‘satisfactory’ or ‘un-satisfactory’ using standard criteria. In 72 h after tuberculin administration, the test-reader measured the size of the tuberculin.

To determine the prevalence of infection, justifying the appropriateness of using the current batch of tuberculin and ensuring the comparability of results with other studies, Welisara Chest clinic administered tuberculin to 82 smear-positive TB patients within 1 week of diagnosis. With the expected frequency based on moving averages, the sensitivity of the batch of tuberculin used was 86.7% at 10 mm and 74.6% at 14 mm. Since these values were approximate to the sensitivity of 90% at 10 mm and 75-85% at 14 mm demarcation reported in different studies all over the world, tuberculin PPD RT 23 was demonstrated to be appropriate for the field study.

While the study was in progress, due to death of a child recipient of rubella vaccine in the school programme, enrolment of study participants had to be limited to 103 clusters as all injection procedures were not permitted until a further notice by the Ministry of Education.

Statistical methods

The frequency distribution of reaction sizes in the form of a histogram was plotted from observed tuberculin reaction sizes. Depending on the form of the histogram, following scenarios were considered to determine the prevalence of infection. In the event of having a bi-modal graph showing two distinct modes and an easily definable anti-mode as seen in low prevalence of non-specific tuberculin sensitivity, frequencies of all reactions greater than the anti-mode were assumed to be attributable to TB infection. If the frequency distribution of reaction sizes displayed a bi-modal graph, but without a clearly identifiable anti-mode, the mirror-image technique was used for determining the prevalence of TB. In this method, the frequency assumed to be TB was estimated by doubling the frequencies of reactions larger than the second mode and adding it to the frequency at the second mode (mirror-image technique). As seen in areas of low prevalence of TB, when neither the anti-mode nor the mode on the right side of the distribution was clearly distinguishable, we intended to use the mode of reaction sizes observed among smear-positive pulmonary tuberculosis cases as the alternative mode for the frequency distribution of the study participants.

All frequencies of reactions of study participants greater than the alternative mode were to be doubled. Then, the doubled frequencies were to be added to the frequency at the alternative mode to estimate the frequency of children assumed to be infected using the mirror-image technique.

The following formula was used for estimating the prevalence ($P$) of TB infection:

$$ P = \frac{\text{Number of children assumed to be infected}}{\text{Total number of children analysed}} \times 100 $$

As the number of test-read children was not uniform in each cluster, first, the proportion of children assumed to be infected in each cluster was calculated. After weights, equal to the inverse of initial probability of a cluster being selected (ratio of the population of $i$th cluster to the district stratum-specific population), were assigned, the proportions were pooled to estimate the proportion of children assumed to be infected in each district. The proportions of children assumed to be infected in a stratum were estimated by pooling the estimates of children assumed to be infected for each district using the proportion of district population to the stratum population as the weight. The stratum specific estimates were pooled to obtain the overall national estimate with the proportion of the stratum population to the total population of all strata as the weight. Formulae used in this calculation process are given in Appendix I. This estimate of prevalence was used to calculate ARTI. The following formula, where $P$ was the estimated prevalence while ‘$A$’ was the mean age of test-read children, was used for the calculation:

$$\text{ARTI} = 1 - (1 - P)^{1/A}$$

RESULTS

Of the estimated sample size of 5186, only 4352 (84%) study participants were enrolled due to the death of a school-child following rubella vaccination. Overall, the enrolment rates in urban, estate and rural sectors were 73.0%, 98.5% and 85.6%, respectively. The number of children administered tuberculin satisfactorily was 4318 (99.2%). This consisted of 2346 (54.3%) girls and 1972 (45.7%) boys. The majority ($n = 4238, 98.2\%$) were vaccinated with BCG in infancy. The BCG scar was found in a great majority ($n = 4039, 95.3\%$). Of the children who were administered tuberculin, 4202 (97.3%) were test-read and analysed. The frequency distribution of tuberculin reaction sizes among children aged 10 years irrespective of the BCG scar and vaccination status is given in Figure 1. The proportion of children without a reaction was 57.1%. 
A second mode of reactions potentially attributable to the infection with tubercle bacilli is distinguishable at 15 mm, although not distinctly clear. However, in this case, an anti-mode could not be identified. Therefore, the mode of reaction sizes of smear-positive Pulmonary Tuberculosis (PTB) cases was considered as the alternative mode of the frequency distribution of reaction sizes attributable to TB infection in the study participants [Figure 2]. The proportion without a reaction among smear-positive PTB patients was 7.4%.

Although this frequency distribution of tuberculin reaction sizes among smear-positive PTB cases is generally unimodal, in this series, we found two clearly visible modes at 15 mm and 20 mm. However, when accounted for the possible digit preference by smoothing data in terms of converting to two point moving averages, the mode was at 15 mm. This overlapped with the value of the suspected mode of reactions assumed to be attributable to the infection in the study participants. Hence, the frequency assumed to be TB among study participants was determined by doubling the frequency of tuberculin reactions larger than 15 mm and adding to the frequency at 15 mm (mirror-image technique). The estimated prevalence and ARTI based on this frequency assumed to be TB are indicated in Table 1.

The prevalence of TB and ARTI computed was similar among both the sexes. The prevalence among males and females were 4.2% (95% CI: 0-12%) and 4.1% (95% CI: 1.4-6.8%), respectively. The ARTI for males and females were 0.4% (95% CI: 0-1.2%) and 0.4% (95% CI: 0.1-0.7%), respectively. However, in contrast to the estate (2.3%, 95% CI: 0-6.4%) and rural sectors (2.2%, 95% CI: 0-5.7%), the prevalence was much higher in the urban sector (13.9%, 95% CI: 8.4-19.4%). The national prevalence was 4.2% (95% CI: 1.7-7.2%), while the ARTI was 0.4% (95% CI: 0.2-0.7%).

**DISCUSSION**

Although the estimation of ARTI is the simplest, most-efficient and reliable indicator of the epidemiological situation of TB, many developing countries still do not estimate ARTI. The present study was the first national tuberculin survey that enabled estimation of the prevalence and the annual risk of TB in Sri Lanka. It provided baseline data to evaluate the impact of disease control and for future appraisals of epidemiological trends. One limitation of this study, performed in 2009, was its applicability of results to 2004 [2009 - the age of the study population/2]. Assessing the trends in repeat surveys can minimize this limitation.

One general recommendation in planning surveys to determine ARTI is that national-level surveys are preferred in smaller countries, while, in larger nations, separate surveys are preferred at sub-national levels with adequate, separate sample sizes for each stratum. We, as a small country, primarily planned for computation of a single-national estimate. In spite of this, we present separate estimates for urban, rural and estate sectors. However, over sampling in urban, rural and estate strata in this study or conducting independent surveys in different strata, including different socio-economic and age groups with adequate strata specific samples, would have given more precise strata-specific estimates of the ARTI. It could have resulted in better delineation of the disease prevalence and enhanced the understanding of the challenges of disease control and planning remedial
the non-uniformity in the methodology. Variability in limitative for comparing ARTI estimates across studies irrespective of the status of BCG vaccination and scar in approach by computing ARTI having enrolled children status and BCG scar. Many studies have justified this study of mere 5% of study participants without a BCG scar demonstrated that obtaining a sufficient population of children without BCG scar is operatively infeasible in Sri Lanka. In contrast, the BCG coverage is also very high in the country. In this context, we had to recruit children irrespective of their BCG vaccination status and BCG scar. Many studies have justified this approach by computing ARTI having enrolled children irrespective of the status of BCG vaccination and scar in settings with very high BCG coverage. These estimates were demonstrated to be comparable to that derived from unvaccinated children. The possible contamination due to BCG vaccination in skin test results also could be removed by applying mirror-image technique to the analysis.

We enrolled only 82.4% of the desired sample size, and we had to discontinue the study following the government circular temporarily stopping all injection procedures in schools following the death of the rubella vaccine recipient. This response rate (82.4%) was slightly above the 80% threshold recommended by Sackett to be considered internally valid. However, non-enrolment of 27% of children in the urban sector is indeed a great limitation to interpret the validity of the high estimate of ARTI for the urban sector.

Although not distinctly clear, the frequency distribution of tuberculin reaction sizes in the study appeared to be bimodal without an anti-mode. Similar distributions are observed in areas of low prevalence of infection and moderate to high prevalence of non-specific sensitivity that obscure a clear separation of reactions due to infection with tubercle bacilli from others. In contrast, the impact of environmental mycobacteria on interpretation of results cannot be determined due to non-availability of studies on the influence of environmental mycobacterium on the tuberculin reactivity in the country. Alternatively, the mode of reaction sizes among smear-positive pulmonary tuberculosis cases (15 mm) supplemented determination of the prevalence of TB by mirror-image technique.

Our national estimate of ARTI (0.4%, 95% CI: 0.2-0.7%) was low as compared with that of many developing countries. However, it is still higher than the ARTI, which is far below 0.05% in industrialized countries. One limitation for comparing ARTI estimates across studies is the non-uniformity in the methodology. Variability in dose, type of tuberculin used and the difference in cut-off points also play a role in different reported estimates. Nevertheless, extensive ARTI estimates in the range of 0.75-3% are available for several states in India, the neighbouring country. Among children aged 1-9 years in the eastern and western zones of India, the ARTI was 1.3% and 1.8%, respectively. The same in Orissa state of India was 1.7-1.8%. In the northern zone, among children of the same age, it was 1.9%. In the southern zone, ARTI among children aged 1-9 years was 1.0%. Observed high rates of transmission are expected in India as it contributes to one-third of the global burden of TB. Although Indian estimates were generally high, ARTI estimates for children aged 10 years in Trivandrum in Kerala, India, which in terms of many health indicators is similar to Sri Lanka, was as low as 0.75%.

The estimate of ARTI for many other developing countries is in the range of 1-3%. ARTI for Philippines was 2.3%, while for Algeria, Egypt, the Republic of Korea, Kenya and United Republic of Tanzania, it was <2%. Thus, by the standards of developing countries, our estimate reflected the effectiveness of TB control activities in the country. However, no comments can be made on trend due to the non-availability of previous national estimates.

The national estimate of ARTI indicates that, on an average, there are about 400 newly infected cases or re-infected cases with potential to progress to the disease per 100 000 population (95% CI: 200-700/100 000) every year. This is in contrast to the estimates of the incidence rates of all forms of TB and the nationally reported new case detection rates, which were 66 and 48 per 100 000 population, respectively, in 2009. Based on the parametric relationship derived by Styblo, the estimate of the annual incidence of new cases with smear-positive PTB cases derived from the present study was similar to the nationally reported figure of incidence of smear-positive cases for 2009 (20 per 100 000).

Like in many countries, a higher ARTI (1.4%; 95% CI: 0.8-2.1%) has been observed in the urban sector. The slightly wide confidence interval of the urban estimate indicates the small sample size, mainly due to pre-mature cessation of the study. Both estate and rural sectors have estimates suggestive of low transmission of TB infection. The higher risk of infection in the urban sector than in the rural and estate sectors may be due to high population density and poor socio-economic situation.

Results underscore the need for paying greater attention to the urban sector and indicate possible weaknesses in the operation of the control programme in urban areas.

**CONCLUSION**

Our study concluded that the national estimate of
ARTI was lower than that reported in many developing countries. However, a relatively high risk was observed in the urban sector as compared with the estate and rural sectors. Although still far from the ideal, the relatively lower ARTI at the national level may reflect improving socio-economic status, the better and organized delivery of general healthcare as well as organized TB control activities. Despite this lower risk, nearly 10-fold low annual new case detection rate relative to the expected annual burden of newly infected and re-infected cases based on our study is a concern. Therefore, in the light of our findings, the National TB Programme needs to strengthen its efforts to detect newly infected or re-infected disease load capable of progressing to the disease. In addition, a fresh approach for a package of control activities in urban areas of the country is required.

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P_r - Proportion of infected children in the ith cluster
P - Probability of selection of children (number of test read children/population of the ith cluster)

Pooling of district estimates of a given stratum was done as shown below to obtain estimates for the urban, rural and estate sectors.

\[
P_{d} = \frac{\sum P_{i} / \cap}{\sum [1 / \cap]}
\]

\[
P_{d} \cdot \text{Prevalence of tuberculosis in the district}
\]
\[ P_i \text{ - Prevalence of infection in the rural/urban/estate strata} \]

\[ P_{di} \text{ - The proportion of infected children in the } i^{th} \text{ district} \]

\[ w_i \text{ - The corresponding weight–the proportion of the district population to the population of the respective stratum} \]

The stratum specific estimates were pooled to obtain the overall national estimates using the following formula:

\[ P = \sum w_i P_i \]

\[ P_i \text{ - The prevalence in the urban/rural/estate strata} \]

\[ w_i \text{ - The corresponding weight–the proportion of the stratum population to the national population} \]

Standard error for stratum specific estimates was computed using the following formula\(^{[8,13]}:\)

\[ \sqrt{\frac{\sum w_i(P_{di} - P_s)^2}{\sum (w_i)^2}} \]

\[ P_{di} \text{ - Prevalence for the district} \]

\[ P_s \text{ - Prevalence for the stratum} \]

\[ w_i \text{ - The corresponding weight–the proportion of the district population to the population of the respective stratum} \]

Standard error for the pooled national estimate was computed using the following formula:

\[ \sqrt{\frac{\sum V_i^2 S^2_i}{(\sum V_i)^2}} \]

\[ S_i \text{ - standard error for strata (urban, rural, estate)} \]

\[ V_i \text{ - proportion of population in the respective area} \]
Threat of HIV/AIDS in children: social, education and health consequences among HIV orphans and vulnerable children in Myanmar


ABSTRACT

Background: There is very limited information available on HIV related orphans and vulnerable children (HIV-OVC) in Myanmar. Hence, the objective of this study was to identify and compare the social, education and health consequences among HIV-OVC and children from the families not related to HIV in the same neighbourhoods (neighbouring children).

Materials and Methods: A cross-sectional, comparative survey was carried out in three geographical locations. Face-to-face interviews were conducted with guardians and children using a pretested structured questionnaire including Strength and Difficulties Questionnaire (SDQ) for behavioural problems. Outcome measures were compared using Chi-squared test or ‘t’ test or ‘Rank-sum’ test.

Results: A total of 300 HIV-OVC and 300 neighbouring children were included. A greater number of HIV-OVC than their neighbouring children have experienced family displacement from their original homes (27% and 1%), child/sibling displacement (20% and 2.7%) and family dispersion (20.3% and 1.3%) \( P < 0.001 \). More guardians of HIV-OVC reported that the disease affected their children’s education (28.2% and 16.3%; \( P < 0.05 \)). Fifteen per cent of HIV-OVC and 10.5% of neighbouring children had to work for their families \( P < 0.05 \). Psychological condition was assessed on emotional, conduct, hyperactivity/inattention, peer relationship and prosocial behaviour. A greater number of HIV-OVC were noted in the abnormal category with regard to hyperactivity and prosocial behaviours \( P < 0.05 \).

Conclusions: Higher incidence of social and psychological consequences among HIV-OVC call for more community support programmes and creation of job opportunities to minimize social impact in the affected families. Future programmes should focus on counselling of HIV-OVC and providing psychological support.

Key words: HIV/AIDS, Myanmar, orphans and vulnerable children, psychological, social

INTRODUCTION

Globally, the HIV pandemic remains a serious challenge to public health, while AIDS is the leading cause of death worldwide for people aged 15-49 years. Although the number of annual AIDS-related deaths is declining, there were an estimated 1.8 million deaths in 2009.\(^1\) In Asia, the number of people living with HIV increased...
from 4.2 million in 2001 to 4.9 million in 2009. Similarly, AIDS-related deaths also rose from 250 000 in 2001 to 300 000 in 2009.\[^1\] Furthermore, HIV/AIDS affects children in many ways, including higher infant and child morbidity and mortality rates, lower life expectancy and higher rates of orphaning.\[^2\] By the end of 2009, the epidemic had left behind 16.6 million AIDS orphans.\[^1\]

Even with the expansion of access to antiretroviral treatment, it is estimated that, by 2015, the number of orphaned children will still be overwhelmingly high.\[^2\] The number of orphans in some sub-Saharan African countries exceeds 1 million, and, in some countries, children who have been orphaned by AIDS comprise half or more of all orphans nationally.\[^3\] Most of the AIDS orphans who live outside of Africa live in Asia, where the total number of orphans (orphaned for all reasons) exceeds 73 million.\[^4\] The problems faced by AIDS orphans include emotional impact, household impact, educational impact and stigmatization.\[^1,4,7\] HIV/AIDS has many direct and indirect impacts on children’s rights, ranging from the consequences of psychological impact of losing one or both parents, to reduced access to quality education and health services.\[^8,9\] Children’s rights to survival, health, development and education as well as protection from economic and sexual abuse have been threatened by the HIV/AIDS epidemic.\[^10\] Previous studies focusing on HIV/AIDS orphans in China and Africa have highlighted the psychological problems\[^11,12\] and problems of unmet basic needs such as food inadequacy, discontinuation of schooling and inaccessible healthcare services\[^13\] faced by the orphans.

Myanmar is one of the countries afflicted by HIV/AIDS similar to other developing countries in South East Asia. According to the National AIDS Programme (NAP), the adult HIV prevalence is about 0.61% in Myanmar.\[^14\] Limited information is available for orphans and vulnerable children (OVC) due to AIDS in Myanmar. A previous qualitative study on HIV/AIDS orphans acknowledged that there were adverse socioeconomic consequences such as school discontinuation, family dispersion, effect on a family’s economy and stigma/discrimination.\[^15\] However, the study could not identify the extent of these consequences. Therefore, this study aimed to explore the situation and extent of social and psychological health consequences faced by OVC due to HIV/AIDS (HIV-OVC).

**OBJECTIVES**

The objectives of this study were to identify and compare the social situation, educational condition and psychological and health status of OVC due to HIV/AIDS (HIV-OVC) with that of children from the families not related to HIV in the same neighbourhoods (neighbouring children).

**MATERIALS AND METHODS**

A community-based, cross-sectional, comparative study was carried out in North Okkalapa, Monywa and Tachileik Townships. These townships were selected specifically because of a high prevalence of HIV/AIDS and presence of community-based activities focusing on HIV/AIDS.

**Study samples**

According to a 20% anticipated difference of study outcomes between two groups, a ratio of HIV-OVC and neighbouring children to be 1:1 and an 80% power to detect this difference, at least 98 children from each group were required. Therefore, a total of 196 children were needed in each township.

HIV orphans were defined as the orphans who were younger than 18 years and have lost one or both parents due to AIDS. Vulnerable children were defined as those who have HIV-positive parent(s). Age group-matched neighbouring children from the same area were considered during the selection of the comparison group. If one HIV-OVC was selected as the study sample, one control child of the same age (±6 months) who lived in the same street/village was also chosen.

A list of HIV-OVC was compiled from different sources, and it was checked for duplication by identifying their name, age, parents’ name and address. Next, required samples were obtained through simple random sampling. Children from both urban and rural areas were included in each township. The survey team visited 10-20 wards in urban areas and 15-25 villages in rural areas, according to the random selection from the sampling list.

**Data collection**

After developing a structured questionnaire, a pretest was carried out in a nonproject township. A reliability test was performed for Strength and Difficulties Questionnaire (SDQ) and the Cronbach-alpha value was 0.7 for all items (range: 0.6-0.7 for each ‘5’ items scale). SDQ\[^16,17\] is a brief behavioural screening questionnaire for emotional and behavioural disorders in children and adolescents aged 4-16 years. The SDQ consists of 25 items: emotional symptoms (5 items), conduct problems (5 items), hyperactivity/inattention (5 items), peer relationship problems (5 items) and prosocial behaviour (5 items).

Responsible persons from the NAP, local and international nongovernmental organizations (NGOs) either working with HIV/AIDS orphans or people living with HIV/AIDS (PLHIV) in the study townships were contacted. These organizations were informed about the objectives of the study and were invited to attend the advocacy meeting, which was held in each township before field data collection.
Face-to-face interviews were carried out by using a pretested structured questionnaire, which consisted of two parts. The first part was for guardians and the second part was for children. If the child was younger than 10 years, the guardians responded to both the parts. Face-to-face interviews were also undertaken with guardians/care takers for SDQ questions.

Data analysis
Data entry and data analysis were done using EpiData software (version 3.1; EpiData Association, Denmark) and R software (version 2.9.1; R foundation for Statistical Computing, Austria).

Responses to psychological questionnaires were assigned a score ranged from ‘0’ to ‘2’, according to the direction of the statement. Next, composite scores were calculated and categorized as ‘normal’, ‘borderline’ and ‘abnormal’.

Descriptive statistics were shown as percentages for categorical variables and mean/median for continuous variables. Outcome measures were compared between two groups using Chi-squared test for categorical variable and ‘t’ test or ‘Rank-sum’ test for continuous variables.

Ethical consideration
The proposal was approved by the Institutional Ethical Review Committee of Department of Medical Research (Lower Myanmar). Written informed consents were obtained from the guardians after detailed explanation about the study. To ensure confidentiality, only code numbers were mentioned on the questionnaires and interview records.

FINDINGS

Background of the participants
A total of 600 respondents were included in the study. Among them, 300 children were HIV-OVC and the remaining 300 were their neighbouring children. The ages of the children ranged from 1 month to 17 years with a median of 8.5 years. Among them, 24% were aged 1 month to 5 years, 44.3% were 6-10 years and 31.7% were older than 10 years. Males and females constituted approximately the same proportion (50.5% and 49.5%, respectively).

Less than half (43.3%) of the HIV-OVC have both parents alive, while 17.3% of HIV-OVC were double orphans, 28.3% were paternal orphans and 11% were maternal orphans. Moreover, about two thirds (63.7%) of fathers and 85% of mothers were HIV positive. One third (33.0%) of HIV-OVC and 27% of neighbouring children were staying with extended family members.

The age of the guardians, including parents, also ranged from 17 to 78 years, with a mean age of 39.5 years. Distribution of the occupation and education of the head of the household was similar in both groups; about half of them were manual labourers (42% of HIV-OVC and 50% of neighbours) and about one fourth (25% and 28%, respectively) of them has passed middle school. Median monthly family income was lower in the HIV-OVC group than in the non-HIV group (80 000 and 96 000 Kyats, respectively) ($P < 0.001$).

Social situation of the children and their families
This study focused on social situation such as displacement from original homes, sibling/child displacement and family dispersion, which are illustrated in Table 1. All three conditions were significantly higher in HIV-affected families than in non-HIV families. A significant difference was detected for family displacement, where 27% of the HIV affected families were displaced from their original homes either within the same township or to other townships ($P < 0.001$). Similarly, higher proportions of child displacement (20% vs 2.7%) and family dispersion (20.3% vs 1.3%) were seen for HIV-OVC than non-HIV families ($P < 0.001$) [Table 1].

Education and work conditions
Education and work-related characteristics of the children are shown in Table 2. Currently, more than 80% of both HIV-OVC and related children without HIV have been attending school. Higher proportions (28.2% vs. 16.3%) of guardians of HIV-OVC stated that HIV status of parents affect their children’ education. Specifically, the different types of effects on education included school drop-outs, school absenteeism, inability to pay school expenses, moved to another school and delay in school enrolment.

Regarding the work-related characteristics, 15% of HIV-OVC and 10.5% of non-HIV-related children had to work for their families ($p<0.1$) and their monthly income ranged from 0 to 96 000 Kyats [Table 2].

Psychological status of the children
Table 3 describes the psychological status of the children, which was measured using a standard behavioural questionnaire (SDQ). Each of the 25 items is scored on a 3-point scale (‘0’ = ‘not true’, ‘1’ = ‘somewhat true’ and ‘2’ = ‘certainly true’), with higher scores indicating greater problems. Contrast is true for prosocial behaviour. Next, the total difficulties score was calculated by adding emotional, conduct, hyperactivity and peer relationship problems. Higher total scores were seen in abnormal behavioural problems. The mean total difficulties score was significantly higher among HIV-OVC than among non-HIV-related children ($P < 0.05$). The total number of children in the two groups was ‘272’ and ‘274’ since SDQ questions were only for the children aged between 4 and 16 years.

Next, the total scores were categorized as ‘normal’, ‘borderline’ and ‘abnormal’ behaviour. Significant differences
were detected between the two groups for hyperactivity and prosocial behaviour \((P < 0.05)\). However, similar patterns of behavioural conditions were seen for other attributes. An abnormal total difficulties score was seen in 21% of HIV-Orphans and vulnerable children \((P < 0.05)\) [Table 3].

### Health condition

Health-related characteristics are shown in Table 4. Of the 300 HIV-Orphans, 40 children (13%) were HIV positive, in which 16 (40%) had already received antiretroviral therapy (ART). Among the HIV-positive children, 45% were aged 5 years or younger. Nearly half of the children had a history of illness within 6 months. Most common illnesses included cough and cold, pneumonia, diarrhoea and skin infection. A greater number of HIV-Orphans children experienced skin infection than non-HIV-related children (10.2% and 5.3%, respectively) \((P < 0.1)\). Besides illness within 6 months, 5.7% of HIV-Orphans and 4.3% of normal children had a history of hospitalization within 1 year [Table 4].

#### DISCUSSION

The present study identified and compared the social, education, psychological and health conditions of HIV-Orphans and vulnerable children.
and children from the non-HIV related families in the same neighbourhoods. Significant differences in social conditions such as family displacement from their original homes, child/sibling displacement and family dispersal were detected between HIV-OVC and neighbouring children. A higher proportion of HIV-OVC than their counterparts had experienced the aforementioned social consequences after their parents died or were infected with HIV. In particular, 27% of HIV-OVC from the current study had experienced family displacement from their original homes. This was much lower than in a study carried out in Zambia where 61% had moved from their original homes. These kinds of social consequences were mostly linked with financial hardship faced by the affected families. Moreover, a few families moved to places where they could get support from different national and international non-governmental organizations (NGO/INGOs). Significant social consequences among HIV-affected families could have a psychological impact on children.

In our study, 15.4% of HIV-OVC had to work for their families, which was lower than the proportion of working OVC children found in a study from China.\[18\] Regarding education, more than 80% of the children aged 5 years or more were currently enrolled in schools. Parents/guardians of HIV-OVC mentioned the negative effects of HIV on the education of their children. Findings from Africa suggested that orphans are at risk of poorer educational outcomes, with maternal deaths having stronger negative effects than paternal deaths.\[19\]

The present study identified that 13% of HIV-OVC were HIV positive. Among them, 45% were aged 5 years or younger. In Myanmar, activities with regard to prevention of mothers to child transmission (PMCT) were initiated in 2001 and have covered 245 out of 328 townships. This finding of HIV positivity among children calls for the need for strengthening PMCT activities. Regarding psychological conditions, significant differences between the two groups were detected for total difficulties, and hyperactivity and prosocial behaviour. Specifically, higher proportions of HIV-OVC were found to have behavioural problems than their counterparts. Similarly, in Ghana, the total difficulties score was found to be higher in HIV-orphans than in nonorphans and orphans not related to HIV/AIDS. However, hyperactivity and pro-social behaviours showed no difference.\[20\] Another study from China identified that HIV-OVC demonstrated poorer psychosocial adjustment than comparison children.\[21\]

Surprisingly, findings from the current study revealed that more than half of the children from both the groups had peer relationship problems, which was also reported from Africa.\[22\] However, in Thailand, no difference was detected regarding behavioural problems among HIV-affected pre-school children in comparison with their controls.\[22\] Higher proportions of HIV-OVC than non-HIV-related children from the current study had high risk of developing behavioural problems in adult life.

This study data highlight that there were adverse social and psychological consequences faced by HIV-affected families, and more attention should be paid towards psychosocial support for HIV-OVC in addition to material assistance.

## CONCLUSIONS

Development of community support programmes and creation of job opportunities are needed to minimize social impact among the affected families. Counseling of HIV-OVC and psychosocial support focusing on children’s behavior should be strengthened to minimize the risk of behavioral problems and part-time formal education programmes for working children should be expanded.

## ACKNOWLEDGMENT

This study was funded by UNICEF, Country Office in Myanmar.

## ENDNOTE

1. A family displaced from their original house to another place.
2. A child displaced from his/her family to another house/place.
3. Family members dispersed to different places.

## REFERENCES


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Development of birth weight for gestational age charts in a Sri Lankan setting - methodological issues

T. Ruwanpathirana, Dulitha N. Fernando¹, Hemanta Senanayake²

ABSTRACT

Background: This study was taken up to identify the main types of low birth weight (LBW) for the development of weight for gestational age charts relevant to the country/regional level for the formulation of preventive strategies.

Materials and Methods: A sample of mothers registered by Public Health Midwives (PHMs) from two Medical Officers of Health (MOH) areas in Colombo district were followed up until delivery in five selected hospitals. Period of gestation (POG) was assessed between 10 and 12 weeks using ultrasonography. Records of 474 mother/newborn pairs were used for development of gestational age-related birth weight charts for each sex and POG. Mothers with one or more risk factors for LBW were excluded. Mothers with POG less than 38 weeks and more than 40 weeks were limited. Information on all possible risk factors contributing to LBW were assessed.

Results: Incidence of small for gestational age (SGA) assessed using the 10th centile value for each POG, was 19.0% for males and 18.0% for females. Percentages of symmetrical and asymmetrical SGA newborns were 72.1% and 27.9%, respectively.

Conclusion: The charts were developed paying attention to all methodological aspects that highlighted the key issues relevant to development of weight for gestational age charts in a developing country setting. As action was taken to minimize the biases introduced by such issues, the charts developed could be used for assessment of incidence and risk factors for SGA until charts based on national level data are available.

Key words: Assessment of gestational age-related birth weight, incidence of small for gestational age newborns, low birth weight

INTRODUCTION

The prevalence of low birth weight (LBW) has not shown much improvement over the past two decades in Sri Lanka. Studies that provide data on the two categories of LBW as pre-term and small for gestational age (SGA) newborns are limited. Some have used clinical methods in making the assessment,¹² while another³ used customized computer generated software programmes.

It is suggested that the best clinical methods available have approximately 50% accuracy when compared with assessments based on ultrasonography (USG) performed at 10-12 weeks of pregnancy.⁴ Development of country-specific reference curves for weight, height and head circumference for gestational age are needed to enable identification of the two main groups of LBW babies, SGA and pre-term that will provide basic data on incidence and risk factors of SGA, based on which...
preventive strategies to further reduce LBW levels could be developed. More recent trends are to develop customized growth charts for each pregnancy for each mother.\textsuperscript{[5]} The key variables required to develop such curves are accurate assessment of the gestational age and birth weight. It is also necessary to identify all mothers who have any risk factor for LBW so that they could be excluded.

This report describes the first attempt made to develop weight for gestational age charts undertaken in Sri Lanka with the focus on the methodological issues experienced in undertaking such a task.

**MATERIALS AND METHODS**

The study was performed in two Medical Officer of Health (MOH) areas\textsuperscript{1}, Kaduwela and Homagama in the Colombo district. A total of 1200 pregnant mothers registered by the field level health staff (Public Health Midwives [PHMs])\textsuperscript{2} within the first 8 weeks of amenorrhoea during the 6 months commencing from January 2010 comprised the study population. Those who were not permanent residents of the areas, those who planned to deliver in a hospital other than the five hospitals identified, those having mental disabilities and those who live in institutions were excluded.

**Sampling**

Using available data\textsuperscript{[3]} the sample size was calculated as 1114 mothers who fulfilled the eligibility criteria. However, all 1200 mothers registered were included.

**Study instruments**

To develop weight for gestational age charts, pregnant women were followed up from 14 weeks of gestation until delivery and obtained accurate information on the period of gestation (POG) and the weight of the newborn at the time of delivery. All mothers were recruited prior to period of amenorrhea (POA) of 8 weeks and the POG assessed by measuring the crown rump length by using trans-abdominal USG between 10 and 14 weeks. We used a CHISON 600M ultrasound scanner with a curvilinear probe of 3.5 MHz. Their follow up included identification of all possible factors that are likely to influence birth weight.

Thus, data collection required obtaining a wide range of information from the dating USG to details regarding delivery and accurate assessment of the birth weight, as well as identifying other factors that are likely to have a negative effect on birth weight. Hence, a total of seven questionnaires were used. A brief description is given as follows.

Questionnaire 1 was administered at the first visit by a pre-intern Medical Officer and included basic socio demographic information, current and past obstetric history, present and past medical and surgical histories and other possible risk factors for SGA. Findings of the clinical examination, urine full report and haemoglobin level were also recorded.

Questionnaire 2 was administered by the area PHM during the second trimester to collect information for development of wealth index,\textsuperscript{[6]} assessment of home risk factors and family history of disabled and LBW children.

A self administered Questionnaire 3A, was used to assess the psychological stress level of the pregnant mothers as this was considered an important risk factor for LBW\textsuperscript{[7]}. The instrument used was the translated GHQ 30, which had been validated and used in Sri Lanka\textsuperscript{[8,9]}

Questionnaire 3B administered by the PHM during a clinic visit at a POA of approximately 34 weeks, obtained information from the mother and available records on the health conditions developed during the present pregnancy.

Questionnaire 3C: An internationally recognized tool, Pregnancy Physical Activity Questionnaire (PPAQ), a self administered questionnaire was used to assess the workload during pregnancy.\textsuperscript{[10]}

Questionnaire 4A collected information related to the birth of the newborn, which was administered by PHM to the mother during the first post partum visit. Information related to childbirth, any complications in the newborn and on any medical conditions that the mother may have developed during the last weeks of pregnancy up to the delivery were collected. Available records were the main sources of information.

Questionnaire 4B aimed to collect information from the mothers who experienced either an abortion or a still birth, by the PHM.

**Training of personnel**

The principal investigator was trained in performing USG by a consultant obstetrician. A pre-intern medical officer was trained as the research assistant and all PHMs of the two study areas were trained in field level data collection. All staff of the labour rooms of the five hospitals where deliveries took place was re-trained in taking the measurements of the newborn.

**Method of data collection**

Informed written consent was obtained from each mother. USG was performed by the same investigator using the same instrument. Data collection took place both at the clinics and at the field level as mentioned earlier. All the steps in the data collection process were supervised. Electronic SECA scales and length measuring boards were provided to all labour rooms. Accuracy of the scales was checked with standard weights once in 3 months
as instructed by the manufactures. Birth weights were obtained within one hour of birth using the SECA scales.

Ethical approval was obtained from the Ethics Review Committee of the Faculty of Medicine, University of Colombo. Data entry files were designed using EPI INFO software and analysis was made using IBM SPSS Statistics (Statistical Package for Social Sciences) version 15.

RESULTS

Records related to births were available for all 1200 mothers. Of them, only 474 (39%) mothers could be included in this assessment as 726 (61%) of them had one or more risk conditions. The common risk conditions could be broadly grouped as those related to poor nutritional status (anaemia, low body weight index [BMI], etc.) and medical (e.g., hypertension, diabetes) and other pregnancy-related conditions. All mothers were followed up throughout pregnancy and during delivery by the research team and by the field health staff as is the usual practice.

Records of these 474 mother/newborn pairs were grouped according to sex of the newborn and POG at delivery using the USG as the basis of assessment. In each group, the mean birth weight, standard deviation and the centile values were calculated [Table 1a and b]. Number of mothers in the two extreme groups (<38 and >40 weeks) was less than 30 each, hence the centile values were not calculated, as their validity was considered to be low.

Among the male newborns, the mean birth weights at POG 38, 39 and 40 were used to develop the curve [Figure 1]. Similarly, among the female newborns, the mean birth weight values of POG 39 and 40 were used to develop the curve [Figure 2]. The charts were drawn using Microsoft Excel 2007 software. The limited number of newborns in each POG category resulted in a relatively smooth curve, thus not requiring the use of special software.

The incidence of SGA was calculated by assessing the number of newborns with birth weights lower than the 10th centile value for each POG for each sex, as a percentage of the total sample of newborns (938) with POG 38-40 weeks. There were 100 SGA male singleton newborns giving a SGA rate of 19% and with the comparable figure among female singletons being 18%. Among the babies who had birth weights more than 2500 g, 11.6% were classified as SGA [Table 2].

Two main patterns are identified in Intra Uterine Growth Restriction (IUGR), namely, symmetrical and asymmetrical.[11] The pathogenesis and the consequences of the two types are different as described by several authors.[12,13] This differentiation is made by using the Ponderal Index.[11]

Ponderal Index = Birth weight in grams/(Birth length in cm)$^3 \times 100$

Cut-off value for asymmetrical SGA was 2.4.[14]

There were 136 newborns in whom both SGA and length details were available and were identified as SGA, 72.1% were identified as those with asymmetrical SGA and 27.9% as symmetrical.

DISCUSSION

Since 1963, when Lubchenco developed the weight for gestational age curves, attempts were made in many countries to develop such curves, for use in assessing gestational age-related birth weight.[15] In most developing countries, SGA contributes to the larger portion of LBW babies.[7] This may be due to inadequate focus on programmes aimed at reducing country-/region-specific risk factors. Thus, development of country-specific gestational age curves and identification of the specific risk factors is of importance.

### Table 1: Centile values

<table>
<thead>
<tr>
<th>POG (Weeks)</th>
<th>N</th>
<th>B. Wt (g) Centile</th>
<th>Mean (g)</th>
<th>SD (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>a) For male singletons</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>37</td>
<td>8</td>
<td>2250</td>
<td>2942</td>
<td>3130</td>
</tr>
<tr>
<td>38</td>
<td>44</td>
<td>2680</td>
<td>2997</td>
<td>3467</td>
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<td>39</td>
<td>58</td>
<td>2650</td>
<td>3060</td>
<td>3535</td>
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<tr>
<td>40</td>
<td>116</td>
<td>2580</td>
<td>3037</td>
<td>3600</td>
</tr>
<tr>
<td>41</td>
<td>12</td>
<td>3090</td>
<td>3490</td>
<td>3900</td>
</tr>
<tr>
<td></td>
<td>b) For female singletons</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>37</td>
<td>14</td>
<td>2240</td>
<td>2520</td>
<td>3250</td>
</tr>
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<td>38</td>
<td>16</td>
<td>2185</td>
<td>2820</td>
<td>3150</td>
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<tr>
<td>39</td>
<td>70</td>
<td>2550</td>
<td>3025</td>
<td>3385</td>
</tr>
<tr>
<td>40</td>
<td>116</td>
<td>2800</td>
<td>3180</td>
<td>3600</td>
</tr>
</tbody>
</table>

### Table 2: Small for gestational age in singleton pregnancies by sex and POG

<table>
<thead>
<tr>
<th></th>
<th>SGA</th>
<th>Non-SGA</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Males</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POG 38 weeks</td>
<td>26</td>
<td>80</td>
<td>106</td>
<td>100.0</td>
</tr>
<tr>
<td>POG 39 weeks</td>
<td>44</td>
<td>116</td>
<td>160</td>
<td>100.0</td>
</tr>
<tr>
<td>POG 40 weeks</td>
<td>30</td>
<td>230</td>
<td>260</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>426</td>
<td>526</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>Females</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POG 39 weeks</td>
<td>14</td>
<td>114</td>
<td>128</td>
<td>100.0</td>
</tr>
<tr>
<td>POG 40 weeks</td>
<td>60</td>
<td>224</td>
<td>284</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>74</td>
<td>338</td>
<td>412</td>
<td>100.0</td>
</tr>
<tr>
<td>Grand total</td>
<td>174</td>
<td>764</td>
<td>938</td>
<td>100.0</td>
</tr>
</tbody>
</table>
This study used a longitudinal approach where a sample of mothers was identified early with an accurate assessment of the POG using USG. Assessing POG accurately using USG is not a routine activity in antenatal clinics in many developing countries including Sri Lanka. This poses limitations in using routine data from hospital settings in developing weight for gestational age charts. In this attempt to develop birth weight for gestational age charts, all information on the risk conditions for LBW had to be collected using specially developed study instruments, by trained investigators. They were followed up until delivery at identified hospitals. Use of cross-sectional methods to develop weight for gestational age charts, although more feasible, poses problems related to the ascertainment of the POG and other risk factors.

Obtaining accurate assessment of the birth weight is crucial in this type of study and this was facilitated by training, supervision of staff and provision of SECA digital weighing scale to labour rooms of all relevant hospitals. Such scales have been used in many studies.[16]

The main limitation encountered in developing the curves was the limited numbers from whom data could be used. Among the mothers on whom birth data were available, 61% had factors that could influence birth weight, hence were not included in the development of the curves.

Most studies that have focused on developing such curves have used data from large national level databases or had based them on data from samples of mothers recruited over a period of 5 years or more.[15,17] Some have used data collated from a number of small scale studies.[18]

In this study that used a longitudinal approach to develop gestational age-related birth weights, USG was performed on all mothers at a POA of 10-12 weeks as specified in the inclusion criteria. Ensuring adequate follow up with minimal ‘drop out’ rates and obtaining accurate measurements on the other key variable, birth weight required a detailed follow up and frequent assessment of the accuracy of the weighing instruments used.

The main limitation of our study was the inability to develop gestational age-related birth weight curves for POG less than 38 and more than 40 weeks. From the experience gained, it is clear that a larger number of mothers had to be enrolled into the study to enable such an assessment, which could not be done. However, since
the vast majority of births occur between 37 and 41 weeks, the chart that has been developed would still be useful as an indicator of the status of growth of these babies. Even with this limitation, the SGA charts developed are useful to be used within a country for categorizing LBW newborn children as belonging to the SGA or non-SGA group, to identify risk factors for developing appropriate interventions to reduce LBW rates. Even though the prevalence of LBW in Sri Lanka has remained at 15-18% over the past decade, non-availability of SGA charts has been a limitation in identifying the prevalence of the two types of LBW to develop appropriate interventions. This study fills this void and hence makes a valuable contribution to the knowledge required for prevention of LBW.

**CONCLUSIONS**

The charts reported in the study, despite limitations, could be used for assessment of incidence and risk factors for SGA until such time that charts based on national level data are available.

**ENDNOTE**

1. The field level administrative unit responsible for provision of preventive health services.

2. Previous studies have estimated that the coverage of registration of pregnant women by PHMs is over 95%.

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Assessing compliance to smoke-free legislation: results of a sub-national survey in Himachal Pradesh, India

Ravinder Kumar, Gopal Chauhan, Srinath Satyanarayana, Pranay Lal, Rana J. Singh, Nevin C. Wilson

ABSTRACT

Introduction: Exposure to second-hand smoke (SHS) is a serious public health concern. The Indian smoke-free legislation ‘Prohibition of Smoking in Public Places Rules, 2008’ prohibits smoking in public places, including workplaces.

Objective: To measure the status of compliance to legal provisions that protects the public against harms of SHS exposure, identifies the potential areas of violations and informs policy makers for strengthening enforcement measures.

Design: A cross-sectional survey in 1401 public places across 11 district headquarters in Himachal Pradesh, India, using a compliance guide developed by partners of the Bloomberg initiatives to reduce tobacco use.

Results: In 1401 public places across 11 district headquarters, 42.8% public places had signage; in 84.2% public places, no smoking was observed and in 83.7%, there was absence of smoking accessories such as ashtray, matchbox and lighter. Tobacco litter like cigarette butts was absent in 64.7% of the public places. Overall, at the state level, there was more than 80% compliance on at least three of the five indicators. Among all categories of public places, educational institutions and offices demonstrated highest compliance, whereas most frequently visited public places, eateries and accommodation facilities had least compliance.

Conclusions: The compliance to ‘Prohibition of Smoking in Public Places Rules, 2008’ was variable in various district headquarters of Himachal Pradesh. This study identified the potential areas of violations that need attention from enforcement agencies and policymakers.

Key words: Cigarettes and other tobacco products act, jurisdiction, public places, smoke-free

INTRODUCTION

Tobacco use is the single most preventable cause of premature adult death. There are more than one billion smokers globally, who can potentially expose all others to second-hand smoke (SHS). More than 80% of the world’s smokers live in low- and middle-income countries. It is now unequivocally established that exposure to SHS is as harmful as active smoking and causes death, disease and disability. Every year, exposure to SHS causes over 600 000 premature deaths worldwide.

India has a high prevalence of exposure to SHS. About 29.9% adults of age ≥15 years are exposed to SHS in workplaces, 52.3% at home and 29% at public places. India enacted a comprehensive legislation in May 2003 for tobacco control called as the Cigarettes and Other Tobacco Products Act (COTPA). Section 4 of COTPA prohibits...
smoking in public places, public transport, workplaces and all other places accessible to public.\textsuperscript{[5]}

With respect to protecting the public from SHS, the emphasis, globally, has been on the enforcement of appropriate legislation. A Cochrane Review of 50 studies from developed countries confirms that legislation when enforced can effectively reduce SHS exposure, especially at workplaces and public places.\textsuperscript{[6]}

In the context of developing countries like India, enactment of legislation is not sufficient to stop smoking in public places. India’s experiences in enforcing public health laws has been dismal.\textsuperscript{[7]} In India, four jurisdictions were declared smoke-free based upon a locally adopted tool in May 2010.\textsuperscript{[8]}

According to Global Adult Tobacco Survey,\textsuperscript{[4]} smoking prevalence in Himachal Pradesh is lower than the national average, but exposure from SHS is high. In all district headquarters, rigorous enforcement of the provisions of COTPA has been instituted after gaining political and administrative support and after creating awareness among the public. This study measured the compliance to legal provisions that protect the public against harms of SHS exposure and identifies areas of violations, where enforcement needs to be strengthened. This study also demonstrates the feasibility of administering a simple, cost-effective method for assessing compliance that can inform enforcers and policymakers.

\section*{MATERIALS AND METHODS}

\textbf{Study design and setting}

A cross-sectional survey was designed using a protocol developed by the Bloomberg Initiative to Reduce Tobacco Use and its partners (which include Campaign for Tobacco-Free Kids, Johns Hopkins Bloomberg School of Public Health and International Union Against Tuberculosis and Lung Disease).\textsuperscript{[9]} The survey was conducted on 19-28 May 2011 in the State of Himachal Pradesh (population 6.8 million; area 55,673 km\textsuperscript{2}), India, which comprises 12 districts. There is a high-level of political and administrative commitment for tobacco control in the State, which declared its capital and district headquarters, Shimla smoke-free in 2010.\textsuperscript{[10]} This survey was conducted to measure compliance in advancing smoke-free in the 11 (other) district headquarters of the State.

\textbf{Sampling methodology}

This survey measured compliance of smoke-free status in public places. Public places are defined under COTPA.\textsuperscript{[5]}

To identify public places within district headquarters, a list of all public places (except public transport) within municipal jurisdiction was obtained from district authorities. For the purpose of the surveys, the public places were grouped into seven broad categories, namely, educational institutions, accommodation facilities, eateries, offices, healthcare facilities, other 'most frequently visited public places' and public transport. The investigation team also prepared a list of public places that may not have been registered or reported under local municipal authorities. The list of public transport facilities was prepared during the field visit at major bus and taxi stands at the time of survey. The final list was developed after triangulation of these lists. Category-wise sample size was determined using the range prescribed by the compliance guide.\textsuperscript{[9]} In all 1401 public places in district headquarters were selected through a simple random sampling method [Table 1].

\textbf{Study tool}

An observational checklist was adapted from the compliance guide\textsuperscript{[9]} and was pilot tested in Kusumpati sub-town of Shimla city. Five criteria were adapted from the guide, which conform to the smoke-free provisions of COTPA as key to measure compliance. These included the following:

1. Presence of no smoking signage: Any pictorial, graphical or textual message displayed in a public place, which warns that smoking is prohibited in a public place, was recorded as a signage. Each signage was further tested for compliance with specifications,
as prescribed by COTPA for size, textual content, colour, font and design\(^{[11]}\).

2. Absence of active smoking: At the time of observation.
3. Absence of smoking aids: Smoking aids like ashtrays, matchboxes and lighters are a proxy indicator that smoking is permitted in that public place; its absence indicates that smoking is not encouraged.
4. Absence of odour emanating from cigarette or bidi: An indirect evidence of no (recent) smoking in that public place.
5. Absence of cigarettes butts or bidi ends: An indicator suggesting that smoking has not taken place in recent times.

### Investigation team

Four teams comprising four trained field investigators were designated by the Directorate of Health Service to undertake and complete the survey at district headquarters level. Field investigators were trained to observe violations and to record these on the checklist. Errors and omissions made in the recording were discussed and further clarified to field investigators. The checklist was also refined after the field training based on comments of investigators to improve recording observations.

### Data collection

Public places were observed during the peak visiting hours as per the compliance guide.\(^{[9]}\) Photographs were taken as an additional evidence of potential or actual violations. Observations were made for 7-10 min in each public place and recorded within the checklist after exiting the premises, but before beginning the process for the next observation. During the field surveys, the principal investigator visited at least 25\% of the observed public places in every district headquarters, along with field investigator to verify and validate the recordings.

### Data analysis

Data were collected, triangulated and entered at district headquarters level; 10\% of observation checklists were randomly selected and cross-checked to detect any error and validate the data entry. District-wise and category-wise data analysis was done using Epi Info 3.5.3 (Centers for Disease Control and Prevention, Atlanta, United States of America).\(^{[12]}\)

### Ethical approval

The survey protocol was reviewed and approved by the Department of Health and Family Welfare, Government of Himachal Pradesh. In public places with restricted entry (like schools, hotel rooms, offices), verbal and prior informed consent was taken from the in-charge. The data were coded and confidentiality of details was maintained.

### RESULTS

There was significant variation in signage display across district headquarters (17\% in Solan to 89\% in Keylong). In Keylong and Chamba, the signage conformed to COTPA specifications (text, size and design) as compared with other district headquarters [Table 2].

Despite showing low coverage of signage in districts, these districts offered high levels of protection (e.g. Kullu and Solan in Table 2). However, these districts performed variably on other criteria for compliance.

Among all categories, educational institutions had the least signage display (26.6\%), while offices had the highest (62.2\%), but both of these had least active smoking (97.2\% and 95.9\%, respectively) [Table 3]. Therefore, the correlation between display of signage and absence of active smoking is not clearly established. Public places like eateries and accommodation facilities having moderate signage display show relatively higher incidence of active smoking. Furthermore, ‘most frequently visited public places’ had the second highest percentage of signage display, yet highest violation were observed in terms of active smoking in these places.

### Table 2: District wise results of the smoke-free compliance survey in Himachal Pradesh, India

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Bilaspur (n=107)</th>
<th>Mandi (n=148)</th>
<th>Kullu (n=122)</th>
<th>Chamba (n=133)</th>
<th>D/ShaLa (n=153)</th>
<th>Hamirpur (n=136)</th>
<th>Una (n=132)</th>
<th>Nahan (n=136)</th>
<th>Solan (n=153)</th>
<th>Keylong (n=88)</th>
<th>Recong-PeO (n=93)</th>
<th>Total N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. and percentage of public places displaying signage</td>
<td>41 (38.03)</td>
<td>33 (22.3)</td>
<td>24 (19.7)</td>
<td>103 (77.4)</td>
<td>70 (45.8)</td>
<td>55 (40.4)</td>
<td>42 (31.8)</td>
<td>75 (55.1)</td>
<td>27 (17.6)</td>
<td>79 (89.8)</td>
<td>51 (42.8)</td>
<td>600 (%)</td>
</tr>
<tr>
<td>No. and percentage of public places observing no-active smoking</td>
<td>87 (81.3)</td>
<td>113 (76.4)</td>
<td>111 (90.9)</td>
<td>123 (92.5)</td>
<td>117 (76.4)</td>
<td>112 (82.3)</td>
<td>117 (88.6)</td>
<td>107 (88.2)</td>
<td>107 (82.9)</td>
<td>73 (84)</td>
<td>84 (90.3)</td>
<td>1179 (%)</td>
</tr>
<tr>
<td>No. and percentage of public places with no-smoking aids</td>
<td>86 (80.3)</td>
<td>123 (83.1)</td>
<td>105 (86.1)</td>
<td>114 (85.7)</td>
<td>107 (69.9)</td>
<td>111 (84.5)</td>
<td>122 (92.4)</td>
<td>125 (91.9)</td>
<td>135 (88.2)</td>
<td>74 (80.7)</td>
<td>71 (79.5)</td>
<td>1173 (%)</td>
</tr>
<tr>
<td>No. and percentage of public places with absence of odour from cigarette or bidi</td>
<td>73 (68.2)</td>
<td>111 (75.0)</td>
<td>109 (89.3)</td>
<td>117 (87.9)</td>
<td>119 (77.8)</td>
<td>110 (80.8)</td>
<td>114 (86.3)</td>
<td>124 (91.0)</td>
<td>133 (81.8)</td>
<td>72 (88.2)</td>
<td>82 (93.1)</td>
<td>1164 (%)</td>
</tr>
<tr>
<td>No. and percentage of public places with no cigarettes or bidi butts found</td>
<td>63 (58.9)</td>
<td>108 (73.0)</td>
<td>72 (59.0)</td>
<td>70 (52.6)</td>
<td>111 (72.5)</td>
<td>91 (66.9)</td>
<td>60 (45.5)</td>
<td>116 (85.3)</td>
<td>130 (85.0)</td>
<td>44 (50.0)</td>
<td>42 (45.2)</td>
<td>907 (%)</td>
</tr>
</tbody>
</table>
All healthcare facilities also showed low signage display in comparison to other public places, yet there was a moderately high compliance to the act of smoking, which was verified with the absence of smoking aids, smell of tobacco smoke or tobacco litter.

Public transport facilities had a moderate level of signage (49%) and showed comparatively higher levels of compliance to all criteria.

**DISCUSSION**

This study confirms that signage display is currently inadequate and that more efforts are needed to cover public places within the districts of the state. Signage display was >90% in previously conducted studies in four Indian jurisdictions and another jurisdiction in north India. Similar results were seen in compliance surveys done in developed countries such as Ireland, Scotland and Ontario city, where there has been a high level of enforcement leading to high compliance. However, the mere presence of signage does not necessarily translate into protection from SHS. The districts headquarter Solan showed the least signage (17.6%), but a better compliance in no-active smoking (88.2%) than the district headquarter Keylong with highest signage display and relatively low compliance to no-active smoking. In fact, there are other factors that come into play, including increased public awareness, earned media support and strong enforcement of law, which contributes towards better compliance to no-active smoking. The present study had notably less compliance in terms of absence of active smoking than in the previously declared Indian jurisdictions.

Active smoking was found to be variable within and across the districts. Districts per se had variable numbers of public places and by type, therefore such variance is expected. Furthermore, ‘most frequently visited public places’ had the second highest percentage of signage display, yet had the highest violation in term of active smoking. ‘Most frequently visited places’ were difficult to monitor since they did not have clearly identified enforcement authority or manager and hence compliance and reporting of violations were expected to be low. In terms of overall compliance, our results are similar to those reported in an earlier compliance study from Mohali district in India.

Minimal signage display and least violations *in toto* in educational institutions suggests that smoking and perhaps tobacco use are confined by the type and nature of the public place and may be attributed to greater awareness among visitors to this public place. Increased public awareness appears to have improved compliance on all criteria despite moderate level of signage in public transport system. Public places like eateries (restaurants and bars) and accommodation facilities (hotels and lodges) had very high violations in nearly all indicators. Our data are in agreement with another study from Latin America, which reported higher levels of airborne nicotine level in bars/restaurants in comparison with that in educational institutions.

**CONCLUSIONS**

The findings of this study have wider implications for implementation of smoke-free legislation in India. While display of signage in public places conveyed the effectiveness of the tobacco control initiatives (of the State), good compliance in term of prescribed signage is essential for enforcement. The study identified the potential areas of violations that needs attention from enforcement agencies and policy makers. Sustained awareness campaigns, backed by enforcement drives, followed by periodical compliance surveys using simple methods that prioritize additional attention and revising strategies will strengthen implementation of smoke-free legislation in Himachal Pradesh and perhaps in other parts of India.
ACKNOWLEDGMENTS

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Growth parameters at birth of babies born in Gampaha district, Sri Lanka and factors influencing them

Priyantha J. Perera, Nayomi Ranathunga¹, Meranthi P. Fernando, Tania D. Warnakulasuriya², Rajitha A. Wickremasinghe³

ABSTRACT

Background: Growth parameters at birth are important for clinical decision-making. In Sri Lanka, the data from the World Health Organization (WHO) Multicentre Growth Reference Study (MGRS) are used to interpret these measurements.

Materials and Methods: A descriptive cross-sectional study was conducted between September and October 2010 in hospitals of Gampaha district, Sri Lanka. The weight, length and head circumference of all normal-term babies born in the Gampaha district during this period were measured within 8 h of birth using standard techniques. Measurements were taken by medical graduates trained and supervised by a consultant paediatrician. Socio-demographic data were obtained using an interviewer-administered questionnaire.

Results: Of the 2215 babies recruited, 1127 were males. The mean birth weight, mean length and mean head circumference at birth were 2.92 kg, 49.1 and 33.6 cm, respectively. Boys weighed and measured more than girls in all parameters, but the differences were not statistically significant. Growth parameters of babies included in this study deviated from that in the MGRS data. Mean values of MGRS data were between 75th and 90th centiles of this study population. Birth order, family income and maternal education were significantly (P < 0.01) associated with growth parameters. Contrary to common belief, growth parameters continued to increase progressively up to 41 weeks. Maternal age less than 20 years or more than 35 years was negatively associated with birth weight (P < 0.01).

Conclusions: Growth parameters of new-born babies deviated significantly from the values of the MGRS data. Growth characteristics of one population may not be applicable to another population due to variations in maternal, genetic and socio-economic factors. Using growth charts not applicable to a population will result in wrong interpretations.

Key words: Birth weight, growth parameters, head circumference, length, new born, Sri Lanka

INTRODUCTION

Growth parameters at birth depend on intrauterine growth, which is affected by many factors such as intra-uterine environment, physical and mental well-being of the mother, maternal nutrition and genetic factors.[1] The weight, length and head circumference of babies are measured at birth in view of their clinical significance. Small for gestational age (SGA) remains one of the most important predictors of the outcome of the babies’ health.[2] SGA is commonly defined as a baby with birth weight less than 10th centile for a given gestational age.[3]
SGA babies are divided as symmetrically or asymmetrically growth-restricted babies, depending on their length and head circumference. This distinction has practical implications, as complications expected in these two categories of babies are different. For a meaningful interpretation of growth parameters, it is important that appropriate reference standards are available for comparison. At present, growth charts developed by the World Health Organization (WHO), based on results of a Multicentre Growth Reference Study (MGRS), are used in Sri Lanka. However, MGRS included children brought up under optimal conditions and reflects growth patterns of babies with maximum growth potentials. MGRS was based on the theory that growth of children from birth to 5 years depends mainly on nutrition, feeding practices, environment and healthcare without consideration of other factors such as genetics or ethnicity.

Two previous studies have been conducted in Sri Lanka to determine the average birth weight, but none focused on all three growth parameters. One study performed in the Mawanella area, in the Kegalle district, had a small sample size, while the other study performed in the Gampaha district had a large sample size but the weights were measured by ward staff. Measurements taken by ward staff in this study were not supervised or verified for accuracy.

The present study was conducted to determine the growth parameters at birth for a cohort of Sri Lankan children and to assess the accuracy of using MGRS data to interpret growth of Sri Lankan children. Factors influencing growth parameters at birth were also studied.

**MATERIALS AND METHODS**

**Study setting**
Sri Lanka is a low-middle income country, with impressive health statistics such as a maternal mortality ratio of 33.4 per 100 000 live births and a neonatal mortality rate of 10 per 1000 live births. More than 99% of deliveries take place in hospitals. Sri Lanka is divided into 25 administrative districts and Gampaha district is the second most populous district with an estimated mid-year population of 2,066,096, which is approximately 12% of the total Sri Lankan population. Gampaha district had 9.2% of poor households in 2002. There are four large government hospitals and many private hospitals within the district, but only six private hospitals have facilities for obstetric care at delivery. Antenatal care to pregnant mothers is provided by many antenatal clinics scattered throughout the district, but delivery of babies take place mainly in the above-mentioned hospitals.

**Study design**
This was a descriptive cross-sectional study conducted between September and October 2012. All four large government hospitals and the six private hospitals referred earlier were selected for the study.

**Subject selection**
Permission to conduct the study was obtained from health authorities of the district and the heads of the hospitals where the study was conducted. All babies born in these hospitals during the study period, following a period of gestation (POG) of ≥37 weeks, were recruited in the study. Babies with uncertain POG, antenatally diagnosed intrauterine growth restriction, chromosomal abnormalities and major congenital abnormalities were excluded from the study. Babies of mothers who had diabetes mellitus, hypertension, multiple pregnancies or any other major medical problem were also excluded.

**Data collection**
The weight, length and head circumference were measured within 8 h of birth. Standardized beam balance scales were used to measure birth weight. Scales were standardized weekly during the study period. Weight was recorded to the second decimal in kilograms. Foldable infantometers were used to measure the body length using standard techniques. Two investigators were assigned to each of the large government hospital; one investigator positioned the baby correctly and the other took the measurement. Occipital-frontal circumference (OFC) was measured using a non-stretchable, plastic tape using standard techniques. In babies with significant moulding and caput succedaneum, measurement of OFC was delayed until they settled. OFC and length were recorded to the first decimal in centimetres.

Data collection was done by trained medical graduates. The training including measuring growth parameters and data collection was conducted by the principal investigator.

**Data analysis**
Descriptive statistics and frequency tabulations were generated using IBM SPSS Statistics version 16. Independent sample t-test and analysis of variance (ANOVA) were used to compare means.

**Ethical issues**
Ethical approval to conduct the study was obtained from the Ethical Review Committee of the Faculty of Medicine, University of Kelaniya. Informed written consent was obtained from the mothers to include their babies in the study. Aseptic precautions were taken during handling of babies. Babies who were found to have any problems were referred for appropriate action.

**RESULTS**

Of the 2215 babies (1127 males and 1088 females) included in the study, 80 were born in private hospitals and the rest in government hospitals. Parents of 166 babies...
were resident outside the Gampaha district. All babies born during the study period who fulfilled the inclusion criteria were recruited into the study, except for eight whose mothers refused consent.

As expected with large numbers, birth weight, length, and head circumference were normally distributed.

The mean birth weight of all babies was 2.93 kg, while the mean length was 49.1 cm and the mean head circumference was 33.6 cm. All three parameters were higher in boys, but the differences between the sexes were not statistically significant [Table 1].

Birth weight ranged 1.89-4.25 kg for boys and 1.89-4.20 kg in girls. The range of birth length was 41.0-53.2 cm for boys and 40.7-53.0 cm for girls. The range of head circumference was 30.1-36.2 cm for boys and 30.0-36.1 cm for girls. The growth parameters at birth by sex are summarized in Table 1.

Variation in growth parameters at birth by selected socio-economic characteristics are given in Table 2. Birth weight increased with an increase in family income (P < 0.001). The majority of mothers were not employed. The employment status of the mother was not associated with growth parameters at birth. The majority of mothers were educated up to grades 6-11. Both birth weight (P < 0.001) and head circumference (P = 0.002) increased with an increase in maternal education.

Growth parameters at birth by selected maternal factors are summarized in Table 3.

Up to the 34 years of age, all three growth parameters at birth were positively correlated to maternal age; however, birth weight was the only significant parameter (P < 0.001). Beyond 35 years, growth parameters decreased with age.

The mean birth weight of babies born to teenage mothers (mothers <20 years) was significantly lower (P < 0.001) than the mean birth weight of babies born to mothers ≥20 years (2.78 kg vs. 2.93 kg). The length of babies born to teenage mothers at birth was significantly less than that of babies born to mothers >20 years of age (P = 0.024) [Table 3].

Fifty-eight percent of the babies were born following a POG of >39 weeks. All three growth parameters increased with advancing POG (P < 0.001). The second and higher-order children were heavier than the first-born children (P < 0.001) [Table 3].

The 10th centiles of the study population for birth weight, length, and head circumference were 2.45 kg, 46.4 and 32.2 cm for males and 2.39 kg, 45.9 and 32.0 cm for females,

### Table 1: Growth parameters at birth by sex

<table>
<thead>
<tr>
<th></th>
<th>Entire sample (n=2215)</th>
<th>Males (n=1088)</th>
<th>Females (n=1127)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Weight (kg)</td>
<td>Length (cm)</td>
<td>Head circumference (cm)</td>
</tr>
<tr>
<td>Mean</td>
<td>2.93</td>
<td>48.5</td>
<td>33.6</td>
</tr>
<tr>
<td>Median</td>
<td>2.90</td>
<td>48.5</td>
<td>33.5</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>0.40</td>
<td>2.0</td>
<td>1.1</td>
</tr>
<tr>
<td>3rd centile</td>
<td>2.20</td>
<td>44.7</td>
<td>31.3</td>
</tr>
<tr>
<td>10th centile</td>
<td>2.42</td>
<td>46.0</td>
<td>32.0</td>
</tr>
<tr>
<td>25th centile</td>
<td>2.65</td>
<td>47.1</td>
<td>32.9</td>
</tr>
<tr>
<td>50th centile</td>
<td>2.90</td>
<td>48.5</td>
<td>33.5</td>
</tr>
<tr>
<td>75th centile</td>
<td>3.20</td>
<td>50.0</td>
<td>34.4</td>
</tr>
<tr>
<td>90th centile</td>
<td>3.47</td>
<td>51.3</td>
<td>35.0</td>
</tr>
<tr>
<td>97th centile</td>
<td>3.71</td>
<td>52.1</td>
<td>35.5</td>
</tr>
</tbody>
</table>

1 US$ = SL Rs 115.00 (at time of study)
respectively. In this study, 29%, 22% and 17% of children fell below the 10th centiles of the MGRS for birth weight, length and head circumference. Similarly, 1%, 3% and 1% of babies of this study were >90th centile of the MGRS for birth weight, length and head circumference [Table 4].

Table 5 gives the classification of babies by the centiles of the MGRS study and the centiles of this study. Based on the centiles of this study, 378 babies had at least one parameter below the 10th centile. Based on the MGRS study, 828 babies had at least one parameter below the 10th centile.

All three growth parameters at birth were higher in boys than in girls, as in previous studies,[4] but the differences were not statistically significant. As with most biological parameters with large samples, birth weight, length and head circumferences were normally distributed in boys, girls and in the total sample. In the MGRS, the mean birth weights for boys and girls were 3.3 and 3.2 kg, respectively, as compared with 2.97 kg and 2.89 kg for boys and girls in this study. In this study population, the mean birth weights of 3.3 kg for boys and 3.2 kg for girls in the MGRS study fell between the 75th and 90th centiles. The mean length of both boys (49.8 cm) and girls (49.1 cm) and the mean head circumference of girls (33.8 cm) in the MGRS was between the 50th and 75th centiles of these parameters in this study.

As there is a wide discrepancy between data from MGRS and this study, it can be postulated that using MGRS data to interpret growth parameters of Sri Lankan babies at birth is inappropriate, as it may result in an underestimation of growth. Results of this study highlight the importance of each country to have its own growth charts to interpret growth parameters, rather than relying on growth charts based on a different population.

Our data are similar to previous studies performed in Sri Lanka.[5,6]

When growth charts are developed, the children with maximum growth potentials are considered. In this study, babies with any condition that influence intrauterine growth were excluded. Therefore, growth parameters described in this study are for normal-term babies of the Gampaha district of Sri Lanka. By including babies born in private hospitals, babies of a higher socio-economic stratum in the community were also included. The Gampaha district ranks second out of all districts of Sri Lanka with regard to socio-economic status of the population.[10] As socio-economic factors play a significant role in determining the growth parameters at birth, the values for the entire country would probably be less than those reported here.

New-born babies who are SGA and large for gestational age (LGA) can have many complications. SGA babies...
with asymmetric growth retardation are more prone to hypoglycaemia than symmetrically growth-retarded babies. The diagnosis of SGA and LGA are based on the 10th and 90th centile weights for a given sex and gestational age, respectively. A baby with a birth weight below the 10th centile, but with a length and OFC > 10th centile is considered asymmetrically growth retarded. Serious errors may occur if inappropriate growth standards are applied for a given population. Based on the centiles of this study population, 378 babies were below the 10th centile of at least one parameter. If the MGRS study centiles are used, 828 babies lie below the 10th centile of at least one parameter. The additional 450 babies, which need to be followed-up with special attention if the MGRS cut-off values are considered, is an additional burden on the existing low-resource settings. Besides, these babies may in fact not require additional care.

Mother’s employment status was not associated with growth parameters at birth. Mother’s employment status may have both positive and negative influences on pregnancy. Sleep deprivation, shift work, travelling, physical and mental stress can have a negative effect on foetal growth. In contrast, employed females are more likely to be better educated, have a higher family income and belong to higher socio-economic stratum.

Birth weight was higher in the second- and higher-order children as compared with the first-born children. It is difficult to explain exactly why the second-order babies had higher growth parameters than the first-born ones. A possible explanation is that a female is more knowledgeable about pregnancy and is probably more aware of the importance of antenatal care and thus more likely to seek antenatal care in the second pregnancy compared with the first one.

In Sri Lanka, it is a common practice, especially in the private sector, to deliver babies electively after completion of 37 weeks of POG, by caesarean section for social reasons. The main reason is the belief in auspicious times. This practice is based on the belief that foetal growth has attained its maximum by 37 weeks of gestation. Our results show that all three growth parameters continue to increase until 41 weeks of gestation. By delivering babies electively after 37 weeks of POG, without a definite indication, deprives the baby of growing to its maximum potential before birth.

Conclusions and recommendations
The mean weight, length and OFC at birth of babies in this study population are significantly lower than for babies in the MGRS study. We showed that an additional burden of 450 babies out of 2215 can be misclassified as requiring specialized care if MGRS data are used. This would increase the burden on the already low-resourced health system. In addition, trying to improve the nutritional state of normal babies misclassified as poorly nourished may in fact be detrimental, as the risk of metabolic syndrome is higher when children are overfed to achieve a higher growth centile than their genetic potential. In addition, a significant number of overweight children will be missed by using the findings of the MGRS, as we may be pushing our children to the point of being overweight by using the growth charts provided by the MGRS. Therefore, it would be better if Sri Lanka has its own growth charts so as to carry out meaningful growth monitoring. Birth order, family income, POG and maternal education had significant effects on growth parameters at birth. Maternal age less than 20 years or more than 35 years had a significant negative effect, especially on birth weight.

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Integration of leprosy services into the General Health Service in Sri Lanka: overcoming challenges to implementation in a remote district

Thushanthi S. Wijesinghe, Pushpa Ranjan Wijesinghe

ABSTRACT

Sri Lanka took a policy decision to integrate leprosy services into the general health services (GHS) in 1999. This paper aims to summarize the emergence of new, specific challenges and how they were overcome during the integration of leprosy services to the GHS in a remote, leprosy endemic district in Sri Lanka. In this article, the regional epidemiologist as the team leader describes the principles used for transition to an effective integrated model of leprosy services from a centralized leprosy control model in the district. In addition, rationale for integration is viewed from the epidemiological and operational perspectives. National and district leprosy epidemiological data from secondary sources are also reviewed for corroborating the effectiveness of integration. Challenges surfaced were mainly related to the transfer of ownership of the programme, selection of appropriate service providing institutions easily accessible to clients, sustainability of leprosy services at the GHS, ensuring participation of all stakeholders in capacity building programmes and co-ordination of patient care in the absence of a dermatologist in the district. An empowered district team leader with specified roles and responsibilities, his sound technical and managerial know how and ability to translate ‘team work’ concept to practice were found to be essential for successful implementation of integration. Decision-making powers at the district level and flexibility to introduce new, area-specific changes to the centrally prepared core activities of integration were also vital to overcome locally surfaced challenges.

Key words: Access, challenges, integration, leprosy, sustainability

INTRODUCTION

In the integration of leprosy services, case-finding, treatment, disability care and rehabilitation closer to the community become the responsibility of general health services (GHS).\(^1\) Policy making, planning, training, supervision and dealing with referrals are retained at specialized, intermediary and national levels.\(^2,3\) Integration improves community awareness, case-finding, access and regularity of treatment.\(^4\) Additionally, delivery of services at non-specialized units gradually decreases society’s negative perception of the disease and affected persons.\(^2,5\)

Several countries have translated integration into a reality.\(^6,7\) Transition from a specialized campaign to an integrated service is complex.\(^8\) Although problems arose due to inadequate planning in some countries,\(^9,10\) good preparation and meticulous planning addressed specific challenges in Sri Lanka.\(^8\) However, due to varying
operational and logistic issues, some unanticipated, local challenges emerged in different districts. We describe how we overcame these challenges in Polonnaruwa district during integration.

**PRE-INTEGRATION LEPROSY SERVICES**

Segregation of leprosy patients was initiated by Dutch colonialists and made compulsory by the British through the Lepers ordinance in 1901. Given the socio-economic impact of leprosy, a leprosy control plan was formulated. Subsequently, segregation of only infective cases, rehabilitation of discharged patients, special homes for paediatric and crippled patients, BCG vaccination and treating patients in local hospitals, dispensaries and homes were implemented. In 1954, a vertical anti-leprosy campaign to plan, implement, co-ordinate and evaluate leprosy control activities was established. The field programme of the campaign was conducted through 225 clinics by public health inspectors one each for 25 districts. They conducted clinics, village surveys, multi-drug delivery, contact tracing, default retrieval and educational programmes. The dermatologists and medical officers in the curative health network maintained links with these 225 field clinics run by the preventive care network for referring diagnosed leprosy patients for multi-drug treatment and further follow-up.\(^{[8,11]}\)

Meanwhile, a deformity rate of about 10% among new cases reflected inadequate diagnostic services and misdiagnosis of leprosy.\(^{[12,13,14]}\) Given poor geographical and temporal access of only 225 clinics to patients, expansion of services was vital to eliminate leprosy in remaining districts.

Further, with a low prevalence, centrally operated control activities were not cost-effective. Leprosy services provided through the GHS was seen as an alternative for easy access and to address residual problems facing leprosy elimination [Figure 1].\(^{[8]}\)

Integration of leprosy services in Sri Lanka focused on key objectives\(^{[15]}\) given in Box 1.

**PRE-INTEGRATION LEPROSY CONTROL IN POLONNARUWA DISTRICT**

Polonnaruwa was a priority district for leprosy elimination at the sub-national level [Table 1].\(^{[12]}\)

The District Leprosy Elimination Programme was exclusively carried out by one well-trained and experienced Public Health Inspector. Self-referrals and patients directed by the curative network were followed up by the Public Health Inspector in field clinics. Complicated cases were referred to the anti-leprosy campaign for specialized management. Patient records were also maintained by the Public Health Inspector.

**RATIONALITY FOR INTEGRATION**

Thus, through the efforts of the Leprosy Elimination Programme, the country achieved World Health Organization’s (WHO’s) leprosy elimination target by 1995.\(^{[8]}\) Nevertheless, the sub national elimination target of less than 1 case per 10 000 population had yet to be achieved in a few districts.\(^{[12]}\)

<table>
<thead>
<tr>
<th>Box 1: Key objectives for integration of leprosy services in Sri Lanka</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transferring the ownership of leprosy elimination activities to a district health team led by the Regional Epidemiologist</td>
</tr>
<tr>
<td>Ensuring availability of diagnostic and treatment services at all curative health institutions</td>
</tr>
<tr>
<td>Ensuring readiness and willingness of the health care providers in the GHS to diagnose and manage leprosy</td>
</tr>
<tr>
<td>Making the community aware of changes and new service delivery sites</td>
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<tr>
<td>Ensuring an operational system of record keeping and monitoring</td>
</tr>
</tbody>
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**Figure 1:** General health services in Polonnaruwa

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**LOCAL CHALLENGES SURFACED DURING INTEGRATION**

**Ensuring harmony between the new team leader and the previous owner**

Sustaining a harmonious relationship with the previous owner was the biggest challenge for the new team leader. Conceptually, replacement of a veteran by a novice naturally leads to dependence of novice on the veteran without realizing that leadership belongs to the novice.\(^8\)

Such dependence tends to confuse health workers in the GHS as to which line of authority to follow, particularly in our case, given the strong image of the previous owner related to leprosy. Therefore, effectively utilizing and sustaining his services in the new role, self-perceived as ‘demoted’ in the post-integration period was daunting.

As in the Jigawa state, Nigeria, where previous vertical staff members were reluctant to integration due to uncertainty of their future role,\(^1\) the discontent on losing the ownership was expressed clearly by the previous owner, as in our case too. However, we convinced decisiveness of his active participation, energy and past experience for success.
Obstacles to harmonious relationship were minimized by making both integral members of the district team. The district being highlighted nationally for successfully overcoming this challenge in the post-integration period is a testimony to the effectiveness of our strategy. Similar effective strategies making vertical staff a part of the change have been stressed in Tamil Nadu, India, and in Nigeria.\[9,10\]

The experience and skills of the team leader in human resource management contributed positively to transform attitudes and utilize services of the previous owner against his perception of demotion and uncivilized abandonment by authorities. The modern team building principles were used herein. ‘Mutual dependence’, that is when a group of individuals cast aside self-interests and focus their efforts towards a unified goal, is one principle.\[16\] The second principle was ‘Designated Roles’.\[16\] Managerial roles of the team leader and roles of the previous owner in monitoring multi-drug supply, [Figure 2] disability care, staff education and supporting the team leader were clearly explained. The central circular on roles of different officers in an integrated setting\[17\] helped defining specific roles. Similarly, Nigerians too had emphasized new, specific roles to previous vertical staff during pre-integration discussions in their successful integration in Jigawa state in 1999, in contrast to their failed attempt in 1996.\[10\] Third principle was ‘planned work’.\[16\] Planning was a democratic, consensual process with active involvement of both officers. Underlined principle was that integration was a process of collective efforts. In the implementation (worked plan\[16\]), previous owner was given freedom to execute his new roles independently and wherever collective involvement was needed, team leader participated with the previous owner. These two key managers contacted the community through the routine package of primary healthcare (PHC) delivered by PHC workers. Special engagement with the community for active detection of patients was discouraged as a policy. A massive nationwide social marketing campaign targeted the general public for increased self-referrals to the GHS. Ghana similarly demonstrated that decentralization of leprosy control could enhance the ownership at peripheral levels.\[18\]

Initiation and sustainability of information management

Reluctance of pharmacists in the GHS to accept record keeping

Although the vertical staff in India were reluctant to hand over record keeping to the GHS,\[19\] we experienced reluctance of some GHS pharmacists to accept record keeping citing it was an additional burden. This was threatening integration with possible failure of obtaining complete patient and multi-drugs stock data from the GHS [Figure 2]. Internationally too, there were instances of bouncing back of record keeping to the vertical staff due to ill-prepared pre-integration.\[9,20\] Thus, it was certain that not only knowledge, skills, but also motivation and positive attitudes were needed to transfer responsibilities to workers in GHS. The team leader identified reluctant pharmacists individually and in ‘one to one’ encounters listened to grievances, explained importance of record keeping, simplicity of forms, negligibility of the additional burden and feasibility of the task. Reasoning was based on expected numbers of daily leprosy patients per institution, on the basis of previous statistics. It resulted in institutional treatment record keeping universally by pharmacists in Polonnaruwa. Results demonstrated benefits of reassurance of the feasibility of tasks, simplifying procedures and registers for workers in the GHS.\[2\]

Information management related to the post-integration follow-up of treatment completion

Although having less fragmented management information is an advantage of decentralized health services,\[21\] after integration, we experienced fragmented information on patients registered in the district but collected multi-drugs from other districts. It caused difficulties in updating treatment completion records. Thus, in contrast to the pre-integration, where Public Health Inspector knew treatment completion status of each patient under his care, in the post-integration, it was not known for nearly 15-20% of patients. This necessitated immediate attention given the Tamil Nadu experience of an apparent reduction in treatment completion despite an increase in new case detection after integration.\[9\]

Having foreseen this issue, an Individual Treatment Card posted to the campaign soon after filling the last dose of multi-drugs was designed to update treatment completion status.\[22\] Nevertheless, only 60% of cards were received by the campaign\[22\] resulting in inability of the district to receive information on treatment completion.

Divisional level analysis of leprosy data

In pre-integration, data for local analysis was available in patient registers at divisional levels. However, this was impractical in the post-integration without a proper mechanism of flow of patient information to the divisional level. Having emphasized the importance of availability of data at the divisional level, we designed an alternative data flow from the district to the divisional level. An additional monthly return to each division with details of newly detected patients, date of their first treatment and details of subsequent multi-drug doses of previous patients was designed. Using this return, divisions were able to complete their data bases.

However, we encountered a divisional level indifference to managing information due to the negative influence of the pre-integration system where divisional statistics were maintained by the Public Health Inspector. Outcome could
have been bouncing back of information management to the vertical staff. We avoided this by training newly designated ‘Programme Planning Officers’ to manage leprosy information at the divisional level.

**Re-orientation of all healthcare providers in leprosy services**

Capacity building at district/sub-district levels was the key in transition from vertical to an integrated programme.[18] Although re-orientation of medical officers was a challenge for the centre[8] with a national figure of only 85% of re-oriented provincial doctors,[22] in our district, their response to re-orientation was overwhelming. In all institutions, team leader identified absentees and special individual or group re-orientation sessions on symptoms, diagnosis, management and rehabilitation of leprosy patients were held for them. This strategy enabled re-orientating all medical officers in GHS in the district as opposed to 85% of provincial and 60% of central ministry hospital doctors trained nationally.[22] Additionally, PHC workers were re-oriented for detecting suspected leprosy cases in community, referring to GHS, de-stigmatization, counselling and community involvement.

Leprosy services are more accessible and effective when provided closer to community.[23] In Sri Lanka, traditional medical care, sought by many with symptoms such as numbness, joint pain, paralysis, etc., is crucial for service provision closer to community. Inadequate knowledge of traditional practitioners on leprosy was a reason for high deformity rates in Sri Lanka despite low prevalence of leprosy.[13,14] Therefore, re-orientation programmes were extended to all traditional practitioners to dispel myths and familiarize them with signs and symptoms of leprosy. Although the task was challenging, their participation rate and enthusiasm was remarkably high.

**Ensuring and sustaining easily accessible services in the local context**

Although ensuring availability of diagnostic and treatment services at all curative institutions[15] was a key national objective, due to some district-specific characteristics indicated in Box 2, we faced a dilemma as to whether we should deviate from this national policy.

**Box 2: Reasons for considering preventive institutions for leprosy services**

- Increase in self-referrals to monthly leprosy clinics at divisional health offices due to pre-integration familiarity
- Preference of patients diagnosed prior to integration to continue treatment from divisional offices
- In certain areas, due to easy access, preference for patronizing divisional offices for diagnosis and treatment
- Customarily reference of suspected patients to the divisional offices by PHC workers
- High demand of the MOHs to be actively involved in leprosy diagnosis and treatment

Considering relevance of these reasons for easily accessible services, district authorities allowed preventive institutions to continue leprosy services. Brazil[2] and Myanmar[23] similarly have effectively used family health teams to provide leprosy care in the post-integration.

**Patient care without specialist dermatologists in the district**

Although integration does not exclude specialized elements,[2] interestingly, absence of a dermatologist in the district had overall positive effects on integration. Low interest in leprosy by medical officers due to increasing specialist dermatologists was reported as a reason for their low attendance for re-orientation programmes in large hospitals during integration.[8] Despite more than 60% of leprosy patients in Sri Lanka[24] and 80%[25] in China being detected in institutions with a dermatologist in the post-integration period, in Polonnaruwa, the majority of new patients was detected by non-specialists at all levels.

**Lessons learnt**

One lesson to be learnt from our experience is the possibility of unfolding different local challenges during actual implementation notwithstanding meticulous national planning and preparation preceding it. Change is always fraught with difficulties but proper management strategies help overcome these.[26] We elaborate that commitment and innovation by district managers are vital for success and lack of which has the potential for failures of the programme as demonstrated in Jigawa state in Nigeria[10] and in Tamil Nadu.[9] Based on our experience, we highlight the indispensable nature of having an empowered, district team leader with specified roles and responsibilities to address these issues successfully and sustain services.

For the future benefits of programmes, it is worth mentioning that sound technical and managerial know-how and commitment of the team leader are essential in solving multi-faceted challenges. Such district health managers empowered to effectively monitor integration and correct operational problems early have also been reported from Ghana.[18] However, we accentuate the challenging role of the manager in the presence of the previous owner. We opine that efforts such as accepting the previous owner in the team to compensate his perceived loss of status, spelling clear roles for him, practicing team work concept and creating a favourable environment for operation used to off-set challenges in our district will be useful in similar future exercises.

Implementation of integration varies within and between countries.[2] In this context, we learned that peripheral decision-making power and flexibility in introducing new area specific activities to core activities in central plans were essential to better address local issues. This context specific integration[22] may prove to be handy for programme managers in different settings.
Easy access to multi-drugs is an advantage of integrated services. Visschedijk et al., opined that accessibility and quality of leprosy services depend on the health system through which they are implemented. Therefore, demonstrating the district decision allowing preventive institutions also to provide these services, we highlight the importance of identifying the most appropriate institutions to provide diagnosis and treatment based on easy access, client’s acceptability and service providers’ willingness.

In this exercise, we also learned that re-orientation should focus not only on knowledge enhancement but also positive attitudes of staff towards the service and patients. It required multiple methods of capacity-building and motivation for new roles without additional benefits. At times, extreme measures such as ‘One to one’ encounters with individuals reacting negatively to integration were effective.

In post-integration, prevalence (0.9-1.5/10 000 population) and New Case Detection Rate (NCDR) (1.6-2.1/10 000 population) increased relative to 1998 (prevalence 0.7/10 000 population, NCDR-1/10 000 population). Detection of relatively higher grade II deformity rates (12.2-16.1%) in post-integration indicated capturing of patients previously undetected by the vertical programme. Diagnosis and treatment of leprosy patients at all levels of institutions indicated competence of medical officers and access wise, it reflected provision of leprosy services closer to the community. This was consistent with the national trend of more patients being detected by non-specialized institutions in remote districts without dermatologists. As suggested by Feenstra, these reflect the success of integration. Based on this experience, we recommended that decision-making powers and flexibility vested upon district managers to introduce area-specific changes to centrally planned core activities be continued for effective context specific solutions to future challenges.

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Legislation an essential tool for ensuring access to medicines policy goals

Michele Forzley, Jane Robertson¹, Anthony Smith¹

ABSTRACT

Effective national legislation is critical to support the activities of a Medicines Regulatory Authority. However, the law is an under-recognized mechanism for managing issues in the implementation of access to medicines and other medicines policy goals. Regulations are a more flexible tool, have legal effect and the advantage that they can be created or changed without the need to go to the Parliament. Closer collaboration between the health and legal sectors is important as is political commitment for enforcement of the law. Some regional case studies illustrate the opportunities to use the law as an effective tool to implement medicine policies and to meet access to medicine challenges.

Key words: Case studies, Law, medicines regulation, medicinal products

BACKGROUND

Effective medicines legislation and regulations are critical to establishing the framework for and supporting the activities of a Medicines Regulatory Authority (MRA). The value of law to achieving health objectives has been demonstrated in a few areas such as tobacco control.[1] In some cases, misapplied or inadequate laws can act counter to good health outcomes, for example, laws limiting access to narcotic analgesics may deny patients effective pain relief or palliative care.[2] Some of the key requirements for effective legislation and the importance of greater collaboration between the legal and health sectors to achieve good medicines law were discussed in a symposium at the Asia Pacific Conference on National Medicines Policies.[3] In this symposium, solutions available to all MRAs and grounded in law and regulation were demonstrated as key to solving several MRA challenges. These are reported in this article along with some observations on ways forward to making the law an explicit component of medicines policy work.

THE ROLE OF LEGISLATION

Three key legal concepts and their application are relevant for medicines law – legislation, regulation and governance. Legislation includes all forms of laws including international treaties, national legislation and sub-national laws. The law (legislation) defines the universal principles and establishes the MRA, creates the legal mandates and the infrastructure, processes and authority for the MRA to perform its functions. Regulations are used as a legal tool to amplify legislation, to provide more detail and to define the processes, annex schedules or other practical elements required to support MRA activity. Regulations are a more flexible tool, yet still have legal effect and have the advantage that they can be created or changed without the need to go to the Parliament. Policies, standards, codes, models and guidelines can have the effect of law and are useful to support the implementation of medicines policies. Governance is the manner of governing and management; good governance is effective, equitable, accountable, transparent and follows the rule of law. However, having medicines law is not enough. There must be political will to respect and enforce the law.

COUNTRY EXPERIENCES AND LESSONS LEARNED ABOUT GOOD PRACTICES

Three different country experiences were presented
and these demonstrated the value of legislation and administrative regulation to solving medicines regulatory and access issues. Though each problem was different, legal tools were part of the solution. These included suspension of a law through the use of an administrative regulation, the segregation of tax revenue by a law to fund medicines purchases and the integration of non-health sector law to combat corruption.

**Bhutan**

In the case of Bhutan (population 750 000), a supplier default on a 3 year contract for pharmaceuticals led to an acute shortage of medicines in 2010-2011. The MRA established under the Bhutan Medicines Act (2003) requires that all medicinal products are registered by it. There is currently no local manufacturing capacity in Bhutan apart from a single manufacturer for traditional medicines. So all medicines are imported, mainly from India and to a lesser extent Bangladesh. Faced with the acute shortage of essential medicines, a solution had to be found and it was found in the law. The application of the law was effectively suspended through a regulation that created an exemption from registration requirements if a product had been approved by selected reputable MRAs in another country. This legal solution could be effective in any country with limited capacity and facilities for medicine evaluation.

**Palau**

The challenges in Palau (population 20 000) related to medicines financing. While the law of Palau obligates the government to provide essential medicines, it had been difficult to obtain enough money from the legislature to purchase them as funding for medicines must compete with other demands on the national budget. Two solutions were implemented. The first was to create a minimum inventory list of medicines. In effect this was an essential medicines list, an important tool for medicines regulation and prioritisation for purchasing. This dramatically reduced the number of different medicines to be purchased and consequently the total medicines bill which had been higher than the funds available. While this reduced the amount of money required from the legislature, it did not deal with the issue of not having the money available when needed to buy medicines. In response, through legislation, the Government created a hospital trust fund in parallel with the introduction of compulsory health insurance and medical savings. These were financed through a 2.5% tax on all citizens, which were designated by law to the trust fund for the purchase of medicines. This guaranteed access to funds has dramatically increased the availability of essential medicines in Palau.

**Corruption**

The third country experience discussed was that of corruption, an activity affecting both developed and emerging economies. An example came from an Asian country where high medicines prices were in part due to ‘informal’ payments that encouraged doctors to prescribe and institutions to purchase particular generic products. It was estimated that around 40% of the generic medicine prices went as incentives to doctors to prescribe. These payments resulted in the purchase of medicines of lower quality, as well as influencing prescribing practices, sometimes towards less appropriate medicine choices. This situation is more likely to occur in environments where there are low salaries for health professionals, an acceptance and rationalisation of ‘informal’ payments as a professional norm and few consequences for corrupt practices. There are practical, policy and legal responses in these situations. The practical is to ensure appropriate remuneration for doctors and other health professionals. Policy options include efficient, supervised health system management practices for quality assurance of medicines and procurement; legal responses include collaborating with the justice and law enforcement sectors to enforce existing laws. Sometimes it may be necessary to enact new legislation to define illegal and criminal behaviours such as bribery, unjust enrichment or other abuses. The United Nations (UN) Convention against Corruption is available to guide countries on best practices. Countries ratifying the convention must follow it by aligning national laws and practices with those required by the convention. Anti-corruption work being undertaken in other sectors of government may provide a framework and model for similar activities in the health sector.

**BUILDING LEGAL CAPACITY AND STRENGTHENING SYSTEMS WITH LEGISLATION**

The absence of lawyers from the work of the pharmaceutical sector in some countries is a real barrier to the use of effective legal tools and therefore effective regulation. Greater collaboration between the legal and health sectors on medicines law is required. The medicine and health sectors need to work together to learn how to access legal tools and resources; the legal community need to understand good practice in the medicines sector so that good legal practices can be applied. Appropriate legislation jointly drafted needs to be enacted and relevant laws and regulations enforced.

A practical example of this lack of collaboration is found in the example of inspection of medicine facilities. Conference participants reported that often, medicines inspectors do not have sufficient authority to act under the law or there is insufficient evidence obtained to sustain successful prosecution in the courts. In some cases, new or amended legislation may be required to provide the necessary authority to inspectors and regulators. Along with this, there should be training on how to use the
powers such as those to seize suspect materials and products, or to shut down manufacturing plants.

Regulators (usually with pharmacy/life sciences but no legal background) must know how to work with law enforcement agencies and also learn the information that must be collected to aid police and prosecutors to take action under relevant laws. Effective enforcement requires political commitment and well-functioning legal institutions and strong co-ordination between various government agencies. Increasing civil society engagement in matters related to health in general, and to the availability and affordability of good quality medicines in particular, will be an important means for maintaining the pressure on politicians and giving voice to the concerns of patients. This will help ensure accountability and transparency in the development of medicines legislation and avoid the perception of undue influence of lobby groups such as the pharmaceutical industry on policy development.

WAYS FORWARD

Capacity building and sharing of knowledge and experiences are important to strengthen the use of legislation as a tool for medicines policies development and implementation in the region; working collaboratively with the legal sector is essential. Best practice legal models and tools from other parts of the world should be identified and disseminated. There is considerable scope for increased use of more flexible administrative regulations to support MRA functions and activities. Regular meetings and sharing of best practices could be an effective strategy. A model best practices template for least developed countries with no manufacturing capacity may be useful.

It is important that the law is respected and upheld, and that the civil and criminal sanctions available are applied. In some jurisdictions, there are mismatches between breaches and the penalties that can be imposed; these need to be addressed. Well publicized legal action may serve as an effective deterrent to infringements of medicine-related law by others. Local legal capacity may need to be increased and building teams with international experts may assist. An example of an effective model is the Access to Opioid Medication in Europe (ATOME) project in which local lawyers are trained on international standards on opioid medicines practice after which they assess national laws to identify legislative barriers to access to opioid medicines and recommend solutions.[2] Efforts are being made to raise awareness of corrupt practices in the pharmaceutical sector and programmes such as the World Health Organization’s (WHO) Good Governance for Medicines programme[5] and the Medicines Transparency Alliance (MeTA)[6] promote good governance, transparency and accountability.

The recognition of law as an essential tool for medicines policy is overdue. This conference was an important step towards putting legal processes firmly on the regional agenda to support national medicines policies and their implementation.

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Generic medicines policies in the Asia Pacific region: ways forward

Tuan A. Nguyen, Mohamed A. A. Hassali¹, Andrew McLachlan²

ABSTRACT

Generic medicines are a key strategy used by governments and third-party payers to contain medicines costs and improve the access to essential medicines. This strategy represents an important opportunity provided by the global intellectual property regimes to discover and develop copies of original products marketed by innovator companies once the patent protection term is over. While there is an extensive experience regarding generic medicines policies in developed countries, this evidence may not translate to developing countries. The generic medicines policies workshop at the Asia Pacific Conference on National Medicines Policies 2012 provided an important opportunity to discuss and document country-specific initiatives for improving access to and the rational of use of generic medicines in the Asia Pacific region. Based on the identified barriers and enablers to implementation of generic medicines policies in the region, a set of future action plans and recommendations has been made.

Key words: Access to medicines, developing countries, essential medicines, rational use

INTRODUCTION

The World Health Organization (WHO) began to develop practical guides for member states in formulating national medicines policies in 1975. The guidelines were first published in 1988 and then updated in 2001. The WHO recommended individual countries to develop their own locally appropriate national medicines policy, primarily focused on improved access to, quality and rational use of medicines.

Access to medicines continues to be one of the biggest challenges confronting the global political agenda.¹ Despite some progress made, one-third of the world’s population continues to lack a regular access to essential medicines, with the figure increasing to 50% in the poorest countries of Africa and Asia.² This long-standing WHO intuitive estimate has been supported by results of recent household surveys and the study by Cameron et al.,³ which is the first exact measurement of access to medicines in developing and middle-income countries.² The United Nation’s Millennium Development Goal 8E acknowledges the need to provide access to affordable essential medicines in developing countries.⁴

Lack of access to essential medicines in developing countries relates to two classes of medicines.⁵ The first is a lack of access to new (patented) medicines as a result of the Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement, which restricts access to newer essential medicines due to higher costs. It can also arise because of absence of medicines, as there are insufficient commercial incentives for the global pharmaceutical industry to develop new medicines to treat diseases associated with poverty, given the market-driven nature of the industry. The second is a lack of access to existing medicines because of patients’ inability to pay for them. This reason is deemed ‘the most frequently cited cause of inadequate access to medicines’ in developing countries.⁵ Often, all the three reasons are responsible.

Usually, generic medicines with proven safety and efficacy represent a key strategy used by governments and third-party payers to contain cost of healthcare and...
improve access to existing medicines. This strategy is promising considering the impending expiry of patents of many ‘blockbuster’ medicines. However, while there is an extensive experience from developed countries with regard to pro-generic medicines policies, empirical studies in developing countries are lacking.[6] This makes it especially difficult for developing countries to decide on a course of action. In the generic medicines policies workshop at the Asia Pacific Conference on National Medicines Policies,[7] country-specific initiatives for improving access to and rational use of generic medicines in Asia Pacific region were discussed and documented. Key barriers and enablers to development and implementation of generic medicines policies were identified and steps to address barriers and enablers were proposed.

COUNTRY EXPERIENCES AND LESSONS LEARNED

Workshop participants indicated that many countries in Asia Pacific region did not officially have a generic medicines policy or position their generic medicines policy as an integral part of their National Medicines Policy. Few regional countries have comprehensively implemented generic medicines policies with strong regulatory requirements (i.e. statutory provisions and regulations to expedite generic entry, permit generic substitution and/or mandate generic prescribing policies) in combination with incentives for the development of the generic markets, acceptance and rational generic medicine use. For example, Vietnam adopted a National Medicine Policy in 1996, but there were no generic medicines policies embedded. It was not until 2009 that an Aide Memoire on Strategic Collaboration in Pharmaceuticals was signed by WHO and the Ministry of Health of Vietnam, which mentioned a strategy to develop and promulgate a national generic medicines policy to ensure affordability of safe and quality medicines.[8] Another example came from Malaysia, whose 2007 National Medicines Policy contained a generic medicines policy, although some of its key components have not been implemented.[9]

Key barriers
A number of barriers to the development and implementation of a comprehensive generic medicines policy was documented in the workshop. The first is the mistrust in the pharmaceutical quality of available generic medicine products in some countries in terms of safety and efficacy. The lack of clear bioequivalence assessment systems as a regulatory requirement in generic medicines registration or lack of appropriately skilled inspectors and monitoring to ensure the quality of generic medicine products was reportedly attributable to this mistrust. Even in some countries where bioequivalence was assessed, the mistrust still existed because of the lack of effective communication from regulators to make clear statements about the procedures involved in approving generic medicines. References came from several countries, including those in Pacific Islands.

The mistrust related to the pharmaceutical quality of generic medicine partly results in a poor acceptance of generic medicines by consumers and health professionals. Lack of knowledge of generic medicines and misconceptions that discount price equates to ‘discount’ quality also contributed to this poor acceptance. In addition, widespread unethical promotional incentives for prescribers from some pharmaceutical companies were reported to influence physician prescribing behaviour, leading to recommendation of more expensive branded generics. Meanwhile, only few regional countries have included financial incentives to physicians and pharmacists in their generic medicines policies to promote prescribing and dispensing of generic medicines.

These barriers were believed to render weak generic markets and low uptake of generic medicines, although generic substitution and/or generic prescribing have also been reported in many regional countries. The failure to fully implement generic substitution policies and guidelines also contributed to this resulting low uptake. However, the increase in generic medicines uptake does not automatically translate to savings or improvement in affordable access if pricing policies fail to ensure low prices of generic medicines. This was witnessed from several regional countries, where generic prices were only slightly lower than the originator brand prices (e.g., in Australia) or in some cases even higher (e.g., in Malaysia).

Key enablers
Facing these barriers, Asia Pacific regional countries have undertaken various initiatives for improving access to and use of generic medicines. These initiatives can be classified into ‘four Cs’ enabler groups. The first is to co-ordinate the implementation of generic medicines policies including procurement, re-imbursement, retail price controls, reference pricing and alignment of financial incentives among prescribers, dispensers and consumers to support the uptake of low-priced generic medicines. The second is commitment to procedures and infrastructure to demonstrate, evaluate and promote bioequivalence and maintain product quality to build confidence in generic medicines. The third is communication from regulators about the procedures involved in approving generic medicines to promote trust in generics quality to the community. Finally, community trust must be obtained through education to public/consumers and health professionals to support understanding and confidence in generic medicine products and allow informed choices by consumers. These ‘four Cs’ are interconnected and must be achieved simultaneously if the generic medicine policies are to be successful.
BUILDING EFFECTIVE COMPETITIVE MARKETS FOR GENERIC MEDICINES

A principal assumption in generic medicine policies is that generics are significantly less expensive than their originator medicine counterparts. This is because, on the one hand, generic manufacturers do not incur the cost of medicine discovery and are thus able to maintain profitability at a lower price. On the other hand, they face increasing competition as the medicines are no longer protected by patents, resulting in increase in the number of manufacturers/ suppliers. However, effective, efficient competition will not arise from a completely unregulated pharmaceuticals market. Core regulations including general laws (e.g. criminal law, contract law, competition law and anti-corruption law) and pharmaceutical sector regulation must be in place and adequately enforced to create competitive markets for generic medicines.[10]

WAYS FORWARD

Given the complex, varied and interdependent factors influencing the success of generic medicines policies, Asia Pacific regional countries need to integrate their generic medicines policies within the broader framework of national medicines policies and make active efforts to promote confidence in their quality and use. The national medicine regulatory agency needs to be strengthened with a capacity to assure the quality of generic medicines. A robust and functioning medicine regulatory system will assure the actual quality of generic medicines, but the perceived low quality of generic medicines must also be addressed. This can be achieved through effective communication from regulators regarding requirement for generic medicines registration, in combination with educational campaigns to public and health professionals. Other effective initiatives include publishing details of Good Manufacture Practice inspections as per the WHO Prequalification Programme or publishing test results as does the Global Fund.

When the scepticism of and uncertainty about the quality of generic medicines has been successfully addressed, supportive regulations providing for substitution of generic medicines are necessary. Of equal importance is the availability of policies that align pro-generic medicine incentives for prescribers, dispensers and patients to increase generic medicines uptake. Pricing and purchasing policies such as reference pricing and tendering may also be needed to ensure low prices of generic medicines. For sustainability of effective generic medicines policies, the progress in implementation of these policies needs to be monitored. It includes regular reporting on quality monitoring, prices and use of generic medicines, as well as assessment of changes in consumer and healthcare professional attitudes to generic medicine products.

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Recent WHO Publications

Birth defects in South-East Asia: a public health challenge: Situation analysis

**Publisher:** World Health Organization, Regional Office for South-East Asia. New Delhi: 2013. 126 pages.
**DOC NO.:** SEA-CAH-13

The World Health Assembly has expressed concern about the high number of stillbirths and neonatal deaths occurring worldwide, and the large contribution of neonatal mortality to under-five mortality. The Assembly recognized the importance of birth defects as a cause of stillbirths and neonatal mortality, and that the attainment of MDG 4 on reduction of child mortality will require accelerated progress in reducing neonatal mortality, including prevention and management of birth defects. Resolution WHA 63.17, adopted in May 2010, forms the basis of initiatives on the prevention of birth defects in the WHO South-East Asia Region. Epidemiological information is required to design effective preventive strategies for birth defects and evaluate them upon implementation. It has been observed that, at present, none of the Member States has nationally representative data and information related to birth defects.

In view of this, the WHO Regional Office for South-East Asia has developed situation analysis based on the published literature and information obtained from experts and national programme managers from the Member States. The information from different countries varies in extent but provides a reasonable insight on the burden and common types of birth defects, and surveillance and preventive activities for birth defects that may be available in the existing programmes in the Member States. Further opportunities for preventive services, challenges and support required to develop surveillance and preventive actions for birth defects in the countries are also described. The Regional situation analysis would be useful to develop prevention programmes for birth defects in the Member States of the Region.

Tuberculosis control in South-East Asia Region: Annual TB report 2013

**Publisher:** World Health Organization, Regional Office for South-East Asia. New Delhi: 2013. 165 pages.
**ISBN:** 9789290224303.

All 11 Member States have sustained country-wide access to DOTS. Each year, more than 2 million TB cases are being registered for treatment and the treatment success rate among new smear-positive pulmonary TB cases has remained above 85% since 2005, and was
88% in 2010. The TB mortality rate has decreased by 40% since 1990 and the South-East Asia Region is on track to achieve the global target of a 50% reduction by 2015. The decline in the prevalence is observed in all Member countries and in some countries, it is over 50%. Approximately 40% of the estimated global number of cases occurs in the South-East Asia Region (based on current estimates) as well as more than one fourth on the MDR-TB burden. The collaboration between TB and HIV control programmes is improving. Many of the constraints to effective implementation of TB control services in Member States relate to underlying weaknesses and under-financing of national health systems in general, many of which are already overstretched in terms of both infrastructure and staffing. To enable universal access and continuing scale-up of critical interventions, there is an urgent need to sustain current financial commitments and to advocate for additional financial resources.
Original research articles on public health, primary health care, epidemiology, health administration, health systems, health economics, health promotion, public health nutrition, communicable and noncommunicable diseases, maternal and child health, occupational and environmental health, social and preventive medicine are invited which have potential to promote public health in the South-East Asia Region. We also publish editorial commentaries, perspectives, state of the art reviews, research briefs, report from the field, policy and practice, letter to the editor and book reviews etc.

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