Original Article

Estimating the Burden of Disease from Unsafe Injections in India: A Cost–benefit Assessment of the Auto-disable Syringe in a Country with Low Blood-borne Virus Prevalence

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ABSTRACT

Background: Unsafe medical injections are a prevalent risk factor for viral hepatitis and HIV in India. **Objectives:** This review undertakes a cost–benefit assessment of the auto-disable syringe, now being introduced to prevent the spread of hepatitis B virus, hepatitis C virus, and human immunodeficiency virus (HIV). **Materials and Methods:** The World Health Organization methods for modeling the global burden of disease from unsafe medical injections are reproduced, correcting for the concentrated structure of the HIV epidemic in India. A systematic review of risk factor analyses in India that investigate injection risks is used in the uncertainty analysis. **Results:** The median population attributable fraction for hepatitis B carriage associated with recent injections is 46%, the median fraction of hepatitis C infections attributed to unsafe medical injections is 38%, and the median fraction of incident HIV infections attributed to medical injections is 12% in India. The modeled incidence of blood-borne viruses suggests that introducing the auto-disable syringe will impose an incremental cost of $46–48 per disability adjusted life year (DALY) averted. The epidemiological evidence suggests that the incremental cost of introducing the auto-disable syringe for all medical injections is between $39 and $79 per DALY averted. **Conclusions:** The auto-disable syringe is a cost-effective alternative to the reuse of syringes in a country with low prevalence of blood-borne viruses.

Keywords: Cost–benefit, hepatitis B virus, hepatitis C virus, HIV, injections

Introduction

In India, transmission of blood-borne viruses in unsafe health care is endemic.[1] Poor sharps waste management and misconceptions about injection safety both contribute to injection equipment reuse in India. Recent outbreak investigations suggest that many injection providers believe it is safe to reuse a syringe after changing the needle, that it is safe to reuse injection equipment to access an IV line, or that it is safe to reuse injection equipment on the same patient when reconstituting from a multidose vial, without sterilization.[2] These misconceptions are still reported in high-income developed countries and are thought to be prevalent in the developing world.[3] Even more troubling, recycling of sharps waste for repackaging and resale is practiced on a large scale in India, uncovered recently in the investigation of a deadly hepatitis B outbreak.[4] The goal of this review is to evaluate the incremental cost–benefit of using the auto-disable syringe for all medical injections in India, in terms of prevented disability and mortality from hepatitis B, hepatitis C, and HIV infections. India's Ministry of Health issued an advisory to 24 Governors and State Health Ministers to introduce auto-disable syringes for all medical injections in 2008 to prevent injection equipment reuse in health care settings. Most

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states have not implemented this policy for curative injections, although auto-disable syringes are now used nationwide for immunization injections. Most injections in India are not immunization injections, as injectable drugs are widely preferred over oral formulations.[5] The benefit of using only auto-disable syringes in a country with a low prevalence of blood-borne viruses has not been previously assessed.

Materials and Methods

The total number of human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV) infections that would result from unsafe medical injections in India in 2010, barring the introduction of auto-disable syringes for all medical injections, is estimated following the mass action model used to develop the World Health Organization global burden of disease estimates.[6] The incidence of each blood-borne virus I_v is a product of the size of the susceptible population p_s, the probability of transmission in an unsafe medical injection for each virus p_{tv}, and the number of contaminated medical injections performed n_c as given in equation (1). Based on a systematic review of studies of needlestick accidents in health workers, the WHO estimates that the probability of HIV transmission in an unsafe medical injection is 1.2%, the probability of HBV transmission is 6% for HBeAg-negative source patients and 30% for HBeAg-positive patients, and the probability of HCV transmission is 1.8%.[6]

$$I = p_{sv} \times p_{tv} \times n_c \quad (1)$$

The number of contaminated injections n_c is calculated from the unsafe reuse rate p_r, the prevalence of each virus in the general population p_v (or the adjusted probability that used injection equipment will be contaminated with the virus), and the number of injections per person-year n, as given in equation (2).

$$n_c = p_r \times p_v \times n \quad (2)$$

Because India's HIV epidemic is concentrated, the model for HIV is adjusted for associations between unsafe injection frequency and HIV prevalence across geographic and demographic segments of the population. The 2004 INCLEN injection safety report evaluated unsafe injection frequency in states and territories with varying HIV prevalence, and the National AIDS Control Organization of India reports HIV prevalence by state and territory.[7,8] The 2005–2006 Demographic and Health Survey for India is used to relate unsterile injection frequency to HIV prevalence across age groups, gender and marital status, ethnic and religious groups, rural or urban residence, wealth and education level.

Risk factor analyses investigating an association between injections and hepatitis B, hepatitis C and incident HIV infections in India were identified in a systematic search using Pub Med. The population attributable fractions from these risk factor analyses are used to validate the model. The incremental cost per disability adjusted life year (DALY) from each prevented hepatitis B, hepatitis C and HIV infection is calculated in a cost–benefit assessment of the use of the auto-disable syringe, priced at $0.0425 in India.

Results

In a nationwide survey in 2004, the estimated injection frequency varied by recall interval from 2.9 to 5.8 injections per person-year, of which 32% had the potential to transmit blood-borne viruses.[7] The Demographic and Health Survey for India indicates that 0.71% of unsafe injections given to adults were potentially contaminated with blood from an HIV-positive patient, before adjusting for associations between unsafe injection frequency and HIV prevalence. HIV prevalence in children under age 15 (29% of the population) is only 0.00028%.[9] In ecological regression, rural unsterile injection frequency is associated with HIV prevalence ($P = 0.036$, $R^2 = 0.30$, $\beta = 1.4$). The selected demographic predictors of HIV prevalence are also associated with unsafe injection frequency in adults ($P = 0.010$, $R^2 = 0.23$, $\beta = 0.32$). Equation (3) reports the adjustments for the probability of an unsafe injection given to a susceptible patient being contaminated with HIV, where β_1 is the adjustment factor for geographic region, β_2 is the adjustment factor for demographic group, p_a is the probability the injection is being given in an adult patient care setting and p_c is the probability that the injection is being given to a child. The estimated probability that an unsafe injection given to an HIV-negative patient will be contaminated with blood from an HIV-positive patient is 0.85%.

$$p_v = 0.71 \times (\beta_1 + \beta_2) \times p_a + 0.00028 \times (\beta_1 + \beta_2) \times p_c \quad (3)$$

Three studies of sexually transmitted disease (STD) patients in India investigated an association between medical injections and incident HIV infections, with a median population attributable fraction of 12%. The modeled annual incidence of HIV from unsafe medical injections is 10–21 cases per 100,000. In South India, the adult incidence of HIV was 50 cases per 100,000 in 2008.[10] Thus, this mass action model attributes 20–42% of HIV transmission in India to unsafe medical injections, a far larger fraction than that supported by risk factor analyses in patients with competing risks. HIV incidence in these STD clinic attendees was far higher (5.1–8.2 per 100 person-years at risk) than the population average, suggesting that competing risks were greater in study participants than in the general population.

Table 1: Population attributable fraction of hepatitis infections linked to injections in India

Setting	Virus	Odds Ratio	PAF (%)
Pune, 1995[12]	HIV	1.47 (0.86–2.53)	NS
Pune, 1996[13]	HIV	1.72 (1.11–2.64)	16
Pune, 2003[14]	HIV	1.28 (0.97–1.69)	9
Tamil Nadu, 1981[15]	HBV	2.0 (Not reported)	50
Maharashtra, 1996[16]	HBV	0.3 (95% CI 0.2–0.8)	0
Andhra Pradesh, 1998[17]	HBV	4.8 (95% CI 1.3–18.2)	46
Bihar, 1998[18]	HBV	8.4 (95% CI 2.1–33.9)	78
Bihar, 1999[19]	HBV	7.6 (95% CI 1.3–45.2)	12
Bihar, 1998[18]	HCV	4.5 (95% CI 1.6–12.1)	62
Bihar, 1999[19]	HCV	11.8 (95% CI 3.0–45.4)	18
Tamil Nadu, 2001[20]	HCV	5.8 (95% CI 1.6–21.6)	28
Tamil Nadu, 2003[11]	HCV	8.8 (95% CI 2.2–34.5)	38
West Bengal, 2003[21]	HCV	3.8 (95% CI 1.5–10.2)	60

NS: Not significant, HIV: Human immunodeficiency virus, HBV: Hepatitis B virus, HCV: hepatitis C virus

The median population attributable fraction for chronic hepatitis B across five risk factor analyses to look at injection risks is 46%. These studies are shown in Table 1. The modeled incidence of hepatitis B is 0.2–0.4%, or 10–20% of prevalent infections. This discrepancy suggests that either the modeled transmission efficiency of hepatitis B infections is a conservative estimate or the populations in which injections have been investigated as a risk factor for hepatitis B infection are at increased risk for unsafe injections.

The median fraction of hepatitis C infections attributed to injections across five risk factor analyses, also shown in Table 1, is 38%. The average annual incidence suggested by the age distribution of hepatitis C infection in India is 0.1%.[11] For hepatitis C, the modeled incidence is 0.03–0.05%, or 30–50% of prevalent infections.

Following the age-adjusted global burden of disease model for South Asia, these estimates predict that 352,000–646,000 DALYs from hepatitis B infection, 48,700–81,200 DALYs from hepatitis C infection and 2,605,000–5,210,000 DALYs from HIV infection would result which can be prevented by the use of the auto-disable syringe in 2010. These infections could be prevented at an incremental cost of $46–48 per DALY. Estimating HIV, HBV and HCV incidence from the median population attributable fractions in epidemiological investigations instead, the incremental cost may be higher or lower at $39–79 per DALY.

Discussion

Unsafe medical injections carry a risk of blood-borne virus transmission (HIV, HBV, HCV) when the injection equipment is reused without sterilization.[22] This has been shown in case–control studies indicating an association between blood-borne virus infection and receipt of medical injections,[23-25] with many of these studies demonstrating a dose–response relationship[26-28] Corroborating evidence is available from blood-borne virus epidemics in populations of injection drug users[29-31] and from the outcomes of accidental needlesticks in health workers.[32-34] Phylogenetic analysis of outbreak strains of nosocomial HIV, HBV and HCV have further confirmed the biological plausibility of unsafe medical injections as a vehicle for transmission.[35-37] Continuing unsafe injection practices in India have been well documented and remain a serious threat to public health.[5,38,39]

The present model of blood-borne virus transmission in India through medical injection equipment reuse has several important limitations. Risk factor analyses investigating medical injection risks in India have not controlled for the full range of confounding variables thought to influence the association between medical injections and HIV, also likely to influence the association with HBV. Model-based cost–benefit assessments of the introduction of auto-disable syringes for all medical injections are as uncertain as the model parameters, and the modeled patient mixing patterns only indirectly capture differences in patient populations at facilities with high and low levels of injection equipment reuse. Taken together, however, model-based and empirical evidence of iatrogenic HIV, HBV and HCV transmission in India supports the introduction of auto-disable syringes as a cost-effective intervention. The estimated cost per DALY averted is a fraction of average earned annual income in India by either estimation method, indicating that the introduction of auto-disable syringes for all medical injections is a cost-effective national policy for a low-income country with low prevalence of blood-borne viruses. This is an improvement from the incremental cost per DALY averted estimated for South Asia in 2003.[40]

This review indicates that unsafe injections are associated with HIV at the individual level and at the population level in India. Unsterile injections may serve as a bridge for HIV transmission between high-risk groups and the general population, as has been documented on a tragic scale in the town of Jalal Pur in Pakistan.[41] Among patients at STD clinics, cyclic HIV transmission dynamics are possible, and high rates of hepatitis C infection in female sex workers are suggestive of a role for blood exposures in concentrated HIV epidemics.[42] Nevertheless, given the mismatch between modeled and epidemiological estimates of HIV transmission from unsafe medical injections, the true extent of iatrogenic HIV transmission remains unclear.

The most uncertain parameter in the model of blood-borne virus transmission is the transmission efficiency of each virus in a medical injection. The probability

of HIV, HBV or HCV transmission in a contaminated medical injection may be similar to the risk from a needlestick accident. However, descriptive studies of needlestick accidents are few and the ranges of transmission efficiency estimates across these studies are wide. Recently, it has been argued that rinsing injection equipment eliminates the blood-borne virus transmission risk.[43] However, a comparison of the inoculum volume in a needlestick injury (in which the needle is inserted but the plunger of the syringe is not depressed) and in an injection shows that after adjustment for both rinsing the syringe and injecting the remaining contents of the syringe, the transmission efficiency in an unsafe injection is probably of the same order of magnitude as the transmission efficiency in a needlestick accident.[44]

Some other model parameter estimates are less uncertain. The 95% Confidence Intervals around the injection frequency estimates on 2 weeks and 3 months recall intervals were 5.3–6.3 injections and 2.8–3.2 injections per person per year.[7] The 95% Confidence Interval around the proportion of medical injections with the potential to transmit blood-borne viruses was 29–34%.[7] On the other hand, the adjustment for patient mixing patterns accounting for the association between HIV prevalence and exposure to unsafe medical injections was not empiric in the sense that demographic groups do not necessarily mix assortatively in clinical settings. Moreover, the adjustments did not account for the population distribution of the demographic characteristics that predict unsafe injection frequency and HIV prevalence.

The average registered medical practitioner reuses disposable syringes three times without sterilization, but this model assumes that blood-borne viruses are only transmitted from the first patient to the second.[1] Multidose vial contamination when an injection needle is used to reconstitute medication is also prevented by the introduction of auto-disable syringes, but this has not been modeled. In these respects, the model is a conservative one.

Finally, the model does not account for deaths from septicemia, a common complication of unsterile injecting among injection drug users that results from bacterial contamination.[45] Septicemia can result from injection equipment reuse irrespective of whether injection equipment has been used on a patient previously infected. In hospitalized patients with a bacterial culture positive intravenous catheter, 61% had a concomitant bacterial infection.[46] Injection equipment prepared for reuse by boiling is frequently culture positive (e.g., 33% contamination rate in one assay in Tanzania), and by implication injection equipment reused without sterilization is likely to be infectious.[47] In countries with a low prevalence of blood-borne viruses, the primary benefit of preventing injection equipment reuse may be the prevention of potentially serious bacterial infections. However, the burden of disease from nosocomial bacteremia has not previously been modeled.

Today, auto-disable syringes are required for all medical injections in India, Burkina Faso, the Democratic Republic of Congo, Nigeria, Tanzania, and Uganda, and the importation of syringes that are not auto-disable syringes is restricted in Burkina Faso and Tanzania. These national injection safety policies address a patient safety crisis recognized even in high-income developed countries – the widespread practice of injection equipment reuse without sterilization.[48,49] The WHO recommends the use of auto-disable syringes for all immunization injections, and United Nations Children's Fund (UNICEF) recommends that auto-disable syringes also be used for reconstitution. More extensive use of auto-disable syringes may be needed in countries with generalized HIV epidemics to prevent these nosocomial infections.

In India, implementation of this policy still faces serious obstacles, as State Ministries of Health have not embraced the national government's advisory and the new Minister of Health has not pressed the issue. In Kerala, Karnataka and Madhya Pradesh, the policy has been opposed, although 25–47% of injections in government health facilities in these states carry a risk of blood-borne virus transmission from patient to patient. Only eight states and the central government owned hospitals have partially introduced auto-disable syringes for curative injections. HIV surveillance in India does not investigate iatrogenic risks, and awareness of medical injections as an important secondary HIV transmission route is not widespread.[50] As other developing countries move toward a zero-tolerance policy for iatrogenic HIV transmission, medical injection equipment reuse continues to contribute to widespread undetected blood-borne virus transmission in India. Implementation of the national advisory to use auto-disable syringes for all medical injections could radically improve patient safety and reduce the burden of disease from chronic and stigmatizing infections in the most vulnerable segments of society.

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