

The Sindh Disposable Syringe Act: putting the act together

Arshad Altaf,¹ Sonali Vaid²

The World Health Organization (WHO) is concerned that conventional disposable syringes are being widely reused and that this practice has contributed to the spread of blood-borne infections, such as hepatitis B, hepatitis C and HIV. Research has shown that unless a physical barrier to syringe reuse is introduced, economic drivers and cultural resistance to waste lead to continued reuse in developing countries, regardless of training, advocacy and regulatory factors.¹ One of the main means to address syringe reuse has been the introduction of syringes with reuse prevention features (<http://qdsyringe.wordpress.com/2011/11/13/safe-syringes-for-injection-safety/>). This includes the auto disable (AD) syringes in which the plunger gets locked after it is used once and certain types of syringes in which the plunger additionally breaks, preventing any possibility of reuse. AD syringes are routinely used in the immunization sector worldwide, and in many countries they are by law used in the curative sector.

Pakistan has one of the highest prevalence of hepatitis B and C in the world. The nationwide prevalence of hepatitis B is 2.5% and of hepatitis C is 4.9%.² A number of studies have closely linked reuse of disposable syringes by healthcare providers with spread of hepatitis B and C in Pakistan. Two recent studies which had established strong association with spread of hepatitis C in particular because of reuse of syringes are referenced in this commentary here.^{3,4} To address the spread of these life-threatening illnesses and stop the reuse of single use disposable syringes, the Sindh Government passed a bill to regulate the use of disposable syringes in 2011.

According to the Provincial Assembly of Sindh Notification of 24th February, 2011 (No.PAS/Legis-B-25/2010) "The Sindh Regulation and Control of Disposable Syringe Bill, 2010 having been passed by the Provincial Assembly of Sindh on 12th January, 2011 and assented by the Governor of Sindh on 17th February, 2011 is hereby published as an Act of the Legislature of Sindh." It is further mentioned in the notification as "Sindh Act No: IV of 2011." The full Act is available at

<http://www.pas.gov.pk/uploads/acts/Sindh%20Act%20No.IV%20of%202011.pdf>, the official website of Provincial Assembly of Sindh. The main clause of this Act states that "no person shall manufacture, sell or use disposable syringes other than auto lock, auto destruct or auto break for injection, drawing of blood and other purposes." It goes on to state that "all directors, managers, secretaries or agents shall follow this Act and those contravening will be punished with imprisonment for a term that may extend to two years or fine which may extend to five hundred thousand rupees (approximately US\$ 5000) or with both."

Despite the current legislation regulating the use of AD syringes, we have noted several gaps in the "Sindh Act No: IV of 2011." The first and foremost gap in this bill is its lack of implementation. We checked with the Hepatitis Control Program of Sindh which itself is only using AD syringes for vaccination and treatment purposes. But the main tertiary hospitals of Karachi are still using conventional disposable syringes for therapeutic purposes. The heads of these hospitals and/or procurement departments are violating this law and can face jail terms or huge fines if any person from a law enforcement agency makes a simple visit and inquires about this issue. We are quite sure that these and other healthcare providers in the province are not even aware that such a law even exists in the province.

The second gap in the Act is about selling and manufacturing AD syringes. While it mentions that no person shall manufacture or sell syringes other than AD, the Act clearly misses a key requirement which is that the syringe should be compliant with ISO (International Organization for Standardization) Standard 7886-4 and that the manufacturer should comply with ISO Quality Systems Standards for Medical Devices Manufacturing ISO 13485. ISO compliance is essential to ensure that accepted international quality standards are met in the manufacturing of the AD syringes. As the Act stands right now, any supplier or manufacturer can provide any type of AD syringes, and no one can legally question its quality or standard of manufacturing. A study was supported by the World Health Organization and conducted in provincial capitals of Pakistan in 2003-4 to assess the quality of syringes available in the local market. Syringes were purchased from 30 randomly selected pharmacies in

¹Bridge Consultants Foundation, Karachi, Pakistan, ²USAID Health Care Improvement Project, University Research Company, Bethesda, USA.

Correspondence: Arshad Altaf . Email: arshad.altaf@gmail.com

the four provincial capitals. A check list based on the ISO 7886 standard was developed and used to assess the quality of syringes. The study found that 34% of the syringes sold in the main cities of Pakistan was substandard, a significant proportion by any means.⁵

Finally, the most important missing link is the reuse of syringes by healthcare providers. This is a nationwide practice which is wreaking havoc in patients' lives. Trained and untrained providers prescribe unnecessary injections and reuse syringes for economic reasons. The patient is often unaware of the life-threatening effect of this practice. The roll-out of AD syringes alone will not be sufficient if this gap is not addressed. The locking mechanism of the AD syringe has to be manually operated, meaning the user has to push the plunger completely with a little force after using the syringe in order to disable it and prevent further reuse. It is thus still possible for someone with the intention to reuse the AD syringe to circumvent its safety feature by not pressing the plunger fully. Currently there is no legal deterrent to prevent healthcare providers from reusing needles and syringes. Making unsafe injection practice illegal under such an Act would have been the most logical place to address this issue. However, that opportunity has also been missed. No law exists in the province or country right now which would hold healthcare providers accountable for reuse of syringes and needles.

In conclusion, not only have the provisions of the Act not been implemented at all, but the Act itself is not comprehensive enough and overlooks key issues such as standards for AD syringes and reuse of disposable needles and syringes. We all know that amending a law in Pakistan is a daunting task. But this Act is critical to stopping the

scourge of Hepatitis B and C in the province. Prudent measures such as forming a team of members of provincial assembly and technical public health experts to address this issue should be the foremost priority of Provincial Ministry of Health. However, efforts to amend the Act will be meaningless if the law is not implemented and accountability for ensuring implementation is not enforced. The problem of unsafe syringes and needles needs to be addressed in a comprehensive manner with requisite technical input from public health experts and in partnership with industry and healthcare providers. This should include working with healthcare establishments to ensure roll-out of AD syringes in the therapeutic sector and with the injection manufacturing industry to ensure adequate production to meet the needs at a feasible cost. We hope that the Sindh Government will lead the country in being proactive and ensuring a systematic process to strengthen the Sindh Regulation and Control of Disposable Syringes Act, 2010 and in ensuring its implementation.

References

1. Lloyd JS, Milstien JB. Auto-disable syringes for immunization: issues in technology transfer. *Bull World Health Organ* 1999; 77: 1001-7.
2. Qureshi H, Bile KM, Jooma R, Alam SE, Afridi HU. Prevalence of hepatitis B and C viral infections in Pakistan: findings of a national survey for effective prevention and control measures. *East Mediterr Health J* 2010; (16 Suppl): S15-S23.
3. Ver Hoeve E, Codlin AJ, Jawed F, Khan AJ, Samad L, Vatcheva KM, et al. Persisting role of healthcare settings in hepatitis C transmission in Pakistan: cause for concern. *Epidemiol Infect* 2013; 141: 1831-9.
4. Centers for Disease Control and Prevention (CDC). Establishment of a viral hepatitis surveillance system - Pakistan, 2009-2011. *MMWR Morb Mortal Wkly Rep* 2011; 60: 1385-90.
5. An Assessment of Quality of Syringes Available in Pakistan. External Report Submitted to World Health Organization; 2004.