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Policy and practice

Joumana Hermez1, Maha Ismail[1], Oliver Morgan[2], Muhammad Safdar Pasha[3], Karl Schenkel2, Meg Doherty [2], Muhammad Tayyab [2], Yetmgeta Eyayou Abdella [2], Muhammad Asif Sayed [4], Naveed Masood Memon4, Rana Jawad Asghar5, Musa Rahim [3], Saqib Sheikh [6], Hammad Ali [7], Elizabeth M Rabold [7], Robert Fontaine [7], Yvan Hutin [1] and Rana Hajjeh [1]

[1]World Health Organization Regional Office for the Eastern Mediterranean Region, Cairo, Egypt (Correspondence to Joumana Hermez: Hermezj@who.int). [2]World Health Organization Headquarters, Geneva, Switzerland.

[3] World Health Organization Pakistan Country Office.

[4] Pakistan Field Epidemiology and Laboratory Training Program, Pakistan.

[5] Global Health Strategists and Implementers.

[6] Sindh AIDS Control Program.

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US Centers for Disease Control and Prevention.

Abstract

Background: Following reports of an outbreak of HIV infection among children in Larkana District, Pakistan, an international team investigated the extent and cause of the outbreak between April and June 2019.

Aims: To investigate the incidence of HIV among children in Larkana District, Pakistan and describe the distribution of cases by time, place and person.

Methods: Self-referred persons were tested for HIV using the national testing protocol. Local epidemiology of HIV was reviewed to generate hypotheses. An infection prevention and control (IPC) team conducted site visits and reviewed IPC practices.

Results: Between 25 April and 27 June 2019, a total of 30 191 persons were tested for HIV in Larkana District, and 876 of them tested positive. Of those who tested positive, 719 (82%) were children aged

Conclusions: Investigations indicate that unsafe healthcare practices in formal and informal healthcare settings as the most likely cause of the 2019 outbreak of HIV infection in Larkana, Pakistan. Measures should be taken to improve IPC practices at the facility level, especially in pediatric and antenatal care clinics.

Key words: HIV, pediatric, outbreak, Pakistan, unsafe practices, iatrogenic, exposure, IPC

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Introduction

In 2020, the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) estimated that there were 200 000 persons living with HIV in Pakistan (1), a country with a population of 207 million (2). The epidemic is concentrated among key populations, i.e. injecting drug users, men who have sex with men, and transgender people. At the end of 2018, the number of children aged

Pakistan has faced challenges in infection prevention and control (IPC), particularly with unsafe injections. Since the late 1990s, several studies reported that overuse (4) and unsafe use (5–8) of injections were a major drivers of a large epidemic of hepatitis C and hepatitis B infections. Unlike in most other countries, injection use indicators have not improved in recent years in Pakistan (9).

Several outbreaks of HIV infection have previously been reported in Pakistan (10). A recent systematic review by Rabold et al. identified 7 outbreaks between 2002–2019 (11) among injecting drug users, the general population due to unsafe injections administered in healthcare settings and in the community, and hemodialysis patients. These outbreaks reflected major challenges in basic infection control practices. While these outbreaks caused substantial concern at the time, they were not followed by systematic IPC interventions that could have led to improved national IPC practices in Pakistan.

In April 2019, the media reported that several children without known risk factors were diagnosed with HIV in the Ratodero Taluka Subdistrict in Larkana District (12). The Sindh Provincial Department of Health, in coordination with the District Commissioner in Larkana and the Sindh AIDS Control Programme (SACP), began a major campaign to test people for HIV at the Taluka Headquarters Hospital in Ratodero, including the testing of hundreds of children (13). After identifying more pediatric HIV infections, SACP established 5 additional provisional testing facilities at various primary healthcare sites in the district. Initial data collected by SACP from HIV treatment centres showed that 94% of mothers of HIV-positive children were HIV negative,

suggesting that the primary mode of transmission was not perinatal. On 23 May 2020, the Pakistan Federal Minister of Health requested support from WHO to conduct an outbreak investigation to identify the source of infection and propose interventions for control. This paper summarizes the findings of the investigation as well as recommendations to the Ministry of National Health Services Regulations and Coordination, government officials, and other key stakeholders.

Methods

WHO sent a multi-disciplinary rapid response team (RRT) to Larkana that included epidemiologists; clinicians specialized in pediatric HIV and IPC; laboratory scientists; and blood safety specialists from SACP, the Field Epidemiology and Laboratory Training Programme (FELTP) Pakistan, Aga Khan University (AKU), UNAIDS, UNICEF, United States Centers for Diseases Control and Prevention (US CDC), and WHO. The RRT's first aim was to identify potential causes of the outbreak, including mother-to-child transmission, transmission from cultural practices, transmission from key populations through sexual or intravenous drug use practices, or iatrogenic exposure through healthcare exposures.

HIV testing procedures

In the SACP-led testing facilities established because of the rise in HIV cases in Larkana District, all persons who presented were eligible for testing. Testing was conducted using a 3-serial-testing strategy which followed the national HIV testing algorithm, consisting of 3 serial tests. The first test (A1) was conducted using Alere Combo®, the second (A2) using Unigold®, and the third (A3) using SD Bioline® (14). A1 and A2 were conducted at the testing facility and A3 was conducted at the treatment centre. To follow this testing algorithm, SACP staff physically relocated to Larkana District to train healthcare workers on implementation; provided the test kits; monitored stocks; and supervised storage, handling, and testing procedures. A3 was reserved for treatment centres so that it could be conducted by experienced laboratory personnel as part of quality assurance. The RRT observed the testing procedures and the quality of the test kits at all the testing sites.

A case was defined as any child aged 18 months or older or any adult with 3 positive serial tests (A1+A2+A3). For children **Descriptive epidemiology**

We used Microsoft Excel for compiling and analyzing all collected data. Using daily totals from testing facilities as compiled by the Ministry of National Health Services, we generated epidemic curves showing the number of persons tested, the number who tested positive, and a 7-day simple moving average of test positivity. We reviewed patient registers at the treatment centres and extracted information regarding age, sex, residence [district and subdistrict (Taluka)], final HIV status, and CD4 count. Using 2017 census data (15), we calculated age- and sex-specific

attack rates for confirmed cases registered at the treatment centre who resided in Larkana District. We mapped the distribution of pediatric (aged **IPC investigations**

Experts in IPC visited 5 public and private acute care hospitals, 10 private clinics, 1 dispensary, 1 pharmacy, and 1 barber shop in Ratodero and Larkana City, and the local office of the Expanded Programme of Immunization (EPI) to observe basic IPC measures to identify gaps and breaches. Cleanliness, disinfection and injection practices, handling of sharp and used injection material, and medical waste disposal were assessed through observations and interviews using checklists for IPC and waste management, and photos taken without identifiable staff or patients.

The IPC group also conducted site visits at 10 blood banks (public and private), the thalassemia care centre, the regional blood centre with its satellite hospital blood bank, private clinics, and hospitals. Checklists for blood transfusions, IPC, and waste management were used during observations and interviews. Data on blood collection, testing, processing, and utilisation at the bedside were collected from the Sindh Blood Transfusion Authority, Larkana District Blood Transfusion Authority, and individual blood banks.

To understand the background of HIV epidemiology in the region and investigate potential horizontal and vertical modes of transmission of HIV infection, we reviewed available surveillance data from tuberculosis clinics and antenatal clinics. We also reviewed national and Larkana-specific surveillance data on key populations (17) (e.g. men who have sex with men, female sex workers, transgender people, and injecting drug users) and met with service providers to identify possible interactions between key populations and the general population, including children.

Protection of human subjects

Protection of human subjects was observed in alignment with WHO guidelines on ethical issues in public health surveillance (2017). It was also reviewed by the US CDC and was conducted in compliance with applicable federal laws and US CDC policies (see e.g. 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq.). Adult guardians (parents, grandparents, or uncles/aunts) of children diagnosed with HIV provided verbal consent to testing and participation in an interview.

Results

Descriptive epidemiology

Between 25 April and 27 June 2019, a total of 30 191 persons were tested for HIV in Larkana

District (Figure 1A), and 876 persons tested positive (Figure 1B). The 7-day test percentage positivity ranged between 1.5% and 5.5%. Of those who tested positive, 719 (82%) were children aged

Additional demographic and clinical information were available for 494 (71%) of the 698 confirmed cases. Among these cases, with an age range of 1 month to 65 years, 444 (92%) were children and 63% were male. Of these, 216 (43%) cases were aged between 3 and 6 years. The overall age-specific attack rate for children was 4.9 per 10 000 (Figure 2). The attack rate was higher among males than females for all ages

HIV-positive children were identified across 7 districts, but 71% (n=325) were from Taluka Ratodero. The baseline CD4 count was available for 68 (15%) children aged 500 cells/µl, 11 had 200-49 cells/µl, and 4 (14%) had **Informative interviews at the treatment centre**

The informative interviews with parents or guardians conducted by FELTP resulted in data on 211 children aged **Infection prevention and control**

Observations of IPC practices during the site visits identified gaps in the basic implementation of IPC measures, including a high risk of exposure to sharp equipment (direct and indirect reuse of syringes and drip sets) and the unsafe disposal of healthcare waste, such as used syringes and needles. These gaps were observed in facilities in close proximity to where children played in the street. At the barber shop, the IPC experts noted that razor blades were reused for several clients and there was an overall lack of hygiene protocol. At EPI sites, all the vaccinations observed by the IPC experts were administered with single-use syringes (1 ml auto-disable syringe with integrated needles) and with appropriate sharp disposal and waste management.

Background HIV data

Quality assurance procedures and HIV positivity of screened blood products varied across the reviewed blood banks, blood centres, and health facilities. Two blood centres used WHO pre-qualified test kits with daily quality control; they reported between 0.24% and 0.3% HIV positivity among screened donor blood. In contrast, at both public and private blood banks, donor blood was screened with test kits that were not on the WHO list of prequalified in vitro diagnostic products and were used without quality control. The reported HIV positivity of screened blood from blood banks was 0.04%. Unauthorised blood banks operating in the community were also identified.

Systematic testing for co-infection with HIV was not conducted at all the sites providing care for tuberculosis. No routine data was available for HIV prevalence in ANC or other services. In the few centres where routine HIV testing was offered to pregnant women, positive results were

very rare. However, the rapid HIV test kits used in these sites were not prequalified by WHO. Epidemiological data from key populations in Larkana District revealed an HIV prevalence of 18% among transgender people, 16% among injecting drug users, 5% among male sex workers, 4% among female sex workers, and 4% among men who have sex with men (17). Key informants from non-governmental organizations (NGOs) working with these populations could not identify any links between them and the Ratodero children affected by the outbreak.

Discussion

We report an unprecedented HIV outbreak in Larkana District involving a large number of children. From April to June 2019, 876 persons were reported as HIV infected; 82% of which were children aged

First, only 10% of patients' mothers were infected with HIV (13), which is not consistent with vertical transmission as the primary cause of the outbreak. Infants would also be expected to have a higher prevalence of HIV than older age bands due to HIV-associated mortality, which was not observed among the children, with highest age-adjusted attack rates being in the 2 to 4-year age band.

Second, the frequency of traditional skin piercing and circumcision procedures was low for the children evaluated in the informative interviews, with far more children reporting therapeutic medical interventions.

Third, there were no identified interactions (e.g. sexual abuse, drug use) between the infected children and the high-risk key population. The young age of most of the children also points away from the initiation of high-risk behaviours; data from integrated HIV biobehavioural surveillance (IBBS) in Larkana District suggest that the average age for initiating injecting drugs and selling sex by transgender, female, or male sex workers was 23, 15, 17, and 16 years, respectively (17). The collective findings pointed to unsafe medical practices and exposures as the primary cause of the outbreak.

Our findings regarding unsafe healthcare practices are supported by the results of a subsequent case-control investigation conducted by FELTP, which included 100 children newly identified as HIV-positive living in Ratodero and matched to 200 control children (18). This investigation revealed a strong association with intravenous infusions, often given through reused drip sets in the clinics of private practitioners. Intramuscular injections were not associated with being a case. Though still associated with infection, reused syringes were far less common than reused intravenous infusions and had a weaker association. Another case-control investigation conducted by Aga Khan University identified parenteral routes due to unsafe injection and blood

safety practices as the predominant mode of HIV transmission, while also noting a high prevalence of hepatitis B (18%) and C (6%) among cases (13).

Unsafe injection practices have been reported as leading causes of hepatitis B, hepatitis C, and HIV outbreaks in Pakistan (11). The use of shared glass or disposable syringes in medical practice, when not properly disinfected, contributes to the global burden of blood-borne infections (19) and was cited as the leading cause of several HIV, hepatitis B, and hepatitis C outbreaks in Cambodia (20), India (21), China (22), and Pakistan (23).

In 2009, up to 38% of physicians and unqualified healthcare providers in Pakistan reused their injection equipment, while overprescribing injections for their clients (23). The general population in Pakistan believes that injections are more effective than oral medications (24). The financial incentives for healthcare workers also perpetuate excessive injection practices; patients in rural communities presenting to general practitioners and unqualified providers usually expect treatment that includes injected medicines. Determinants of unsafe injection practices include a lack of awareness regarding the risks (25) and the limited availability of safe injection devices.

The repeated outbreaks of HIV infection in Pakistan also have several social determinants, including widespread poverty, power imbalances between men and women, labour migration, and a lack of awareness about HIV transmission modes among the general population (26). Concurrently, malpractice by health practitioners and widespread quackery have often been cited as the direct cause of blood-borne virus outbreaks (27, 28). Unnecessary and unsafe use of injections, unsafe healthcare, and the resulting repeated HIV outbreaks reflect the structural weaknesses of the health system.

The HIV outbreak in Larkana District has proved to be a catalyst for change. In response to the outbreak, the Health Department of Sindh established a family-centred HIV testing and ART clinic at Taluka Hospital Ratodero for children, their parents, guardians, and other adults. Based on the results of the investigation, the Health Department started a province-wide IPC programme. An immediate policy for safe injection procedures at hospital level was developed and implemented, and a supply chain of adequate infection control and safe injection material in government hospitals was initiated. The Sindh Health Department then released an IPC policy assigning a provincial IPC group to manage and coordinate IPC activities, and assigned fulltime IPC teams at hospitals. WHO also developed an IPC training package that was endorsed by the provincial team. A cadre of provincial IPC master trainers were trained to provide further IPC step-down trainings to hospital teams.

Immediate expansion of the work is now required to reach private practitioners and NGOs providing healthcare at the community level. A public-private collaboration with the Sindh Health Care Commission (SHCC) is needed to strengthen the auditing of IPC practices within private clinics and facilities and unlicensed healthcare providers. This health system strengthening approach to reinforcing IPC in Sindh Province is imperative to ending this HIV outbreak among children in Larkana District and should establish a strong foundation for the prevention of other outbreaks in the future.

Limitations

Our investigation had 2 limitations. First, testing was limited to self-referrals. Some infected individuals may still not have been tested and diagnosed. Because of this limitation, the spatial distribution should be interpreted with care as it probably reflects HIV-testing-seeking behaviour more than the actual distribution of cases. Second, we were not able to determine the timing of acquisition of infection, so the diagnoses probably represented prevalent cases. The epidemic curve likely reflects the timing of the testing efforts rather than incidence. To compensate for this limitation, we assessed other clinical syndromic criteria to determine the clinical stage for affected children and estimate the duration of the infection.

Conclusion and recommendations

Data from 2021 indicate that the outbreak in Larkana District is still ongoing, with 1492 cases diagnosed as of February 2021. Sustained actions are needed to prevent future outbreaks. First, it is important to strengthen HIV case-based surveillance to enable the detection of changes in the epidemic among low-risk groups in Pakistan. This could be done through improved case notification and sentinel surveillance among pregnant women and implementation of mechanisms to respond rapidly to unusual signals, such as the detection of cases of HIV infection among children. The Ministry of National Health Services Regulations and Coordination in Pakistan announced on World Hepatitis Day 2019 that it has started a country-wide policy to improve IPC and blood and injection safety (28). This new initiative addresses IPC, injection safety, testing and treatment for blood-borne pathogens, and strengthened surveillance (29). Improving community awareness and engagement is also necessary to reduce the demand for and administration of unnecessary and unsafe injections. Implementing these activities will hopefully ensure that the Larkana District outbreak is the last occurrence of this series of healthcare-associated HIV outbreaks in Pakistan. As Pakistan currently develops its investment case for Universal Health Coverage, strengthening health systems based on a primary healthcare approach is the way forward (30). The COVID-19 pandemic—in addition to highlighting the importance of advancing IPC measures in Pakistan—has provided many lessons on essential public health functions (31). The outbreak in Larkana District shows that safety in healthcare and equity in delivering essential health services are the only paths towards achieving the health-related Sustainable Development Goal

(SDG-3).

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Competing interests: None declared.

Flambée épidémique de VIH chez les enfants au Pakistan
Résumé

Contexte : Suite à des rapports signalant une flambée épidémique d'infection à VIH chez des enfants dans le district de Larkana (Pakistan), une équipe internationale a enquêté sur l'ampleur et la cause de la flambée entre avril et juin 2019.

Objectif : Étudier l'incidence du VIH chez les enfants dans le district de Larkana et décrire la répartition des cas en fonction du temps, du lieu et des individus.

Méthodes : Les patients se présentant volontairement ont été soumis à un test de dépistage du VIH selon le protocole national de dépistage. L'épidémiologie locale du VIH a été examinée afin de formuler des hypothèses. Une équipe pour la prévention et le contrôle des infections a réalisé des visites sur sites et a examiné les pratiques en la matière.

Résultats : Entre le 25 avril et le 27 juin 2019, un total de 30 191 personnes ont fait l'objet d'un test de dépistage du VIH dans le district de Larkana, et 876 d'entre elles ont reçu un résultat positif. Parmi les personnes testées positives, 719 (82 %) étaient des enfants de moins de 15 ans. Les techniques traditionnelles de perçage de la peau et la transmission du virus aux enfants par des populations à haut risque ont été exclues au cours de l'enquête. Des entretiens informatifs réalisés auprès des parents ou tuteurs de 211 enfants âgés de moins de 15 ans issus d'un échantillon de commodité ont révélé que 99 % d'entre eux avaient subi une injection ou une perfusion dans le cadre d'un traitement médical au cours des 12 derniers mois. Notre enquête a mis en évidence un manque de données concernant la prévalence du VIH dans la population générale, y compris chez les patients atteints de tuberculose et chez ceux ayant consulté des services de soins prénatals.

Conclusion : L'enquête a démontré que des pratiques de soins de santé non sécurisées dans les établissements de santé formels et informels sont les causes les plus probables de la flambée épidémique de VIH survenue en 2019 dans le district de Larkana (Pakistan). Il est nécessaire de prendre des mesures dans le but d'améliorer les pratiques de prévention et de contrôle des infections au niveau des établissements de santé, en particulier dans les cliniques de soins pédiatriques et prénatals.

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WHO EMRO | A pediatric HIV outbreak in Pakistan

لخدمات الرعاية السابقة للولادة .

: تشير الاستقصاءات إلى أن ممارسات الرعاية الصحية غير المأمونة في مرافقالاستنتاجات
الرعاية الصحية الرسمية وغير الرسمية هي السبب الأرجح لحدوث فاشية العدوى بفيروس
العوز المناعي البشري في عام 2019 بمنطقة لاركانا، باكستان . وينبغي اتخاذ تدابير
لتحسين ممارسات الوقاية من العدوى ومكافحتها على مستوى المرافق، لا سيَّما في عيادات
طب الأطفال والرعاية السابقة للولادة .

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