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Controlling Health Care Associated Infections in the International Research Setting

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Keywords

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Standard infection control precautions and centralized prevention/education has improved health care outcomes for patients and health care workers (HCW).^{1–3} In resource-limited health care settings, implementation of these practices is challenging and transmission of highly resistant organisms within health care facilities is described.^{4–7} High rates of needle stick injuries and ⁸ unsafe injection practices⁹ occur in clinics and hospitals where blood borne infections such as hepatitis and HIV are common; post-exposure prophylaxis is infrequently accessed.¹⁰ Alcohol gels are perceived as expensive and may be unavailable and many settings lack appropriate hand washing facilities.¹¹ Personal protective equipment is often absent, medical equipment may be old and in disrepair. Strict standards for environmental controls are difficult to maintain and health care facilities themselves are often archaic. International recommendations are available for infection control, but programs are not consistently regulated and have few monitoring and enforcement programs.^{12–14}

The National Institute of Allergy and Infectious Diseases (NIAID) supports six networks conducting HIV-related clinical research. Many clinical research sites (CRS) are located outside of the US in resource-limited settings. CRS that have access to the patients and resources necessary to perform high quality research are limited and usually engage in diverse research. A single site might have studies focusing on the prevention of mother-to-child transmission of HIV, intensive pK studies involving new drugs for multiresistant organisms, and protocols testing second-line antiretroviral therapy. Standard clinical care is provided in often crowded facilities where research subjects are present for many hours. Anecdotal observations have suggested there are significant variations in infection control practices among the sites.

Methods

A survey of the infection control resources and practices at the CRS outside of the United States was undertaken, led by the Office of HIV/AIDS Network Coordination (HANC).

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conflicts of interest:

No conflicts reported.

Sites were asked about a formal infection control program, staff safety, respiratory hygiene and tuberculosis control, hand hygiene capabilities, injection practices and blood safety.

Results

74 sites overall were offered the survey, 32 returned completed surveys. 23/32 AIDS Clinical Trials Group sites completed the survey.

Infection control organization

86% of sites had an infection control policy, of these 55% were specific to the CRS. 75% of sites had an infection control officer, directly employed by the sites half the time. The sites without an infection control policy frequently did not have policies addressing the domains surveyed.

Respiratory

60% of sites reported a triage system to identify participants with potential respiratory infections. Commonly the study participant was placed in a well-ventilated area and provided a mask. Less than half of respondents (45.2%) conduct protocol procedures with participants with known or suspected tuberculosis (TB) in a separate clinic area. Natural and mechanical ventilation were common methods of ensuring respiratory hygiene. N95 masks were available in the general clinic in 39% of sites (12/31). Ultraviolet (UV) lights were present in 8/29 general clinic areas and 4/13 dedicated sputum collection areas indoors. A dedicated space for sputum collection was present in 55% of the CRSs. Space for sputum collection was most commonly an area outside (~55%) or a dedicated sputum collection area inside (~45%). In the space for sputum collection, natural and mechanical ventilation was used as infection control measures. 25% of sites reported surgical masks worn by patients. Staff were provided N95 masks 50% of the time in the dedicated sputum collection area; 2/11 sites reported that N95 respirators were available. Educational material on cough hygiene was available at 40% of the respondent sites. 45% of sites had TB surveillance programs for staff members in 45% and routinely screened staff for TB infection 71% of the time

Hand Hygiene

All sites reported sinks with running water; most had manual soap dispensers (25/32) and paper hand towels (27/32). Hand sanitizers were available at half of the sites. Water basins filled remotely were used in some areas in 15/32 sites, bar soap in 13/32 sites, and cloth hand towels in 11/32 sites.

Blood safety

All sites reported a policy for management of needle stick injuries and all sites have appropriate postexposure prophylaxis for HIV. The source patient is tested for hepatitis B at 58% of sites, and hepatitis C at 39%. Post exposure protocols for hepatitis B were present in 42% of sites. A majority of sites reported a needle recapping policy (71%) and 58% used safe needle systems. Sharps containers were generally available.

Discussion

Health care-associated infections are an important cause of morbidity for patients and healthcare providers in resource limited settings. A recent meta-analysis suggested that rates of indicator health care-associated infections might be more than double those of resource

rich settings.¹⁵ Our survey suggested important areas for improvement in the delivery of health care associated with NIAID-sponsored clinical trials.

There is good evidence that organizational support for infection control reduces the transmission of infectious agents and reduces mortality and morbidity in the acute care setting.^{16,17} Critical elements include staff trained in the principles of infection prevention, surveillance, and enforcement of preventative measures. Prevention of occupational illnesses requires pre-employment assessments and immunization for vaccine-preventable illnesses. A quarter of the sites did not have appropriate personnel tasked with infection prevention. Those sites that did not have specific policies related to infection control also did not have policies to address most of the infection control domains.

TB transmission in the health care environment is well described. The association with HIV infection is important and instances of transmission clusters of highly resistant TB have been documented.^{18,19} A review examining the incidence and prevalence of latent TB infection among HCW in low and middle income countries suggested that HCW were at significant risk for TB disease compared to the general population.²⁰ Even in areas where transmission of TB has been described, infection control procedures may be lacking. In eThekweni Municipality, Durban, RSA, only a quarter of primary health clinics triaged patients with cough. This is consistent with our experience. Patients with known or suspected TB are seen in the same facility as patients without TB and segregation of individuals who might be infectious is not commonly undertaken. Cough hygiene has been promoted in resource-rich settings as a way of reducing spread of respiratory pathogens, fewer than half the sites had information available about cough hygiene.

Hand hygiene is a critical measure to reduce healthcare acquired infections. Improvement of hand hygiene practices has been associated with reduced infection rates in hospitalized patients.²¹ In 2009 the WHO described best practices for hand hygiene and methodologies for local manufacture of inexpensive hand sanitizing gel.^{22,23} The multimodal strategy was tested in a reference hospital in Mali and found to be feasible, affordable and effective.²⁴ The WHO has ongoing efforts to promote hand hygiene using alcohol based hand rubs throughout the world; however a recent survey in Uganda of attitudes towards infection control gel for hand hygiene was perceived to be expensive and unavailable.¹¹ In our survey hand hygiene practices varied widely; alcohol based gel was not generally available. The use of hand basins with standing water accompanied by bar soap and multiuse towels was striking.

HCW are at risk for infection with blood borne pathogens, and needle stick injuries are common. One survey in Malawi suggested that half of nurses had a needle stick injury within the previous year.²⁵ This rate is similar to rates in resource-rich settings prior to the widespread adoption of engineered needle-safe solutions.²⁶ The consequences of outdated needle practices combined with high prevalence rates of HIV, hepatitis B and hepatitis C may be catastrophic.²⁷ Although postexposure prophylaxis is available for injuries that might be capable of transmitting HIV, it is unknown to what extent the work force is at risk for hepatitis B as the information is not collected prior to employment.

Participation in research should not place patients at more risk when compared to the local standard of care. The concentration of patients with communicable diseases drawn to the research site to participate in clinical protocols and the need for prolonged face-to-face interactions could lead to an increased risk for preventable infections in the research setting compared to the clinical environment. Arguably research settings should set and demonstrate higher standards for clinical care, even when these levels cannot be implemented immediately throughout the healthcare system. Ethicists have commented that

researchers should not replicate unacceptably low local standards, but should seek to establish competent levels of care that can ultimately be feasibly implemented in the health system, for the benefit of all patients.^{28,29}

Our survey demonstrated important areas for improvement in infection prevention. There are good precedents in the resource-limited setting for developing standards for hand hygiene and the prevention of blood borne illnesses. The most pressing need is for a protocol for the prevention of TB transmission. This has been developed and is being implemented at our sites. TB infection control, however, is best undertaken in an environment of other infection prevention efforts. NIAID and other research sponsors have a unique opportunity to model better healthcare infection control practices; it is hoped that this will lead to improved health care outcomes.

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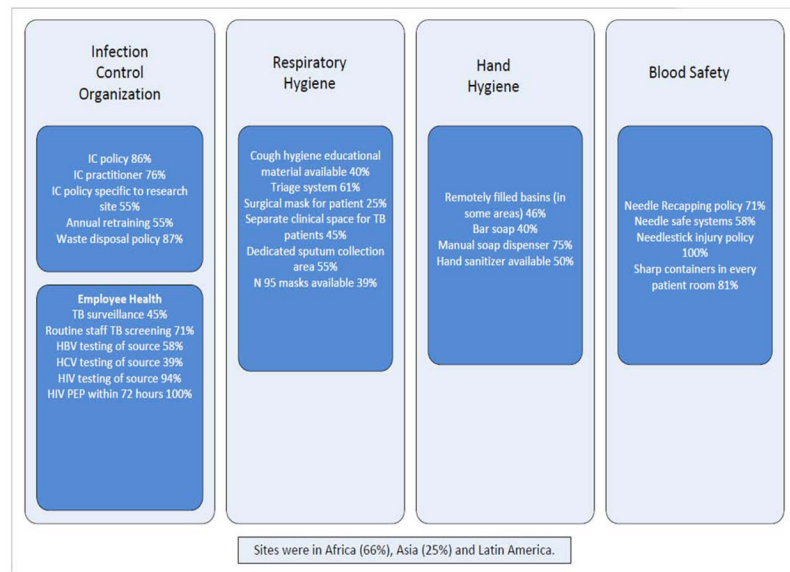


Figure 1.
Selected Infection Control Practices at NIAID Funded Sites.