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Preventing contamination between injections with multiple-use nozzle needle-free injectors: A safety trial

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Summary Multiple-use nozzle jet injectors (MUNJIs), a type of needle-free injector, use a high-pressure stream to penetrate skin and deliver medicament. Concerns for their potential to transmit blood borne pathogens led to development of a hybrid MUNJI for use in mass immunizations. The HSI-500®, referred to here as a protector cap needle-free injector (PCNFI), utilizes a disposable cap as a shield between the reusable injector nozzle and the skin to reduce the risk of contamination. This study aimed to determine the presence of hepatitis B virus (HBV) contamination in post-injection (''next person'') samples immediately following injection in HBV-carrier adults. Tolerability and pain were also assessed. The study ended early because the PCNFI failed to prevent contamination in the first batch tested (8.2% failure rate). The injections were very well tolerated, with most followed by no bleeding (81.2%) or mild bleeding (7.8%). 55.2% of participants experienced no pain while 42.3% experienced mild pain following injection.

Introduction

By 1999, roughly one-third of all immunization and one-half of non-immunization injections in developing countries were considered unsafe [1]. This suggests that reused syringes cause millions of blood borne infections each year [2],

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resulting in 1.3 million early deaths and US$535 million in direct medical costs [3]. Reuse of contaminated syringes, needle-stick injuries among health workers, and threats to the community from improperly disposed and contaminated sharps present serious health risks. While some developing countries are addressing injection safety concerns by introducing single-use, autodisable (AD) syringes for vaccinations, the risks of transmitting chronic infections by needle-stick injury from sharps waste will continue to be a leading hazard for health workers and waste disposal personnel [4].

An alternative to needle and syringe injections are needle-free injections that penetrate the skin with a high-pressure stream and deliver medication into intradermal, subcutaneous, or intramuscular tissues [5]. Some multiple-use nozzle jet injectors (MUNJIs) can have a short injection cycle time, allowing rapid and cost-effective delivery of a medicament to large numbers of people. This is especially advantageous in epidemic situations. Studies show the pain of needle-free injection is generally less than or equal to the pain from a needle and syringe injection, though results vary by study and may depend on the vaccine [6—8]. Bleeding at the injection site is reported as more common with needle-free injection than with needles and syringes [9].

Evidence that MUNJIs could transmit blood borne pathogens between humans was documented in 1986, when a MUNJI was implicated in the transmission of hepatitis B virus (HBV) in 31 cases in a California clinic [10,11]. These cases brought serious concerns and increased scrutiny regarding the safety of these devices [12,13]. In November 1995, a joint meeting of the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) concluded that MUNJIs presented an unacceptable risk to vaccine recipients. By December 1996, amid safety concerns during a large meningitis outbreak in northern Nigeria, WHO revised its policy noting that needle-free injectors designed for use with multidose vials should not be used for immunizations until safe needle-free injectors are identified through independent safety testing [14,15].

PATH has partnered with Pulse Needle Free Systems, formerly Felton International, of Kansas since 1998 in the specification development, design, testing, and evaluation of a new-generation MUNJI. The design of this injector, designated the HSI-500® or the protector cap needle-free injector (PCNFI), uses a disposable plastic cap that acts as a shield between the injector nozzle and the skin to reduce the risk of contamination between injections. The PCNFI is designed for use in mass immunizations where the per-injection cost is estimated to be lower than the alternative AD needle and syringe cost [16].

A similar small-scale pilot study to that reported here was conducted in 2004 at Huntington Medical Research Institute Liver Center in Los Angeles, California. That study, in which no contamination was found, informed the design and plans for this larger study in which we test the hypothesis that the PCNFI would prevent contamination between injections in human volunteers infected with HBV. The primary goal of this study was to determine the presence of HBV contamination in post-injection samples of sterile saline immediately following injection with the PCNFI.

Figure 1 Foot pump and hydraulic hose.

Materials

Protector cap needle-free injectors

The PCNFI is powered by a spring that uses hydraulics and a foot pedal to provide the pressure needed to deliver a subcutaneous injection (Fig. 1). It utilizes a reusable fluid path (Fig. 2) attached to a vial containing the fluid for injection (vaccine or other medicament). The fluid path is loaded on top of the injector hand piece which includes a trigger. The components of the injector are shown below in Figs. 1—3, and Fig. 4 shows a fully assembled device as it would be used in an injection session.

A single-use, disposable plastic cap shield separating the nozzle from the skin is intended to reduce contamination between injections. The cap is designed such that the jet stream of an injection must first penetrate a thin plastic film, forming the smallest possible orifice for the injection stream to pass through. The injection stream must then pass through three additional, sequential coaxial orifices

Figure 2 Protector cap needle-free injector reusable fluid path.