Immunogenicity of Bacille Calmette-Guérin (BCG) via a disposable syringe jet injector versus conventional needle and syringe administration

Hennie D. Geldenhuys1, Helen Mearns1, Jennifer Foster2, Eugene Saxon2, Ben Kagina1, Laura Sagotic2, Courtney Jarrahian3, Michele D. Tameris1, One B. Dintwe1, Michele Van Rooyen1, Kany Kany A. Luabeya1, Gregory Hussey1, Thomas J. Scriba1, Mark Hatherill1, Darin Zehrung4
1South African Tuberculosis Vaccine Initiative (SATVI), Institute of Infectious Disease & Molecular Medicine, and School of Child & Adolescent Health, University of Cape Town, Cape Town, South Africa. 2PATH, Seattle, Washington, United States of America

Background
Disposable-syringe jet injectors (DSJIs) represent a needle-free vaccine delivery method that has the potential to improve injection safety and provide safe, reliable, easy-to-use and affordable vaccine delivery. DSJIs can potentially be used to deliver all injectable vaccines used in global immunization programs at all depths of delivery.

Bacillus Calmette-Guérin (BCG) is the only vaccine that is efficacious at preventing childhood TB and is given at birth as part of the standard South African Expanded Programme on Immunisation.

Aim
Our aim was to compare the safety, reactogenicity, and immunogenicity of Bacille Calmette-Guérin (BCG) vaccine administration by DSJI with traditional intradermal administration by needle and syringe (NS).

Study design
This was a controlled, partially blinded clinical trial in which 66 healthy new-borns were randomized equally into two study arms at birth: BCG vaccination by DSJI or by needle and syringe (NS).

Results
Frequencies of BCG-specific CD4 and CD8 T-cells that produce Th1 cytokines were similar in both DSJI and needle and syringe groups.

Discussion
Safety, reactogenicity, and antigen-specific T-cell immune responses did not differ between disposable syringe jet injector (DSJI) and needle and syringe (NS) techniques.

Future studies into the introduction of DSJIs for BCG administration in global tuberculosis preventative programs would be justified.

Immunology methods
Whole blood samples were incubated for 12hrs at 37°C with BCG, no antigen (negative control) or PHA (positive control).

Intracellular cytokine staining was used to detect cytokines and memory marker expression on CD4 and CD8 T cells.

Study design
This was a controlled, partially blinded clinical trial in which 66 healthy new-borns were randomized equally into two study arms at birth: BCG vaccination by DSJI or by needle and syringe (NS).

131 infants
Screened for eligibility
Excluded (n=65):
- Not meeting inclusion criteria (n=50)
- Refused to participate (n=0)
- Eligible but enrollment target reached prior to enrollment (n=15)

Randomized (n=66)

DSJI (n=33)
Lost to follow up (n=0)
Withdraw consent (n=0)
Analysed (n=33)

NS (n=33)
Lost to follow up (n=0)
Withdraw consent (n=0)
Analysed (n=33)

Participants were followed for up to 14 weeks post-vaccination to assess adverse events, reactogenicity, and immunogenicity.

This work was supported by PATH and the World Health Organization (WHO).

helen.mearns@uct.ac.za