Evaluation of The BD Integra™ 3ml Syringe with Retracting BD PrecisionGlide™ Needle at Texas Children's Hospital and Test-med

Introduction:

In this age of managed care and escalating health care costs, not only is it important to deliver medications safely but to do so in a cost-effective manner. In an effort to meet these needs, BD has designed a 3ml syringe and needle, known as the BD Integra™ Syringe with Retracting BD PrecisionGlide™ Needle.

The BD Integra™ Syringe with Retracting BD PrecisionGlide™ Needle is a safety-engineered device which activates when the user continues to press down on the plunger at the end of the injection, triggering the retraction of the needle backwards into the syringe. An added design feature of this system is low waste space volume.

All needles and syringes have waste space. In traditional needles and syringes, the waste space volume is a consequence of residual medication remaining within the syringe tip, needle hub and cannula after injection is complete. The BD Integra™ Syringe with Retracting BD PrecisionGlide™ Needle has a specially designed hub and corresponding syringe connection site, known as Tru-Lok. As a result of this innovative design, the BD Integra™ Syringe with Retracting BD PrecisionGlide™ Needle has less waste space volume than conventional syringe/needle combinations (data on file).

Two evaluations of the BD Integra™ 3ml Syringe with Retracting BD PrecisionGlide™ Needle were conducted in the Fall of 2003 during two Influenza vaccine programs to evaluate the low waste space design when using multidose vials. The first evaluation was conducted at the Employee Health Department at Texas Children's Hospital in Houston, Texas and the second was conducted at Test-med, an on-site Influenza vaccination provider in San Francisco, California.

By using the BD Integra™ 3ml Syringe with Retracting BD PrecisionGlide™ Needle, both Texas Children's Hospital and Test-med were able to maximize their Influenza vaccine supply and gain, on average, one extra dose per 10 dose vial of Influenza vaccine.

Evaluation & Results:

Texas Children's Hospital, Houston, TX

The objective of this evaluation was to evaluate the number of doses obtained from multidose (10 doses) Influenza vaccine vials (Fluzone®, Aventis Pasteur, lot #U1124AA and U1136AA) using the BD Integra™ 3ml Syringe with Retracting BD PrecisionGlide™ Needle, compared to the number of doses obtained when using a conventional BD™ 3ml syringe with BD SafetyGlide™ needle.

Four experienced Registered Nurses from the Employee Health Department at Texas Children's Hospital participated in the non-blinded evaluation. Each nurse was responsible for drawing up the vaccine from 26 Influenza vaccine vials. A total of 104 vials were drawn up during the entire evaluation. The filled syringes were used for actual vaccination and the evaluation was conducted over the course of several days during scheduled employee Influenza vaccine clinics.

BD Integra™ 3ml Syringes with 23G x 1" pre-attached Retracting BD PrecisionGlide™ Needles (catalog# 305271, lot# 2346439) were used by each nurse to draw from half (13) of the 26 vials, and conventional BD™ 3ml Syringes with BD SafetyGlide™ 23G x 1" Needles (catalog# 305905) were used by the nurses to draw from the remaining 13 vials. The nurses documented the total number of complete doses (0.5ml) withdrawn from each vial; any remaining partial dose (less than 0.5ml) drawn up was also documented.

This institution allowed for the clinician to withdraw vaccine from more than one vial to complete a dose. Therefore when a partial dose was drawn into a syringe and combined with Influenza vaccine from the next vial to form a complete dose, the volume drawn into the syringe from the new vial was also documented. The procedure described above was followed until all 104 vials were used.

Results showed that clinicians using the BD Integra™ 3ml Syringe with Retracting BD PrecisionGlide™ Needle drew greater than 10 full doses from 61.54% of the 52 vials. Clinicians using the conventional BD™ 3ml syringe with BD SafetyGlide™ needle were able to draw greater than 10 full doses from only 19.23% of the remaining 52 vials.

The observed average number of complete plus partial doses drawn from each vial using the BD Integra™ 3ml Syringe with Retracting BD PrecisionGlide™ Needle was 11.67 doses. Using the conventional needle/syringe, the average number of doses drawn from each vial was 10.98. The observed average number of complete plus partial doses drawn with the BD Integra™ 3ml Syringe with Retracting BD PrecisionGlide™ Needle was 0.7 doses higher than the number drawn with the conventional BD™ 3ml syringe with BD SafetyGlide™ Needle, and the difference was statistically significant.

As a result, it can be concluded that the BD Integra™ 3ml Syringe with Retracting BD PrecisionGlide™ Needle is superior compared to the BD™ conventional 3ml syringe/needle combination, in terms of the amount of complete plus partial doses drawn per multidose vial.

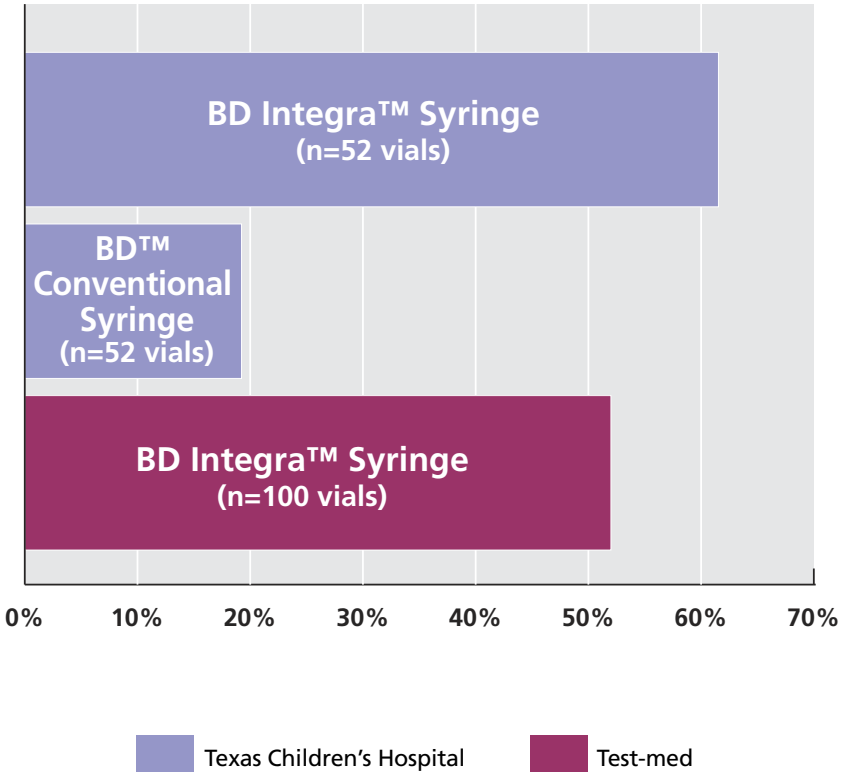
Test-med, San Francisco, CA

The second evaluation was conducted at Test-med in San Francisco, California and the primary objective was to determine the number of full (0.5ml) doses that could be drawn from multidose (10 dose) 5ml Influenza vaccine vials (Fluvirin®, Chiron Vaccines, lot # 765873) using the BD Integra™ 3ml Syringe with a pre-attached 25G x 1" Retracting BD PrecisionGlide™ Needle (catalog # 305270, lot # 3002747). At this site no control syringe/needle was used.

Four Registered Nurses participated in the evaluation. Each nurse was responsible for drawing up the medication from 25 Influenza vaccine vials. A total of 100 vials were used during the entire evaluation. The filled syringes were used for actual vaccination and the evaluation was conducted over the course of several days during scheduled employee Influenza vaccine clinics.

The total number of complete doses (0.5ml) withdrawn from each multidose 5ml Influenza vaccine vial using the BD Integra™ 3ml Syringe with a pre-attached 25G x 1" Retracting BD PrecisionGlide™ Needle was documented. This institution also allowed for the clinician to withdraw vaccine from more than one vial to complete a dose. Therefore, when a partial dose was drawn into a syringe and combined with Influenza vaccine from the next vial to form a complete dose, the volume drawn into the syringe from the new vial was also documented. Clinicians using the BD Integra™ 3ml Syringe with a pre-attached 25G x 1" Retracting BD PrecisionGlide™ Needle drew greater than 10 full doses from 52% of the 100 vials. The results also demonstrated that the observed average of the number of complete plus partial doses drawn from a 5ml vial was 11.58. The 95% confidence interval was between 11.45 and 11.70.

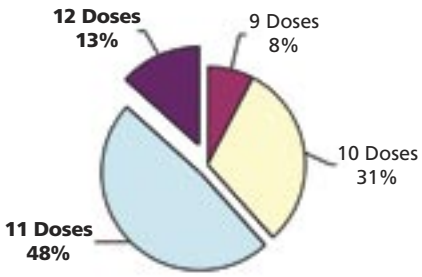
Percent of Vials By Syringe Delivering Greater Than 10 Doses



Percentage of Vials By Site Delivering 8-12 Full Doses

Texas Children's Hospital

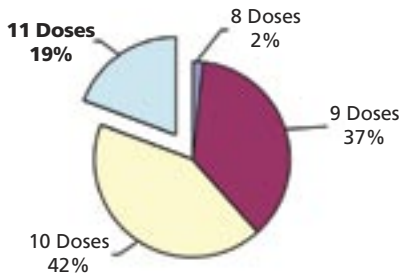
BD Integra™ 3ml Syringe w/
BD Retracting Needle



Percent of Vials Delivering 9-12 Doses
(n=52 Vials)

Texas Children's Hospital

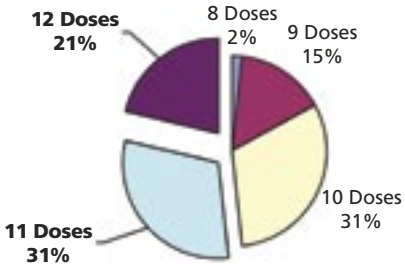
BD™ Conventional 3ml Syringe w/
BD SafetyGlide™ Needle



Percent of Vials Delivering 8-11 Doses
(n=52 vials)

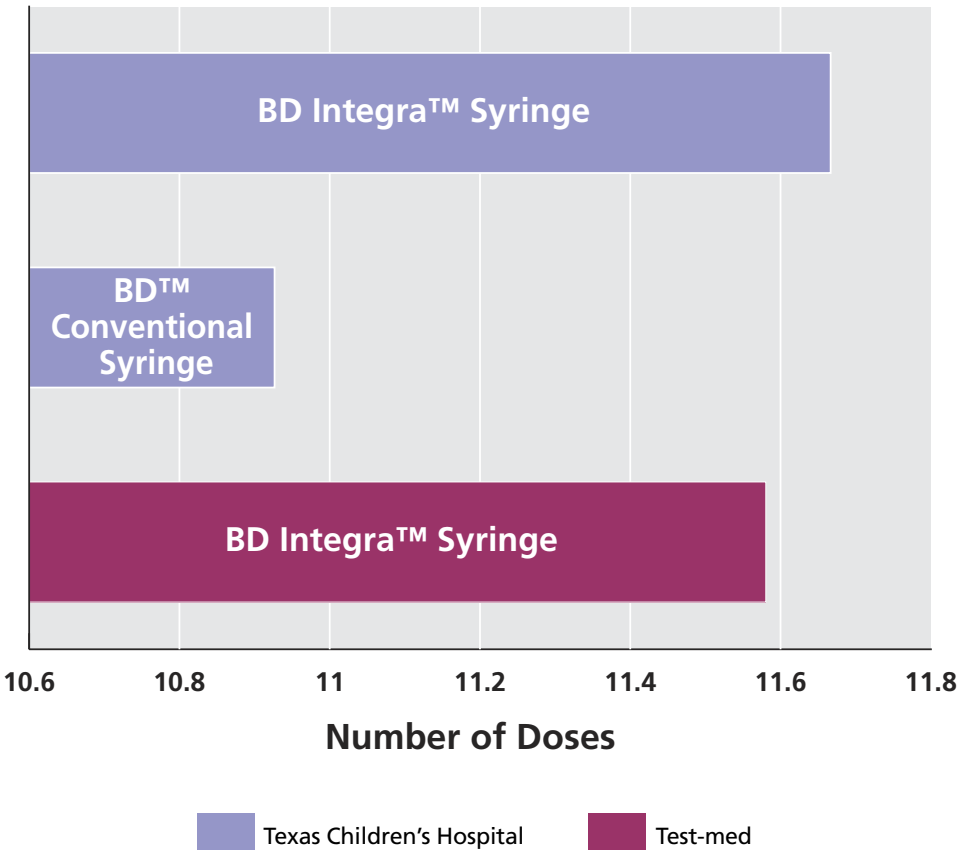
Test-med

BD Integra™ 3ml Syringe w/
BD Retracting Needle



Percent of Vials Delivering 8-12 Doses
(n=100 Vials)

Average Number of Complete Plus Partial Doses



Comment

The results of these two studies demonstrate that in a healthcare setting, the BD Integra™ 3ml Syringe with Retracting BD PrecisionGlide™ Needle has a low waste space design that allows for additional dose(s) to be drawn from a multi-dose vial when compared to needles and syringes with a conventional hub design. Influenza vaccine manufacturers routinely over-fill medication vials in order to compensate for needle and syringe waste space. In these studies, using standard vaccination techniques, the BD Integra™ 3ml Syringe with Retracting BD PrecisionGlide™ Needle allowed the clinicians to utilize a greater proportion of the over-filling for actual medication dosing as compared with the conventional syringe and needle system. These extra doses may have a substantial impact in reducing vaccination costs and in allowing hospitals and clinics to achieve a greater number of vaccinations from their vaccine supply.

Authored by Medical Affairs, BD Medical 2004

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