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RobinVac
by RobinTech

Test Rapport

Comparison of Dosing Accuracy and Variations Related to Vaccination Using Standard Method Vs. RobinVAC

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Executive Summary.

A total of 96 vaccines administered by use of the existing method and 98 vaccines administered by the RobinVAC method has been examined during three test sessions including 4 test series.

The aim was to examine and demonstrate the performance of the RobinVAC Method by the following acceptance criterias:

- Enables drawing of 7 doses from each vial (of Pfizer Comirnaty)
- Dose size same as for existing method
- Dose accuracy same or better than existing methods.

	Vials, Average			Syringe, Average			
	Vaccine in Vial (g)	Drawn in Total (g)	Remaining in vial after draws (g)	Filling (g)	Outdosing (g)	Remaining in Syringe (g)	
Existing Method	2,32	2,01	0,30	0,34	0,29	0,04	*(6 Doses)*
RobinVAC	**2,35**	**2,22**	**0,11**	**0,32**	**0,29**	**0,02**	*(7 Doses)*

All criterias was found to be fulfilled and further it was found that it took an operator about 8 minutes to draw 6 doses from a vial using the standard method, but less than 3 minutes to draw 7 doses from a vial using RobinVAC method.

Contents.

1 Scope.

This reports describes the extend and results of four tests performed on three different occasions at two different sites. The first test session was performed at the Bella Center Vaccination Facility on February 4th and did not include testing the RobinVAC method. This test was to establish a baseline measurement of dose accuracy and variation in practical use of existing (standard) method (6 vials). The second test were performed on March 14th at the Bella Center Vaccination Facility too and involved only the RobinVAC method (4 vials).

On March 18th, a test session (third and fourth test) was carried out at the Øksnehallen Vaccination Facility, in which both the RobinVAC method and the existing standard method (for comparison) were examined (10 vials for each method).

In all tests, as a minimum all vials were weighed before and after dilution prior to drawing and after drawing to establish amount drawn from each vial. Furthermore, each syringe was weighed after drawing and again after injection, to establish outdosed and presumed injected amount.

In some test the vials were also weighed after cleaning and drying, such that the amount of vaccine available in each vial could be established and in some tests the syringes where weighed empty prior to drawing to establish amount of vaccine drawn into each syringe.

All test were performed using Pfizer Comirnaty vaccine.

2 Purpose.

The purpose with the test series were to demonstrate the ability of the RobinVAC method and RobinVAC Tool to ensure 7 doses of 0.3ml being extracted from a Comirnaty vial with a nominal contents of 2.25ml. Furthermore, mean dose size injected and variation were to be determined for both methods, to enable comparison of accuracy of the two methods.

3 Acceptance Criteria.

Three acceptance criteria are established for the RobinVAC method.

1. The method needs to enable drawing and outdosing of 7 doses of a nominal size of 0.3ml from a vial containing 2.25ml and leave at least 0.05ml in the vial after drawing of the 7th dose.
2. The injected doses must be of the same size as by use of the existing method, which should be 0.3ml

3. The variation (standard deviation) of the injected dose must be the same or smaller than that of the existing method currently used, when compared to reference measurements performed on-site.

4 Method and Extend of Measurements.

4.1 Equipment Used.

For all tests a Kern jeweler scale model TGD 50-3C were used to determine the weight of the vials containing condensed vaccine and diluted vaccine prior to, and after drawing of vaccine into syringes. Where empty syringes were weighed prior to drawing, syringes after drawing prior to, and after injection, where also weighed using this scale. A Mettler Toledo AX205 scale were used to measure the weight of the emptied and dried vials from the first test at the Bella Center, as well as establishing the accurate weight of the reference weight. Both scales where calibrated using a 20.000g calibration weight and linearity was checked using a 3.260g reference weight.

All volumes have been calculated assuming a density of 1.00g/ml.

During all tests 1.0ml Chirana disposable syringes where used, with 25mm x G23 injection needles and 40mm x G21 drawing needles.

During drawing using the RobinVAC method, a RobinVAC prototype extraction unit, tilting the vial 35 degrees and fitted with a Redmi smartphone was used.

4.2 Procedure and Extend.

4.2.1 Test 1, Bella center, February 4th. Existing Method.

Six (6) vials were marked and weighed prior to dilution and again after dilution. Dilution where performed by an individual of the regular staff of the vaccine center and according to exiting procedures and instructions.

Seven (7) syringes were marked with numbers and weighed prior to filling. Six (6) doses where drawn from the vial and a 7th dose attempted to be drawn. None of the attempts to draw a 7th dose succeeded and the volume drawn into the syringe was expelled back into the vial. Each of the syringes were weighed again prior to injection, such that the amount drawn in each syringe could be established.

The vials with the remaining vaccine were weighed to establish remaining amount in each vial. The syringe by which a 7th dose were attempted and emptied back into the vial, were weight to establish the amount of vaccine remaining in the syringe dead space.

The staff of the vaccine center performed injection according to existing procedures and instructions, but placed both the used syringe and needle cap in the tray in which it was delivered. The outdosed syringe

and needle cap was then weighed prior to disposal. Thus the amount of vaccine remaining in the syringe dead space and the size of the dose delivered into the recipient could be established.

The used vials were handed over to RobinTech and subsequently flushed and dried, such that the weight of the empty glass of each vial could be established. Thus, the total amount of vaccine available and the total amount remaining (with the amount remaining in the dead space of the syringe used for the attempt to draw a 7th dose added) could be established. It was verified that less than 0.3ml was left over in all six vials and a 7th dose could not have been drawn.

4.2.2 Test 2, Bella center, March 14th. RobinVAC Method.

Four (4) vials were marked and weighed prior to dilution and again after dilution. Dilution where performed by an individual of the regular staff of the vaccine center and according to exiting procedures and instructions.

Seven (7) syringes for each vial (28 syringes in total) were placed in a tray with syringe number and vial number prior to filling. Seven (7) doses where drawn from each vial using the RobinVAC method and Extraction Unit. Each of the syringes were weighed prior to injection.

In order of not slowing down the vaccination process, the syringes were not weighed prior to filling. The amount of vaccine remaining in the dead space of the syringes could therefore not be measured. It has instead been estimated from the mean weight of an empty syringe in the data.

The vials with the remaining vaccine were weighed to establish remaining amount in each vial.

The staff of the vaccine center performed injection according to RobinVAC's procedures and instructions, and placed both the used syringe and needle cap in the tray in which it was delivered. The outdosed syringe and needle cap was then weighed prior to disposal. Thus, the size of the dose delivered into the recipient could be established and the amount of vaccine remaining in the syringe dead space estimated.

The used vials were handed over to RobinTech and subsequently flushed and dried, such that the weight of the empty glass of each vial could be established. The total amount of vaccine available and the total amount remaining in the vials could be established.

4.2.3 Test 3, Øksnehallen, March 18th. RobinVAC Method.

Ten (10) vials were marked and weighed prior to dilution and again after dilution. Dilution where performed by an individual of the regular staff of the vaccine center and according to exiting procedures and instructions.

Seven (7) syringes for each vial (70 syringes in total) were placed in a tray with syringe number and vial number prior to filling. Seven (7) doses where drawn from each vial using the RobinVAC method and Extraction Unit. Each of the syringes were weighed prior to injection.

In order of not slowing down the vaccination process, the syringes were not weighed prior to filling. The amount of vaccine remaining in the dead space of the syringes could therefore not be measured. It has instead been estimated from the mean weight of an empty syringe in the data.

The vials with the remaining vaccine were weighed to establish remaining amount in each vial.

The staff of the vaccine center performed injection according to RobinVAC's procedures and instructions, and placed both the used syringe and needle cap in the tray in which it was delivered. The outdosed syringe and needle cap was then weighed prior to disposal. Thus, the size of the dose delivered into the recipient could be established and the amount of vaccine remaining in the syringe dead space estimated.

The used vials were handed over to RobinTech and subsequently flushed and dried, such that the weight of the empty glass of each vial could be established. The total amount of vaccine available and the total amount remaining in the vials could be established.

4.2.4 Test 4, Øksnehallen, March 18th. Existing Method.

Ten (10) vials were marked and weighed prior to dilution and again after dilution. Dilution where performed by an individual of the regular staff of the vaccine center and according to exiting procedures and instructions.

Seven (7) syringes for each vial (70 syringes in total) were placed in a tray with syringe number and vial number prior to filling. Six (6) doses where drawn from the vial and a few attempts to draw a 7th dose were made. None of the attempts to draw a 7th dose succeeded and the volume drawn into the syringe was expelled back into the vial. Each of the syringes were weighed prior to injection.

In order of not slowing down the vaccination process, the syringes were not weighed prior to filling. The amount of vaccine remaining in the dead space of the syringes could therefore not be measured. It has instead been estimated from the mean weight of an empty syringe in the data.

The vials with the remaining vaccine were weighed to establish remaining amount in each vial. The syringe by which a 7th dose were attempted and emptied back into the vial, were weight to establish the amount of vaccine remaining in the syringe dead space.

The staff of the vaccine center performed injection according to existing procedures and instructions, but placed both the used syringe and needle cap in the tray in which it was delivered. The outdosed syringe and needle cap was then weighed prior to disposal. Thus, the size of the dose delivered into the recipient could be established and the amount of vaccine remaining in the syringe dead space estimated.

The used vials were handed over to RobinTech and subsequently flushed and dried, such that the weight of the empty glass of each vial could be established. Thus, the total amount of vaccine available and the total amount remaining (with the amount remaining in the dead space of the syringe used for the attempt to draw a 7th dose added) could be established. It was verified that less than 0.3ml was left over in all six vials and a 7th dose could not have been drawn.

4.3 Instruction of Operators.

Operators for performing injections were instructed in the injection method prescribed for use with the RobinVAC method. This involves raising the recipients arm to enable an orientation of the syringe of approximately 30 degrees over horizontal during injection. At the time of the test, no aspiration were performed according to common practice of intra muscular injection within the Danish healthcare system. It should be noted that the test were performed just prior to the new instructions given, requiring aspiration.

Injections were administered by the staff of the vaccination facility under supervision of a trained physician (Martin Vesterby) from RobinTech. All common practice for aseptic handling was observed during the injection procedures.

Operators for drawing using the RobinVAC method and Extraction Unit were first shown the procedure by live demonstration by a RobinVAC representative, using water and not vaccine. Following the demonstration, each of the operators trained the use of procedure and equipment for a couple of draws, before drawing 7 doses from a vial with each syringe being weighed prior to and after expelling the dose, to ensure correct filling of syringes. Water was used for all training and not vaccine.

When operators felt comfortable using the extraction unit and RobinVAC method, which were after one or two test vials with water, they completed a test during which they drew 7 doses from a vial. All syringes used during the tests were weighed prior to drawing, after drawing and after expelling the content. The filling and outdosed amount of each syringe was determined. To pass the test, 7 doses within the range of 0.28ml – 0.31ml (outdosed volume) had to be produced from a single vial. These test were performed using water and not vaccine.

After passing the test, the operators were allowed to proceed and went on to draw doses of vaccine into syringes for injection.

5 Results.

5.1 Results from Test 1, Existing method, Bella Center.

In Vial				Use, 6 doses		Fluid balance, Syringes		
Vial No.	Vaccine Condensed (g)	Added Water (g)	Vaccine in Vial (ml)	Drawn 6 Doses (ml)	Remaining in Vial, After 6 Doses (ml)	Drawn Amount (ml)	Outdosed Amount (ml)	Remaining in Syringe (ml)
G1	0,47	1,85	2,29	2,05	0,24			
G2	0,47	1,83	2,27	2,08	0,19			
G3	0,47	1,87	2,30	2,06	0,24			
G4	0,47	1,83	2,26	2,00	0,26			
G5	0,47	1,90	2,33	2,06	0,27			
G6	0,47	1,91	2,35	2,07	0,27			
Mean	***0,47***	***1,86***	***2,30***	***2,05***	***0,25***	***Mean***	***0,343***	***0,303***	***0,038***
Standard Dev.	***0,002***	***0,031***	***0,032***	***0,026***	***0,028***	***Standard Dev.***	***0,012***	***0,017***	***0,008***

Figure 5.1-1: *Results of measurements performed on existing method, February 4th in Bella Center.*

The first test performed at the Bella Center Vaccination Facility showed that the existing method provides a very accurate dosing with a mean dose size of 0.303ml with 95% of the doses measured within the range of 0.27-0.34ml. An average of 0.038ml wasted vaccine remaining in the dead space of syringe and cannula is found. This corresponds very well to what was to be expected from the used low dead space syringe. (A standard syringe with the same type of needle would have an average of approximately 0.09ml of remaining vaccine in the dead space).

It is noted that in order of enabling injection of 0.3ml, an amount of approximately 0.34ml needs to be drawn into the syringe. As it would require at least an additional 0.05ml of vaccine

remaining in the vial to enable drawing without getting air into the syringe, at least 0.39ml is needed to remain in a vial to enable drawing of a 7th dose. As it can be seen from the results, an average of 0.25ml and a maximum of 0.27ml remained in the vials. Thus, almost half a dose is missing from enabling a 7th dose to be drawn.

5.2 Results from Test 2, RobinVAC Method, Bella Center.

Vial No.	Drawn Vaccine Vial (ml)	Outdosed Vaccine Syringes (ml)	Average Amount Drawn* (ml)	Average Amount Remaining in Syringe** (ml)	Estimated Amount in Vial after 7 Draws*** (ml)
A	1,92	1,79	0,32	0,02	-
B	2,24	1,70	0,32	0,04	0,12
C	2,18	2,07	0,31	0,02	0,14
D	2,23	2,11	0,32	0,02	0,07
Mean	***2,14***	***1,92***	***0,318***	***0,023***	***0,11***
Standard Dev.	***0,129***	***0,174***	***0,003***	***0,008***	***0,026***

Outdosed (ml)	
Mean	***0,295***
Standard Dev.	***0,0103***

Syringe discarded before weighing. Amount is for 6 doses all though 7 was drawn

*: Based on mean weight of empty syringe and weight of vial prior and after drawing
**: Based on amount drawn from vial
***: Based on mean weight of empty vial

Figure 5.2-1: *Results of measurements performed on RobinVAC Method, March 14th in Bella Center.*

The second test performed at the Bella Center Vaccination Facility showed that the RobinVAC method provides a very accurate dosing with a mean dose size of 0.295ml with 95% of the doses measured within the range of 0.27-0.32ml. An average of wasted vaccine remaining in the dead space of syringe and cannula is estimated to 0.02ml, which is nearly half of the waste of a low dead space syringe.

It is noted that an average of 0.11ml of vaccine remained in the vial, with a minimum of 0.07ml even after drawing 7 doses.

5.3 Results from Test 3, RobinVAC Method, Øksnehallen.

RobinVAC

Vial No.	Vaccine in Vial (g)	Drawn in Total (g)	Remaining in Vial after Drawing (g)	Average Filling * (g)	Average Outdosing (g)	Average remaining in Syringe * (g)
C*	2,37	2,34	0,03	0,334	0,291	0,043
D	2,31	2,22	0,09	0,317	0,294	0,023
E	2,36	2,24	0,12	0,320	0,298	0,022
F	2,37	2,24	0,13	0,320	0,300	0,021
G	2,33	2,20	0,12	0,315	0,290	0,025
H	2,38	2,22	0,16	0,317	0,298	0,019
I	2,48	2,17	0,32	0,309	0,287	0,022
J	2,38	2,22	0,16	0,317	0,296	0,021
K	2,26	2,20	0,05	0,315	0,290	0,025
L	2,29	2,20	0,09	0,314	0,295	0,019
Mean:	*2,35*	*2,22*	*0,13*	*0,318*	***0,294***	***0,024***
Standard Deviation:	*0,0591*	*0,0433*	*0,0755*	*0,0062*	*0,0040*	*0,0067*

Figure 5.3-1: *Results of measurements performed on RobinVAC Method, March 18th in Øksnehallen.*

The third test performed, this time in Øksnehallen Vaccination Facility verified that the RobinVAC method provides a very accurate dosing with a mean dose size of 0.294ml with 95% of the doses measured within the range of 0.28-0.31ml. An average of wasted vaccine remaining in the dead space of syringe and cannula is estimated to 0.024ml, which is nearly half of the waste of a low dead space syringe.

It is noted that an average of 0.13ml of vaccine remained in the vial, with a minimum of 0.05ml even after drawing 7 doses.

It should further be noted that these results are almost identical to the results obtained at Bella Center Vaccine Facility, suggesting a very high repeatability.

5.4 Results from Test 4, Existing method, Øksnehallen.

Existing Method

Vial No.	Vaccine in Vial (g)	Drawn in Total (g)	Remaining in Vial after Drawing (g)	Average Filling * (g)	Average Outdosing (g)	Average remaining in Syringe * (g)
RA*	2,28	2,07	0,21	0,35	0,305	0,041
RB	2,37	2,02	0,35	0,34	0,292	0,045
RC	2,34	2,02	0,31	0,34	0,304	0,034
RD	2,30	2,05	0,25	0,34	0,295	0,041
RE	2,30	2,01	0,29	0,33	0,287	0,048
RF	2,33	1,96	0,37	0,33	0,293	0,034
RG	2,29	1,99	0,30	0,33	0,291	0,042
RH	2,24	1,88	0,36	0,31	0,289	0,023
RI	2,35	2,07	0,28	0,35	0,293	0,052
RJ	2,36	2,04	0,32	0,34	0,301	0,034
Mean:	*2,31*	*2,01*	*0,30*	*0,335*	***0,295***	***0,039***
Standard deviation:	*0,0387*	*0,0563*	*0,0486*	*0,0094*	*0,0059*	*0,0078*

Figure 5.4-1: *Results of measurements performed on Existing Method, March 18th in Øksnehallen.*

The fourth test performed, again in Øksnehallen Vaccination Facility showed that the existing method provides a very accurate dosing with a mean dose size of 0.295ml with 95% of the doses measured within the range of 0.27-0.32ml. An average of wasted vaccine of 0.039ml remaining in the dead space of syringe and cannula is estimated. This corresponds very well to the results from Bella Center and with what was to be expected from the used low dead space syringe.

It is noted from the results, that an average of 0.30ml and a maximum of 0.37ml remained in the vials, which is actually a full dose. However, since an average filling requires 0.34ml and an additional 0.05ml is required to be present to enable drawing a dose without air in the syringe, none of the vials contained enough vaccine after drawing 6 doses to enable drawing of a 7th dose and all attempts failed.

6 Conclusion

All attemps to draw 7 doses from a vial using the existing method failed during both test using the existing methods, all though is came close at Øksnehallen. However, 7 doses were drawn from all vials during both test using the RobinVAC Method, with ease according to the operators and a good margin according to the estimates of remaining volume in the vials

	Vials, Average			Syringe, Average			
	Vaccine in Vial (g)	Drawn in Total (g)	Remaining in vial after draws (g)	Filling (g)	Outdosing (g)	Remaining in Syringe (g)	
Existing Method	2,32	2,01	0,30	0,34	0,29	0,04	*(6 Doses)*
RobinVAC	**2,35**	**2,22**	**0,11**	**0,32**	**0,29**	**0,02**	*(7 Doses)*

Figure 6-1: *Overview of results from Øksnehallen.*

The average size of the 7th dose was 0.293ml, which is within statistical uncertainty the same as the average of all doses, using either method.

It was found that 95% of all doses using the existing method, during the test were between 0.27ml – 0.32ml, whereas 99,6% of all doses administered using the RobinVAC method were within that interval.

It was found that the RobinVAC method enabled drawing 7 doses of each vial during the tests and that the dose size administered by the RobinVAC method were of the same size as for the existing method. Furthermore, it was found that the dose accuracy appears to be at least as good, if not slightly better, than the existing method and that at least 0.05ml of vaccine remained in a vial after drawing of 7 doses.

The acceptance criterions set forth is hence considered to be fulfilled