Study Report

The "ease of use" of vaccines: a simulation study of the factors impacting the efficiency of the organizational models of vaccination centers.

(Italian translation: “l’"ease of use" dei vaccini": uno studio di simulazione dei fattori con impatto sull’efficienza dei modelli organizzativi dei centri vaccinali)

Authors

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Abstract

Optimizing the efficiency of a vaccination point of dispensing (POD) is particularly relevant during epidemics or in low-resources settings. The decision of adopting proper organisational models and of taking into account the ease-of-use of vaccines could be of a paramount importance for resources-saving. Evidence is therefore urgently needed for healthcare decision-makers. To this aim, in this work we propose to use a simulation optimization approach. In particular, as specific case study, we show how it could be possible to obtain up to 17.5% time saving during a meningococcal vaccination session and relevant cost-saving (e.g., up to 45M euros in real vaccination scenarios).

Keywords

Vaccination, ease-of-use, point-of-dispensing, organisational model, simulation optimization
Introduction

World Health Organization (WHO) in a important documentation states, about ease of use in a vaccination context, that “In some situations the time required to prepare a vaccine is critical, such as during campaigns with long lines of waiting clients or during outreach activities. For these situations a vaccine product that is easier to use and takes less time to prepare can be extremely valuable and can help to increase coverage” and also that “… Immunization programmes may also decide to select products that are similar to those already in use to minimize the burden on health care workers” (1).

Efficiency and management of vaccination is particularly relevant in low resources settings. For example, regarding meningococcal vaccination, a vaccination point of dispensing (POD) could be called to reach a coverage target in a short span of time (e.g., 2-3 weeks (2)). This target could be reached, for instance, in an organizational setting in which is offered only a single specific vaccine (such as during a epidemic vaccination campaign). Another example can be derived from Italian national immunization plans which could mandatorily require the raising of specific vaccine coverage over a given percentage within a period of two/three years, e.g., >95% within 2019 for the meningococcal vaccination in Italy (3), without allocating (and possibly cutting) more resources.

Given that the ease of use of a vaccine could be crucial for its impact on the immunization programme and resources-saving (1) the problem is how to quantify its benefits for a vaccination POD in different scenarios, i.e. target population and specific organisational setting.

Since this problem require in-deep specific analysis it is clear that is quite impossible to solve a thorny topic like this with simple tools currently available or with a common sense approach. Thus we choose to deal with it by resorting to a “simulation optimization approach” (4–7).

The case study

We focused on two kind of vaccination POD dispensing only meningococcal vaccination. The first, i.e., the ideal vaccination POD, is organized according to recommendations of the WHO (2,8) with 1 “vaccination team” (i.e., 1 supervisor, 2 nurses, 3-4 record clerks, 2-3 local community representatives, 1 technician responsible for the cold chain, and 1 driver) supported by fundamental logistics, having a daily goal of 1000 vaccinations (about 300 per working shift).

The second, i.e., the real vaccination POD, is a limited version of the ideal one (but more adherent to a common vaccination center) in terms of available operators: 1 supervisor and 1 security officer are allocated, while nurses (2 or 3, to be investigated the exact number in the following simulation experiments) have to perform all activities reserved to record clerks, communicative representatives and technicians which are not available as in the ideal case. Such a real POD organizational model is based upon observations in a real vaccination setting.
In particular, we are interested in measuring the efficiency impact of the ease-of-use of specific vaccines (1), namely Nimenrix (9) and Menveo (10), which are available on the market and that can be both used in real vaccination POD in Italy. This because such a vaccines are quite different in terms of reconstitution phase as stated in their technical labels (see next figure).

The specific aim of the study is answering to the following questions:

- given the use of Nimenrix vaccine, the vaccination POD under study is able to provide up to 300 doses per shift (i.e., to reach the WHO goal)?
- given the use of Menveo vaccine, the vaccination POD under study is able to provide up to 300 doses per shift (i.e., to reach the WHO goal)?

In Italy, such a focus on meningococcal vaccination is also motivated by the recent epidemics in the Toscana region (13) and by the current national immunization plan “Piano Nazionale Prevenzione Vaccinale” (14), recently approved by the Ministry of Health, which mandatorily extends the coverage of meningococcal vaccination to a cohort of 12-18 years old. Also the raising of vaccine coverage within 2019 to a percentage greater than 95% is an important goal for public health professionals and regulatory agencies in Italy (3).

More in general, worldwide, according to WHO “Meningitis remains a universal public health challenge in countries around the world - cases and outbreaks are highly dreaded. The global number of deaths due to meningitis was estimated at 380,000 annually. Meningitis is an epidemic-prone disease, and as such deserves special attention given the potentially major impact on health systems, the economy and society as a whole due to the disruptive nature of meningitis outbreaks which are costly and challenging to control (15).
Materials and Methods

The study adopts a quantitative research methodology supported by a simulation approach.

We identified three main steps for solving the simulation problem.

- **Step 1 (feasibility of the simulation)** consists of an agile iterative prototyping of the conceptual model and simulator of the vaccination POD. Proofs of concept (POC) of the simulator are implemented by using specialized simulation software in order to define, as fast as possible, the required time and costs for performing
- **step 2 (implementation)** and
- **step 3 (application)** of the simulation.

The modelling process requires the collaboration between subject matter experts (e.g., medical doctors) and modeling experts (e.g., mathematical engineers) in order to answer accurately to the specific questions under investigation by estimating relevant key performance indicators (KPI) of the vaccination POD (next figures).

![Figure. Accuracy of results (adaptation from (16)).](image)

![Figure. Modeling process (adaptation from (17)).](image)

Conceptual model of the vaccination POD

A top-down method is used to build up the conceptual model of the vaccination POD. Areas and zones of the vaccination POD are identified from WHO guidelines (2,8).

![Figure. Conceptual model of the vaccination POD.](image)

Then, parameters characterizing each area and zone both in terms of activities, materials and resources, including relevant parameters assessing the goal under study, are proposed, discussed, chosen and have been quantified by the modelers. These decisions come out
from various documents (including mandatory parameters like “daily session duration”) and from direct observations, not only from the simple choices of the modelers. Some initial assumptions were necessary to better define the model's needs (see “notes” in next figure).

Figure. Relevant parameters defined by the modelers and their ranges.

<table>
<thead>
<tr>
<th>Area</th>
<th>Zone</th>
<th>Parameters</th>
<th>Type</th>
<th>Values</th>
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<th>Range</th>
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<td></td>
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<td>number of vaccinated users + number of administered doses</td>
<td>Output</td>
<td>positive integers</td>
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<td>-</td>
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</table>

**NOTES**

- note 1: we assume no delay between patient arrival (all target patients are ready to enter into vaccination POA)
- note 2: we assume that patient entered into vaccination POA one by one
- note 3: we assume that all patient are in good health status
- note 4: the output value is a control variable; if it’s value is different from 0 it means that some people are not scheduled for next vaccination session
- note 5: we assume that non-clinical activities are optimized at the highest level of efficiency
- note 6: in our experiments we assumed the single utilization of one type of vaccine per session
- note 7: range and statistic distribution come out from 2 video observations
- note 8: this value and its distribution came out from interviews with medical doctor and direct observation in a real vaccination setting
Simulation model of the vaccination POD

The discrete-event simulation (DES) of the vaccination POD, i.e., the simulator (see next figure), is implemented in Simio version 10 (build 168.16501), an integrated development environment for realizing general-purpose simulations (18).

![Vaccination POD Diagram]

Figure. Simulator of the vaccination POD (at the beginning of simulation). Patients are represented by green triangles. Spatial dimension are neglected assuming rapid movements of people (both patients and operators).

Verification of the simulator (i.e., the process of confirming that the simulation is correctly implemented with respect to the conceptual model) and validation of the simulator (i.e., the checking of the accuracy of the computational model's representation of the real system) has been performed by comparing its results with the WHO indications, on field observation (next figure) and results obtained by another independent implementation in R ([https://www.r-project.org/](https://www.r-project.org/)).

Next figure shows the results obtained from several observation in a real vaccination setting. These data (not published), derive from a recent degree thesis (which the authors co-tutored) (19), which has provided crucial measure (in terms of KPI) we used to compare data we adopted in simulation model (particularly in “real setting”).

![Distribution Summary and Data Summary]

Figure. Overall registration and vaccination length of time (in minutes) observed during a study (19) in a vaccination POD of the National Health Service in Rome (1-week, February, 2018) during ordinary vaccination sessions (i.e., in a non-epidemic condition).
Simulation Experiments

Given a target population to cover, such a simulator is used to perform several scenario analysis (i.e., experiments for testing different settings and target), including Simulation Optimization of the vaccination session (particularly its duration) and Response Sensitivity Analysis based on linear regression to relate experiment responses (i.e., time to target) to specific input parameters of interest (i.e., vaccine administration time and vaccine reconstitution time).

Fixed parameters (which are the same for all vaccination POD scenarios under investigation in the following) are:
- shift duration (380 minutes),
- session duration (340 minutes, starting 10 minutes after the beginning of the shift),
- administration length of time (described by a uniform distribution in the range of 20 and 40 seconds), and
- reconstitution length of time (described by a triangular distribution in the range of 50 and 70 seconds with median 60, and a triangular distribution in the range of 69 and 97 seconds with median 83, for Nimenrix and Menveo, respectively).

“Control variables” (a.k.a. controls), i.e., parameters which change over different scenarios hereafter shown, are:
- the target population per session (300 or 280 people),
- the registration area capacity (3 or 4 for the ideal vaccination POD, and 2 or 3, i.e., equal to the clinical area capacity, for the real vaccination POD),
- the clinical area capacity (2 or 3) and
- the adopted meningococcal vaccine (Nimenrix or Menveo).

The simulated vaccination team, which differs from ideal and real POD, is composed by:
- 1 supervisor;
- 1 security officer;
- community representatives in number equal to the registration area capacity or zero for the ideal and real vaccination POD, respectively;
- record clerks in number equal to the registration area capacity or zero for the ideal and real vaccination POD, respectively;
- nurses in number equal to the clinical area capacity;
- technicians in number equal to 1 or zero for the ideal and real vaccination POD, respectively.
Results

By using two instances of the simulator, the ideal vaccination POD and the real vaccination POD defined in the introduction of the case-study have been tested together (next figure).

![Figure. Ideal vaccination POD (left) and real vaccination POD (right) under investigation at the same time (i.e., per single scenario).]

The simulator of the ideal vaccination POD provides the following responses:

- O (i.e., output patients) is the number of vaccinated people;
- T2T (i.e., time to target) measures the time elapsed from the beginning of the vaccination session to the time when all the target population is covered (0 otherwise);
- FT (i.e., free time percentage) measures the ratio between the time remaining to the end of session after the T2T, and the session duration.

In the simulation of the real vaccination POD, the responses O_real, T2T_real and FT_real have the same meaning of O, T2T and FT for the ideal vaccination POD, respectively.

Having fixed exactly the same relevant parameters for both vaccination POD (as stated more in details in the previous section, e.g., the shift duration to 380 minutes) and by varying as control variables the target population per session, the number of vaccinators (i.e., the clinical area capacity) and the presence or absence of supporting personnel (i.e., the registration capacity which characterizes the ideal and real setting, respectively), the analyzed vaccination scenarios are six (next figure). Furthermore, due to the randomness of the parameters vaccine reconstitution and administration length of times, 100 simulation replications per scenario simulation has been executed.

![Figure. Definitive scenario analysis of the Ideal (first three responses columns) and Real (last three responses columns) vaccination POD.]

<table>
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<tr>
<th>Scheme</th>
<th>Replications Required</th>
<th>Completed</th>
<th>Scenario - Controls</th>
<th>Registration Area - Controls</th>
<th>Clinical Area - Controls</th>
<th>Responses</th>
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<th>FT</th>
<th>O_real</th>
<th>T2T_real [Minutes]</th>
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The first two scenarios show us that with a clinical area capacity of 2 units, a target population per session of 300 people (i.e., the WHO goal) cannot be served by using the Menveo vaccine in real vaccination POD. Thus, the comparison of two vaccines can only be performed decreasing the target to 280 people. Having fixed this target, for the real vaccination POD the average free time percentage (i.e., FT\_real) is about 17.54% and 1.73% for Nimenrix and Menveo, respectively (see previous figure at column FT\_real, scenarios Nimenrix-Scenario02-280 vs Menveo-Scenario02-280). More in details, the next two figures show SMORE (Simio Measure of Risk & Error - i.e., box) plots including FT\_real minimum, maximum, mean, median (with upper and lower percentile) and confidence intervals.

![Figure](image)

Figure. Free time (%) in the real vaccination POD when the target population is 280 people, the number of vaccinators is 2, and the used vaccine is Nimenrix and Menveo, respectively.
Such a free time percentages (shown in the previous figure) corresponds to an average time to target (i.e., $T_2T_{\text{real}}$) of 280.3 and 334.1 minutes when the used vaccine is Nimenrix and Menveo, respectively (next figure). Thus, the time saving can be simply evaluated by difference with the session duration (i.e., 340 minutes).

![Figure] Time to target (minutes) in the real vaccination POD when the target population is 280 people, the number of vaccinators is 2, and the used vaccine is Nimenrix and Menveo, respectively.

By continuing the focus on the scenarios characterized by a target population of 280 people, the sensitivity analysis shows that the relevance of reconstitution phase for having free time, i.e., the impact of the ease of use of the vaccine, is 55.72% and 47.76% when the adopted vaccine is Nimenrix and Menveo, respectively. The number of vaccinated users (i.e., $O_{\text{real}} = 280$ people in both cases) is less influenced by the reconstitution of Nimenrix (6.71%) and more sensible to the reconstitution of Menveo (36.98%), while the other impact on the covering of the target population derives from the time spent by the vaccinators doing the administration of the vaccine.

![Scenario “Nimenrix-02-280”](image)
Scenario “Menveo-02-280”

Figure. Sensitivity analysis. Weights (%) of the vaccine administration time (i.e., T_{administration}) and the vaccine reconstitution time (i.e., T_{reconstitution}) on the defined responses (i.e., FT, T2T, O for the ideal vaccination POD, and FT\_real, T2T\_real, O\_real for the real vaccination POD) when the target population is 280 people, the number of vaccinators is 2, and the adopted vaccine is Nimenrix (up) and Menveo (down), respectively.

Results obtained by independent implementation in R showed a good reproducibility of our simulation model, particularly in T2T results (next figure).

![Figure. Results given by the R simulator of the vaccination POD.](image)

In sum, according to the above results, it is possible to answer positively to the initial questions of the case study with some recommendations:

- vaccination POD should allocate operators as in the ideal setting (according to WHO), or
- real vaccination POD with fewer operators than in the ideal case should use the most ease-of-use vaccine, i.e., Nimenrix, which has lowest reconstitution time.
Discussion

In this study, as we are interested in measuring the impact of the ease-of-use of two different meningococcal vaccines available on the market in Italy, namely Nimenrix and Menveo, we compare simulated performance of ideal POD (with a complete vaccination team according to WHO) and real POD (with a reduced vaccination team) providing only one type of vaccination (i.e., mono-type vaccination) to a predefined target patients (assumed to be present at the beginning of the vaccination and in good health status). By adopting this ease-to-organize vaccination session, also non-clinical activities of the POD can be optimized at the highest level of efficiency. This could be considered as a limit of the study. However, if this first impression is exceeded, such a organisational model gives to the vaccination POD the ability to operate efficiently both in emergency situations as well as in normal conditions, even with relevant time and cost saving by leveraging the ease-of-use of the adopted vaccine. Even the quality of the service (18) can be improved more easily by engaging patients and health workers in the study of relevant aspects of the single specific vaccination. Due to lack of usable evidences from literature or observable vaccination POD which operate “in the same condition” hypothesized, the results of the study do not care about vaccine reconstitution errors or possible vaccination side effects.

We in particular evaluated the effects of the advantage given by the reduction of the reconstitution time provided by Nimenrix during a mono vaccination session in a real vaccination POD. Having a target of 280 people per session (340 minutes), the ability of the clinical area (i.e., vaccinators) to achieve it is less sensible to the reconstitution of Nimenrix (6.71%) and more sensible to the reconstitution of Menveo (36.98%), while for the rest it depends from the time spent in doing the administration of the vaccine. The resulting average free time percentage is about 17.5% (60 minutes) and 1.7% (6 minutes) for Nimenrix and Menveo, respectively. The above percentages are critical to understand and suggest how to reach the right number of vaccinated patient in a short span of time. The differences emerged from the sensitivity analysis could be hold in consideration and better investigated in order to offer a more efficient service.

Such a result can be easily applied for obtaining further insights and evaluations (see next figure for some examples of possible economic implications in a real scenario). For example, the application to the case of meningitis epidemics in Tuscany region of Italy could reveal an overall cost saving of about 45 millions of euros by using the Nimenrix vaccine for implementing an hypothetical vaccination campaign according to the WHO recommendations.
Figure. Examples of economic implications. In case of meningitis epidemic and according to recommendations by the WHO, operators of each involved vaccination POD can be temporary hired to cover the target population within 2 weeks from the start of the vaccination campaign. The free time (if any) could be used to close the POD itself in advance for having a cost saving (assuming operator unitary costs per hour).

Although a mono-type vaccination POD is not so frequent to observe in reality, we underline that this can be a valid organization to be taken into consideration when there is a specific request to reach a vaccination goal especially in a low setting resources and in a few days/weeks of vaccine sessions.

Our simulation results are confirmed by independent implementation of the simulator.

Future work could regard the simulation of specific vaccination centres in Italy and the prototyping of simulation-based decision-support software for decision-makers of vaccination POD.
Reference

1. WHO. Principles and considerations for adding a vaccine to a national immunization programme: From Decision to Implementation and Monitoring. April 2014. 2014.


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</table>

Figure. Ideal vaccination POD parameters and their figures.
Figure. Real vaccination POD parameters and their figures for different scenarios.