D7.10 Written report on the SWOT results

777363– DRIVE

Development of Robust and Innovative Vaccine Effectiveness

WP7 – Influenza Vaccine Effectiveness Pilot Studies

Lead contributor	Ornella Punzo ornella.punzo@iss.it; - ISS
	Stefania Bellino stefania.bellino@iss.it - ISS
Other contributors	Liz Miller (ISC) Marianne van der Sande (ISC) Stefania Salmaso (ISC)

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Glossary

SWOT Analysis	Structured planning method that allows to assess strengths, weaknesses, opportunities, and threats of any project/organization/activity
Strengths	Characteristics within the organization that are an advantage for the project in meeting the objective
Weaknesses	Characteristics within the organization that would pose a disadvantage for the project in meeting the objective
Opportunities	Elements in the environment external to the organization that the project could exploit to its advantage in meeting the objective
Threats	Elements in the environment external to the organization that could cause trouble for the project in meeting the objective
Study sites	All individuals/organization actively involved in performing the study at the national and project level

Summary

This document presents the results of the SWOT analysis implementation as outlined in D3.2 (SWOT analysis plan).

The SWOT analysis was implemented in order to evaluate the WP7 studies, aimed at acquiring brand-specific vaccine effectiveness data during 2018/19 influenza season, from an operational quality and feasibility perspective at the site level.

A SWOT analysis is a structured planning method that allows assessing strengths, weaknesses, opportunities, and threats of any project/organization/activity. For this aim, two assessment axes have been considered, i.e. organizational and logistical aspects and one target group, composed by different professional figures involved in the implementation of the studies at site level have been identified (Table 1).

The results of the SWOT analysis will be used to inform protocols (WP7), tools of WP2 (study support application, SOPs, site selection criteria and study tender process, laboratory tool implementation, sampling schemes) and analysis guidelines (WP4).

Background

A SWOT analysis is a structured planning method that allows identifying, with a consensus generating methodology, the internal and external factors that are favourable and unfavourable in achieving an objective, and to use the results to formulate strategic options.

A SWOT analysis can be used to:

- Explore solutions to problems
- Make decisions on how to best proceed towards an objective
- Determine where change is possible by making an inventory of your strengths and weaknesses
- Adjust and refine plans based on upcoming opportunities or unforeseen weaknesses and threats

Methods

The SWOT analysis focuses on four elements that make its acronym: Strengths, Weaknesses, Opportunities, and Threats. For each objective, participants should list concrete/tangible aspects (in bullet points) pertaining to:

- **Strengths**: characteristics within the pilot studies that are an advantage for the project in meeting the objective
- **Weaknesses**: characteristics within the pilot studies that would pose a disadvantage for the project in meeting the objective
- **Opportunities**: elements in the environment external to the studies that the project could exploit to its advantage in meeting the objective
- **Threats**: elements in the environment external to the studies that could cause trouble for the project in meeting the objective

Strengths and Weaknesses focus on internal factors that can include human and physical resources; Opportunities and Threats focus on aspects that that can include future trends in the field, concomitant events, funding sources.

Following the end of the influenza season 2018/19, we conducted this SWOT analysis during a one-day meeting so that participants could exchange their ideas, expressing their points of view in a collaborative atmosphere, in order to assess the quality and feasibility of the operational model after its implementation.

For the purpose of assessing logistical and laboratory aspects, we organized the SWOT analysis in two selected countries, Italy and Finland, during meetings with different stakeholders involved in the management of influenza vaccine effectiveness (IVE) studies. The two settings are different from a health system and also from a surveillance-type perspective. We reckon that within the DRIVE network these two sites are representative both for sample size and for the inclusion of surveillance data. The participants were doctors, nurses, data managers, lab technicians coming from the sites that take part in the network.

We collected data on each identified axis, containing more than one SWOT objective, during group work with participants belonging to the identified target groups for the SWOT analysis (Table 1). The relevant axes selected to analyse different aspects of the sites work were already included in the deliverable submitted originally within DRIVE WP3 (D3.2); the areas classification was slightly modified for homogeneity reasons and also to fit the participants' profile. For this purpose, we divided the participants into groups, one per axis. Each participant was asked to compile an individual SWOT form; then they were asked to reach an overall agreement with other participants through an internal discussion. Finally, each working group combined the individual inputs in a group SWOT analysis.
For each item classified under Strength, Weakness, Opportunity or Threat, a score has been assigned by the experts, using a range from 1 (*very low)* to 5 (*very high)*. The score is meant to reflect the impact of each listed item on reaching the SWOT objectives. At the end of the process, the facilitator promoted a collective discussion on the main points emerged.
We summarized the results in different tables, as the aspects analysed and the issues emerged were different accordingly to the different settings.

Table 1 – Overview of the assessment axes, target group parameters and SWOT objectives proposed

Axes	Target Group		Parameter name	Parameter type (quality/feasibility)	SWOT Objective
Organizational aspects	Study Sites	IT Group 1 + FI	Training	Feasibility	To share principles and procedures among participating healthcare workers before the start of the study: - inclusion/exclusion criteria - enrolment criteria - study protocol adherence - SOP (standard operating procedures)
	Study Sites	IT Group 1	Sample size	Feasibility	To reach a study power able to assess vaccine effectiveness and, possibly, brand-specific vaccine effectiveness: - study enrolment - data availability per brand
Logistical, practical, and laboratory aspects	Study Sites	IT Group 2 + FI	Timeline	Feasibility	To avoid possible delays in collecting the needed information included in the study protocol
	Study Sites	IT Group 2	Validation of exposure	Feasibility	To verify vaccination status through vaccination registers or health care records (complete and correct way)
	Study Sites	IT Group 3	Adding additional data collection components on top of routine surveillance	Feasibility	To allow collection of data elements needed for brand specific vaccine effectiveness
	Study Sites	IT Group 3	Data entry harmonization	Feasibility	To reduce delays in data transfer and errors in merging (normalization of different data sets)
	Study Sites	IT Group 3	Storing and transport of swabs	Feasibility	Promptness in the laboratory response, match circulating strains-composition vaccine

Results

We performed the SWOT analysis to assess the perceived quality and feasibility of the operational model after its implementation for the different stakeholders involved at different implementation levels. Results include data on strengths, weaknesses, and the identification of both opportunities and threats of the studies conducted.
We decided to complete the results submitted by the different groups with the notes taken by us during the discussion with the purpose of enriching the results. We also decided to avoid amending the entries submitted by the participants, to avoid distortion of the results; therefore if we noticed that an item was misplaced in the "wrong" field we did not change its position.

SWOT - Italy

Objective: **Organizational aspects** Group 1 TND GP study

STRENGTHS	WEAKNESSES
• Well established network • Good adhesion to protocol • Surveillance-trained doctors (5) • Knowledge of patients and their comorbidities: Vaccination date, brand and comorbidities are verified (5) • Real-time notification of ILI cases (5) • Real-time virological results (more turnover in the results) (5) • Swabs collection system twice a week (5) • Web platform that provides almost real-time data (5) • Multi-professional team • Timely lab response	• Low vaccination coverage especially in children and adults at risk (small sample) (3) • Sample size is low, but pooling helps; relevance of the season intensity (2-3) • Low coverage in elderly • GP workload too high during peak season (3) • Increase number of swabs during epidemic peaks • Low autonomy on brand choice (2-3)
OPPORTUNITIES	THREATS
• Motivate paediatricians and GPs to vaccinate population at risk (5) • Increase swabs in elderly (5) • Increase swabs during epidemic peaks (5) • Increase vaccination coverage (5)	• Financial budget (additional resources are needed) (5) • During peaks, it is not possible to swab every patient (3) • “Abrupt onset” definition (timeline not clear)

SWOT - Italy

Objective: **Organizational aspects** Group 1 TND-SARI

STRENGTHS	WEAKNESSES
• Some centres have data coding and extraction system (5) • Harmonized protocols for enrolment (5) • Consolidated preparedness network in the field, useful in case of pandemics (5) • Identification of the healthcare-related cases (3) • Residents' training and involvement in the project (5) • Training and communication	• Budget (additional resources are needed) (5) • "Compliance" of (collaboration by) the enrolled doctors (5)
OPPORTUNITIES	**THREATS**
• Sensitization of the doctors on case notification • Training on operational procedures on a more accurate case definition • Identification of healthcare-related cases (3) • Training and communication (5) - Training for different health profiles (5); Communication flow adapted to different *wards* (5) • Centres who have not a data coding and extraction system in place have the chance to build one due to the study • Promotion of the study and of flu vaccination itself in the hospital (5) • Increase vaccination coverage (5)	• Low vaccination coverage (5) • Information retrieval/data recovery on vaccination status and on underlying diseases/comorbidities (4) • Some sites have no capacity to analyse the subtype of influenza virus (5) • Sample size should be increased (5)

SWOT - Italy

Objective: **Organizational aspects** Group 1 Cohort -Healthcare workers

STRENGTHS	WEAKNESSES
• Data management web platform which integrates epidemiological and lab data (5) • "widening" to other hospitals in order to increase population (selection of more motivated subjects) • Health professional it is a low confounders category per se • Brand is known as they get the jab in the hospital clinics (5) • Promotion of flu vaccination itself in the hospital (5) • Promotion of the study (5) • Well-established shared web platform (5) • Training of a group of residents (5)	• More complex and difficult to manage compared to the general population • Low vaccination coverage in health practitioners, therefore obliged to follow-up many subjects • Time constraints: no adequate time for enrolment (5) • Enrolment happens before vaccination, difficult to monitor vaccination uptake and follow up (5) • Delays on ethical committee approval (e.g. lost 3 weeks time) man • Underestimation of ILI cases: health professionals auto-treat themselves and therefore do not get to the doctor or to the hospital admission or to the ward • If the subject is absent to work it is difficult to verify cross-checking the data • Knowledge of ILI case definition by healthcare personnel • Greater effort for this type of study, including on the personnel side (5) • Dedicated and trained personnel (5)
OPPORTUNITIES	**THREATS**

• Start an adequate communication flow in order to minimize loss-to-follow-up (5)
• Future plan: start with active follow-up with a text message, which implies a text reply (higher efficacy)+ a phone call during peak time
• Sensitization to vaccination (5)
• Motivate subjects by providing lab tests results (4)
• Budget: low for such a study (burden) (5)
• Missing data re ward and specific job description or if they have kids at home
• CIRI.IT networking with different professional profiles
• Tailored training path with targeted communication (5)
• Highlight the strong points and benefits of the study (5)
• Impact of flu in ILI cases (5)
• Demonstration of scientific evidence (5)
• Vaccination is NOT enrolment criterion (5)
• Timely virological response (5)
• Effort for clearer understanding of the ILI case definition
	• Change of protocol for 6 times during cohort study, which affected:
	  ○ how to collect data
	  ○ the definitive form
	  ○ the fields (change of definition for each field)
	• Time constraints: no adequate time for personnel training (5)
	• Many subjects enrolled with ILI did not disclose it – need for sensitization of the HCW
	• Loss to follow-up of HCW (5)

SWOT - Italy

Objective: **Logistical, practical, and laboratory aspects** Group 2 - Timeline

STRENGTHS	WEAKNESSES
• Dedicated and trained personnel (5) • Lab availability (5) • Data collection (datasheet clear and well made is crucial) (3) • Production of an operating manual for the person in charge in the centre • Close collaboration with the lab (5) • Chance of face-to-face interviews for enrolled personnel (4) COHORT	• Time and effort for data collection (5) • Low compliance in the ward from clinicians for patient enrolment + access to the patient files (5) TND-SARI • Difficult data collection in chronic patients or in patients in critical conditions (plus difficult to get information from care-giver) (4) • Incomplete data: Data collection is made at different times, is patient files are not available data collection is incomplete (4)
OPPORTUNITIES	**THREATS**
• If flu patients become serious cases surveillance could connect SARI with severe cases (involvement of the Ministry of Health) at no additional cost (5) TND SARI • Sensitization of patients and HCW at no additional cost on flu, flu vaccine and prevention (5) • Collection of further data such as investigation on hospital outbreaks (serological analysis left as secondary objective) (3) + COSTS • Data exportability (3) + COSTS • Feedback to hospital where we operate, especially for TND- SARI (4)	• Low compliance/collaboration from patients, doctors and clinicians (5) • Consent procedures (for privacy reasons etc.) to data collection (5) • Data loss tied to long datasheet to compile (covariates) (4) • Compliance in data retrieval • Missed notification of data (5)

SWOT - Italy

Objective: **Logistical, practical, and laboratory aspects** Group 2 - Validation of exposure

STRENGTHS	WEAKNESSES
• Data collected by GPs TND GP study (in some cases GPs do not record the data, therefore, the info do not coincide between patients/relatives and GPs) (5) • Availability of hospital vaccination registry* COHORT (5)	• No data on vaccine and brand TND SARI (5) • Absence of vaccine registry* or paper registry for previous vaccination TND SARI (5) • Enrolment is far in time from vaccination (5) COHORT (5)
OPPORTUNITIES	**THREATS**
• Vaccine registry development (see Apulia) (5) • Sensitization on vaccines and data on vaccine coverage (4) • Chance to link ward and type of HCW with vaccine coverage (4) COHORT	• Missing data on brand (5) • Missing data on the previous year (vaccination) (3) • Missing data on operator (5) COHORT

SWOT - Italy

Objective: **Logistical, practical, and laboratory aspects** (adding additional data collection components on top of routine surveillance; data entry harmonization; storing and transport of swabs) Group 3 -TND-SARI Case-Control

STRENGTHS	WEAKNESSES
• Storing and transport of swabs (5) • Promptness (5) • Data collection (4) • Real-time data entry (3) CASE-CONTROL	• No sample typing nor sequencing • Data on vaccine brand not immediately available in TND SARI (better in cohort) (4)
OPPORTUNITIES	**THREATS**
• Increase panel of virological & bacterial targets (data on infections) (3) • Monthly interim meeting (4) • Methods harmonization (5) • Real-time data collection/ digitalization through tablets or other devices connected to the internet (not buyable through DRIVE funding) (4)	

SWOT - Italy

Objective: **Logistical, practical, and laboratory aspects** (adding additional data collection components on top of routine surveillance; data entry harmonization; storing and transport of swabs) Group 3 COHORT -Healthcare workers

STRENGHTS	WEAKNESSES
• Self-sampling (5) • Real-time response (5) • Data entry (3)	• HCW sometimes does not give back the swab (4) • Delay in data entry
OPPORTUNITIES	**THREATS**
• Real-time data collection by direct entry on the online *directory* (4) • Other viruses search (RSV?) (3)	• Swab loss (1) • Swab done but not delivered (1) • Swab done before ILI is confirmed

SWOT - Finland

Jorvi hospital site Organizational aspects - Training

STRENGTHS	WEAKNESSES
• IMOVE-experience: existing study protocol and written materials, knowledge and data management (5) • One study nurse and one physician, only a few people to train, systematic screening (3) • Training only needs to be done once if personnel does not change (3) • THL infrastructure and training for information security data systems (Open Clinica) (5) • THL infrastructure for virological subtyping (including PCR)	• No written SOP (no time or funding for doing it, no final DRIVE Codebook in use at the start of the study) -> controversial instructions to the study nurse -> problems in screening the patients and collecting background factors (3) • Little personnel, vulnerable study system (4) • Not enough time for training before influenza season (study permits, hiring the study nurse) (4) • Broad eligibility criteria, difficult to train and remember • No timely instructions • from DRIVE concerning changes in Codebook etc, no training of the sites (3) • Limited time and funding
OPPORTUNITIES	**THREATS**
• Training and common instructions from DRIVE -> harmonization of the sites (3) • Harmonization of the definitions • A simpler definition of SARI would be more useful for training purposes	• Limited time and funding (5) • Inadequate communication from DRIVE

SWOT - Finland

Jorvi hospital site Logistical, laboratory and practical aspects - Timeline and Laboratory testing

STRENGTHS	WEAKNESSES
• Positive pressure to complete study • Medical records and registers available (5) • Clinical samples available from HUSLAB (4)	• Little personnel on the field (2) • Only 2 weeks between screening and data analysis
OPPORTUNITIES	**THREATS**
• Easier access to medical records and registers (Kanta archive, NVR) (4) • Only hospital samples besides ICU samples in the sentinel system • Systematic recording and finding of patient information (3) • New RT-PCR machines at THL	• Not all obligatory background factors can be checked in time for delivery to DRIVE (3) • Not enough time given for completion of surveys by DRIVE (3) • Difficult access to patient records (Apotti) (5) • No funding for laboratory testing (4) • New RT-PCR machines at THL

Conclusions

The SWOT exercise was welcomed as a useful means to compare issues and practices among local study centres, but also as a moment of exchange with both peers, i.e. other centres involved, and the WP7 lead, i.e. us, facilitating the exercise.
All groups suggested a separate analysis for the different study designs, which appear to have different issues and strengths, i.e. TND and Cohort design.
Recurrent themes were the need for more financial support for the studies and the wish for a closer collaboration with the different parties involved such as the HCW for both the hospital-based study and their own involvement as enrolled subjects (in the cohort study). There was also a recurrent "call for feedback" from the sites coordinator towards the DRIVE central coordinators; site managers would be more motivated in their day-to-day work if they could see the results of their individual work, such as the pooled analysis of their single centre data. Moreover, the training of residents and other HCW for the study was valued as a useful moment of learning and also of team-building. Some of the bureaucratic barriers were common along with different sites, involving the approval by the ethics committees or the paperwork related to patient consent and privacy; however, this seems a difficult issue to sort out or eliminate. One of the major strengths identified was related to the strong network available for the study, which is partially pre-existing and partially built for the study itself or reinforced by that.
In the Finnish SWOT analysis, we did not focus on the registry-based study but only on the hospital-based one for uniformity and simplicity reasons. We included the points discussed at the end of the SWOT analysis, although they remained plain points, without an attributed score. We decided not to analyse the score attributed for different reasons. For the Italian sites, it seemed that the scores expressed were skewed to the top and therefore we assumed they would not be very representative of the real picture. On the other hand, for the Finnish site, only 4 people were present for the analysis, while for the Italian sites 15 people took part in the exercise. Therefore, we felt that the Finnish sample would not be representative enough of all the views of the personnel involved in the study.
Ultimately, the funding concerns are the most common issue reported by both Italian and Finnish sites. The management and training issues are similar, and the opportunities related to the training and development of the network are also a recurrent item for discussion.

KEY POINTS common to both sites

- Funding concerns
- Both opportunities and issues in carrying out the training of the personnel
- Issues on communication with the central DRIVE coordination
- Opportunity related to the development of the research network given by the project itself
- Management issues due to the project practical organization, some solvable and others more difficult to overcome (e.g. for lack of dedicated personnel, including administrative and for data entry)