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Organizational design: the case of SARS-CoV-2 vaccination in a healthcare centre

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Abstract

Background. *Only recently Anti-Covid-19 strategies have been applied through specific vaccines, that are a decisive support to modify the evolution of the disease and to reduce the contagion curve. Along vaccination campaigns, the necessity to guarantee rapidity and effectiveness is a critical challenge for all health organizations; their operative capability is applied to carry out govern plans, to ensure safety of the procedures, to adopt good clinical practices, to help with adhesion to vaccine administration and to monitor adverse effects.*

Study design. *The "Centro Clinico Morgagni" is a private accredited diagnosis and treatment Centre with high specialty departments and several hospital beds. The challenge for its administration was to complete the vaccination of all the staff, so a COVID19 crisis unit was established to assure the control of all activities in the center throughout the pandemic. The goal was to complete the vaccination plan following the guidelines with no risks or harm.*

Methods. *An original organizational model, based on different planning methodologies was developed, its task was to define a standard procedure and to give operational instructions based on ISO 9001 for monitoring the entire vaccination process. Also, the model had to define every responsibility role and it had to follow Joint Commission International's methodologies as far as error barriers, drug conservation risks, drug transport and drug administration were concerned.Furthermore, in agreement with the HACCP system, critical control points were highlighted during all the process. The results have been processed in the form of quick references and illustrative panels based on relevant process aspects, which were given to the staff involved in the operations as reference tools for prompt consultation.*

Results. *The vaccination operations at the Centro Clinico Morgagni took place quickly in only four days: 800 staff units were vaccinated – first and second doses with Covid19 mRNA BNT162b2 (Cominraty) - in three different vaccination centers without highlighting significant events that did not comply with the guidelines, nor deviations from the established goals.*

More precisely, starting from 277 bottles corresponding to six doses each, only 0.2% was wasted, while ADR monitoring reported a prevalence of adverse effects in females (78%) compared to males (22%). Adhesion

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for vaccination of qualified personnel, thanks to the activities of the Medical College set up for this purpose, reached 100% of the candidate staff through repeated personalized interviews with only one opposition, compared to the 30 communicated at the beginning.

Conclusions. *It was necessary to ensure the efficiency of the entire process and the model was tested positively. This model can also provide a security control of all the vaccinated personnel; its schematization allows an easy application and flexibility, thus making it an organizational tool that could be reproduced and transferred to other contexts.*

Introduction

The issue of SARS-CoV-2 vaccination has led to the necessity to ensure the safety and full control of the entire process in a very short time. This includes the guarantee of: organizational methods in vaccination centres, such as the coordination between transport phases and vaccine storage, vaccine administration and follow-up to evaluate the occurrence of side effects.

Given the latest news about misapplication in vaccine administration and storage, now more than ever it is necessary to develop a model for controlling all those critical aspects, and it is essential to start a study on risk analysis (1).

In addition, an additional problem concerns the hesitation of a part of healthcare workers to get vaccinated.

Methods

The first step in developing this model (2) is to define weaknesses in vaccination centers. Such weaknesses will be monitored during vaccination:

- Logistics and vaccine conservation
- Vaccine preparation
- Identification of the subjects to be vaccinated
- Medical history collection from the vaccinees
- Vaccine administration
- Patient monitoring
- Prepared doses/consumed doses ratio
- Side effects
- Vaccinal adhesion
- Transmission of data

The critical points are: *Vaccine waste - Vaccine inactivation caused by poor conservation – Contraindications - Patient dismission after procedure - Vaccinal adhesion - Health surveillance*.

Our model highlighted various organizational problems and tracked system dysfunctions, its role is to protect safety through: quality assessment in accordance with ISO 9001 model, the application of the culture of safety by Joint Commission International and enforcing analytic and control methods in analogy to the HACCP system during the whole process.

Basically, this model allows us to define a standard procedure based on ISO 9001.

More precisely, the ISO 9001 procedure defines various phases of the vaccination process: *Admission – Counseling - Medical history and Informed consent collection - Vaccine administration – Observation - Dismission with online registration* (3).

In addition, ISO 9001 instructions provide that the pharmacists and the healthcare workers have the responsibility to prepare and administer the drug following SIFO (4) guidelines' standards, they must stock the vaccine as best as possible, they have to maintain sterility throughout the process, they have to keep traceability and they have to monitor patients.

Furthermore, it is necessary to define

the physical areas of vaccine centres, in particular the essential requirements about furnishings, technological devices and medical equipment and it is also fundamental to have control systems that guarantee process safety in all its phases (5).

The model establishes that preparation rooms must be provided with basic devices, drugs and personnel to ensure the safety of the process, especially to prevent and combat adverse effects".

The vaccine preparation has some critical aspects associated to its safety (6) like: staging, preparation, dilution and administration, to be monitored very carefully to avoid side effects or adverse events.

It is mandatory to provide vaccines with the answers to the "FAQ AIFA" (Frequently Asked Questions to the Italian Drugs Agency – AIFA) and informed consent forms and also to provide personnel with the labels including predefined instructions and warning about guidelines.

Those documents are used for quick reference to vaccine production, to indicate critical points for the supervision of personnel in the vaccination point and to detect identification errors in personnel. It was also necessary to register important variables after the first dose for a quick reference available for the second dose.

The model can be adjusted and modified along the way, for example, if after an initial period the count of prepared and administered/registered doses isn't correct, it is necessary to double check at the end of the day if the data are correct and correctly sent to the specialized staff.

The case analysis allows us to evaluate how the organizational model can be applied to reality and how it can highlight several positive aspects that lead to a good result and the organizational efforts that lead to the final result.

Results

The "Centro Clinico Diagnostico Morgagni" (Morgagni-CC) of Catania is a private diagnostic and acute care centre and a rehabilitation facility certified ISO 9001, accredited by the National Health Service (SSN), constituted by four medical stations with an average annual production of about 8,000 ordinary hospitalizations, 2,000 Day Hospital cases, 6,000 Day Service cases and approximately 150,000 outpatients.

In the occasion of the COVID-19 pandemic emergency, the Morgagni-CC signed an agreement with the Provincial Health Department to accept non-COVID-19 patients from the nearest public hospitals, aiming at reducing the continuous pressure on those hospitals.

The Morgagni-CC established a COVID-19 Crisis Unit to ensure clinical control of activities, and this unit follows national guidelines, protocols and Clinical Pathways (CPWs) for standardization.

Since the Morgagni-CC has become also a vaccine centre, it follows the AIFA and the SSN guidelines.

A pharmacist was responsible for Adverse Drug Reactions (ADRs) for surveillance measures, while the COVID-19 Crisis Unit coordinated the entire vaccination campaign together with the medical staff. Every day briefings were held in every office.

The definition of operational modes and control systems allowed the pursuit of results.

Bottles handling **-** The first day of vaccination was 6th January 2021, and beginning that day the number of employees to be vaccinated was 908 units. The number of subjects vaccinated by the last day (4^{ton} February) was 835, with a difference of (908-835) = 73.

Among those 73 people: 28 had been vaccinated elsewhere, 8 were on Provincial Health Department's centers waiting list and 37 were not vaccinated for the following

reasons: recent COVID infection, pregnancy or maternity and an ongoing acute disease.

The total number of doses injected was 1,659 using a number of bottles equal to 277: the objective was to obtain six doses from each bottle, and it was achieved, except for three bottles with insufficient content, with a waste of only 0.2%. The use of the procedures adopted ensured the full use of all the doses prepared and there were no returns of vaccine in bottles to the Provincial Drug Department, derived from not using the vaccine within the prescribed time frame.

ADR reporting **-** No significant side effects were reported, except for the most common transitory side effects referred in the literature. Out of all 1,659 total administrations, the ADRs were 91 (5.48%), of which 22 in males (22.7%) and 69 in females (75.8%).

Two episodes of syncope were reported, but they were immediately resolved and two panic attacks were reported but they did not reappear at the second dose, thanks to the provided support.

Among the vaccinated, 85% reported local pain in the site where the vaccine was inoculated and 44 people (48.3%: 10 males or 22.7% and 34 females or 77.2%) reported short-term fever.

All previous data and the prevalence of ADRs in women (75.8%) correspond to the data recorded in Italy and reported by AIFA.

Adherence to vaccination **-** The medical team has the responsibility to control the non-adherence to vaccination. This was possible by gathering all the reasons for non-adherence and verifying them in relation to personal health conditions.

All information about vaccine was made available through individual meetings in order to remove prejudices about vaccination.

At the start of vaccination campaign there were 30 non-adhesions, while at the end of it nearly 100% of personnel adhered to the vaccination, just one case did not adhere. This person was put on leave of absence without being paid, until she will accept to be vaccinated or until the pandemic emergency will end.

Conclusions

A model for risk control and sanitary quality management was developed through organizational analysis of processes and routes; such a model is necessary to ensure successful results that are as close as possible to expectations.

The model, proposed in a medium dimension private Healthcare Centre, allowed operators to carry out their activities safely throughout the process and ensured that the various aspects of vaccinal operations were conducted efficiently.

This model is easy to understand thanks to its schematization, proposed measures and practical application. Its intelligibility allows us to transfer and reproduce this model in other contexts.

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Riassunto

Progettazione organizzativa: il caso della vaccinazione SARS-CoV-2 in una struttura sanitaria

Premessa. Le strategie di contrasto alla pandemia COVID-19 hanno solo di recente trovato con la immissione nel circuito sanitario dei vaccini un supporto decisivo in grado di modificare l'evoluzione della patologia e di piegare la curva di diffusione del virus.

La necessità di garantire speditezza ed efficienza alle campagne vaccinali rappresenta un significativo test per le organizzazioni sanitarie e la loro capacità operativa impegnate da un canto alla realizzazione dei piani predisposti dai Governi e dall'altro tenute a garantire sicurezza nelle procedure, buone pratiche, adesione alla somministrazione e monitoraggio degli eventi avversi.

Disegno dello studio. La direzione del Centro Clinico Morgagni, struttura privata accreditata di diagnosi cura con posti letto di alta specialità, dovendo affrontare in-house la vaccinazione del proprio personale ha posto all'unità di crisi COVID 19, istituita per assicurare il governo clinico delle attività in fase pandemica presso il Centro Clinico, l'obiettivo della conduzione della vaccinazione a zero rischi e danni, attraverso la definizione di Linee Guida in grado di offrire la migliore garanzia di successo.

Metodi. È stato sviluppato un modello organizzativo originale frutto di diverse metodologie di progettazione organizzativa, ispirato da un canto alla definizione di una procedura e di una istruzione operativa ISO 9001 per monitorare l'intero processo vaccinale sotto il profilo delle diverse fasi e della definizione dei ruoli di responsabilità e dall'altro alla metodologia Joint Commission International per quanto concerne i sistemi di barriere all'errore e di contrasto del rischio in particolare nei processi di conservazione, trasporto e somministrazione del farmaco. Inoltre si è applicata nel sistema seriale del processo, attraverso l'analisi dei rischi, la evidenziazione dei punti critici di controllo in analogia con il sistema HACCP.

Sono stati prodotti elaborati sotto forma di quick references e tavole illustrative in ordine agli aspetti rilevanti del processo che sono stati somministrati al personale impegnato nelle operazioni quali strumenti di pronta consultazione.

Risultati. Le operazioni di vaccinazione presso il centro clinico diagnostico Morgagni si sono svolte con rapidità in quattro giornate per circa 800 unità – prima dose e richiamo COVID19 mRNA BNT 162b2 Comirnaty - presso i tre centri vaccinali costituiti, senza la registrazione di rilevanti non conformità alle Linee Guida dettate né di scostamenti dagli obiettivi assegnati.

Più precisamente lo sfrido di dosi dai 277 flaconi utilizzati è stato dello 0.2% con un pressoché totale rispetto dell'estrazione di sei dosi a flacone mentre il monitoraggio ADR ha prodotto un report dettagliato e puntuale che ha confermato la prevalenza del genere femminile negli effetti indesiderati 78% versus 22%.

L'adesione alla vaccinazione grazie alle attività del Collegio Medico costituito a tale scopo ha raggiunto attraverso ripetuti colloqui personalizzati il 100% del personale candidato con una sola opposizione dai 30 che in prima battuta avevano manifestato posizione al vaccino.

Conclusioni. Il modello realizzato, testato favorevolmente, era necessario per assicurare che il processo di vaccinazione fosse efficiente ed offrisse una caratteristica di Qualità controllata oltre a possedere sicurezza nell'insieme delle fasi di erogazione nei confronti del personale da vaccinarsi. La schematizzazione del modello ne consente una facile applicabilità e la flessibilità che lo caratterizza e ne fa uno strumento organizzativo riproducibile e agevolmente trasferibile in altri contesti.

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