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Review On Influenza Viruses And Vaccines: The Role Of Vaccine Effectiveness Studies For Evaluation Of The Benefits Of Influenzavaccines.

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ABSTRACT: -

The safety of vaccines is a critical factor in maintaining public trust in national vaccination programs. Vaccines are recommended for children, adults and elderly subjects and have to meet higher safety Standards, since they are administered to healthy subjects, mainly healthy children. Although vaccines are Strictly monitored before authorization, the possibility of adverse events and/or rare adverse events Cannot be totally eliminated. Two main types of influenza vaccines are currently available: parenteral inactivated influenza vaccines And intranasal live attenuated vaccines. Both display a good safety profile in adults and children. However, they can cause adverse events and/or rare adverse events, some of which are more prevalent in children, While others with a higher prevalence in adults. Influenza is a vaccine preventable disease and vaccination remains the most effective Method of controlling the morbidity and mortality of seasonal influenza, especially with respect To risk groups. To date, three types of influenza vaccines have been licensed: inactivated, live-Attenuated, and recombinant haemagglutinin vaccines.

Effectiveness studies allow an assessment of the positive effects of influenzavaccines in the field.

The aim of this review is to provide an overview of influenza vaccine safety according to target groups, Vaccine types and production methods, influenza virus;vaccine; effectiveness etc.

KEYWORDS: Adverse events; Influenza vaccine safety; Vaccine types; age-groups;influenza virus; vaccine; effectiveness.

INTRODUCTION: -

Influenza disease, usually called “the flu”, is a contagious respiratory illness caused by influenza viruses. The common symptoms are fever, aches, chills, chest discomfort, cough, and headache. The incubation period is very short, typically from 1 to 4 days. While the majority of infected subjects recover, some develop Complications, particularly at-risk groups such as pregnant women, young children, the elderly, and individuals with chronic medical conditions. (1,3) One of the most common influenza-related complications is a secondary bacterial infectionby Streptococcus pneumoniae, which increases the morbidity and mortality of influenza infection. (4,5)

The World Health Organization (WHO) estimates that influenza alone results in 290,000–650,000 deaths each year due to respiratory diseases without taking into account deaths from other potentially influenza-related diseases. (6) Before the COVID-19 pan- demic, Italy was experiencing peaks in influenza-related death rates, especially among the elderly during some winter seasons. Influenza viruses spread mainly from person to person through droplets generated by sneezing, coughing and talking. While influenza viruses are globally detected all year round,in temperate climates influenza epidemics occur during winter: November–March in the Northern hemisphere and May–September in the Southern hemisphere. By contrast, influenza seasonality is less defined in tropical regions. (7,8)

Vaccination is the most effective method of controlling sea-sonal influenza infections and the most important strategy for preventing possible pandemic events.1 Influenza vaccines are recommended for children, adults and elderly subjects.2 Since vaccines are mainly administered to healthy people, they need to comply with a higher safety standard. In addition, as they are used to immunize a considerable part of the population, rare adverse events (AEs) may affect a significant number of individuals.3,4 A “vaccine AE” or an “AE following immunization” is defined as “any untoward medical occurrence which occurs during administration of a vaccine or follows immunization and which does not necessarily have a causal relationship with the use of the vaccine. The adverse event may be any unfavorable or unintended sign, an abnormal laboratory finding,a symptom or a disease”. 5 AEs also include those events associated with vaccination errors and reactions correlated with anxiety and product quality defect.

The terms “adverse drug reaction” and “adverse vaccine reaction or effect” are both used to indicate that the development of the AE has a causal relationship withthe medicinal product, as indicated by consistent scientific evidence.

Table 1: Vaccine types and route of administration

Vaccine types	Route of administration
TIV	Parenteral intradermal
QIV	Parenteral
LAIV	Intranasally

Trivalent Influenza Vaccines: -

Trivalent influenza vaccines (TIVs) (containing A/H1N1, A/H3N2 and one B lineage) have been manufactured since 1978, replacing the bivalent inactivated influenza vaccines that had been widely used since 1944. TIV vaccination is recommended for children older than 6 Months and between 6 and 59 months with a predisposition to Severe influenza in Australia and Western Australia, respectively.25 In 2010 in Australia, an increase in febrile convulsions (FCs) was Observed after TIV immunization; however, this involved only one Brand, produced by bioCSL (Fluvax and Fluvax Junior). Subsequently, Li-Kim-Moy and coll.26 reviewed the safety of TIV administration. Specifically, they investigated the rates of fever, FCs and Serious AEs reported in both unpublished and publishedclinical trials conducted on children during the period 2005–2012. The incidence offever or AEs caused by TIV was low, whereas higher fever Rates were correlated with bioCSL influenza vaccines in young children. However, it was not possible to attribute this to the TIV strain Composition. This study highlights the necessity to strictly monitor Seasonal influenza vaccine safety and to report post-administration Data accurately.26 A recent study conducted by Esposito et al.27 Investigated the tolerability and safety of TIV in overweight and. Obese children between 3 and 14 years old, since obesity is an Important risk factor for infections that are facilitated by respiratory diseases.

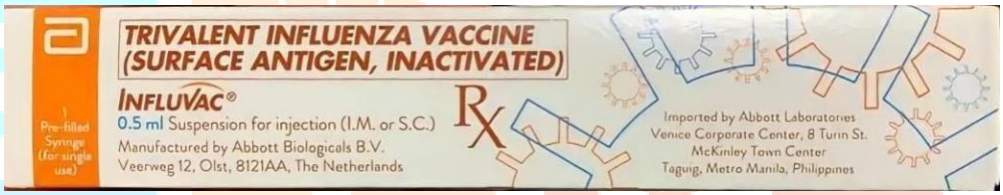

FIG.NO.1: TRIVALENT INFLUENZA VACCINES

Quadrivalent Influenza Vaccines: -

In addition to the 3 strains present in TIV, namely H1N1 and H3N2 influenza A subtypes and influenza B, the formulation of Quadrivalent Influenza Vaccines (QIVs) contains two additional influenza B lineages, Yamagata and Victoria, whichhave Been spreading since 1985 and have reduced the efficacy of TIV.28 QIVs should enhance protection against influenza B by Avoiding the possibility of a B strain mismatch. The first quadrivalent LAIV was licensed in 2012 and, after several QIV for Mutations had been tested, it entered the market. The WHO recommended both B lineages for inclusion in the 2012–2013 influenza seasonal vaccine in the Northern hemisphere.

The safety and reactogenicity of QIV have proved similar to those of seasonal influenza vaccines, as demonstrated by Tinoco et al.36 The most common adversereactions were pain at the injection site, headache and myalgia, all of which disappeared within 3 days of vaccination. No serious AE or death were registered. Similar results regarding the safety of the first QIV introduced in Australia were reported by Regan et al.37 in a sample of 1,685 healthcare providers (HCPs).

Although 7 days after immunization no AE was observed in either QIV- or TIV- vaccinated subjects, a slightly but significantly higher percentage of QIV- immunized than TIV-immunized HCPs reported pain or swelling at the injection site. That study confirmed the safety of QIV, since its reactogenicity was similar tothat of TIV.

FIG.NO.2: QUADRIVALENT INFLUENZA VACCINES

Live attenuated influenza vaccines: -

LAIVs have been used in Russia for decades, and were licensed In the US in 2003for healthy subjects aged 2–49 years41 and in Europe in 2012 for healthy childrenaged 2–17 years. They are Able to induce a stronger immune response than IIV bymimicking natural infection (see below).20 Since they are administered intranasally, several adaptive immune responses, such as Serum antibodies, mucosal and cell-mediated immunity are induced. LAIV vaccinees show the presence of the vaccine virus, but the risk of transmitting the virus to household members is marginal, ranging from 0.58% to 2.87%. In only one case has the Transmission of LAIV virus to a placebo recipient been Reported. In that case, however, transmission did not induce the disease.54 It has been observed that, in children aged 9–36 Months, the presence of the virus is highest 3–5 days after vaccination, reaching up to 80%, whereas it is lower in adults Affected by HIV (1.8%).55 Furthermore, not only do LAIVs Elicit direct protection in vaccinated subjects, they also promote Indirect protection by reducing the transmission of theinfluenza virus among subjects belonging to clinical risk groups. LAIVs have beenreported to cause adverse effects in 15% of Cases. However, these are not serious:nasal congestion, runny Nose and slight fever in adolescents, and sore throat in adults. With the exception of fever, which has been reported on the Day after vaccination, the other symptoms occur 2–3 or 8–9 days after LAIV administration.45 LAIVs have been reported to cause slightly more troublesome moderate adverse effects Than TIV, though the incidence of these is low.

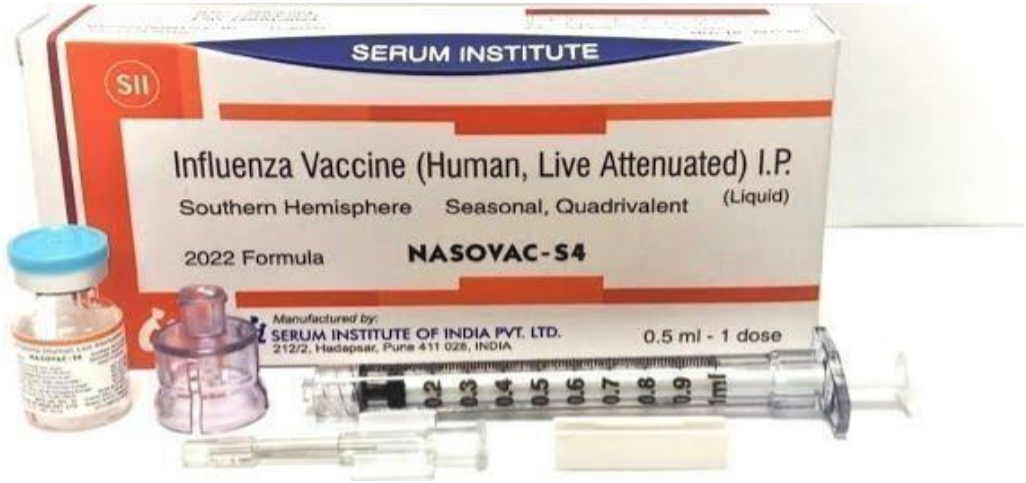

FIG.NO.3: LIVE ATTENUATED INFLUENZA VACCINES

Table 2: Summary of advantages and disadvantages of licensed seasonalinfluenza vaccines.

Licensed Vaccines	Advantages	Disadvantages
Inactivated egg-based	✓ Extensive safety data available Cost-effectiveness ✓ High yields of influenza antigens	Huge number of eggs • Theoretical risk of anaphylactic reaction • Poor growth for someviruses (i.e.,H3N2) Egg-adaptation
Inactivated cell-based	✓ Independence from eggs supply ✓ Free from egg components andadaptation	Shorter experience • Need of qualified production facilities Higher production costs • Extended quality control program
LAIV	Administration route ✓ Broader humoral andcellular responses ✓ Protection against both well-matched and non-matching influenza strains	• Not recommended for Immunocompromised subjects

Recombinant HA	✓ Independence from eggs supply ✓ Viral RNA sequence tostart the process	• Additional studies areneeded

OBJECTIVES:

- Identify the types of influenza viruses requiring vaccinations.
- Summarize the absolute and relative contraindications of the vaccine.
- Review the methods of administering influenza vaccination and eligiblepatients for each type of vaccine.
- Explain interprofessional team strategies for improving care coordination and communication to advance influenza vaccination and improve patient outcomes.

Indications for vaccination:

- All children aged 6 through 59 months. All adults ≥50 years.
- Children and adults with chronic pulmonary disease (including asthma), cardiovascular disease (excluding isolated hypertension), renal, hepatic, neurologic, hematologic, or diabetes mellitus.
- Patients who are immunocompromised (by medications or HIV infection).
- Children and adolescents (6 months to 18 years) who are given aspirin- or medications containing salicylates which increases the risk of developing Reyesyndrome after influenza virus infection.
- Nursing homes residents and residents of long-term facilities.

COVID-19 Considerations:

Individuals in isolation for COVID-19 or quarantine for suspected exposuresshould not be vaccinated if vaccination may pose an exposure risk to others.

For patients who are moderate to severely ill due to COVID-19, vaccination shouldbe postponed until patients have recovered.

For patients who are mildly ill or asymptomatic, postponement is suggested to avoid confusing COVID-19 symptoms with postvaccination reactions.

DOSAGE:-

AGE	DOSE
1) 6 Month to 3 year	0.25 – 0.5 ml
2) Age 3 to 8 year	0.5 ml
3) Age 8 year	0.5 ml
4) Age 9 year above	Single – dose 0.5 ml
5) Age 65 and above	Single – dose 0.5 – 0.7 ml

ADVERSE EFFECTS: -

Adverse events associated with the influenza vaccine include the following:

- Injection site reactions
- Fever
- Irritability
- Drowsiness
- Myalgia
- Nasal spray

- Upper respiratory symptoms
- Fever, headache, vomiting
- Lower respiratory symptoms

RARE:

- Allergic reaction
- Urticaria/anaphylaxis [14]
- Inactivated flu vaccine and pneumococcal vaccine administered at the sametime may show an increased risk for febrile seizures.

DRUG INTERACTIONS: -

Influenza antivirals can decrease the efficacy of LAIV4 (Quadrivalent Live Attenuated Influenza Vaccine) if administered before or after LAIV4. Therefore,individuals who have been prescribed antivirals should be revaccinated with an
age-appropriate RIV4 or IIV4. Recommendations for the use of antivirals are given below. It is important to note that period may be prolonged in the presence of renal insufficiency, which delays the clearance of the

drug.[5]

- Oseltamivir and zanamivir 48 hours before to 2 weeks following LAIV4
- Baloxavir 17 days before to 2 weeks following LAIV4
- Peramivir 5 days before to 2 weeks following LAIV4

CONTRAINDICATIONS

The following are contraindications to receiving the influenza vaccine. However,clinicians should check the prescribing information of the vaccine before administration.

- History of severe allergic reactions (anaphylaxis) to any component of thevaccine
- Infants less than six months of age

Additionally, LAIV is contraindicated in the following population.

- Concomitant aspirin/salicylate-containing medicine in children/adolescents
- Children aged 2-4 years age with asthma or reported wheezing/asthma in thepreceding 12 months or whose health record of wheezing episodes in the preceding 12 months
- Children/adults who are immunocompromised due to any cause, includingbut not limited to medications, anatomic asplenia, congenital or acquired

immunodeficiency states, functional asplenia (e.g., due to sickle-cellanemia), or HIV infection

- Close contacts/caregivers of severely immunosuppressed persons requiring aprotected environment
- Pregnancy
- Individuals with active communication between the CSF and the nasopharynx, oropharynx, nose, ear, or any other cranial CSF leak
- Persons with cochlear implants (because of the potential for CSF leak)
- Administration of influenza antiviral drugs within the previous 17 days forbaloxavir, five days for peramivir, and 48 hours for oseltamivir/zanamivir

PRECAUTIONS:

Moderate/severe acute illness with or without fever. • History of Guillain-Barrésyndrome (GBS) within six weeks of receipt of influenza vaccine.

LAIV has additional precautions for recipients with asthma aged five years and older. Precautions are warranted for patients with medical conditions that mightpredispose them to complications from influenza (e.g., cardiovascular [except isolated hypertension], chronic pulmonary, hepatic, renal, neurologic, metabolic [including diabetes mellitus], or hematologic disorders).

CONCLUSIONS:

Influenza is still a substantial cause of death and suffering during the winter months, and imposed a heavy socioeconomic Burden, especially in young subjects and the elderly. Although vaccination remains the single best defense against Influenza and its complications, in many European countries, Vaccination coverage is suboptimal, especially in comparison with the US. This has serious consequences, such as the evident Excess mortality registered in Italy in elderly subjects who were Not vaccinated against influenza in 2015182 These data, which Should be confirmed by further investigations, highlight the Necessity to increase rates of immunization through the planning and implementation of public health interventions. Furthermore, a higher standardization of vaccine strategies has Beenobserved in the US than in European countries. Although influenza vaccines display a good safety profile, a Growing number of people shun vaccination for fearof negative Side effects, such as the onset of autoimmune conditions. This Fear, in addition to the public's misperceptions concerning Adjuvants and their role, have discouraged vaccination not only Against influenza but also against other infectiousdiseases, allowing them to re- emerge. A significant element in the Overall effectiveness of vaccines is therefore their acceptance by the public.

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