

Analysis of COVID-19 vaccination status and adverse events following immunization against SARS-CoV-2 (COVID-19) in a district of Anyang City in 2021

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Abstract: To analyze COVID-19 vaccination status and adverse events following immunization (AEFI) against SARS-CoV-2 (COVID-19) in a district of Anyang City in 2021. The vaccination data and data of the AEFI against the COVID-19 vaccine were obtained through the China Immunization Planning Information Management System from January 1 to December 31, 2021. For AEFI surveillance data, descriptive epidemiological methods were used to describe its distribution and statistical tests were performed on the differences between different types and doses by SPSS21.0 (Armonk, NY, USA, 2012) ($P < 0.05$). The incidence rate (IT) of AEFI was calculated for 100,000 doses applied. In 2021, a total of 1,167,784 doses of the COVID-19 vaccine were vaccinated in a district of Anyang City. The cumulative number of vaccinations of different types and doses varies greatly; the cumulative number of vaccinations varies greatly in different months and regions; the ratio of cumulative vaccination doses for men and women is 0.99:1; 43.22% vaccinated people were aged 18 to 49. In 2021, a total of 124 cases of the AEFI against the COVID-19 were reported in a district of Anyang City. The reported IT was 10.62/100,000 doses; the number of reported cases in different months and regions varies greatly; It is within 1 day between inoculation and the occurrence, between the occurrence and discovery among AEFI cases; The ratio of male and female AEFI cases was 0.79:1; 52.42% AEFI cases were mainly between 18 and 49 years old; General reactions were mainly high fever (body temperature $\geq 38.6^{\circ}\text{C}$); abnormal reactions were all allergic reactions. There were statistically significant differences in the reported AEFI between different types and doses ($P < 0.05$). The COVID-19 vaccination (Adenovirus Type 5 Vector) had the highest incidence; the third dose had the highest incidence; 99.19% of cases were cured. In 2021, the AEFI monitoring sensitivity is quite different in different regions; the AEFI against COVID-19 has a low incidence rate and good prognosis and the vaccination is safe for the population.

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Keywords: COVID-19 vaccine; adverse events following immunization; Mass vaccination; Safety

1. Introduction

People have suffered the disease caused by a new virus, called SARS-CoV-2, since November 2019^[1]. There is still no specific treatment for COVID-19 and vaccination against COVID-19 is the most effective and economical way to prevent its infection^[2]. The AEFI caused by the vaccination of the COVID-19 is the most concerning issue of the vaccine and the monitoring of the AEFI against the COVID-19 is an important part of its safety monitoring^[3].

The COVID-19 vaccines that were put into use in Anyang City include Inactivated COVID-19 Vaccine (Vero cell), Recombinant Novel Coronavirus vaccine (CHO cell), Recombinant COVID-19 vaccine (Adenovirus Type 5 Vector)^[4]. The basic immunization program: Inactivated COVID-19 Vaccine (Vero cell), 2 doses with an interval of ≥ 21 days, 1 dose of Recombinant COVID-19 vaccine (Adenovirus Type 5

Vector), 3 doses of Recombinant COVID-19 vaccine (Adenovirus Type 5 Vector) with an interval of ≥ 28 days; Booster immunization program: After completing the basic immunization program and with an interval of ≥ 6 months, Inactivated COVID-19 Vaccine (Vero cell) and Recombinant COVID-19 vaccine (Adenovirus Type 5 Vector) are vaccinated once again. The COVID-19 vaccine is an emergency use vaccine. The route of vaccination is an intramuscular injection. The population of vaccination: all people aged ≥ 3 years without contraindications to the vaccine.

In this study, a district of Anyang City was selected as a monitoring point to monitor and analyze the COVID-19 vaccination situation and the AEFI and to evaluate the safety of COVID-19 vaccination and its AEFI monitoring sensitivity.

2. Methods

2.1 Data Sources

The vaccination data and the data of the AEFI against the COVID-19 vaccine were obtained by the China Immunization Planning Information Management System from January 1 to December 31, 2021.

2.2 AEFI Monitoring Scope and Classification

According to the "National AEFI Monitoring Program" [3], AEFI is divided into five categories: adverse reactions (general reactions and abnormal reactions), vaccine quality accidents, vaccination accidents, incidental symptoms, and psychogenic reactions. Except for general reactions, all of them are made by the "expert group of investigation and diagnosis of abnormal reactions to vaccination".

2.3 Statistical analysis

Descriptive epidemiological methods were used to analyze the COVID-19 vaccination situation and its AEFI distribution characteristics in a district of Anyang City. The incidence rate of AEFI (/100,000 doses) = the number of reported cases of AEFI / the number of vaccination doses × 100,000 agents. All statistical analyses were carried out using SPSS 21.0 (Armonk, NY, USA, 2012). The chi-square test was used to compare categorical variables. *P*<0.05 was considered statistically significant.

3. Results

3.1 COVID-19 Vaccination Statuses

A total of 1167,784 doses were included: The cumulative number of doses of COVID-19 vaccine of different types and doses varies greatly. The COVID-19 vaccination status was presented in Table1.

Table 1 the vaccination situation of the COVID-19 vaccine

Types of COVID-19 vaccines	1st dose	2nd dose	3rd dose	Cumulative booster doses	Cumulative number of people vaccinated	Cumulative vaccinations
Vero cell	531727	501674	/	17018	614885	1050419
CHO cell	40430	38758	35759	/	53507	114947
Adenovirus Type 5 Vector	2159	/	/	259	2167	2418
Total	574316	540432	35759	17277	670559	1167784

3.2 Epidemiological characteristics of new corona virus vaccination

3.2.1 Time distribution

The cumulative number of vaccinations in June

(348,759 doses) was the largest; the cumulative number of vaccinations in April (1,837 doses) was the least. The time distribution of the COVID-19 vaccine was presented in Figure 1.

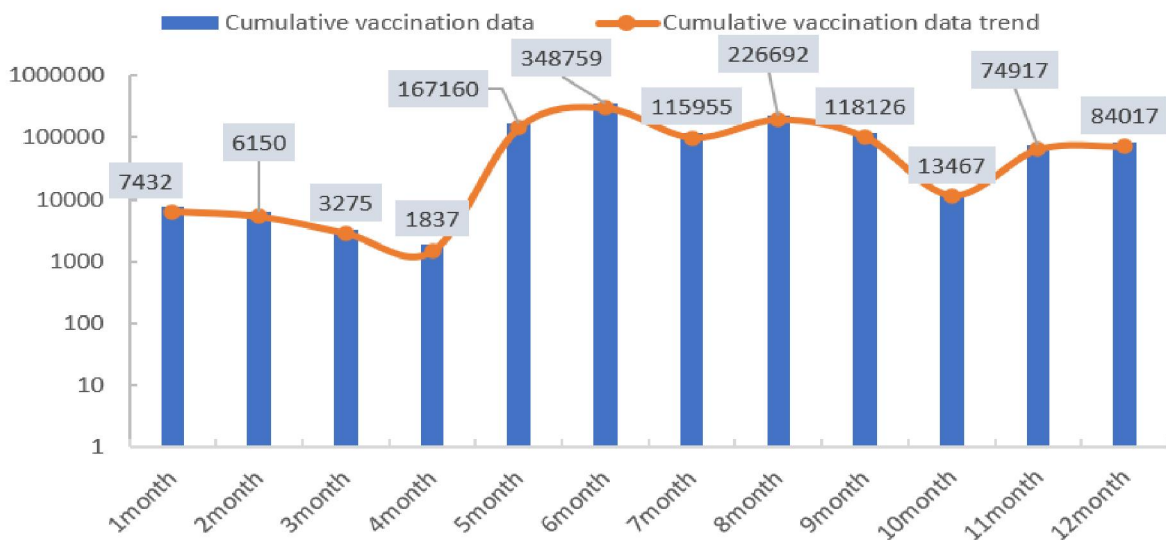


Figure 1 Cumulative vaccination data of the COVID-19 vaccine from January to December

3.2.2 Regional distribution

XiJiao had the biggest number of cumulative vaccinations (250,595 doses, 21.46%); LeiKou

Township (10,321 doses, 0.88%) had the least number of cumulative vaccinations. The regional distribution was presented in Table 2 for details.

Table 2 the cumulative number of COVID-19 vaccine in township

Area	Cumulative vaccinations	Composition ratio (%)
Mei Yuan	53232	4.56
Tie Xi	40234	3.45
Qing Feng	26900	2.31
Sha Chang	37146	3.18
Bei Meng	23747	2.03
Xi Jiao	250595	21.46
Shui Ye	106169	9.09
Qu Gou	86597	7.42
XuJiagou	193805	16.60
Tong Ye	76193	6.52
Lei Kou	10321	0.88
Du Li	14734	1.26
Lun Zhang	58488	5.01
An Feng	88686	7.59
Hong He tun	64976	5.56
JiangCun	35961	3.08
Total	1167784	100

3.2.3 Crowd distribution

The ratio of cumulative vaccination doses between males and females was 0.99:1; 43.22% of people were

aged between 18 and 49. The crowd distribution was presented in Table 3 for details.

Table 3 Cumulative vaccination of COVID-19 vaccine in different demographic characteristics

Demographic characteristics	Cumulative doses	Composition ratio (%)
Gender		
Male	579629	49.63
Female	588155	50.37
Age		
3~11	133697	11.45
12~17	130367	11.16
18~49	504770	43.22
50~54	106101	9.09
55~59	94276	8.07
60~64	61183	5.24
65~69	63424	5.43
≥70	73966	6.33
Total	1167784	100

3.3 The occurrence and epidemiological characteristics of the new coronavirus vaccine AEFI

3.3.1 Basic overview

124 AEFI were reported in 2021, including 112 cases of general reactions, 5 cases of abnormal reactions, and 7 cases of incidental diseases. The 123 cases were reported by the inoculated/guardian and 1 case was reported by the clinician. The completeness rate, classification rate, and township-level report rate of the cases are all 100%.

3.3.2 Epidemiological characteristics

3.3.2.1 Time Distribution

The number of monthly reports is the largest in May (36 cases, 29.03 %) and the least in March (1 case, 0.81 %) and April (1 case, 0.81 %). The reported incidence rate was highest in April (54.44/100,000 doses) and lowest in September (3.39/100,000 doses). The time distribution was presented in Table 4 for details.

Table 4 Time distribution of the number of AEFI reports of the COVID-19 vaccine in 2021

Month	Cases of AEFI	Ratio of cases in AEFI (%)	Incidence Rate (/ 100,000 doses)
1	4	3.23	53.82
2	2	1.61	32.52
3	1	0.81	30.53
4	1	0.81	54.44
5	36	29.03	21.54
6	26	20.97	7.46
7	9	7.26	7.76
8	10	8.06	4.41
9	4	3.23	3.39
10	3	2.42	22.28
11	13	10.48	17.35
12	15	12.10	17.85
Total	124	100	10.62

3.3.2.2 Time interval distribution

It is within 1 day between inoculation to the occurrence and between occurrence to discovery

among AEFI cases and the distributions were (98 cases, 79.03%) and (76 cases, 61.29%). The time interval distribution was presented in Table 5 for details.

Table 5 the number of AEFI about the time interval distribution

time interval (days)	Inoculation → Occurrence		Occurrence → visit /discovery	
	Cases of AEFI	Ratio of cases in AEFI (%)	Number of cases reported by AEFI	Composition ratio
0~1	98	79.03	76	61.29
2~3	22	17.74	18	14.52
4~7	3	2.42	12	9.68
8~14	1	0.81	5	4.03
≥15	0	0	13	10.48
total	124	100	124	100

3.3.2.3 Regional distribution

The clinical diagnosis was mainly high fever (body temperature $\geq 38.6^{\circ}\text{C}$), and the incidence rate was 4.20/ 100,000 doses. Among the abnormal reactions, 1 case of angioedema, 1 case of laryngeal edema, and 1 case of other allergic reactions. The

reported incidence rate was 0.08/ 100,000 doses; 9 cases were clinically diagnosed as other diseases and the reported incidence rate was 7.7/1,000,000 doses. The clinical diagnosis classification of the AEFI was presented in Figure 2 for detail.

Table 6 Regional distribution of the AEFI in a district of Anyang City

Area	Cases of AEFI	The ratio of AEFI (%)	Incidence Rate (/ 100,000 doses)
Mei Yuan	24	19.35	45.09
Tie Xi	2	1.61	4.97
Qing Feng	3	2.42	11.15
Sha Chang	2	1.61	5.38
Bei Meng	4	3.23	16.84
Xi Jiao	18	14.52	7.18
Shui Ye	6	4.84	5.65
Qu Gou	2	1.61	2.31
Xu Jia gou	16	12.91	8.26
Tong Ye	7	5.65	9.19
Lei Kou	4	3.23	38.76
Du Li	5	4.03	33.94
Lun Zhang	14	11.29	23.94
An Feng	1	0.81	1.13
Hong He tun	9	7.26	13.85
Jiang Cun	7	5.65	19.47
Total	124	100	10.62

3.3.3 Clinical diagnosis classification of the AEFI against COVID-19 vaccine

The clinical diagnosis was mainly high fever (body temperature $\geq 38.6^{\circ}\text{C}$), and the incidence rate was 4.20/ 100,000 doses. Among the abnormal reactions, 1 case of angioedema, 1 case of laryngeal

edema, and 1case of other allergic reactions. The reported incidence rate was 0.08/ 100,000 doses; 9 cases were clinically diagnosed as other diseases and the reported incidence rate was 7.7/1,000,000 doses. The clinical diagnosis classification of the AEFI was presented in Figure 2 for detail.

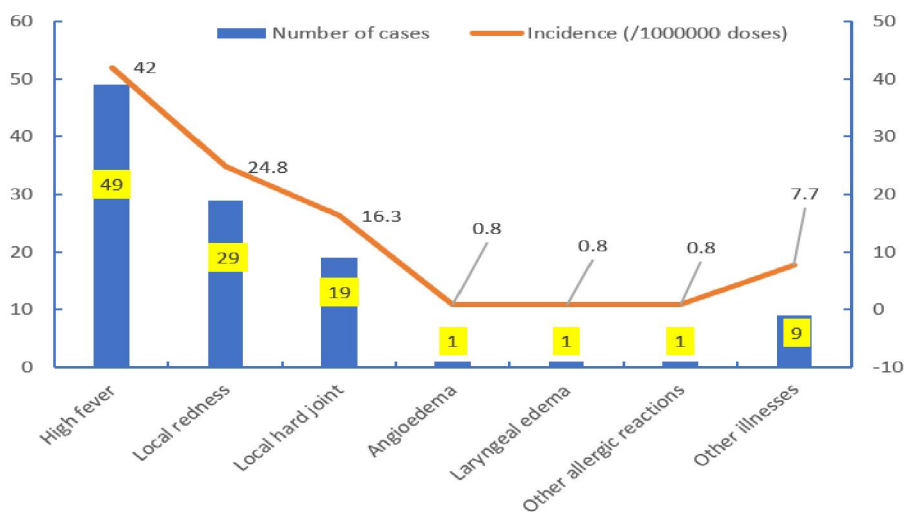


Figure 2 Distribution of clinical diagnosis classification of the AEFI against COVID-19 vaccine

3.3.4 AEFI distribution of COVID-19 vaccines

Different types and doses of vaccination were statistically significant differences in the incidence rate ($P < 0.05$). Among different types of COVID-19 vaccination, the Recombinant COVID-19 vaccine (Adenovirus Type 5 Vector) had the highest incidence

rate of AEFI, 454.92/ 100,000 doses; the third dose of different doses had the highest incidence. The distribution of the COVID-19 vaccine against AEFI in different types and doses was presented in Table 8 for details.

Table 8 Distribution of COVID-19 vaccine against AEFI in different types and doses

variable	Number of AEFI	Composition ratio of	AEFI (%)	Incidence Rate (/100,000 doses)	P value
Different types					<0.05
Vero cell	97	78.23		9.23	
CHO cell	16	12.90		13.92	
Adenovirus Type 5 Vector	11	8.87		454.92	
Different doses					<0.05
1st dose	89	71.77		15.50	
2nd dose	24	19.35		4.44	
3rd dose	11	8.88		20.84	
Total	124	100		10.62	

3.4 Outcome distribution

Among the AEFI cases, 123 cases (99.19%) were cured; 1 case (0.81%) was under treatment, which was the abnormal reaction.

4. Discussion

The main reasons for the large difference in the cumulative numbers of different types of COVID-19 vaccine in a district of Anyang City are the following: The cold chain distribution of the COVID-19 vaccine is the province-city-district level and the district-level units are delivered by the cold chain finally. Each inoculation clinic is determined by the number of vaccines distributed by the higher-level unit; the type of COVID-19 vaccine is voluntarily selected by the recipient with informed consent or recommended by the staff.

The number of injections of the COVID-19 vaccine varies greatly and the number of booster injections is the least. The reasons include some recipients are unclear about the vaccination procedure or have wrong contact information, and the vaccination clinic cannot notify them to get vaccinated as soon as possible; vaccines are unwilling to continue the vaccination due to AEFI after vaccination and it may be that the vaccinated patients find contraindications such as pregnancy after vaccination and cannot continue the vaccination; the minimum number of booster vaccinations is mainly because the booster immunization is carried out later and has 6-month intervals after the basic immunization.

The cumulative number of vaccinations varies

greatly in different months, which may be mainly due to the different age arrangements for vaccination clinics and vaccination groups in the district. From January to April, not all clinics have been vaccinated, and only for people aged 18 to 59; in May, all people over 18 to 59 have been vaccinated; in October, people aged 12 to 17 and over 60 have been vaccinated with booster doses Vaccination; 3-11 years old have been vaccinated in November.

The cumulative number of vaccinations varies greatly in different regions, mainly due to the different resident populations in each region. In addition, two regions, Xujiagou and Xi Jiao have established large-scale temporary vaccination clinics since May.

The reported incidence rate of the COVID-19 vaccine in a district of Anyang City is 10.62/100,000 doses. The COVID-19 vaccine will be vaccinated on a large scale in 2021, which is lower than the national^[3](46.53/100,000 doses) and Henan Province^[6](10.91/100,000 doses), Anyang City^[7](49.96/100,000 doses), the reported incidence of AEFI for other vaccines. The completeness rate, classification rate, and township-level report coverage rate of the case questionnaire are all 100% indicating that the safety of the COVID-19 vaccine is good and the sensitivity of AEFI monitoring of the vaccine in a district of Anyang City is high, which is related to the training of the COVID-19 vaccine before vaccination, and the technical guidance and supervision during the vaccination period.

The number of reported cases of AEFI in different

months is the largest in the second quarter, which may be related to the fact that the inoculation site of the vaccinated people has been exposed to the environment for the longest time and is more likely to be exposed to pathogens and cause local infection^[8,9]; the number of reported cases is the fourth quarter, The main reason is that this season is mainly because people aged 3 to 17 are vaccinated in this season and the weather is gradually getting cooler in this season. This group is younger, has weaker physical fitness, and is prone to respiratory diseases.

The number of reported cases of AEFI varies greatly in different regions, indicating that the monitoring sensitivity of different townships varies greatly, which is consistent with other studies³; it may be related to the importance and professional ability of immunization personnel in different townships to AEFI. This is related to the insufficient number of outpatients engaged in immunization programmers.

Symptoms of AEFI cases of the COVID-19 vaccine mostly appear within 1 day after vaccination, and most of the symptoms are concentrated within 1 day after the onset of symptoms to the hospital or the outpatient clinic for response and treatment, indicating that the vaccine recipients are more concerned about the reaction after the COVID-19 vaccine.

From the perspective of clinical diagnosis classification and outcome, the clinical diagnosis classification is mainly based on general reaction (90.32%), the general reaction is mainly fever and all the cases are cured; in the clinical diagnosis classification, 3 cases of abnormal reactions are all allergic reactions, and 2 cases are allergic reactions. recovered, and 1 case improved; indicating that the safety of the COVID-19 vaccine is high and the prognosis is good.

The highest reported incidence of the COVID-19 vaccine (adenovirus vector) among different types is 4.5492/100,000 doses, which is mainly related to the production method of the vaccine and the type of virus strain used; the reported incidence of the third dose (/100,000 doses) The highest is 20.84/100,000 doses, which may be related to the specific effects of the vaccine itself and the high number of basic immunizations.

To sum up, the COVID-19 vaccine in a certain district of Anyang City will cover the whole in 2021 and the AEFI monitoring sensitivity in different regions is quite different; the COVID-19 vaccine AEFI incidence rate is low and the prognosis is good, and the

vaccination safety is good.

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