



## Has the public lost confidence in vaccines because of a vaccine scandal in China



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### ABSTRACT

**Background:** A vaccine manufacturer in China and regulatory authorities have been the focus of wide-spread outrage due to a vaccine scandal. We conducted a rapid survey during a time of intense mainstream and social media attention to determine whether the public's confidence in vaccines was affected. **Methods:** We selected 7 cities that were not involved in the scandal as the setting for the survey, which was conducted in August 2018. We used a convenience sampling strategy to select subjects in urban streets and rural villages for a face-to-face questionnaire-based survey. Subjects were asked to describe their levels of confidence on a scale from 0 to 9, in which 0 means no confidence, and 9 means very confident. Respondents were asked to assess confidence for two points in time – recollection of their level of confidence before hearing about the scandal and their level of confidence at the time of the survey. **Results:** In total, 683 individuals were invited to participate and 591 questionnaires were completed, for a response rate of 86.5%. Among respondents, 86.80% had heard of the vaccine scandal. The most common channel for hearing about the scandal was social media (e.g., WeChat), 40.6% of respondents. Regardless of gender, age, education level, province, town or country, or having children under 15 years old, respondents reported a significant decrease in confidence in domestically-produced vaccines. The mean pre-scandal confidence level recalled by respondents was 6.7, and the mean confidence level at the time of the survey was 3.2. Confidence in vaccine manufacturers, institutes for drug control, and drug supervision authorities decreased from 5.6 to 6.0 before the vaccine scandal to 2.0–3.2 at the time of the survey. Confidence in vaccine manufacturers decreased the most, from 5.6 before the scandal to 2.0; confidence in institutes for drug control decreased from 5.8 before the scandal to 2.6 at the time of the survey. **Conclusion:** This study demonstrated that public confidence was significantly affected by the vaccine scandal, particularly for vaccine producers and drug regulators. The decline in confidence is a reminder to governments that in order to build public confidence for vaccination, regulators have to reform regulatory practices and manufacturers have to ensure vaccine quality.

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### 1. Key messages

- Vaccines play a key role in controlling infectious diseases, and the safety and effectiveness of vaccines has been well recog-

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nized. However, public hesitancy to vaccinate is still common and sentiment exists against vaccines in certain populations.

- This study measured public confidence to vaccine and authorities within two months of the increase in media attention to a vaccine event, and identified public concerns and public attributions of responsibility.
- The loss of confidence to vaccines and regulators not only brings hesitancy to vaccination, but also brings the potential of disease outbreaks. Resilience to vaccine scandals are not only the producers' and authorities' responsibilities, as engagement of other stakeholders is needed.

## 2. Background

Jilin provincial food and drug supervision authorities issued a notice of penalties to Changchun Changsheng Biotechnology Company (CCBC) for violation of Good Manufacture Practice (GMP) standards during the manufacturing of diphtheria, pertussis, and acellular tetanus (DTaP) vaccines that had been determined to be sub-potent in pertussis and tetanus components by the National Institutes for Food and Drug Control (NIFDC) in October 2017 [1]. Another company, Wuhan Biological Company, also had not met the standards of the China Food and Drug Administration (CFDA) [2] for DTaP vaccine. More than 650,000 doses of a vaccine routinely given to infants and young children in China were recalled after NIFDC testing identified the sub-potent lots [3].

On July 15, 2018 CFDA issued a report indicating that production records for rabies vaccines at CCBC were falsified, and that the quality of the vaccine had been compromised [4]. Based on CFDA's Notice of Penalties, CCBC was in "severe violation of GMP of Medical Products Guidelines," and CFDA required an immediate stop to CCBC's manufacturing of rabies vaccine. None of the rabies vaccine identified in the July 15 notification had entered the market, and no deaths or other severe consequences related to potentially impotent rabies vaccines have been documented as of August 2018 [4]. Later, China's vaccine, food, and drug supervision authorities have been the focus of the widespread outrage after an article swept across social media that was posted online by anonymous writer Shouye on July 21, 2018 [5].

Widely circulated information accelerated the investigation, and on July 23, the State Council sent a team to CCBC for further investigation. CFDA sent teams to all other biological companies to assess quality controls to ensure product safety [6]. The State Council issued investigation results on Aug 15, confirming that unqualified DTaP vaccine produced by CCBC included two batches (201605014-01 and 201605014-02), which totaled 499,800 doses [7]. Later, 7 senior officials were punished or resigned at national and provincial levels [8] and 18 key CCBC employees were arrested [9]. Some officials from NIFDC resigned or were punished. As of August 18, several provincial and ministerial-level officials have been dismissed, resigned or warned, including heads of the drug surveillance system and drug testing institutes, as well as individuals from Wuhan Biological Institute.

Previous studies have found that vaccine events have been associated with declines in parental confidence, and refusal of vaccination [10,11]. To measure the impact of this vaccine scandal, we conducted a rapid survey in August 2018 to determine whether public confidence was affected by the then ongoing scandal. The hypotheses were (1) the public has less confidence in domestically produced vaccines than imported vaccines; (2) the public lost confidence not only in producers, but also in regulators; (3) parents with children less than 15 years old had more concerns than individuals without children; and (4) there will be little difference in confidence between urban and rural populations about domestically-produced vaccines and imported vaccines before and after the vaccine scandal.

## 3. Methods

The survey was conducted in August 2018 in 7 cities of 7 provinces or province-level municipalities: Heilongjiang, Beijing, Guangxi, Gansu, Hubei, Tianjin and Jiangxi. None of the selected cities were directly involved in the DTaP scandal. We defined the vaccine scandal as the low-quality DTaP vaccine mentioned in the Shouye article and the rabies vaccine that was gradually disclosed by the media in the following days. Using a convenience sampling strategy, individuals on urban streets and rural villages

were invited to participate in the survey. We attempted to balance residence (urban/rural), gender, and age groups. The target sample size was based on estimates from previous Knowledge, Attitude and Practices surveys, and we assumed responses to dichotomous variables will be evenly divided.

In each cities, one urban location and one rural location were selected as starting points for the survey. We conducted in-person, questionnaire surveys at supermarket gates, shops, factories, and other locations. We collected information that included age, gender, educational attainment, occupation, whether the subject has children under 15 years old, and whether the subject heard or had not heard about the scandal. We also used 7 questions to ask "have you changed your confidence in domestically-produced vaccines/imported vaccines; vaccine manufacturers; institutes for drug control/drug supervision authorities; health commissions; and centers for disease control and prevention (CDC) from before hearing about the scandal to the time of the survey?" We asked respondents to indicate their confidence as numerical values from 0 to 9, where 0 means no confidence and 9 means very confident.

Epidemiology Data 3.1 was used for data entry by trained data management professionals. Statistical Product and Service Solutions (SPSS, version 22.0) was used for statistical analyses. Analytical methods included descriptive statistics, Chi-square tests and paired-sample T tests. This study was exempt from Ethical Review.

## 4. Results

### 4.1. Demographic characteristics of subjects

In total, 683 individuals were invited to participate; 591 valid questionnaires were obtained, yielded a response rate of 86.5%. The male to female ratio was 1:1.1; subjects' ages ranged from 17 to 81 years, with a median of 33 years; educational attainment was predominantly bachelor's degree (42.6%) followed by senior high school (29.4%). The urban to rural resident ratio was 1:0.9; 58.2% subjects had children under 15 years old (Table 1).

### 4.2. Proportion of having known the vaccine scandal

Among respondents, 86.8% had heard of the vaccine scandal. There was no statistically significant difference in awareness between men and women. Respondents who were younger, had higher educational attainment, were urban residents, or had children under the age of 15 were more concerned about the vaccine scandal than others; differences were statistically significant (Table 1).

### 4.3. Initial channel for hearing of the vaccine scandal

The most common initial channel for hearing about the scandal was social media (e.g., WeChat) (40.6%), followed by news portals (e.g., Tencent News) (20.0%), and television (17.6%) (Fig. 1).

### 4.4. Change in confidence of domestic and imported vaccines

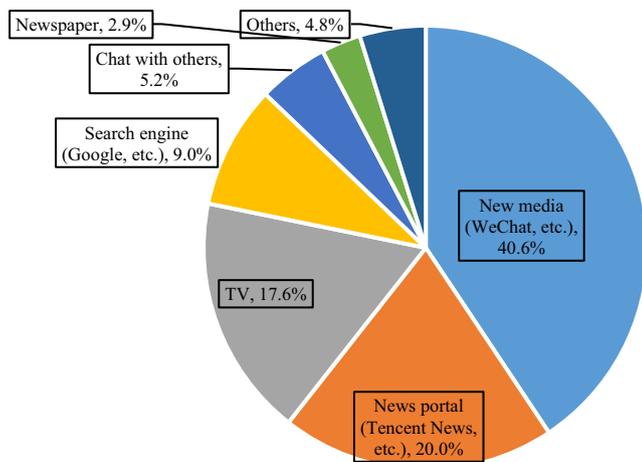
Regardless of gender, age, education level, province, town or country, having or not having children under 15 years old, respondent confidence in domestically-produced vaccines dropped significantly. The average confidence level decreased to 3.2 from 6.7 before the scandal. For imported vaccines, confidence decreased from 6.1 before the scandal to 5.2 at the time of the survey. There was little difference change in confidence between urban and rural residents, and those who had or did not have children under 15 years of age (Table 2).

**Table 1**  
Characteristics and awareness the vaccine scandal.

		N	Percent	Knew the scandal	Percent	$\chi^2$	P(2-sided)
Gender	Male	280	47.4	239	85.4	0.97	0.325
	Female	311	52.6	274	88.1		
Age	≤30	250	42.3	229	91.6	43.57*	<0.001
	31–40	171	28.9	164	95.9		
	41–50	95	16.1	72	75.8		
	51–60	52	8.8	33	63.5		
	≥61	23	3.9	15	65.2		
Education	Primary school	11	1.9	5	45.5	80.38*	<0.001
	Junior high school	104	17.6	67	64.4		
	Senior high school	174	29.4	149	85.6		
	Bachelor's degree	252	42.6	242	96.0		
	Master's degree or above	50	8.5	50	100.0		
Province	Heilongjiang	90	15.2	59	65.6	72.09	<0.001
	Beijing	85	14.4	85	100.0		
	Guangxi	111	18.8	98	88.3		
	Gansu	48	8.1	36	75.0		
	Hubei	57	9.6	54	94.7		
	Tianjin	113	19.1	94	83.2		
	Jiangxi	87	14.7	87	100.0		
	Urban	307	51.9	285	92.8		
Rural	284	48.1	228	80.3			
Occupation	Worker or peasant	83	14.0	56	67.5	43.06#	<0.001
	Teacher/researcher/medical staff/civil servant	100	16.9	95	95.0		
	Business/service/foreign/private Enterprise staff	193	32.7	175	90.7		
	Self-employed persons	33	5.6	29	87.9		
	Unemployed	27	4.6	17	63.0		
	Other	155	26.2	141	91.0		
Have children under 15 years old	344	58.2	310	90.1	7.89	0.005	
No children under 15 years old	247	41.8	203	82.2			
Total		591	100.0	513	86.8		

\* Linear-by-Linear Association.

# Likelihood Ratio.

**Fig. 1.** Initial channels for hearing about the vaccine scandal.

#### 4.5. Change in confidence and responsibility attribution of vaccine authorities

People's confidence in vaccine manufacturers, institutes for drug control, and drug supervision authorities decreased from 5.6 to 6.0 before the scandal to 2.0–3.2 at the time of the survey. Confidence in vaccine manufacturers decreased the most, from 5.6 before the scandal to 2.0 at the time of the survey. Confidence in institutes for drug control, declined from 5.8 before the scandal to 2.6 at the time of the survey (Table 3).

When asked whether the different authorities were responsible, more than half of respondents believe that all authorities have major responsibility for the vaccine scandal. There was variation in attribution of responsibility, as 91.9% believed that vaccine man-

ufacturers were most responsible for the scandal, followed by drug supervision authorities (81.8%) and institutes for drug control (75.7%) (Fig. 2).

## 5. Discussion

During recent years, with the development of national immunization program, the public gets more and more sensitive on vaccine events. After the vaccine scandal, there has been a significant drop in trust in vaccines and related departments. In a global survey that was conducted in 2015, China had a high level of disagreement with the statement that “overall I think that vaccines are safe” [12]. The 2018 China vaccine scandal triggered a further decline in public confidence in vaccination, especially for domestically-produced vaccines. This distrust might finally lead into vaccine hesitancy and induce the drop in vaccine coverage.

After the vaccine scandal, a report called “Death of the Vaccine,” written in 2013, was republished in the social media [13]. “The vaccine is useless” message had spread again in China. However, the number of deaths due to rabies has fallen by more than 50% from 2013 (1,128 deaths) [14] to 2017 (502 deaths). In 2017, China reported no cases of diphtheria, 10,791 cases of typhoid (3 deaths), and 10,390 cases of pertussis (0 deaths) [2,15]. Rabies and DTP vaccines played essential roles in these achievements. Therefore, it is necessary to correctly recognize the positive effects of vaccines. People should improve their health literacy, specifically vaccine literacy, which may reduce some of the negative effects of being exposed to misleading information on vaccination, eventually leading to less vaccination hesitancy [16].

In China, reflecting on this vaccine scandal, drug regulatory authorities have found Changchun Changsheng rabies vaccine unqualified since 2014 [17]. It shows the producer pursued high profits and that regulatory coverage could not reach 100% of the

**Table 2**  
Change in confidence of domestically- produced vaccines and imported vaccines.

		N	Confidence in domestically produced vaccines			Confidence in imported vaccines		
			Before the scandal	After the scandal	Difference	Before the scandal	After the scandal	Difference
Gender	Male	238	6.5	3.3	3.1**	6.1	5.4	0.7**
	Female	272	6.8	3.1	3.7**	6.1	5.1	1.0**
Age	≤30	227	6.6	3.6	3.0**	6.3	5.3	1.0**
	31–40	163	6.6	2.7	4.0**	6.2	5.3	0.9**
	41–50	72	7.1	3.6	3.5**	5.9	5.2	0.7**
	51–60	33	6.4	1.9	4.5**	5.4	5.1	0.3
	≥61	15	6.0	3.4	2.6*	4.0	4.1	−0.1
Education	Primary school	5	6.0	2.4	3.6	5.4	5.2	0.2
	Junior high school	67	6.7	2.5	4.2**	5.7	4.5	1.3**
	Senior high school	148	6.8	3.0	3.7**	5.8	4.9	0.9**
	Bachelor's degree	242	6.6	3.4	3.2**	6.1	5.4	0.7**
Province	Master's degree or above	48	6.8	3.7	3.1**	7.1	6.5	0.6*
	Heilongjiang	58	7.6	3.0	4.5**	5.8	5.5	0.3
Residence	Beijing	84	6.8	3.4	3.4**	5.6	4.9	0.7**
	Guangxi	98	6.9	3.2	3.7**	6.5	4.6	1.9**
	Gansu	36	6.9	4.4	2.5**	6.9	6.3	0.6*
	Hubei	53	6.1	2.8	3.3**	7.0	6.4	0.6**
	Tianjin	94	6.1	2.7	3.4**	5.7	4.9	0.8**
	Jiangxi	87	6.5	3.4	3.1**	5.8	5.2	0.5**
	Urban	283	6.7	3.5	3.2**	6.2	5.5	0.7**
Occupation	Rural	227	6.6	2.8	3.8**	5.9	4.9	1.0**
	Worker or peasant	56	6.6	2.3	4.4**	5.7	5.1	0.6*
Have children under 15 years old	Teacher/researcher/medical Staff/civil servant	93	6.7	3.5	3.2**	6.3	5.5	0.8**
	Business/service/foreign/private Enterprise staff	175	6.7	3.3	3.4**	6.3	5.0	1.4**
	Self-employed persons	28	6.1	2.2	3.9**	5.3	5.0	0.3
	Unemployed	17	6.2	3.4	2.8**	5.5	5.1	0.4
	Other <sup>#</sup>	141	6.7	3.4	3.3**	6.0	5.5	0.5**
No children under 15 years old		308	6.7	3.0	3.7**	6.2	5.2	0.9**
Total		510 <sup>#</sup>	6.7	3.2	3.5**	6.1	5.2	0.9**

\* P < 0.05.

\*\* P < 0.01.

<sup>#</sup> Including drivers, students, retirees and others. & Among the 513 people who knew the scandal in Table 1, there were 3 people who only filled in "they knew the vaccine scandal" but didn't describe their confidence.

**Table 3**  
Change in confidence of vaccine-related departments.

Entity or authority	Before the scandal	After the scandal	Difference	Std. deviation	t	P <sup>#</sup>
Vaccine manufacturers	5.6	2.0	3.6	3.1	26.44	<0.001
Institutes for drug control	5.8	2.6	3.3	2.9	25.20	<0.001
Drug supervision authorities	5.9	2.7	3.2	3.0	24.18	<0.001
Health commissions	5.8	3.0	2.8	2.9	21.64	<0.001
CDCs	6.0	3.2	2.8	2.9	21.89	<0.001

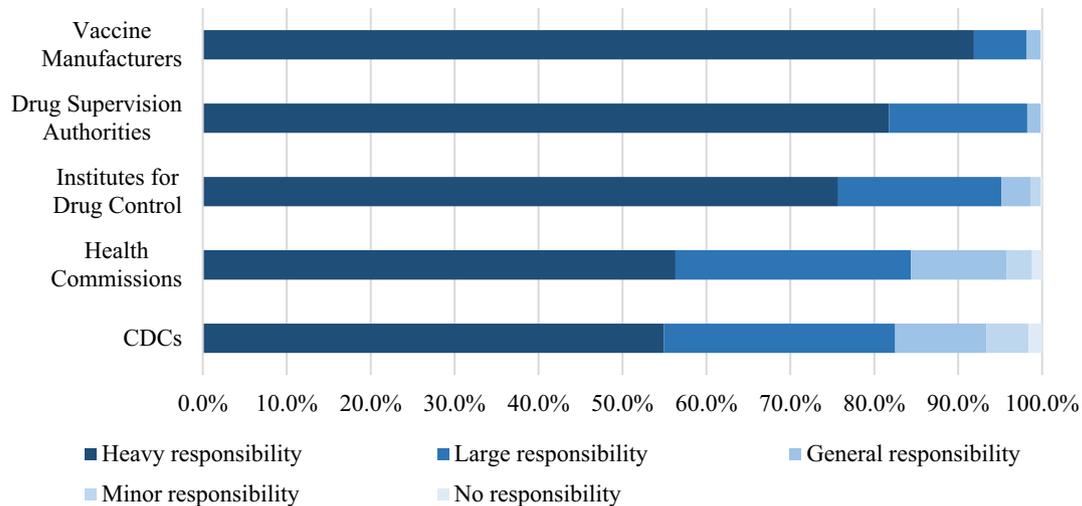
<sup>#</sup> Two-tailed.

vaccine lots [18]. Strict food and drug quality supervision requires a scientific system. In the long run, quality is the foundation of a company's survival, and if a company cannot produce a safe and effective vaccine, scandals will likely recur.

In the past 7 years, China's vaccine regulatory standards have been in line with international standards, and China's drug regulatory model has been transformed from a rights-oriented model to a service-oriented. However, this vaccine scandal hit the public's confidence again, and illustrates the importance of restoring the public's trust in vaccination. It is essential to improve the quality of vaccine production, strengthen regulation, and restore public confidence in vaccination. Therefore, reform must be implemented to assure the quality of vaccines. We make the following suggestions. First, national state council assessed quickly to all vaccine producers and shared timely with public the findings, which demonstrates the government's strong willingness to protect people's health and the government's attitude toward illegal vaccine production. Second, we should aware that in the past three years

the inspection system has played a key role in the identification of quality problems. Drug regulatory authorities should take immediate action and remedial measures after receiving reports. Finally, widespread understanding of the benefits of vaccines helps to increase vaccination coverage rates [19]. Our study found that WeChat was widely used. WeChat, a social software similar to Twitter and Facebook, has become the main source of public information [20]. In the future, social media can be used promote positive vaccination information to the public.

The strengths of the study are first attempt to quickly evaluate the public confidence to authorities after scandal and used face to face interview by the trained professionals in a short duration, therefore it reflected the real context. There are some limitations to our study. First, the public does not fully understand vaccine, production, and regulation, potentially making the study suffer from information bias. Second, subjects were from 7 cities and cannot represent the entire country. And the sampling strategy, in supermarket etc. could have overestimated the proportion of



**Fig 2.** Responsibility attribution of vaccine-related departments or authorities.

people well connected. That recruitment bias is likely to have functioned in a specific way. Third, there was no independent data point on confidence obtain before the scandal. Since the same survey was used to measure both “before” and “after” confidence, the “before” measure may be associated with recall bias or may be influenced by knowledge of the scandal. We assume this bias is minor and will not influence trends and is unlikely change our findings, in addition, if the public lost confidence in 7 cities that were not directly involved in the DTaP scandal, the cities involved the scandal directly must have more influence.

## 6. Conclusion

This quick survey in 7 cities in China indicated that the public's confidence was heavily affected by the vaccine scandal, particularly confidence in vaccine producers and drug regulators. The loss of vaccine confidence will lead into vaccine hesitancy in the short run and induce the coverage dropping in the long run. Hence, it is necessary for manufactures to improve the quality, safety and effectiveness of vaccines. The scandal is a reminder to governments that regulators have to reform regulation, boost vaccine quality, and build public confidence in vaccination.

## Declarations

### Ethics approval and consent to participate

We applied for an ethical exemption and Peking University Institutional Review Board Office (IRB00001052) agreed with it after review. We confirmed that informed consent was obtained from all participants by the verbal consent. The initials of the questionnaire briefly describe the background, purpose, risks and benefits of the study. The investigator verbally describes and confirms the informed consent. And the ethics committee has approved this procedure.

### Consent for publication

Not applicable.

### Availability of data and materials

The data supporting the conclusions of this article are included within the article and its additional files.

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## Authors' contributions

All authors made significant contributions to the conception of this study. BH and SW analysed the data and drafted the manuscript with contributions from other authors. All authors read and approved the final manuscript.

## Declaration of Competing Interest

The authors declare that they have no competing interests.

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Not applicable.

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