Vaccine 28 (2010) 6455–6462

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Impact of unfounded vaccine safety concerns on the nationwide measles–rubella immunization campaign, Georgia, 2008

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ARTICLE INFO

Article history:
Received 11 June 2010
Received in revised form 9 July 2010
Accepted 14 July 2010
Available online 30 July 2010

Keywords:
Mass immunization campaigns
Vaccine safety
Measles–rubella vaccine
Georgia
European Region
Adverse events following immunization

ABSTRACT

Vaccine safety fears following media reports of adverse events led to low (50.3%) coverage in a supplementary measles–rubella immunization campaign in Georgia in 2008. Review of adverse events associated with the campaign identified 432 reports (<0.1% of ~493,000 vaccinees) including 338 (78.2%) cases of syncope. There were no deaths. Causality assessment was performed for 79 cases perceived by providers as severe and with clinical details available. Conditions likely caused by the vaccine were identified in 13 (16.5%) cases (allergic and local reactions, thrombocytopenia). Thirty-seven (46.8%) cases had symptoms consistent with syncope or anxiety attack; 36 (97.3%) of them were initially misdiagnosed as anaphylactic shock/allergies/"postvaccinal reactions". Twenty-nine (36.7%) cases had coincidental illnesses. Safety fears were unfounded and exaggerated by media reports and providers' difficulties in recognizing syncope/anxiety attacks. Risk communication strategies to address perceived vaccine safety concerns are urgently needed to ensure that the goal of measles and rubella elimination in the European Region of the World Health Organization is met.

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1. Introduction

Over the last decade, hesitancy to vaccinate children because of the parents' often unfounded concerns about vaccine safety has become a substantial challenge to sustaining successful immunization programs in many European countries. A prominent example is the experience of the United Kingdom, where the reports, now scientifically discredited, of an alleged causal link between measles–mumps–rubella (MMR) vaccine and autism resulted in the decline in immunization coverage for these diseases, which in turn led to the resurgence of measles with re-established endemicity, and to large-scale outbreaks of mumps [1–6]. A decline in demand for vaccination in several Western European countries is one factor that endangers achieving the goal of measles and rubella elimination in the European Region of the World Health Organization (WHO) by 2010 [4,7,8]. Recently, exaggerated vaccine safety concerns have also emerged as an increasingly important challenge to measles and rubella elimination efforts in the eastern countries of the European Region. In 2008, intense anti-vaccination media coverage in Ukraine occurred after the death of an adolescent vaccinated at the beginning of a nationwide measles–rubella (MR) supplementary immunization activity (SIA), which aimed to vaccinate approximately 8.5 million persons aged 16–29 years. The SIA was cancelled, even though the death was determined to be coincidental by the national Ministry of Health and WHO [8,9].

In late 2008, the success of a nationwide MR SIA in Georgia was also undermined by vaccine safety concerns [8]. During 2004–2005, as a result of historic weaknesses of its immunization program throughout the late 1980s and 1990's (e.g. a long list of unwarranted contraindications, problems with vaccine quality and cold chain, interruptions in vaccine supply after the collapse of Soviet Union leading to low coverage), Georgia experienced a large-scale concurrent outbreak of measles and rubella primarily affecting adolescents and young adults [10,11]. This outbreak, as well as historic data on measles and rubella incidence in Georgia and previous routine and supplementary immunization activities have been reviewed elsewhere [10].

To address gaps in population immunity to measles and rubella, a nationwide SIA was planned for the fall of 2008, using combined MR vaccine (Serum Institute of India [SII], Pune, India). The target for the 2008 SIA was all persons aged 6–27 years (approximately 980,000 persons). These birth cohorts accounted for 78.4%

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0264-410X/$ – see front matter. Published by Elsevier Ltd.
doi:10.1016/j.vaccine.2010.07.043

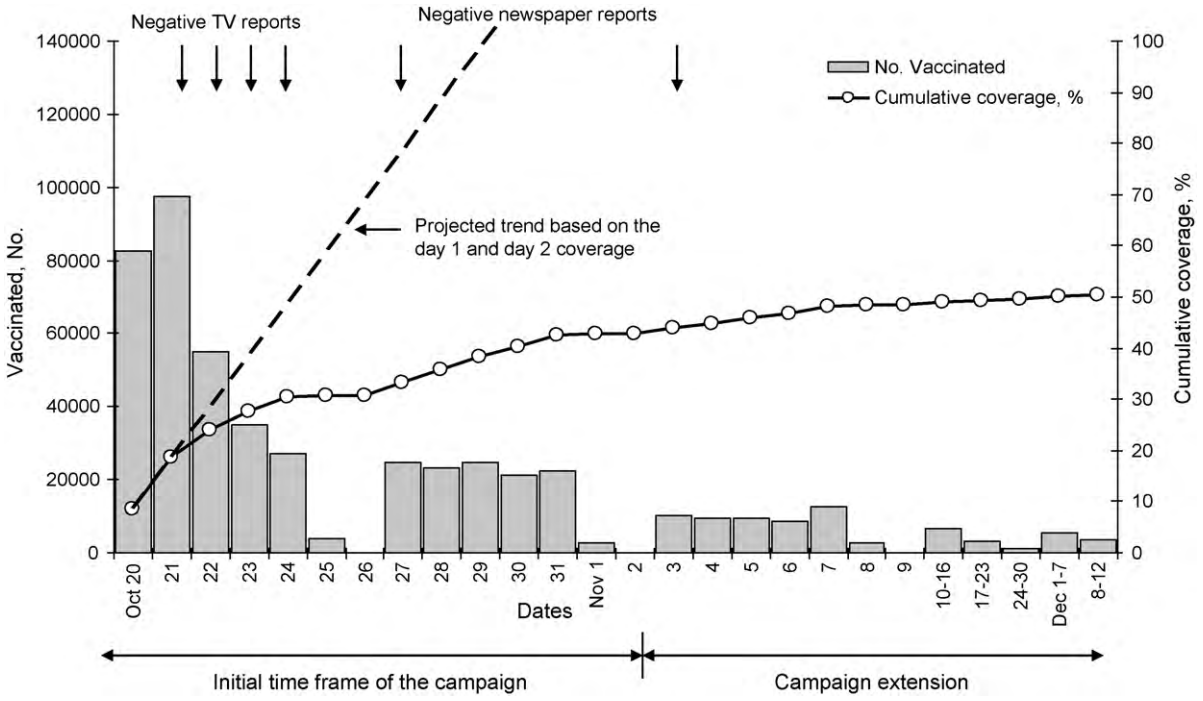

Fig. 1. Numbers of vaccinated persons and cumulative coverage, measles–rubella immunization campaign, Georgia, October 20–December 12, 2008.

of measles and 85.0% of rubella cases during the 2004–2005 outbreak [10]. The campaign was initially scheduled for 2 weeks from September 29 to October 12, 2008 but was postponed for 3 weeks because of the August 2008 war [12], and was ultimately launched on October 20, 2008. The 18.4% coverage achieved in the target age groups during the first 2 days of the campaign (Fig. 1) suggested that by the end of the planned 2-week period, high coverage would likely be attained. However, on the evening of October 21, a national television network aired a report of a cluster of adverse events following immunization (AEFI) with MR vaccine among schoolchildren in the capital city of Tbilisi. Over the subsequent 2 weeks, several other reports critical of the vaccine and the SIA appeared on TV and in printed media. Resulting vaccine safety fears led to a dramatic decline in the number of vaccinations beginning on October 22. By the end of the 2-week period planned for the SIA, national coverage was only 42.8%. Although the Ministry of Health extended the campaign through mid-December and the national public health officials made efforts to reassure the public, vaccine acceptance remained low. In this report, we analyse reported AEFI cases, their impact on the SIA, and explore contributing factors to the events that occurred during the 2008 MR campaign in Georgia.

2. Methods

We analysed immunization coverage and AEFI data reported daily by regional public health centers to the National Center for Disease Control and Public Health (NCDC) from October 20, 2008 to January 7, 2009. AEFI surveillance in Georgia is passive and comprises of reporting of suspected AEFIs by health care providers to regional public health centers, who in turn report them to NCDC. AEFI surveillance was enhanced in connection with this campaign by providing additional training to public health workers and health care providers and requesting daily reporting during the SIA. Standardized form was provided for aggregate reporting of SIA-associated AEFIs. The reporting form included aggregate numbers of vaccinations by date, region and district, and age group, and aggregate numbers of AEFIs by date and reporting category. AEFI reporting categories included events generally expected in connection with administration of measles and rubella vaccines: anaphylactic shock, other allergic reactions, encephalopathy/encephalitis, syncope/near fainting, fever, local reaction, thrombocytopenia, post-injection abscess, toxic shock syndrome, hospitalization for other causes and death. In addition, demographic and clinical information for AEFI cases perceived by healthcare providers as serious was submitted to NCDC using different formats, ranging from brief description of symptoms to full medical records. Since there was no standardized definition of serious cases, and the determination was based on providers' clinical judgment, available clinical data for these cases were reviewed by a group of vaccine-preventable disease experts to validate the reported diagnosis.[1] If clinical data were not compatible with the reported diagnosis, the group used their best clinical judgment based on available information to propose an alternative categorization. The results of the assessment were reviewed by the National Expert Committee on adverse events following immunization which included clinicians (pediatricians, pediatric neurologist, allergist, infectious disease specialist) and epidemiologists.

Causality assessment based on the WHO-The Uppsala Monitoring Centre (UMC) system [13,14] was conducted for AEFIs with the reported case-based data. We used the following definition for the likelihood of a causal link between vaccination and the adverse event: "certain" – the event has plausible temporal relationship to vaccination and cannot be explained by any other cause; "probable" – the event has plausible temporal relationship to vaccination and is unlikely to be attributed to disease or other causes; "possible" – the event has plausible temporal relationship to vaccination but could also be explained by disease or other causes; "coincidental" – implausible temporal relationship, disease or other causes provide plausible explanations, or both; "unclassifiable" – insufficient data to assign a causality category. In accordance to the 4th edi-

[1] The group included the following co-authors of this report: NK, NT, TL.