



**Socioeconomic, cultural and behavioural features of prior and anticipated influenza vaccine uptake in urban and rural Pune District, India: a mixed-methods case study**

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Complete List of Authors:	Kudale, Abhay; Maharashtra Association of Anthropological Sciences, Centre for Health Research and Development (MAAS-CHRD) Purohit, Vidula; Maharashtra Association of Anthropological Sciences, Centre for Health Research and Development (MAAS-CHRD) Sundaram, Neisha; Swiss Tropical and Public Health Institute, Epidemiology and Public Health Schaetti, Christian; Swiss Tropical and Public Health Institute, Epidemiology and Public Health Weiss, Mitchell; Swiss Tropical and Public Health Institute, Epidemiology and Public Health
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4 **Socioeconomic, cultural and behavioural features of prior**  
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7 **and anticipated influenza vaccine uptake in urban and rural**  
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10 **Pune District, India: a mixed-methods case study**  
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15 Abhay Kudale<sup>1</sup>, Vidula Purohit<sup>1</sup>, Neisha Sundaram<sup>2,3</sup>, Christian Schaetti<sup>2,3</sup>, Mitchell G. Weiss<sup>2,3,\*</sup>  
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18  
19 <sup>1</sup> The Maharashtra Association of Anthropological Sciences–Centre for Health Research and  
20 Development (MAAS–CHRD), 201, Akanksha Residency, B-Wing, Near Shivaji Statue, Aundh  
21 Gaon, Pune–411007, Maharashtra, India,  
22  
23

24  
25 <sup>2</sup> Department of Epidemiology and Public Health, Swiss Tropical and Public Health Institute, PO  
26 Box, Socinstrasse 57, 4002 Basel, Switzerland  
27  
28

29  
30 <sup>3</sup> University of Basel, Petersplatz 1, 4003 Basel, Switzerland  
31  
32

33 E-mail:

34 AK: [abhaykudale@yahoo.com](mailto:abhaykudale@yahoo.com)

35 VP: [vidula96@hotmail.com](mailto:vidula96@hotmail.com)

36 NS: [neisha.sundaram@unibas.ch](mailto:neisha.sundaram@unibas.ch)

37 CS: [christian.schaetti@unibas.ch](mailto:christian.schaetti@unibas.ch)

38 MGW: [mitchell-g.weiss@unibas.ch](mailto:mitchell-g.weiss@unibas.ch)  
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46 \*Corresponding Author  
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## Abstract

### *Introduction*

Ensuring production capacity of efficacious vaccines for pandemic preparedness alone may not be sufficient for effective influenza control. Community willingness to accept the vaccine is also critical. Population acceptance must therefore be recognised as a major determinant of vaccine effectiveness, and the social, cultural and economic determinants of population acceptance require study for effective policy and action.

Pune is a focus of pandemic influenza in India. The experience of the 2009/2010 pandemic in Pune, capacity for vaccine production and experience with vaccine use provide a unique opportunity to address key questions about an effective vaccine intervention strategy for influenza control in India.

This study will examine socioeconomic, cultural and behavioural determinants of anticipated acceptance of influenza vaccines among urban and rural populations of Pune district. Additionally, community ideas about seasonal influenza and its distinction from pandemic influenza will be investigated. Proposed research also considers the influence of health professionals, policy makers and media professionals on the awareness, preference and use of influenza vaccines.

### *Methods and analysis*

This is a mixed-methods study including urban and rural community surveys, in-depth interviews with health professionals, case studies at two hospitals where suspected influenza cases were referred during the pandemic, and in-depth interviews with media professionals and public health policy makers.

### *Ethics and dissemination*

This protocol was approved by the ethics review committees of the Maharashtra Association of Anthropological Sciences and the World Health Organization, and by the Ethics Commission of

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3 Basel, Switzerland. The proposed research will provide a better understanding of communication and  
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5 education needs for vaccine action for influenza control in India and other low- and middle-income  
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7 countries. Findings and the approach for health social science research will have implications for  
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9 containment of pandemic influenza in other settings and for effective vaccine action planning for  
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11 other vaccines.  
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15 **Key words:** Influenza; vaccine; social, economic and cultural determinants; cultural epidemiology;  
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17 vaccine acceptance; vaccine uptake; India  
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## Article summary

### *Article focus*

- Effective control of influenza requires not only efficacious vaccines and functioning health systems but also community awareness and willingness to use available vaccines.
- This protocol describes a case study of influenza vaccine uptake using a mixed-methods approach in urban and rural Pune, India.

### *Key messages*

- It is important to consider social and cultural features of the population and health system, and cultural experience and ideas about influenza influence prior and anticipated uptake of influenza vaccines.
- This approach to health social science is relevant for other conditions in other countries.

### *Strengths and limitations of this study*

- The study will examine a topic of broad significance – pandemic influenza preparedness – in a city of India and its rural surroundings most seriously affected by influenza H1N1 morbidity and mortality.
- Although local research in other settings is required for planning vaccine action, findings from this study are likely to be relevant for consideration in other areas of India and elsewhere, even if they are not directly applicable.

## Introduction

Vaccines and antivirals are important pharmacological interventions for prevention and containment of influenza. Efficacious and safe inactivated vaccines remain the cornerstone of influenza prophylaxis in most countries.<sup>1</sup> Vaccines are considered valuable not only in influenza prevention but also in mitigating severity and impact of the disease.<sup>2-4</sup> The capacity for influenza vaccine deployment is a critical public health priority for pandemic influenza preparedness.<sup>5</sup>

Seasonal influenza vaccination represents complementary interests for avoiding severe influenza and its complications. Approximately 50 industrialised countries and some others with recent rapid economic development offer influenza vaccination to nationally defined high-risk groups, including elderly people and individuals with cardiovascular, metabolic, renal or immune-suppressing conditions. Influenza vaccination in pregnancy is considered safe, and is recommended for pregnant women during the influenza season.<sup>1</sup> As seasonal virus and pandemic influenza viruses circulate concurrently in many countries, both vaccines are recommended for simultaneous vaccination in these countries.<sup>6,7</sup>

Although recent assessment of the role of human vaccines for control of pandemic and seasonal influenza acknowledges the importance of community acceptance and popular ideas that discourage use of safe and effective vaccines, they focus on questions of production and distribution.<sup>8</sup> Production capacity is required, but it is not itself sufficient for effective policy. Lower than anticipated rates of influenza vaccine uptake throughout the world, especially among health workers and students in vaccine programmes responding to the 2009/2010 pandemic influenza, highlight the problem.<sup>9-11</sup> Population acceptance must therefore be recognised as a major determinant of vaccine effectiveness, and the social, cultural and economic determinants of population acceptance require study and consideration for effective policy and action.

## ***Public health priority of influenza vaccines in India***

Following the emergence of avian influenza (H5N1) in 2003 and responding to World Health Organization (WHO) policy, the government of India prepared a detailed Pandemic Preparedness and Response Plan (PPRP). The National Institute of Communicable Diseases was responsible for development of the plan, which would be implemented when necessary. Declaration of the H1N1 pandemic by the WHO led to revision of the India PPRP.<sup>10</sup> The update provided an action plan for early detection of clusters of influenza, guidelines for appropriate case management and institution of other public health measures to contain and control the H1N1 outbreak in India.<sup>11</sup>

Influenza vaccination was acknowledged as the best preventive strategy to deal with a pandemic in the PPRP. However, as vaccine manufacture for a novel virus takes around six months, the vaccine would only be available for a second wave of the pandemic. In view of the potential limited vaccine supply, the plan identified priority recipients, namely, health workers, the elderly, infants, people with existing health problems, and those who were responsible for essential services. In the event of a pandemic, a National Immunization Programme would be invoked to vaccinate these priority groups, and if vaccine supply was sufficient, which was considered an “unlikely scenario”, the entire population would be vaccinated. The plan also explicitly acknowledged that vaccine action for seasonal influenza was not a priority, but acknowledged that surveillance was needed.

As seasonal influenza is not considered a public health problem in India, a policy for seasonal influenza vaccination does not exist. The priority for such a policy would only be apparent if the morbidity and mortality from seasonal influenza is known. This needs to be done through an effective influenza surveillance network.

To ensure pandemic vaccine production capacity, the PPRP nevertheless indicated a national policy that included production of seasonal influenza vaccines, so that vaccine manufacturers would be able

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3 to switch to a pandemic strain when needed. The plan also supported a public-private partnership for  
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5 pandemic vaccine preparation.  
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### 8 **Research on influenza vaccine acceptance**

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10 Acceptance of seasonal influenza vaccines has been studied in various countries for the general  
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12 population and for special groups, such as the elderly, students and health workers.<sup>12-16</sup> A recent study  
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14 found that among 802 student respondents in Vellore, India, only 12.7% had been vaccinated in the  
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16 2009/2010 pandemic; virtually the same proportion (13.0%) indicated plans to be vaccinated in the  
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18 future, and most (74.0%) said they probably or definitely would not be vaccinated.<sup>17</sup> Among other  
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20 studies in India, a knowledge, attitudes and practices (KAP) study in Chandigarh showed that only  
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22 14% of paediatricians were aware of the level of the WHO pandemic alert in 2009.<sup>18</sup> A study of high-  
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24 school students in Bareilly, Uttar Pradesh, during the pandemic found high levels of awareness and  
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26 concern, including 97% using a mask for protection; girls were better aware of the role of medicines  
27  
28 and vaccines than boys.<sup>19</sup> Kamate *et al.* found high levels of awareness of pandemic influenza in  
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30 Udaipur, Rajasthan, but inadequate attention to prevention; vaccines were not considered.<sup>20</sup>  
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35 Although the literature indicates the nature of interest and approach of various KAP studies in India,  
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37 and some studies have considered self-reported reasons for use and non-use of the vaccine, careful  
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39 study of social and cultural determinants of vaccine uptake or refusal by examining patterns of  
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41 behaviour that respondents are not necessarily able to explain for themselves is required.  
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43 Consideration of patterns of behaviour (i.e. intention to be vaccinated and actual uptake) and  
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45 sociocultural determinants need not, and should not, be limited to self-reported respondent accounts.  
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47 Just as the evidence base for risk and treatment of disease relies on study of epidemiological patterns,  
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49 rather than anecdotal clinical reports, the evidence base for social and cultural determinants of  
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51 behaviour should also be rooted in evidence based on study of how illness-, treatment- and vaccine-  
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53 related experience and meaning are related to behaviour, and with regard to our current interest, the  
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55 acceptance and use of influenza vaccine. The approach and methods of cultural epidemiology have  
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57 been developed to address such questions. Social and cultural concepts (e.g. patterns of distress,  
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3 priority symptoms, perceived causes and treatment preferences) may be formulated in operational  
4 terms and assessed as explanatory variables for analysis of behavioural outcomes. Complementary  
5 qualitative data that are linked in an integrated data set clarify the meaning and implications of  
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7 patterns identified from quantitative analysis.  
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## 10 11 ***Pandemic influenza in India and Pune*** 12

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14 After the WHO declared an influenza pandemic (level 6) on 11 June 2009, active surveillance was  
15 initiated in India to detect cases among persons returning from travel to influenza-affected countries.  
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17 Pune was a major focus of the pandemic in India. The first pandemic H1N1 case was detected in the  
18 city on 22 June 2009, and the first death, a 14-year-old schoolgirl, was reported on 3 August 2009 and  
19 sensationalised in the media.<sup>21</sup>  
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26 Out of the 93 reported influenza deaths in Pune, 65 were urban and 28 from rural areas. All but eight  
27 urban and one of the rural deaths were from pandemic H1N1 infection. Mortality was approximately  
28 1 in 11 confirmed hospitalised cases, and rural areas had higher rates of transmission and mortality.  
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30 By August 2010 press coverage estimated that the death toll had reached 300.<sup>22</sup> The epidemic was  
31 classified as a category 3 level of severity, a severe public health problem.<sup>23</sup>  
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39 With publicity, awareness and increasing fear of pandemic influenza, vaccination was recommended  
40 by the Indian Medical Association, and vaccine demand intensified, acknowledging the value of both  
41 injectable and intranasal products.<sup>24</sup> Tabloids also raised questions about the safety of the intranasal  
42 vaccine in a report of a fatality of a man with respiratory symptoms who took the vaccine even though  
43 it was contraindicated.<sup>25</sup> In any event, the enthusiastic demand for the vaccine during the pandemic  
44 appears not to have been generalised throughout the country, nor sustained without equivocation in  
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46 Pune.  
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55 Features of acceptance, demand and refusal require further attention in the interest of pandemic  
56 preparedness to ensure vaccine effectiveness and the validity of assumptions of the PPRP. Study  
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designs and a framework for instruments that have been developed for research on anticipated acceptance of oral cholera vaccines<sup>26 27</sup> would address critical open questions about the public response component of influenza vaccine effectiveness.

## **Research objectives**

This study will examine social, cultural and economic determinants of prior use and anticipated acceptance of influenza vaccines among urban and rural populations of Pune District, Maharashtra, India. The following are specific study objectives:

- (a) To elucidate community experience, meaning and behaviour concerning pandemic and seasonal influenza, and awareness, preference and use of vaccines to prevent them. The study will clarify the nature, variety and distribution of illness explanatory models of influenza, perceived risk and consequences of pandemic and seasonal influenza in both urban and rural areas;
- (b) To clarify the role of clinicians in determining influenza vaccine acceptance and uptake in rural and urban areas, considering their awareness, acceptance and personal use, and their vaccine prescribing practices;
- (c) To clarify relevant policy concerning awareness and priority of influenza vaccine for pandemic and seasonal influenza.

## **Methods and analysis**

### **Study setting**

The study will proceed in both urban and rural areas of Pune district, which is situated in Western Maharashtra in the Sahyadri mountain range of the Western Ghats. The district has a population of approximately 7.2 million according to the 2001 census. The district headquarters is Pune city, which has a population of 4 million and is the second largest urban agglomeration in the state of Maharashtra after Mumbai. The incidence of seasonal influenza is higher, but not exclusively confined to the rainy and winter seasons (October to January). The city has been an area of recent rapid growth.

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5 Urban community and clinical study sites have been selected in representative areas of the city where  
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7 two major hospitals (one government-run and one private) that treated people with influenza during  
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9 the pandemic are located. Deenanath Mangeshkar Hospital (DMH) is a private hospital in an area  
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11 known as Erandawane. The 5 km surrounding area has historically been a middle-class Maharashtrian  
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13 neighbourhood. It has expanded since the mid-1980s as the city expanded beyond the older central  
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15 areas. The area also includes upper middle-class neighbourhoods, and some areas are also changing  
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17 with an influx of students and working professionals from other states. The DMH urban study site will  
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19 include non-slum middle-class neighbourhoods. The Dr. Naidu Hospital (NH) is a government  
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21 hospital located in an area known as Sangamwadi, on the extended border of central Pune near Pune  
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23 railway station. The surrounding area within 5 km has two extremes of population, one a posh locale  
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25 (Koregaon Park) and another that includes densely populated slums (Tadiwala Road Zopadpatti, Patil  
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27 Estate Zopadpatti, etc.). The NH urban study site will comprise slum neighbourhoods.  
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31 Two rural study sites (subdistricts) have also been selected for urban-rural comparative study  
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33 interests. Velhe is relatively more remote and comprises 128 villages with a population of  
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35 approximately 56,000 (Census 2001). Maval, which is more easily accessible from Pune, comprises  
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37 184 villages with an estimated 305,000 inhabitants.  
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### 40 **Study groups**

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42 Research activities include study of community residents, clinicians and several groups of key  
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44 informants.  
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49 **Urban and rural community members.** The sample of approximately 400 respondents in total will  
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51 include adult male and female residents of the four community study sites (two urban and two rural),  
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53 stratified by sex and age group.  
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3 **Clinicians.** Urban clinicians working in government and private hospitals and other private practice  
4 settings. Rural clinicians who work either in government-run community health centres, block-level  
5 primary health centres (PHCs) or other private practice settings run by private rural health  
6 practitioners.  
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13 **Key informants.** The following five categories of key informants will be included in the study:

- 14 • Adult urban and rural community members with history of pandemic influenza;
  - 15 • Adult urban and rural community members with and without history of H1N1 vaccination;
  - 16 • Health personnel including clinicians, nurses, paraprofessionals, administrators and support  
17 staff working at NH and DMH;
  - 18 • Reporters and personalities working in the print, television and radio media who were involved  
19 in reporting on the H1N1 pandemic;
  - 20 • Policy makers at district and state government levels.
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### 30 ***Study design***

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32 Research activities will include urban and rural community surveys and in-depth interviews, clinician  
33 key-informant interviews, case studies at the two hospitals (DMH and NH) where many pandemic  
34 influenza case suspects were referred and in-depth interviews with media professionals and public  
35 health policy makers.  
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### 41 ***Community study***

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43 The community research will include three successive activities: formative ethnographic research, a  
44 cultural epidemiological survey and in-depth interviews with three sets of community respondents  
45 (i.e. respondents with a history of pandemic influenza and respondents with a history of H1N1  
46 vaccination and non-vaccination).  
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## Formative qualitative community research

Qualitative research will proceed with focus group discussions (FGD) with community residents at the study sites. These FGDs clarify background features of the setting and sociocultural features of influenza and vaccine experience, which in turn will guide construction of interview questions and coding categories for the subsequent survey.

## Cultural epidemiological survey with EMIC interview

A cultural epidemiological study design<sup>28</sup> will make use of ethnographic key informant interviews and focus group discussion data to develop explanatory model interviews based on the framework of the explanatory model interview catalogue (EMIC) for cultural epidemiology.<sup>29</sup> The data will include both qualitative narrative and coded categorical data indicating the distribution of features of the illness explanatory models and outcome variables concerned with vaccine acceptance. Although the approach is mostly closely related to OCV acceptance studies in Zanzibar,<sup>26 30</sup> Kenya<sup>27</sup> and Democratic Republic of Congo (DRC), it is rooted in a broad range of studies of infectious diseases, such as onchodermatitis,<sup>31</sup> malaria<sup>32</sup> and tuberculosis.<sup>33-37</sup>

**Instrument.** An explanatory model interview based on the EMIC framework will be adapted from the instruments used in the studies of oral cholera vaccine in Zanzibar, Kenya and DRC, based on illness-related, vaccine-specific and setting-specific features of the study. The structure of EMIC interview begins with questions about respondent characteristics. A sequence of two vignettes follows, depicting easily recognisable presentations of seasonal influenza and pandemic influenza. Each vignette is followed by a series of questions concerning recognition and cultural features of the condition (name, seriousness, course and outcome), perceived causes, treatment and prevention. The questions about pandemic influenza, however, are more extensive than questions about the seasonal influenza vignette, and they are followed by additional questions about prior and anticipated use of a vaccine if pandemic influenza were to recur, and vaccination priority for vulnerable members of the household. Pilot EMIC interviews will be prepared and tested in areas apart from the study site communities.

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5 **Design.** For the community survey with the EMIC interviews, household respondents in the four  
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7 study sites will be randomly selected based on the local voters' list, stratified by sex and age group  
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9 (18-45 years and 46-65 years). Inclusion criteria are as follows: aged between 18 and 65, Marathi or  
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11 English speaker, initial residence in Pune district since 2009 or earlier and mental/physical ability to  
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13 stand an interview. Trained research assistants working in teams of two will conduct the interview,  
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15 one interviewing and the other responsible for maintaining the data records. Interviews will be voice-  
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17 recorded for consenting respondents; without consent, the data will be based solely on interview  
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19 notes.

### 20 21 22 **Community case studies: pandemic influenza and H1N1 vaccination**

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24 In the third stage of the community study, in-depth interviews will follow the EMIC interview survey  
25  
26 to elaborate experience of pandemic influenza and vaccine acceptance and non-acceptance,  
27  
28 respectively. A subset of EMIC interview respondents with a history of pandemic influenza, with a  
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30 history of H1N1 vaccination and those who did not take the H1N1 vaccine will be interviewed a  
31  
32 second time as respondents for these community case studies. These will include identified cases of  
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34 pandemic influenza (n=6-8: 3-4 urban and 3-4 rural, with equal sex ratio), H1N1 vaccination (n=6-8:  
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36 3-4 urban and 3-4 rural, with equal sex ratio) and H1N1 non-vaccination (n=6-8: 3-4 urban and 3-4  
37  
38 rural, with equal sex ratio). The recovery and vaccine-user vs. non-users perspectives will be  
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40 elaborated in these interviews with an in-depth interview guide.

### 41 42 43 ***Clinician key informant interviews***

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45 Clinicians who were directly involved either in the clinical management of patients with pandemic  
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47 influenza or in related public health pandemic H1N1 prevention activities will be requested to  
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49 participate in key informant interviews. We will identify such key informant clinicians during earlier  
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51 stages of the study from FGDs, EMIC interview data or with other respondent-based information that  
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53 identifies clinicians engaged in relevant activities. These clinicians will be selected purposively, and  
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55 the interview will be guided by a key informant agenda.  
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5 From urban Pune, 6-10 clinicians who are working either in public or private sector settings ( $\geq 2$  each)  
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7 and practicing in non-slum and slum areas ( $\geq 2$  each) will be considered for the key informant  
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9 interviews. In rural Pune, 4-6 clinicians who are working in community health centres or rural  
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11 hospitals or block-level PHCs ( $\geq 2$  each) and private practitioners in hospital and private practice  
12  
13 settings ( $\geq 2$  each) will be considered for the key informant interviews.  
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### 15 16 *Hospital case studies*

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18 Dr. Naidu Hospital (NH) and Deenanath Mangeshkar Hospital (DMH) served as referral centres for  
19  
20 treating cases of pandemic H1N1 influenza in Pune. In view of the large number of patients treated at  
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22 each hospital, the experience acquired among clinicians working there and the authority conferred  
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24 upon them by this experience, we will examine the experience of each as a case study. This will  
25  
26 involve a series of interviews with administrators, clinicians and support staff, and a review of  
27  
28 available records to clarify vaccine-related experience and activities during the pandemic, and in  
29  
30 subsequent planning for pandemic and seasonal influenza preparedness. Data from community  
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32 respondents treated at these centres, especially from in-depth interviews in the third phase of  
33  
34 community study, will contribute to these hospital case studies. Approximately 5-10 interviews per  
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36 institution will be undertaken. Secondary data from media reporting on the H1N1 pandemic will be  
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38 compiled and analysed, and interviews will also be conducted with key-informant reporters and media  
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40 personalities. These activities will clarify how the balance of public awareness, popular interest and  
41  
42 public health priorities affects the interrelationship of media reporting and health system operations,  
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44 with special consideration of NH and DMH, which were focal points of media reporting.  
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### 48 49 *Policy review*

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51 Policy documents concerning pandemic preparedness and action plans, and influenza vaccine policy  
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53 will be collected and analysed with reference to a framework for review and synthesis. As a follow-up  
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55 activity to policy document analysis, key informant interviews with district and state government  
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57 level policy makers will be conducted. Approximately 2-5 key informants will be interviewed at  
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3 district and state levels. During these interviews, current thinking of policy makers and questions of  
4 policy concerning seasonal and pandemic influenza with particular attention to the role of vaccine  
5 policy will be emphasised.  
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11 A summary of the study components and methods, instruments and sampling is presented in table 1.  
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## 13 14 **Data management and analysis**

### 15 16 17 **Data management**

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20 Quantitative data from EMIC interviews with general community members will be entered into a  
21 computer database in Epi Info.  
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26 Qualitative data from EMIC interviews, FGDs, key informant and in-depth interviews will be entered  
27 in a word processor and imported into MAXQDA, using appropriate techniques for automatic and  
28 manual coding.  
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### 32 33 34 **Approach to analysis**

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36 The primary interest of the study will be to clarify descriptive, comparative and analytic accounts of  
37 explanatory models of influenza and how they explain awareness, acceptance and use of vaccines.  
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40 Comparative analysis will focus on questions of gender and rural-urban features of pandemic and  
41 seasonal influenza, and prior use and determinants of anticipated acceptance or refusal of influenza  
42 vaccines.  
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### 46 47 48 **Quantitative analysis**

49 Explanatory variables in this study would be social, cultural and economic features of illness  
50 experience, meaning and behaviour, and questions of awareness, preference and use of the intranasal  
51 vaccine for prevention of pandemic and seasonal influenza. Key questions concerned with explaining  
52 levels and determinants of acceptance will proceed with an initial bivariate analysis and logistic  
53 regression models for various levels of cost: fully subsidised (no charge); subsidised at 50% of cost  
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3 (intranasal vaccine: INR 75, injectable vaccine: INR 250); market rate (INR 150, INR 500); and black  
4 market rate (INR 300, INR 1,000). (The black market rate is relevant to conditions of high demand,  
5 which characterised periods of the pandemic in Pune.) Analysis will focus on the intranasal vaccine,  
6 and also consider it with reference to the injectable vaccine. Separate models will be analysed if  
7 differences appear substantial. Analysis of the determinants of acceptance will focus on pandemic  
8 influenza vaccine acceptance, but it will also consider seasonal influenza if a substantial enough  
9 percentage of respondents indicate acceptance.  
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### 18 Qualitative analysis

19 Notes and selective transcription of community-based FGD data will be entered in document groups  
20 of MAXQDA and thematically coded deductively with reference to the FGD agenda, which in turn is  
21 based on the structure of the EMIC interviews that the FGDs are intended to inform. Additional  
22 inductive coding will be employed as indicated to provide appropriate consideration of findings for  
23 which coding had not been anticipated.  
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32 EMIC interview data from community respondents will be imported into MAXQDA using the pre-  
33 structured coding feature to automatically code narratives according to the structure of the semi-  
34 structured interview, item-by-item. Thematic coding will facilitate analysis of narratives to elaborate  
35 the details and practical implications of categorical variable values, to explain comparisons (gender-  
36 based and urban-rural) and to explain the nature and basis of identified quantitative findings from  
37 statistical analysis. Selection variables will be imported from the quantitative data set to facilitate this  
38 integrated approach to quantitative and qualitative analysis (i.e. mixed-methods research).  
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48 Key informant clinician interview data will be coded with reference to awareness, acceptance,  
49 personal use and prescribing patterns, which will be analysed accordingly.  
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55 Interview data and notes on relevant statistics from key hospitals of case studies will be thematically  
56 coded, enabling us to triangulate vaccine-related experience from alternative vantage points (hospital,  
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3 media, community, clinicians and policy makers), and to explain implications of the pandemic  
4  
5 experience of influenza for vaccine action planning.  
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9 Key informant policy maker data will be coded with reference to priorities of influenza vaccine  
10  
11 preparedness for pandemic outbreaks, and for consideration of policy concerning seasonal influenza.  
12

## 13 14 **Ethics and dissemination**

### 15 16 17 18 ***Ethics***

19  
20 The project protocol was approved by the institutional ethics committee of the Maharashtra  
21  
22 Association of Anthropological Sciences, Pune, India, the World Health Organization Research Ethics  
23  
24 Review Committee, Geneva, Switzerland, and the Ethics Commission of Basel, Basel, Switzerland.  
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26 Confidentiality and anonymity for research participants will be strictly observed during the fieldwork  
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28 and in subsequent publications. Written informed consent will be obtained prior to conducting  
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30 interviews.  
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### 33 34 ***Dissemination and discussion***

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36 Findings from this study will be presented in scientific and public health conferences and published in  
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38 international peer-reviewed journals. Feedback will be provided to public health officials at local and  
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40 higher levels.  
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44 Experience and findings from this study will contribute to effective planning and implementation of a  
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46 pandemic influenza vaccine strategy for India. Findings and the approach for health social science  
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48 vaccine research will have implications and potential applications elsewhere for pandemic and  
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50 seasonal influenza and for strategic planning of effective vaccine action for other vaccines as well.  
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56 The following are anticipated specific contributions of the research:  
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- Clarify features and determinants of influenza vaccine acceptance that should guide policy to ensure that efficacious vaccines are also effective in the context of real public health action. Findings should thereby contribute to preparedness for a vaccine response to pandemic influenza, and guide strategic planning to address gaps and misunderstandings about the benefits and risks of influenza vaccines;
- Document level of awareness and acceptance of vaccines for seasonal influenza, indicating the potential value of influenza vaccines in India. Clarify the national priorities and potential market with reference to global interests in vaccine production for pandemic preparedness;
- Identify priorities and approaches for community action to contribute to health system preparedness for control of pandemic and seasonal influenza. Clarify current views of clinicians and other health professionals concerning both enthusiasm and reluctance to promote vaccine action for control of influenza;
- Develop and clarify the value of an approach to studying vaccine acceptance in local settings, so that planning may consider the relevance of cultural features of illness on anticipated and actual vaccine acceptance. Previous studies of OCV acceptance have shown that consideration of cultural determinants of acceptance enhances the capacity of analysis to explain vaccine acceptance and uptake beyond consideration of sociodemographic determinants only.

## Competing interests

None.

## Authors' contributions

AK participated in the conception and design of the study and drafted the manuscript. VP helped in the design and coordination of the study and drafting of the manuscript. NS helped in the design and coordination of the study and reviewed the manuscript. CS helped in the design and coordination of the study and reviewed the manuscript. MGW obtained funding and initiated the study, participated in

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3 the conception and design of the study and critically revised and reviewed the manuscript. All authors  
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5 read and approved the final manuscript version.  
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13  
14 will have no role in the conduct, analysis or reporting of study results.  
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16

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## Tables

Table 1 Summary of study components: methods, instruments and sampling

Study components	Methods	Study instruments	Study participants	Sampling	Sample size
Community	Focus group discussions	FGD guide with topical agenda	Male and female community groups (integrated urban, segregated rural)	Purposive sampling	Minimum 4 FGD: 2 urban, 2 rural
	EMIC framework	EMIC interview	Men and women, general community members	Random sample from 2 urban and 2 rural study sites	400: 100 from 2 urban and 2 rural sites (50% M/F, 50% <46/>45)
	In-depth interviews of case studies (recovered from H1N1 pandemic; vaccinated and unvaccinated persons)	In-depth interview guide for community respondents	Community residents with history of pandemic influenza	Purposive sampling	6-8: 3-4 urban, 3-4 rural
		In-depth interview guide for community respondents	General community members (a) with and (b) without history of H1N1 vaccination	Purposive sampling	(a) 6-8 acceptors: 3-4 urban, 3-4 rural; (b) 6-8 non-acceptors: 3-4 urban, 3-4 rural
Clinicians	In-depth interviews of key informants	Key informant interview agenda for clinicians	Clinicians from public and private sector settings in urban and rural areas	Purposive sampling	Urban: 6-10 (≥3 public, 3 private) Rural: 4-6 (≥2 public, 2 private)
Hospital case studies (NH and DMH)	Case studies (in-depth interviews, media coverage and other available sources)	Case study guidelines for DMH and NH	DMH and NH clinicians, other hospital personnel, media reporters, etc.	Purposive sampling	Urban: 5-10 interviews per institution
Policy makers	Policy document review	Policy document review framework	National and state level policy documents concerning H1N1 and seasonal influenza vaccine		
	In-depth interviews of key informants	Key informant interview agenda for policymakers	District and state health officials and policy makers	Purposive sampling	2-5 policy makers at state and district levels

FGD: Focus group discussion, EMIC: Explanatory model interview catalogue, H1N1: pandemic influenza A(H1N1), NH: Dr. Naidu Hospital, DMH: Deenanath Mangeshkar Hospital